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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS-1720-F]

RIN 0938-AT64

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule addresses any undue regulatory impact and burden of the physician self-referral law. This final rule is being issued in conjunction with the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork initiative and the Department of Health and Human Services' (the Department or HHS) Regulatory Sprint to Coordinated Care. This final rule establishes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also establishes a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; establishes a new exception for donations of cybersecurity technology and related services; and amends the existing exception for electronic health records (EHR) items and services. This final rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

DATES: These regulations are effective on [Insert date 60 days after the date of display in the **Federal Register**], except for amendment number 3, which further amends section 411.352(i), which is effective January 1, 2022.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory History

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payor) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, *see* 66 FR 857 through 858.

This rulemaking follows a history of rulemakings related to the physician self-referral law. The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related

only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the **Federal Register** on January 4, 2001 as a final rule with comment period (66 FR 856). The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 as an interim final rule with comment period (69 FR 16054). Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the **Federal Register** on September 5, 2007 as a final rule (72 FR 51012).

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the Fiscal Year (FY) 2009 Inpatient Prospective Payment System final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) revisions to the "stand in the shoes" provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per unit of service ("per-click") and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of "entity."

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the Calendar Year (CY) 2011 Physician Fee Schedule (PFS) final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR

71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. On November 15, 2016, we included in the CY 2017 PFS final rule, at §411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), requirements identical to regulations that have been in effect since October 1, 2009 that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (81 FR 80533 through 80534).

On November 23, 2018, in our most recent substantive update, the CY 2019 PFS final rule (83 FR 59715 through 59717), we incorporated into our regulations provisions at sections 1877(h)(1)(D) and (E) of the Act that were added by section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123). Specifically, we codified in regulations our longstanding policy that the writing requirement in various compensation arrangement exceptions in §411.357 may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. We also amended the special rule for temporary noncompliance with signature requirements at §411.353(g), removing the limitation on the use of the rule to once every 3 years with respect to the same physician and making other changes to conform the regulatory provision to section 1877(h)(1)(E) of the Act.

B. Health Care Delivery and Payment Reform: Transition to Value-Based Care

1. The Regulatory Sprint to Coordinated Care

The Department identified the broad reach of the physician self-referral law, as well as the Federal anti-kickback statute and beneficiary inducements civil monetary penalty (CMP) law, sections 1128B(b) and 1128A(a)(5) of the Act, respectively, as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors. Industry stakeholders informed us that, because the consequences of noncompliance with the physician self-referral law (and the anti-kickback statute) are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). To address these concerns, and to help accelerate the transformation of the health care system into one that better pays for value and promotes care coordination, HHS launched a Regulatory Sprint to Coordinated Care (the Regulatory Sprint), led by the Deputy Secretary of HHS. This Regulatory Sprint aims to remove potential regulatory barriers to care coordination and value-based care created by four key Federal health care laws and associated regulations: (1) the physician self-referral law; (2) the anti-kickback statute; (3) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA); and (4) the rules under 42 CFR part 2 related to opioid and substance use disorder treatment. Through the Regulatory Sprint, HHS aims to encourage and improve—

- A patient's ability to understand treatment plans and make empowered decisions;
- Providers' alignment on an end-to-end treatment approach (that is, coordination among providers along the patient's full care journey);
- Incentives for providers to coordinate, collaborate, and provide patients with tools to be more involved; and
- Information-sharing among providers, facilities, and other stakeholders in a manner

that facilitates efficient care while preserving and protecting patient access to data.

The Department believes that the realization of these goals would meaningfully improve the quality of care received by all American patients. As part of the Regulatory Sprint, CMS, the HHS Office of Inspector General (OIG), and the HHS Office for Civil Rights (OCR) each issued requests for information to solicit comments that may help to inform the Department's approach to achieving the goals of the Regulatory Sprint (83 FR 29524, 83 FR 43607, and 83 FR 64302, respectively). We discuss our request for information in this section of this final rule.

2. Policy Considerations and Other Information Relevant to the Development of this Final Rule

a. Medicare Payment was Volume-Based when the Physician Self-Referral Statute was Enacted

When the physician self-referral statute was enacted in 1989, under traditional fee-for-service (FFS) Medicare (that is, Parts A and B), the vast majority of covered services were paid based on volume. Although some services were "bundled" into a single payment, such as inpatient hospital services that were paid on the basis of the diagnosis-related group (DRG) that corresponded to the patient's diagnosis and the services provided (known as the Hospital Inpatient Prospective Payment System, or IPPS), in general, Medicare made a payment each time a provider or supplier furnished a service to a beneficiary. Thus, the more services a provider or supplier furnished, the more Medicare payments it would receive. Importantly, these bundled payments typically covered services furnished by a single provider or supplier, directly or by contract; payments were not bundled across multiple providers, with each billing independently. This volume-based reimbursement system continues to apply under traditional Medicare to both services paid under a prospective payment system (PPS) and services paid under a retrospective FFS system.

As described in this final rule, the physician self-referral statute was enacted to address concerns that arose in Medicare's volume-based reimbursement system where the more designated health services that a physician ordered, the more payments Medicare would make to the entity that furnished the designated health services. If the referring physician had an

ownership or investment interest in the entity furnishing the designated health services, he or she could increase the entity's revenue by referring patients for more or higher value services, potentially increasing the profit distributions tied to the physician's ownership interest. Similarly, a physician who had a service or other compensation arrangement with an entity might increase his or her aggregate compensation if he or she made referrals that resulted in more Medicare payments to the entity. The physician self-referral statute was enacted to combat the potential that financial self-interest would affect a physician's medical decision making and ensure that patients have options for quality care. The law's prohibitions were intended to prevent a patient from being referred for services that are not needed or steered to less convenient, lower quality, or more expensive health care providers because the patient's physician may improve his or her financial standing through those referrals. This statutory structure was designed for and made sense in Medicare's then-largely volume-based reimbursement system.

b. The Medicare Shared Savings Program, the Center for Medicare and Medicaid Innovation, and Medicare's Transition to Value-Based Payment

Since the enactment of the physician self-referral statute in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-Federal payors and patients. For some time, CMS has engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA), the Deficit Reduction Act of 2005 (Pub. L. 109-171) (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) (MIPPA) guided our early efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's payment systems and provides the Secretary with broad authority to test innovative payment and service delivery models.

Section 3022 of the Affordable Care Act established the Medicare Shared Savings Program (Shared Savings Program). The Congress created the Shared Savings Program to promote accountability for a patient population and coordinate items and services under Medicare Parts A and B and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. In essence, the Shared Savings Program facilitates coordination among providers to improve the quality of care for Medicare FFS beneficiaries and reduce unnecessary costs. Physicians, hospitals, and other eligible providers and suppliers may participate in the Shared Savings Program by creating or participating in an accountable care organization (ACO) that agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Since enactment, we have issued numerous regulations to implement and update the Shared Savings Program. For example, in keeping with the Secretary's vision for achieving value-based transformation by pioneering new payment models, in 2018, we finalized changes to the Shared Savings Program that are intended to put the program on a path toward achieving a more measurable move to value, demonstrate savings to the Medicare program, and promote a competitive and accountable marketplace (83 FR 67816). Specifically, we finalized a significant redesign of the participation options available under the Shared Savings Program to encourage ACOs to transition to two-sided risk models (in which they may share in savings and are accountable for repaying shared losses), increase savings and mitigate losses for the Medicare Trust Funds, and increase program integrity.[1]

Section 1115A of the Act, as added by section 3021 of the Affordable Care Act, established the Center for Medicare and Medicaid Innovation (the Innovation Center) within CMS. The purpose of the Innovation Center is to test innovative payment and service delivery

[1] For more information about the Shared Savings Program, *see* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html.

models to reduce expenditures for the care furnished to patients in the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of that care. Using its authority in section 1115A of the Act, the Innovation Center has tested numerous health care delivery and payment models in which providers, suppliers, and individual practitioners participate. Most Innovation Center models generally fall into three categories: accountable care models, episode-based payment models, and primary care transformation models. The Innovation Center also tests initiatives targeted to the Medicaid and CHIP population and to Medicare-Medicaid (dual eligible) enrollees, and is focused on other initiatives to accelerate the development and testing of new payment and service delivery models, as well as to speed the adoption of best practices.[2]

The Congress also granted the Secretary broad authority to waive provisions of section 1877 of the Act and certain other Federal fraud and abuse laws when he determines it is necessary to implement the Shared Savings Program (*see* section 1899(f) of the Act) or test models under the Innovation Center's authority (*see* section 1115A(d)(1) of the Act).[3]

c. Commercial Payor and Provider-Driven Activity

Although payments made directly from a payor to a physician generally do not implicate the physician self-referral law unless the payor is itself an entity that furnishes designated health services, remuneration between physicians and other health care providers that provide care to a payor's enrolled patients (or subscribers) likely does implicate the physician self-referral law. Commercial payors and health care providers have implemented and continue to develop numerous innovative health care payment and care delivery models that do not include or specifically relate to CMS. Even though the physicians and health care providers that participate in these initiatives do not necessarily provide designated health services payable by Medicare as

[2] For more information about the Innovation Center's innovative health care payment and service delivery models, *see* https://innovation.cms.gov/.

[3] For more information about waivers issued using these authorities and guidance documents related to specific waivers, *see* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.

part of the initiatives, financial relationships between them may nonetheless implicate the physician self-referral law, which, in turn, may restrict referrals of Medicare patients.

d. Request for Information Regarding the Physician Self-Referral Law (CMS-1720-NC)

The Secretary identified four priorities for HHS, the first of which is transforming our health care system into one that pays for value. Dramatically different from the system that existed when the physician self-referral statute was enacted, a value-driven health care system pays for outcomes rather than procedures. We believe that a successful value-based system requires integration and coordination among physicians and other health care providers and suppliers. The Secretary laid out four areas of emphasis for building a system that delivers value: (1) maximizing the promise of health information technology (IT); (2) improving transparency in price and quality; (3) pioneering bold new models in Medicare and Medicaid; and (4) removing government burdens that impede care coordination. (See https://www.hhs.gov/about/leadership/secretary/priorities/index.html#value-based-healthcare.) This final rule focuses primarily on the final two areas of emphasis for value-based transformation—pioneering new models in Medicare and Medicaid and removing regulatory barriers that impede care coordination.

As the Secretary and the Administrator of CMS (the Administrator) have acknowledged, there are burdens associated with the physician self-referral regulations that may be inhibiting health care professionals and organizations, especially with respect to care coordination. In 2017, through the annual payment rules, CMS requested comments on improvements that could be made to the health care delivery system to reduce unnecessary burdens for clinicians, other providers, and patients and their families. In response, commenters shared information regarding the barriers to participation in health care delivery and payment reform efforts, both public and private, as well as the burdens of compliance with the physician self-referral statute and regulations. As a result of our review of these comments, and with a goal of reducing regulatory burden and dismantling barriers to value-based care transformation while also protecting the

integrity of the Medicare program, on June 25, 2018, we published in the **Federal Register** a Request for Information Regarding the Physician Self-Referral Law (the CMS RFI) seeking recommendations and input from the public on how to address any undue impact and burden of the physician self-referral statute and regulations (83 FR 29524).

Comments on the CMS RFI fell within five general themes. First, commenters requested new exceptions to the physician self-referral law to protect a variety of compensation arrangements between and among parties in CMS-sponsored alternative payment models and also those models that are sponsored by other payors, including Federal payors. Commenters also requested protection for care coordination arrangements, including arrangements where entities and physicians share resources to facilitate the care of their common patients. Generally, commenters recognized the need for appropriate safeguards in exceptions for arrangements among parties that participate in alternative payment models. Second, commenters requested a new exception to permit entities to donate cybersecurity technology and services to physicians. Third, commenters provided helpful feedback on terminology and concepts critical to the physician self-referral law, such as commercial reasonableness, fair market value, and compensation that "takes into account" the volume or value of referrals and is "set in advance." Fourth, some commenters expressed concerns that new exceptions or easing current restrictions could exacerbate overutilization and other harms. For example, some commenters indicated that financial gain should never be permitted to influence medical decision making, and some expressed concern that value-based payment systems drive industry consolidation and reduce competition. Finally, a few commenters provided feedback on issues that were not specifically discussed in the CMS RFI, such as requests to eliminate or keep the statutory restrictions for physician-owned hospitals and requests to eliminate, expand, or limit the scope and availability of the in-office ancillary services exception. Commenters on the CMS RFI provided valuable information used to develop the proposals that we are finalizing in this final rule.

e. Notice of Proposed Rulemaking

In the October 17, 2019 **Federal Register**, we published a proposed rule (84 FR 55766) (the proposed rule) in which we proposed a comprehensive package of reforms to modernize and clarify the regulations that interpret the physician self-referral law. These proposed policies were developed in support of the CMS Patients over Paperwork initiative, the Regulatory Sprint, and based on our experience in administering the physician self-referral law, including the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). The CMS Patients over Paperwork initiative emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. Reducing unnecessary burden generally is a shared goal of the Patients over Paperwork initiative and the Regulatory Sprint. The Regulatory Sprint is focused specifically on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care.

To facilitate the transition of our health care system to one that is based on value rather than volume, we proposed new exceptions to the physician self-referral law for value-based arrangements, along with integrally-related definitions for value-based enterprises, activities, arrangements, and purposes, the providers and suppliers that participate in a value-based enterprise, and the target patient population for whom the parties' efforts are undertaken. We also proposed new and revised policies that balance program integrity concerns against the burden of the physician self-referral law's referral and billing prohibitions by: providing guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations; reassessing the scope of the statute's reach; and establishing new exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services.

As part of the Regulatory Sprint and also in the October 17, 2019 **Federal Register**, OIG published a proposed rule under the anti-kickback statute and CMP law to address concerns regarding provisions in those statutes that may act as barriers to coordinated care (84 FR 55694). Because many of the compensation arrangements between parties that participate in alternative payment models and other novel financial arrangements implicate both the physician self-referral law and the anti-kickback statute, we coordinated closely with OIG in developing certain provisions of our proposals. Our aim was to promote alignment across our agencies, where appropriate, to ease the compliance burden on the regulated industry. In some cases, our proposals were different in application or potentially more restrictive than OIG's comparable proposals, in recognition of the differences in statutory structures, authorities, and penalties. In other cases, OIG's proposals were more restrictive. In the proposed rule, we stated that, for some arrangements, it may be appropriate for the anti-kickback statute, which is an intent-based criminal law, to serve as "backstop" protection for arrangements that might be protected by an exception to the strict liability physician self-referral law (84 FR 55772).

C. Application and Scope of the Physician Self-Referral Law

As we emphasized in the proposed rule, our intent in interpreting and implementing section 1877 of the Act has always been "to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent," and we have not vacillated from this position (84 FR 55771; *see* also, 66 FR 860). Our 1998 proposed rule was informed by our review of the legislative history of section 1877 of the Act, consultation with our law enforcement partners about their experience implementing and enforcing the Federal fraud and abuse laws, and empirical studies of physicians' referral patterns and practices, which concluded that a physician's financial relationship with an entity can affect a physician's medical decision making and lead to overutilization. At the time of our earliest rulemakings, we did not have as much experience in administering the physician self-referral law or working with our law enforcement partners on investigations and actions involving violations

of the physician self-referral law. Thus, despite our stated intention to interpret the law's prohibitions narrowly and the exceptions broadly, we proceeded with great caution when designing exceptions.

Over the past decade, we have vastly expanded our knowledge of the aspects of financial relationships that result in Medicare program or patient abuse. Our administration of the SRDP, which has received over 1200 submissions since its inception in 2010, has provided us insight into thousands of financial relationships—most of which were compensation arrangements—that ran afoul of the physician self-referral law but posed little risk of Medicare program or patient abuse. We made revisions to our regulations and shared policy clarifications in the CY 2016 and 2019 PFS rulemakings to address many issues related to the documentation requirements in the statutory and regulatory exceptions to the physician self-referral law, but had not, until now, addressed other requirements in the regulatory exceptions that stakeholders identified as adding unnecessary complexity without increasing safeguards for program integrity. As described in more detail in section II of this final rule, we are eliminating certain requirements in our regulatory exceptions that may be unnecessary and revising existing exceptions. We are also establishing new exceptions for nonabusive arrangements for which there is currently no applicable exception to the physician self-referral law's referral and billing prohibitions.

D. Purpose of the Final Rule

This final rule modernizes and clarifies the regulations that interpret the Medicare physician self-referral law. Following an extensive review of policies that originated in the context of a health care delivery and payment system that operates based on the volume of services, and to support the innovation necessary for a health care delivery and payment system that pays for value, we are establishing new, permanent exceptions to the physician self-referral law for value-based arrangements and definitions for terminology integral to such a system. This final rule also includes clarifying provisions and guidance intended to reduce unnecessary regulatory burden on physicians and other health care providers and suppliers, while reinforcing

the physician self-referral law's goal of protecting against program and patient abuse. Finally, we are establishing new exceptions for nonabusive arrangements for which there is currently no applicable exception to the physician self-referral law's referral and billing prohibitions.

II. Provisions of the Final Rule

A. Facilitating the Transition to Value-Based Care and Fostering Care Coordination

1. Background

Transforming our health care system into one that pays for value is one of the Secretary's priorities. As we stated in the proposed rule, there is broad consensus throughout the health care industry regarding the urgent need for a movement away from legacy systems that pay for care on a FFS basis (84 FR 55772). Identifying and addressing regulatory barriers to value-based care transformation is a critical step in this movement. We are aware of the effect the physician self-referral law may have on parties participating or considering participation in integrated care delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost, and we share the optimism of commenters on the CMS RFI and the proposed rule that the changes to the physician self-referral regulations will allow greater innovation and enable HHS to realize its goal of transforming the health care system into one that pays for value.

The health care landscape when the physician self-referral law was enacted bears little resemblance to the landscape of today. As many commenters on the CMS RFI and the proposed rule highlighted, the physician self-referral law was enacted at a time when the goals of the various components of the health care system were often in conflict, with each component competing for a bigger share of the health care dollar without regard to the inefficiencies that resulted for the system as a whole—in other words, a volume-based system. According to these commenters, the current physician self-referral regulations—intended to combat overutilization in a volume-based system—are outmoded because, by their nature, integrated care models protect against overutilization by aligning clinical and economic performance as the benchmarks

for value. And, in general, the greater the economic risk that providers assume, the greater the economic disincentive to overutilize services. According to some of these commenters, the current prohibitions are even antithetical to the stated goals of policy makers, both in the Congress and within HHS, for health care delivery and payment reform. We agree in concept and, as described below in this section II.A. of this final rule, we are finalizing an interwoven set of definitions and exceptions that depart from the historic exceptions to the physician self-referral law in order to facilitate the transition to a value-based health care delivery and payment system.

We intend for the policies finalized in this final rule to facilitate an evolving health care delivery system, and endeavored to design policies that will stand the test of time. We believe that our final policies achieve the right balance between ensuring program integrity, making compliance with the physician self-referral law readily achievable, and providing the flexibility required by participants in value-based health care delivery and payment systems. As we did with respect to the proposed rule, we coordinated closely with OIG in developing our final exceptions, definitions, and related policies. However, for the reasons described in this final rule, the final definitions and exceptions that pertain to the physician self-referral law differ in some respects from the final definitions and safe harbors that pertain to the anti-kickback statute. Compensation arrangements may implicate both statutes and, therefore, should be analyzed for compliance with each statute.

2. Definitions and Exceptions

In §411.357(aa), we are finalizing new exceptions to the physician self-referral law for compensation arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise of which they are participants. The exceptions apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. Although revisions to the physician self-referral regulations

are crucial to facilitating the transition to a value-based health care delivery and payment system, nothing in our final policies is intended to suggest that many value-based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not satisfy the requirements of existing exceptions to the physician self-referral law.

For purposes of applying the exceptions, we are finalizing new definitions at §411.351 for the following terms: value-based activity; value-based arrangement; value-based enterprise; value-based purpose; VBE participant; and target patient population. The definitions are essential to the application of the exceptions, which apply only to compensation arrangements that qualify as value-based arrangements. Thus, the exceptions may be accessed only by those parties that qualify as VBE participants in the same value-based enterprise. The definitions and exceptions together create the set of requirements for protection from the physician self-referral law's referral and billing prohibitions. Again, where possible and feasible, we have aligned with OIG's final policies to ease the compliance burden on the regulated industry. Specifically, with respect to the value-based terminology as defined in this final rule, we are aligned with the OIG in most respects, and points of difference are explained below.

To facilitate readers' review of our final policies, we first discuss the value-based definitions we are finalizing in this final rule.

a. Definitions

The final definitions and exceptions together create the set of requirements for protection from the physician self-referral law's referral and billing prohibitions. The "value-based" definitions are interconnected and, for the best understanding, should be read together. In the proposed rule (84 FR 55773), we proposed the following terms and definitions for purposes of applying the new exceptions at §411.357(aa):

- *Value-based activity* means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from

taking an action. We also proposed that the making of a referral is not a value-based activity.

- *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) the value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.

- *Value-based enterprise* means two or more VBE participants: (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

- *Value-based purpose* means: (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

- *VBE participant* means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

- *Target patient population* means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

We are finalizing the definitions as proposed, with the modifications described below in this section II.A.2.a. of this final rule.

The activities undertaken by the parties to a compensation arrangement are key to the

arrangement qualifying as a "value-based arrangement" to which the exceptions at §411.357(aa) apply. We refer to these activities as value-based activities. In the proposed rule, we acknowledged that sometimes value-based activities are easily identifiable as the provision of items or services to a patient and, other times, identifying a specific activity responsible for an outcome in a value-based health care system can be difficult (84 FR 55773). We appreciate that remuneration paid in furtherance of the objectives of a value-based health care system does not always involve one-to-one payments for items or services provided by a party to an arrangement. For example, a shared savings payment distributed by an entity to a downstream physician who joined with other providers and suppliers to achieve the savings represents the physician's agreed upon share of such savings rather than a payment for specific items or services furnished by the physician to the entity (or on the entity's behalf). And, when payments are made to encourage a physician to adhere to a redesigned care protocol, such payments are made, in part, in consideration of the physician refraining from following or altering his or her past patient care practices rather than for direct patient care items or services provided by the physician. Therefore, at final §411.351, "value-based activity" is defined to mean the provision of an item or service, the taking of an action, or the refraining from taking an action, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are participants. In the proposed rule, we stated that the act of referring patients for designated health services is itself not a value-based activity. In addition, as a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law, and payments for referrals are antithetical to the purpose of the statute (84 FR 55773). Because of this view, we proposed to expressly state in the definition of "value-based activity" that the making of a referral is not a value-based activity in order to make clear that the exceptions would not protect the direct payment for referrals. For the reasons discussed in response to comments below, we are not finalizing this part of our proposal. However, as discussed in section II.D.2.c. of this final rule,

we are revising the definition of "referral" at §411.351 to affirm our policy that, as a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law.

Our final definition of "value-based activity" requires that the activities must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise. For example, if the value-based purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement might require routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. The value-based activity—that is, the physician's participation in the post-discharge meetings—would be reasonably designed to achieve the enterprise's value-based purpose. In contrast, if the value-based purpose of the enterprise is to reduce the costs to or growth in expenditures of payors while improving or maintaining the quality of care for the target patient population, providing patient care services (the purported value-based activity) without monitoring their utilization would not appear to be reasonably designed to achieve that purpose.

The definition of "value-based arrangement" is key to our final policies aimed at facilitating the transition to value-based care and fostering care coordination, as the final exceptions apply only to arrangements that qualify as value-based arrangements. At final §411.351, "value-based arrangement" is defined to mean an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (1) a value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise. We have revised the language of our proposed definition by substituting "to which the only parties are" for "between or among" to make clear that all parties to the value-based arrangement must be VBE participants in the same value-based enterprise. For instance, a value-based arrangement between an imaging center and a physician would not be a value-based arrangement if the imaging center is not part of the same value-based enterprise

as the physician. Effectively, the parties to a value-based arrangement must include an entity (as defined at §411.351) and a physician; otherwise, the physician self-referral law's prohibitions would not be implicated. Also, because the exceptions at final §411.357(aa) apply only to compensation arrangements (as defined at §411.354(c)), the value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies.

Patient care coordination and management are the foundation of a value-based health care delivery system. Reform of the delivery of health care through better care coordination—including more efficient transitions for patients moving between and across care settings and providers,[4] reduction of orders for duplicative items and services, and open sharing of medical records and other important health data across care settings and among a patient's providers (consistent with privacy and security rules)—is integrally connected to reforming health care payment systems to shift from volume-driven to value-driven payment models. We expect that most value-based arrangements would involve activities that coordinate and manage the care of a target patient population, but did not propose to limit the universe of compensation arrangements that will qualify as value-based arrangements to those arrangements specifically for the coordination and management of patient care. Rather, we sought comment on our approach and whether we should revise the definition of "value-based arrangement" to require care coordination and management in order to qualify as a value-based arrangement. As discussed in more detail later in this section, the final definition of "value-based arrangement" does not require care coordination and management in order to qualify as a value-based arrangement; therefore, we are not including a corollary definition of "care coordination and management" in our final regulations.

The final exceptions at §411.357(aa) apply only to value-based arrangements, the only

[4] For purposes of this section, the term "providers" includes both providers and suppliers as those terms are defined in 42 CFR 400.202, as well as other components of the health care system. The term is used generically unless otherwise noted.

parties to which, as described previously, are a value-based enterprise and one or more of its VBE participants or VBE participants in the same value-based enterprise. At final §411.351, value-based enterprise is defined to mean two or more VBE participants: (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). A "value-based enterprise" includes only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care delivery and payment system. As we stated in the proposed rule, an "enterprise" may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers (84 FR 55774). An "enterprise" may also consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s). Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients. The definition of "value-based enterprise" finalized at §411.351 is focused on the functions of the enterprise, as it is not our intention to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise.

To qualify as a value-based enterprise, among other things, each participant in the enterprise, whom we refer to as a VBE participant, must be a party to at least one value-based arrangement with at least one other participant in the enterprise. If a value-based enterprise is

comprised of only two VBE participants, they must have at least one value-based arrangement with each other in order for the enterprise to qualify as a value-based enterprise. (Provided that a value-based enterprise exists, an arrangement between the enterprise and a physician who is a VBE participant in the value-based enterprise may qualify as a "value-based arrangement" for purposes of the exceptions at §411.357(aa) if the value-based enterprise is itself an "entity" as defined at §411.351.) In addition, a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. This may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or this may be the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties (for example, if the "enterprise" consists of just the two parties). Finally, a value-based enterprise must have a governing document that describes the enterprise and how its VBE participants intend to achieve its value-based purpose(s). Implicit in this requirement is that the value-based enterprise must have at least one value-based purpose.

Also critical to qualifying as a value-based arrangement are the scope and objective of the arrangement. As noted previously, only an arrangement for activities that are reasonably designed to achieve at least one of the value-based enterprise's value-based purposes may qualify as a value-based arrangement to which the exceptions at §411.357(aa) apply. At final §411.351, value-based purpose is defined to mean: (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population. As we stated in the proposed rule, some of these goals are recognizable as part of the successor frameworks to the "triple aim" that are integral to CMS' value-based programs and our larger quality strategy to

reform how health care is delivered and reimbursed (84 FR 55774). Our definition of "value-based purpose" identifies four core goals related to a target patient population. One or more of these goals must anchor the activities underlying every compensation arrangement that qualifies as a value-based arrangement to which the exceptions at final §411.357(aa) apply.

In the proposed rule, we sought comment on whether it would be desirable or necessary to codify in regulation text what is meant by "coordinating and managing care" and, if so, whether "coordinating and managing care" should be defined to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population (84 FR 55775). This definition was intended to correspond to a similar definition proposed by OIG. As described in more detail below, we are not finalizing a definition of "coordinating and managing care" in our regulations. We also sought comment regarding whether additional interpretation of the other proposed value-based purposes is necessary, but did not receive comments on the need for additional interpretation of any other aspect of the definition of "value-based purpose." We respond to comments on this topic below.

We proposed to define VBE participant (that is, a participant in a value-based enterprise) to mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. We noted in the proposed rule that the word "entity," as used in the definition of "VBE participant," is not limited to non-natural persons that qualify as "entities" as defined at §411.351 (84 FR 55775). We proposed to use the word "entity" in the definition of "VBE participant" in order to align with the definition proposed by OIG. We sought comment regarding whether the use of the word "entity" in this definition would cause confusion due to the fact that the universe of non-natural persons (that is, entities) that could qualify as VBE participants is greater than the universe of non-natural persons that qualify as "entities" under §411.351 and, if so, what alternatives exist for defining "VBE participant" for purposes of the

physician self-referral law. As discussed in more detail below, we are modifying the definition of VBE participant in this final rule to mean a *person or entity* that engages in at least one value-based activity as part of a value-based enterprise. The phrase "person or entity" is used more frequently throughout our regulations and, even though the word "entity" (as included in the definition of "VBE participant") is not limited to an "entity" as defined at §411.351 and its use could result in some confusion for stakeholders, we believe that it is less disruptive to use the already-common phrase "person or entity" to define VBE participant. We may consider whether to replace the word "entity" throughout our regulations in those instances where it is not intended to be limited to the defined term at §411.351. However, any revisions to our regulations to achieve this substitution would occur through future notice-and-comment rulemaking.

In the proposed rule, we also discussed the experiences of our law enforcement partners, including oversight experience, and the resulting concern about protecting potentially abusive arrangements between certain types of entities that furnish designated health services for purposes of the physician self-referral law (84 FR 55775). Specifically, we discussed concerns about compensation arrangements between physicians and laboratories or suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that may be intended to improperly influence or capture referrals without contributing to the better coordination of care for patients (84 FR 55776). We stated that we were considering whether to exclude laboratories and DMEPOS suppliers from the definition of VBE participant or, in the alternative, whether to include in the exceptions at §411.357(aa), a requirement that the arrangement is not between a physician (or immediate family member of a physician) and a laboratory or DMEPOS supplier. We also stated that, in particular, we were uncertain as to whether laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. In addition, due to our (and our law enforcement partners') ongoing program integrity concerns with certain other

participants in the health care system and to maintain consistency with policies proposed by OIG, we stated that we were also considering whether to exclude the following providers, suppliers, and other persons from the definition of "VBE participant": pharmaceutical manufacturers; manufacturers and distributors of DMEPOS; pharmacy benefit managers (PBMs); wholesalers; and distributors. At final §411.351, "VBE participant" is defined to mean a person or entity that engages in at least one value-based activity as part of a value-based enterprise. The definition of "VBE participant" finalized here does not exclude any specific persons, entities, or organizations from qualifying as a VBE participant.

Lastly, we are finalizing the definition of "target patient population" as proposed, without modification. Specifically, the target patient population for which VBE participants undertake value-based activities is defined at final §411.351 to mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that: (1) are set out in writing in advance of the commencement of the value-based arrangement; and (2) further the value-based enterprise's value-based purpose(s). We affirm in this final rule that legitimate and verifiable criteria may include medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes), geographic characteristics (for example, all patients in an identified county or set of zip codes), payor status (for example, all patients with a particular health insurance plan or payor), or other defining characteristics. As we stated in the proposed rule, selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as we would not consider the selection criteria to be legitimate (even if verifiable) (84 FR 55776).

We received comments on the proposed definitions of value-based activity, value-based arrangement, value-based enterprise, value-based purpose, VBE participant, and target patient population. Our responses follow.

Comment: Most commenters supported our proposed definition of value-based activity, but many requested further guidance regarding what CMS would consider appropriate value-based activities. Specifically, some commenters asked whether particular items or services, such as transportation services or the provision of non-medical personnel, would qualify as value-based activities. Commenters did not explain how the arrangements for those particular items or services would implicate the physician self-referral law; that is, whether the items or services are in-kind remuneration provided by an entity to a physician or an immediate family member of a physician under an arrangement between a physician (or immediate family member of a physician), whether the items or services are provided by one of the parties to a value-based arrangement and paid for by the recipient of the items or services, or whether the services are provided to patients.

Response: We decline to provide a list of items or services, actions, and ways to refrain from taking an action that qualify as value-based activities. We are concerned that even a non-exhaustive list of common value-based activities could unintentionally limit innovation and inhibit robust participation in value-based health care delivery and payment systems. The final definition of "value-based activity" provides the flexibility for parties to design arrangements that further the value-based purpose(s) of value-based enterprises. The determination regarding whether the provision of an item or service, the taking of an action, or the refraining from taking an action constitutes a value-based activity is a fact-specific analysis and turns on whether the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise.

With respect to the examples provided by the commenters, we note that the scope of the physician self-referral law is limited to a financial relationship between a physician (or the immediate family member of a physician) and the entity to which the physician makes referrals for designated health services. We assume that the commenters were referring to the provision of transportation services to a beneficiary, which would not implicate the law unless the

beneficiary was a physician or an immediate family member of a physician. With respect to the commenters' inquiry regarding the provision of non-medical personnel, assuming that the commenters were referring to the provision of non-medical personnel to a physician by an entity, we are uncertain whether the commenter is referring to in-kind remuneration between an entity and a physician in the form of the services of non-medical personnel without expectation of payment or whether the provision of non-medical personnel would be paid for in cash under the terms of an arrangement between an entity and a physician. Therefore, we are unable to provide specific guidance in response to the inquiry.

Comment: A few commenters requested guidance on what it means for a value-based activity to be reasonably designed to achieve at least one value-based purpose. Some of the commenters expressed concern that our solicitation of comments in the proposed rule could be interpreted to signal that success is required in order for the protections of the value-based exceptions to apply, noting that success of a value-based activity in achieving the intended value-based purpose is never guaranteed. One of the commenters urged CMS to confirm that "satisfying the value-based purposes element of various value-based definitions does not necessarily mean actual success in achieving the purposes but means engaging in collaboration and activities 'reasonably designed to achieve' one or more of these value-based purposes."

Response: The determination regarding whether a value-based activity is reasonably designed to achieve at least one value-based purpose is a fact-specific determination. Parties must have a good faith belief that the value-based activity will achieve or lead to the achievement of at least one value-based purpose of the value-based enterprise in which the parties to the arrangement are VBE participants. We recognize that parties may undertake activities that do not ultimately achieve the value-based purpose(s) of the enterprise. Nothing in our final regulations requires that the value-based purpose(s) must be achieved in order for a value-based arrangement to be protected under an applicable exception at §411.357(aa). However, if the parties are aware that the provision of the item or service, the taking of the

action, or the refraining from taking the action will not further the value-based purpose(s) of the value-based enterprise, it will cease to qualify as a value-based activity and the parties may need to amend or terminate their arrangement. As discussed in section II.A.2.b.(3). of this final rule, we are including a requirement in the final exception for value-based arrangements at §411.357(aa)(3)(vii) that parties must monitor whether they have furnished the value-based activities required under the arrangement and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise.

Comment: A few commenters requested guidance on how parties can document or otherwise show that a value-based activity is "reasonably designed" to achieve a value-based purpose.

Response: We do not dictate how parties should analyze the design of their value-based arrangements to ensure that the value-based activities they undertake are reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which they are participants or how they should substantiate their efforts. We note that contemporaneous documentation is a best practice, and we encourage parties to follow this practice. We also remind parties that the burden of proof to show compliance with the physician self-referral law is set forth at §411.353 and is applicable to parties utilizing the new exceptions for value-based arrangements at final §411.357(aa). We emphasize that the new exceptions do not impose an additional or different burden of proof. It is the responsibility of the entity submitting a claim for payment for designated health services furnished pursuant to a referral from a physician with which it has a financial relationship to ensure compliance with the physician self-referral law at the time of submission of the claim. That is, parties must ensure that their financial relationship satisfies all the requirements of an applicable exception at the time the physician makes a referral for designated health service(s).

Comment: Several commenters expressed concern with our statement that the making of a referral is not a value-based activity and requested that CMS revise the definition of value-

based activity to include the making of a referral. These commenters noted that the definition of "referral" at §411.351 includes the establishment of a plan of care that includes the provision of designated health services. The commenters also asserted that referrals are an integral part of a value-based health care delivery and payment system, especially with respect to care planning, and contended that excluding the making of a referral from the definition of "value-based activity" would significantly limit the utility of the exceptions. Some commenters urged CMS to revise the definition of "value-based activity" to specifically include the making of a referral as a value-based activity.

Response: The commenters raise important points about the scope of the definition of "referral" at §411.351 and the exclusion of the making of a referral from the definition of "value-based activity." It was not our intention to exclude the development of a care plan that includes the furnishing of designated health services from the definition of "value-based activity." Accordingly, we are not finalizing the reference to the making of a referral in the definition of "value-based activity." We are defining value-based activity to mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. Care planning activities that meet the definition of "referral" at §411.351 will qualify as "the taking of an action" for purposes of applying the definition of "value-based activity." As discussed in section II.D.2.c. of this final rule, we are revising the definition of "referral" at §411.351 to codify in regulation text our policy that a referral is not an item or service for purposes of section 1877 of the Act and the physician self-referral law regulations.

Comment: Most commenters supported the proposed definition of "value-based arrangement." However, a few commenters requested that we expand the definition to specifically include the following alternative payment models (APMs): advanced APMs, all-payor/other-payor APMs, and Merit-based Incentive Payment System (MIPS) Alternative

Payment Models (APMs) under the Quality Payment Program (QPP). The commenters also requested that we include State-based Medicaid initiatives in the definition of "value-based arrangement."

Response: We decline to adopt the commenters' suggestion and are finalizing the definition as proposed. The models referenced by the commenters relate to value-based payments from a payor to a physician under a payment arrangement between the payor and the physician. For purposes of the physician self-referral law, a compensation arrangement is an arrangement between a physician (or immediate family member of a physician) and the entity to which the physician makes referrals for designated health services. The definition of "value-based arrangement" relates to a compensation arrangement between a physician and an entity that participate in the same value-based enterprise. It does not cover compensation arrangements between a payor and a physician.

Comment: Most commenters generally supported our proposed definition of "value-based enterprise," although one commenter had concerns with the requirement that each VBE participant must be a party to a value-based arrangement with at least one other VBE participant in the value-based enterprise. This commenter interpreted this requirement to preclude the addition of VBE participants to a value-based arrangement after the value-based arrangement has begun. The commenter requested that we permit parties to add VBE participants to a value-based arrangement throughout the duration of the arrangement, either on an ongoing basis or at least annually.

Response: The design and structure of contracts is separate and distinct from the analysis of financial relationships under the physician self-referral law. Although nothing in our regulations prohibits having multiple parties to a contract or adding parties after the effective date of the contract, each of the financial relationships that results from the contract must be analyzed separately under the physician self-referral law. The commenter described adding new physicians to an existing value-based arrangement. For purposes of determining compliance

with the physician self-referral law, an arrangement between an entity and a "new" physician engaging in value-based activities will not be viewed as an "addition" to an existing value-based arrangement but, rather, a separate and distinct compensation arrangement that must be analyzed for compliance with an applicable exception. To illustrate, assume that a hospital and a physician organization enter into a value-based arrangement under which the physician organization agrees that all its physicians will abide by the hospital's care protocols for a period of 2 years. During the course of the value-based arrangement, the physician organization hires a new physician who agrees to abide by the hospital's care protocols as called for by the physician organization's arrangement with the hospital. Assuming the new physician stands in the shoes of the physician organization under §411.354(c), the "addition" of the new physician to the physician organization creates a separate new financial relationship between the hospital and the new physician that must satisfy the requirements of an applicable exception to the physician self-referral law. Nothing in the definition of "value-based enterprise" will preclude a new VBE participant from providing value-based activities and participating in a value-based arrangement with another VBE participant or the value-based enterprise itself (if the value-based enterprise is an entity for purposes of the physician self-referral law).

Comment: Many commenters sought additional guidance regarding the type of organized network or group of persons or entities that may qualify as a value-based enterprise.

Response: A value-based enterprise may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers and suppliers. A value-based enterprise may also be an informal affiliation, even consisting of only the two parties to a value-based arrangement. The definition of "value-based enterprise" is intended to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care delivery and payment system. Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians,

providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients. Simply stated, a value-based enterprise is a network of individuals and entities that are collaborating to achieve one or more value-based purposes of the value-based enterprise. We do not believe that it would be beneficial to dictate particular legal or other structural requirements for a value-based enterprise. Rather, the definition of "value-based enterprise" is intended to encompass a wide-range of structures to help facilitate health care providers' transition to a value-based health care delivery and payment system.

Comment: A few commenters requested guidance with respect to the requirement that the value-based enterprise have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise, specifically with respect to the responsibilities, requirements, structure, and composition of the accountable body. One commenter requested confirmation that an ACO could rely on its existing governing body and would not need to establish a separate accountable body or identify a person other than the ACO's governing body to be responsible for the financial and operational oversight of the value-based enterprise. Several commenters expressed concern that requiring one individual or entity to assume responsibility for the financial and operational oversight of the value-based enterprise could create tension between VBE participants and limit the utility of the exceptions for smaller value-based enterprises. Other commenters asserted that the establishment of the accountable body or person and the development of the governing document would require the expenditure of significant resources, including legal expenses, and questioned whether this burden is necessary. One of these commenters suggested that this requirement is especially burdensome for small or rural practices that may not have sufficient resources to satisfy the requirement. Some commenters also requested explicit guidance regarding the governing document that describes the value-based enterprise and how its VBE participants intend to achieve the enterprise's value-

based purpose(s).

Response: Transparency and accountability are critical to a successful transition to a value-based health care delivery and payment system. It is essential that CMS and our law enforcement partners are able to identify the person or organization ultimately responsible for the financial and operational oversight of a value-based enterprise. We do not believe that requiring a value-based enterprise to have an accountable body or responsible person and a governing document creates an administrative or financial burden beyond what parties that wish to transition to value-based health care would already incur.

We are not persuaded to abandon the requirement that a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. As discussed in the proposed rule and as noted above, the accountable body or person that is responsible for the financial and operational oversight of the enterprise may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or may be the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties (if the "enterprise" is a network consisting of just the two parties) (84 FR 55774). We expect that a value-based enterprise would establish an accountable body or designate a responsible person commensurate with the scope and objectives of the value-based enterprise and its available resources.

We are also maintaining the requirement that the enterprise must have a governing document that describes the value-based enterprise and how its VBE participants intend to achieve its value-based purpose(s). Parties regularly enter into payor contracts, employment relationships, service arrangements, and other arrangements for items and services related to the provision of patient care services. It is a matter of general contracting practice that these contracts and written agreements specify the rights, responsibilities, and obligations of the parties. We expect that independent health care providers that wish to organize and collaborate

to achieve value-based purposes would utilize these same basic practices to reduce their arrangements to writing, including their arrangement to form a value-based enterprise. We believe that the same is true for the development of a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). We remind parties that we are not dictating particular legal or other structural requirements for a value-based enterprise; rather, the final regulations accommodate both formal and informal value-based enterprises. As a result, the written agreements and contracts that parties enter into in the normal course of their business dealings could serve as the documentation required under the new exception for value-based arrangements.

It is simply not possible to establish one set of financial and operational oversight requirements that would be applicable to value-based enterprises of all types and sizes. The financial and operational oversight of a value-based enterprise and the related governing document for a value-based enterprise made up of only a hospital and physician will look very different from that of an ACO that contracts with thousands of providers and suppliers. Again, we do not dictate the structure or composition of the accountable body; rather, we simply require that the accountable body or responsible person for the value-based enterprise exercise appropriate financial and operational oversight of the value-based enterprise. Similarly, we do not dictate the format or content of the governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). The necessary infrastructure to effectively oversee the financial and operational activities of the value-based enterprise and the governing document will depend on the size and structure of the value-based enterprise.

Comment: Several commenters recommended that CMS not limit the types of entities that may qualify as a VBE participant out of concern that any such limitations could slow down or inhibit the movement of the entire health care industry towards value-based health care delivery and significantly limit the utility of the exceptions. The commenters provided detailed

examples of how laboratories and DMEPOS suppliers, in particular, contribute to the value-based health care delivery and payment system by collaborating with other sectors of the health care industry to improve care, lower costs, and ensure that patients are receiving appropriate care. Other commenters expressed concern that the exclusion of laboratories and DMEPOS suppliers from participation in value-based enterprises would impact the ability of health systems that own laboratories or DMEPOS suppliers from participating in value-based health care delivery.

Response: We are not excluding any specific persons, entities, or organizations from the definition of "VBE participant." We find the commenters' assertions that laboratories and DMEPOS suppliers may play a beneficial role in the delivery of value-based health care persuasive. However, we will continue to monitor the evolution of the value-based health care delivery and payment system to ensure that the inclusion of all types of providers and suppliers as VBE participants does not create a program integrity risk.

Comment: A number of commenters supported the inclusion of coordinating and managing the care of a target patient population as an appropriate value-based purpose, although the majority of these commenters urged CMS to not define "coordinating and managing care" in regulation text, suggesting that the phrase is self-explanatory and defining it could inadvertently limit or interfere with innovation. Commenters that were open to the inclusion of a definition of "coordinating and managing care" stressed the need for any such definition to be drafted broadly. Other commenters suggested that, if we codify a definition of "coordinating and managing care," it should align with any definition of the same term adopted by OIG.

Response: We agree with the commenters that it is not necessary to define "coordinating and managing care" for purposes of the definition of "value-based purpose." In addition, we do not believe that it is necessary to define "coordinating and managing care" for purposes of the exceptions finalized at §411.357(aa), as they are not limited only to value-based arrangements for the coordination or management of care.

Comment: Many commenters requested that we include as a value-based purpose the maintenance of quality of care for the target population without requiring a reduction in costs to payors.

Response: We decline to include the maintenance of quality of care as a permissible value-based purpose in the absence of reduction of the costs to or growth in expenditures of payors. Although we recognize that the maintenance of quality of care may advance the goals of a value-based enterprise or the specific parties to a value-based arrangement, we do not believe that the maintenance of quality of care in the absence of a reduction in the costs to or growth in expenditures of payors advances the goals of the Regulatory Sprint. Thus, it is not appropriate to include the maintenance of quality of care as a stand-alone value-based purpose that would unlock access to the exceptions at §411.357(aa). We note that numerous CMS programs and Medicare payment mechanisms already require the maintenance of quality across the care continuum and encourage improvement and maintenance of quality through use of payment incentives and payment reductions. For example, under the Hospital Inpatient Quality Reporting Program, CMS collects quality data from hospitals paid under the IPPS. Data for selected measures are used for paying a portion of hospitals based on the quality and efficiency of care, including the Hospital-Acquired Condition Reduction Program, Hospital Readmissions Reduction Program, and Hospital Value-Based Purchasing Program, which rewards acute care hospitals with incentive payments based on the quality of care they provide, rather than just the quantity of services they provide.

Comment: The majority of commenters supported the definition of "value-based purpose" and urged CMS to finalize the definition without modifications. A few commenters requested that we revise the definition of "value-based purpose" to include the reduction in costs to or growth in expenditures of health care providers and suppliers. These commenters asserted that limiting the definition of value-based purpose to reducing the costs to or growth in expenditures of only payors fails to recognize the benefits to Medicare that come from the

reduction of provider costs, such as reporting lower costs to Medicare on the hospital's cost report, which, in turn, result in lower Medicare expenditures. These commenters pointed to internal cost savings programs that distribute savings generated from implementing specific cost saving measures to physicians. The commenters expressed concern that hospital-initiated quality and efficiency programs that drive down hospital costs, improve efficiency, and improve quality of care would not be protected by the exceptions because the hospital's program would not directly reduce costs to or growth in expenditures of payors.

Response: We are not persuaded to revise the definition of "value-based purpose" as requested by the commenters. We believe that the four purposes included in the definition are sufficiently inclusive to allow for innovative value-based arrangements while protecting against program or patient abuse. We do not believe that permitting a value-based enterprise to exist solely for the purpose of reducing costs to its VBE participants would adequately protect the Medicare program and its beneficiaries from abuse. Moreover, allowing parties to share in the reduction of costs without also improving or maintaining quality of care for patients or otherwise benefitting payors does not advance the transition to a value-based health care delivery and payment system. We note that nothing in this final rule precludes the sharing of cost savings and other entity-specific savings programs, provided those programs are part of a value-based arrangement for value-based activities reasonably designed to further at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are VBE participants. The compensation to a physician under such a value-based arrangement could include a share of the savings that result from a hospital's internal cost sharing (or gainsharing) program.

Comment: A few commenters specifically supported the inclusion as a value-based purpose "transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population." These commenters stated that allowing a value-based

enterprise to operate for this purpose is necessary to achieve CMS' goal of transitioning to a value-based health care delivery and payment system and strikes the right balance between precision and flexibility. The commenters asserted that value-based enterprises would rely on this purpose to cover the clinical integration and infrastructure activities necessary to develop and implement a value-based enterprise and to meet future operational and capital requirements. Commenters likened this value-based purpose to the purpose underlying the pre-participation waiver for the Shared Savings Program. The commenters recommended that we make no further refinement to this value-based purpose.

Response: The commenters' understanding of the scope of this value-based purpose is correct. As we discussed in the proposed rule, this value-based purpose is intended to accommodate efforts aimed at transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for the target patient population (84 FR 55775). Generally speaking, we interpret "transitioning" to mean undergoing the process or period of transition from one state or condition to another and, specifically, with respect to this value-based purpose, the process or period of transition from furnishing patient care services in a FFS volume-based system to furnishing patient care services in a value-based health care delivery and payment system. Thus, this value-based purpose applies during the period of a value-based enterprise's start-up or preparatory activities. In the proposed rule, we interpreted this value-based purpose as a category that includes the integration of VBE participants in team-based coordinated care models, establishing the infrastructure necessary to provide patient-centered coordinated care, and accepting (or preparing to accept) increased levels of financial risk from payors or other VBE participants in value-based arrangements (84 FR 55775). This purpose will also apply to activities undertaken by an unincorporated value-based enterprise that wishes to formalize its legal and operational structure, as well as the preparation by a value-based enterprise to accept financial risk and the preparation of VBE participants to furnish services in a manner focused on

the value of those services instead of volume.

We agree that this value-based purpose shares certain aspects of the pre-participation waiver under the Shared Savings Program. In our discussion of the Shared Savings Program pre-participation waiver in our October 29, 2015 Shared Savings Program Final Waivers in Connection with the Shared Savings Program Final Rule (80 FR 66726) (the SSP waivers final rule), we provided examples of start-up arrangements as guideposts for determining whether a particular arrangement may qualify for protection under the pre-participation waiver (80 FR 66733). We believe those examples, to the extent they create a compensation relationship for purposes of the physician self-referral law, may be illustrative for purposes of interpreting the scope of "transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population." In the SSP waivers final rule (80 FR 66733), we stated that the following types of start-up arrangements may qualify under the Shared Savings Program pre-participation waiver:

- Infrastructure creation and provision.
- Network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care.
- Care coordination mechanisms, including care coordination processes across multiple organizations.
- Clinical management systems.
- Quality improvement mechanisms including a mechanism to improve patient experience of care.
- Creation of governance and management structure.
- Care utilization management, including chronic disease management, limiting hospital readmissions, creation of care protocols, and patient education.

- Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses.
- Hiring of new staff, including care coordinators (including nurses, technicians, physicians, and/or non- physician practitioners), umbrella organization management, quality leadership, analytical team, liaison team, IT support, financial management, contracting, and risk management.
- IT, including EHR systems, electronic health information exchanges that allow for electronic data exchange across multiple platforms, data reporting systems (including all payor claims data reporting systems), and data analytics (including staff and systems, such as software tools, to perform such analytic functions).
- Consultant and other professional support, including market analysis for antitrust review, legal services, and financial and accounting services.
- Organization and staff training costs.
- Incentives to attract primary care physicians.
- Capital investments, including loans, capital contributions, grants, and withholds.

Many of these activities similarly facilitate a value-based enterprise's (and its VBE participants') transition from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Comment: We received a number of comments regarding the selection criteria that may be used to choose a target patient population and, specifically, what it means for selection criteria to be legitimate and verifiable. Although several commenters supported the standard that selection criteria must be legitimate and verifiable, stating that it struck the right balance between encouraging innovation and protecting against fraud and abuse, other commenters expressed concern with the use of the term "legitimate," asserting that it is ambiguous and may expose parties to litigation and enforcement risk. Some commenters requested that we instead prohibit

the specific selection criteria that we believe are inappropriate, such as cherry-picking and lemon-dropping, while others requested that we provide a list of selection criteria that would be deemed permissible. A few commenters asked whether specific selection criteria would be acceptable, such as identifying the target patient population by the MS-DRG assigned to the patient, geography, demographic criteria (for example, age or socioeconomic status), or payor (for example, Medicaid or non-Federal payor).

Response: At final §411.351, "target patient population" means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s). We do not believe that it is necessary to further define the term "legitimate." It has been used throughout the physician self-referral regulations for decades. For example, the exception for personal service arrangements includes a requirement at §411.357(d)(1)(iii) that the aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The term "legitimate" does not carry a new or different definition for purposes of interpreting the value-based definitions or the exceptions at §411.357(aa). We refer readers to section II.B.2. of this final rule for further discussion of the term "legitimate" within our regulations. With respect to the commenters' requests for lists of impermissible and permissible selection criteria, it is not feasible to provide such an exhaustive list of selection criteria that we consider unacceptable. Similarly, we believe that providing a list of acceptable selection criteria could serve to interfere with or limit a value-based enterprise's or VBE participant's ability to identify and utilize selection criteria. Deeming provisions sometimes have a chilling effect because they are, in practice, interpreted by the regulated industry as mandatory or otherwise prescriptive rules. We believe the approach we have finalized balances the need for clear guidelines with the need for flexibility. Finally, with respect to the commenters' request for confirmation that specific selection criteria are permissible, we

reiterate that the determination whether the selection criteria used to identify a target patient population are legitimate and verifiable is dependent on the facts and circumstances of the parties. If the criteria are selected primarily for their effect on the parties' profits or purely financial concerns, they will not be considered legitimate and, therefore, are impermissible. None of the selection criteria examples shared by the commenters are *per se* impermissible.

Comment: Some commenters expressed concern with our statement in the proposed rule that choosing a target patient population in a manner driven by profit motive or purely financial concerns would not be legitimate (84 FR 55776). These commenters suggested that this calls into question proven cost-saving techniques, such as product standardization, aimed at reductions in cost or unnecessary care that impact financial performance. The commenters requested that CMS clarify the distinction between reducing costs and problematic criteria, and asked us to explicitly acknowledge that it is permissible to choose a target patient population that could generate cost reductions from activities like product standardization alone.

Response: It appears to us that these commenters have conflated the acceptable criteria for selecting a target patient population and the requirements for selecting activities to be performed under a value-based arrangement. The target patient population is the group of individuals for whom the parties to a value-based arrangement are undertaking value-based activities. Our statement regarding profit motive or purely financial concerns relates to choosing the patient population for which the parties will undertake value-based activities and not the value-based activities themselves. We reiterate that the selection of the target patient population may not be driven by profit motive or purely financial concerns. As we stated in the proposed rule, selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as we will not consider the selection criteria to be legitimate (even if verifiable) (84 FR 55776). Choosing a target patient population solely because it appears likely to reduce the costs to one of the parties to a value-based arrangement

would be suspect. As described earlier in this section and in our response to other comments, a value-based activity must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise. With respect to the commenter's specific inquiry, we note that a value-based activity that requires a physician to utilize a standardized list of products, where appropriate, may be reasonably designed to achieve at least one value-based purpose of the value-based enterprise, depending on the enterprise's value-based purposes.

Comment: A large number of commenters expressed concern with a requirement that the patients in the target patient population have at least one chronic condition to be addressed by the value-based arrangement and urged CMS to not limit the target patient population to chronic patients. The commenters stated that such a requirement would severely constrict the types of value-based arrangements protected under the new exceptions.

Response: Although we sought comment as to whether we should incorporate a requirement that patients in the target patient population have at least one chronic condition in order to align with OIG's proposals, we are not including this provision in the final definition of "target patient population" at §411.351. As finalized, target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s). We are not limiting a target patient population to patients with at least one chronic condition.

Comment: A few commenters requested clarification that the definition of "target patient population" would include patient populations that are retroactively attributed, noting as an example the use of a retrospective claims-based methodology.

Response: A target patient population must be selected based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement. The commenter's concerns appear to relate to the requirement that selection criteria for the target patient population must be set out in writing in advance of the

commencement of the value-based arrangement. Where a target patient population is ascribed to the value-based enterprise (or the VBE participants that are parties to the specific value-based arrangement) by the payor, the payor establishes the criteria for selecting the target patient population. However, this does not affect the obligation of the value-based enterprise or its VBE participants to select the target patient population for purposes of the physician self-referral law and qualification to use the exceptions at §411.357(aa). The definition of "target patient population" at final §411.351 requires that the target patient population is selected by the value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement under which value-based activities are undertaken for the target patient population and that further the value-based enterprise's value-based purpose(s). Thus, where a target patient population is ascribed to the value-based enterprise (or the VBE participants that are parties to the specific value-based arrangement) by the payor, the value-based enterprise or its VBE participants must ensure that the requirements of the definition of "target patient population" are satisfied.

In the circumstances described by the commenters, the selection criteria for the target patient population could be described as "the target patient population to be identified by the payor in accordance with criteria established by the payor for retrospective attribution." The value-based enterprise or the VBE participants that are parties to the specific value-based arrangement under which value-based activities are undertaken for the target patient population must ensure that the payor's methodology for attribution of the target patient population are legitimate and verifiable and that they will further the value-based enterprise's value-based purpose(s). In addition, the selection criteria must be documented in advance of the commencement of the value-based arrangement. It is not sufficient for the value-based enterprise or its VBE participants to merely state that the selection criteria will be determined by another party (in this case, the payor). The value-based enterprise or its VBE participants may need to collaborate with the payor to ensure that the patient population attributed meets the

definition of "target patient population."

Comment: Most commenters supported the proposed definition of "VBE participant." A few commenters objected to the use of the term "entity" in the definition of "VBE participant," because the term "entity" is ascribed a specific meaning at §411.351, but, as used in the definition of "VBE participant," would not be limited to that meaning. Commenters noted that using the same term in two different ways within the same regulatory scheme creates unnecessary complexity and compliance concerns. Commenters sought clarity on this issue, and requested that we either revise the definition of "entity" at §411.351 or use a different term for purposes of the definition of "VBE participant."

Response: Although we understand the commenter's concerns, we are not revising the definition of "VBE participant" to replace the term "entity" with another term, nor are we revising the definition of "entity" at §411.351. In the physician self-referral regulations, the term "entity" is used to indicate an entity (as defined at §411.351) furnishing designated health services and also to indicate its general meaning of an organization (such as a business) that has an identity separate from those of its members. As used in the final definition of "VBE participant," the term "entity" is not limited to an entity furnishing designated health services. Rather, it has its general meaning.

Although we retain the term "entity" in the definition of "VBE participant," we are replacing the term "individual" (as proposed) with the term "person." Thus, under our final regulation, VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise. We intend for "person or entity" to refer to both natural and non-natural persons. Again, the term "entity" in this context is not limited to an entity that furnishes designated health services. Our review of the physician self-referral regulations indicates that the term "person or entity" is used numerous times throughout the regulations. For example, as defined at §411.351, a "referring physician" is a physician who makes a referral or who directs another *person or entity* to make a referral or who controls

referrals made by another *person or entity*. The regulations regarding indirect compensation arrangements at §411.354(c)(2) state that one element of an indirect compensation arrangement is that there exists between the referring physician (or a member of his or her immediate family member) and the entity furnishing designated health services an unbroken chain of any number (but not fewer than one) of *persons or entities* that have financial relationships between them. The regulations also use this term in the context of the *person or entity* from whom the referring physician or immediate family member receives aggregate compensation under the arrangement. The exceptions for the rental of office space and the rental of equipment reference a *person or entity* in the exclusive use requirements at §411.357(a)(3) and (b)(2). For consistency with our existing regulations, we are including the term "person or entity" in our final definition of "VBE participant."

b. Exceptions

The physician self-referral law (along with other Federal fraud and abuse laws) provides critical protection against a range of troubling patient and program abuses that may result from volume-driven, FFS payment. These abuses include unnecessary utilization, increased costs to payors and patients, inappropriate steering of patients, corruption of medical decision making, and competition based on buying referrals instead of delivering quality, convenient care. While value-based payment models hold promise for addressing these abuses, they may pose risks of their own, including risks of stinting on care (underutilization), cherry-picking, lemon-dropping, and manipulation or falsification of data used to verify outcomes. Moreover, during the transformation to value-based payment, many new delivery and payment models include both FFS and value-based payment mechanisms in the same model, subjecting providers to mixed incentives, and presenting the possibility of arrangements that pose both traditional FFS risk and emerging value-based payment risks.

When the physician self-referral law was expanded in 1993 to apply to designated health services beyond the clinical laboratory services to which the original 1989 law applied,

according to the sponsor of the legislation, the Honorable Fortney "Pete" Stark, the physician self-referral law was intended to address physician referrals that drive up health care costs and result in unnecessary utilization of services. (*See* Opening Statement of the Honorable Pete Stark, Physician Ownership and Referral Arrangements and H.R. 345, "The Comprehensive Physician Ownership and Referral Act of 1993," House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, p. 144.) Mr. Stark went on to emphasize the importance of a physician's ability to offer patients neutral advice about whether or not services are necessary, which services are preferable, and who should provide them. He noted that the physician self-referral law would improve consumers' confidence in their physicians and the health care system generally. In other words, the legislation was proposed (and the law ultimately enacted) to counter the effects of physician decision making driven by financial self-interest—overutilization of health care services, the suppression of patient choice, and the impact on the medical marketplace.

As discussed in section I.B.2.a. of this final rule, in 1989 and 1993, the vast majority of Medicare services were reimbursed based on volume under a retrospective FFS system. The statutory exceptions to the physician self-referral law's referral and billing prohibitions were developed during this time of FFS, volume-based payment, with conditions which, if met, would allow the physician's ownership or investment interest or compensation arrangement to proceed without triggering the ban on the physician's referrals or the entity's claims submission. We believe that the exceptions in section 1877 of the Act indicate the Congress' stance on what safeguards are necessary to protect against program or patient abuse in a system where Medicare payment is available for each service referred by a physician and furnished by a provider or supplier. To date, the exceptions for compensation arrangements issued under section 1877(b)(4) of the Act, which grants the Secretary authority to establish exceptions for financial relationships that the Secretary determines do not pose a risk of program or patient abuse, have generally followed the blueprint established by the Congress for compensation arrangements that

exist in a FFS system.

Value-based health care delivery and payment shifts the paradigm of our analysis under section 1877(b)(4) of the Act. When no longer operating in a volume-based system, or operating in a system that reduces the amount of FFS payment by combining it with some level of value-based payment, our exceptions need fewer "traditional" requirements to ensure the arrangements they protect do not pose a risk of program or patient abuse. This is because a value-based health care delivery and payment system, by design, provides safeguards against harms such as overutilization, care stinting, patient steering, and negative impacts on the medical marketplace. Using the Secretary's authority under section 1877(b)(4) of the Act, we are adding three exceptions for compensation arrangements that do not pose a risk of program or patient abuse when considered in concert with: (1) the program integrity and other requirements integrated in the definitions used to apply the exceptions only to compensation arrangements that qualify as "value-based arrangements;" and (2) the disincentives to perpetrate the harms the physician self-referral law was intended to deter that are intrinsic in the assumption of substantial downside financial risk and meaningful participation in value-based health care delivery and payment models.

In removing regulatory barriers to innovative care coordination and value-based arrangements, we are faced with the challenge of designing protection for emerging health care arrangements, the optimal form, design, and efficacy of which remains unknown or unproven. This is a fundamental challenge of regulating during a period of innovation and experimentation. Matters are further complicated by the substantial variation in care coordination and value-based arrangements contemplated by the health care industry, variation among patient populations and providers, emerging health technologies and data capabilities, and our desire not to chill beneficial innovations. Thus, a one-size-fits-all approach to protection from the physician self-referral law's prohibitions is not optimal. The design and structure of our exceptions are intended to further several complementary goals. First, we have endeavored to remove

regulatory barriers, real or perceived, to create space and flexibility for industry-led innovation in the delivery of better and more efficient coordinated health care for patients and improved health outcomes. Second, consistent with the Secretary's priorities, the historical trend toward improving health care through better care coordination, and the increasing adoption of value-based models in the health care industry, the final exceptions are intended to create additional incentives for the industry to move away from volume-based health care delivery and payment and toward population health and other non-FFS payment models. In this regard, our exception structure incorporates additional flexibilities for compensation arrangements between parties that have increased their participation in mature value-based payment models and their assumption of downside financial risk under such models. As discussed in the proposed rule (84 FR 55776) and in more detail in this section II.A.2.b. of the final rule, our expectation is that meaningful assumption of downside financial risk would not only serve the overall transformation of industry payment systems, but could also curb, at least to some degree, FFS incentives to order medically unnecessary or overly costly items and services, key patient and program harms addressed by the physician self-referral law (and other Federal fraud and abuse laws).

The current exceptions to the physician self-referral law include requirements that may create significant challenges for parties that wish to develop novel financial arrangements to facilitate their successful participation in health care delivery and payment reform efforts (84 FR 55776 through 55778). Most of the commonly relied upon exceptions to the physician self-referral law include requirements related to compensation that may be difficult to satisfy where the arrangement is designed to foster the behavior shaping necessary for the provision of high-quality patient care that is not reimbursed on a traditional FFS basis. Requirements that compensation be set in advance, fair market value, and not take into account the volume or value of a physician's referrals or the other business generated by the physician may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures). For example, depending on their

structure, arrangements for the distribution of shared savings or repayment of shared losses, gainsharing arrangements, and pay-for-performance arrangements that provide for payments to refrain from ordering unnecessary care, among others, may be unable to satisfy the requirements of an existing exception to the physician self-referral law. Thus, rather than being a check on bad actors, in the context of value-based care models, the physician self-referral law may actually be having a chilling effect on models and arrangements designed to bend the cost curve and improve quality of care to patients.

We have carefully considered the CMS RFI comments, the comments to the proposed rule, and anecdotal information shared by stakeholders regarding the impact of the specific requirements that compensation must be set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician, law enforcement and judicial activity related to these requirements, and our own observations from our work (including our work on fraud and abuse waivers for CMS accountable care and other models). We remain concerned that the inclusion of such requirements in the exceptions for value-based arrangements at §411.357(aa) would conflict with our goal of addressing regulatory barriers to value-based care transformation. As discussed in more detail below, we are not including these requirements in the final exceptions for value-based arrangements at §411.357(aa). We note that two of the final exceptions for value-based arrangements are available to protect arrangements even when payments from the payor are made on a FFS basis. Even so, we are not finalizing a requirement that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. Instead, we are finalizing a carefully woven fabric of safeguards, including requirements incorporated through the applicable value-based definitions. The disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the value-based definitions will operate in tandem with the

requirements included in the exceptions and are sufficient to protect against program and patient abuse. This is especially true where a value-based enterprise assumes full or meaningful downside financial risk.

The beneficiary's right to choose a provider of care is expressed and reinforced in almost every aspect of the Medicare program. We believe that a patient's control over who provides his or her care directly contributes to improved health outcomes and patient satisfaction, enhanced quality of care and efficiency in the delivery of care, increased competition among providers, and reduced medical costs, all of which are aims of the Medicare program. Protection of patient choice is especially critical in the context of referrals made by a physician to an entity with which the physician has a financial relationship, as the physician's financial self-interest may impact, if not infringe on, patients' rights to control who furnishes their care. For this reason, we are making compliance with §411.354(d)(4)(iv) a requirement of the exceptions that apply to employment arrangements, personal service arrangements, or managed care contracts that purport to restrict or direct physician referrals, including the exceptions at §411.357(aa) for value-based arrangements. We are finalizing in all three exceptions at §411.357(aa) a separate requirement to ensure that, regardless of the nature of the value-based arrangement and its value-based purpose(s), the regulation adequately protects a patient's choice of health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. Specifically, even if the applicable exception at §411.357(aa) does not require that the arrangement is set out in writing, any requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties, and the requirement may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

We believe that well-coordinated and managed patient care is the cornerstone of a value-based health care system. We solicited comments regarding whether it is necessary to include in

the exceptions for value-based arrangements, a requirement that the parties to a value-based arrangement engage in value-based activities that include, at a minimum, the coordination and management of the care of the target patient population or that the value-based arrangement is reasonably designed, at a minimum, to coordinate and manage the care of the target patient population (84 FR 55780). We are not including such a requirement in the final exceptions at §411.357(aa). In our experience, and as confirmed by commenters, most arrangements that qualify as value-based arrangements, by their nature, have care coordination and management at their heart, eliminating the need for an explicit requirement. Moreover, we remain concerned that requiring every value-based arrangement to include the coordination and management of care of the target patient population could leave beneficial value-based arrangements that do not directly coordinate or manage the care of the target patient population without access to any of the new exceptions at §411.357(aa) and potentially unable to meet the requirements of any existing exception to the physician self-referral law.

Finally, we have endeavored to be as neutral as possible with respect to the types of value-based enterprises and value-based arrangements the final exceptions will cover in order to allow for innovation and experimentation in the health care marketplace and so that compliance with the physician self-referral law is not the driver of innovation or the barrier to innovation. The final exceptions at §411.357(aa) are applicable to the compensation arrangements between parties in a CMS-sponsored model, program, or other initiative (provided that the compensation arrangement at issue qualifies as "value-based arrangement"), and we believe that compensation arrangements between parties in a CMS-sponsored model, program, or other initiative can be structured to satisfy the requirements of at least one of the exceptions at §411.357(aa). It is our expectation that the suite of value-based exceptions finalized here will eliminate the need for any new waivers of section 1877 of the Act for value-based arrangements. (We note that parties are not required to utilize the value-based exceptions and may elect to use the waivers applicable to the CMS-sponsored models, programs, or initiatives in which they participate.) However, the

final exceptions are not limited to CMS-sponsored models (that is, Innovation Center models) or establish separate exceptions with different criteria for arrangements that exist outside of CMS-sponsored models.

At §411.357(aa)(1), we are finalizing an exception that applies to a value-based arrangement where a value-based enterprise has, during the entire duration of the arrangement, assumed full financial risk from a payor for patient care services for a target patient population. At §411.357(aa)(2), we are finalizing an exception that applies to a value-based arrangement under which the physician is at meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the entire duration of the arrangement. Finally, at §411.357(aa)(3), we are finalizing an exception that applies to any value-based arrangement, provided that the arrangement satisfies specified requirements.

We received the following general comments on the value-based exceptions and our responses follow.

Comment: Several commenters encouraged CMS and OIG to work together to more closely align their final rules. The commenters expressed concern that notable differences between the two rules, if finalized as proposed, would create a dual regulatory environment, where a value-based arrangement could meet the requirements for protection under one law but not the other, which could hinder the transition to a value-based health care delivery and payment system. These commenters expressed concern with administrative burden and compliance concerns in the event that the OIG and CMS final rules are not aligned. One commenter viewed the exceptions to the physician self-referral law as having little value if the safe harbors to the anti-kickback statute are not revised to mirror the exceptions noting that participants are likely to abide by the more stringent requirements included in the safe harbors.

Response: We share the commenters' concerns about dual regulatory schemes and the challenges for stakeholders in ensuring compliance with both. We have worked closely with OIG to ensure consistency between our respective rules to reduce administrative burden on the

regulated industry. As noted in section II.A.2.a. of this final rule, the final value-based definitions at §411.351 are aligned in nearly all respects with OIG's final value-based definitions. However, because of the fundamental differences in the statutory structure, operation, and penalties between the physician self-referral law and the anti-kickback statute, complete alignment between the exceptions to the physician self-referral law and safe harbors to the anti-kickback statute is not feasible. Reflecting these statutory differences, the regulations that CMS and OIG are finalizing include intentional differences that allow the anti-kickback statute to provide "backstop" protection for Federal health care programs and beneficiaries against abusive arrangements that involve the exchange of remuneration intended to induce or reward referrals under arrangements that could potentially satisfy the requirements of an exception to the physician self-referral law. In this way, the CMS and OIG regulations, operating together, balance the need for parties entering into arrangements that are subject to both laws to develop and implement value-based arrangements that avoid the strict liability referral and billing prohibitions of the physician self-referral law, while ensuring that law enforcement, including OIG, can take action against parties engaging in arrangements that are intentional kickback schemes.

Comment: A few commenters recommended that we finalize one all-inclusive exception to the physician self-referral law for any type of value-based arrangement rather than the three-exception structure proposed. These commenters asserted that replacing the three value-based exceptions with one exception would reduce the complexity of the regulatory scheme and the burden associated with the transition to value-based health care delivery and payment.

Response: We are finalizing our proposed structure with three exceptions to the physician self-referral law that apply based on the level of risk assumed by the value-based enterprise or the physician who is a party to the value-based arrangement and the characteristics of the value-based arrangement. We disagree with the commenters that one exception would be less complex and burdensome, and do not believe that a one-size fits all approach to exceptions

to the physician self-referral law to facilitate the transition to a value-based health care delivery and payment system is possible.

Comment: The majority of commenters strongly urged CMS to not include in any of the final value-based exceptions the "traditional" requirements that compensation is set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated by the physician for the entity. Some commenters also requested that we not include a requirement that the value-based arrangement is commercially reasonable. The commenters opined that inclusion of these standards in the context of value-based health care delivery and payment is neither appropriate nor necessary, and asserted that inclusion of these standards would create a barrier to the transition to a value-based health care delivery and payment system, leaving the value-based exceptions of limited or no utility. These commenters noted that nonmonetary remuneration, in particular, that is provided under a value-based arrangement is not necessarily consistent with the fair market value of items or services provided by the recipient (or value-based activities undertaken by the recipient) and asserted that requiring that such compensation is fair market value would impact the ability of parties to share necessary infrastructure, care coordination, and patient engagement tools. The commenters also stated that many value-based arrangements are, by nature, related to the volume or value of referrals, and requiring that compensation is not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated by the physician would limit the utility of the exceptions. Finally, a few commenters asserted that there is no need for a commercial reasonableness standard in light of the definition of "value-based purpose," which the commenters interpreted to serve the same function and require the same analysis as that of the commercial reasonableness of an arrangement. These commenters also asserted that value-based arrangements are, by their nature, commercially reasonable. In contrast, a few commenters urged CMS to include requirements that the value-based arrangement is commercially reasonable, the compensation is not determined in any manner that

takes into account the volume or value of a physician's referrals or other business generated by the physician, and the compensation is fair market value in order to protect against program or patient abuse. The commenters did not explain why omitting these requirements creates a risk of program or patient abuse.

Response: As noted above and for the reasons described in the proposed rule, we are not including in the final exceptions at §411.357(aa) the traditional requirements that compensation is set in advance, consistent with fair market value of the value-based activities provided under the value-based arrangement, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. However, we are requiring that the compensation arrangement is commercially reasonable. As we stated in the proposed rule, disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address are built into the value-based definitions and will operate in tandem with the requirements included in the exceptions to protect against program and patient abuse (84 FR 55777). It is this framework that allows us to forgo the requirements in the current exceptions to the physician self-referral law that may create significant challenges to innovation in a value-based health care delivery and payment system.

We are cognizant that requirements that remuneration be fair market value and not take into account the volume or value of a physician's referrals or the other business generated by a physician may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures). We agree with the commenters that these standards, which play an important role in the other exceptions to the physician self-referral law, may be counter to the underlying policy goals of value-based health care delivery and payment. We also agree that compensation arrangements that qualify as value-based arrangements under the new value-based definitions at §411.351, satisfy all the requirements of an applicable exception at final §411.357(aa), and are aimed at reducing cost and

improving quality are likely commercially reasonable. Even so, we believe that this additional program integrity safeguard is warranted. As defined at final §411.351, "commercially reasonable" means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. The requirement at final §411.357(aa)(3)(vi) will ensure that parties to a value-based arrangement structure the arrangement in a manner intended to further their legitimate business purposes, which must include achievement of the value-based purpose(s) of the value-based enterprise of which they are participants.

Comment: Several commenters urged us to create separate exceptions for CMS-sponsored model arrangements and CMS-sponsored model patient incentives consistent with existing waivers for these programs that would work in conjunction with or mirror the safe harbors at proposed 42 CFR 1001.952(ii). Some commenters expressed concern over parties having to identify and comply with an applicable exception to the physician self-referral law and also comply with the safe harbor under the anti-kickback statute for CMS-sponsored programs. Several other commenters requested assurance that all existing fraud and abuse waivers for CMS-sponsored models, programs, and initiatives will remain in effect as implemented and will not be impacted by the new exceptions for value-based arrangements.

Response: The commenters did not provide any specific examples of existing financial arrangements under a CMS-sponsored model, program, or other initiative between an entity and a physician (or immediate family member) to which none of the exceptions at final §411.357(aa)(3) would apply. We carefully evaluated our final exceptions against the existing CMS-sponsored models, programs, and other initiatives, and are confident that at least one of the new exceptions at §411.357(aa) is applicable to the types of compensation arrangements contemplated under each model, program, or initiative. The design of the final exceptions should result in a smooth transition from participation in a CMS-sponsored model, program, or initiative if the parties wish to continue their compensation arrangements and rely on the new

value-based exceptions at §411.357(aa). Thus, it is not necessary to establish an exception specific to arrangements undertaken pursuant to a CMS-sponsored model, program, or initiative as requested by the commenters. Importantly, the existing model-specific or program-specific fraud and abuse waivers will remain in place and are not affected by the existence of the value-based exceptions. Also, the Secretary retains authority under section 1115A(d)(1) of the Act to waive certain fraud and abuse laws as necessary solely for purposes of testing payment and service delivery models developed by the Innovation Center, and this authority can be used to address future financial arrangements under Innovation Center models that may not fit within the final value-based exceptions framework. Finally, the final fraud and abuse waivers issued in connection with the Shared Savings Program are permanent waivers that are unaffected by the value-based exceptions finalized in this final rule.

Comment: Some commenters sought clarification regarding the interaction between the value-based exceptions and existing exceptions to the physician self-referral law. A few commenters questioned whether an entity currently relies on the exception for *bona fide* employment relationships at §411.357(c) to protect compensation arrangements with employed physicians may continue to utilize the exception at §411.357(c), or whether its compensation arrangements that qualify as value-based arrangements must satisfy the requirements of one of the new value-based exceptions at §411.357(aa). The commenters stated a desire to continue to utilize the exception at §411.357(c) for value-based arrangements with employed physicians rather than the new value-based exceptions. The commenters also sought guidance regarding whether the value-based exceptions could be utilized concurrently with "traditional exceptions" when an entity has multiple compensation arrangements with the same physician and, if so, how requirements of the exceptions, such as the requirement that compensation is fair market value, would apply if the parties are utilizing multiple exceptions. A few commenters requested that we confirm that compensation for care coordination, quality improvement, and cost containment activities are not prohibited under the exception for *bona fide* employment relationships or the

services exceptions at §411.355.

Response: Nothing in this final rule mandates the use of the value-based exceptions. As we have stated before, parties may use any applicable exception to the physician self-referral law provided that all the requirements of the exception are satisfied (66 FR 916 and 72 FR 51047). The value-based exceptions, however, are only available to parties that qualify under the value-based definitions. Parties may utilize the exception at §411.357(c) to protect a value-based arrangement, however, the value-based arrangement must satisfy all the requirements of the exception in order to avoid the referral and billing prohibitions of the physician self-referral law. The same is true with respect to the availability of and compliance with any other existing exception that is applicable to the parties' financial relationship or the physician's referrals of designated health services. The exception for *bona fide* employment relationships includes requirements that the arrangement is commercially reasonable, the compensation paid to the physician is fair market value, and the compensation is not determined in any manner that takes into account the volume or value of the physician's referrals. None of these requirements are included in the final exceptions at §411.357(aa). Thus, depending on the terms and conditions of the value-based arrangement, the arrangement may be unable to satisfy all the requirements of the exception for *bona fide* employment relationships. That determination is, of course, fact-specific.

Comment: Several commenters expressed concern that the requirements of the value-based definitions and exceptions could disadvantage rural providers and small physician practices that desire to participate in value-based arrangements, and that these providers and suppliers face greater challenges when transitioning to a value-based health care delivery and payment system. The commenters stated that these challenges include financial burdens, the complexity of the value-based exceptions and definitions, and inadequate resources to successfully implement value-based arrangements. Commenters urged CMS to make revisions to the proposed value-based exceptions to accommodate rural providers and small physician

practices, specifically suggesting that we either limit the number of requirements under the value-based exceptions that would be applicable to rural providers and small physician practices to help alleviate the burden associated with complying with the exceptions or establish a separate, less onerous exception applicable only to these providers and suppliers.

Response: We are not persuaded that an exception for value-based arrangements that is exclusively available to rural providers and small physician practices is necessary, nor are we revising the exceptions to limit the requirements under the value-based exceptions applicable to these providers and suppliers. We understand the challenges faced by rural providers and small physician practices, including resource limitations, and appreciate the important role of rural providers as a safety net for their communities. The value-based arrangements exception finalized at §411.357(aa)(3) is applicable to all value-based arrangements, regardless of the size or nature of the parties to the arrangement, the financial risk undertaken by the value-based enterprise, or the financial risk undertaken by the physician who is a party to the value-based arrangement. We expect that this exception may be utilized by rural providers and small physician practices more frequently than the full financial risk and meaningful downside financial risk exceptions. As discussed elsewhere in this final rule, we are not requiring a financial contribution from the recipient of remuneration under any of our final value-based exceptions. We believe this addresses some of the commenters' concerns.

(1) Full Financial Risk (§411.357(aa)(1))

We proposed at §411.357(aa)(1) an exception to the physician self-referral law (the "full financial risk exception") that applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed "full financial risk" for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time; that is, the value-based enterprise is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the

cost of such patient care items and services. For Medicare beneficiaries, we noted that we intend for this requirement to mean that the value-based enterprise, at a minimum, is responsible for all items and services covered under Parts A and B. We are finalizing the exception with one modification. We are extending the period of time during which the exception will be available prior to the value-based enterprise's financial responsibility for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population. Specifically, we are replacing the requirement that the value-based enterprise is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement with a 12-month timeframe. Thus, under this final rule, the value-based enterprise must be financially responsible (or must be contractually obligated to be financially responsible within the 12 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. As described in more detail below, we believe that extending this "pre-risk period" to 12 months is consistent with the timeframe established in the Shared Savings Program pre-participation waiver (80 FR 66742), and, as with the Shared Savings Program pre-participation waiver, we do not believe that establishing a 12-month pre-risk period poses a risk of program or patient abuse.

As we stated in the proposed rule, full financial risk may take the form of capitation payments (that is, a predetermined payment per patient per month or other period of time) or global budget payment from a payor that compensates the value-based enterprise for providing all patient care items and services for a target patient population for a predetermined period of time (84 FR 55779). We noted that the full financial risk exception would not prohibit other approaches to full financial risk and sought comment on other approaches to full financial risk that may exist currently or that stakeholders anticipate for the future. We are not prescribing a specific manner for the assumption of full financial risk in this final rule.

A value-based enterprise need not be a separate legal entity with the power to contract on its own (84 FR 55779). Rather, networks of physicians, entities furnishing designated health services, and other components of the health care system collaborating to achieve the goals of a value-based health care system, organized with legal formality or not, may qualify as a value-based enterprise. A value-based enterprise may assume legal obligations in different ways. For example, all VBE participants in a value-based enterprise could each sign the contract for the value-based enterprise to assume full financial risk from a payor. Or, the VBE participants in a value-based enterprise could have contractual arrangements among themselves that assign risk jointly and severally. Or, similar to physicians in an independent practice association (IPA), VBE participants could vest the authority to bind all VBE participants in the value-based enterprise with a designated person that contracts for the assumption of full financial risk on behalf of the value-based enterprise and its VBE participants. As explained in more detail below, we are not requiring that the value-based enterprise is a separate legal entity with contracting powers or requiring a particular structure for the value-based enterprise.

The value-based enterprise's financial risk must be prospective; that is, the contract between the value-based enterprise and the payor may not allow for any additional payment to compensate for costs incurred by the value-based enterprise in providing *specific* patient care items and services to the target patient population, nor may any VBE participant claim payment from the payor for such items or services. We define "prospective basis" in this final rule at §411.357(aa)(1)(vii) to mean that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population. As noted in the proposed rule (84 FR 55780) and discussed more fully below, the final definition of "full financial risk" does not prohibit a payor from making payments to a value-based enterprise to offset losses incurred by the enterprise above those prospectively agreed to by the parties. The payment of shared savings or other incentive payments for achieving quality, performance, or

other benchmarks are also not prohibited. The final exception is available to protect value-based arrangements entered into in preparation for the implementation of the value-based enterprise's full financial risk payor contract where such arrangements begin after the value-based enterprise is contractually obligated to assume full financial risk for the cost of patient care items and services for the target patient population but prior to the date the provision of patient care items and services under the contract begin. As stated above, the final exception limits this period to the 12 months prior to the effective date of the full financial risk payor contract. In other words, the value-based enterprise must be at full financial risk within the 12 months following the commencement of the value-based arrangement.

We believe that full financial risk is one of the defining characteristic of a mature value-based payment system. When a value-based enterprise is at full financial risk for the cost of all patient care services, the incentives to order unnecessary services or steer patients to higher-cost sites of service are diminished. Even when downstream contractors are paid on something other than a full-risk basis, the value-based enterprise itself is incented to monitor for appropriate utilization, referral patterns, and quality performance, which we believe helps to reduce the risk of program or patient abuse. Accordingly, these kinds of payment limitations provide stronger and more effective safeguards against increases in the volume and costs of services than the physician self-referral law ever placed on the FFS system. Nonetheless, as a precaution, we proposed and are finalizing several important safeguards in the full financial risk exception.

The value-based enterprise must be at full financial risk during the *entire duration* of the value-based arrangement for which the parties to the arrangement seek protection (84 FR 55780). Thus, the final exception will not protect arrangements that begin at some point during a period when the value-based enterprise has assumed full financial risk, but that continue into a timeframe when the safeguards intrinsic to full-financial risk payment, such as the disincentive to overutilize or stint on medically necessary care, no longer exist. However, one or both of the other exceptions finalized at §411.357(aa)(2) and (3) may be available to protect value-based

arrangements that exist during a period when the value-based enterprise is not at full financial risk (or contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population.

We also proposed and are finalizing a requirement that the remuneration under the value-based arrangement is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. As we discussed in the proposed rule, we recognize that payments under certain incentive payment arrangements, such as gainsharing arrangements, may be difficult to tie to specific items or services furnished by a VBE participant (84 FR 55780). We do not interpret the requirement at §411.357(aa)(1)(ii) as mandating a one-to-one payment for an item or service (or other value-based activity). Gainsharing payments, shared savings distributions, and similar payments may result from value-based activities undertaken by the recipient of the payment for patients in the target patient population. The requirement that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population addresses this issue. We intend for this to be an objective standard; that is, the remuneration must, in fact, be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population (84 FR 55780). The final exception, therefore, will not protect payments for referrals or any other actions or business unrelated to the target patient population, such as general marketing or sales arrangements. With respect to in-kind remuneration, it is our position that the remuneration must be necessary and not simply duplicate technology or other infrastructure that the recipient already has. Finally, although the remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, parties would not be prohibited from using the remuneration for the benefit of patients who are not part of the target patient population.

In the proposed rule, we discussed the fact that integrated into most of the CMS-

sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population (84 FR 55780). This is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services. Therefore, we proposed a requirement at §411.357(aa)(1)(iii) that remuneration under a value-based arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. We are finalizing this requirement at §411.357(aa)(1)(iii). We note that remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act.

In addition, we proposed to protect only those value-based arrangements under which remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement (84 FR 55781). Although this requirement is similar to the requirement that remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, as discussed in the proposed rule, it is intended to address a different concern. We are finalizing at §411.357(aa)(1)(iv) the requirement that the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. The final exception does not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration. By way of example, if the value-based enterprise is at full financial risk for the total cost of care for all of a commercial payor's enrollees in a particular county, the exception will not protect a value-based arrangement between an entity and a physician that are VBE participants in the value-based enterprise if the entity requires the physician to refer Medicare patients who are not part of the target patient population for designated health services furnished by the entity. Similarly, the exception will not protect a

value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement requires that the physician perform all his or her other orthopedic surgeries at the hospital.

We also proposed and are finalizing a requirement at §411.357(aa)(1)(v) related to directing a physician's referrals to a particular provider, practitioner, or supplier (84 FR 55781). Under final §411.357(aa)(1)(v), if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (A) the requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties; and (B) the requirement to make referrals to a particular provider, practitioner, or supplier may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. See section II.B.4. of this final rule for a complete discussion of our interpretation of this requirement.

Finally, we proposed to require that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement be maintained for a period of at least 6 years and made available to the Secretary upon request (84 FR 55781). We noted in the proposed rule that requirements similar to this are found in our existing regulations in the group practice rules at §411.352(d)(2) and (i), the exception for physician recruitment at §411.357(e)(4)(iv), and the exception for assistance to compensate a nonphysician practitioner at §411.357(x)(2) (84 FR 55781). We are finalizing at §411.357(aa)(3)(xi) the requirement that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request. We expect that parties are familiar with these requirements and that the maintenance of such records is part of their routine business practices.

As we discussed in the proposed rule (84 FR 55781), we consider the exception at

§411.357(aa)(1) comparable, in some respects, to the exception at §411.357(n) for risk-sharing arrangements, which, as we noted in Phase II, is intended to be a broad exception with maximum flexibility, covering all risk-sharing compensation paid to a physician by any type of health plan, insurance company, or health maintenance organization (that is, any "managed care organization" (MCO)) or IPA, provided the arrangement relates to enrollees and meets the conditions set forth in the exception (69 FR 16114). A downstream arrangement that creates an indirect compensation arrangement between an MCO or IPA and a physician is included within the scope of the exception for risk-sharing arrangements. (See section II.A.2.b.(4) of this final rule for a full discussion of the applicability or the exception for risk-sharing arrangements at §411.357(n).) Although the final exception at §411.357(aa)(1) is not limited to "risk-sharing compensation" paid to a physician, but, rather, covers any type of remuneration paid under a value-based arrangement that is for or results from value-based activities undertaken by the recipient of the remuneration, for the reasons discussed throughout section II.A. of this final rule, we believe that the flexibility provided in the exception for risk-sharing arrangements is also warranted in the full financial risk exception. Finally, like the exception at §411.357(n) for risk-sharing arrangements, we did not propose, nor are we finalizing, documentation requirements in the full financial risk exception. Nevertheless, it is a good business practice to reduce to writing any arrangement between referral sources as it allows the parties to monitor and confirm that an arrangement is operating as intended.

We received the following comments and our responses follow.

Comment: Several commenters urged CMS to expand the definition of "full financial risk" at §411.357(aa)(1)(vii) to exclude defined sets of patient care items or services for a target patient population, or specific diseases or conditions, similar to episode-based bundled payment models. By way of example, commenters suggested that full financial risk should be limited to only the items and services required to treat patients with diabetes or during an episode of care for a knee replacement. Commenters perceived the full financial risk exception as having

limited utility, asserting that the health care industry is currently not well-positioned to take on full financial risk for all patient care items and services covered by the applicable payor for each patient in the target patient population. Commenters suggested that allowing protection under the full financial risk exception for arrangements where the parties take on full financial risk for only a subset of items or services covered by the applicable payor, such as joint replacement surgery, would increase the utility of the full financial exception and help to facilitate the transition to a value-based health care delivery and payment system.

Response: We are not revising the definition of "full financial risk" to mean a defined set of patient care items or services (similar to episode-based bundled payment models) or anything less than financial responsibility, on a prospective basis, for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population. To do so could undermine the Secretary's policy goals of moving more health care providers and practitioners into two-sided risk payment structures. The full financial risk exception applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed "full financial risk" on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. It also applies to a value-based arrangement between the value-based enterprise (if it is an entity as defined at §411.351) and a physician who is a VBE participant in the value-based enterprise. The value-based enterprise must be financially responsible (or be contractually obligated to be financially responsible within the 12 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. As noted in the proposed rule and above, we believe that full financial risk is an important defining characteristic of a mature value-based health care delivery and payment system (84 FR 55780). When a value-based enterprise is at full financial risk for the cost of all patient care items and services, the incentives to order

unnecessary services or steer patients to high-cost sites of services are diminished. Those same incentives are not necessarily present in episode-based bundled payment models. Expanding the applicability of the exception at §411.357(aa)(1) to protect value-based arrangements under episode-based bundled payment models would result in heightened program integrity concerns, and therefore, would not fall within the Secretary's authority under section 1877(b)(4) of the Act upon which we relied to establish this exception. We recognize that providers may not be well-positioned at this time to transition to a full financial risk model; however, it is our hope that, by reducing the burden of the physician self-referral law, we can provide a pathway for participants in the value-based system to evolve and more meaningfully participate in the value-based system. As discussed in detail in II.A.2.b.(3). of this final rule, we are finalizing at §411.357(aa)(3) an exception applicable to value-based arrangements where the value-based enterprise assumes less than full financial risk, including arrangements where neither the value-based enterprise nor the parties to the particular arrangement have assumed any financial risk. That exception may facilitate the entry of providers and suppliers into value-based health care delivery and payment with the goal of moving eventually to two-sided risk models.

Comment: Several commenters stated that the full financial risk exception would be of limited utility if high-cost or specialty items and services, such as organ transplants or pharmacy benefits, are not carved out of the definition of "full financial risk." The commenters noted that, even in more advanced value-based arrangements, payors exclude high-cost or specialty items or services from the risk arrangement. The commenters urged CMS to permit a value-based enterprise to qualify as being at full financial risk without taking on the responsibility for high cost or specialty items and services. Similarly, these commenters requested clarification regarding the ability of the value-based enterprise to offset losses while still meeting the definition of full financial risk for purposes of the exception. Other commenters urged CMS to allow a value-based enterprise to enter into payor arrangements with risk mitigation terms to protect against catastrophic losses, such as risk corridors, global risk adjustments, reinsurance,

stop loss agreements.

Response: We decline to carve out high-cost or specialty items or services from the definition of "full financial risk." In addition, we do not believe that revisions are necessary to specifically address mechanisms by which parties to a full financial risk payor arrangement may protect against significant or catastrophic losses. Further, the exclusion of high-cost or specialty items and services could potentially interfere with private payor contracts among health care providers, suppliers, and physicians. Importantly, nothing in the final full financial risk exception or the definition of "full financial risk" prohibits a value-based enterprise from contracting with a payor for stop-loss protection or applying risk corridors to limit exposure to significant losses related to such high-cost items or services or overall expenses. A payor arrangement may include risk mitigation terms such as risk corridors, global risk adjustments, reinsurance, or stop-loss provisions to protect against significant and catastrophic losses. As noted above, the financial risk assumed by the value-based enterprise must be prospective; thus, the contract between the value-based enterprise and the payor may not allow for any additional fee for service or other payments to compensate for costs incurred by the value-based enterprise in providing specific patient care items and services to the target patient population, nor may any VBE participant claim payment from the payor for such items or services.

Risk mitigation tools are not new to CMS-sponsored value-based initiatives. In fact, some of the initiatives of the Innovation Center, where Medicare is the payor, anticipate potential burdens on participants related to high cost items and services and the need for protection against significant and catastrophic losses. These Innovation Center initiatives include stop-loss provisions to mitigate the risk of overall costs being higher than expected. For instance, the Bundled Payment for Care Improvement, Next Gen ACO, and Comprehensive Care for Joint Replacement models all include some form of stop-loss assurance to mitigate financial risk.

Finally, there is nothing in this final rule that will prohibit a value-based enterprise and a payor from negotiating and designing a full financial risk payor arrangement that would address

the concerns raised by the commenters. We are not imposing a specific limit on the amount of loss coverage a value-based enterprise may have, but we caution that we will expect any stop-loss or other risk adjustment provisions to act as protection for the value-based enterprise against catastrophic losses and not a means by which to shift material financial risk back to the payor. To be clear, the definition of "full financial risk" would not permit the full offset of a value-based enterprise's losses.

Comment: The majority of commenters agreed that the full financial risk exception should extend to compensation arrangements related to activities taken in preparation for the implementation of the value-based enterprises' full financial risk payor contract, but requested that CMS extend the 6-month "pre-risk" period to a 12-month period. The commenters noted that at least 12 months of preparation are often necessary to develop and operationalize a successful value-based enterprise, even when it will not be assuming full financial risk. Commenters highlighted activities such as the development of care redesign protocols, implementation of IT infrastructure, and deployment of care coordinators as necessary for the successful undertaking of full financial risk by a value-based enterprise and its VBE participants.

Response: We are persuaded to extend the "pre-risk" period under the full financial risk exception to 12 months. Under the regulation finalized in this final rule, the value-based enterprise must be financially responsible (or be contractually obligated to be financially responsible within the 12 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Extending this pre-risk period to 12 months should allow parties sufficient time to work together in preparation for taking on full financial risk. A 12-month period is consistent with the Shared Savings Program pre-participation waiver, and we are not aware of any program integrity concerns with respect to the 12-month start-up period to date. We see no reason why providing for a 12-month pre-risk period in the full financial risk exception would pose a risk of program

or patient abuse.

Comment: Some commenters explained that certain States, such as California, require providers or suppliers that assume full financial risk for health care items and services are required to become licensed as a health plan. The commenters noted that the expense and regulatory burden associated with becoming a licensed health plan would deter most providers or suppliers from taking that step, making the full financial risk exception of no utility to them. The commenters recommended that CMS modify the full financial risk exception to address this State law issue. Some of the commenters also noted that certain States prohibit a provider or supplier from assuming financial risk for items and services other than those typically provided by that provider or supplier type. For instance, a hospital could not assume financial risk for physician services and vice versa.

Response: We are not prescribing a specific manner for the assumption of full financial risk by a value-based enterprise. The full financial risk exception applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed full financial risk on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Nothing in this final rule precludes the various VBE participants in the value-based enterprise from aggregating the risk that each individual VBE participant assumes to reach full financial risk for the value-based enterprise as a whole. For instance, assume a value-based enterprise has as its VBE participants a hospital, skilled nursing facility, physicians, and a full complement of providers and suppliers that, together, provide all the patient care services covered by an applicable payor. If each of the VBE participants is at full financial risk for the cost of all patient care items or services that it furnishes, the VBE participants could aggregate their risk so that the value-based enterprise is, in total, at full financial risk for the cost of all patient care items or services covered by the applicable payor. Essentially, the hospital could assume full financial risk for hospital services, the skilled nursing facility could assume full

financial risk for skilled nursing services, the physicians could assume full financial risk for physician services, etc. As long as there are no services covered by the applicable payor for which the VBE participants have not assumed full financial risk, the value-based enterprise will be at full financial risk for purposes of §411.357(aa)(1). We see no reason why allocating the full financial risk among the VBE participants of the value-based enterprise—as opposed to a single organization (the value-based enterprise) assuming the full financial risk—would pose an additional risk of program or patient abuse. Finally, we note that nothing in this final rule preempts any applicable State law, and we remind parties that other exceptions may be available to protect arrangements where State law restrictions make satisfaction of certain requirements of an exception challenging or impossible.

Comment: Many commenters acknowledged the importance of preserving patient choice but stressed that, in a value-based health care delivery and payment system, the ability to guide a patient to a high quality provider is imperative. The commenters requested that we include any patient choice requirements in the regulation text of the value-based exceptions rather than cross-referencing the requirements of the special rules on compensation at §411.354(d)(4)(iv).

Response: As discussed above, protection of patient choice is especially critical in the context of referrals made by a physician to an entity with which the physician has a financial relationship, as the physician's financial self-interest may impact, if not infringe on, a patient's right to control who furnishes his or her care. We are finalizing in the full financial risk exception a separate requirement to ensure that, regardless of the nature of the value-based arrangement and the value-based enterprise's value-based purpose(s), the regulation adequately protects a patient's choice of health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. The final exception provides at §411.357(aa)(1)(v) that, if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (A) the requirement to make

referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties; and (B) the requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. We have included this language in all three of the value-based exceptions.

Comment: A few commenters questioned whether the full financial risk exception is even necessary, suggesting that CMS should instead modify the exception at §411.357(n) for risk-sharing arrangements to accommodate value-based arrangements where the value-based enterprise is at full financial risk.

Response: We decline to modify the exception at §411.357(n) to accommodate value-based arrangements as requested by the commenters. As discussed more fully in section II.A.2.b.(4) of this final rule, the exception at §411.357(n) applies to compensation arrangements between an MCO or an IPA and a physician for services provided to enrollees of a health plan, provided that the compensation arrangement qualifies as a risk-sharing arrangement. The compensation arrangement between the MCO or IPA and the physician may be direct or indirect. The exception does not apply to a compensation arrangement—whether direct or indirect—between a physician and an entity that is anything other than an MCO or IPA. The value-based exceptions finalized in this final rule will apply to any value-based arrangement, direct or indirect, between a physician and any entity that furnishes designated health services to which the physician makes referrals. Thus, the value-based exceptions are broader in applicability than the exception for risk-sharing arrangements. As discussed in the proposed rule and above, we have designed a carefully woven fabric of definitions and exceptions that protect against program and patient abuse while providing flexibility for experimentation in the design and implementation of value-based care arrangements (84 FR 55777). We believe that this framework is crucial to achieving the Department's goal of moving to a value-based health care

delivery and payment system, and that most value-based arrangements between an entity and a physician in a value-based enterprise that has assumed full financial risk should remain within this framework.

(2) Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician (§411.357(aa)(2))

As we stated in the proposed rule, a few CMS RFI commenters opined that the health care industry is in the early stages of its transition to value-based health care delivery and payment (84 FR 55781). After reviewing the comments on the CMS RFI and the proposed rule, we acknowledge that, although CMS, non-Federal payors, and a significant segment of the health care industry have made advancements in value-based health care delivery and payment, many physicians and providers are not yet prepared or willing to be responsible for the total cost of patient care services for a target patient population. However, we are also aware that some physicians are participating in or considering participating in alternative payment models that provide for potential financial gain in exchange for the undertaking of some level of downside financial risk.

Financial risk assumed directly by a physician will likely affect his or her practice and referral patterns in a way that curbs the influence of traditional FFS, volume-based payment. Further, financial risk is tied to the achievement or, or failure to achieve, value-based purposes incents the type of behavior-shaping necessary to transform our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces the costs to or growth in expenditures of payors. Arrangements under which a physician is at meaningful downside financial risk for failure to achieve predetermined cost, quality, or other performance benchmarks contain inherent protections against program or patient abuse. In recognition of this, we proposed an exception that would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise (the "meaningful downside financial risk

exception") (84 FR 55781). Under the meaningful downside financial risk exception, although the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement, the remuneration could be paid to or from the physician.

We proposed to define "meaningful downside financial risk" to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. We stated that we believe that this level of financial risk is high enough to curb the influence of traditional FFS, volume-based payment and achieve the type of behavior-shaping necessary to facilitate achievement of the goals set forth in this final rule (84 FR 55782). We related the definition of "meaningful downside financial risk" to the 25 percent threshold determined by the Secretary for the statutory and regulatory exceptions for physician incentive plans at section 1877(e)(3)(B) of the Act and §411.357(d)(2), respectively, which reference "substantial financial risk" to a physician (or physician group), and sought comment on whether defining meaningful downside financial risk as 25 percent of the value of the remuneration the physician receives under the value-based arrangement is appropriate. Upon consideration of the public comments, we are revising the definition of "meaningful downside financial risk" to mean that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. Because the exception does not limit the type of remuneration that may be provided, under the final regulation, the risk of repayment or the amount the physician must be at risk to forgo may be no less than 10 percent of the *value* of the remuneration to account for remuneration that may be provided in-kind, such as infrastructure or care coordination services. In the proposed rule, we also provided an alternative definition to meaningful downside financial risk that would also include the physician's full financial risk to the entity, recognizing that a physician who assumes full financial risk for all or a defined set of patient care services for the target patient population would certainly be considered at "meaningful downside financial risk" (84 FR 55782). We are not finalizing our proposal for an

expanded definition of "meaningful downside financial risk."

As discussed in the proposed rule, because the exception at §411.357(aa)(2) does not require the type of global risk to the value-based enterprise that is required in the full financial risk exception, additional or different requirements are necessary to protect against program or patient abuse (84 FR 55782). We proposed requiring that the physician must be at meaningful downside financial risk for the entire duration of the value-based arrangement to curtail any gaming that could occur by adding meaningful downside financial risk to a physician during only a short portion of an arrangement. We are finalizing this requirement at §411.357(aa)(2)(i). To buttress our oversight ability and that of our law enforcement partners, we proposed a requirement that the nature and extent of the physician's financial risk is set forth in writing. We are finalizing this requirement at §411.357(aa)(2)(ii). We note that this is also a good business practice that allows the parties to monitor their value-based arrangements and ensure that they are operating as intended. For similar reasons, but also as a safeguard against manipulating a value-based arrangement to reward referrals, we proposed to require that the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided. We noted that the special rule on compensation at §411.354(d)(1) that deems compensation to be set in advance when certain conditions are met would apply, however, that provision is merely a deeming provision and parties are free to confirm satisfaction of the requirement another way. We are finalizing this requirement at §411.357(aa)(2)(iii).

Integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population (84 FR 55782). This is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services, and we proposed including this safeguard in the meaningful downside financial risk exception by

requiring that remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. Remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act. We are finalizing this requirement at §411.357(aa)(2)(v).

For the reasons we explained with respect to the full financial risk exception, we proposed to include in the meaningful downside financial risk exception requirements that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement; and that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request. We are finalizing our proposals to include these requirements in the meaningful downside financial risk exception at §411.357(aa)(2)(iv), (vi), and (viii).

We also proposed a requirement at §411.357(aa)(2)(vii) related to directing a physician's referrals to a particular provider, practitioner, or supplier (84 FR 55781). Under final §411.357(aa)(2)(vii), if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (1) the requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties; and (2) the requirement to make referrals to a particular provider, practitioner, or supplier may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. See section II.B.4. of this final rule for a complete discussion of our interpretation of this requirement.

We received the following comments on the proposed meaningful downside financial risk exception. Our responses follow.

Comment: Several commenters disagreed with the design of the meaningful downside financial risk exception and the focus of the exception on the physician's level of risk rather than that of the entity. The commenters viewed the meaningful downside financial risk exception, as proposed, as being of limited utility and not reflective of current real-world financial risk arrangements. Some commenters urged CMS to modify the meaningful downside financial risk exception to protect arrangements where the entity assumes the financial risk noting that entities, such as hospitals, are better positioned to assume risk from payors. These commenters expressed concern as to whether physician behavior has evolved to the point of being able to assume meaningful downside financial risk as required by the exception. Some commenters requested that we permit an entity to assume meaningful downside financial risk and then allocate the risk down to the physician.

Response: We are not making the modifications suggested by the commenters. These commenters appear to misunderstand the scope of the meaningful downside financial risk exception and the intent behind it. The meaningful downside financial risk exception covers individual compensation arrangements that qualify as value-based arrangements between an entity and a physician that are VBE participants in the same value-based enterprise, regardless of whether the value-based enterprise or the entity has assumed financial risk from a payor. The exception is available to protect value-based arrangements under which the physician has assumed financial risk *from the entity* that is party to the arrangement, and where such risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise of which the physician and the entity are VBE participants. The value-based exceptions at §411.357(aa) are designed to accommodate movement toward two-sided financial risk. Although we recognize that many physicians may not be prepared or willing to assume full (or substantially full) financial risk, the exception at §411.357(aa)(2) is available to protect those value-based

arrangements under which either meaningful downside financial risk is incorporated into the physician's compensation. There is great potential for behavior-shaping when a physician's failure to achieve value-based purposes is tied to his or her remuneration. This behavior-shaping is critical to transforming our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces costs to or growth in expenditures of payors.

Comment: Most of the commenters that addressed the proposed exception at §411.357(aa)(2), disliked the 25 percent threshold for qualification as meaningful downside financial risk. These commenters asserted that a 25 percent threshold is too high and would limit physician participation in value-based health care delivery and payment systems. Some of the commenters suggested that physicians who are new to value-based health care would be reluctant to put 25 percent of their compensation at risk. These commenters requested that we reduce the threshold to 10 percent, referencing a 2018 Deloitte Survey of U.S. physicians[5] that surveyed 624 primary care and specialty physicians practicing in a variety of health care settings and found that most physicians are willing to tie approximately 10 percent of their compensation to quality and cost measures (the Deloitte Study). Several other commenters suggested a 5 percent threshold, noting that certain CMS payment systems or programs, such as advanced APMs and MIPS APMs, set financial risk percentages for physicians ranging from 5 to 9 percent. A few commenters suggested that we adopt a threshold of 15 percent for consistency with the contribution requirement under the exception for EHR items and services at §411.357(w). Some of the commenters suggested a scaled approach under which the exception initially would require a lower level of downside financial risk and increase to a higher level of downside financial risk as the physician acclimates to and participates in the value-based health care delivery and payment system. The commenters suggested that, in the alternative, CMS

[5] https://www2.deloitte.com/us/en/insights/industry/health-care/volume-to-value-based-care.html (last accessed June 18, 2020).

could set a lower threshold for meaningful downside financial risk in this final rule and increase the threshold in a future rulemaking. A few commenters viewed the 25 percent threshold as appropriate and consistent with the physician incentive plan rules applicable to Medicare and Medicaid managed care plans and federal health maintenance organizations.

Response: We find the commenters' statements and the Deloitte Study compelling, and our final regulation incorporates a lower threshold for meaningful downside financial risk of no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. The Deloitte Study found that physicians are willing to tie a greater percentage of their compensation (10 percent) to cost and quality measures than they have been previously, but physicians still need cost and quality data and analytic tools that may not be readily available to all physicians to find success in a value-based health care delivery and payment system. We believe that the assumption by a physician of 10 percent downside financial risk is sufficient to curb the influences of traditional FFS payment systems. We reiterate that, the downside financial risk threshold, for purposes of the exception at §411.357(aa)(2), relates to remuneration *from an entity* to a physician. Therefore, we do not believe that it is appropriate to link this threshold to the level of risk related to payments for services *from a payor*, for example, by linking to risk levels under MIPS or the Medicare Access and CHIP Reauthorization Act (MACRA).

Comment: Several commenters urged us to revise the definition of "meaningful downside financial risk" to mirror the risk levels found in OIG's proposed safe harbor for value-based arrangements with substantial downside financial risk. The commenters suggested this would avoid the need for parties to navigate different regulatory frameworks under the anti-kickback statute and physician self-referral law. These commenters asserted that the lack of alignment between OIG and CMS could create unnecessary burden on the regulated industry.

Response: It appears that the comments are based on a perception of the meaningful downside financial risk exception as a parallel to the OIG substantial downside financial risk safe

harbor. It is not. Under the substantial downside financial risk safe harbor, the required financial risk is at the value-based enterprise level. That is, the value-based enterprise, either directly or through its VBE participants, must assume substantial downside financial risk in order for the safe harbor to be available. Under the meaningful downside financial risk exception, the focus is on the risk assumed by the individual physician to the value-based arrangement being assessed for satisfaction of the requirements of the exception. It would be incongruous to match the risk requirements in the exception and safe harbor as requested by the commenters.

Comment: Some commenters questioned whether the meaningful downside financial risk exception applies only when a physician is required to repay remuneration already received or whether the exception would also apply to value-based arrangements under which a portion of the physician's compensation is withheld until achievement of the value-based purpose(s) of the value-based enterprise. Other commenters asked whether the meaningful downside financial risk exception is applicable to value-based arrangements under which the physician is eligible to receive or would forgo incentive pay, depending on whether the physician satisfies the goals of the value-based arrangement or the performance or quality standards required under the value-based arrangement. A few commenters expressed concern that a repayment requirement could result in noncompliance where cash flow or other factors impact the ability of the physician to make repayment. The commenters also asserted that a "repayment-only" policy is inconsistent with the structure of many financial risk arrangements that permit payments to either be withheld, reduced, or repaid for not meeting stated goals or performance and quality standards.

Response: We are clarifying the regulation at §411.357(aa)(2)(ix) to explicitly state that meaningful downside financial risk means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. The scope of the meaningful downside financial risk exception is not limited to value-based arrangements under which a physician is required to repay remuneration already received from the entity. The structures of the financial terms of a value-based arrangement

described by the commenters are permissible, provided that the arrangement otherwise complies with the value-based definitions and satisfies all the requirements of the meaningful downside financial risk exception. Withholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures are all permissible options for structuring the financial terms of a value-based arrangement between an entity and a physician, provided that the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise and not the goals of the parties or the arrangement (unless the parties alone comprise the value-based enterprise). In addition, the meaningful downside financial risk exception applies only where the physician is at risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement. To illustrate, if a physician is entitled to a base payment of $50,000 with the ability to earn an additional $25,000 for performing certain value-based activities, meaningful downside financial risk equals at least 10 percent of the total compensation of $75,000, or $7,500. The $25,000 that is at risk for purposes of this example exceeds the 10 percent requirement. However, unless the receipt of the $25,000 is tied to the achievement of the value-based purpose(s) of the value-based enterprise, the arrangement will not satisfy the requirement at final §411.357(aa)(2)(i). By way of another example, assume that there exists a value-based arrangement between an entity and a physician that are the only VBE participants in the value-based enterprise (that is, they are a value-based enterprise of two) under which the total remuneration potentially due to the physician is $100,000, but $20,000 is withheld and payable only upon successfully completing the value-based activities called for under the arrangement. Meaningful downside financial risk equals at least 10 percent of the total compensation of the $100,000 total available remuneration, or $10,000. The $20,000 withhold in this example exceeds the 10 percent requirement.

Comment: Some commenters shared their confusion regarding the proposed alternative definition of meaningful downside financial risk under which a physician would be considered to

be at meaningful downside financial risk if the physician is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. The commenters requested that CMS revise or omit the alternative definition. The commenters also questioned the utility of the definition, noting that it is unlikely that an individual physician would assume full financial risk from an entity (or a payor).

Response: We agree with the commenters that it is unlikely that an individual physician would assume full financial risk from the entity with which the physician has the value-based arrangement for the cost of all or a defined set of items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. We are not finalizing this portion of the definition of "meaningful downside financial risk" and have omitted the language from the final regulation. As set forth at final §411.357(aa)(2)(ix), meaningful downside financial risk means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

Comment: A number of commenters requested that CMS adopt the same "pre-risk" period during which the exception is applicable prior to the assumption of financial risk that was included in the proposed full financial risk exception, but did not explain the need for a pre-risk period under the meaningful downside financial risk exception, which applies only to a single arrangement between an entity and a physician. Most of the commenters requested a 12-month "pre-risk" period.

Response: We are not permitting the use of the meaningful downside financial risk exception during the period prior to the physician's assumption of meaningful downside financial risk. We see no need to allow the use of the exception at §411.357(aa)(2) prior to the physician's assumption of meaningful downside financial risk and believe that it would be a program integrity risk to do so. The Secretary's authority at section 1877(b)(4) of the Act to

issue exceptions to the physician self-referral law is limited to only those financial relationships that the Secretary determines do not pose a risk of program or patient abuse. We are concerned that unscrupulous parties could "front load" the remuneration by providing high-value remuneration to the physician in the "pre-risk" period before the physician is required to assume meaningful downside financial risk. This concern is heightened in light of the final definition of "meaningful downside financial risk," which sets the threshold for downside financial risk at 10 percent of the value of the remuneration rather than the 25 percent threshold proposed. Further, we note that financial risk in an arrangement between an entity and an individual physician, which is the foundation of the meaningful downside financial risk exception, is not an analog to the financial risk assumed by a value-based enterprise, which is the foundation of the full financial risk exception. As we explained in section II.A.2.b.(1). of this final rule, VBE participants may need to develop infrastructure and perform certain activities necessary to be successful in a full financial risk payment model before the enterprise's assumption of full financial risk. The same is not true with respect to a physician who assumes meaningful downside financial risk under an individual value-based arrangement with an entity.

Comment: Several commenters asserted that the requirement that the methodology used to determine the amount of the remuneration under the value-based arrangement is set in advance of the undertaking of the value-based activities for which the remuneration is paid fails to provide sufficient flexibility. The commenters requested that we "soften" the set in advance requirement to accommodate the change of compensation formulas or other requirements established by payors.

Response: We decline to revise the requirement as requested by the commenters. As a safeguard against gaming or manipulating a value-based arrangement to reward referrals, we require in the final meaningful downside financial risk exception that the methodology used to determine the amount of the remuneration is set in advance of the undertaking of the value-based activities for which the remuneration is paid. We interpret this requirement in the same way as

the requirement found throughout the exceptions to the physician self-referral law that compensation (or a formula for the compensation) is set in advance before the furnishing of the items or services for which the compensation is to be paid. In the final meaningful downside risk exception, we are requiring only that the methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid. Parties need not know the ultimate amount of remuneration under the value-based arrangement. Thus, prior to the commencement of a value-based arrangement, if the parties agree that a physician will be paid $10 for each completed patient assessment (assuming the completion of the patient assessment qualifies as a "value-based activity"), the methodology for determining the amount of the physician's remuneration is set in advance. If the parties later determine to increase the payment to $12 for each completed patient assessment, the revised remuneration would be considered set in advance, provided that the new remuneration terms are effective on a prospective basis only. We explore our policies regarding compensation that is set in advance with respect to outcome measures in our discussion of the value-based arrangements exception at §411.357(aa)(3) in section II.A.1.2.b.(3). and more generally in section II.D.5. of this final rule.

(3) Value-Based Arrangements (§411.357(aa)(3))

The transformation to a value-based health care delivery and payment system is heavily dependent on physician engagement. As we noted in the proposed rule, commenters on the CMS RFI stated that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without a strong, aligned partnership between entities furnishing designated health services and physicians (84 FR 55783). Those commenters noted that this alignment of financial interests is key to the behavior shaping necessary to succeed in a value-based payment system. They also asserted that permitting physicians and physician groups (especially smaller practices that are not used to risk-sharing or are too small to absorb downside financial risk) to assume only upside risk—or, for

that matter, no financial risk—would encourage more physicians to participate in care coordination activities now while they continue to build toward entering into two-sided risk-sharing arrangements. In consideration of these and similar comments, as well as our belief that bold reforms to the physician self-referral regulations are necessary to foster the delivery of coordinated patient care and achieve the Secretary's vision of transitioning to a truly value-based health care delivery and payment system, we proposed an exception at §411.357(aa)(3) for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise or any of its VBE participants (the "value-based arrangement exception") (84 FR 55783).

As proposed, the value-based arrangement exception would permit both monetary and nonmonetary remuneration between the parties, although we considered whether to limit the scope of the exception to nonmonetary remuneration only and sought comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system (84 FR 55783). The final exception is not limited to the provision of only nonmonetary compensation. We also proposed to include in the value-based arrangement exception certain requirements that were included in the proposed meaningful downside financial risk exception, some of which were also included in the proposed full financial risk exception (84 FR 55783). We stated that we would interpret these requirements in the same way as in the proposed full financial risk and meaningful downside financial risk exceptions, and included them in the value-based arrangement exception for the same reasons articulated with respect to those exceptions. These requirements are: the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; remuneration is not provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement; the methodology used to determine the amount of

the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided; and records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request (84 FR 55783).

Because the exception at proposed §411.357(aa)(3) would be applicable even to value-based arrangements where neither party, but especially not the physician, has undertaken any downside financial risk, we stated that safeguards beyond those included in the meaningful downside financial risk exception are necessary to protect against program or patient abuse (84 FR 55783). To address this, we proposed to replace the requirement that remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement with a requirement that remuneration is not conditioned on the volume or value of referrals of *any* patients, including patients in the target patient population, to the entity or the volume or value of *any* other business generated, including business covered by the value-based arrangement, by the physician for the entity. We did not propose to include a requirement that the remuneration is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. We sought comments regarding this alternative proposal; the interplay of the alternative requirement with our longstanding policy that the entity of which the physician is a *bona fide* employee or independent contractor, or that is a party to a managed care contract with the physician, may direct the physician's referrals to a particular provider, practitioner, or supplier, as long as the compensation arrangement meets specified conditions designed to preserve the physician's judgment as to the patient's best medical interests, avoid interfering in an insurer's operations, and protect patient choice; and whether including such an alternative requirement would impede parties' ability to achieve the value-based purposes on which their value-based arrangement is premised if the entity cannot direct referrals as historically permitted. We are finalizing the proposed safeguards that are also included in the

meaningful downside risk exception at §411.357(aa)(2), but we are not finalizing the alternative proposal regarding the conditioning of remuneration. Final §411.357(aa)(3)(ix) requires that the remuneration under the value-based arrangement is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. However, we are finalizing a requirement regarding patient choice, which is included in the regulations for all three of the value-based exceptions. See section II.B.4. of this final rule for a complete discussion of our interpretation of this requirement.

In addition, we proposed requirements in the exception at §411.357(aa)(3) that the value-based arrangement is set forth in writing and signed by the parties, and that the writing includes a description of the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any (84 FR 55783). We believe that the documentation requirements are self-explanatory. We stated that, although we expect that parties would plan to satisfy the writing requirement in advance of the commencement of the value-based arrangement, the special rule at §411.354(e)(3) (modified, in part, from existing §411.353(g)(1)(ii)) would apply. We are finalizing our proposal regarding the writing and signature requirements in the exception at §411.357(aa)(3). We remind readers that the value-based purpose of the arrangement must relate to the value-based enterprise as a whole (which, as noted previously in section II.A.2.a. of this final rule, may be the two parties to the value-based arrangement), and that the exception will not protect a "side" arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise of which they are participants, even if the arrangement itself serves a value-based purpose.

We also proposed to require that the performance or quality standards against which the

recipient of the remuneration will be measured, if any, are objective and measurable, and that such standards must be determined prospectively, with any changes to the performance or quality standards set forth in writing and applicable only prospectively (84 FR 55784). Because commenters expressed concern regarding the term "performance or quality standards," and in an effort to reduce burden on stakeholders by aligning our terminology with OIG, we are modifying this requirement to apply to "outcome measures" rather than "performance or quality standards" and defining "outcome measure" at §411.357(aa)(3)(xii) to mean a benchmark that quantifies: (A) improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. Final §411.357(aa)(3)(ii) requires that the outcome measures against which the recipient of remuneration will be assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support. To promote clarity, we discuss our proposals and respond to comments on our proposals regarding the performance or quality standards against which a recipient of remuneration will be assessed in terms of the "outcome measures" against which the recipient of the remuneration will be assessed. We discuss this modification more fully below.

We recognize that outcome measures may not be applicable to all value-based arrangements—for example, an arrangement under which a hospital provides needed infrastructure to a physician in the same value-based enterprise may not require the physician to meet specific outcome measures in order to receive or keep the infrastructure items or services. However, if the value-based arrangement does include outcome measures that relate to the receipt of the remuneration—for example, an arrangement to share the internal cost savings achieved if the physician meaningfully participates in the hospital's quality and outcomes improvement program and reaches or exceeds predetermined benchmarks for his or her personal performance or quality measurement—such outcome measures must be determined in advance of their implementation. The exception would not protect arrangements where the outcome

measures are set retrospectively (84 FR 55784). In the proposed rule, to align with OIG's proposals, we considered whether to require that outcome measures be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery (84 FR 55784). We sought comment regarding whether we should include this as a requirement of the value-based arrangement exception and the burden or cost of including such a requirement. As discussed more fully below, we are not including a requirement in this final rule that outcome measures must be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery in this final rule.

As we stated in the proposed rule, we expect that, as a prudent business practice, parties would monitor their arrangements to determine whether they are operating as intended and serving their intended purposes—regardless of whether the arrangements are value-based—and have in place mechanisms to address identified deficiencies, as appropriate (84 FR 55784). We explained that there is an implicit ongoing obligation for an entity to monitor each of its financial relationships with a physician for compliance with an applicable exception. In general, if a physician has a financial relationship with an entity that does not satisfy all the requirements of an applicable exception (after applying any special rules), section 1877(a)(1)(A) of the Act prohibits the physician from making a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under Medicare, section 1877(a)(1)(B) of the Act prohibits the entity from presenting or causing to present a claim under Medicare for the designated health services furnished pursuant to a prohibited referral, and section 1877(g)(1) of the Act prohibits Medicare from making payment for a designated health service that is provided pursuant to a prohibited referral. Thus, parties must ensure the compliance of their financial relationship with an applicable exception at the time the physician makes a referral for designated health service(s).

In the proposed rule, we discussed at length the importance of monitoring arrangements that implicate the physician self-referral law (84 FR 55784). More specifically, we discussed the

implicit ongoing compliance monitoring obligation for arrangements that would qualify for protection under the value-based arrangement exception at §411.357(aa)(3). We provided a detailed example of appropriate monitoring of a value-based arrangement for compliance with the proposed exception at §411.357(aa)(3), including the consequences of value-based activities that can no longer be considered to be reasonably designed to achieve the value-based purpose(s) of a value-based enterprise (84 FR 55784 through 55785). We considered whether to include program integrity safeguards that: (1) require the value-based enterprise or the VBE participant providing the remuneration to monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, require the physician to cease referring designated health services to the entity, either immediately upon the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination (84 FR 55785). We sought comment regarding whether we should include these as requirements of the value-based arrangement exception, how parties could monitor for achievement of value-based purposes, and the burden or cost of including such a requirement. Specifically, we sought comment regarding whether we should require that monitoring should occur at specified intervals and, if so, what the intervals should be. Recognizing that cost savings, in particular, may take an extended period of time to achieve, we also sought comment regarding whether to impose time limits with respect to a value-based enterprise's or VBE participant's determination that the value-based purpose of the enterprise will not be achieved through the value-based activities required under the arrangement; that is, require that the value-based purpose must be achieved within a certain timeframe, such as 3 years, and, if it is not, the value-based purpose would be deemed not achievable through the value-based activities required under the arrangement.

As explained in our response to comments below, we are including an explicit monitoring requirement at final §411.357(aa)(3)(vii). Parties seeking to utilize the value-based arrangement

exception (or the value-based enterprise in which they participate) must monitor the value-based arrangement no less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, to determine whether the parties have furnished the value-based activities required under the arrangement, and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise. If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. The parties may do so by terminating the value-based arrangement or by modifying the arrangement to terminate the ineffective value-based activity after completion of the monitoring. If the parties complete the required action within the applicable timeframe, the ineffective value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties. In addition, during the same timeframes, either the value-based enterprise or one or more of the parties to the arrangement must monitor progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring. If the parties fail to monitor outcome measures within the prescribed timeframes, or fail to terminate or replace an unattainable outcome measure within the prescribed timeframe, the value-based arrangement will no longer satisfy the requirements of the exception at §411.357(aa)(3). We emphasize that parties may amend their value-based arrangements to address identified deficiencies at any time, provided that the amendments are prospective only, including any amendments to the compensation terms of the arrangement. We refer readers to section II.E.1. of this final rule for a discussion of the provisions on amending arrangements newly codified at §411.354(d)(1).

We believe that requiring immediate termination of a value-based arrangement due to an ineffective value-based activity would be counterproductive to the underlying goal of encouraging the transition to a value-based health care delivery and payment system. We are providing for the noted "grace periods" because we recognize that parties to a value-based arrangement may need time to address an ineffective value-based activity identified through their monitoring. As discussed in the proposed rule, the physician self-referral law would prohibit a physician from making referrals to an entity, and prohibit the entity from submitting claims for designated health services referred by the physician, if the value-based arrangement does not satisfy all the requirements of an applicable exception at the time of the referral. This includes the requirement that the value-based activities undertaken under the arrangement, by definition, are reasonably designed to achieve one or more value-base purposes of the value-based enterprise (84 FR 55785). We believe that it is necessary to allow parties an appropriate amount of time to address the findings of their monitoring without fear of violating the physician self-referral law. We also believe that a policy under which parties that act quickly to rectify the ineffectiveness of their value-based activities will not run afoul of the physician self-referral law does not pose a risk of program or patient abuse. As described above, we are finalizing a policy under which a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties if the parties terminate the arrangement within 30 consecutive calendar days after the completion of the required monitoring or modify their arrangement to terminate the ineffective value-based activity within 90 consecutive calendar days after completion of the monitoring. Similarly, we are finalizing a policy that provides for 90 consecutive calendar days for parties to terminate or replace an outcome measure that their monitoring indicates is unattainable.

To illustrate the monitoring requirement at final §411.357(aa)(3)(vii) with respect to monitoring of value-based activities, we apply it here in the context of the scenario described in

the proposed rule (84 FR 55784 through 55785). Assume a hospital revised its care protocol for screening for a certain type of cancer to incorporate newly issued guidelines from a nationally recognized organization. The new guidelines, and the revised protocol, no longer support a single screening modality for the disease. Instead, the organization recommends screening by combining two modalities to achieve more accurate results. The revised guidelines and hospital care protocol are intended to improve the quality of care for patients by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results (which can be frequent for single-modality screening for the disease). The hospital observes that most community physicians continue to refer patients to the hospital for single-modality screening. To align referring physician practices with the hospital's revised care protocol, the hospital offers to pay physicians $10 for each instance that they order dual-modality screening in accordance with the revised care protocol during a 2-year period beginning on January 1, 2021. The hospital expects that it would take approximately 2 years to shape physician behavior to always follow the recommended care protocol (except when not medically appropriate for the particular patient). Assume that both single-modality and dual-modality screening are designated health services payable by Medicare. In this illustration, the value-based enterprise is the hospital and identified community physicians. (The hospital and the community physicians could also be part of a larger value-based enterprise.) The target patient population is patients in the hospital's service area that receive screening for the particular disease. The value-based activity is adherence with the hospital's revised care protocol by ordering dual-modality screening instead of single-modality screening. The value-based purpose of the value-based enterprise is to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results.

At its inception, provided that an arrangement between the hospital and a physician satisfies all the requirements of §411.357(aa)(3), the physician's referrals of designated health services to the hospital and the hospital's submission of claims to Medicare for the designated

health services referred by the physician would not violate the physician self-referral law. However, assume that during the first year of the arrangement, the hospital determines through its monitoring that its data analysis indicates that the use of dual-modality screening not only does not result in earlier detection of cancer, but results in more false positive results, invasive biopsies, and unnecessary treatment than single-modality screening. As a result, the hospital determines that the use of dual-modality screening, despite the nationally-recognized recommendations, will not achieve the goal of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results. The compliance monitoring, which occurred in the first year of the arrangement, has identified that the continuation of the value-based activity, dual-modality screening, is no longer expected to further the value-based purpose of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results. Once the hospital has identified the ineffective value-based activity, the hospital has two options to maintain compliance with the physician self-referral law. Under final §411.357(aa)(3)(vii)(B), the parties could terminate the arrangement within 30 consecutive calendar days of the date of completion of the monitoring indicating that the value-based activity was ineffective, or the parties could modify the arrangement to terminate the ineffective value-based activity within 90 consecutive calendar days of completion of the monitoring and, if they choose, replace it with a different value-based activity with prospective applicability. If the parties fail to take one of these actions, the physician would be prohibited from making referrals of any designated health services to the hospital from the date the hospital became aware that its value-based arrangement no longer satisfied the requirements of §411.357(aa)(3) (unless the arrangement satisfies the requirements of another applicable exception to the physician self-referral law, which it likely would not). In addition, the hospital would be prohibited from submitting claims to Medicare for any improperly referred designated health services. The parties' lack of knowledge does not affect

compliance with the physician self-referral law. The hospital's (or value-based enterprise's) failure to monitor as required under our final regulations for progress toward achievement of the value-based purpose of the value-based enterprise would not nullify the parties' noncompliance with the physician self-referral law. The physician's referrals would be prohibited due to the fact that adherence to the revised care protocol could not, in fact, achieve the value-based purpose of the value-based enterprise and would no longer qualify as a "value-based activity" as that term is defined at final §411.351. In turn, the arrangement would not qualify as a "value-based arrangement" and the exception at §411.357(aa)(3) would no longer be available to protect the physician's referrals.

In the proposed rule, we also considered whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the nonmonetary remuneration (84 FR 55785 through 55786). We stated that requiring financial participation by a recipient of nonmonetary remuneration under a value-based arrangement would help ensure that the nonmonetary remuneration is appropriate and beneficial for the achievement of the value-based purpose(s) of the value-based enterprise, as well as ensuring that the recipient will actually use the nonmonetary remuneration. However, we also stated our concern that such a requirement could inhibit the adoption of value-based arrangements. As discussed in section II.D.11.d.(1). of this final rule, even though many commenters asserted that the 15 percent contribution requirement under the existing exception for EHR items and services is burdensome to some recipients and acts as a barrier to adoption of EHR technology, we are retaining the 15 percent contribution requirement for the existing EHR exception as an important program integrity safeguard where the compensation arrangement between the parties is not a value-based arrangement. We are concerned, however, that requiring a 15 percent contribution from the recipient of nonmonetary compensation under a value-based arrangement could inhibit the goal of transitioning to a value-based health care delivery and payment system. We are not including a contribution requirement in the value-based

arrangement exception finalized in this final rule.

We received the following comments and our responses follow.

Comment: The vast majority of commenters supported the adoption of a value-based arrangement exception and urged CMS to finalize the exception without modification in order to support the transition to a value-based health care delivery and payment system. Commenters expressed appreciation for the creation of a value-based exception with no downside risk, asserting that the exception will be beneficial to rural providers, small practices, and others wanting to explore value-based health care delivery and payment, but not yet well-positioned to take on meaningful financial risk. A few commenters suggested that the value-based arrangement exception is complex and burdensome, and could act as a deterrent to participation in value-based health care. A small number of commenters urged us not to finalize the value-based arrangement exception, citing program integrity concerns.

Response: We agree with the commenters that the exception at §411.357(aa)(3) is necessary to facilitate robust participation in a value-based health care delivery and payment system. We are finalizing the exception with the modifications discussed above and in our response to other comments in this section II.A.2. Although we appreciate the program integrity concerns raised by some commenters, we are confident that the integrated approach to safeguards against program and patient abuse found in the value-based definitions and exceptions will ensure that even "no risk" value-based arrangements that satisfy all the requirements of the definitions and the requirements of §411.357(aa)(3) will not pose a risk of program or patient abuse.

Comment: The majority of commenters urged CMS not to limit the value-based arrangement exception to nonmonetary remuneration. The commenters pointed to value-based arrangements commonplace in the industry, such as payment for adherence to care protocols or shared savings models that utilize cash incentives to shape physician behavior, improve quality, and reduce waste. One commenter expressed concern that, by limiting the type of remuneration

permissible under the exception, CMS would create a complicated patchwork of protections depending on the type of remuneration at issue.

Response: We are not limiting the value-based arrangement exception to nonmonetary remuneration only. Limiting the exception to nonmonetary remuneration could undermine the Secretary's goal of robust participation in a value-based health care delivery and payment system by artificially restricting the types of arrangements that are appropriate for protection from the prohibitions of the physician self-referral law.

Comment: Commenters nearly universally opposed the inclusion of a contribution requirement for nonmonetary remuneration provided under a value-based arrangement. Commenters asserted that such a contribution requirement would create a barrier to widespread participation in a value-based health care delivery and payment system. Many commenters echoed our concerns in the proposed rule that a contribution requirement for nonmonetary remuneration would unfairly impact small and rural physician practices, providers, and suppliers that cannot afford the contribution (84 FR 55786).

Response: We agree with the commenters that requiring a 15 percent contribution for nonmonetary remuneration provided under a value-based arrangement could create barriers to the transition to a value-based health care delivery and payment system, particularly for small and rural physician practices, providers, and suppliers. The final value-based arrangement exception does not require a contribution for nonmonetary remuneration.

Comment: A few commenters expressed concern regarding the requirement that a value-based arrangement must be set forth in writing and signed by the parties. These commenters viewed these documentation requirements as unnecessary and creating an administrative burden. A few commenters requested confirmation that the writing requirements of §411.357(aa)(3) may be satisfied through a collection of contemporaneous documents evidencing the conduct between the parties and that a single, formal contract is not required. These same commenters also requested confirmation that the special rule for signature requirements at §411.354(e) (formerly

at §411.353(g)) would apply to value-based arrangements. One commenter requested that we eliminate the signature requirement from the value-based arrangement exception to avoid what the commenter called "technical violations."

Response: We do not consider the documentation requirements under the final value-based arrangement exception burdensome. As discussed above, we view the documentation requirements as self-explanatory and a necessary program integrity safeguard. As we have stated in prior rulemakings, we believe that it is a usual and customary business practice to document and sign arrangements and the requirements of the exceptions to the physician self-referral law do not add burden to these practices. (*See*, for example, 83 FR 59993.) Nothing in the final value-based arrangement exception at §411.357(aa)(3)—or any other exception to the physician self-referral law—requires a single formal contract to satisfy the writing requirement of the exceptions.

Comment: Several commenters raised concerns with our discussion in the proposed rule that parties have an implicit obligation to monitor their arrangements for compliance with the physician self-referral law (84 FR 55784). These commenters asserted that the use of the term "implicit" introduces ambiguity that is not appropriate for a strict liability statute. The commenters requested that any monitoring obligations, including the scope and frequency of the monitoring, be clearly stated in the regulations. A few of the commenters suggested that CMS provide flexibility in monitoring and assessing progress of a value-based arrangement, asserting that the monitoring requirement should be tailored to the resources and sophistication of the parties to the value-based arrangement. Some commenters stated that monitoring for compliance with the requirements of an applicable exception at the outset of an arrangement and upon renewal of the arrangement is a common industry practice and suggested that we adopt a similar policy for monitoring value-based arrangements.

Response: The commenters' statements regarding parties' obligations to monitor for ongoing compliance with the physician self-referral law are surprising, as are their statements

that references to this implicit obligation would introduce ambiguity into their ability to utilize the value-based arrangement exception. Our expectation of monitoring for ongoing compliance in the context of the physician self-referral law is not a new concept. As we stated in Phase II, section 1877 of the Act is clearly intended to make entities responsible for monitoring their compensation arrangements with physicians (69 FR 16112). As discussed above, the core principle of the physician self-referral law is that, if a physician has a financial relationship with an entity that does not satisfy all the requirements of an applicable exception (after applying any special rules), section 1877(a)(1)(A) of the Act prohibits the physician from making a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under Medicare, section 1877(a)(1)(B) of the Act prohibits the entity from presenting or causing to present a claim under Medicare for the designated health services furnished pursuant to a prohibited referral, and section 1877(g)(1) of the Act prohibits Medicare from making payment for a designated health service that is provided pursuant to a prohibited referral. Parties must ensure the compliance of their financial relationships with an applicable exception at the time the physician makes a referral for designated health service(s).

We agree with the commenters that the government's expectations regarding monitoring of value-based arrangements should be explicitly stated in regulation text, and we are including at final §411.357(aa)(3)(vii) a monitoring requirement that provides the guidelines requested by the commenters. Under the final regulation, the value-based enterprise or one or more of the parties to a value-based arrangement must monitor the arrangement no less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year. This timeframe coincides with that proposed by OIG in its safe harbors for value-based arrangements and finalized elsewhere in this issue of the **Federal Register**. To facilitate the assessment of ongoing compliance with the physician self-referral law, we are finalizing our proposal to require that the value-based enterprise or one or more of the parties to the value-based arrangement must monitor whether the parties have furnished the value-based

activities required under the arrangement and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise. If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. In addition, during the same timeframes, either the value-based enterprise or one or more of the parties to the arrangement must monitor progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure.

As discussed in response to the comment below, the final regulation at §411.357(aa)(3)(vii) sets forth specific timeframes in which the parties must take action following completion of monitoring that identifies an ineffective value-based activity or that an outcome measure is unattainable during the remaining term of the arrangement. If the parties take action within the timeframe specific to the chosen action (that is, termination or modification of the value-based arrangement), a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise for the entire period during which it was undertaken by the parties. Similarly, the arrangement will not fail to satisfy the requirements of the exception at §411.357(aa)(3) if, within 90 consecutive calendar days after completion of the monitoring, the parties terminate or replace an outcome measure determined to be unattainable. We are not prescribing in this final rule how value-based enterprises, entities, and physicians should monitor their value-based arrangements; rather, we expect value-based enterprises, entities, and physicians to design their monitoring and other compliance efforts in a manner that is appropriate for the particular value-based arrangement.

Comment: Several commenters urged us not to require termination of a value-based arrangement due to a value-based activity no longer furthering the value-based purpose of the value-based enterprise. These commenters recommended that we establish a timeframe for

"curing" noncompliance or create a transition period that allows the parties to the value-based arrangement to redesign or replace the deficient value-based activity, with a couple commenters suggesting 90 days for that timeframe. A few commenters suggested giving parties the option of terminating the arrangement in its entirety or allowing them to implement a written plan to remediate the noncompliance no later than 60 days from the date they determine that the value-based activities are unable to achieve the value-based purposes. One commenter requested that we adopt a policy that an arrangement would not lose protection under the value-based arrangement exception for a period of 12 months from the date of commencement of the arrangement as long as the value-based activities were reasonably designed to achieve the value-based purpose at its outset. Some commenters suggested that a policy under which a physician's referrals are considered to violate the physician self-referral law if value-based activities do not immediately succeed in achieving the value-based purpose(s) of the value-based enterprise would create a "fear of failure" that would dissuade parties from attempting to deliver health care in new and innovative value-based ways. These commenters asserted that allowing parties to cure defects in arrangements would remove the "fear of failure" and promote value-based health care delivery. A different commenter requested that we establish a specific timeframe for a value-based arrangement to achieve its value-based purpose without risking violation of the physician self-referral law.

Response: As discussed above, if parties to a value-based arrangement, through monitoring efforts or otherwise, determine that a value-based activity no longer furthers the value-based purpose(s) of the value-based enterprise, the parties may either terminate the arrangement or modify the arrangement to remove the ineffective value-based activity. The commenters mistakenly assumed that termination of a value-based arrangement is required if a value-based activity is no longer reasonably designed to further the value-based purpose(s) of the value-based enterprise. Our proposal required the cessation of the physician's referrals of designated health services, either immediately or within 60 days of the determination that the

value-based activities would be unable to achieve the value-based purpose(s) of the value-based enterprise. We did not intend to prohibit modification of arrangements that would allow continuation of physician referrals.

We recognize that the design and implementation of value-based arrangements require a certain level of fluidity, although we are not persuaded to implement a 12-month "deeming" timeframe under which a value-based arrangement would be deemed to satisfy the requirement that its value-based activities are reasonably designed to further the value-based purpose(s) of the value-based enterprise for a period of 12 months from their implementation. Such a policy would permit parties with actual knowledge that the value-based activities will be unable to achieve the value-based purpose(s) to make referrals and submit claims for designated health services potentially much longer than we believe is necessary to make appropriate modifications to their arrangement.

We agree with the commenters that identified 90 days as the amount of time that parties would need to make adjustments to their value-based arrangements when they are aware that a value-based activity will no longer further the value-based purpose(s) of the value-based enterprise. We note that this timeframe is consistent with other timeframes for remediating temporary noncompliance, documentation deficiencies, and other discrepancies in our regulations. We do not believe that parties that elect to terminate their value-based arrangement would need as much time. Accordingly, we have established in our final regulation timeframes in which the parties to a value-based arrangement may address any identified deficiencies with their value-based activities without running afoul of the physician self-referral law. Under the final regulations at §411.357(aa)(3)(vii)(B)(*1*) and (*2*), a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise for the entire period during which it was undertaken if the parties terminate the arrangement within 30 consecutive calendar days or modify the arrangement within 90 consecutive calendar days after completion of the monitoring. We believe that parties to a value-based arrangement

that identify ineffective value-based activities should be able to decide whether to terminate the entire arrangement and effectuate such a termination within 30 consecutive calendar days of identifying the ineffective value-based activities. In order to protect against program and patient abuse that could arise with an unlimited timeframe in which to terminate specific value-based activities, we are establishing at §411.357(aa)(3)(vii)(B)(*2*) a 90-day timeframe for the termination of value-based activities that are not expected to further the value-based purpose(s) of the value-based enterprise. To maintain consistency with other regulations that require remedial action within certain timeframes, the regulation requires that the termination of the arrangement or the ineffective value-based activity must occur within the specified number of consecutive calendar days. The provisions of final §411.357(aa)(3)(vii)(B)(*1*) and (*2*) should address the concerns raised by the commenters without risking program or patient abuse.

Comment: Several commenters inquired about the proposed requirement that performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable. The commenters generally supported a requirement that performance or quality standards must be objective and measurable, but requested additional guidance regarding what qualifies as a "performance or quality standards." The commenters generally opposed our alternative proposal to require that performance or quality standards must be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. Commenters asserted that this alternative proposal and the use of the language "designed to drive meaningful improvements" created ambiguity that would hinder participation in value-based arrangements.

Response: The final regulations at §411.357(aa)(3)(i)(F) and (ii) replace the term "performance and quality standards" with the term "outcome measures." The final exception requires at §411.357(aa)(3)(ii) that the outcome measures against which the recipient of remuneration under a value-based arrangement will be measured, if any, are objective and measurable, and any changes to the outcome measures must be made prospectively and set forth

in writing. We have also added a new paragraph (xii) that defines "outcome measure," for purposes of the value-based arrangement exception, to mean a benchmark that quantifies: (A) improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. This definition is intended to align with OIG's final regulations. We are sympathetic to commenters' concerns regarding the difficulty in ascertaining that a measure is designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. We are not adopting our alternative proposal to require that outcome measures against which recipients of remuneration are measured are designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery.

Comment: Many commenters appear to have misinterpreted the meaning of the requirement at §411.357(aa)(3)(ii) that the outcome measures against which the recipient of the remuneration will be measured, if any, are objective and measurable, and any changes to the outcome measures must be made prospectively and set forth in writing. The commenters interpreted this provision to require the inclusion of outcome measures in all value-based arrangements and questioned whether that is practical. Some of the commenters noted that preventive care and primary care services do not necessarily lend themselves to outcome measures, asserting that benefits of these services may not be immediately measureable.

Response: The requirements at final §411.357(aa)(3)(i)(F) and (ii) specifically include the language "if any" to indicate that outcome measures are not required in every value-based arrangement. We recognize that outcome measures may not be available for or applicable to certain value-based activities. For instance, the adoption of the same EHR system or the completion of training on the EHR system are potential value-based activities that likely would not have an associated outcome measure. However, if outcome measures are included as part of the value-based arrangement, those outcome measures must be objective and measurable and

determined prospectively. In addition, under final §411.357(aa)(3)(vii), either the value-based enterprise or one or more of the parties to the arrangement must monitor progress toward attainment of the outcome measure(s) against which the recipient of the remuneration is assessed. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

Comment: A few commenters stated that they interpreted the requirement that the outcome measures against which the recipient of the remuneration will be measured, if any, are objective and measurable, and any changes to the outcome measures must be made prospectively and set forth in writing to mean that constant improvement or the achievement of the outcome measures is required. Some of the commenters also interpreted this requirement to mean that parties to a value-based arrangement may not substitute outcome measures or make other adjustments to the outcome measures during the term of the value-based arrangement. These commenters asserted that it is common for parties to value-based arrangements to reevaluate outcome measures and make modifications necessary to continue moving towards achievement of the purposes of the value-based enterprise. The commenters sought confirmation that parties are permitted to modify their arrangements, including making changes to outcome measures, and make other necessary adjustments over the course of a value-based arrangement without losing the protection of the exception.

Response: The commenters may have misinterpreted the requirements of the proposed exception. We are defining "outcome measure" in this final rule to mean a benchmark that quantifies: (A) improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. Outcome measures are used to evaluate the provision and effectiveness of value-based activities to ensure that the value-based activities are continuing to further the value-based purposes of the value-based enterprise. Nothing in this final rule

prohibits the replacement or substitution of outcome measures against which the recipient of the remuneration is measured under a value-based arrangement, provided that any changes to the outcome measures are made prospectively and set forth in writing.

For example, assume that a physician can earn incentive pay under a value-based arrangement for providing certain post-discharge follow-up services to patients in a target patient population following their discharge from the hospital, and that the value-based purpose of the value-based enterprise is to improve the quality of patient care by facilitating a smooth transition from an acute care setting to the appropriate post-acute care setting and lowering readmissions to the hospital. The physician's remuneration for providing post-discharge follow-up services under the arrangement may be, in whole or in part, dependent on whether the hospital reduces its readmission rate to 65 percent or lower for patients treated by the physician. The "outcome measure" is the readmission rate. If the parties wish to revise this outcome measure—for example, because the hospital realizes that a readmission rate of 65 percent or lower is too easily attainable or is unrealistic given the severity of the medical conditions of the patients in the target patient population and, specifically, the patients treated by the physician—they may make necessary adjustments to the readmission measure, provided any changes to the measure are prospective only and set forth in writing. It would not be permissible to change the outcome measure to a lower, more attainable readmission percentage and apply that new outcome measure retroactively in order to allow the physician to earn the incentive payment under the value-based arrangement as originally designed. To the extent that commenters were concerned that parties may not amend their value-based arrangements to require more or different value-based activities than those included in the arrangement as originally designed, we emphasize that nothing in final §411.357(aa)(3) prohibits termination or substitution of value-based activities to be undertaken under a value-based arrangement, provided that all modifications to the value-based arrangement are effective prospectively and comply with any applicable regulations regarding the modification of compensation arrangements.

(4) Indirect Compensation Arrangements to which the Exceptions at §411.357(aa) are Applicable (§411.354(c)(4))

The prohibitions of section 1877 of the Act apply if a physician (or an immediate family member of a physician) has an ownership or investment interest in an entity or a compensation arrangement with an entity. For purposes of the physician self-referral law, a compensation arrangement is any arrangement involving direct or indirect remuneration between a physician (or an immediate family member of the physician) and an entity, and remuneration means any payment or other benefit made directly, indirectly, overtly, covertly, in cash, or in kind. (*See* §§411.351 and 411.354(c).) In Phase I, we finalized regulations that define when an indirect compensation arrangement exists between a physician and the entity to which he or she refers designated health services (66 FR 864). For purposes of applying these regulations, in the FY 2009 IPPS final rule, we finalized additional regulations that deem a physician to stand in the shoes of his or her physician organization if the physician has an ownership or investment interest in the physician organization that is not merely a titular interest (73 FR 48693). These regulations are found at §411.354(c)(2) and (3).

Under our current regulations, if an indirect compensation arrangement exists, the exception for indirect compensation arrangements at §411.357(p) is available to protect the compensation arrangement. In addition, if the entity with which the physician has the indirect compensation arrangement is a MCO or IPA, the exception at §411.357(n) is also available to protect the compensation arrangement. If all the requirements of one of the applicable exceptions are satisfied, the physician would not be barred from referring patients to the entity for designated health services and the entity would not be barred from submitting claims for the referred services. No other exception in §411.357 is applicable to indirect compensation arrangements. However, the parties may elect to protect individual referrals of and claims for designated health services using an applicable exception in §411.355 of our regulations.

As we stated in the proposed rule (84 FR 55786), an unbroken chain of financial

relationships described in §411.354(c)(2)(i) may include a value-based arrangement as defined at §411.351 in this final rule. Thus, an unbroken chain of financial relationships that includes a value-based arrangement could form an "indirect compensation arrangement" for purposes of the physician self-referral law if the circumstances described in §411.354(c)(2)(ii) and (iii) also exist. Unless the entity furnishing the designated health services is a MCO or IPA, the parties would have to rely on the exception at §411.357(p), which includes requirements not found in the exceptions for value-based arrangements at §411.357(aa), in order to ensure the permissibility of all the physician's referrals to the entity (assuming no other financial relationships exist between the parties). (If the parties elect to utilize a "services" exception at §411.355, designated health services are protected only on a service-by-service basis, and satisfaction of the requirements of an applicable exception permits only the referral of and claims submission for the particular designated health service that satisfied the requirements of the exception.) As commenters on the CMS RFI noted and commenters on the proposed rule confirmed, because compensation to the physician under a value-based arrangement could take into account the volume or value of referrals or other business generated by the physician for the entity or may not be fair market value for specific items or services provided by the physician, an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships that forms the indirect compensation arrangement may be unable to satisfy the requirements of §411.357(p). To avoid a blanket prohibition on indirect compensation arrangements that enhance value-based health care delivery and payment, we are finalizing our proposal to make additional exceptions available to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships described in §411.354(c)(2)(i).

As described in section II.A.2.b. of this final rule, we are finalizing exceptions available only to compensation arrangements that qualify as value-based arrangements. Although the exceptions do not limit their applicability to value-based arrangements directly between a

physician and the entity to which he or she refers designated health services, the definition of "value-based arrangement" finalized at §411.351 establishes that the only potential parties to a value-based arrangement are the value-based enterprise and VBE participants. In order to fully support the transition to a value-based health care delivery and payment system, we believe that it is important to make the exceptions at §411.357(aa) applicable to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships described in §411.354(c)(2)(i). Following review of the comments on our proposed alternative approaches for addressing indirect compensation arrangements in which one link in the unbroken chain of financial relationships between an entity and a physician is a value-based arrangement, with technical revisions to the proposed regulation text, we are finalizing our primary proposal to make the exceptions at §411.357(aa) applicable to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships described in §411.354(c)(2)(i). Specifically, under the regulation finalized at §411.354(c)(4)(iii), the exceptions at §411.357(aa) are available to protect the physician's referrals to the entity when an indirect compensation arrangement (as defined at §411.354(c)(4)(2)) includes a value-based arrangement (as defined at §411.351) to which the physician (or the physician organization in whose shoes the physician stands) is a direct party. To be clear, the link closest to the physician may not be an ownership interest; it must be a compensation arrangement that meets the definition of value-based arrangement finalized at §411.351.

Under this final rule, parties would first determine if an indirect compensation arrangement exists and, if it does, determine whether the compensation arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party qualifies as a value-based arrangement. If so, the exceptions at §411.357(aa) for value-based arrangements would be applicable. To illustrate, assume an unbroken chain of financial relationships between a hospital and a physician that runs: hospital—(owned by)—parent

organization—(owns)—physician practice—(employs)—physician. Thus, the links in the unbroken chain are ownership or investment interest—ownership or investment interest—compensation arrangement. For purposes of determining whether an indirect compensation arrangement exists between the physician and the hospital, under §411.354(c)(2)(ii), we would analyze the compensation arrangement between the physician practice and the physician. Assume also that the compensation paid to the physician under her employment arrangement varies with the volume or value of her referrals to the hospital because she is paid a bonus for each referral for designated health services furnished by the hospital, provided that she adheres to redesigned care protocols intended to further one or more value-based purposes (as defined at §411.351 in this final rule). Finally, assume that the hospital has actual knowledge that the physician receives aggregate compensation that varies with the volume or value of her referrals to the hospital. The unbroken chain of financial relationships establishes an indirect compensation arrangement; therefore, in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services, the indirect compensation arrangement must satisfy the requirements of an applicable exception. Under the final regulation at §411.354(c)(4)(iii), if the compensation arrangement in this example between the physician practice and the physician qualifies as a value-based arrangement (as defined at §411.351 in this final rule), the exceptions at §411.357(aa) would be available to protect the value-based arrangement (that is, the indirect compensation arrangement) between the hospital and the physician. (The parties could also utilize an applicable exception in §411.355 to protect individual referrals for designated health services or the exception at §411.357(p) to protect the indirect compensation arrangement between the hospital and the physician, but it is unlikely that all the requirements of §411.357(p) would be satisfied in this hypothetical fact pattern.)

In the proposed rule, we described an alternative proposal under which we would define "indirect value-based arrangement" and specify in regulation that the exceptions at §411.357(aa)

would be available to protect an indirect value-based arrangement (84 FR 55787). Under our alternative proposal, an indirect value-based arrangement would exist if: (1) between the physician and the entity there exists an unbroken chain of any number (but not fewer than one) of persons (including but not limited to natural persons, corporations, and municipal organizations) that have financial relationships (as defined at §411.354(a)) between them (that is, each person in the unbroken chain is linked to the preceding person by either an ownership or investment interest or a compensation arrangement); (2) the financial relationship between the physician and the person with which he or she is directly linked is a value-based arrangement; and (3) the entity has actual knowledge of the value-based arrangement in subparagraph (2). We proposed that, if an unbroken chain of financial relationships between a physician and an entity qualifies as an "indirect value-based arrangement," the exceptions at §411.357(aa) would be applicable and the requirements of at least one of the applicable exceptions must be satisfied in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services. Following review of the comments on our alternative approach for addressing indirect compensation arrangements in which one link in the unbroken chain of financial relationships between an entity and a physician is a value-based arrangement, we are not finalizing the alternative proposal.

We also stated in the proposed rule that we were considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of "indirect value-based arrangement" if the link closest to the physician (that is, the value-based arrangement to which the physician is a party) is a compensation arrangement between the physician and a pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. In the alternative, we stated that we were considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of "indirect value-based

arrangement" if one of these persons or organizations is a party to any financial relationship in the chain of financial relationships. Finally, we stated that we were considering whether to include health technology companies in any such exclusion in order to align our policies with policies proposed by OIG (84 FR 55786 through 55787). We sought comment on these approaches and their effectiveness in enhancing program integrity. We are not finalizing any of the proposed restrictions on the identity of the parties to the financial relationships in the unbroken chain of financial relationships between an entity and a physician.

We received the following comments and our responses follow.

Comment: The majority of the commenters that commented on this proposal preferred our primary approach for addressing indirect compensation arrangements in which one of the financial relationships between a physician (or the immediate family member of the physician) and the entity to which the physician refers patients for designated health services is a value-based arrangement. Commenters noted that an indirect compensation arrangement that involves a value-based arrangement may not satisfy the requirements of the exception at §411.357(p) because the compensation paid to the physician may take into account the volume or value of the physician's referrals or the other business generated by the physician for the entity, or the compensation may not meet the fair market value requirement of the exception.

Response: We are finalizing regulations at §411.354(c)(4)(iii) to provide that the exceptions at §411.357(aa) are applicable when an unbroken chain described in §411.354(c)(2)(i) includes a value-based arrangement (as defined in §411.351) to which the physician (or the physician organization in whose shoes the physician stands) is a direct party. In order to determine whether the physician's referrals to the entity with which the physician has the indirect compensation arrangement do not violate the physician self-referral law, parties would determine whether the value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party satisfies all the requirements of one of the exceptions finalized at §411.357(aa) (or another applicable exception). If the

value-based arrangement to which the physician is a direct party is with an entity (as defined at §411.351) other than the entity with which the physician has the indirect compensation arrangement, that direct compensation arrangement must also satisfy the requirements of an applicable exception in order for the physician to make referrals to that entity.

Comment: A few commenters expressed concern regarding our statement in the proposed rule that, besides the exception at §411.357(p), no other exception in §411.357 is applicable to indirect compensation arrangements (84 FR 55786). The commenters requested that we confirm that the exception at §411.357(n) for risk-sharing arrangements is applicable to indirect compensation arrangements, including an indirect compensation arrangement that involves a value-based arrangement. One of the commenters noted that the exception for risk-sharing arrangements expressly references compensation conveyed "directly or indirectly" to a physician. This commenter and others asserted that the exception for risk-sharing arrangements should remain available to entities, such as hospitals, that have indirect compensation arrangements with physicians resulting from risk-sharing arrangements.

Response: Some of the commenters misunderstand the application of the exception for risk-sharing arrangements. The exception at §411.357(n) applies to compensation arrangements between a MCO or an IPA and a physician for services provided to enrollees of a health plan, provided that the compensation arrangement qualifies as a risk-sharing arrangement. In Phase I, we established the exception at §411.357(n) for remuneration provided pursuant to a risk-sharing arrangement *between a physician and a health plan*. There, we stated that physicians generally are compensated for services to managed care enrollees in one of three ways, the first two of which do not vary based on the volume or value of referrals: (1) a salary, in the case of a physician who is an employee; (2) a "fee-for-service" contractual arrangement under which the physician assumes no risk; or (3) a risk-sharing arrangement, under which the physician assumes risk for the costs of services, either through a capitation arrangement, or through a withhold, bonus, or risk-corridor approach. We noted that the first two types of compensation

arrangements are eligible for the statutory exceptions for *bona fide* employment relationships and personal service arrangements,[6] while the third is potentially eligible for the exception for risk-sharing arrangements at §411.357(n). The exception at §411.357(n) does not apply to a compensation arrangement—whether direct or indirect—between a physician and an entity that is anything other than a MCO or IPA.

The risk-sharing arrangement between the MCO or IPA and the physician may be direct or indirect. An indirect risk-sharing arrangement would run MCO or IPA—subcontractor—physician; for example, MCO—(compensation arrangement)—hospital—(compensation arrangement)—physician. In this example, if the MCO is an "entity" (as defined at §411.351), the unbroken chain of financial relationships may constitute an indirect compensation arrangement under §411.354(c)(2). If so, the exception at §411.357(n) would be available to protect the physician's referrals to the MCO, provided that all the requirements of the exception are satisfied. The exception for indirect compensation arrangements at §411.357(p) would also apply. If the MCO or IPA is not itself furnishing designated health services (as described in §411.351), it would not be an "entity" and, in the example above, would not have a direct or indirect compensation arrangement with the physician. (Note that, in Phase I, we clarified and significantly narrowed the situations in which a MCO will be considered an entity furnishing designated health services by refocusing the definition on the party submitting a claim to Medicare rather than the party "providing for" or "arranging for" the furnishing of designated health services for which a claim is submitted to Medicare.)

To be clear, the exception for risk-sharing arrangements at §411.357(n) is not applicable to all risk-sharing arrangements between entities and physicians that provide services to enrollees of the same health plan. Contrary to commenters' stated understanding of the application of §411.357(n), the exception for risk-sharing arrangements does not apply to indirect

[6] In and since the publication of Phase I, we established additional regulatory exceptions that may be applicable to the first two types of compensation arrangements discussed at 66 FR 912.

compensation arrangements between hospitals and physicians, even if both are contractors (or subcontractors) of the same MCO or IPA. In Phase II, a commenter requested confirmation that the exception at §411.357(n) is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, or health maintenance organization. We confirmed the commenter's understanding of the applicability of the exception (69 FR 16114), and stated that all downstream entities are included. We purposefully declined to define the term "managed care organization" so as to create a broad exception with maximum flexibility. Although we did not in Phase II (or any subsequent rulemaking) modify the text of §411.357(n) to extend the applicability of the exception to compensation pursuant to a risk-sharing arrangement (directly or indirectly) between a physician and any entity other than a MCO or IPA, we recognize why the commenters on the proposed rule could be under the impression that our response in the Phase II preamble was intended to do so. For this reason, we are finalizing revisions to the exception at §411.357(n) to clarify the scope and application of the exception. The revisions are effective as of the date set forth in this final rule and apply prospectively only.

Comment: A few commenters requested that we include a reference to §411.357(n) in the regulation text identifying which exceptions are applicable to indirect compensation arrangements that involve value-based arrangements.

Response: To clarify the applicability of the exception for risk-sharing arrangements, we are finalizing regulations at §411.354(c)(4)(ii) and (iii)(B) that expressly state that the exception at §411.357(n) is applicable in the case of an indirect compensation arrangement in which the entity furnishing designated health services described in §411.354(c)(2)(i) is a MCO or IPA. If the entity with which the physician has an indirect compensation arrangement is not a MCO or IPA, the exception for risk-sharing arrangements is not applicable to the indirect compensation arrangement.

(5) Price Transparency

Price transparency is a critical component of a health care system that pays for value and aligns with our desire to reinforce and support patient freedom of choice. We believe that transparency in pricing can empower consumers of health care services to make more informed decisions about their care and lower the rate of growth in health care costs. Health care consumers today lack meaningful and timely access to pricing information that could, if available, help them choose a lower-cost setting or a higher-value provider. Patients are often unaware of site-of-care cost differentials until it is too late (*see* Aparna Higgins & German Veselovskiy, *Does the Cite of Care Change the Cost of Care*, Health Affairs (June 2, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160602.055132/full/). Multiple surveys and studies have revealed that patients want their health care providers to engage in cost discussions, and one recent national survey found that a majority of physicians want to have cost of care discussions with their patients (*see* Caroline E. Sloan, MD & Peter A. Ubel, MD, *The 7 Habits of Highly Effective Cost-of-Care Conversations*, Annals of Internal Medicine (May 7, 2019), https://annals.org/aim/issue/937992, and *Let's Talk About Money*, The University of Utah (2018), https://uofuhealth.utah.edu/value/lets-talk-about-money.php). The point of referral presents an ideal opportunity to have such cost-of-care discussions.

In the CMS RFI, we solicited comment on the role of transparency in the context of the physician self-referral law. In particular, we solicited comment on whether, if provided by the referring physician to a beneficiary, transparency about a physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) would reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address. Many commenters replied that making a physician's financial relationships and cost of care information available could be useful. One commenter suggested that providing clear and transparent information was vital in the health care industry where patients are often vulnerable, confused, and unsure of their options. This commenter further opined that informed patients are

empowered to take charge of their health care and better assist their providers in fulfilling their health care needs. Several commenters shared similar support for transparency efforts. Another commenter stated that transparency of a physician's financial relationships along with price and quality of care information would be valuable to patients in choosing providers and care pathways. This commenter maintained that these actions would also engage patients in protecting against possible unintended consequences of value-based arrangements. Other commenters raised concerns that information on price transparency and a physician's financial relationships with other health care providers, in combination with already-required disclosures under HIPAA, informed consent information and forms, insurance payment authorization forms, and other paperwork that patients receive or must complete would serve only to inundate patients with paperwork that they will find confusing or simply not read. These commenters contended that, although transparency is an appealing concept, requiring additional disclosures would result in more burden than benefit.

The June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First[7] recognizes the importance of price transparency. The Executive Order directs Federal agencies to take historic steps toward getting patients the information they need and when they need it to make well-informed decisions about their health care. CMS has already acted on the Executive Order in two ways. First, by finalizing price transparency requirements in the CY 2020 OPPS final rule (84 FR 65524) to improve the availability of meaningful pricing information to the public by requiring hospitals to make public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges, plus discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for all items and services provided by the hospital beginning January 1, 2021. Second, through the Transparency in Coverage final rule (85 FR

[7] Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, June 24, 2019, available at: https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/.

72158), HHS, along with the Departments of Labor and Treasury, finalized requirements for health insurance issuers and plans in the individual and group markets to make health care prices and expected out-of-pocket costs for enrollees available to the general public to help facilitate more informed health care purchasing decisions with the goal of driving down health care costs. We continue to believe that all consumers need price and quality information in advance to make an informed decision when they choose a good or service, including at the point of a referral for such goods or services. As we stated in the proposed rule, by making meaningful price and quality information more broadly available, we can protect patients and increase competition, innovation, and value in the health care system (84 FR 55788).

We remain committed to ensuring that physician self-referral law policies do not infringe on patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. We continue to believe that it is important for patients to have timely access to information about all aspects of their care, including information about the factors that may affect the cost of services for which they are referred. As stated in the proposed rule, a patient who is made aware, for example, that costs may differ based on the site of service where the referred services are furnished, may become a more conscious consumer of health care services (84 FR 55788). Access to such information may also spark important conversations between patients and their physicians, promoting patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. In conjunction with their physicians' determination of the need for recommended health care services and the urgency of that need, information on the factors that may affect the cost of such services could ensure that patients have the information they need to shop and seek out high-quality care at the lowest possible cost.

It remains CMS' goal to establish policies that facilitate consumers' ability to participate actively and meaningfully in decisions relating to their care. At the same time, we continue to be cognizant that including requirements regarding price transparency in the exceptions to the

physician self-referral law raises certain challenges for the regulated industry. In the proposed rule, we sought comments on how to pursue our price transparency objectives in the context of the physician self-referral law, both in the context of a value-based health care system and otherwise, and how to overcome the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the physician self-referral regulations (84 FR 55788). Specifically, we requested comments regarding the availability of pricing information and out-of-pocket costs to patients (including information specific to a particular patient's insurance, such as the satisfaction of the patient's applicable deductible, copayment, and coinsurance obligations); the appropriate timing for the dissemination of information (that is, whether the information should be provided at the time of the referral, the time the service is scheduled, or some other time); and the burden associated with compliance with a requirement in an exception to the physician self-referral law to provide information about the factors that may affect the cost of services for which a patient is referred. Finally, we sought comment regarding whether the inclusion of a price transparency requirement in a value-based exception would provide additional protections against program or patient abuse through the active participation of patients in selecting their health care providers and suppliers.

In furtherance of our goal of price transparency for all patients, we solicited comments regarding whether to consider a requirement related to price transparency in every exception for value-based arrangements at §411.357(aa) (84 FR 55789). While we did not propose regulatory changes, we considered whether to require that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out-of-pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance that they have. Because of limits on currently available pricing data, we continue to believe that such a requirement could be an important first step in breaking down barriers to cost-of-care discussions that play a beneficial role in a value-based health care system. We further explained the public notice provided or

reflected in the policy could be made in any form or manner that is accessible to patients. For example, a notice on the physician's website, a poster on the wall in the physician's office, or a notice in a patient portal used by the physician's patients would all be acceptable. We stated our expectation that any notice would be written in plain language that would be understood by the general public. We refer readers to the Plain Writing Act of 2010 (Pub. L. 111-274, enacted on October 13, 2010) for further information. We sought comment on whether, if we finalize such a requirement, it would be helpful for CMS to provide a sample notice and, if we provide a sample notice, whether we should deem such a notice to satisfy the requirement described. We stated that we would not require public notice in advance of referrals for emergency hospital services to avoid delays in urgently needed care. We solicited comment on other options for price transparency requirements in the value-based exceptions to the physician self-referral law, as well as whether we should consider for a future rulemaking the inclusion of price transparency requirements in exceptions to the physician self-referral law included in our existing regulations.

We received several comments from both consumers of health care and entities that provide health care services. Nearly all the commenters were united in their support that patients should have access to clear, accurate, and actionable cost-sharing information and recognized the important role price transparency has in patient care. However, many supportive commenters also asserted that requiring price transparency disclosures as a requirement of an exception to the physician self-referral law is not an appropriate mechanism for promoting price transparency objectives given the strict liability nature of the law. We continue to believe that health care markets work more efficiently and provide consumers with higher-value health care if we promote policies that encourage choice and competition. We thank the commenters for their thoughtful responses, which will help inform future agency policy making on this important objective. We are not finalizing any price transparency provisions in this rulemaking.

B. Fundamental Terminology and Requirements

1. Background

As described in the proposed rule and in greater detail in this section of the final rule, many of the statutory and regulatory exceptions to the physician self-referral law include one, two, or all the following requirements: the compensation arrangement itself is commercially reasonable; the amount of the compensation is fair market value; and the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some cases, other business generated between the parties). These requirements are presented in various ways within the statutory and regulatory exceptions, but it is clear that they are separate and distinct requirements, each of which must be satisfied when included in an exception. As we stated in the proposed rule, the regulated industry and its complementary parts, such as the health care valuation community, have sought additional guidance from CMS regarding whether compliance with one of the requirements is dependent on compliance with one or both of the others (84 FR 55789). In addition, these and other stakeholders have requested clarification on our policy with respect to when an arrangement is considered commercially reasonable, under what circumstances compensation is considered to take into account the volume or value of referrals or other business generated between the parties, and how to determine the fair market value of compensation. According to stakeholders and commenters on the proposed rule, False Claims Act (31 U.S.C. 3729 through 3733) case law has exacerbated the challenge of complying with these three fundamental requirements.

Endeavoring to establish bright-line, objective regulations for each of these fundamental requirements, we proposed a new definition of "commercially reasonable" at §411.351, proposed to establish special rules that identify the universe of circumstances under which compensation would be considered to take into account the volume or value of a physician's referrals or the other business generated by a physician for the entity paying the compensation, and proposed to revise the definitions of "fair market value" and "general market value" in our regulations at

§411.351. Our overall intention with these policies is to reduce the burden of compliance with the physician self-referral law, provide clarification where possible, and achieve the goals of the Regulatory Sprint. As we stated in the proposed rule, we believe that clear, bright-line rules would enhance both stakeholder compliance efforts and our enforcement capability. We believe that the policies finalized here will provide the clarity that will benefit the regulated industry, CMS, and our law enforcement partners (84 FR 55789).

In developing our proposals for guidance on the fundamental terminology and requirements, we considered three basic questions—

- Does the arrangement make sense as a means to accomplish the parties' goals?
- How did the parties calculate the remuneration?
- Did the calculation result in compensation that is fair market value for the asset, item, service, or rental property?

These questions relate, respectively, to the definition of commercial reasonableness, the volume or value standard and the other business generated standard, and the definition of fair market value. In this section of the final rule, we provide detailed descriptions of our final definitions and special rules. Importantly, our final policies relate only to the application of section 1877 of the Act and our physician self-referral regulations. Although other laws and regulations, including the anti-kickback statute and CMP law, may utilize the same or similar terminology, the policies finalized in this final rule do not affect or in any way bind OIG's (or any other governmental agency's) interpretation or ability to interpret such terms for purposes of laws or regulations other than the physician self-referral law. In addition, our interpretation of these key terms does not relate to and in no way binds the Internal Revenue Service with respect to its rulings and interpretation of the Internal Revenue Code or State agencies with respect to any State law or regulation that may utilize the same or similar terminology. We note further that, to the extent terminology is the same as or similar to terminology used in the Quality Payment Program within the PFS, our final policies do not affect or apply to the Quality Payment

Program.

We received the following general comment on our discussion of the three key requirements in the exceptions to the physician self-referral law, and our response follows. We respond to comments specific to each of the key requirements in sections II.B.2. through II.B.4. of this final rule.

Comment: Several commenters requested that CMS' articulation of the "big three" requirements should be preserved in the final rule. Specifically, commenters described as "cornerstones" of exceptions to the physician self-referral law the requirements that: (1) the compensation arrangement is commercially reasonable; (2) the compensation is not determined in any manner that takes into account the volume or value of a physician's referrals (the volume or value standard) or the other business generated by a physician for the entity (the other business generated standard); and (3) the amount of compensation is fair market value for the items or services furnished under the arrangement. Commenters strongly agreed with our statements that these requirements are separate and distinct and should be disentangled from each other.

Response: We agree with the commenters that it is important to reiterate that the statutory and regulatory requirements regarding compensation arrangements that are commercially reasonable, compensation that is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician, and compensation that is fair market value for items or services actually furnished are separate and distinct requirements, each of which must be satisfied when included in an exception to the physician self-referral law.

2. Commercially Reasonable (§411.351)

In the proposed rule, we proposed to include at §411.351 a definition for the term "commercially reasonable." As described previously, many of the statutory and regulatory exceptions to the physician self-referral law include a requirement that the compensation

arrangement is commercially reasonable. For example, the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships requires that the remuneration provided to the physician is pursuant to an arrangement that would be commercially reasonable (even if no referrals were made to the employer). The exception at section 1877(e)(3)(A) of the Act for personal service arrangements uses slightly different language to describe this general concept, and requires that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The exception at §411.357(y) for timeshare arrangements, which the Secretary established in regulation using his authority at section 1877(b)(4) of the Act, requires that the arrangement would be commercially reasonable even if no referrals were made between the parties. Despite the prevalence of this requirement (in one form or another), as we stated in the proposed rule (84 FR 55790), we addressed the concept of commercial reasonableness only once—in our 1998 proposed rule—where we stated that we are interpreting "commercially reasonable" to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals (63 FR 1700). Until now, the physician self-referral regulations themselves lacked a codified definition for the term commercially reasonable.

As discussed previously in this section II.B.2., the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. The determination of commercial reasonableness is not one of valuation. We continue to believe that this determination should be made from the perspective of the particular parties involved in the arrangement. In addition, the determination that an arrangement is commercially reasonable does not turn on whether the arrangement is profitable; compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable. In the proposed rule, we described numerous examples of compensation arrangements that commenters on the CMS RFI asserted

would be commercially reasonable, despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received. We acknowledge that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. Examples of reasons why parties would enter into such transactions include community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes.

To provide the certainty requested by stakeholders, we proposed to codify in regulation the definition of "commercially reasonable" at §411.351. We proposed two alternative definitions for the term. First, we proposed to define "commercially reasonable" to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In the alternative, we proposed to define "commercially reasonable" to mean that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. We sought comment on each of these definitions as well as input from stakeholders regarding other possible definitions that would provide clear guidance to enable parties to structure their arrangements in a manner that ensures compliance with the requirement that their particular arrangement is commercially reasonable. We also proposed to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties (84 FR 55790). After considering the comments on the definition of "commercially reasonable," we are finalizing in our regulation at §411.351 that commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the

parties, including their size, type, scope, and specialty. The final regulation also states that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Finally, many of the exceptions to the physician self-referral law require that an arrangement is commercially reasonable "even if no referrals were made between the parties" or "even if no referrals were made to the employer." The exceptions use varying phrasing to describe this requirement and we do not repeat each iteration here. Although we did not include this language in the final definition of "commercially reasonable," it remains an important constraint when determining whether an arrangement satisfies the requirements of an applicable exception. As described elsewhere in this final rule, we have revised the exception for fair market value compensation to include this important constraint in the requirement at §411.357(l)(4) that a compensation arrangement is commercially reasonable. In addition, we included this requirement in the new exception for limited remuneration to a physician that we are finalizing at §411.357(z).

We received the following comments and our responses follow.

Comment: Most commenters supported our proposal to define the term "commercially reasonable" in regulation, stating a preference for one of the two alternative definitions that we proposed. A few commenters offered alternative definitions of "commercially reasonable," such as an arrangement that is "appropriately designed to meet the parties' legitimate business goals from the perspective of the parties to the arrangement" and an arrangement that is "entered into for a legitimate business interest and is reasonably structured to achieve the legitimate business interest." A small number of commenters urged us not to finalize the proposed definition so that parties could rely on CMS' statements in the 1998 proposed rule, noting that it has been workable for industry stakeholders for many years.

Several commenters requested that, if we finalize the first alternative proposed definition, we strike the limitation that the arrangement is on similar terms and conditions as like

arrangements. These commenters asserted that parties to an arrangement would not have access to data to identify "like arrangements" or be aware of their terms and conditions. In addition, parties may enter into a novel compensation arrangement that bears minimal, if any, resemblance to existing arrangements against which it could be compared for "similar terms." The commenters also highlighted the burden associated with obtaining third party opinions in order to satisfy this requirement. Other commenters preferred the second alternative definition because of its focus on the comparison to other similarly situated providers, suppliers, and physicians, although one of these commenters noted that the requirement that an arrangement makes "commercial sense" could exclude arrangements for noncommercial purposes, such as meeting community needs. A few other commenters suggested combining the two proposed definitions in order to emphasize that the determination of commercial reasonableness should be from the perspective of, and further a legitimate business need of, the particular parties to the arrangement, and also that the arrangement should be compared to arrangements with similarly situated parties. One of these commenters also suggested that the definition of "commercially reasonable" should reflect the importance of evaluating the market conditions relevant to the arrangement. A few other commenters offered that CMS should finalize a policy under which an arrangement would be commercially reasonable if it meets either of the proposed alternative definitions. Another commenter urged CMS to ensure that the definition of "commercially reasonable" does not shelter abusive arrangements.

Response: We agree that a definition requiring a compensation arrangement to be on similar terms as like arrangements in order to be commercially reasonable does not provide for the clarity that we and stakeholders seek and, in fact, could increase the burden on parties that must seek the expertise of outside organizations to ensure compliance with the requirement that their arrangement is commercially reasonable. We are finalizing a modified definition of "commercially reasonable" to address commenters' concerns. In line with the suggestion of some commenters, the final definition of "commercially reasonable" incorporates aspects of each

of the proposed alternative definitions. Under the definition finalized at §411.351, commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. We believe that the definition of "commercially reasonable" at final §411.351 is consistent with the guidance we provided in the 1998 proposed rule, appropriately considers the characteristics of the parties to the actual arrangement being assessed for its commercial reasonableness, and will adequately ensure that parties cannot protect abusive arrangements under the guise of "commercial reasonableness."

Comment: One commenter asked us to confirm that the test of commercial reasonableness relates primarily to the non-financial elements of an arrangement.

Response: We understand the commenter to be inquiring whether the existence of the compensation arrangement must be commercially reasonable as opposed to whether the precise compensation terms of the arrangement must be commercially reasonable. That is, we understand the commenter to be seeking confirmation that the concept of commercial reasonableness does not relate to the amount of or formula for compensation paid under an arrangement, but rather whether the entire arrangement is commercially reasonable. As we stated in the proposed rule and previously in this final rule, when determining the commercial reasonableness of an arrangement, the question to ask is whether the arrangement makes sense as a means to accomplish the parties' goals. The test is not whether the compensation terms alone make sense as a means to accomplish the parties' goals; however, the compensation terms of an arrangement are an integral part of the arrangement and impact its ability to accomplish the parties' goals (84 FR 55790).

Comment: One commenter urged us to adopt a policy under which an arrangement would be presumed to be commercially reasonable if, contemporaneously with the commencement of the arrangement, the governing body of the entity (or its designee) documents in writing that the arrangement furthers the legitimate business purpose of the parties. Another

commenter urged us to adopt an irrebuttable presumption that, if the purpose of an arrangement is documented and achieved, the commercial reasonableness of the arrangement cannot be contradicted by extrinsic evidence. The commenter asserted that, in the absence of such a presumption, entities are left susceptible to the potential for False Claims Act litigation predicated on an unsupported inference of ill intent on behalf of the contracting parties.

Response: We do not believe that merely documenting in writing that an arrangement furthers a legitimate business purpose of the parties is sufficient to ensure that the arrangement is commercially reasonable, even if the identified purpose is achieved. Moreover, our final definition of "commercially reasonable" requires more than furtherance of a legitimate business purpose of the parties. The arrangement must also be sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. If the only requirement to demonstrate that an arrangement is commercially reasonable is contemporaneous written documentation stating that it is commercially reasonable, unscrupulous parties could satisfy the requirement simply by including sufficient template language in their documentation, even if, in reality, the arrangement could not further the legitimate business purposes of the parties (assuming they have a legitimate business need for the arrangement) or is not sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. Further, the fact that an arrangement ultimately achieved a legitimate business purpose of the parties does not necessarily mean that it was a commercially reasonable arrangement. Where a financial relationship exists between a physician (or an immediate family member of a physician) and an entity to which the physician makes referrals for designated health services, compliance with the physician self-referral law requires substantive compliance, not merely documentary (or "paper") compliance, with the requirements of an applicable exception. An irrebuttable presumption of commercial reasonableness that ensures that parties are shielded from allegations of violation of the False Claims Act if their documentation includes specific language or their arrangement ultimately achieved its intended purpose would pose a risk of

program or patient abuse.

Comment: A few commenters requested that we include in regulation text a non-exhaustive list of legitimate business purposes for purposes of applying the definition of "commercially reasonable." One commenter specifically referenced our discussion in the proposed rule of examples of compensation arrangements that CMS RFI commenters believed would be commercially reasonable even if they did not result in profit for one or more of the parties.

Response: As we stated in the proposed rule, we find compelling the comments of commenters on the CMS RFI regarding the types of arrangements they believed would be commercially reasonable even if they did not result in profit for one or more of the parties (84 FR 55790). However, these types of arrangements do not depict the entire universe of arrangements that could be commercially reasonable. We decline to provide examples in regulation text of arrangements that may be commercially reasonable, because the determination of whether a compensation arrangement is commercially reasonable is dependent on the facts and circumstances of the parties. Even a non-exhaustive list of the types of arrangements that are potentially commercially reasonable could inadvertently limit or otherwise proscribe the types of arrangements that parties undertake. Moreover, it is not possible to know definitively that, in every instance, a particular type of arrangement would be commercially reasonable. An arrangement that is commercially reasonable for one set of parties may not be commercially reasonable for another.

Comment: One commenter that asked us to provide examples of arrangements that would be considered commercially reasonable asserted that examples are necessary so that parties may avoid unintentional noncompliance with the commercial reasonableness requirement, particularly in the context of value-based arrangements for which the commercial reasonableness of the arrangement is required. Another commenter stated its assumption that CMS "expects that value-based payments must still be tested for commercial reasonableness"

and asked us to confirm its belief. The commenter specifically requested us to confirm that, for any new exceptions for value-based arrangements, the determination of commercial reasonableness may be based on more than just cost savings to the value-based enterprise. The commenter asserted that, in arrangements where cost savings are negligible, enhanced access to care, increased care coordination, and improved quality of care may support a determination of the value-based arrangement's commercial reasonableness.

Response: As we explained in section II.A.2. of this final rule, the new exceptions for value-based arrangements finalized at §411.357(aa) do not include a requirement that the value-based arrangement is commercially reasonable. Of course, parties may utilize any applicable exception to demonstrate compliance with the physician self-referral law. If the exception upon which parties to a value-based arrangement rely includes a requirement that the arrangement is commercially reasonable, the arrangement must further a legitimate business purpose of the parties. In addition, it must be sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. However, as we stated in the proposed rule, the determination of whether the arrangement is commercially reasonable is not one of valuation (84 FR 55790), and an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Comment: A few commenters expressed concern that the term "legitimate business purpose" does not provide enough certainty for stakeholders. Another commenter asked how the requirement that an arrangement must further a legitimate business purpose of the parties in order to be commercially reasonable is different from a query into the subjective intent of the parties (that is, whether a purpose of the arrangement is to induce or reward referrals).

Response: The term "legitimate business purpose" appears in both the statutory and regulatory exceptions to the physician self-referral law. The commenter did not clearly explain how the use of this term in the definition of "commercially reasonable" is any less clear or appropriate than its use in the special rule at §411.354(d)(4)(v) or the exceptions for the rental of

office space at §411.357(a)(3), the rental of equipment at §411.357(b)(2), personal service arrangements at §411.357(d)(1)(iii), and fair market value compensation at §411.357(l)(4) (prior to its revision in this final rule). Given that the language finalized in our definition of "commercially reasonable" is identical to that used in longstanding statutory and regulatory exceptions and our special rule at §411.354(d)(4)(v), we see no reason why stakeholders would be suddenly unable to ascertain the meaning of the term. We see great benefit in using consistent terminology throughout our regulations where we intend an identical policy or standard. With respect to the second commenter's question, we believe that the requirement represents an objective standard. This requirement in the definition of "commercially reasonable" is similar to the requirements in the exceptions referenced, all of which represent objective standards. Although identifying the business purpose of an arrangement may entail an inquiry into the parties' intent for the arrangement, the requirement in the definition of "commercially reasonable" that the arrangement furthers a legitimate business purpose of the parties would be considered only after the determination that there actually exists a legitimate business purpose for the arrangement. As we stated in the proposed rule, conduct that violates a criminal law, such as inducing or rewarding referrals in violation of the anti-kickback statute, would not be a legitimate business purpose for an arrangement (84 FR 55791). Thus, the arrangement would not be commercially reasonable, and the question of whether the arrangement furthers a legitimate business purpose would not be reached.

Comment: One commenter agreed that an arrangement does not further the legitimate business purposes of the parties if, for example, a hospital engages more medical directors than it needs to furnish required medical direction, but asked for additional guidance on our interpretation of the term "legitimate business purpose." Another commenter expressed concern that unscrupulous parties could identify the goal of attracting a physician's business as a "legitimate business purpose" of its compensation arrangement with the physician. This commenter also suggested that an arrangement that is unprofitable should have discrete and well-

documented factors establishing that it furthers a legitimate business purpose of the parties (such as a regulatory or licensure requirement or a patient access issue) in order to qualify as commercially reasonable.

Response: As we noted in the proposed rule, arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements (84 FR 55790). For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable. Although the evaluation of compliance with the physician self-referral law always requires a review of the facts and circumstances of the financial relationship between the parties, the commercial reasonableness of multiple arrangements for the same services is questionable.

In the proposed rule, we discussed numerous examples of compensation arrangements described by CMS RFI commenters as commercially reasonable, in their opinions, despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received (84 FR 55790). The underlying purposes of the compensation arrangements described by the CMS RFI commenters included addressing community need, timely access to health care services, fulfillment of licensure or regulatory obligations (including those under the Emergency Medical Treatment and Labor Act (EMTALA)), the provision of charity care, and the improvement of quality and health outcomes. We believe that all of these purposes could qualify as "legitimate business purposes" of the parties to an arrangement, depending on the facts and circumstances of the parties.

We share the second commenter's concern that unscrupulous parties could claim that a compensation arrangement is commercially reasonable by claiming that attracting a physician's business is a "legitimate business purpose" for their arrangement. In the proposed rule, we explained that we were not proposing to include the phrase "even if no referrals were made" in the definition of "commercially reasonable" because this qualifying phrase (or similar language) appears in the regulation text of many exceptions that require an arrangement to be commercially reasonable (84 FR 55791). Thus, it would be redundant to include the language in the definition of "commercially reasonable" itself. We were clear that we were not proposing to remove this qualifying language from the exceptions in which it appears. We believe that this qualifying language provides critical protection against program or patient abuse, as an arrangement must be commercially reasonable even if no referrals were made by the physician. As described in greater detail in sections II.D.10. and II.E.1. of this final rule, we are adding this language where it had not previously been included in the exception for fair market value compensation at §411.357(l) and in the new exception for limited remuneration to a physician finalized at §411.357(z). An arrangement whose purpose is to attract a physician's business, even if the parties claim this purpose, would not be commercially reasonable in the absence of the physician's referrals and, thus, would not satisfy this important requirement of the exceptions generally applicable to compensation arrangements that call for items or services to be provided by a physician.

Finally, in the proposed rule, we also discussed our review of Internal Revenue Service (IRS) Revenue Ruling 97-21 and its conclusion that a hospital may not engage in substantial unlawful activities and maintain its tax-exempt status because the conduct of an unlawful activity is inconsistent with charitable purposes (84 FR 55790). In this final rule, we are similarly taking the position that an activity that is in violation of a criminal law would not be a legitimate business purpose of the parties and, therefore, would not be commercially reasonable for purposes of the physician self-referral law. We note that the absence of a criminal violation

would not, in and of itself, establish that an arrangement is commercially reasonable.

Comment: Several commenters addressed our preamble discussion regarding the requirement in our regulations that a compensation arrangement must be commercially reasonable even if no referrals were made between the parties. One commenter suggested that, if CMS intends that an arrangement should be commercially reasonable even in the absence of referrals, that phrase should be added to the exceptions or, if referrals may be considered, CMS should so state. These commenters requested that we expressly confirm that the term "referral" in these references in our exceptions has the meaning set forth in §411.351 of our regulations. Another commenter asserted that the "even if no referrals were made" requirement is an integral part of commercial reasonableness in applying the physician self-referral law. This commenter suggested that we add this limiting phrase to §411.357(l)(4).

Response: We agree with the commenters regarding the inclusion of the language "even if no referrals were made between the parties" and, for the reasons explained in our response to the previous comment, have added this language to the exception for fair market value compensation at §411.357(l) and the new exception for limited remuneration to a physician at §411.357(z). Unless the context indicates otherwise, the term "referral" has the meaning set forth in §411.351 throughout the physician self-referral regulations, including in this limiting phrase.

Comment: Most commenters that addressed the definition of "commercially reasonable" expressed appreciation for the clarification in the proposed rule of our position that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable (84 FR 55790), and supported the inclusion of this policy statement at proposed §411.351. Commenters echoed the potential reasons set forth in the proposed rule why an arrangement may not be profitable, but yet still commercially reasonable, and added that, despite the parties' prediction of profitability at the onset of an arrangement, an arrangement may simply not "pan out." Many of these commenters requested that we extend our

policy regarding the effect that the profitability of a compensation arrangement has on the arrangement's ability to satisfy the requirement that it is commercially reasonable to state that commercial reasonableness is unrelated, wholly unrelated, or irrelevant to the profitability of the arrangement to one or more of the parties. One commenter suggested that we state in regulation text that profitability is not a requirement for an arrangement to be commercially reasonable. Another commenter expressed concern that the use of the word "may" does not provide a bright-line rule for stakeholders. One commenter noted that the concept of commercial reasonableness has been used as an enforcement tool for business decisions that might not have turned out to be good business decisions, but were made in good faith, or that are strategic in nature without making absolute "commercial sense." In contrast, a few commenters asserted that there are circumstances under which it would not be commercially reasonable for parties to enter into an arrangement that they know would result in substantial losses to one or more of the parties. One commenter, while agreeing that the issue of commercial reasonableness is not solely determined by physician practice profitability, stated that physician practice losses may indicate arrangements that should be further scrutinized as possible fraud and abuse risks.

Response: We decline to adopt the commenters' suggestions regarding the extension of our policy. Although we believe that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable, we are not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to a determination of its commercial reasonableness, for instance, in a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no identifiable need or justification—other than to capture the physician's referrals—for the arrangement.

We agree with the commenters that it is appropriate and helpful to include in regulation text our policy regarding the impact of an arrangement's profitability on its ability to satisfy the requirement that it is commercially reasonable. We are not adopting the alternative characterization of our policy as "profitability is not a requirement for an arrangement to be

commercially reasonable" because we do not believe that this language is as clear or precise as the language we proposed. We are finalizing in regulation text at §411.351 our policy that "an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

Comment: One commenter asked for confirmation that any definition of "commercially reasonable" finalized by CMS will not apply to regulations enforced by the IRS, OIG or pursuant to state law.

Response: The commenter is correct. The introductory language to §411.351 where the definition of "commercially reasonable" appears in our regulation text states that the definitions in [Title 42, part 411, Subpart J] apply only for purposes of section 1877 of the Act and [Subpart J].

Comment: One commenter asked how CMS interprets the requirements at §411.357(a)(3) and (b)(2) in the exceptions for the rental of office space and equipment, respectively, that the leased office space or equipment does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement. The commenter noted that this requirement and a requirement that the compensation arrangement is commercially reasonable are included in each of these statutory (and regulatory) exceptions. The commenter expressed confusion about our description in the proposed rule of the requirement in the statutory exception for personal service arrangements that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement as another form of the requirement that an arrangement is commercially reasonable (84 FR 55790).

Response: We believe that the requirement that the leased office space or equipment does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement is intended to prevent sham lease arrangements under which a lessee pays remuneration to the lessor under the guise of rental charges where the rental charges are for

office space or equipment for which the lessee has no genuine or reasonable use. The statutory and regulatory exceptions for the rental of office space and the rental of equipment also include a requirement that the lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor. The new definition of "commercially reasonable" at final §411.351 applies for purposes of interpreting this requirement. Thus, the particular lease arrangement must further a legitimate business purpose of the parties to the arrangement and must be sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.

The statutory exception at section 1877(e)(3)(A) of the Act for personal service arrangements includes a requirement that the aggregate services contracted for under the personal service arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. We included this requirement in the regulatory exception for personal service arrangements at §411.357(d)(1)(iii). Unlike the exceptions for the rental of office space and the rental of equipment, the exception for personal service arrangements does not include—either in the statute or our regulations—a separate requirement that the arrangement is commercially reasonable. The commenter raises a valid point regarding our statement in the proposed rule that, with respect to the exception for personal services, the "does not exceed what is reasonable and necessary" requirement is a different form of the requirement that the arrangement is commercially reasonable. Upon further review of the similarities and differences in the requirements in the statutory and regulatory exceptions for the rental of office space, the rental of equipment, and personal service arrangements, we are retracting our statement from the proposed rule that the requirement at section 1877(e)(3)(A) of the Act (incorporated at §411.357(d)(1)(iii)) equates to a requirement that the personal service arrangement is commercially reasonable.

As we stated in this section II.B.2., with respect to lease arrangements for office space and equipment, we interpret the "does not exceed what is reasonable and necessary" requirement

as a protection against sham lease arrangements under which a lessee pays remuneration to the lessor under the guise of rental charges where the rental charges are for office space or equipment for which the lessee has no genuine or reasonable use. We similarly interpret this requirement in the context of the exception for personal service arrangements as a protection against sham arrangements for the services of a physician for which the entity has no genuine or reasonable use. In the proposed rule, we stated that arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements (84 FR 55790). We provided the example of a hospital that enters into multiple arrangements for medical director services for a single department even though the hospital needs only one medical director for the department. We stated that the commercial reasonableness of multiple arrangements for the same services is questionable. Multiple arrangements for the same personal services may also result in the failure of the duplicate arrangements to satisfy the "reasonable and necessary" requirement in the exception for personal services at section 1877(e)(3)(A) of the Act and §411.357(d)(1)(iii). In the proposed rule, we also discussed our view that an activity that is in violation of criminal law would not be a legitimate business purpose of the parties and, therefore, would not be commercially reasonable for purposes of the physician self-referral law (84 FR 55791). Activity that is in violation of criminal law would also fail to satisfy the requirement in the exception for personal service arrangements that the services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law. Thus, although the exception for personal service arrangements does not include a requirement that the arrangement is commercially reasonable, the other requirements in the exception guard against program or patient abuse in an important and essentially equivalent way.

We note that the exception for personal service arrangements at §411.357(d)(1) includes a requirement that the arrangement covers all the services to be furnished by the physician (or an

immediate family member of the physician) to the entity. The exception permits the use of a master list of contracts that is maintained and updated centrally and available for review by the Secretary upon request. In addition, a personal service arrangement must have a duration of at least 1 year in order to qualify for protection under the exception at §411.357(d)(1). We are aware that, because personal service arrangements may not satisfy these requirements, parties often rely on the exception at §411.357(l) for fair market value compensation to protect their arrangements for the personal services of physicians and their immediate family members. We remind readers that the exception for fair market value compensation includes a requirement that the arrangement is commercially reasonable, and as explained in section II.D.10. of this final rule, we are revising the regulation text of that exception to require that the arrangement is commercially reasonable even if no referrals were made between the parties.

3. The Volume or Value Standard and the Other Business Generated Standard (§411.354(d)(5) and (6))

Many of the exceptions at section 1877(e) of the Act ("Exceptions Relating to Other Compensation Arrangements") and in our regulations include a requirement that the compensation paid under the arrangement is not determined in any manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in any manner that takes into account other business generated between the parties. We refer to these as the "volume or value standard" and the "other business generated standard," respectively. Throughout the regulatory history of the physician self-referral law, we have shared our interpretation of these standards and responded to comments as they arose. Despite our attempt at establishing clear guidance regarding the application of the volume or value standard and the other business generated standard, commenters to several requests for information, including the CMS RFI, identified their lack of a clear understanding as to whether compensation will be considered to take into account the volume or value of referrals or other business generated by

the physician as one of the greatest risks they face when structuring arrangements between entities furnishing designated health services and the physicians who refer to them. They stated that, not only do they face the risk of penalties under the physician self-referral law, but, because a violation of the physician self-referral law may be the predicate for liability under the False Claims Act, entities are susceptible to both government and whistleblower actions that can result in significant penalties through litigation or settlement. In the proposed rule, we proposed regulations intended to provide objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician. We also provided a brief history of the guidance to date on the volume or value standard and the other business generated standard. We believe it is useful to repeat that history in this final rule.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a physician practice must meet to qualify as a "group practice" (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699 through 1700). In the discussion of group practices, we stated that we believe that the volume or value standard precludes a group practice from paying physician members for each referral they personally make or based on the volume or value of the referred services (63 FR 1690). We went on to state that the most straightforward way for a physician practice to demonstrate that it is meeting the requirements for group practices would be for the practice to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients (63 FR 1690). However, because our definition of "referral" at §411.351 includes only referrals for designated health services, we also noted that a physician practice could compensate its members on the basis of non-Medicare and non-Medicaid referrals, but would be required to separately account for revenues and distributions related to referrals for designated health services for Medicare and Medicaid patients (63 FR 1690). (See section II.C. of this final rule for a

discussion of the historical inclusion of Medicaid referrals in our regulations and our revisions to the group practice rules.) Outside of the group practice context, these principles apply generally to compensation from an entity to a physician. We also addressed the other business generated standard in the 1998 proposed rule, stating that we believe that the Congress may not have wished to except arrangements that include additional compensation for other business dealings and that, if a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value standard and the other business generated standard, responding to comments on the proposals included in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to permit time-based or unit of service-based compensation formulas (66 FR 876). We also stated that the phrase "does not take into account other business generated between the parties" means that the fixed, fair market value payment cannot take into account, or vary with, referrals of designated health services payable by Medicare or Medicaid or any other business generated by the referring physician, including other Federal and private pay business (66 FR 877), noting that the phrase "generated between the parties" means business generated by the referring physician for purposes of the physician self-referral law (66 FR 876). We stated that section 1877 of the Act establishes a straightforward test that compensation should be at fair market value for the work or service performed or the equipment or [office] space leased—not inflated to compensate for the physician's ability to generate other revenue (66 FR 877). Finally, in response to a comment about whether the compensation paid to a physician for the purchase of his or her practice could include the value of the physician's referrals of designated health services to the practice, we stated that compensation may include the value of designated health services made by the physician to his or her practice if the designated health services referred by the selling physician satisfied the requirements of an applicable exception, such as the in-office ancillary services

exception, and the purchase arrangement is not contingent on future referrals (66 FR 877). This policy would apply also to the value of the physician's referrals of designated health services to his or her practice if the compensation arrangement between the physician and the practice satisfied the requirements of an applicable exception.

Also in Phase I, we established special rules on compensation at §411.354(d)(2) and (3) that deem unit-based compensation not to take into account the volume or value of referrals or other business generated between the parties if certain conditions are met (66 FR 876 through 877). These rules state that unit-based compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. Unit-based compensation will be deemed not to take into account the volume or value of other business generated between the parties to a compensation arrangement if the compensation is fair market value for items or services actually provided and does not vary during the term of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business. We note that the special rules use the phrase "takes into account referrals" (or other business generated) rather than "takes into account *the volume or value of* referrals" (or other business generated). Both special rules apply to time-based or per-unit of service-based ("per-click") compensation formulas. However, as we later noted in Phase II, the special rules on unit-based compensation are intended to be safe harbors, and there may be some situations not described in §411.354(d)(2) or (3) where an arrangement does not take into account the volume or value of referrals or other business generated between the parties (69 FR 16070).

In Phase II, we clarified that personally performed services are not considered other business generated by the referring physician (69 FR 16068). We also stated that fixed compensation (that is, one lump-sum payment or several individual payments aggregated

together) can take into account or otherwise reflect the volume or value of referrals (for example, if the payment exceeds the fair market value for the items or services provided) (69 FR 16059). We noted that a determination whether the compensation does, in fact, take into account or otherwise reflect the volume or value of referrals will require a case-by-case examination based on the facts and circumstances. (We note that the language "otherwise reflects" was determined to be superfluous and removed from our regulation text in Phase III (72 FR 51027).)

Until now, we had not codified regulations defining the volume or value standard or the other business generated standard, although the special rule at §411.354(d)(4) sets forth the circumstances under which a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier without running afoul of the volume or value standard. For the reasons explained in more detail below and in our responses to comments, in this final rule, we are finalizing special rules at §411.354(d)(5) and (6) that supersede our previous guidance, including guidance with which they may be (or appear to be) inconsistent. Our final policies relate to the volume or value and other business generated standards as they apply to the definition of remuneration at section 1877(h)(1)(C) of the Act and §411.351 of our regulations, the exception for academic medical centers at §411.355(e)(1)(ii), and various exceptions for compensation arrangements in section 1877(e) of the Act and §411.357 of our regulations, including the new exception established in this final rule for limited remuneration to a physician at §411.357(z). In addition, the regulation at final §411.354(d)(5)(i) applies for purposes of section 1877(h)(4) of the Act and the group practice regulations at §411.352(g) and (i). The final policies do not apply for purposes of applying the exceptions at §411.357(m), (s), (u), (v), and (w), or for purposes of applying the new exception finalized in this final rule at §411.357(bb) for cybersecurity items and services. We are including regulation text at §411.354(d)(5)(iv) and (6)(iv) regarding the application of the volume or value standard and the other business generated standard for purposes of applying these exceptions. Given the

revisions to our regulations at §411.354(c)(2) and (d)(1), which eliminate language regarding compensation that is determined in any manner that takes into account the volume or value of referrals or other business generated by a physician, the final special rules at §411.354(d)(5) and (6) do not apply for purposes of determining the existence of an indirect compensation arrangement under §411.354(c)(2) or applying the special rule on compensation that is deemed to be set in advance at §411.354(d)(1). For the reasons discussed below in response to comments, the final special rules at §411.354(d)(5) and (6) do not apply for purposes of applying the special rules for unit-based compensation at §411.354(d)(2) and (3). We are including regulation text at §411.354(d)(5)(iv) and (6)(iv) regarding the application of the volume or value standard and the other business generated standard for purposes of applying the special rules for unit-based compensation.

As we stated in the proposed rule, we believe there is great value in having an objective test for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties (84 FR 55793). Our final rules establish such a test. We are finalizing an approach that, rather than deeming compensation under certain circumstances not to have been determined in a manner that takes into account the volume or value of referrals or takes into account other business generated between the parties, defines exactly when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties. Under our final regulations, which we believe create the bright-line rule sought by commenters and other stakeholders, outside of the circumstances at §411.354(d)(5) and (6), compensation will not be considered to take into account the volume or value of referrals or take into account other business generated between the parties, respectively. In other words, only when the mathematical formula used to calculate the amount of the compensation includes referrals or other business generated as a variable, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation

of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated. We believe that our final regulations are consistent with the position we articulated in Phase I where we stated that, in general, we believe that a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's referrals of designated health services (66 FR 908).

In the proposed rule, we explained that, even with nonsubstantive changes to standardize (where possible) the language used to describe the volume or value standard and the other business generated standard in our regulations, due to the varying language used throughout the statutory and regulatory schemes, we find it impossible to establish a single definition for the volume or value and other business generated standards (84 FR 55793). Therefore, instead of a definition at §411.351, we proposed special rules for compensation arrangements that would apply regardless of the exact language used to describe the standards in the statute and our regulations. We also explained that, because section 1877 of the Act defines a compensation arrangement as any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity, we believe that it is necessary that the tests address circumstances where the compensation is from the entity to the physician, as well as where the compensation is from the physician to the entity. Therefore, we proposed two separate special rules for the volume or value standard and two separate special rules for the other business generated standard.

Under our proposals, compensation from an entity to a physician (or immediate family member of the physician) would take into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with

the number or value of the physician's referrals to the entity. For example, if the physician (or immediate family member) *receives additional compensation* as the number or value of the physician's referrals to the entity increase, the physician's (or immediate family member's) compensation would positively correlate with the number or value of the physician's referrals. In the proposed rule, we stated that, unless the special rule at §411.354(d)(2) for unit-based compensation applies and its conditions are met, the physician's (or immediate family member's) compensation would take into account the volume or value of referrals (84 FR 55793). For the reasons explained in our response to comments below, we are retracting this statement. Under the policies set forth in this final rule, as described in our response to comments below, the special rules at §411.354(d)(2) and (3) are not applicable to compensation that takes into account the volume or value of referrals under final §411.354(d)(5)(i) or (6)(i) or to compensation that takes into account other business generated by a physician under final §411.354(d)(5)(ii) or (6)(ii). We have revised the regulation text at §411.354(d)(2) and (3) accordingly. If compensation takes into account the volume or value of referrals or the volume or value of other business generated under final §411.354(d)(5) or (6), that determination is final. The special rules at §411.354(d)(2) and (3) may not be applied to then deem the compensation not to take into account the volume or value of referrals or other business generated.

To illustrate our proposed policy, in the proposed rule, we provided an example under which a physician organization does not qualify as a group practice under §411.352 of the physician self-referral regulations. Under the example, the physician organization pays its physicians a percentage of collections attributed to the physician, including personally performed services and services furnished by the physician organization (the physician's "pool"). If a physician's pool includes amounts collected for designated health services furnished by the physician organization that he ordered but did not personally perform, the physician's compensation takes into account the volume or value of his referrals to the physician organization. Assuming the physician is paid 50 percent of the amount in his pool, the

mathematical formula that illustrates the physician's compensation would be: compensation = (.50 x collections from personally performed services) + (.50 x collections from referred designated health services) + (.50 x collections from non-designated health services referrals). The policy proposed with respect to when compensation from an entity to a physician (or immediate family member of the physician) takes into account other business generated would operate in the same manner (84 FR 55793).

Analogously, we proposed that compensation from a physician (or immediate family member of the physician) to an entity takes into account the volume or value of referrals only if the formula used to calculate the compensation paid by the physician includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that negatively correlates with the number or value of the physician's referrals to the entity. For example, if a physician (or immediate family member) *pays less compensation* as the number or value of the physician's referrals to the entity increases, the compensation from the physician to the entity would negatively correlate with the number or value of the physician's referrals. In the proposed rule, we stated that, unless the special rule at §411.354(d)(2) for unit-based compensation applies and its requirements are met (which seems unlikely), the compensation would take into account the volume or value of referrals (84 FR 55793). We are retracting this statement. Under the policies set forth in this final rule, as described above and in our response to comments below, the special rules at §411.354(d)(2) and (3) are not applicable to compensation that takes into account the volume or value of referrals under final §411.354(d)(5)(i) or (6)(i) or to compensation that takes into account the volume or value of other business generated by the physician under final §411.354(d)(5)(ii) or (6)(ii). If compensation takes into account the volume or value of referrals or the volume or value of other business generated under final §411.354(d)(5) or (6), that determination is final. The special rules at §411.354(d)(2) and (3) may not be applied to then deem the compensation not to take into account the volume or value of referrals or other business generated.

To illustrate our proposed policy, in the proposed rule, we provided an example under which a physician leases medical office space from a hospital. Our example assumed that the rental charges are $5,000 per month and the arrangement provides that the monthly rental charges will be reduced by $5 for each diagnostic test ordered by the physician and furnished in one of the hospital's outpatient departments. Under our proposal, the compensation (that is, the rental charges) would take into account the volume or value of the physician's referrals to the hospital. The mathematical formula that illustrates the rental charges paid by the physician to the hospital would be: compensation = $5,000 – ($5 x the number of designated health services referrals). The proposed policy with respect to when compensation from a physician (or immediate family member of the physician) to an entity takes into account other business generated would operate in the same manner (84 FR 55793 through 55794).

We are finalizing our proposals with modifications to the structure of the regulations. The final regulations are designated at §411.354(d)(5)(i), (ii), and (iii) (with respect to compensation from an entity to a physician (or immediate family member of a physician)) and §411.354(d)(6)(i), (ii), and (iii) (with respect to compensation from a physician (or immediate family member of a physician) to an entity). As set forth at final §411.354(d)(5)(iv) and (6)(iv), these special rules do not apply for purposes of applying the exceptions at §411.357(m), (s), (u), (v), and (w), or for purposes of applying the new exception established in this final rule at §411.357(bb) for cybersecurity items and services. Although our final regulations are "special rules" on compensation, we interpret them in the same manner as definitions. That is, the special rules are intended to define the universe of circumstances under which compensation is considered to take into account the volume or value of referrals or other business generated by the physician. If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation is not considered to take into account the volume or value of the physician's referrals or other business generated by the physician, as appropriate, for purposes of the

physician self-referral law.

We also proposed additional policies at proposed §411.354(d)(5)(i)(B) and (ii)(B), and at proposed §411.354(d)(6)(i)(B) and (ii)(B), outlining narrowly-defined circumstances under which fixed-rate compensation (for example, a fixed annual salary or an unvarying per-unit rate of compensation) would be considered to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation. For the reasons described in response to comments below and in section II.B.4. of this final rule, we are not finalizing the proposed regulations. However, to address the concerns prompting the policy described in the proposed rule with respect to referrals of designated health services, we are revising §411.354(d)(4), which sets forth requirements that must be met if a physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; that is, if, under the *bona fide* employment relationship, personal service arrangement, or managed care contract the physician's referrals are directed to a particular provider, practitioner, or supplier. The final policy is designated at §411.354(d)(4)(vi) and states that, regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician, neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier. See section II.B.4. of this final rule for further discussion of §411.354(d)(4)(vi).

In the proposed rule, we stated that we believe that the modifier "directly or indirectly" is implicit in the requirements that compensation is not determined in <u>any</u> manner that takes into account the volume or value of referrals or the volume or value of other business generated (84 FR 55794). We are finalizing our proposal to remove the modifier from the regulations where it appears in connection with the standards and the related requirements. We also highlighted that, where the statute or regulations specifically allow parties to determine compensation in a manner that only indirectly takes into account the volume or value of referrals (for example, in the

exception for EHR items and services at §411.357(w)(6) and the rules for a group practice's distribution of profit shares and payment of productivity bonuses at section 1877(h)(4)(B) of the Act and §411.352(i)), our regulations include guidance regarding direct versus indirect manners of determining compensation. We solicited comment on the need for additional guidance or regulation text that includes deeming provisions related to the volume or value standard in these exceptions. Based on the comments we received, we are not revising our regulations to provide further guidance on the deeming provisions (except as provided in section II.D.11. of this final rule with respect to the deeming provision in the exception at §411.357(w) for EHR items and services).

Finally, in the proposed rule, we discussed related guidance in our Phase II regulation (69 FR 16088 through 16089). In Phase II, a commenter presented a scenario under which a hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic; the physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site-of-service reduction); and the hospital also bills for the hospital outpatient services, which may include some procedures furnished as "incident to" services in a hospital setting. The Phase II commenter's concern was that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a referral of designated health services (that is, the facility fee). In response, we stated that the fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement). We acknowledged stakeholder concerns that, following the July 2, 2015 opinion of the United States Court of Appeals for the Fourth Circuit in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* (792 F.3d 364) (*Tuomey*), CMS may no longer endorse this policy. We stated that we believe that the objective tests for determining whether compensation

takes into account the volume or value of referrals or the volume or value of other business generated may address these concerns; however, for clarity, we reaffirmed the position we took in the Phase II regulation. We stated that, with respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We also clarified that our guidance extends to compensation arrangements that do not rely on the exception for *bona fide* employment relationships at §411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule at §411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula—even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions in the special rule at §411.354(d)(2) (*see* 69 FR 16067). This is true whether the compensation arrangement is analyzed under an exception applicable to compensation arrangements directly between an entity and a physician or is an indirect compensation arrangement analyzed under the exception at §411.357(p). Our position has not changed since the publication of Phase II, and we reaffirm here our statements in the proposed rule. An association between personally performed physician services and designated health services furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to the entity or the volume or value of other business generated by the physician for the entity. Although commenters requested that we codify these policies in regulation text, we decline to do so, as we do not believe that it is necessary given the policies set forth in the final regulations at §411.354(d)(5) and (6). However, as described below in our

response to comments, we are revising the regulations at §411.354(c)(2) regarding the existence (that is, definition) of an indirect compensation arrangement. We believe the revisions to §411.354(c)(2) may alleviate the commenters' concerns.

We received the following comments and our responses follow.

Comment: Most commenters supported the proposed special rules on the volume or value standard and the other business generated standard. Some commenters requested modification of the standards, as described in other comments below. The commenters in support of our proposed special rules generally appreciated the clarification of terms that they asserted have been a source of confusion among providers, physicians, *qui tam* relators, and courts. The commenters stated that the objective tests established in the proposed special rules are easily understood, which, in turn, will greatly ease the burden on providers and suppliers attempting to ensure compliance with the volume or value and other business generated standards, as well as make a clear path for law enforcement and the regulated industry. Commenters urged CMS to finalize objective standards for this critical terminology. In contrast, one commenter asserted that the proposed special rules do not adequately explain what is meant by "includes the physician's referrals to the entity as a variable" and would create significantly more confusion than the current standard. This commenter asserted that this lack of clarity could allow for abusive compensation arrangements and hamper enforcement efforts.

Response: We are finalizing most of our proposals to establish objective tests for whether compensation takes into account the volume or value of a physician's referrals to an entity or the volume or value of other business generated by a physician for an entity. We agree with the commenters that our final policies will establish a clear path for parties to design compensation arrangements that comply with the volume or value standard and other business generated standard found in many of the exceptions to the physician self-referral law. In turn, the objective standards should assist in law enforcement efforts by making it clear whether compensation paid to or from a physician takes into account the volume or value of a physician's

referrals to an entity or the volume or value of other business generated by a physician for an entity. As discussed more fully in our response to other comments, we are also clarifying in regulation text that, if compensation takes into account the volume or value of a physician's referrals to an entity or the volume or value of other business generated by a physician for an entity under final §411.354(d)(5) or (6), no special rule, including those at §411.354(d)(2) and (3), may be applied to reverse that determination.

We disagree with the commenter that asserted that the proposed special rules would create significantly more confusion related to the volume or value standard and the other business generated standard, and note that nearly all other commenters that addressed these specific proposals asserted that the proposed special rules would provide clarity for parties seeking to ensure that compensation is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician. With respect to the meaning of "includes the physician's referrals to the entity as a variable" as included in the regulation text at final §411.354(d)(5)(i) and (6)(i), we refer readers to the examples provided in the proposed rule and restated above that illustrate the mathematical formulas for determining compensation that takes into account the volume or value of a physician's referrals. The term "variable" has the meaning it does with respect to general mathematical principles—a symbol for a number we do not yet know. Thus, if an entity pays a physician one-fifth of a bonus pool that includes all collections from a set of services furnished by an entity, including those from designated health services referred by a physician to the entity, the formula used to calculate the physician's compensation is: (.20 x the value of the physician's referrals of designated health services) + (.20 x the value of the other business generated by the physician for the entity) + (.20 x the value of services furnished by the entity that were not referred or generated by the physician). The value of the physician's referrals to the entity is a variable in this formula, as is the value of the other business generated by the physician.

Comment: A small number of commenters did not support our proposals for special rules

that identify the universe of compensation formulas that take into account the volume or value of a physician's referrals or the other business generated by the physician for an entity. One of the commenters asserted that the standards were too narrow to protect the Medicare program from abuse, noting that, under our proposals, a hospital could make payment to a physician in anticipation of future referrals without a mathematical formula explicitly delineating it. Other commenters opposed CMS finalizing any of its proposals, while not specifically opposing the proposed special rules for the volume or value and other business generated standards.

Response: Although we agree with the commenters regarding the importance of program integrity, we believe that the certainty afforded by the objective standards we are finalizing is critical to reduce the burden associated with compliance with the physician self-referral law's volume or value and other business generated standards. We believe that the policies finalized at §411.354(d)(5) and (6), coupled with the new condition at §411.354(d)(4)(vi) prohibiting an entity from making the existence of a compensation arrangement or the amount of the compensation contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier (as well as the other requirements of our exceptions) mitigates the potential for program or patient abuse asserted by the commenters. We remind parties that arrangements that involve remuneration from an entity to a physician (or vice versa) implicate the anti-kickback statute. An arrangement under which a hospital makes a payment to a physician in anticipation of future referrals would be suspect under the anti-kickback statute. Moreover, our revised definition of "referral" at §411.351 clarifies that referrals are not items or services to be protected under the exceptions to the physician self-referral law, regardless of whether or not it is possible to ascribe a fair market value to them.

Comment: A large number of commenters requested that CMS specifically address personal productivity compensation by finalizing in regulation text the interpretations we described in the proposed rule (84 FR 55795). Some commenters requested that CMS confirm that personal productivity compensation is permissible in all settings. Others requested that we

revise the exceptions for personal service arrangements, fair market value compensation, and indirect compensation arrangements to expressly permit compensation formulas based on a physician's personal productivity. All of the commenters noted that productivity pay for personally performed services is among the most prevalent compensation methodologies used by hospitals and other entities to compensate surgeons and other proceduralists, as well as physicians who do not attend to patients in a hospital setting. Commenters stated that, despite our affirmative statements in the proposed rule that, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula even when the entity bills for designated health services that correspond to such personally performed services, and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions of the special rule at §411.354(d)(2) (84 FR 55795), they remain concerned that an entity may still have to defend its compensation practices in the event of a False Claims Act allegation because satisfaction of all the requirements of an applicable exception to the physician self-referral law is an affirmative defense.

Response: We decline to revise the text of the regulations as requested by the commenters. We reaffirm our statements in the proposed rule, including those with respect to productivity-based compensation under a *bona fide* employment relationship. We also confirm that our policy applies to indirect compensation arrangements. To be clear, under a *bona fide* employment relationship, personal service arrangement, or indirect compensation arrangement, a physician may be compensated for his or her personally performed services using a unit-based compensation formula—even when the entity with which the physician has a direct or indirect compensation arrangement bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the unit-based compensation meets the conditions of the special rule at §411.354(d)(2). Similarly, under a personal service arrangement or indirect compensation

arrangement, a physician may be compensated for his or her personally performed services using a unit-based compensation formula—even when the entity with which the physician has a direct or indirect compensation arrangement bills for other business that correspond to such personally performed services—and the compensation will not take into account other business generated by the physician if the unit-based compensation meets the conditions of the special rule at §411.354(d)(3).

We note that the policies described in the proposed rule (84 FR 55795) and in this response regarding the application of the special rules for unit-based compensation have been superseded by the policies finalized in this final rule. However, these policies would be applied when analyzing compensation arrangements for compliance with the physician self-referral law during periods prior to the effective date of this final rule. They have never applied and will continue not to apply for purposes of analyzing ownership or investment interests for compliance with the physician self-referral law, as none of our exceptions in §411.356 include a requirement identical or analogous to the volume or value standard or other business generated standard. To reiterate, neither the special rules at §411.354(d)(2) and (3) nor any guidance regarding our interpretation of the volume or value standard or other business generated standard are relevant for purposes of applying the exceptions at §411.356(c)(1) and (3), both of which incorporate the requirements of §411.362, including the requirement at §411.362(b)(3)(ii)(B) that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

Comment: A significant number of commenters requested that we clarify that the positions CMS took in prior litigation, including *Tuomey*, and the discussion in the proposed rule regarding productivity-based compensation were based on its then-current policy, not on the policies finalized here. Commenters asserted that this is necessary to avoid confusing the special rules on the volume or value standard and other business generated standard that we are

finalizing in this final rule—under which productivity compensation would not trigger the volume or value standard of the exceptions for *bona fide* employment relationships, personal service arrangements, or fair market value compensation—with *Tuomey's* "correlation theory." The commenters also asserted that, under the policies finalized here, there would no longer be a need for the productivity bonus "safe harbor" at §411.357(c)(4).

Response: Productivity compensation based solely on a physician's personally performed services does not take into account the volume or value of the physician's referrals or other business generated by a physician under the policies finalized in this final rule. Such compensation would satisfy the volume or value standard and the other business generated standard, where it appears, in the exceptions for *bona fide* employment relationships, personal service arrangements, and fair market value compensation, all of which apply to direct compensation arrangements between entities and physicians. Although the productivity bonus "safe harbor" at §411.357(c)(4) would not be necessary to protect productivity compensation based solely on a physician's personally performed services under this final rule, the provision is included in section 1877(e)(2) of the Act and, therefore, we are not removing it from our regulations. *Prior to this final rule*, productivity compensation based solely on a physician's personally performed services would not take into account the volume or value of a physician's referrals if the conditions of the special rule at §411.354(d)(2) were met. Thus, even prior to this final rule, the productivity bonus "safe harbor" at §411.357(c)(4) would not have been necessary to ensure that a physician's referrals to his or her employer did not violate the physician self-referral law due to the fact that the physician received productivity compensation from the employer based solely on the physician's personally performed services. As we stated in the proposed rule and repeated above, the special rules at §411.354(d)(5) and (6), as finalized, supersede our previous guidance, including guidance with which they may be (or appear to be) inconsistent (84 FR 55792). The policies finalized here are prospective only and represent CMS policy regarding the volume or value standard and the other business generated standard going

forward from the effective date of this final rule.

Comment: Two commenters asked us to confirm whether a "tiered" compensation model would take into account the volume or value of a physician's referrals. The commenters both presented the following example: for the first 50 procedures that a physician performs at a hospital, the physician is paid $X per procedure. For the next 25 procedures that the physician performs at the hospital, the physician is paid $X + $20. The commenters did not specify whether the physician made the referrals for the corresponding designated health services furnished by the hospital.

Response: The commenters did not provide sufficient facts to enable us to respond to their request. Parties may use the process set forth in our regulations at §§411.370 through 411.389 to request an advisory opinion on whether a specific referral or referrals relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act.

Comment: One commenter expressed support for the approach of identifying the universe of circumstances in which compensation will be considered to take into account the volume or value of referrals or other business generated, rather than the current approach that identifies limited circumstances in which compensation is deemed to not take into account the volume or value of a physician's referrals or other business generated by the physician for an entity. The commenter asserted that the regulatory certainty provided under our approach will allow hospitals to encourage physicians to improve quality, reduce cost, and provide leadership by permitting quality and outcomes-based bonuses payable to physicians, bonuses to physician leaders based on system success, and unit-based compensation based on personally performed services that sometimes, but not always, result in referrals of designated health services. Another commenter asked whether incentive compensation paid only in the event of the hospital's achievement of overall financial performance goals would take into account the volume or value of a particular physician's compensation. The commenter gave the example of a physician

receiving a 15 percent bonus if the system has a 2 percent margin, and a 20 percent bonus if the system has a 4 percent margin.

Response: We agree that identifying for stakeholders the universe of circumstances in which we believe compensation is determined in a manner that takes into account the volume or value of a physician's referrals or other business generated by the physician is preferable to our former policy, which articulated a general rule that compensation may not be determined in any manner that takes into account the volume or value of referrals (or other business generated by a physician) and provided a single "safe harbor" for assurance that the specific compensation does not violate the general rule. We caution that outcomes-based bonuses, as described by the commenter, could fall within the circumstances of the special rules at final §411.354(d)(5) and (6), depending on how they are structured and whether referrals to the entity or other business generated by the physician for the entity are variables anywhere in the mathematical formula for determining the compensation. Although bonus compensation based on "system success" may not include referrals to or other business generated for the entity as a variable in many instances, the determination of whether the formula to determine the compensation includes such variables must be made on a case-by-case basis. As we explain above and in our response to other comments, unit-based compensation based solely on personally performed services would not include the physician's referrals to or the other business generated by the physician for the entity as a variable and, regardless of whether an entity furnishes designated health services in conjunction with the physician's personally performed services, would not take into account the volume or value of the physician's referrals or other business generated by the physician.

Comment: Many commenters noted that our proposed interpretations of the volume or value and other business generated standards do not readily translate in the context of nonmonetary compensation such as the donation of EHR items and services or medical staff incidental benefits. These commenters requested that we not apply the special rules at §411.354(d)(5) and (6) to the exceptions where the remuneration to or from a physician

generally is not calculated as a mathematical formula.

Response: We agree with the commenters in part. The final special rules at §411.354(d)(5) and (6) do not apply for purposes of applying the exceptions for medical staff incidental benefits at §411.357(m), professional courtesy at §411.357(s), community-wide health information systems at §411.357(u), electronic prescribing items and services at §411.357(v), electronic health records items and services at §411.357(w), and cybersecurity technology and related services at new §411.357(bb). These exceptions have "volume or value" requirements that are somewhat unique and the special rules are not a perfect fit. We have included language at final §411.354(d)(5)(iv) and (6)(iv) to indicate the inapplicability of the special rules for purposes of applying these particular exceptions to the physician self-referral law. However, the requirement in the exception for nonmonetary compensation at §411.357(k)(1)(i), which requires that the nonmonetary compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician, is similar to those in the exceptions where cash remuneration may be provided and the special rules at final §411.354(d)(5) and (6) can be easily applied.

Comment: A few commenters requested that CMS confirm that the proposed special rules at §411.354(d)(5) and (6) would apply to the determination of whether an indirect compensation arrangement exists. Another commenter requested confirmation that the special rules set forth at final §411.354(d)(5) and (6) would apply to the determination of whether a physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals (§411.352(g)) and the requirements under the special rules for profit shares and productivity bonuses at §411.352(i).

Response: Except as specified in §411.354(d)(5)(iv) and (6)(iv), the proposed special rules interpreting the volume or value standard at §411.354(d)(5)(i) and (6)(i) apply in all instances where our regulations require an analysis of whether compensation is determined in any manner that takes into account the volume or value of a physician's referrals. Likewise,

except as specified in §411.354(d)(5)(iv) and (6)(iv), the proposed special rules interpreting the other business generated standard at §411.354(d)(5)(ii) and (6)(ii) apply in all instances where our regulations require an analysis of whether compensation is determined in any manner that takes into account the volume or value of other business generated by a physician. Given the revisions to the regulations at §411.354(c)(2) finalized in this final rule, and because the special rules at final §411.354(d)(5) and (6) have only prospective application, the special rules at §411.354(d)(5) and (6) do not apply to the determination of whether an indirect compensation arrangement exists under §411.354(c)(2). For the reasons explained in the response to a comment below, the special rules at final §411.354(d)(5) and (6) do not apply for purposes of applying the special rules on unit-based compensation at §411.354(d)(2) and (3). As described in section II.C.1. of this final rule, the terms "based on" and "related to" exist in the regulation text at §411.352(g) and (i). We interpret these terms to equate to "takes into account" when referring to the volume or value of referrals. Thus, the special rule at final §411.354(d)(5)(i) applies for purposes of interpreting and applying the group practice regulations at §411.352(g) and (i), which apply only to compensation from the group practice to the physician and the physician's referrals (but do not apply to the other business generated by the physician for the group practice).

Comment: Citing concerns related to recent False Claims Act litigation, many commenters asked CMS to refrain from using the term "correlation" in the final regulations. Commenters suggested that we use the term "causal relationship" in lieu of "correlation" in the special rules. The commenters were concerned that the term "correlation" could create an inference that compensation could violate the volume or value or other business generated standards without a causal relationship between referrals or other business generated and the compensation to or from the physician.

Response: We have provided definitions for "positive correlation" and "negative correlation" to indicate specifically what mathematical formulas will be problematic under the

final rules. We believe that our regulations, as finalized, are clear and express the agency's interpretation of the volume or value standard and the other business generated standard.

Comment: A few commenters requested that CMS require that the physician's referrals are a written or otherwise expressly articulated variable in the formula for calculating the compensation paid to a physician. The commenters asserted that, under the proposed special rule, it is not clear how the formula would be assessed, and recommended language would signify that, for purposes of applying §411.357(d)(5), the test is not one of subjective intent. The commenters made the same request, for the same reasons, with respect to the other business generated standard. Another commenter suggested that we require that the compensation formula has a "direct and explicit" variable that results in an increase or decrease in the physician's compensation that "directly, explicitly and" positively (or negatively) correlates with the number of value of the physician's referrals to (or other business generated for) the entity in order to take into account the volume or value of referrals (or other business generated).

Response: We decline to adopt the commenter's suggestions. We believe that the special rules finalized at §411.354(d)(5) and (6) sufficiently articulate objective tests for assessing whether compensation takes into account the volume or value of a physician's referrals or the other business generated by a physician for an entity. We disagree that the final special rules lack clarity or imply that the volume or value standard and other business generated standard are subjective tests. Compensation paid *to a physician* takes into account the volume or value of referrals if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity, regardless of whether the formula is written in a particular place or manner. The same applies to compensation that takes into account other business generated by the physician for the entity making the payment to the physician.

Comment: A large number of commenters requested that we not finalize our proposal to consider fixed-rate compensation for which there is a predetermined, direct correlation to the physician's prior referrals to the entity or the other business previously generated by the physician for the entity to take into account the volume or value of referrals or other business generated by the physician. Noting that fixed rate compensation (for example, $200,000 per year) qualifies as unit-based compensation, some commenters asserted that, even if we were to finalize this proposal, once the special rules for unit-based compensation at §411.354(d)(2) and (3) are applied, fixed-rate compensation that fails the proposed test(s) would nonetheless be deemed not to take into account the volume or value of referrals or other business generated under the existing regulations at §411.354(d)(2) and (3). Other commenters stated that the proposal regarding fixed-rate compensation would not establish the objective rule we sought and would continue the uncertainty that the industry currently faces.

Response: We agree with the commenters that the special rules for unit-based compensation at §411.354(d)(2) and (3) essentially nullify the proposed special rule regarding fixed-rate compensation that takes into account the volume or value of a physician's referrals or other business generated by the physician for an entity. We are not finalizing our proposals for additional special rules outlining the circumstances under which we would consider fixed-rate compensation to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation.

In the proposed rule, we stated that merely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the entity; however, we also stated that we are concerned with an "if X, then Y" correlation between compensation in the current term and prior referrals or previous other business generated by a physician (84 FR 55794). Our proposed policy focused on fixed-rate compensation under a current arrangement where there is a predetermined, direct correlation between the volume or

value of a physician's prior referrals or the other business previously generated for the entity and the rate of compensation paid to or by the physician (or immediate family member of the physician). We provided examples of objectionable tiered compensation structures that condition a physician's compensation on the volume or value of his or her referrals to an entity. The conditioning of the existence of a compensation arrangement would also fall within such a structure; for example, "if the value of the physician's referrals does not equal $1,000,000 in the prior period, the physician's employment arrangement will be terminated and his compensation from the entity will equal $0." We believe that there is a risk of program or patient abuse when a physician will receive no future compensation if he or she fails to refer as required. The same is true if the amount of the physician's compensation conditioned on the volume or value of a physician's referrals to an entity (or another provider, practitioner, or supplier). Therefore, in lieu of the proposed policies treating "if X, then Y" compensation methodologies as potential concerns under the volume or value standard and other business generated standard, we are revising the special rule at §411.354(d)(4) to address our concerns when a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier (including the entity providing the compensation to the physician)—in other words, when the physician's referrals are directed to a particular provider, practitioner, or supplier. Under the policy at final §411.354(d)(4)(vi), regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier. We discuss this revision in more detail in section II.B.4. of this final rule.

Comment: A few commenters requested clarification of the examples in the proposed rule regarding fixed-rate tiered compensation set using a predetermined, "if X, then Y"

methodology. One commenter suggested that our statement in the proposed rule that the tiered compensation methodology in the example provided (84 FR 55794) is at odds with our confirmation that a productivity bonus will not take into account the volume or value of referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service.

Response: The example of tiered compensation referenced by the commenter related to our proposal regarding fixed-rate compensation. We are not finalizing our proposal to consider fixed-rate compensation to take into account the volume or value of referrals or other business generated by a physician. Therefore, it is unnecessary to further address the examples as requested by the commenters *in the context of the volume or value standard*. We note that the regulation at final §411.354(d)(4)(vi) regarding making the existence of a compensation arrangement or the amount of a physician's compensation contingent on the volume or value of a physician's referrals to a particular provider, practitioner, or supplier may apply to the commenter's examples. See section II.B.4. of this final rule for a further discussion of final §411.354(d)(4)(vi).

Comment: A few commenters asserted that the existing special rules at §411.354(d)(2) and (3) regarding per-unit compensation create confusion when considered in light of the new special rules interpreting the volume or value standard and other business generated standard. Some of the commenters suggested that CMS should remove the regulations at §411.354(d)(2) and (3), because they would no longer be necessary if we finalize our proposals at §411.354(d)(5) and (6). The commenters suggested revisions to §411.354(d)(2) and (3) in the event CMS does not finalize the proposals for special rules at interpreting the volume or value standard and other business generated standard §411.354(d)(5) and (6). One commenter described a hypothetical arrangement under which a hospital contracts with a surgeon for professional services, the surgeon performs surgeries at the hospital, and the hospital pays the surgeon a fixed amount per personally-performed relative value unit (RVU) that is consistent

with the fair market value of the physician's services. Assuming that the compensation would be viewed as not taking into account the volume or value of the physician's referrals to the hospital or other business generated by the physician for the hospital, the commenter asked whether this is the case based on the application of the special rules at final §411.354(d)(5) and (6) or whether it is because the unit-based compensation satisfies the requirements of the special rules for per-unit compensation at §411.354(d)(2) and (3). The commenter then questioned whether the special rules for unit-based compensation at §411.354(d)(2) and (3) would continue to be necessary if we finalize our proposals.

Response: We agree with the commenters that, under the policies finalized here, there is effectively no longer a need for the "unit-based deeming provision" at §411.354(d)(2). The same is true for the deeming provision at §411.354(d)(3). Unit-based compensation that does not include a physician's referrals to the entity as a variable in the formula used to calculate the physician's (or immediate family member's) compensation would not take into account the volume or value of the physician's referrals and, therefore, there would be no need to apply the special rule at §411.354(d)(2). Similarly, unit-based compensation that does not include other business generated by a physician for the entity as a variable in the formula used to calculate the physician's (or immediate family member's) compensation would not take into account the volume or value of other business generated and, therefore, there would be no need to apply the special rule at §411.354(d)(3). If the formula used to calculate a physician's (or immediate family member's) compensation does include the physician's referrals to the entity or other business generated by the physician for the entity as a variable (for example, a payment of $50 to the immediate family member of a physician for each patient who receives items or services furnished by the DMEPOS supplier making the payment, including items or service referred by the physician), the compensation would take into account the volume or value of the physician's referrals or other business generated and, under the revisions to §411.354(d)(2) and (3) finalized here, the special rules for unit-based compensation would not apply.

On and after the effective date of this final rule, the special rules at §411.354(d)(2) and (3) will be either unnecessary or inapplicable to deem unit-based compensation not to take into account the volume or value of a physician's referrals or other business generated by a physician. However, it is important to preserve the regulations at §411.354(d)(2) and (3) to assist parties, CMS, and law enforcement in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance with the physician self-referral law. Therefore, we are not removing the regulations at §411.354(d)(2) and (3) from the physician self-referral regulations, although we are adding language to both §411.354(d)(2) and (3) to make clear that the regulations may not be applied to deem unit-based compensation *not* to take into account the volume or value of referrals or other business generated by a physician if the compensation formula used to calculate the physician's (or immediate family member's) compensation is determined to take into account the volume or value of referrals or other business generated under final §411.354(d)(5) or (6). Because the special rules at final §411.354(d)(5) and (6) have prospective application only, we are confirming in regulation text at §411.354(d)(5)(iv) and (6)(iv) that they do not apply for purposes of applying the special rules on unit-based compensation at §411.354(d)(2) and (3), which, as we explained, remain in our regulations only for historical purposes to assist parties, CMS, and law enforcement in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance with the physician self-referral law.

Comment: Several commenters expressed strong support for the proposal to remove the term "varies with" from the regulations at §411.354(c)(2)(ii) and (iii) identifying when an indirect compensation arrangement exists, stating that this would be consistent with CMS' expressed intent for the volume or value standard and other business generated standard to have the same meaning wherever they occur in our regulations. Using the same example from the immediately previous comment, one commenter asked whether, under the regulation at proposed §411.354(c)(2), the compensation arrangement would constitute an indirect compensation

arrangement if the compensation was paid to the physician by an affiliate of the hospital with which the hospital has a financial relationship, forming an unbroken chain of financial relationships between the hospital and the physician. Other commenters questioned whether *any* unbroken chain of financial relationships would create an indirect compensation arrangement if CMS finalizes its proposals to remove the term "varies with" from the regulations at §411.352(c)(2) and establish the special rules interpreting the volume or value standard and other business generated standard at §411.354(d)(5) and (6).

Response: As we stated in the proposed rule, we proposed nonsubstantive changes to standardize where possible the language used to describe the volume or value standard and the other business generated standard in our regulations (84 FR 55793). Our proposal to remove the term "varies with" from the regulation at §411.354(c)(2) originated with our attempt at standardizing this language. Upon consideration of the comments and after developing our responses, we are not finalizing our proposal to remove the term "varies with" from §411.354(c)(2). If finalized as proposed, the regulatory scheme outlining the conditions under which an indirect compensation arrangement exists would have eliminated most unbroken chains of financial relationships between entities that furnish designated health services and the physicians who refer to them from the scrutiny of the physician self-referral law without affording CMS the opportunity to confirm that the compensation paid to the physician does not pose a risk of the harm section 1877 of the Act is intended to avoid, namely, that the compensation could improperly influence the physician's medical decision making. We continue to believe in the importance of ensuring that compensation paid to a physician by someone (or some organization) that has a financial relationship with an entity does not improperly influence the physician's medical decision making, resulting in the overutilization of designated health services, patient steering, or other program or patient abuse. However, we believe that the regulatory scheme that casts a wide net to include the vast majority of unbroken chains of financial relationships between an entity and a physician and then weeds out most of

those unbroken chains through a showing of compliance with the requirements of the special rules at §411.354(d)(2) and (3) and the exception at §411.357(p) is unnecessarily burdensome. The identification of truly problematic physician compensation may be achieved at an earlier stage of analysis. Therefore, we are revising §411.354(c)(2) to more precisely identify compensation arrangements that may pose a risk of program or patient abuse.

As we stated in Phase I, the existence of a financial relationship between an entity and a physician (or the immediate family member of a physician) is the factual predicate triggering the application of section 1877 of the Act (66 FR 864). (For a similar discussion in Phase II, *see* 69 FR 16057.). Because section 1877 of the Act expressly contemplates that a financial relationship and, specifically, a compensation arrangement, may be directly or indirectly between an entity and a physician (or an immediate family member of a physician), in Phase I, we established a three-part test for determining when an indirect compensation arrangement exists (66 FR 865 through 866). Once all three parts of the test are met, there exists an indirect compensation arrangement that must satisfy the requirements of an applicable exception in order to avoid the referral and billing prohibitions of the physician self-referral law. Also in Phase I, we finalized the exception at §411.357(p) for indirect compensation arrangements that would apply to unbroken chains of financial relationships that result in indirect compensation arrangements. In Phase I, we explained that some of the statutory and regulatory exceptions operate to exclude certain categories of services from the reach of section 1877 of the Act when certain requirements are satisfied. In effect, services described in those exceptions are not designated health services for purposes of the physician self-referral law (66 FR 867). The service-based exceptions are found in §411.355 of our regulations. Thus, even if there is an indirect compensation arrangement between an entity and a physician, the service-based exceptions may apply to and protect referrals of the particular services described in the exception. However, referrals for designated health services that do not satisfy the requirements of an applicable service-based exception would be prohibited unless the indirect compensation arrangement

satisfies all the requirements of the exception for indirect compensation arrangements at §411.357(p) (66 FR 867) or, if the entity is a MCO or IPA, the exception at §411.357(n) for risk-sharing arrangements. (We refer readers to section II.A.2.b.(4). of this final rule for a discussion of the applicability of the exception at §411.357(n) to indirect compensation arrangements.) In Phase I, we also finalized special rules related to unit-based compensation at §411.354(d)(2) and (3) to be applied when analyzing compliance with the requirements of the exceptions in §411.357, including the exception for indirect compensation arrangements at §411.357(p) (66 FR 876 through 878).

Following the publication of Phase I, we received comments regarding the interplay of the definition of "indirect compensation arrangement," the exception at §411.357(p) for indirect compensation arrangements, and the special rules that deem unit-based compensation not to take into account the volume or value of referrals or other business generated at §411.354(d)(2) and (3), respectively, when certain conditions are met. The commenters questioned whether an indirect compensation arrangement exists at all if a referring physician receives time-based or unit-of-service based compensation that is fair market value and does not vary over the term of the arrangement—that is, compensation that, by definition, does not take into account the volume or value of referrals or other business generated under §411.354(d)(2) and (3). Commenters noted that, similarly, the exception for indirect compensation arrangements at §411.357(p), like §411.354(d)(2) and (3), does not look to aggregate compensation and incorporates a fair market value test. Given this, the commenters pointed out that the ultimate result would be the same whether time-based and unit-of-service based compensation arrangements are initially excluded from the definition of "indirect compensation arrangement" at §411.354(c)(2) or included in the definition and then excepted under §411.357(p) after applying the special rules at §411.354(d)(2) and (3). In response, we stated that, although we agree that the ultimate result may be the same—time, unit-of-service, or other "per click" based arrangements are generally permitted if they are at fair market value without reference to referrals—we believe that [the Phase I

regulatory] construct more closely corresponds to the statutory treatment of direct compensation arrangements (69 FR 16059). We elected to retain the regulatory structure finalized in Phase I, noting a two-fold intent. We stated that we intended to include in the definition of "indirect compensation arrangement" any compensation arrangements (including time-based or unit-of-service based compensation arrangements) where the aggregate compensation received by the referring physician varies with, or otherwise takes into account, the volume or value of referrals or other business generated between the parties, regardless of whether the individual unit of compensation qualifies under §411.354(d)(2) and (3) (69 FR 16059). We continued that we intended to exclude under the exception at §411.357(p) that subset of indirect compensation arrangements where the compensation is fair market value and does not reflect the volume or value of referrals or other business generated (and the other requirements of the exception are satisfied). We stated that per-unit compensation will meet this test if it complies with the conditions of §411.354(d)(2) and (3).

In developing our response to the commenters to the proposed rule, we revisited the regulatory construct for determining which unbroken chains of financial relationships between entities and physicians (or immediate family members of a physician) establish indirect compensation arrangements and how to determine if they pose a risk of program or patient abuse. One of the driving goals of this final rulemaking, which is a shared goal of the Patients over Paperwork initiative and the Regulatory Sprint, is to reduce unnecessary burden on providers and suppliers. As we discussed in section I.D. of this final rule, our final policies are intended to balance genuine program integrity concerns against the considerable burden of the physician self-referral law's referral and billing prohibitions. We see no need to continue to treat compensation arrangements that may qualify as "indirect compensation arrangements" in the exact same way that the statute treats direct compensation arrangements when that construct creates unnecessary burden on the regulated industry. We believe that it is possible to simplify the analysis of whether an unbroken chain of financial relationships between an entity and a

physician (or immediate family member of a physician) poses a risk of program or patient abuse without raising program integrity concerns, and we are finalizing revisions to the regulations at §411.354(c)(2) that we believe achieve the same result as the Phase I regulatory construct in protecting against program or patient abuse but reduce unnecessary burden on the regulated industry.

We are revising our regulations at §411.354(c)(2)(ii) to effectively incorporate and apply the conditions of the special rules on unit-based compensation at the definitional level when determining whether an indirect compensation arrangement exists that must satisfy the requirements of an applicable exception in order to avoid the prohibitions of the physician self-referral law. Unless all the elements of final §411.354(c)(2)(i), (ii) and (iii) exist, the unbroken chain of financial relationships between an entity furnishing designated health services and a physician (or immediate family member of a physician) will not be considered an indirect compensation arrangement. Nor will the unbroken chain of financial relationships be considered a direct compensation arrangement under §411.354(c)(1). Therefore, the referral and billing prohibitions of the physician self-referral law will not apply. Under the regulations finalized in this final rule, an unbroken chain of financial relationships between an entity and a physician will be considered an indirect compensation arrangement if the physician (or immediate family member of the physician) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing the designated health services, and any of the following are true: (1) the individual unit of compensation received by the physician (or immediate family member) is not fair market value for items or services actually provided; (2) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's)

compensation that positively correlates with the number or value of the physician's referrals to the entity; or (3) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity. In addition, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity.

We acknowledge that our final policies will reduce the number of unbroken chains of financial relationships that fall within the ambit of the physician self-referral law as indirect compensation arrangements (although they may still implicate the anti-kickback statute, depending on the facts and circumstances). We also acknowledge that, by analyzing unit-based compensation at the definitional stage at final §411.354(c)(2)(ii), many unbroken chains of financial relationships will no longer be required to satisfy the writing requirement at §411.357(p)(2), potentially limiting our and law enforcement's visibility into the compensation received by physicians who make referrals for designated health services to the entities at the other end of the unbroken chain of financial relationships between them. However, as we have stated many times in previous rulemakings and in this final rule, we believe that it is a common practice (if not the best practice), and required by other Federal and State statutes and regulations, for parties to reduce their arrangements to writing, including the compensation and other terms of their arrangements. Also, we remind readers that compliance with the physician self-referral law is a prerequisite for submitting a claim to Medicare for a designated health service referred by a physician who has (or whose immediate family member has) a financial relationship with the entity submitting the claim. Included in the burden of proof to show that a

claim for designated health services is permissible is the burden to show either that the physician self-referral law does not apply because the parties do not have a financial relationship within the meaning of the physician self-referral law or, if the law does apply because the parties have a financial relationship within the meaning of the physician self-referral law, that all the requirements of an applicable exception are satisfied. An entity's mistaken belief that no indirect compensation arrangement exists does not eliminate the need to satisfy the requirements of an applicable exception to the physician self-referral law.

Comment: One commenter requested that we deem certain compensation formulas that *do* include the physician's referrals to an entity or other business generated by a physician for the entity as a variable to nonetheless *not* take into account the volume or value of referrals or other business generated if the compensation arrangement is consistent with value-based care goals but does not qualify for or satisfy the requirements of the new exceptions at §411.357(aa).

Response: We decline to permit any arrangement under which compensation is determined using a formula that includes a physician's referrals to or other business generated for the entity as a variable and creates the positive or negative correlation with the compensation paid to or from the physician, as applicable. If a compensation arrangement does not qualify for or does not satisfy all the requirements of an exception at new §411.357(aa), the compensation paid under the arrangement may not take into account the volume or value of the physician's referrals or other business generated by the physician for the entity. Although the new exceptions at §411.357(aa) do not include a requirement that the compensation does not take into account the volume or value of a physician's referrals or other business generated by the physician, they include substitute safeguards against program or patient abuse through their limited application and included requirements. Permitting an arrangement to circumvent those safeguards and the volume or value and other business generated standards of the traditional exceptions would pose a risk of program or patient abuse.

Comment: One commenter requested clarification of the term "other business

generated." The commenter stated that industry guidance suggests that other business generated means services that are not designated health services. The commenter proposed that the definition of "other business generated" should include only services paid by government payors, and should not extend to services paid by private or commercial payors.

Response: Our interpretation of the term "other business generated" is longstanding and settled. In Phase I, we stated that, based on our review of the legislative history, we believe that the Congress intended the "other business generated" language to be a limitation on the compensation or payment formula parallel to the statutory and regulatory prohibition on taking into account referrals of designated health services. We further stated that, in the provisions in which the phrase appears, affected payments cannot be based or adjusted in any way on referrals of designated health services or on any other business referred by the physician, including other Federal and private pay business (66 FR 877). We see no reason to revisit this interpretation as suggested by the commenter.

Comment: A few commenters objected to our proposals to establish special rules on the volume or value standard and the other business generated standard based on what appear to be fair market value concerns. The commenters provided the example of a hospital that determines the amount of fixed-rate compensation at a higher level than a physician practice might pay the physician because the hospital knows that it can direct the physician's referrals to the hospital and its affiliates to "make up the difference" in billings for those services.

Response: We assume the commenters are referring to compensation that is based on the physician's personally performed services and not referrals of designated health services or other business generated by the physician for the entity paying the compensation, for instance, a salary of $300,000 per year. Although the formula for calculating fixed-rate compensation for a physician's personally performed services would not include the physician's referrals to the entity or other business generated by the physician for the entity as variables—in our example, the physician's compensation would be $300,000 x the number of years of the arrangement's

duration—the compensation arrangement must satisfy all the requirements of an applicable exception in order not to trigger the referral and billing prohibitions of the physician self-referral law. Compensation that is inflated to recognize the ability of the hospital to receive payment under the IPPS and OPPS for designated health services that it requires the physician to refer to the hospital or a specific provider, practitioner, or supplier within the hospital's health system may not be fair market value for the physician's personally performed services under our existing definition of "fair market value" and the revised definition of "fair market value" finalized in this final rule. See section II.B.5. of this final rule for a detailed discussion of our final policies with respect to the definition of "fair market value." Also, as described above and in more detail in section II.B.4. of this final rule, if any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy the conditions of §411.354(d)(4).

4. Patient Choice and Directed Referrals (§411.354(d)(4))

Historically, when the conditions of the special rule at §411.354(d)(4) are met, compensation from a *bona fide* employer, under a managed care contract, or under a personal service arrangement is deemed not to take into account the volume or value of referrals, even if the physician's compensation is predicated, either expressly or otherwise, on the physician making referrals to a particular provider, practitioner, or supplier. This special rule was established in Phase I after many commenters objected to our statement in the 1998 proposed rule that fixed payments to a physician could be considered to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer designated health services to a given entity, such as an employer or an affiliated entity (63 FR 1700). In Phase I, we acknowledged that the proposed interpretation could have had far-reaching effects, especially for managed care arrangements and group practices (66 FR 878). We determined that we would not consider a physician's compensation to take into account the volume or value of his or her referrals, as long as the directed referral requirement does not apply

if a patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment (66 FR 878). In addition, the referral requirement must be set out in writing and signed by the parties, and the compensation to the physician must be: (1) set in advance for the term of the compensation arrangement; and (2) consistent with fair market value for the services performed. Finally, the compensation arrangement must otherwise comply with an applicable exception in §411.355 or §411.357.

We continue to believe in the importance of preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization. In the proposed rule, we expressed concern that, given our proposed interpretation of the volume or value standard, §411.354(d)(4) may apply in fewer instances, if at all, to serve these important goals. To reiterate how critical these protections are, we proposed to include in the exceptions applicable to the types of contracts or arrangements to which the special rule has historically applied an affirmative requirement that the compensation arrangement meet the conditions of the special rule at §411.354(d)(4). To that end, we proposed to include in the exceptions at §411.355(e) for academic medical centers, §411.357(c) for *bona fide* employment relationships, §411.357(d)(1) for personal service arrangements, §411.357(d)(2) for physician incentive plans, §411.357(h) for group practice arrangements with a hospital, §411.357(l) for fair market value compensation, and §411.357(p) for indirect compensation arrangements, a requirement that, in addition to satisfying the other requirements of the exception, the relevant arrangement must comply with the conditions of the revised special rule at §411.354(d)(4). In making this proposal, we relied on the authority granted to the Secretary under sections 1877(b)(4), (e)(2)(D), (e)(3)(A)(vii), (e)(3)(B)(i)(II), and (e)(7)(vii) of the Act. We solicited comment as to whether, given the nature of academic medical centers, the conditions of revised §411.354(d)(4) are necessary. We are finalizing our proposal to include an affirmative requirement that the compensation arrangement meet the conditions of the special

rule at §411.354(d)(4) in all of the exceptions identified in the proposed rule. As explained in section II.E.1. of this final rule, we are also finalizing this requirement in the new exception for limited remuneration to a physician at §411.357(z). Although the requirement is not included in the new exceptions for value-based arrangements at final §411.357(aa), as discussed in section II.A.2. of this final rule, we have incorporated into these exceptions specific requirements related to remuneration paid to a physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier.

In the 1998 proposed rule, highlighting stakeholder inquiries regarding whether an arrangement fails to meet the volume or value standard only in situations in which a physician's payments from an entity fluctuate in a manner that reflects referrals, we expressed our view that an arrangement can also fail to meet this standard in some cases when a physician's payments from an entity are stable, but predicated, either expressly or otherwise, on the physician making referrals to a particular provider. We gave the example of a hospital that includes as a condition of a physician's employment the requirement that the physician refer only within the hospital's own network of ancillary service providers, such as to the hospital's own home health agency. We stated that, in these situations, a physician's compensation reflects the volume or value of his or her referrals in the sense that the physician will receive no future compensation if he or she fails to refer as required. We continue to believe that conditioning a physician's future compensation on his or her referrals could improperly influence the physician's medical decision making, potentially impacting patient choice or the utilization of services. However, upon further examination of the policy goals behind our statements in the 1998 proposed rule (63 FR 1700), the special rule finalized in Phase I (66 FR 878), and the comments on the proposed rule, we no longer believe that compensation predicated, either expressly or otherwise, on the physician making referrals of designated health services to a particular provider, practitioner, or supplier should be evaluated for compliance with the volume or value standard.

As described in the proposed rule (84 FR 55789) and in section II.B.3. of this final rule,

after reviewing the statute and our regulations in a fresh light, we now believe that the volume or value standard is most appropriately interpreted as relating to how compensation is calculated; that is, what formula is used to determine the amount of the physician's compensation. We are finalizing special rules at §411.354(d)(5)(i) and (6)(i) that set forth mathematical formulas that identify compensation that takes into account the volume or value of a physician's referrals. However, a review of the mathematical formula that determines the amount of the physician's compensation would not be sufficient to identify a referral requirement that could lead to program or patient abuse. Rather, payment conditioned on the physician's referrals of designated health services to a given entity, such as an employer or an affiliated entity, should be evaluated for compliance with the special rule at §411.354(d)(4), which is mandatory under the policies finalized in this final rule.

As we explained in the proposed rule (84 FR 55794) and our response to comments in section II.B.3. of this final rule, there is a risk of program or patient abuse when a physician will receive no future compensation if he or she fails to refer as required. The same is true if the amount of the physician's compensation is tied to the physician's referral to a particular provider, practitioner, or supplier. To address this risk, we are revising §411.354(d)(4) to include a condition at §411.354(d)(4)(vi) that neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. This condition must be met regardless of whether the physician's compensation takes into account the volume or value of his or her referrals to the entity with which the physician has the compensation arrangement. As applied, under final §411.354(d)(4)(vi), where an entity requires a physician to refer patients for designated health services to a particular provider, practitioner, or supplier and the applicable exception requires compliance with §411.354(d)(4), in addition to meeting the other conditions of §411.354(d)(4), neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the number or value of the physician's referrals to the

particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

In the proposed rule, we described this type of contingency as a direct "if X, then Y" correlation (84 FR 55794). The proposed special rule built upon the concerns described above, which we originally described in the 1998 proposed rule as relating to a nexus between fixed-rate compensation and the volume or value of a physician's compensation. We believe that the condition at final §411.354(d)(4)(vi) provides a clearer standard for stakeholders and better addresses our concerns than the proposed special rule that would have considered fixed-rate compensation to take into account the volume or value of referrals if there is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

We provide the following example to illustrate the application of our final regulation at §411.354(d)(4)(vi). Assume that a hospital directly employs a cardiologist to treat patients in the hospital's outpatient cardiology department. The physician is paid a predetermined, unvarying annual salary. Under the employment arrangement, the hospital requires the physician to refer patients to the hospital or other providers and suppliers wholly owned by the hospital, unless the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. When negotiating an extension of the employment arrangement and revised compensation terms, the hospital reviews the past performance of the physician, including the physician's referrals for diagnostic testing. At final §411.357(c)(5), the exception for *bona fide* employment relationships requires compliance with the conditions of the special rule for directed referrals at §411.354(d)(4). (The exceptions for personal service arrangements and fair market value compensation have identical requirements at

§411.357(d)(1)(viii) and (l)(7), respectively.) Under §411.354(d)(4)(vi), the amount of the physician's compensation may not be contingent on the number or value of the physician's referrals under the directed referral requirement. Thus, if, for example, the hospital increases the physician's compensation in the renewal term only if the physician made a targeted number of referrals for diagnostic testing to the hospital or the designated wholly-owned providers and suppliers in the current term, the compensation would not meet the condition at §411.354(d)(4)(vi). Similarly, if, for example, the hospital refuses to renew the employment arrangement (or terminates it in the current term) unless the value of the physician's diagnostic testing referrals generates sufficient profit to the hospital (or its wholly-owned providers and suppliers), the existence of the compensation arrangement would be contingent on the value of the physician's referrals in violation of §411.354(d)(4)(vi).

We also proposed to revise §411.354(d)(4) to eliminate certain language regarding: (1) whether the "set in advance" and "fair market value" conditions of the special rule apply to the compensation arrangement (as stated in the regulation) or to the compensation itself; and (2) when compensation is considered fair market value. The proposed revisions were intended to clarify that the physician's *compensation* must be set in advance. Any changes to the compensation (or the formula for determining the compensation) must also be set in advance (that is, made prospectively). (See section II.D.5. of this final rule for a detailed discussion of the "set in advance" deeming provision at §411.354(d)(1).) We proposed to clarify that the physician's *compensation* must be consistent with the fair market value of the services performed. In addition, we proposed to eliminate the parenthetical language in existing §411.354(d)(4) as it conflates the concept of fair market value and the volume or value standard. As noted in response to the comment in section II.B.1. of this final rule, these are separate standards, and compliance with one is not contingent on compliance with the other. We also proposed nonsubstantive revisions for clarity. We noted that, although revised §411.354(d)(4) sets forth protections that apply to both the compensation arrangement that includes a directed

referral requirement and also specifically to the compensation itself, for continuity in the application of the regulation, we would leave the regulation in §411.354(d), which sets forth special rules on *compensation*, rather than include it in §411.354(e), which sets forth special rules for *compensation arrangements*. We are finalizing the proposed restructuring of and nonsubstantive revisions to §411.354(d)(4).

We received the following comments and our responses follow.

Comment: Many commenters recognized that directed referral requirements would be permitted without limitation if we finalized our proposed interpretation of the volume or value standard at §411.354(d)(5). Commenters agreed that compliance with the conditions of the special rule at §411.354(d)(4) provides important protections for patients and the independence of a physician's medical decision making. Several commenters supported our proposal to continue this protection by including in the exceptions at §411.355(e) for academic medical centers, §411.357(c) for *bona fide* employment relationships, §411.357(d)(1) for personal service arrangements, §411.357(d)(2) for physician incentive plans, §411.357(h) for group practice arrangements with a hospital, §411.357(l) for fair market value compensation, and §411.357(p) for indirect compensation arrangements an affirmative requirement for compliance with §411.354(d)(4) when a physician's compensation is conditioned on his or her referrals to a particular provider, practitioner, or supplier.

Response: We agree with the commenters that patient choice, independent medical decision making, and avoiding interference with managed care contracts should be protected. We are finalizing our proposals and, as discussed in section II.E.1. of this final rule, are including the requirement in the new exception for limited remuneration to a physician at §411.357(z). As the previous commenter described, directed referral requirements can take the form of conditioning the *existence* of the arrangement itself on the physician's referrals to a particular provider, practitioner, or supplier, or they may condition the *amount* of the physician's compensation on his or her referrals to a particular provider, practitioner, or supplier. Because

both types of conditioning represent threats to patient choice and the independence of a physician's medical decision making, in order to reflect both of these conditioning requirements, we are revising the language of §411.354(d)(4), with which the compensation arrangement must comply under the exceptions at §§411.355(e) and 411.357(c), (d)(1), (d)(2), (h), (l), (p), and (z). In each of the exceptions noted, if the physician referrals are directed to a particular provider, practitioner, or supplier, the arrangement must satisfy the conditions of §411.354(d)(4).

Comment: A few commenters stated that they did not oppose the policy stated in the proposed rule (84 FR 55796) that §411.354(d)(4) applies to both the situation where the compensation *arrangement* is contingent on the physician's required referrals and the situation where the compensation *amount* is contingent on the physician's required referrals, but requested guidance on the precise function of the special rule at §411.354(d)(4) in light of our proposed interpretation of the volume or value standard. One of these commenters focused on the contractual terms between the parties to the compensation arrangement, and asked whether the volume or value standard would be violated if the breach of a directed referral requirement resulted only in termination of the arrangement, rather than an impact on the amount of the physician's compensation from the entity. This commenter provided a second example of a directed referral requirement that it stated would affect the amount of a physician's compensation. Under that example, a physician is paid different stipulated percentages of a bonus pool depending on the percentage of the physician's referrals that are "in network" (that is, to a particular provider, practitioner, or supplier). The commenter requested clarification of the applicability of the special rule at §411.354(d)(4) and whether provisions such as those described would violate the volume or value standard as proposed. A different commenter described a compensation arrangement under which a physician is paid an amount that does not result from a mathematical model tied to individual referrals of designated health services, but rather a "model" under which the entity knows it will generate revenue by requiring physician referrals to a particular provider, practitioner, or supplier. The commenter stated that, under the scenario

presented, the entity is not rewarding (paying) the physician for referrals but would terminate the physician's employment if he or she does not actively participate in the mandated referrals. The commenter asked whether CMS views this type of compensation model as taking into account the volume or value of the physician's referrals.

Response: In light of this specific comment and other similar comments, we revisited the history of §411.354(d)(4) and our previously-stated concerns regarding directed referral requirements that ultimately led to the establishment of the special rule. As we stated in Phase I, we understand that directed referral requirements are a common and integral part of employment relationships, personal service arrangements, and managed care contracts (66 FR 878). Even so, we continue to believe that payments tied to referral requirements can be abused, and appropriate safeguards should be in place to protect against the risk of program or patient abuse when an entity directs a physician where to make referrals of designated health services. After review of the regulatory history of our interpretation of the volume or value standard and the establishment of the special rule at §411.354(d)(4), we now believe that the best approach to addressing the risks of directed referral requirements is to affirmatively require compliance with the conditions of §411.354(d)(4) whenever an entity conditions the compensation of a physician with whom it has an employment relationship, personal service arrangement, or managed care contract on the physician's referrals for designated health services to a particular provider, practitioner, or supplier. Compensation conditioned, either expressly or otherwise, on the physician making referrals of designated health services to a particular provider, practitioner, or supplier should not be evaluated for compliance with the volume or value standard. Because we are finalizing requirements in certain exceptions for affirmative compliance with the conditions of §411.354(d)(4), and directed referral requirements will no longer be considered in the context of compliance with the volume or value standards, we are applying the condition at final §411.354(d)(4)(vi), rather than the final regulation at §411.354(d)(5)(i), in our response to the commenters.

The condition at §411.354(d)(vi) applies to a directed referral requirement which, if not achieved, would result in the termination of a physician's compensation arrangement, even if it would not impact the amount of the physician's compensation from the entity. The condition at §411.354(d)(4)(vi) prohibits making the existence of a compensation arrangement contingent on the number or value of the physician's referrals to a particular provider, practitioner, or supplier. If the compensation arrangement would be terminated if the physician failed to refer a sufficient number of patients for designated health services, or if the value of the physician's referrals of designated health services failed to achieve the target established under the directed referral requirement, the directed referral requirement would be impermissible and the compensation arrangement would not satisfy the applicable exception's requirement of compliance with §411.354(d)(4). We emphasize that §411.354(d)(4)(vi) does not prohibit directed referral requirements based on an established percentage—rather than the number or value—of a physician's referrals. Therefore, if the directed referral requirement in the commenter's example provided for termination of the compensation arrangement if the physician failed to refer 90 percent, for example, of his or her patients to a particular provider, practitioner, or supplier, it would not run afoul of the special rule at §411.354(d)(4) or jeopardize compliance with the requirement of the applicable exception.

With respect to the commenter's second example that ties the amount of the physician's compensation to achievement of a directed referral requirement, the condition at §411.354(d)(4)(vi) would apply in the same manner. A directed referral requirement under which a physician is paid different stipulated percentages of a bonus pool depending on the percentage of the physician's referrals that are "in network" (that is, to a particular provider, practitioner, or supplier) would not be categorically prohibited under §411.354(d)(4)(vi); however, we caution that the composition of the bonus pool must be analyzed to ensure that the formula for the compensation ultimately paid to the physician does not include referrals of designated health services or other business generated by the physician as a variable. Also, if the

directed referral requirement was tied to the number or value of the physician's referrals, it would run afoul of the special rule at §411.354(d)(4) and and the compensation arrangement would not satisfy the applicable exception's requirement of compliance with §411.354(d)(4).

Comment: One commenter expressed support for the affirmative requirement for compliance with the conditions of §411.354(d)(4) where a physician is directed to refer patients to a particular provider, practitioner, or supplier under the physician's compensation arrangement with the entity directing the referrals. The commenter recommended that we finalize our proposal to make the compliance requirement mandatory, and that we apply the rule where the referral requirement is not only express, but where it occurs as the practical result of processes that steer a physician's referrals for designated health service to a provider, practitioner, or supplier selected by the entity.

Response: The affirmative obligation finalized in the exceptions at §§411.355(e) and 411.357(c), (d)(1), (d)(2), (h), (l), (p), and (z) is not limited to express or written requirements to refer patients to particular provider, practitioner, or supplier selected by the entity paying the compensation. Rather, the condition at §411.354(d)(4)(vi), as finalized, prohibits making the existence of the compensation arrangement or any compensation paid to the referring physician contingent on the physician's referrals to a particular provider, practitioner, or supplier.

Comment: One commenter expressed general agreement with the proposals to include compliance with the conditions of §411.354(d)(4) as an affirmative requirement in exceptions applicable to compensation for physician services in those instances where the physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier. The commenter also supported leaving the regulation in §411.354(d)(4), rather than include it with other special rules related to compensation arrangements at §411.354(e).

Response: We are finalizing our proposals with the modifications explained in the responses to other comments. We agree with the commenter that the regulation should remain at §411.354(d)(4). We believe this will avoid disruption with stakeholder compliance efforts and

our enforcement efforts.

Comment: One commenter urged CMS not to adopt an affirmative requirement to comply with the conditions of §411.354(d)(4) when a physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier. Despite its stated support for patient preference in referrals, the commenter asserted that the requirement would place additional burden on physicians and other providers.

Response: Where such referral requirements have existed, they have historically implicated the volume or value standard under our historic interpretation of that standard. Thus, parties would have had to comply with the conditions of §411.354(d)(4) in order to be assured not to run afoul of the volume or value standard, or offer some other proof of compliance with the volume or value standard. This is not a new requirement.

Comment: A few commenters discussed what they termed "employee workplace requirements" that require an employed physician to treat the employer's patients in a specified workplace, typically the location of a medical practice or clinic and the address of an affiliated hospital. The commenters questioned whether such requirements were of concern to CMS. The commenters requested that CMS provide guidance on employee workplace requirements, suggesting that several approaches might be appropriate. The commenters offered that CMS could take the position that employee workplace requirements are not directed referral requirements that trigger the need for compliance with the volume or value standard because the employed physician is merely restricted by his or her employment from working elsewhere and is not expressly required to refer patients to the employer. In the alternative, the commenters offered that CMS could take the position that such workplace requirements are directed referral requirements because the employer is effectively requiring the physician to refer his or her patients to the employer and, for example, an affiliated hospital for designated health services. If so, the commenters requested that CMS confirm that §411.354(d)(4) requires only that the employer permits the physician to refer the patient to another physician who can provide the

services (such as a surgery or other procedure) at a different location based on patient preference, payor requirements, or the best medical interest of the patient. The commenters requested specific confirmation that §411.354(d)(4) does not require the employer to permit the employed physician to personally treat the patient in a location other than that specified in the physician's employment contract.

Response: Under the policies finalized in this final rule, a directed referral requirement will not trigger analysis for compliance with the volume or value standard at final §411.354(d)(5). However, a compensation arrangement will have to satisfy the conditions of §411.354(d)(4) if any of the physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier and the parties intend to rely on the exception at §411.355(e) or §411.357(c), (d)(1), (d)(2), (h), (l), (p), or (z). The commenter is correct that the requirement to comply with §411.354(d)(4) is not intended to interfere with employer's rights or operations or infringe on the employer-employee relationship. The condition at §411.354(d)(4)(iv)(B) requires only that the requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. Requiring that the employed physician refer the patient to another physician for treatment is permissible, provided that the referral is appropriate. We wish to make clear that the permissibility of the referral to another physician for purposes of the physician self-referral law has no bearing on whether the employed physician complies with any State law and common law requirements, such as laws regarding patient abandonment.

Comment: Many commenters noted that the term "referrals" is used throughout our physician self-referral regulations. Commenters stated that, although the term is defined at §411.351, they were uncertain whether the term "referrals" has the meaning ascribed to it at §411.351 in all instances in which it appears in the regulations. Several commenters asked if the

term "referrals" in §411.354(d)(4) is intended to encompass more than the defined term "referrals" at §411.351. One commenter stated that, if the meaning of "referrals," as used at §411.354(d)(4), is not limited to the definition at §411.351, the proposed inclusion of a requirement for compliance with the conditions of §411.354(d)(4) as an element of the exceptions for *bona fide* employment relationships, personal service arrangements, and others has the effect of introducing an all-payor volume or value standard into these exceptions. The commenters requested that CMS expressly clarify in commentary that, unless otherwise noted, when "referrals" appears in the physician self-referral regulations, it has the meaning set forth at §411.351.

Response: The introductory language to §411.351 states clearly that, unless the context indicates otherwise, the term "referral" has the meaning set forth in §411.351. The term "referral," as used at §411.354(d)(4) and the new requirement in certain exceptions that, if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4) have the meaning set forth in the definition of "referral" at §411.351. In Phase I, we discussed the scope of the term "referral" with reference to a requirement that a physician refer designated health services to a given entity (66 FR 878). As we stated above in section II.B.2. of this final rule, unless the context indicates otherwise, the term "referral" has the meaning set forth in §411.351 throughout the physician self-referral regulations, including in the special rules on compensation at §411.354(d).

5. Fair Market Value (§411.351)

The term "fair market value," as it is defined at section 1877(h)(3) of the Act, consists of three basic components. Fair market value is defined generally as "the value in arms length [sic] transactions, consistent with the general market value." The statutory definition includes additional qualifications for leases generally, providing that fair market value with respect to rentals or leases also means "the value of rental property for general commercial purposes (not

taking into account its intended use)." Finally, with respect to the lease of office space, in particular, the statutory definition further stipulates that fair market value also means that the value of the rental property is "not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee." Most of the statutory exceptions at section 1877(e) of the Act relating to compensation arrangements include requirements pertaining to fair market value compensation, including the exceptions for the rental of office space, the rental of equipment, *bona fide* employment relationships, personal service arrangements, isolated transactions, and payments by a physician. Many of the regulatory exceptions created using the Secretary's authority under section 1877(b)(4) of the Act also include requirements pertaining to fair market value compensation, including the exceptions for academic medical centers, fair market value compensation, indirect compensation arrangements, EHR items and services, and assistance to compensate a nonphysician practitioner.

The term "fair market value" is defined in our regulations in §411.351. In the 1992 proposed rule (57 FR 8602) and the 1995 final rule (60 FR 41978), we incorporated the statutory definition of "fair market value" into our regulations without modification. In the 1998 proposed rule (63 FR 1686), we proposed to include in our definition of "fair market value" a definition of "general market value," to explain what it means for a value to be "consistent with the general market value." In an attempt to ensure consistency across our regulations, we proposed to adopt the definition of "general market value" from part 413 of our regulations, which pertains to reasonable cost reimbursement for end stage renal disease services. In the context of determining the cost incurred by a present owner in acquiring an asset, §413.134(b)(2) defined "fair market value" as "the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition." We modified the definition drawn from

§413.134(b)(2) to include analogous provisions for determining the fair market value of any items or services, including personal services, employment relationships, and rental arrangements. As proposed in the 1998 proposed rule, "general market value" would mean:

> The price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.

The proposed definition of "fair market value" in the 1998 proposed rule did not substantively modify the provisions of the fair market value definition pertaining to leases in general and office space leases in particular.

In Phase I, we finalized the definition of "fair market value" from the 1998 proposed rule with one modification (66 FR 944 through 945). The definition of "fair market" value finalized in Phase I clarified that a rental payment "does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements." In Phase I we also responded to commenters that requested guidance on how to determine fair market value in a variety of circumstances. We stated that we would accept any commercially reasonable method for determining fair market value. However, we noted that, in most exceptions, the fair market value requirement is further modified by language that precludes taking into account the volume or value of referrals, and, in some cases, other business generated by the referring physician. We concluded that, in determining whether compensation is fair market value, requirements pertaining to the volume or value of referrals

and other business generated may preclude reliance on comparables that involve entities and physicians in a position to refer or generate business (66 FR 944). Elsewhere in Phase I, we suggested a similar underlying connection between the fair market value requirement and requirements pertaining to the volume or value of a physician's referrals and other business generated (66 FR 877). In a discussion of our then-interpretation of the fair market value standard in light of our Phase I interpretation of the requirement that compensation not take into account other business generated, we stated that—

> [T]he additional limiting phrase 'not taking into account * * * other business generated between the parties' means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid [designated health services] or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

Despite our intimation in Phase I that the concepts of fair market value and the volume and value of referrals or other business generated were fundamentally interrelated, the definition of fair market value finalized in Phase I did not include any reference to the volume or value of a physician's referrals.

In Phase II, we made two significant modifications to the definition of "fair market value." First, we proposed certain "safe harbors" for determining fair market value for hourly payments made to physicians for physician services (69 FR 16092 and 16107). (These safe harbors were not finalized.) Second, and more importantly, we incorporated into the definition of "fair market value" a reference to the volume or value standard found in many exceptions to the physician self-referral law. The Phase II definition of "fair market value" provided, in relevant part, that fair market value is usually the price at which *bona fide* sales have been

consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. We explained our view that the determination of fair market value under the physician self-referral law differs in significant respects from standard valuation techniques and methodologies. In particular, we noted that the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another (69 FR 16107). We made no substantive changes to the definition of "fair market value" in Phase III or in any of our subsequent rulemaking.

As a preliminary matter and as described previously in section II.B.1. of this final rule, a careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard. (See section II.B.3. of this final rule for a detailed discussion of the volume or value standard and the other business generated standard.) The volume or value and other business generated standards do not merely serve as "limiting phrases" to modify the fair market value requirement. In order to satisfy the requirements of the exceptions in which these concepts appear, compensation must both: (1) be fair market value for items or services provided; and (2) not take into account the volume or value of referrals (or the volume or value of other business generated by the physician, where such standard appears). We believe that the appropriate reading of the statute is that the requirement that compensation does not take into account the volume or value of referrals—which is plainly set out as an independent requirement of the relevant exceptions—is not also part of the definition of "fair market value." We note that the statutory definition of "fair market value" at section 1877(h)(3) of the Act includes no reference to the volume or value of referrals (or other business generated between the parties or by the physician). For these reasons and as described further below, we are finalizing our proposal to eliminate the

connection to the volume or value standard in the definitions of "fair market value" and "general market value."

Our proposals to revise the definition of "fair market value" at §411.351 were premised on our goal to give meaning to the statutory language at section 1877(h)(3) of the Act. As described previously in this section II.B.5., the statute states a general definition of "fair market value" and then modifies that definition for application to leases of equipment and office space. One of the modifications applies to leases of both equipment and office space; the other applies only to the lease of office space. To illustrate this more clearly in our regulations, we proposed to modify the definition of "fair market value" to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space. (We proposed to use the terms "rental" of equipment and "rental" of office space as those are the titles of the statutory exceptions at section 1877(e)(1)(A) and (B) of the Act and our regulatory exceptions at §411.357(a) and (b).) We are finalizing our proposals to restructure the regulation in this way. We believe that this approach provides parties with ready access to the definition of "fair market value," with the attendant modifiers, that is applicable to the specific type of compensation arrangement at issue. Under the final regulation at §411.351, generally, fair market value means the value in an arm's-length transaction, consistent with the general market value of the subject transaction. With respect to the rental of equipment, fair market value means the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. And with respect to the rental of office space, fair market value means the value in an arm's length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction. We are not finalizing the proposed

references to "like parties and under like circumstances." We note that the structure of the final regulation merely reorganizes for clarity, but does not significantly differ from, the statutory language at section 1877(h)(3) of the Act.

We also proposed changes to the definition of "general market value," which, until now, was included within the definition of fair market value at §411.351. As we explained in the proposed rule, the definition of "fair market value" finalized in Phase II states the following, some of which relates to fair market value and some of which relates to the included term, "general market value" (84 FR 55797). Numerical references are added here for ease but did not appear in the regulation at §411.351:

(1) Fair market value means the value in arm's-length transactions, consistent with the general market value.

(2) General market value means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

(3) Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

(4) With respect to rentals and leases described in §411.357(a), (b), and (l) (as to equipment leases only), "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use).

(5) In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

(6) For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Items one, four, and five essentially restate the language at section 1877(h)(3) of the Act, albeit with the intervening language in items two and three, and item six was added in Phase I in response to a comment for the purpose of interpreting the modifier "(not taking into account its intended use)" in item four and at section 1877(h)(3) of the Act. We stated in the 1998 proposed rule that items two and three were our attempt to give meaning to the statutory requirement that the fair market value of compensation must be "consistent with the general market value." In doing so, we relied on a regulation that relates to the circumstances under which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. We stated in the proposed rule that we no longer see the benefit of connecting the definition of "general market value" to principles of reasonable cost reimbursement for end stage renal disease services in order to explain what it means for a value to be consistent with general market value, as required by the statute. Moreover, the definition at §413.134(b)(2) upon which we relied states that fair market value (not general market value) is defined as the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. The regulation goes on to state that, usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition. This definition more closely ties to the widely accepted IRS definition of "fair market value,"[8] not general market value. Therefore, we

[8] Fair Market Value is defined as "the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts." (IRS Rev. Ruling 59-60)

considered whether current §411.351 includes an appropriate definition for "general market value."

We stated in the proposed rule that we see no indication in the legislative history or the statutory language itself that the Congress intended that the definition of "general market value" for purposes of the physician self-referral law should deviate from general concepts and principles in the valuation community. We discussed in detail the basis for our proposals to revise the definition of "general market value" in accordance with our belief that the Congress used the term "general market value" to ensure that the fair market value of the remuneration is generally consistent with the valuation that would result using accepted valuation principles (84 FR 55798). However, after reviewing the comments, to which our detailed responses are provided below, we believe that our proposals, if finalized, could have had an unintended limiting effect on the regulated community, as well as the valuation community. Our use of the term "market value" in our preamble discussion, although not carried into the proposed definition of "general market value," may have been inaccurate. Therefore, we are retracting our statements equating "general market value," as that term appears in the statute and our regulations, with "market value," the term we identified as uniformly used in the valuation industry (84 FR 55798).

We continue to believe that the general market value of a transaction is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. Thus, for example, when parties to a potential medical director arrangement determine the value of the physician's administrative services, they must not consider that the physician could also refer patients to the entity when not acting as its medical director. After reviewing the comments on our proposed definition of "general market value" and the existing regulation at §411.351, we determined that the best way to state this policy is to remove the language regarding the volume or value standard (item three above) and restructure the definition to emphasize our policy that the

valuation of the remuneration terms of a transaction should not include any consideration of other business the actual parties to the transaction may have with one another. Also, for clarity and as supported by commenters, we are finalizing definitions of "general market value" specific to each of the types of transactions contemplated in the exceptions to the physician self-referral law—asset acquisition, compensation for services, and rental of equipment or office space. Under our final regulation at §411.351, "general market value" means, with respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other. With respect to compensation for services, "general market value" means the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other. And, with respect to the rental of equipment or the rental of office space, "general market value" means the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

In the proposed rule, we stated that it is our view that the concept of fair market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers and sellers, and under like circumstances), while general market value relates to the value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe. We provided examples of compensation arrangements under which compensation outside the parameters of salary survey data could be appropriate (84 FR 55798 through 55799). Although we are not finalizing the proposed analytical framework related to "hypothetical" versus "actual" transactions, we continue to believe that the fair market value of a transaction—and particularly, compensation for physician services—may not always align with published valuation data compilations, such

as salary surveys. In other words, the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician's services. For this reason, we are affirming the examples provided in the proposed rule and restate them here, with modifications to eliminate terminology not included in our final analytical framework and regulations. As we stated in the proposed rule, extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction (84 FR 55799). By way of example, assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of $450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be $450,000 per year, this particular physician commands a significantly higher salary. In this example, compensation substantially above $450,000 per year may be fair market value. On the other hand, hypothetical data may result in hospitals and other entities paying more than they believe appropriate for physician services. Assume a hospital is engaged in negotiations to employ a family physician. Independent salary surveys indicate that compensation of $250,000 per year would be appropriate for a family physician nationally; no local salary surveys are available. However, the cost of living in the geographic location of the hospital is very low despite its proximity to good schools and desirable recreation opportunities, and, due to declining reimbursement rates and a somewhat poor payor mix, the hospital's economic position is tenuous. Although the physician may request the $250,000 that the salary survey indicates would be appropriate for a hypothetical (unidentified) physician to earn, and the hospital may believe that it is compelled to pay the physician this amount, the fair market value of the physician's compensation may be less than $250,000 per year (84 FR 55799).

We also proposed to remove from the regulation text at §411.351 the statement that, for purposes of the definition of "fair market value," a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements (84 FR 55798). This language was added to the regulation text as a result of our response in Phase I to a commenter to the 1998 proposed rule, where we stated that a rental payment does not violate the requirement that the fair market value of rental property is the value of the property for general commercial purposes, not taking into account its intended use, merely because it reflects any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added (66 FR 945). That is, the rental payment may reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. This regulation text appears to have caused confusion among stakeholders. Although it remains our policy, to avoid further confusion and provide certainty in the final definitions of "fair market value" and "general market value," we are finalizing our proposal to remove this language from the definition of "fair market value" at §411.351.

Lastly, we noted in the proposed rule that many CMS RFI commenters requested that we simply return to the statutory language defining fair market value (84 FR 55798). Some commenters on the proposed rule made similar requests. We continue to disagree that this would be the best approach. We believe that it is important to provide guidance with respect to the requirement that compensation is fair market value in order not to stymy our enforcement efforts (or those of our law enforcement partners). This guidance is also crucial to support the compliance efforts of the regulated industry.

We received the following comments and our responses follow.

Comment: Some commenters supported our proposal to remove the language regarding bargaining between well-informed buyers and sellers who are not otherwise in a position to

generate business for the other party, suggesting that this language essentially links the volume or value standard with the definition of "fair market value." The commenters noted that CMS clearly stated in the proposed rule that the volume or value standard and other business generated standard are distinct and separate requirements of many exceptions to the physician self-referral law (84 FR 55797). These commenters also referenced court opinions in which they believe the standards were blended or conflated by the court, causing confusion, additional litigation, and what they termed a "torrent of unnecessary effort to reexamine arrangements long-believed to comply with the law." The commenters contended that parties should not have to search for market data that isolates transactions with physicians who are not in a position to refer to the entities with which they have compensation arrangements. In contrast, one commenter strongly opposed our proposal to remove the language regarding well-informed buyers and sellers that are not otherwise in a position to generate business for each other from the definition of "general market value." A few other commenters asserted that, by defining general market value as the value determined by the parties to the subject transaction, the standard would simply be a subjective test of how parties to the transaction value the services, which could include additional payment for referrals or the generation of business. These commenters asserted that delinking the definition of "general market value" from the ability to generate business could result in the parties comparing the subject transaction to other transactions under which compensation is inflated by the value of referrals. One commenter suggested that we include in regulation text our preamble statement that [general] market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another (84 FR 55798). The commenter asserted that this would address the legitimate concern about valuations for purposes of the physician self-referral law being distorted by considerations of referrals. The commenter suggested that we include this statement at the end of the proposed definition of "general market value" for clarity.

Response: Although we disagree with the characterization of our proposal to define general market value merely as the value determined by the parties to the subject transaction, we find the program integrity concerns highlighted by the latter commenters compelling. It was not our intention to define "general market value" in a way that permits the inappropriate consideration of the value of a physician's referrals or the other business that a physician could generate for an entity in a determination of the fair market value of compensation. In Phase I, based on our then-interpretation that the "volume or value restriction" in the exceptions to the physician self-referral law established a limitation on the fair market value of compensation rather than represent a separate and distinct requirement of the exceptions, we stated that, depending on the circumstances, the "volume or value" restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business for each other (66 FR 944). In Phase II, we stated that, if parties are using comparables to establish fair market value, they should take reasonable steps to ensure that the comparables are not distorted (69 FR 16107). Although we have renounced the interpretation of the volume or value and other business generated standards as merely limiting or modifying the fair market value requirement (84 FR 55797), we continue to believe that precluding reliance on comparables that involve entities and physicians in a position to refer or generate business for each other in the determination of fair market value and general market value is an important program integrity safeguard. We are finalizing a definition of "general market value" that retains this language from the current regulation defining general market value. We believe this will be less disruptive to the regulated industry and valuation professionals that have developed compliance protocols and valuation standards that have incorporated this requirement for the past two decades, while still achieving our goal of disentangling the volume or value and other business generated standards from the requirement that compensation is fair market value. We are not including in the definition of "general market value" a statement that general market value is based solely on consideration of the economics of the subject transaction and should not include any

consideration of other business the parties may have with one another. Although we continue to believe that the determination of general market value should be based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another, we do not believe that it is necessary to include this statement because the final definition of "general market value" retains the essentially equivalent requirement for *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

Compensation to or from a physician should not be inflated or reduced simply because the entity paying or receiving the compensation values the referrals or other business that the physician may generate more than a different potential buyer of the items or services. This means that a hospital may not value a physician's services at a higher rate than a private equity investor or another physician practice simply because the hospital could bill for designated health services referred by the physician under the OPPS, whereas a physician practice owned by the private equity investor or other physicians would have to bill under the PFS, which may have lower payment rates. Put another way, the value of a physician's services should be the same regardless of the identity of the purchaser of those services. We recognize that reliance on similar transactions in the marketplace could simplify the process of determining fair market value for purposes of the physician self-referral law, but adopting such a standard would allow parties to consider the additional (or investment) value to certain types of entities, skewing the buyer-neutral fair market value.

Comment: One commenter asserted that the definition of "fair market value" should include a statement that organizations compensating individuals at an ongoing loss may create risk that the compensation is not representative of fair market value. The commenter explained its concern in an example involving a hospital compensating a physician at an amount greater than the collections for the physician's services, asserting that the hospital is able to do so because it controls referrals within its network and increased facility revenues offset the

physician practice losses. In the commenter's view, this creates a situation in which hospitals are taking into account the value of referrals when setting physician compensation. The commenter noted that, from a fair market value and [general] market value perspective, two hypothetical parties (that cannot consider the fact that one party can generate business for the other) would never enter into a situation in which the physician's compensation and benefits exceeded direct revenue. A different commenter asserted that a payment to a physician above what the entity collects for the physician's services is inherently not fair market value.

Response: We agree that, in some circumstances, an entity's compensation of a physician at an ongoing loss may present program integrity concerns, but see no need to include the language requested by the commenter in regulation. As we stated earlier, we are retaining the language "not in a position to generate business" in the definition of "general market value." We believe this addresses the commenter's concern, at least in part, as it requires that the nature or identity of the purchaser of the items or services (in the commenter's example, the hospital) is irrelevant to a determination of "general market value" and, thus, "fair market value." In the commenter's example, the value of the physician's services is the value to any willing buyer, and the fact that the hospital could make up losses for the physician's compensation through designated health services reimbursed at facility rates under OPPS rather than PFS, may not be considered. Also, we disagree that parties would *never* enter into such an arrangement. As we stated above in section II.B.2 (with respect to the definition of "commercially reasonable"), there are many valid reasons and legitimate business purposes for entering into an arrangement that will not result in profit for one or more of the parties to the arrangement.

Comment: A few commenters raised the point that, with respect to our statements in the proposed rule connecting the statutory term "general market value" to the valuation principle of "market value" (84 FR 55798), "general market value" does not equate to the "market value" of a transaction, as that term is used in the valuation industry. One of these commenters suggested that what CMS described as "market value" actually corresponds to "investment value" as

defined by the four commercial valuation disciplines: business valuation, compensation valuation, machinery and equipment valuation, and real estate valuation. Commenters expressed concern that this focus would narrow the universe of appropriate valuation methodologies for purposes of the physician self-referral law solely to the "market value" approach. One commenter asserted that stakeholders should not be restricted to exclusive use of the market approach to value a physician's personal services or promote exclusive use by valuators of physician compensation survey data. Other commenters requested that hospitals should be permitted to use existing written offers to a physician from other similarly situated providers to support a valuation. One of these commenters requested guidance on how fair market value should be determined and documented for timeshare arrangements, citing the "cost plus" guidance from Phase I regarding equipment leases as potentially appropriate (66 FR 876 through 877). Another of the commenters asked for additional guidance on recruiting and paying physicians in rural areas, including the use of supply, demand, access, and community need to support the fair market value of a physician's compensation. Another commenter requested that CMS provide additional guidance or examples on what data, facts, and circumstances should be applied to evaluate fair market value. The commenter requested specific guidance on the relevance of payor mix, market supply and demand data, cost of living, physician skills, and experience. A different commenter noted costs of care, costs for medical liability insurance, costs of equipment and staffing, certificate of need laws, and provider and related taxes on health care services and centers as relevant factors when determining the fair market value of compensation.

Response: As discussed above, we are retracting our statements in the proposed rule equating "general market value" with the valuation principle of "market value" (84 FR 55798). We did not intend to limit the valuation of assets, compensation, or rental property to the market approach or prescribe any other particular method for determining the fair market value and general market value of compensation. As we have stated consistently in prior rulemakings, to

establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another (66 FR 944). We emphasize that our use of the language "commercially reasonable" in Phase I (and again in Phase III (72 FR 51015 through 51016)) was also not intended to limit the valuation of assets, compensation, or rental property to a specific valuation approach or prescribe any other particular method for determining the fair market value and general market value of compensation. Rather, as stated in Phase II and reiterated in Phase III, we will consider a range of methods of determining fair market value and that the appropriate method will depend on the nature of the transaction, its location, and other factors (69 FR 16107 and 72 FR 51015 through 51016). We decline to affirm the specific valuation suggestions of the commenters because the amount or type of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the circumstances in any given case (66 FR 944), but refer readers to the Phase I rulemaking for an extensive discussion on potentially acceptable valuation methods (66 FR 944 through 945).

Comment: Several commenters expressed appreciation for the examples in the proposed rule regarding when an arrangement may involve compensation above or below what national market data (salary surveys) suggests would be appropriate. The commenters stated that the ability to factor in unique circumstances, such as whether a physician is particularly remarkable in his or her field, will allow entities to design compensation packages that more fully account for the broader circumstances of an arrangement. One commenter emphasized that the analysis of fair market value is always predicated on an analysis of the actual terms of a transaction and the actual facts and circumstances, while another commenter agreed specifically that extenuating circumstances may dictate that parties to an arm's-length transaction veer from values identified

in salary surveys and other hypothetical valuation data that is not specific to the actual parties. The commenter urged CMS to include this language (or similar language) in regulation text to provide further assurances to stakeholders of CMS' policy. Another commenter requested that we acknowledge that there are other factors that may justify *higher* levels of compensation rates for physician services in markets that may have relatively low cost of living standards due to market supply and demand. A different commenter discussed the difficulty of establishing fair market value in rural areas and other challenging markets. This commenter noted that, in some instances, a hospital might need to compensate a physician above what is indicated in some published salary schedules in order to convince the physician to relocate to the market area and fill a dire patient need. The commenter was concerned that the example in the proposed rule regarding lower cost of living in certain markets could be read to prohibit compensation above what is found in salary schedules. Some commenters requested additional examples of circumstances that could justify deviating from salary survey data. A few other commenters objected to the examples and disagreed that extenuating circumstances could require a downward deviation from salary surveys.

Response: It appears from the comments that stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value for a physician's professional services. It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases. However, we decline to include in regulation text, as requested by one of the commenters, a statement that extenuating circumstances may dictate that parties to an arm's-length transaction should veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the transaction when determining the fair market value of the compensation under their transaction. We believe such a statement is unnecessary in light of our policy discussion in the proposed rule and this final rule and our concern that it could reduce the clarity in the definitions of "fair market value" and "general market value" that we and

stakeholders seek.

Consulting salary schedules or other hypothetical data is an appropriate starting point in the determination of fair market value, and in many cases, it may be all that is required. However, we agree with the commenter that asserted that a hospital may find it necessary to pay a physician above what is in the salary schedule, especially where there is a compelling need for the physician's services. For example, in an area that has two interventional cardiologists but no cardiothoracic surgeon who could perform surgery in the event of an emergency during a catheterization, a hospital may need to pay above the amount indicated at a particular percentile in a salary schedule to attract and employ a cardiothoracic surgeon. We also agree with the commenter that emphasized the need for an analysis of the actual terms of a transaction and the actual facts and circumstances of the parties. In our view, each compensation arrangement is different and must be evaluated based on its unique factors. That is not to say that common arrangements, where the services required are identical regardless of the identity of the physician providing them, do not lend themselves well to the use of salary surveys for determining compensation that is fair market value.

Our examples in the proposed rule were intended to show that a variety of factors could affect whether the amount shown in a salary schedule is too high or too low to be fair market value for the services of the subject transaction. In some instances, it is exactly right. Parties do not necessarily fail to satisfy the fair market value requirement simply because the compensation exceeds a particular percentile in a salary schedule; nor are parties required to pay a physician what is shown in a salary schedule if the specific circumstances do not warrant that level of compensation. With respect to the commenters that took issue with the statements in the proposed rule that the fair market value of a particular physician's services may be below what is indicated in a salary schedule, we believe that salary schedules should not be used by a physician to demand compensation that is above what well-informed parties that are not in a position to generate business for each other would agree is the fair market value of the physician's services.

We wish to be perfectly clear that nothing in our commentary was intended to imply that an independent valuation is required for all compensation arrangements.

Comment: Two commenters, in identical statements, expressed concern with the proposed definition of "general market value." The commenters contended that, despite the statutory language that fair market value means the value in an arm's-length transaction, consistent with the general market value, there is no reason to believe that the reference to "general market value" modifies "fair market value" such that fair market value means anything other than what it means to the business valuation profession, and suggested that CMS leave the determination of fair market value to the business valuation profession. These commenters shared a definition of "fair market value" found in the International Glossary of Business Valuation Terms, with slight modification to recognize the valuation of services and resources as well as property and goods; specifically, the price, expressed in terms of cash equivalents, at which property, services, and resources would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's-length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts. The commenters asserted that this definition would not require valuators to limit themselves to the market approach or depart from time-honored valuation principles of their profession, including consideration of more than just physician compensation survey data. Ultimately, the commenters requested that CMS not adopt a new definition of "fair market value" (with or without a definition of "general market value") to take advantage of the consensus reached within the valuation profession.

Response: We decline to retain the current definition of "fair market value" (with or without a definition of "general market value") as requested by the commenters. First, the term "general market value" is included in the statutory definition of "fair market value" and we cannot ignore it for purposes of the statutory exceptions or remove it from our regulations. Second, we expect that our retraction of certain statements from the proposed rule and the

clarification of previous commentary on valuation methods will assuage the commenters' concerns. As described above, we are finalizing only slight modifications to the existing definitions of "fair market value" and "general market value" to clearly indicate the statute's specific requirements for determining the fair market value of rental property and to disentangle the volume or value and other business generated standards of the exceptions to the physician self-referral law from the definition of "general market value."

Comment: Most commenters supported the reorganization of the definitions, noting that the proposed structure provides better clarity. Some commenters urged CMS to adopt the definitions of "fair market value" and "general market value" as proposed. The commenters expressed appreciation for the restructuring of the existing definition of "fair market value" to extract the separate term "general market value" and the link to the volume or value standard. One of the commenters stated that the proposed definition of "fair market value" better aligns with the definition set forth in the statute.

Response: We agree that the final structure of the definitions of "fair market value" and "general market value" is clearer than our existing regulations. As we discussed above and in response to earlier comments, we are finalizing slight modifications to the proposed definitions. We are finalizing our proposal to remove the link to the volume or value standard in the definition of "general market value" as requested by the commenters. We believe that structuring the definition of "fair market value" to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space facilitate parties' compliance with the fair market value requirement in the exceptions to the physician self-referral law that apply to the specific type of compensation arrangement between them. Similarly, we believe that definitions of "general market value" specific to each of the types of transactions contemplated in the exceptions to the physician self-referral law—asset acquisition, compensation for services, and rental of equipment or office space—will facilitate stakeholders' understanding of the requirements for fair market value

compensation that is consistent with the general market value and ease overall compliance efforts.

Comment: A large number of commenters requested that we establish rebuttable presumptions that compensation is fair market value or "safe harbors" that would deem compensation to be fair market value if certain conditions are met. The commenters variously suggested that the following should be deemed to be fair market value: compensation set within a range of percentiles identified in independent salary surveys (with a wider band of permissible compensation for physicians who practice in medically underserved areas, health professional shortage areas, or rural areas), compensation set within the parameters of an independent third-party valuation, and compensation set in accordance with a valuation process that meets certain conditions patterned after those set forth in IRS regulations at 26 CFR 53.4958-6 (related to excess benefit transactions). Some of the commenters asserted that a "safe harbor" based on a range of values in salary surveys would be consistent with what they stated was established CMS policy that compensation set at or below the 75th percentile in a salary schedule is appropriate and compensation set above the 75th percentile is suspect, if not presumed inappropriate.

Response: For the reasons explained in Phase I (66 FR 944 through 945), Phase II (69 FR 16092), and Phase III (72 FR 51015), we decline to establish the rebuttable presumptions and "safe harbors" requested by the commenters. We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy.

C. Group Practices (§411.352)

In the proposed rule, we proposed certain revisions to the group practice rules at §411.352 that relate to corresponding proposals regarding the definitions and special rules for "commercially reasonable" compensation arrangements, "fair market value" compensation, and the volume or value standard applicable throughout the physician self-referral law and

regulations (84 FR 55799 through 55802). We also proposed a revision to the rules regarding the distribution of overall profits intended to support our policies related to the transition from a volume-based to a value-based health care system (84 FR 55800 through 55801). We discuss these proposals and our final regulations in section II.C.2. of this final rule.

1. Interpretation of the "Volume or Value Standard" for Purposes of the Group Practice Regulations (§411.352(g))

As we discussed in the proposed rule, in conjunction with our proposals related to the volume or value standards, we reviewed the physician self-referral regulations to ensure that the standards related to the volume or value of a physician's referrals (the volume or value standard) and the other business generated by the physician (the other business generated standard) are expressed using standardized terminology (84 FR 55799). We identified several occurrences of inconsistent expression of the standards. Although section 1877 of the Act uses more than one phrase to describe the volume or value and other business generated standards, which may be one reason for variations in the regulation text, we believe that the references are all to the same underlying prohibition on compensation that fluctuates with the volume or value of a physician's referrals or the other business generated by a physician for the entity providing the remuneration. Therefore, as discussed in section II.B.3. of this final rule, we proposed and are finalizing conforming changes throughout our regulations to delineate these standards as a prohibition on compensation that takes into account the volume or value of a physician's referrals or other business generated by the physician for the entity providing the remuneration. However, because the language in §411.352(g) and (i) mirrors the statutory language at section 1877(h)(4)(iv) of the Act, we did not propose changes to the "volume or value" regulation text in either of those paragraphs. The terms "based on" and "related to" remain in the regulation text at §411.352(g) and (i). We are affirming here that we interpret the requirements of §411.352(g) and (i) to incorporate the volume or value standard as it relates to a physician's referrals; that is, compensation to a physician who is a member of a group practice may not be determined in any

manner that takes into account the volume or value of the physician's referrals (except as provided in §411.352(i)), and profit shares and productivity bonuses paid to a physician in the group may not be determined in any manner that takes into account the volume or value of the physician's referrals (except that a productivity bonus may directly take into account the volume or value of the physician's referrals if the referrals are for services "incident to" the physician's personally performed services).

Prior to the revisions we are finalizing in this final rule, the regulation at §411.352(g) stated that "[n]o physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in §411.352(i)" (emphasis added). We interpret this to mean that, in order to satisfy this requirement for qualification as a "group practice," no physician who is a member of the group practice receives compensation that directly or indirectly takes into account the volume or value of his or her referrals (unless permitted under §411.352(i)). Our interpretation is consistent with the interpretation of "related to" set forth in Phase I, where we used the terms "based on," "related to," and "takes into account" interchangeably when describing the final group practice regulations (66 FR 908 through 910).

Prior to the revisions we are finalizing in this final rule, the regulation at §411.352(i) stated that a physician in a group practice may be paid a share of overall profits of the group practice, provided that the share is not determined in any manner that is directly related to the volume or value of referrals by the physician. We have long interpreted "is directly related to" the volume or value of referrals to mean "takes into account" the volume or value of referrals. In Phase I, we discussed this provision and stated that the Congress expressly limited profit shares for group practice members to methodologies that do not directly take into account the member's designated health services referrals, and that, under the statutory scheme, revenues generated by designated health services may be distributed to group practice members and physicians in the group in accordance with methods that indirectly take into account referrals (emphasis added)

(66 FR 862 and 908).

Despite the varying language of the regulations, as detailed in the proposed rule (84 FR 55800), we consider the regulations at §411.352(g) and (i) to prohibit compensation to physicians in a group practice that is determined in any manner that takes into account the volume or value of the physician's referrals to the group practice. The new special rule at §411.354(d)(5) establishes the universe of compensation that we consider to be determined in a manner that takes into account the volume or value of a physician's referrals to the entity paying the compensation. As described in section II.B.3. of this final rule, this special rule applies in all instances where our regulations include the volume or value standard, except as specified in §411.354(d)(5)(iv). Therefore, with respect to both §411.352(g) and (i), when determining whether the physician's compensation, share of overall profits, or productivity bonus is based on, is directly or indirectly related to, or takes into account the volume or value of the physician's referrals to the group practice, the special rule at final §411.354(d)(5) applies.

We received the following general comment and our response follows.

Comment: Some commenters argued that we should not finalize our proposals because group practices need the utmost flexibility to participate and succeed in value-based health care delivery and payment systems.

Response: Nothing in our final regulations prohibits a group practice (or any physician practice) that furnishes designated health services and the physicians who are owners, employees, or independent contractors of the practice from qualifying as a value-based enterprise. The new exceptions at §411.357(aa)(3) may be available to such an enterprise, assuming it meets all the requirements of the definitions and exceptions. Those exceptions do not include fair market value or volume or value requirements. The regulations at §411.352 apply to group practices that operate in a FFS payment environment. We do not agree that our final regulations at §411.352 will prohibit a group practice from participating and succeeding in a value-based health care delivery and payment system.

2. Special Rules for Profit Shares and Productivity Bonuses (§411.352(i))

a. Distribution of Profits Related to Participation in a Value-Based Enterprise

We proposed a new §411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than payments made directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. Certain downstream distribution arrangements are currently protected under waivers in the Shared Savings Program and certain Innovation Center models. However, outside of the Shared Savings Program or an Innovation Center model, profit shares or productivity bonuses paid to a physician in a group practice that are determined in any manner that directly takes into account the volume or value of his or her referrals to the group practice are strictly prohibited by the physician self-referral statute and regulations.

The special rules for the profit shares and productivity bonuses paid to physicians in a group practice prohibit calculation methodologies that directly take into account the volume or value of the recipient physician's referrals to the group practice. Thus, by way of example, in a 100-physician group practice where only two of the physicians participate with a hospital as a value-based enterprise in a commercial payor-sponsored alternative payment model, the profits from the designated health services ordered by the physicians and furnished by the group practice to beneficiaries assigned to the model may not be allocated directly to the two physicians. We explained in the proposed rule that commenters on the CMS RFI interpreted this to mean that the special rules at §411.352(i) would restrict the group practice to allocating alternative payment model-derived income that includes revenues from designated health services among all physicians in the group (or a component of at least five physicians in the group) in order to ensure that such income is allocated in a manner that only indirectly takes into account the volume or value of the two physicians' referrals. The commenters suggested that this restriction discourages physician participation in alternative payment or other value-based care models because physicians cannot be suitably rewarded for their accomplishments in

advancing the goals of the model, which is at odds with the Secretary's vision for achieving value-based transformation by pioneering bold new payment models. We also described the assertion of another commenter on the CMS RFI that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without the participation of physicians in value-based health care delivery and payment models with other health care providers. We stated that we share the commenters' concerns regarding physician participation in value-based health care delivery and payment models and are also concerned that our regulations could undermine the success of the Regulatory Sprint or the larger transition to a value-based health care system. Therefore, we proposed changes to §411.352(i) with respect to the payment of profit shares to eliminate this potential barrier to robust physician participation in value-based care delivery (84 FR 55800). We are finalizing our proposal with modifications to the regulation text as proposed. As explained in our responses to comments below, the policy will be codified at revised §411.352(i)(3) and effective on January 1, 2022.

For the reasons described elsewhere in this final rule, in the exceptions for value-based arrangements at new §411.357(aa), we did not propose to prohibit remuneration that takes into account the volume or value of a physician's referrals. The revisions finalized at §411.352(i)(3) are an extension of this policy. Specifically, we are finalizing a provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. Under our final policy at §411.352(i)(3), such profits may be distributed to the participating physician and will not be considered to directly relate to (or take into account) the volume or value of the physician's referrals. In other words, a group practice may distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician's participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration will be deemed not to be based on (or take into

account) the volume or value of the physician's referrals. The regulation finalized at §411.352(i)(3) would permit the 100-physician group practice in the previous example to distribute the profits from designated health services derived from the two physicians' participation in value-based enterprise directly to those physicians. Physician #1 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the value-based enterprise (and its corresponding participation in the model), and Physician #2 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the value-based enterprise (and its corresponding participation in the model). Neither distribution would jeopardize the group's ability to qualify as a "group practice" under §411.352. In the proposed rule, we sought comment regarding whether we should permit the distribution of "revenue" from designated health services, as opposed to "profits" from designated health services in order to effectuate the goals described elsewhere in the proposed rule (84 FR 55801) and this final rule. As explained in our responses to comments below, we are finalizing our proposal to apply the rule at final §411.352(i)(3) to "profits" from designated health services, which will be effective on January 1, 2022.

We received the following comments and our responses follow.

Comment: Commenters widely supported our proposal to address the distribution of profits from designated health services that are derived from the participation in a value-based enterprise by a physician in a group practice. Commenters urged us to finalize our proposal to permit the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise without having to aggregate the profits with the overall profits of the group practice or a component of five physicians within the group practice. Commenters asserted that this flexibility will encourage physicians to incorporate value-based elements into their practices, as well as physician participation in value-based enterprises on an individual basis and in circumstances where the entire group practice's

participation may not be warranted or desirable.

Response: We agree with the commenters regarding the potential impact of the permitted distributions; namely, that individual physicians in a group practice may be encouraged to participate in a value-based enterprise with providers and suppliers outside of the physician's own group practice even when the group practice does not participate as a whole in the value-based enterprise. We believe that the protection afforded by the safeguards in the new definitions and exceptions related to value-based care delivery and payment will ensure that distribution of profits to an individual physician (or subset of physicians) within a group practice should not increase the risk of inappropriate utilization of designated health services or program or patient abuse.

Comment: One commenter noted that proposed §411.352(i)(3) was not structured in the same way as the "special rules" for distribution of overall profits and payment of productivity bonuses. The commenter expressed concern that the proposed regulation text would not create the deeming provision we intended. The commenter requested that we revise the regulation to expressly state that, where a group practice's profits from designated health services are directly attributable to a physician's participation in a value-based enterprise and those profits are distributed to the physician, the compensation to the physician is deemed not to take into account the volume or value of the physician's referrals under §411.352(g). The commenter asserted that making these revisions would eliminate any inference that §411.352(i)(3) is not an exception to §411.352(g).

Response: The commenter is correct about the structure of the three provisions in §411.352(i) that describe methodologies for the distribution of profits from designated health services and the payment of productivity bonuses. We agree that standard language and further clarification of the provision at §411.352(i)(3) is warranted to ensure the provision operates as a deeming provision as we intend. We have revised the final regulation accordingly. Specifically, final §411.352(i)(3) provides that notwithstanding paragraph (g) of §411.352, profits from

designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at §411.351, may be distributed to the participating physician.

Comment: With respect to our proposal to permit the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, we sought comment regarding whether we should permit the distribution of "revenue" from designated health services, as opposed to "profits" from designated health services in order to effectuate the goals described elsewhere in the proposed rule and this final rule. One commenter stated that the furnishing of certain designated health services does not always result in profit for the group practice and suggested that permitting the distribution of revenue from designated health services would provide needed flexibility to encourage physicians to participate in value-based care delivery. Another commenter suggested that we permit the distribution of revenue from designated health services to simplify the regulation because revenues are easier to calculate than profits.

Response: We have no reason to doubt the commenter's assertion that a group practice does not realize a profit on every designated health service that it furnishes. Thus, it is possible that a group practice could have no profits to distribute to a physician in the group who makes a referral of designated health services for a patient in the target patient population while undertaking value-based activities as a VBE participant in a value-based enterprise. Although it may be true that it is easier to calculate revenues than to calculate profits, in general, we believe that a group practice's distribution of revenues to a referring physician rather than profits, which are calculated by deducting the expenses incurred in furnishing the designated health service, could serve as an inducement to make additional and potentially inappropriate referrals to the group practice. This is consistent with our statement in the 1998 proposed rule that rewarding a physician each time he or she self-refers for a designated health service can constitute an incentive to overutilize services (63 FR 1691). We are unclear how the sharing of a group practice's revenues with a physician would encourage the physician's participation in value-

based care delivery or how the physician's participation in his or her individual capacity in a value-based enterprise would mitigate our concerns regarding the inducement to refer any of the physician's patients outside the target patient population for designated health services furnished by the group practice. We are not adopting the commenters' recommendation to permit the distribution of revenues from designated health services that are directly attributable to a physician's participation in a value-based enterprise.

b. Clarifying Revisions

(1) Restructuring of the Regulation at §411.352(i)

We proposed to restructure and renumber §411.352(i) as well as clarify several provisions of the regulation. As we stated in the proposed rule, we believe that the revisions will enable groups to determine with more certainty whether compensation paid to a physician in the group as profit shares or productivity bonuses takes into account the volume or value of referrals and, if it does, whether there is a direct or indirect connection to the volume or value of the physician's referrals (84 FR 55801). Except as noted above with respect to the uniformity of the structure of the provisions in §411.352(i), we received no comments on the general restructuring of the regulations, and are finalizing our proposal to restructure and renumber the regulations at §411.352(i) without modification to the proposed numbering and headers of the regulation. Our purpose in restructuring the regulation is to more closely adhere to the structure of section 1877(h)(4)(B) of the Act and to express in affirmative language which profit shares and productivity bonuses are permissible; that is, permitting the payment of a profit share or productivity bonus that does not directly take into account the volume or value of referrals is the affirmative and more simple way of saying, as our current regulations do, that the profit share or productivity bonus is permissible but only if it does not directly take into account the volume or value of referrals. In addition, the special rules for profit shares and productivity bonuses, as finalized, follow the format of our special rules on compensation at §411.354(d) and our special rules for compensation arrangements at §411.354(e). As stated in the proposed rule, our addition

of introductory language at §411.352(i) and revised language at §411.352(i)(1) and 411.352(i)(2) do not constitute a substantive change to the noted provisions (84 FR 55801).

(2) Overall Profits

We proposed revisions to clarify our interpretation of the overall profits of a group that can be distributed to physicians in the group. Until now, the term "overall profits" was defined to mean two different things: (1) the group's entire profits derived from designated health services; and (2) the profits derived from designated health services of any component of the group practice that consists of at least five physicians. As stated in the proposed rule, stakeholders informed us that they were confused about the definition. For example, stakeholders informally inquired whether the profits of a group practice that has only two, three, or four physicians may be distributed at all. We proposed to revise the definition of "overall profits" to mean the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. To further clarify this definition, we proposed regulation text at revised §411.352(i)(1)(ii) stating that, if there are fewer than five physicians in the group, "overall profits" means the profits derived from all the designated health services of the group. We stated that we believe that this more precisely states the policy articulated in Phase I (66 FR 909 through 910). For the reasons explained in our responses to comments, we are finalizing the definition of "overall profits" at §411.352(i)(1)(ii) as proposed.

We highlight that the final regulation at §411.352(i)(1)(ii) includes the words "all the" before "designated health services." As we stated in the proposed rule, stakeholders' informal inquiries regarding the permissible methods of distributing profits from designated health services indicated that the regulation text may not have precisely evidenced our intent (84 FR 55801). Such inquiries included whether it is permissible to distribute profit shares of only some types of designated health services provided by a group practice without distributing the profits from the other types of designated health services provided by the group practice, and whether a

group practice may share profits from one type of designated health service with a subset of physicians in a group practice and the profits from another type of designated health service with a different (possibly overlapping) subset of physicians in the group practice. As discussed, we are finalizing at §411.352(i)(1)(ii) that overall profits means "the profits derived from all the designated health services." Thus, the profits from all the designated health services of any component of the group that consists of at least five physicians (which may include all physicians in the group) must be aggregated before distribution. Under this final rule, a physician practice that wishes to qualify as a group practice may not distribute profits from designated health services on a service-by-service basis. To illustrate, suppose a physician practice provides both clinical laboratory services and diagnostic imaging services—both designated health services—to its patients in a centralized building (as defined at §411.351) or a location that qualifies as a "same building" under §411.351 and meets the requirements at §411.355(b)(2)(i). If the practice wishes to qualify as a group practice, it may not distribute the profits from clinical laboratory services to one subset of its physicians and distribute the profits from diagnostic imaging to a different subset of its physicians.

We are cognizant that, under the requirement at §411.352(e), to qualify as a "group practice," the overhead expenses of, and income from, a practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Essentially, a group practice's compensation methodology must be established prospectively. Based on the comments, it is our understanding that group practice physician compensation methodologies are often established prior to the beginning of a calendar year. We are concerned that the regulations we are finalizing in this final rule may require group practices that relied on their interpretation of §411.352(i) (as it existed prior to this final rule) to adjust their compensation methodologies and, if so, they may not have sufficient time prior to the end of the current calendar year to make necessary adjustments to their compensation methodologies. As explained in our responses to comments

below, we are delaying the effective date of revised §411.352(i)(1) until January 1, 2022. Through December 31, 2021, the definition of "overall profits" will be as set forth at existing §411.352(i)(2).

We also proposed to remove the reference to Medicaid from the definition of "overall profits." We believe that the inclusion of this reference unnecessarily complicates the regulation. In the proposed rule, we noted that it is possible that the reference to designated health services payable by Medicaid is related to the definition of "referral" in the 1998 proposed rule (63 FR 1692). There, with respect to the definition of group practice, we stated that, because of our interpretation of what constitutes a "referral," an entity wishing to be considered a group practice in order to use the in-office ancillary services exception may not compensate its members based on the volume or value of referrals for designated health services for Medicare or Medicaid patients but could do so in the case of other patients (63 FR 1690). However, when the 1998 proposed policies were finalized, the definition of "referral" omitted all references to Medicaid. Nonetheless, the reference to Medicaid in final §411.352(i)(2), which was also proposed in the 1998 proposed rule (as a definition in §411.351), was not congruently omitted when finalized. We explained further in the proposed rule that, under the definition of "designated health services" at §411.351, "designated health services payable by . . . Medicaid" would not include any services. This is because the definition of "designated health services" includes only those services payable in whole or in part by Medicare. Although the qualifying language in this definition potentially allows for a different definition "as otherwise noted in this subpart," the regulations at existing §411.352(i)(2) do not expressly articulate an alternative definition for "designated health services." Rather, they simply state that the overall profits of a group include profits derived from designated health services payable by Medicare *or Medicaid*. For consistency with the definitions and regulations we proposed (and are finalizing here), we proposed to eliminate the references to Medicaid in the definition of "overall profits." We are finalizing our proposal. However, as explained in our responses to comments below, we are

delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the other revisions to the definition of "overall profits."

Our group practice regulations also articulate the general rule that overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of designated health services. In this final rule, we are finalizing our proposal to move the prefatory language of this requirement from existing §411.352(i)(2) to revised §411.352(i)(1)(iii) without substantive change. We are also finalizing our proposal to replace the varying language in the methods deemed not to relate directly to the volume or value of referrals (the deeming provisions). One of the current deeming provisions references "the group's profits" and another references "revenues" where both should reference "overall profits." We are finalizing the revision to use the term "overall profits" in both of these deeming provisions in order to articulate more clearly that the deeming provisions relate to methods for distributing a share of overall profits, not "profits" or "revenues." To avoid complications associated with the restructuring of §411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the revised definition of "overall profits."

We also proposed to revise the language related to one of the deemed permissible methods for distributing shares of overall profits by replacing "are not [designated health services] payable by any Federal health care program or private [payor]" with "and would not be considered designated health services if they were payable by Medicare." This change is reflected in revised §411.352(i)(1)(iii)(B). Current regulations provide that a share of overall profits will be deemed not to directly take into account the volume or value of referrals if revenues derived from designated health services are distributed based on the distribution of the group practice's revenues attributed to services that are not designated health services payable by "any Federal health care program or private payer." As we explained in the proposed rule, the definition of "designated health services" includes only those specified services that are payable

by Medicare (84 FR 55802). Thus, we believe a better way to reflect our policy that overall profits may be distributed based on the distribution of the group practice's revenues from services other than those in the categories of services that are "designated health services" is to deem the payment of a share of overall profits not to directly take into account the volume or value of a physician's referrals if overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services *and would not be considered designated health services if they were payable by Medicare*. We proposed to revise the regulation in this manner and renumber current §411.352(i)(2)(ii) to §411.352(i)(1)(iii)(B). We are finalizing this proposal. As noted, to avoid complications associated with the restructuring of §411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the revised definition of "overall profits."

Lastly, we did not propose to revise the third deeming provision to replace the term "revenues" with "overall profits." The third deeming provision states that a share of overall profits will be deemed not to relate directly to the volume or value of referrals if revenues derived from designated health services constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group. We did, however, propose nonsubstantive updates to the language used in this deeming provision and we are finalizing those nonsubstantive changes. Final §411.352(i)(1)(iii)(C) deems as a permissible methodology for distributing overall profits a methodology under which revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group. Again, to avoid complications associated with the restructuring of §411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective

date of the revised definition of "overall profits."

We received the following comments and our responses follow.

Comment: One commenter characterized our policy clarifications as an attempt to micromanage the organization, governance, and operation of group practices. The commenter opposed any revisions to the group practice regulations (except for the addition of new §411.352(i)(3), which the commenter found beneficial for group practices). The commenter asserted that we should not finalize the revisions to §411.352(i)(1) because the statute is not prescriptive with respect to what methodologies are permissible for distributing overall profits to physicians. Another commenter asserted that we gave no rationale to support our interpretation of the statutory term "overall profits" as meaning profits from all the designated health services of a group practice or a component of at least five physicians in the group practice (which may include all physicians in the group practice).

Response: The commenter is correct that section 1877(h)(4)(B) of the Act does not prescribe the methodology that a group practice may use to pay shares of its overall profits, provided that the share is not determined in any manner that is directly related to the volume or value of referrals by the physician to whom the share is paid. The commenter appears to confuse our proposal to clarify our interpretation of the term "overall profits" as used in section 1877(h)(4)(B) of the Act with a proposal to limit payment methodologies, although our final regulations may indeed result in some group practices modifying their physician compensation with respect to payment of shares of overall profits from designated health services.

We have long interpreted the term "overall profits" as the profits from the group practice's overall pooled revenues from designated health services (63 FR 1691). In the 1998 proposed rule, we stated that we regard "overall profits of the group" to mean all of the profits a group can distribute in any form to physicians in the group, even if the group is located in two different states or has many different locations within one state, and that we would not interpret "overall profits" as the profits that belong only to a particular specialty or subspecialty group (63

FR 1691). When finalizing our proposals related to the payment of shares of overall profits in Phase I, we stated that the Congress recognized that, in the case of group practices, revenues derived from designated health services must be distributed to the group practice physicians in some fashion, even though the physicians generate the revenue (66 FR 876). However, because the Congress wished to minimize the economic incentives to generate unnecessary referrals for designated health services, section 1877(h)(4)(B) of the Act permits a physician in the group practice to receive a share of the overall profits of the group practice, provided that the share is not determined in any manner that is directly related to the volume or value of referrals by the physician. We described our proposals in the 1998 proposed rule as requiring that profits must be aggregated at the group level and not at a component level (66 FR 908). In Phase I, we defined "share of overall profits" to mean a share of the *entire* profits of the *entire* group (or any component of the group that consists of at least five physicians) derived from designated health services (66 FR 908) (emphasis added). We stated that overall profit shares must be derived from aggregations of the entire practice or a component of the practice consisting of at least five physicians (66 FR 907). The regulation text defining "overall profits" finalized in Phase I stated that overall profits means the group's entire profits derived from "DHS" payable by Medicare or Medicaid or the profits derived from "DHS" payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. The regulation text does not accord precisely with our preamble guidance that states that overall profits means the entire profits of the entire group. It has not been revised until now.

We note that, in §411.351, the regulation text provides a definition for "designated health services (DHS)." The definition states that DHS means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in §411.351, and lists the various individual categories of services that are considered designated health services. Stakeholders may have evaluated this portion of the definition of "designated health services" within the context of the definition of "overall profits" and

interpreted "overall profits" to mean the group's entire profits from any one of the individual categories of designated health services identified in the definition at §411.351. This was not our intention when using the acronym "DHS" in the definition of "overall profits" in the regulation text at §411.352(i).

We are finalizing our proposal to clarify our longstanding interpretation of the term "overall profits" as used in section 1877(h)(4)(B) of the Act at final §411.352(i)(1)(ii). However, because the regulation text at §411.352(i) has not fully and exactly depicted the policy set forth in our Phase I preamble guidance, we are making the revisions prospective. In addition, for the reasons set forth in the response to comments below, we are delaying the effective date of the revisions to §411.352(i) until January 1, 2022.

Comment: Some commenters opposed our proposal to define "overall profits" to mean the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group, asserting that group practices should be able to distribute profits of some types of designated health services, but not others. Other commenters asked for clarification regarding whether a group practice could retain its profits (from designated health services or otherwise), or whether our revisions would require a group practice to distribute all of its profits to physicians in the group in order to qualify as a group practice.

Response: Nothing in final §411.352(i)(1)(ii) (or any other physician self-referral regulation) requires the distribution of a group practice's profits from designated health services. However, if a group practice wishes to pay shares of overall profits to any of its physicians, it must first aggregate: (1) the entire profits from the entire group; or (2) the entire profits from any component of the group that consists of at least five physicians. Once aggregated, the group practice may choose to retain some of the profits or distribute all of the profits through shares of overall profits paid to its physicians. A group practice need not treat all components of at least five physicians the same with respect to the distribution of shares of overall profits from

designated health services. That is, the group practice may choose to distribute all of the overall profits from designated health services of one of its components of five physicians to the physicians in that component, and choose to retain some or all of the overall profits from designated health services of another of its components of five physicians. Moreover, we are aware that group practices may utilize eligibility standards to determine whether a physician is eligible for a profit share, such as length of time with the group practice, whether the physician is an owner, employee, or independent contractor of the group practice, or the amount of time that the physician practices (for example, full-time or part-time). Nothing in our regulations prohibits the use of eligibility standards, provided that they do not result in the payment of a profit share that is determined in a manner that is directly related to the volume or value of a physician's referrals. In sum, a group practice may determine for itself how much of the aggregate overall profits it chooses to share with its physicians and which physicians are entitled to a share of the group practice's overall profits; however, all payments of shares of overall profits must comply with the requirements of §411.352(g) and (i).

Comment: A number of commenters opposed our proposal to define "overall profits" from designated health services to mean the profits from all the designated health services of the group practice (or a component of the group that consists of at least five physicians), asserting that group practices should be permitted to distribute the profits from designated health services on a service-by-service basis, which some of the commenters referred to as "split pooling." These commenters variously stated that service-by-service profit shares would allow physicians to receive profits shares more closely related to the services they referred, their specialty, the services they provide, or the expenses they have personally incurred. One of the commenters explained that, for large or multispecialty group practices, in particular, different practice locations or specialties commonly use ancillary designated health services to varying degrees in connection with the delivery of care in their location or specialty, and another stated that the proposed "limits" may inadvertently penalize the "practices" within a group that are more

profitable due to efficiency and reward those that are less efficient. Another of the commenters asserted that a service-by-service allocation methodology aligns compensation with the physicians who are furnishing professional services in conjunction with designated health services and incurring the related expenses. The commenter complained that not allowing what it referred to as "pooling by designated health service," physicians who have no treatment involvement in the designated health services are nonetheless rewarded financially. A different commenter gave the example of a subset of physicians within a group practice that agree to assume all of the costs of expensive diagnostic testing equipment when there is a dispute within the group as to whether to purchase the equipment. The commenter asserted that service-by-service distribution of profits is appropriate so that the physicians who bear the cost of the equipment also receive the profits arising from the use of the equipment. One commenter stated that distributing profits from designated health services on a service-by-service basis is not an issue, but offered no reason why this is the case. In contrast, several commenters commended CMS for proposing the clarifying language at §411.352(i)(1)(ii) and supported finalizing the regulatory revisions.

Response: Section 1877(h)(4)(B) of the Act permits a group practice to pay a physician in the group practice a share of overall profits of the group. In Phase I, we shared our interpretation that the term "overall profits" means the *entire* profits of the *entire* group (or any component of the group that consists of at least five physicians) derived from designated health services (66 FR 908) (emphasis added). The proposed revisions at §411.352(i)(1)(ii), which we are finalizing in this final rule, incorporate this long-held interpretation. Commenters provided no justification for their preferred interpretation of the statutory term "overall profits"—which makes no reference to designated health services as the services that generated the profits—as meaning the profits from any one type of designated health service.

We remind readers that, in order to qualify as a group practice, a physician practice must meet all the requirements set forth in §411.352. These include that the practice is a unified

business with centralized decision making by a body representative of the practice that maintains effective control over the practice's assets and liabilities (including, but not limited to, budgets, compensation, and salaries) and consolidated billing, accounting, and financial reporting. In addition, revenues from patient care services must be treated as receipts of the practice. Certain of the justifications for the commenters' assertions that we should permit a group practice to share the profits from designated health services on a service-by-service basis call into question whether a physician practice that operates as described in the comments could satisfy the unified business test at §411.352(f) or, potentially, whether the revenues from patient care services are treated as receipts of the practice, as required at §411.352(d)(1).

As we stated in Phase I, the Congress intended to confer group practice status on *bona fide* group practices and not on loose confederations of physicians who come together substantially in order to capture the profits from referrals of designated health services protected under the exception for in-office ancillary services (66 FR 875). For that reason, we established the unified business test at §411.352(f). To meet the unified business test, a group practice must be organized and operated on a *bona fide* basis as a single integrated business enterprise with legal and organizational integration (66 FR 906). We designed the group practice rules at §411.352 to preclude group practice status for loose confederations of physicians that are group practices in name, but not operation. In Phase I, in response to a comment on our 1998 proposed rule, we stated that we generally agree that a group practice should consist of a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan, and that this aspect of a group practice is addressed by the unified business test at §411.352(f) (66 FR 898). The essential elements of a unified business are: (1) centralized decision making by a body representative of the practice that maintains effective control over the group's assets and liabilities (including budgets, compensation, and salaries); and (2) consolidated billing, accounting, and financial reporting. As we stated in Phase I, group practices may distribute the

revenues from services that are not designated health services in any manner they wish. The unified business test permits group practices to use cost- and location-based accounting with respect to services that are not designated health services, and, in some cases, with respect to services that are designated health services if the compensation method is not directly related to the volume or value of the physician's referrals and other conditions are satisfied (66 FR 895). However, if a physician practice's payment methods do not indicate a unified business (or indicate a business that is unified solely with respect to the provision of designated health services), the physician practice may not qualify as a group practice under section 1877(h)(4) of the Act and §411.352 (66 FR 907).

With respect to the specific comments regarding the need for the payment of profit shares on a service-by-service basis, we assume the reference to "practices" within a group practice pertains to specialties or locations of the group practice. We remind parties that, if a "practice" within a group practice is comprised of five or more physicians, the group practice may aggregate the profits from all the designated health services of the component and pay shares of the overall profits to the physicians in the component, provided that the group practice satisfies all the requirements of §411.352, including §411.352(g) and (i). If a "practice" within a group practice is not comprised of at least five physicians, the group practice would have to include additional physicians in the component and aggregate the profits from all the designated health services of the component.

Comment: One commenter stated that disparate state certificate of need and self-referral laws result in a patchwork of permitted and prohibited designated health services within different segments or practice locations of the same group practice. The commenter suggested that requiring group practices that operate in multiple states to aggregate all their profits from designated health services will be challenging, but did not elaborate on what those challenges are.

Response: Group practices may use the "component of five" rule to aggregate and

distribute profit shares. We think that most large group practices, including those that operate in more than one state, will be able to use the component of five rule to establish workable profit distribution methodologies to address issues related to the distribution of profits from designated health services for which all physicians in the group do not make referrals and discrepancies in the types of designated health services furnished among practice locations due to state certificate of need and self-referral laws.

Comment: Some of the commenters that objected to the proposed revisions to the group practice rules regarding the distribution of shares of overall profits noted that our proposals, if finalized, would require changes to the internal compensation practices in many medical groups. Some of these commenters requested that, if we finalize the proposed changes to the regulation text, we provide a sufficient timeframe of at least one year for all group practices to revise their compensation methodologies. Another commenter was generally supportive of the revisions to §411.352(i), but expressed concern about the time and effort involved in revising compensation arrangements for group practices that have separated profits by service type until now.

Response: We agree with the commenters that parties may need time to revise compensation methodologies and arrangements for group practice physicians. For that reason, we are delaying the effective date of final §411.352(i)(1) until January 1, 2022. We believe this will provide group practices sufficient time to evaluate their current compensation methodologies for compliance with final §411.352(i)(1) and make necessary revisions. Through December 31, 2021, the definition of "overall profits" will be as set forth at existing §411.352(i)(2). We note that the delayed effective date applies to all revisions at final §411.352(i)(1), including the removal of the reference to "Medicaid." Also, to avoid complications associated with the restructuring of §411.352(i), we are also delaying the effective date of final §411.352(i)(2) and (4) to coincide with the effective date of the revised definition of "overall profits."

Comment: One commenter was concerned that new §411.352(i)(3) would negatively

impact physicians who are employees or independent contractors of a group practice, noting that only group practice owners are able to share in the group's profits.

Response: The commenter is mistaken. Nothing in section 1877 of the Act or our physician self-referral regulations limits the payment of a share of overall profits to owners of a group practice. Under section 1877(h)(4)(B) of the Act and our regulations, any physician in the group may be paid a share of overall profits of the group practice.

Comment: One commenter requested confirmation that a group practice may designate more than one component of at least five physicians for the allocation of overall profits from designated health services as long as the profits from all the designated health services referred by the physicians in a component are aggregated and the profits shared with the physicians in that component. The commenter also sought confirmation that the various components could be established by grouping together physicians of the same specialty or by any other pooling mechanism, as long as each component consists of at least five physicians.

Response: A group practice may designate more than one component of at least five physicians for the allocation of overall profits from designated health services as long as the profits from all the designated health services referred by the physicians in a component are aggregated and the profits shared with the physicians in that component. Provided that the share of overall profits received by a physician is not determined in any manner that is directly related to the volume or value of the physician's referrals, a group may establish components of at least five physicians by including physicians with similar practice patterns, who practice in the same location, with similar years of experience, with similar tenure with the group practice, or who meet other criteria determined by the group practice. We continue to believe, as we stated in Phase I, that a threshold of at least five physicians is likely to be broad enough to attenuate the ties between compensation and referrals of designated health services (66 FR 909).

Comment: Some commenters asked whether a group practice must use a single methodology for distributing the shares of overall profits attributable to each of its designated

components of five physicians. In other words, if a group practice has three designated "pools" of at least five physicians (components A, B, and C), must the group practice use the same methodology for distributing the profits for components A, B, and C? The commenters referenced the example in the proposed rule where we stated that a group practice may not distribute the profits from clinical laboratory services to one subset of its physicians or using a particular methodology and distribute the profits from diagnostic imaging to a different subset of physicians (or the same subset of its physicians but using a different methodology) (84 FR 55801).

Response: The example provided in the proposed rule was intended to illustrate the application of the policy that does not permit service-by-service distribution of profits from designated health services (which one of the commenters referred to as "split pooling"). However, as noted by the commenters, the statement could appear to prohibit the use of different distribution methodologies for different components of five physicians in a group practice. To the extent that parties understood this to be our policy and an indication of how we would interpret the regulations, we are clarifying that a group practice may utilize different distribution methodologies to distribute shares of the overall profits from all the designated health services of each of its components of at least five physicians, provided that the distribution to any physician is not directly related to the volume or value of the physician's referrals. To illustrate, assume a group practice comprised of 15 physicians furnishes clinical laboratory services, diagnostic imaging services, and radiation oncology services. Assume further that the group practice has divided its physicians into three components of five physicians (component A, component B, and component C) for purposes of distributing the overall profits from the designated services of the group practice. Under the final regulations, for each component, the group practice must aggregate the profits from all the designated health services furnished by the group and referred by any of the five physicians in the component. The group practice may distribute the overall profits from all the designated health services of component A using one methodology (for

example, a per-capita distribution methodology), distribute the overall profits from all the designated health services of component B using a different methodology (for example, a personal productivity methodology in compliance with §411.352(i)(1)(iii)(B)), and distribute the overall profits from all the designated health services of component C using a third methodology that does not directly relate to the volume or value of the component physicians' referrals (or the methodology used for component A or B). However, a group practice must utilize the same methodology for distributing overall profits for every physician in the component. That is, using the illustration above, the group practice must use the per-capita distribution methodology for each physician in component A, the personal productivity methodology for each physician in component B, and the same methodology (whichever it utilizes) for each physician in component C. As described in our responses to other comments in this section II.C.2.b., the group practice could not use different methodologies to distribute the profits of the different types of designated health services within a component.

Comment: Most commenters that commented on our proposals to revise the group practice regulations supported the removal of the reference to Medicaid from the definition of "overall profits" and the clarifying discussion in the proposed rule.

Response: As stated above, we are finalizing our proposal to revise §411.352(i). However, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the other revisions to the definition of "overall profits."

(3) Productivity Bonuses

For consistency with the regulations related to the payment of a share of overall profits, we proposed to revise the introductory language in the deeming provisions for productivity bonuses at renumbered §411.352(i)(2)(ii) to state that a productivity bonus must be calculated in a reasonable and verifiable manner. We also proposed to renumber the regulation that lists the deeming provisions related to the payment of productivity bonuses from §411.352(i)(3) to §411.352(i)(2) and proposed minor changes to the deeming provisions themselves. In addition,

we proposed to update the language of existing §411.352(i)(1) (relocated to §411.352(i)(2)(i)) to remove "or both" as unnecessary because the word "or" is interpreted to mean the conjunctive "and" as well as the disjunctive "or." We stated that groups may continue to pay a productivity bonus based on services that the physician has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus does not directly take into account the volume or value of the physician's referrals (except that the bonus may directly take into account the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

To correct a misstatement about the nature of §414.22 of this chapter included in existing §411.352(i)(3)(i), we proposed to revise the deeming provision related to the physician's total patient encounters or relative value units to state that a productivity bonus will be deemed not to relate directly to the volume or value of a physician's referrals if it is based on the physician's total patient encounters or the relative value units personally performed by the physician. We sought comment in the proposed rule regarding whether this provision should limit the methodology to physician work relative value units as defined at §414.22(a) or whether any personally-performed relative value units should be an acceptable basis for calculating a productivity bonus that is deemed not to relate directly to (that is, directly take into account) the volume or value of referrals. The regulation that deems a productivity bonus not to directly take into account the volume or value of a physician's referrals under certain circumstances includes a provision similar to that at final §411.352(i)(1)(iii)(B). Therefore, we proposed corresponding revisions at §411.352(i)(2)(ii)(B) (to be renumbered from current §411.352(i)(3)(ii)) that would deem the payment of a productivity bonus not to directly relate to (or, as explained in this section II.C.2.b(1), take into account) the volume or value of a physician's referrals if the services on which the productivity bonus is based are not revenues derived from designated health services and would not be considered designated health services if they were payable by Medicare. Finally, we proposed to replace the term "allocated" with "distributed" at (redesignated)

§411.352(i)(1)(iii)(C) as the latter term reflects the actual payment of the profit share (84 FR 55802). We are finalizing all of our proposals related to the payment of productivity bonuses by a group practice. However, to avoid complications associated with the restructuring of §411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates at final §411.352(i)(2) until January 1, 2022 to coincide with the effective date of the revised definition of "overall profits."

We received the following comments and our responses follow.

Comment: One commenter requested that we permit a physician to receive a productivity bonus based on services that the physician or the physician's "care team" has personally performed, provided that the productivity bonus is not determined in any manner that is directly related to the volume or value of the physician's referrals of designated health services.

Response: Whether or not a productivity bonus paid to a physician in a group practice would violate the prohibition on compensation that takes into account the volume or value of the physician's referrals at §411.352(g) depends on the basis for the productivity bonus. To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on services personally performed by the physician (which are not referrals, even if they are designated health services), the productivity bonus (or the portion of the productivity bonus) would not violate §411.352(g). To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on services performed by a member of the physician's care team that are not designated health services, the productivity bonus (or the portion of the productivity bonus) would not violate §411.352(g). To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on designated health services ordered by the physician and furnished by members of the physician's care team "incident to" the physician's services and billed to Medicare as such, the

productivity bonus (or the portion of the productivity bonus) would not violate §411.352(g). To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on designated health services ordered by the physician and furnished by members of the physician's care team, but not furnished "incident to" the physician's services, the productivity bonus (or the portion of the productivity bonus) may only indirectly relate to the volume or value of the physician's referrals for the designated health services furnished by the members of the physician's care team.

Comment: Most commenters that commented on our solicitation regarding whether the deeming provision related to the relative value units personally performed by a physician did not support a limitation of this deeming methodology to only the physician's relative value units as defined at §414.22. Commenters urged us to finalize our proposal to include as a deemed permissible productivity bonus methodology one that is based on the physician's total patient encounters. One commenter urged us not to make any revision to this regulation, stating that it works as currently structured and revising it would create additional regulatory burden.

Response: We are finalizing §411.352(i)(2)(ii)(A) as proposed. Under our longstanding regulations, as well as those proposed, a physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed or services "incident to" such personally performed services (or both). The productivity bonus may not be determined in any manner that is directly related to the volume or value of referrals by the physician, except that the productivity bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services. The regulation at §414.22(a) relates to the establishment of physician work RVUs. The regulation at §414.22(b) relates to the computation of practice expense RVUs. The regulation at §414.22(c) relates to the computation of malpractice expense RVUs. We believe the reference to §414.22 generally to describe a "physician's RVUs" is misplaced in our current regulations. Our clarification is intended only to marry the general requirement for productivity

bonuses based on services that are personally performed by a physician with the deeming provision that allows productivity bonuses based on total patient encounters or RVUs. It is not intended to, nor do we believe it will, limit the payment of productivity bonuses currently permissible under our regulations. Therefore, we see no reason why the revisions finalized at §411.352(i)(2)(ii)(A) would create additional regulatory burden for group practices.

D. Recalibrating the Scope and Application of the Regulations

As we stated previously and in our Phase I rulemaking, our intent in implementing section 1877 of the Act was "to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent" (66 FR 860). One purpose of this final rule is to reexamine our current regulations to assess whether we have held true to that intention. In doing so, we have considered our own experience in administering the SRDP, stakeholder interactions, comments to the CMS RFI and to our proposed rule, and our experience working with our law enforcement partners. In the proposed rule, we proposed revisions to, including deletions of, certain requirements in our regulatory exceptions. In this section II.D. of the final rule, we explain which of our proposals to recalibrate the scope and application of the physician self-referral regulations that we are finalizing and any modifications resulting from our consideration of the comments on the proposed rule.

1. Decoupling the Physician Self-Referral Law from the Federal Anti-Kickback Statute and Federal and State Laws or Regulations Governing Billing or Claims Submission

Section 1877 of the Act established numerous exceptions to the statute's referral and billing prohibitions and granted the Secretary authority to establish regulatory exceptions for other financial relationships that do not pose a risk of program or patient abuse. The majority of the exceptions issued using the Secretary's authority under section 1877(b)(4) of the Act (which we often refer to as the "regulatory exceptions") require that the arrangement does not violate the anti-kickback statute. Most of these exceptions also require that the arrangement does not violate any Federal or State law or regulation governing billing or claims submission.

In Phase I, we stated that the requirements pertaining to the anti-kickback statute and billing or claims submission are necessary in regulatory exceptions to ensure that the excepted financial relationships do not pose a risk of program or patient abuse (66 FR 863). Even though we acknowledged that the physician self-referral law and the anti-kickback statute are different statutes, we were concerned that, if the regulatory exceptions did not require compliance with the anti-kickback statute, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception. In Phase II, we stated our interpretation that the statutory "no risk" standard is not limited to risks as determined under the physician self-referral law (69 FR 16108). We added that many arrangements that might otherwise warrant an exception under section 1877 of the Act—a strict liability statute—pose some degree of risk under the anti-kickback statute; these arrangements cannot, therefore, be said to pose *no* risk. Similarly, we stated that some arrangements that may be permissible under the physician self-referral law could pose a risk of violating certain laws pertaining to billing or claims submission. Therefore, we concluded that the regulatory exceptions created using the Secretary's authority under section 1877(b)(4) of the Act must require that the excepted financial relationship not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

A substantial number of CMS RFI commenters expressed opposition to the continued coupling of the physician self-referral law with the anti-kickback statute and other billing and claims submission laws, explaining the significant burden associated with the inclusion of these requirements in regulatory exceptions to the physician self-referral law. CMS RFI commenters noted that the physician self-referral law is a strict liability statute and compliance with each element of an exception is mandatory if the entity wishes to submit a claim for designated health services referred by a physician with which it has a financial relationship, while the anti-kickback statute is an intent-based criminal statute and compliance with a safe harbor is not required. These commenters asserted that the inclusion of a requirement for compliance with the

anti-kickback statute is misplaced in an exception to the physician self-referral law because it introduces an intent-based requirement into a strict liability statute. The commenters further noted that this requirement can make it unreasonably difficult for entities to meet their burden of proof under §411.353(c)(2) that a referral and claim for designated health services does not violate the physician self-referral law. CMS RFI commenters also noted that the requirement for compliance with the anti-kickback statute and the requirement pertaining to Federal or State laws or regulations governing billing or claims submission are not necessary, because parties remain subject to these laws or regulations, regardless of whether their financial relationships otherwise comply with the physician self-referral law. As discussed below, commenters on the proposed rule have many of these same concerns.

As we stated in the proposed rule, based on our experience working with our law enforcement partners in reviewing conduct that implicates the physician self-referral law and other Federal fraud and abuse laws, when a compensation arrangement violates the intent-based criminal anti-kickback statute, it will likely also fail to meet one or more of the key requirements of an exception to the physician self-referral law (84 FR 55803). That is, the compensation in such cases likely is not fair market value or is determined in a manner that takes into account the volume or value of the physician's referrals or other business generated for the entity. As noted in the proposed rule, since the Phase I regulation was issued, we are unaware of any instances of noncompliance with the physician self-referral law that turned solely on an underlying violation of the anti-kickback statute (or any other Federal or State law governing billing or claims submission). We also emphasized in the proposed rule and reiterate here that, although we were considering removing the requirement that the arrangement does not violate the anti-kickback statute from some or all of the regulatory exceptions, we believe that the Secretary has the authority under the statute to impose a requirement that the financial relationship not violate the anti-kickback statute or any other requirement if the Secretary determines it necessary and appropriate to ensure that an excepted financial relationship does not pose a risk of program or

patient abuse. We also stated that we intend to monitor excepted financial relationships, and that we may propose in a future rulemaking to reinstate the requirements for deletion in some or all of the exceptions issued pursuant to the Secretary's statutory authority if we determine such requirements are necessary or appropriate to protect against program or patient abuse (84 FR 55802 through 55803).

Based on our experience working with our law enforcement partners since our regulations were finalized, as well as comments received in response to the CMS RFI, we stated in the proposed rule that we no longer believe that it is necessary or appropriate to include requirements pertaining to compliance with the anti-kickback statute and Federal and State laws or regulations governing billing or claims submission as requirements of the exceptions to the physician self-referral law. We noted further that the Congress did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the statute or its subsequent revision in order to avoid the law's referral and billing prohibitions. Therefore, we proposed to remove from the exceptions in 42 CFR part 411, subpart J the requirement that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission wherever such requirements appear. Specifically, we proposed to remove the following sections from our regulations: §411.353(f)(1)(iii); §411.355(b)(4)(v), (e)(1)(iv), (f)(3), (f)(4), (g)(2), (g)(3), (h)(2), (h)(3), (i)(2), (i)(3), (j)(1)(iv); §411.357(e)(4)(vii), (j)(3), (k)(1)(iii), (l)(5), (m)(7), (p)(3), (r)(2)(x), (s)(5), (t)(3)(iv), (u)(3), (w)(12), (x)(1)(viii), and (y)(8). We also proposed to delete the following clause from §411.357(e)(6)(i) and (n): ", provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission." Finally, we proposed to remove the definition of "does not violate the anti-kickback statute" in §411.351. We noted that the exceptions for referral services at §411.357(q) and obstetrical malpractice subsidies at §411.357(r)(1) provide that arrangements satisfy the requirements of the exception if the arrangements comply with the

requirements of certain specified safe harbors to the anti-kickback statute, and stated that our proposal did not apply to or affect these provisions.

After reviewing comments on our proposed rule, we no longer believe that it is appropriate to remove the requirement that the arrangement does not violate the anti-kickback statute from the exception for fair market value compensation at §411.357(l), and we are not finalizing our proposal to remove that requirement at §411.357(l)(5). We are finalizing our proposal to remove the requirement that the arrangement does not violate the anti-kickback statute from all other regulatory exceptions, and to remove requirements pertaining to Federal or State laws or regulations governing billing or claims submissions from all the regulatory exceptions, including §411.357(l)(5). In the proposed rule, we noted that the Congress did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the statute or its subsequent revision in order to avoid the physician self-referral law's referral and billing prohibitions (84 FR 55803). However, the regulatory exception for fair market value compensation at §411.357(l) applies to many arrangements that also could be protected by a statutory exception. In particular, as explained in section II.D.10 of this final rule, we are finalizing our proposal to permit arrangements for the lease of office space to be excepted under §411.357(l). The statutory exception for the rental of office space at section 1877(e)(1) of the Act and §411.357(a) of our regulations requires, among other things, that the space rented or leased does not exceed that which is reasonable or necessary for the legitimate purposes of the lease and is used exclusively by the lessee when being used by the lessee. There are similar requirements in the statutory exception for the rental of equipment at §411.357(b)(2). The regulatory exception for fair market value compensation, on the other hand, does not include such requirements. To the extent that the exception for fair market value compensation does not contain substitute requirements or safeguards, there is a possibility that certain potentially abusive arrangements that would not be permitted under a statutory exception could be protected by this regulatory exception.

We believe that requiring that the arrangement does not violate the anti-kickback statute in the exception for fair market value compensation at §411.357(l) serves as a substitute safeguard, in lieu of certain safeguards that are included in the statutory exceptions but omitted from §411.357(l). The exclusive use requirement in the statutory exceptions for the rental of office space and equipment, for example, prevents sham or "paper" leases, where a lessor receives payment from a lessee for space that the lessor continues to use (63 FR 1714 and 69 FR 16086). We believe that sham or paper lease arrangements would likely violate the anti-kickback statute. Therefore, the requirement at §411.357(l)(5) that the arrangement not violate the anti-kickback statute provides a substitute safeguard for the statutory exclusive use requirement and serves to prevent program or patient abuse. Without the requirement that the arrangement not violate the anti-kickback statute, sham lease arrangements or other abusive arrangements could potentially be excepted under §411.357(l), and the exception for fair market value compensation would not satisfy the requirement at section 1877(b)(4) of the Act that financial relationships protected by the exception do not pose a risk of program or patient abuse. On the other hand, we are no longer convinced that the requirement at §411.357(l)(5) that an arrangement must not violate Federal or State laws or regulations governing billing or claims submission is needed as a substitute safeguard to prevent program or patient abuse, and we are therefore finalizing the proposal to remove that requirement from §411.357(l)(5). In sum, the exception for fair market value compensation offers greater flexibility than certain overlapping statutory exceptions insofar as it omits some statutory requirements, but the greater flexibility could, in certain instances, increase the risk of program or patient abuse. Therefore, the requirement that the arrangement does not violate the anti-kickback statute should not be deleted from §411.357(l)(5).

We emphasized in the proposed rule and reiterate here that our final rule in no way affects parties' liability under the anti-kickback statute. Indeed, the Congress clarified when enacting section 1877 of the Act that "any prohibition, exemption, or exception authorized under

this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act" (H. Report 101-386, 856 (1989)). Most importantly, the fact that a financial relationship satisfies the requirements of an applicable exception to the physician self-referral law does *not* entail that the financial relationship does not violate the anti-kickback statute. (*See* 66 FR 879.) Similarly, compliance with the anti-kickback statute does not entail compliance with the physician self-referral law. To the extent that a financial relationship is governed by other laws or regulations, our action does not affect the parties' compliance obligations under those other laws or regulations. Specifically, claims submitted to the Medicare program must comply with all laws, regulations, and other requirements governing billing and claims submission.

After reviewing the comments on the proposed rule, we are finalizing our proposal to remove the requirement that an arrangement not violate the anti-kickback statute from all the regulatory exceptions except the exception for fair market value compensation at §411.357(l). Because this requirement will remain in §411.357(l), we are not finalizing our proposal to delete the definition of "does not violate the anti-kickback statute" at §411.351. We are finalizing without modification our proposal to remove from all the applicable regulatory exceptions the requirement that an arrangement not violate any Federal or State law or regulation governing billing and claims submissions.

We received the following comments and our responses follow.

Comment: Nearly all the commenters that addressed the proposal favored removing provisions requiring that the arrangement does not violate the anti-kickback statute or Federal and State laws or regulations governing billing and claims submissions from the regulatory exceptions. The commenters stated that the requirements are unnecessary because parties must comply with these laws independently of the physician self-referral law. One of these commenters stated that removing the requirement that an arrangement that satisfies an exception to the physician self-referral law must also fit within a safe harbor under the anti-kickback is a

welcome streamlining of the regulations. Some commenters stressed that the incorporation of the intent-based Federal anti-kickback statute into the strict-liability framework of the physician self-referral law causes confusion and compliance risk without affording any additional protection of the Medicare program. Commenters in favor of removing the requirement that the arrangement does not violate the anti-kickback statute also requested that CMS delete the definition of "does not violate the anti-kickback statute" in §411.351. One of these commenters maintained that the definition is circular, because it includes the phrase "does not violate the anti-kickback provision in section 1128B(b) of the Act." Lastly, one commenter generally opposed removing the requirement that the arrangement does not violate the anti-kickback statute from the regulatory exceptions, stating that finalizing the proposal would lead to program or patient abuse.

Response: We agree with the majority of the commenters that the requirement that an arrangement not violate any Federal or State law or regulation governing billing or claims submission should be removed from all the regulatory exceptions. Parties have an independent obligation to follow such laws, and we no longer believe that the Secretary must require compliance with such laws and regulations to ensure that financial relationships excepted under a regulatory exception do not pose a risk of program or patient abuse.

With respect to the anti-kickback statute, we continue to believe that, as a general matter, the requirement that the arrangement does not violate the anti-kickback statute in most regulatory exceptions would not further protect against program or patient abuse because the parties to the compensation arrangement are already required to comply with all Federal laws, including the anti-kickback statute. We understand the concerns raised by commenters that inclusion of the intent-based anti-kickback statute in the strict liability framework of the physician self-referral law may increase the burden of compliance with the physician self-referral law, and we are finalizing our proposal to remove this requirement from all regulatory exceptions except the exception at §411.357(l) for fair market value compensation. As previously noted in this final

rule, the requirement that the arrangement does not violate the anti-kickback statute in §411.357(l)(5) is an important substitute requirement for certain statutory requirements that would otherwise apply to arrangements to which the regulatory exception at §411.357(l) is applicable, such as the exclusive use requirement for leases of office space and equipment. Given the current requirements in the exception for fair market value compensation, we are not convinced that it is appropriate to protect leases of office space and certain other arrangements under §411.357(l) without the requirement that the arrangement does not violate the anti-kickback statute. Thus, we are not finalizing our proposal to remove this requirement from §411.357(l)(5).

Because we are not finalizing our proposal to remove the requirement that the arrangement does not violate the anti-kickback statute from the exception for fair market value compensation, we are not deleting the definition of "does not violate the anti-kickback statute" at §411.351. We note that the requirement that the arrangement does not violate the anti-kickback statute at §411.357(l)(5) does not and never has required that an arrangement fit into a safe harbor under the anti-kickback statute; rather the requirement remains that the arrangement does not violate the anti-kickback statute. As the term is defined at §411.351, an arrangement "does not violate the anti-kickback statute" if it meets a safe harbor under the anti-kickback statute, has been specifically approved by OIG in a favorable advisory opinion issued to a party to the particular arrangement with respect to the particular arrangement (and not a similar arrangement), or does not violate the anti-kickback provisions in section 1128B(b) of the Act. We did not propose and are not finalizing any specific substantive modifications of this definition.

Lastly, we are taking this opportunity to reiterate that the Secretary retains the authority to impose, in future rulemaking, requirements pertaining to the anti-kickback statute and Federal or State laws or regulations governing billing or claims submissions in some or all of the regulatory exceptions issued under section 1877(b)(4) of the Act, if the Secretary determines that

such requirements are necessary to prevent program or patient abuse. We intend to monitor excepted financial relationships, and we may propose in a future rulemaking to include the requirements in some or all of the exceptions issued pursuant to the Secretary's authority if we determine such requirements are necessary or appropriate to protect against program or patient abuse.

2. Definitions (§411.351)

a. Designated Health Services

Section 1877(1)(A) of the Act provides that, unless the requirements of an applicable exception are satisfied, if a physician (or an immediate family member of a physician) has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of a designated health service for which payment may otherwise be made under Title XVIII of the Act (that is, Medicare). The referral prohibition is codified in our regulations at §411.353(a). In the 1998 proposed rule, we interpreted the phrase "designated health service for which payment otherwise may be made" broadly to mean "any designated health service that ordinarily 'may be' covered under Medicare (that is, that could be a covered service under Medicare in the community in which the service has been provided) for a Medicare-eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for that particular individual (for example, the individual may not have met his or her deductible)" (63 FR 1694). Our definition of the term "designated health services" in the 1998 proposed rule was consistent with this broad interpretation of the referral prohibition.

Section 1877(h)(6) of the Act defines "designated health services" by listing various categories of services that qualify as designated health services (for example, clinical laboratory services). In the 1998 proposed rule, we stated that a designated health service remains such "even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes" (63 FR 1673). By way of example, we stated that clinical laboratory services that are provided by a skilled nursing facility (SNF) and

reimbursed as part of the SNF composite rate would remain designated health services for purposes of section 1877 of the Act, even though SNF services are not listed as designated health services at section 1877(h)(6) of the Act and Medicare would not separately pay for the clinical laboratory service furnished by the SNF. The now-deleted exception at §411.355(d), which was first finalized in the 1995 final rule, served as a counterbalance to the broad interpretation of designated health services that was proposed in the 1998 proposed rule. As finalized in the 1995 final rule, §411.355(d) provided that the referral prohibition in §411.353 did not apply to services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice, if payment for those services was included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge (60 FR 41980). We explained that the application of a composite rate payment "constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered" (60 FR 41940). In the 1998 proposed rule, we proposed an amendment to §411.355(d) that would have excepted services furnished under other payment rates that that the Secretary determines provide no financial incentive for under- or overutilization or any other risk of program or patient abuse (63 FR 1666). However, in Phase I, instead of expanding the exception at §411.355(d) to include services furnished under other payment rates, we narrowed the definition of "designated health services" to exclude certain services that are paid as part of a composite rate, and solicited comments on whether the exception at §411.355(d) was still necessary in light of the narrowed definition of "designated health services" (66 FR 923 through 924). We ultimately determined in Phase II that §411.355(d) was no longer necessary, given the change to the definition of "designated health services" finalized in Phase I, and we removed the exception from our regulations (69 FR 16111).

As finalized in Phase I, the definition of "designated health services" includes only designated health services payable, in whole or in part, by Medicare, and does not include

services that would otherwise constitute designated health services, but that are reimbursed by Medicare as part of a composite rate, except to the extent that the services are specifically identified in §411.351 and are themselves payable through a composite rate. SNF services paid by Medicare under the Part A composite rate (that is, the Skilled Nursing Facility Prospective Payment System (SNF PPS)), for example, are not designated health services, even if the bundle of services includes services that would otherwise be designated health services, such as clinical laboratory services.[9] In contrast, although home health and inpatient and outpatient hospital services are paid under a composite rate, they remain designated health services under the definition finalized in Phase I because section 1877(h)(6) of the Act explicitly lists these services as designated health services. We explained in Phase I that our ultimate definition of "designated health services" was based on issues of statutory construction (66 FR 923). In particular, commenters on the 1998 proposed rule asserted that the definition of designated health services would have expanded the list of services that are considered to be designated health services beyond the services explicitly listed at section 1877(h)(1) of the Act. For example, clinical laboratory services furnished by a SNF and reimbursed under the SNF PPS would have been considered designated health services under the definition, even though SNF services are not included in the statutory list of designated health services. The commenters maintained that, where the Congress intended the physician self-referral law to cover specific services, including services that are paid under a composite rate such as home health services, it did so by explicitly listing the services at section 1877(h)(6) of the Act. We agreed and finalized the definition of "designated health services" to include only those services paid under a composite rate that are explicitly listed at section 1877(h)(1) of the Act; that is, home health services and inpatient and outpatient hospital services.

[9] ESRD services are also reimbursed on a composite rate, and thus are not considered to be designated health services. In this context, we refer readers to the CY 2018 ERSD PPS Final Rule, where we explained that, for purposes of the physician self-referral law, the "composite rate" for ESRD services is interpreted as the per-treatment payment amount (82 FR 50751). To the extent that outpatient prescription drugs are included in the ESRD per-treatment payment amount, they do not qualify as designated health services.

As we stated in the proposed rule, in light of our experience with the SRDP and our review of the comments to the CMS RFI, we reviewed the regulatory history of our definition of "designated health services" at §411.351 to identify whether further clarification regarding what constitutes a designated health service is necessary (84 FR 55805). We proposed to revise the definition of "designated health services" to clarify that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). To illustrate, suppose that, after an inpatient has been admitted to a hospital under an established Medicare Severity Diagnosis Related Group (MS-DRG), the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission, and the specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of Medicare payment under the IPPS has already been established by the MS-DRG (diagnostic imaging is bundled into the payment for the inpatient admission), and, unless the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the MS-DRG. Moreover, insofar as the provision of the X-ray does not affect the rate of payment, the physician has no financial incentive to over-prescribe the service. As illustrated here, we do not believe that the X-ray is a designated health service that is payable, in whole or part, by Medicare, and our definition of "designated health services" at §411.351 would exclude this service from the definition of designated health services, even though it falls within a category of services that, when billed separately, would be "designated health services." Thus, assuming the specialist had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception to the physician self-referral law at the time the X-ray was ordered, the inpatient hospital services would not be tainted by the unexcepted financial relationship, and the hospital would not be prohibited from billing Medicare for the admission. On the other hand, if the physician who ordered the inpatient

hospital admission had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception, §411.353(b) would prohibit the hospital for billing for the inpatient hospital services. In the proposed rule, we stated that we are aware that not all hospitals are paid under the IPPS (84 FR 55805). We solicited comments as to whether our proposal regarding certain hospital services that are not "designated health services payable, in whole or in part, by Medicare" should be extended to analogous services provided by hospitals that are not paid under the IPPS, and, if so, how we should effectuate this change in our regulation text. We also stated that, although hospital outpatient services are also paid under a composite rate, we believe that there is typically only one ordering physician for outpatient services, and it would be rare for a physician other than the ordering physician to refer an outpatient for additional hospital outpatient services that are compensated within the same ambulatory payment classification (APC) under the Hospital Outpatient Prospective Payment System (OPPS). For this reason, we did not propose to apply the modified definition of "designated health services" at §411.351 to outpatient hospital services paid under the OPPS.

In this final rule, we are extending the proposed policy to apply to hospital services furnished to inpatients that are paid under additional prospective payment systems. Specifically, we are revising the definition of "designated health services" to state that, for services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS): (i) Acute Care Hospital Inpatient (IPPS); (ii) Inpatient Rehabilitation Facility (IRF PPS); (iii) Inpatient Psychiatric Facility (IPF PPS); or (iv) Long-Term Care Hospital (LTCH PPS). For the reasons explained in our response to comments below, we are not extending the proposed policy to apply to hospital services furnished to outpatients. We are also making nonsubstantive revisions to the definition of "designated health services" for consistency regarding the terms "paid" and "payable" and making a minor grammatical change.

We received the following comments and our responses follow.

Comment: The vast majority of commenters that commented on this proposal supported our proposal to exclude from the definition of "designated health service payable, in whole or in part, by Medicare" those services furnished by a hospital to an inpatient that do not affect the amount of Medicare's payment to the hospital under the IPPS. Commenters indicated that the revision would bring clarity to hospitals when assessing compliance with the physician self-referral law and calculating potential overpayments for violations of the law. Some commenters highlighted the onerous compliance burdens associated with quantifying a potential overpayment when the financial relationship that does not satisfy the requirements of an applicable exception is with a physician other than the physician who referred the patient for the inpatient admission. Nearly all of the commenters that supported our proposal requested that we expand the policy to other composite rate payment systems under which hospitals are paid. Some commenters suggested limiting the expansion to payments for services to inpatients under the IRF PPS, IPF PPS, and LTCH PPS. Other commenters suggested that we expand the policy to any composite rate payment system under which a hospital is paid for either inpatient or outpatient services, including OPPS. The commenters suggesting expansion to OPPS stated (in identical language) that they are aware of circumstances where physicians other than the ordering physician refer outpatients for additional outpatient services that would not be compensated separately under the OPPS; however, none of these commenters provided a specific example or identified a specific APC.

Response: We believe that expanding our policy to other payment systems applicable to the furnishing of services to inpatients would not pose a risk of program or patient abuse. The IRF PPS, IPF PPS, and LTCH PPS operate similarly to IPPS. No additional payment is available where additional hospital services are ordered after a patient's admission by a physician who was not responsible for the patient's admission, except in limited circumstances. We are not persuaded to expand the policy to the OPPS. As we stated in the proposed rule, we

believe that there is typically only one ordering physician for outpatient services, and it would be rare that a physician other than the ordering physician would refer an outpatient for additional outpatient services that would not be paid separately under the OPPS (84 FR 55805). The commenters that asserted the existence of circumstances where physicians other than the ordering physician refer outpatients for additional outpatient services that would not be paid separately under the OPPS provided no evidence or examples of such circumstances for us to confirm. Finally, we believe that extending the rule to designated health services paid under the OPPS would be burdensome and challenging for stakeholders, CMS, and our law enforcement partners to implement and enforce. We decline to extend the policy to the OPPS.

Comment: One commenter questioned whether a service would be considered a designated health service if the hospital's furnishing of the service to an inpatient decreased the IPPS payment to the hospital. Another commenter requested clarification of the meaning of "affects" the amount of Medicare payment. A few commenters requested additional examples of hospital services that would or would not "affect" an IPPS payment under the revised definition of "designated health services," if finalized.

Response: Although we do not believe it is likely that the ordering of additional services for an inpatient would decrease the amount of Medicare's payment for the admission, we are replacing the word "affect" with "increase" to express our policy with more precision. As noted, under the definition of "designated health services" finalized at §411.351, for services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS): (i) Acute Care Hospital Inpatient (IPPS); (ii) Inpatient Rehabilitation Facility (IRF PPS); (iii) Inpatient Psychiatric Facility (IPF PPS); or (iv) Long-Term Care Hospital (LTCH PPS).

Comment: One commenter in opposition to our proposal described a summary of the proposed rule prepared by an independent law firm that identified what the law firm assumed the

rationale behind our proposal to be: physicians have no financial incentive to overprescribe services that do not affect the rate of payment. The commenter disagreed with that rationale as support for our proposal, and described a complicated situation that could present a risk of abuse based on hospital referrals to service lines within the hospital in which certain physicians, but not the referring physicians addressed in our proposal, could profit. The commenter expressed concern that the revised definition of "designated health services" would likely eliminate inpatient hospitalization from the reach of the physician self-referral law. The commenter also asserted that there exists no opposition to the current definition of "designated health services" and urged CMS not to finalize the proposal.

Response: All inpatient and outpatient hospital services will remain designated health services except for services furnished to an inpatient after he or she becomes an inpatient and only where those additional services do not increase the amount of Medicare's payment to the hospital for the inpatient admission. For the reasons stated in the proposed rule and in this final rule, we are finalizing our proposal with the modification described above.

Comment: A few commenters expressed uncertainty with respect to a hospital's ability to know *whether* services furnished to an inpatient pursuant to a prohibited referral from a physician other than the physician who made the referral for the inpatient admission result in outlier payments under the IPPS such that the "caveat" in the exclusion from the definition would apply. The commenters also stated that they lacked clarity regarding *when* a hospital could know that an outlier payment is triggered by a particular inpatient admission. The commenters asserted that this makes the revised definition of "designated health services" unworkable.

Response: We see no reason why a hospital would be unable to identify referrals made by physicians with whom the hospital has financial relationships that do not satisfy the requirements of an applicable exception. As we have stated repeatedly throughout our rulemaking history, the physician self-referral law's billing prohibition requires that the entity

submitting a claim to Medicare for payment for designated health services has the burden of ensuring that the services were not furnished as a result of a prohibited referral. It is incumbent upon hospitals to implement effective compliance programs to identify financial relationships with physicians that do not satisfy the requirements of an applicable exception to the physician self-referral law and take action not to submit prohibited claims for payment. If a hospital did not identify the financial relationship with a referring physician until after a claim was submitted and paid, the hospital would need to identify admissions for which payments in excess of the expected MS-DRG payment (or other PPS payment) were received and identify any prohibited referrals for services furnished to the inpatients for whom the excess payments relate. We believe that our rules and regulations regarding outlier payments are clear and we are unaware of any reason that a hospital would be unable to utilize its medical record and billing systems to identify inpatient admissions that resulted in payments in addition to the expected MS-DRG payment (or other PPS payment) for the inpatient admission.

b. Physician

In the 1992 proposed rule, we stated that, for purposes of the physician self-referral law, physicians are certain professionals who are "legally authorized to practice by the State in which they perform their professional functions or actions and when they are acting within the scope of their licenses." (57 FR 8593). We included in the definition a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of optometry, and a chiropractor who meets certain qualifications. In Phase I, we finalized our definition of "physician" at §411.351, defining the term as "a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined at section 1861(r) of the Act." (66 FR 955). Since Phase I, our definition of "physician" at §411.351 has consistently referred to the definition of "physician" at section 1861(r) of the Act. However, although the definition of "physician" at §411.351 cross-references section 1861(r) of the Act, the two definitions are not entirely harmonious. In particular, the definition of

"physician" at §411.351 does not include all the limitations imposed by the definition of "physician" at section 1861(r) of the Act. In order to correct this discrepancy and provide uniformity between Title XVIII of the Act and our regulations with regard to the definition of a "physician," in the proposed rule, we proposed to amend the definition of "physician" at §411.351 (84 FR 55805 through 55806). Under the proposed definition, the types of practitioners who qualify as "physicians" for purposes of the physician self-referral law would be defined by cross-reference to section 1861(r) of the Act. Therefore, the definition of "physician" at §411.351 would incorporate the statutory limitations imposed on the definition of "physician" by section 1861(r) of the Act. As proposed, the definition at §411.351 would continue to provide that a physician is considered the same as his or her professional corporation for purposes of the physician self-referral law. After reviewing the comments, we are finalizing the definition of "physician" as proposed.

We received the following comment and our response follows.

Comment: Several commenters generally supported the regulatory change to cross-reference the definition of "physician" at §411.351 to the definition in section 1861 of the Act. A few commenters maintained that the definition of "physician" should be limited to doctors who have a Doctor of Medicine, Doctor of Osteopathic Medicine, or a recognized equivalent physician degree. One commenter questioned the practical effect of incorporating into our definition of physician at §411.351 the statutory limitations imposed in the definition of "physician" under section 1861(r) of the Act. Specifically, the commenter asked whether the policy excludes podiatrists, optometrists, and chiropractors from the definition of "physician" for purposes of the physician self-referral law, because, according to the commenter, the statutory limitations related to those three types of practitioners restrict when they are considered physicians under section 1861(r) of the Act to very limited circumstances, none of which reference the physician self-referral law.

Response: We are finalizing the definition of "physician" as proposed. The revised

definition will align the regulatory definition of "physician" at §411.351 with the statutory definition of "physician" in section 1861(r) of the Act to ensure that there are no inconsistencies between our regulations and the statutory definition. Because the physician self-referral statute is in Title XVIII of the Act, in the absence of a definition of "physician" in section 1877 of the Act, definitions of general applicability, such as the definition of "physician" at section 1861(r) of the Act, are applicable to the physician self-referral law. Under section 1861(r) of the Act, a "physician" includes a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor, but provides for limitations on when such doctors are considered "physicians" for purposes of Title XVIII of the Act. We do not believe that the definition of "physician" in our regulations should be either more limited or more expansive than the statutory definition. Thus, to the extent that the statutory definition of "physician" includes doctors other than doctors of medicine and osteopathy, those practitioners fall within the ambit of the physician self-referral law. However, we do not believe that the referral prohibition at §411.353(a) should apply to any doctor during the period he or she is not considered to be a physician for purposes of Title XVIII of the Act. In those instances when a doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or chiropractor is considered a physician under section 1861(r) of the Act, the doctor or chiropractor will be considered a physician for purposes of the physician self-referral law.

c. Referral

In Phase II, we stated that the exception for fair market value compensation is not available to protect recruitment arrangements (69 FR 16096). We noted that a hospital is not permitted to pay a physician for the benefit of receiving the physician's referrals, and that such payments are antithetical to the premise of the statute. In the proposed rule, we reaffirmed that a physician's referrals are not items or services for which payment may be made under the physician self-referral law, and that neither the existing exceptions to the physician self-referral

law nor the exceptions proposed in the proposed rule would protect such payments. We proposed to revise the definition of "referral" at §411.351 to explicitly state our longstanding policy that a referral is not an item or service for purposes of section 1877 of the Act and the physician self-referral regulations (84 FR 55806). After reviewing the comments, we are finalizing our modification of the definition of "referral" as proposed.

We received the following comment and our response follows.

Comment: Numerous commenters supported the proposed revision of the definition of "referral." We also received comments on our proposed definition of "referral" that pertained to the volume or value standard and the payment of productivity bonuses.

Response: We are finalizing the definition as proposed. Comments pertaining to the volume or value standard and the payment of productivity bonuses are addressed in section II.B.3. of this final rule.

d. Remuneration

A compensation arrangement between a physician (or an immediate family member of such physician) and an entity (as defined at §411.351) implicates the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term "compensation arrangement" as any arrangement involving any "remuneration" between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following does not create a compensation arrangement between the parties: items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Furthermore, under our definition of "remuneration" at §411.351, the provision of such items, devices, or supplies is not considered to be remuneration.

In the 1998 proposed rule we explained our interpretation of the phrase "used solely" at section 1877(h)(1)(C)(ii) of the Act (66 FR 1693 through 1694). We observed that some pathology laboratories had been furnishing physicians with materials ranging from basic collection and storage items to more specialized or sophisticated items, devices, or equipment. We clarified that, in order for these items and devices to meet the statutory requirement, they must be used *solely* to collect, transport, process, or store specimens for the entity that provided the items and devices, or to order or communicate the results of tests or procedures for such entity. We provided examples of items that could meet the "used solely" test, including cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices. We emphasized that an item or device would not meet the "used solely" requirement if it is used for any purpose besides the purposes listed in the statute. In particular, we noted that certain surgical tools that can be used to collect or store samples, but are also routinely used as part of a surgical or medical procedure, would not satisfy the "used solely" requirement.

As finalized in Phase I, the definition of "remuneration" included a parenthetical stipulating that the provision of surgical items, devices, and supplies would not qualify for the carve-out to the definition of "remuneration" for items, devices, or supplies that are used solely for the purposes listed at section 1877(h)(1)(C)(ii) of the Act (66 FR 947). We explained that we did not believe that the Congress intended section 1877(h)(1)(C)(ii) of the Act to allow entities to supply physicians with surgical items for free or below fair market value prices, noting that such items may have independent economic value to physicians apart from the six statutorily permitted uses. We stated our belief that the Congress intended to include at section 1877(h)(1)(C)(ii) of the Act single-use items, devices, and supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens. In this context, we explained that reusable items may have value to physicians unrelated to the collection of specimens, and therefore could not meet the "used solely" requirement. Lastly, we stated that

the provision of an excessive number of collection supplies creates an inference that the supplies are not provided "solely" to collect, transport, process, or store specimens for the entity that furnished them.

We made no changes to the definition of "remuneration" in Phase II or Phase III. In the CY 2016 PFS final rule, we clarified that the provision of an item, device, or supply that is used for *one or more* of the six purposes listed in the statute, and no other purpose, does not constitute remuneration (80 FR 71321). In two advisory opinions issued in 2013 we applied the definition of "remuneration" at §411.351 to two proposed arrangements to provide certain devices to physicians free of charge. In CMS-AO-2013-01, we concluded that, based on the specific facts certified by the requestor of the opinion, the provision of liquid-based Pap smear specimen collection kits did not constitute remuneration, because the collection kits are not surgical devices, and because the devices are used solely in the collection of specimens. Among other things, our "used solely" analysis highlighted the following facts, as certified by the requestor: (1) the Pap smear collection kits contain only disposable items that cannot be reused after a specimen is collected; and (2) the entity furnishing the Pap smear collection kits has a system in place to ensure that physicians receive only the quantity of devices necessary for their practice needs, and to address potential instances of separation of the devices into their component parts for use other than to collect specimens. In contrast, in CMS-AO-2013-02, we concluded that, based on the specific facts certified by the requestor of the opinion, the furnishing of certain disposable biopsy brushes for use in obtaining a biopsy of visible exocervical lesions constituted remuneration under the definition at §411.351. We noted that, as certified by the requestor, the biopsy brush is a disposable, single-use, cervical biopsy device that is used to collect a specimen to be sent to a laboratory. After reviewing FDA rules and regulations and American Medical Association guidelines, and consulting with CMS medical officers, we concluded that the device is a "surgical item, device, or supply" for purposes of the physician self-referral law and, therefore, that the provision of the device constitutes remuneration under §411.351.

After further consideration of our interpretation of section 1877(h)(1)(C)(ii) of the Act and the analysis set forth in the 2013 advisory opinions, in the proposed rule, we proposed certain modifications to the definition of "remuneration" at §411.351 (84 FR 55806 through 55807). Specifically, we proposed to remove the parenthetical in the current definition of "remuneration," which stipulates that the carve-out to the definition of "remuneration" does not apply to surgical items, devices, or supplies. We stated that we are no longer convinced that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that the item, device, or supply is not used solely for one of the six purposes listed at section 1877(h)(1)(C)(ii) of the Act. Rather, the relevant inquiry for purposes of the physician self-referral law is whether the item, device, or supply is used solely for one or more of the statutory purposes, regardless of whether the device is also classified as a surgical device. To be clear, we continue to believe that the Congress intended the carve-out at section 1877(h)(1)(C)(ii) of the Act to cover single-use items, devices, or supplies of low value[10] that are primarily provided by laboratories to ensure proper collection of specimens, but we are no longer convinced that the mere fact that an item, supply, or device is classified as a "surgical device" means that it does not fall within the carve-out.

In the proposed rule, we also clarified the "used solely" requirement at §411.351. Although the furnished item, device, or supply may not be used for any purpose other than one or more of the six purposes listed in the statute, we recognize that, in many instances, the item, device, or supply could theoretically be used for numerous purposes. For example, a specimen lockbox could potentially be used for several purposes; it could be used to store unused specimen collection supplies or as a doorstop. However, if, during the course of the arrangement, the specimen box provided to the physician is not used for any of these purposes and is, in fact, used only for one or more of the six purposes outlined in the statute and our regulations, the furnishing

[10] *See*, for example, the OBRA 1993 Conference Report, H.R. 103-213 pp. 818 through 819, which characterized section 1877(h)(1)(C)(ii) of the Act as an "exception" for "certain minor remuneration."

of the specimen box would not be considered remuneration between parties. In other words, the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes does not automatically mean that the furnishing of the item, device, or supply at no cost constitutes remuneration. We proposed to add the phrase "in fact" to the "used solely" requirement to clarify that an item, device, or supply can have several uses, including uses that are not among the six purposes listed in the statute; however, the furnishing of such items, supplies, or devices would not be considered remuneration if the item, device, or supply in question is, in fact, only used for one or more of the six purposes outlined in the statute. We again refer readers to the guidance provided in the 1998 proposed rule and in Phase I on steps that a party can take to ensure that the furnished items, supplies, or devices are used appropriately (63 FR 1693 through1694 and 66 FR 947 through 948, respectively).

Although we proposed certain modifications to the definition of "remuneration," we did not propose to exclude from the definition of "remuneration" those items, devices, or supplies whose main function is to prevent contamination or infection, even if the item, device, or supply could potentially be used for one or more of the six statutory purposes at section 1877(h)(1)(C)(ii) of the Act. In Phase I, we made clear that, although sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies that are used *solely* to collect, transport, process, or store specimens (66 FR 948). Sterile gloves are essential to the specimen collection process, but their primary purpose is to prevent infection or contamination. In addition, sterile gloves are fungible, general purpose items, and we continue to believe it would be impractical for parties to monitor the use of the gloves to ensure that they are used solely for one or more of the purposes listed at section 1877(h)(1)(C)(ii) of the Act. Likewise, although there may be certain specialized equipment (including surgical tools) that may be used for one or more of the purposes described in the statute, in order not to be considered remuneration, the item, device, or supply must not have a primary function of preventing infection or contamination, or some other purpose besides one of the six purposes

listed in the statute.

After reviewing the comments, we are finalizing our revision of the definition of "remuneration" as proposed.

We received the following comments and our responses follow.

Comment: Numerous commenters supported our proposed revision of the definition of "remuneration," including our proposal to remove the phrase "not including surgical supplies, devices, or supplies" and our proposal to clarify that items, devices, and supplies are not remuneration if they are, "in fact," used exclusively for one or more of the permitted purposes. Several of the commenters that supported our proposed revision of the definition of "remuneration" also supported our statement that those items, devices, or supplies whose main function is to prevent contamination or infection are not carved out of the definition of "remuneration." One commenter suggested that the proposed changes to the definition will reduce physician hesitancy regarding the acceptance of such items, devices, and supplies and will reduce administrative burden.

Response: We agree that the revisions to the definition of "remuneration" will provide additional clarification and reduce administrative burden, and are revising the definition of "remuneration" as proposed.

Comment: One commenter objected to the proposal to strike the parenthetical pertaining to surgical items, devices, or supplies from the definition of "remuneration" and urged CMS not to finalize the proposal. The commenter maintained that CMS did not explain the rationale for the policy change in the proposed rule, and that CMS did not provide any examples of surgical items, devices, or supplies that would not be considered remuneration. According to the commenter, it is relatively straightforward for a laboratory to determine if an item, device, or supply is classified as "surgical," and thus is not excluded from the definition of remuneration. The commenter asserted that it would be more difficult, if not impossible, for a laboratory to determine whether a physician in fact uses a surgical item, device, or supply for one of the

permitted purposes under the statute. The commenter noted that CMS acknowledged in the proposed rule the difficulty of monitoring the use of sterile gloves. The commenter concluded that, given the difficulty of monitoring actual use, the proposal, if finalized, would create a "slippery slope" that would permit unscrupulous actors to provide items, devices, or supplies that are routinely used as part of a surgical procedure as opposed to one of the permitted purposes under the statute. A different commenter raised similar objections to the proposal. This commenter acknowledged that the proposal to no longer categorically include surgical items, devices, or supplies in the definition of "remuneration" provides some additional flexibility under our regulations, but urged CMS to ensure that the items, devices, or supplies not considered to be remuneration continue to be single-use items, devices, or supplies with little, if any, independent value to the physicians who receive them. The commenter expressed concern that, under the proposal, valuable items, devices, or supplies, such as bone marrow kits, would no longer be considered remuneration, thus increasing the risk of program or patient abuse. The commenter also expressed concern that it would increase the burden on parties to monitor the use of items, devices, or services, to ensure that physicians are in fact using the items, devices, or services for one or more of the permitted purposes under the statute.

Response: The purpose of the revision to the definition of "remuneration" is to increase flexibility under our regulations and to clarify the "used solely" requirement. As noted in the proposed rule, we no longer believe that the mere fact that an item, device, or supply is classified as "surgical" means that the item, device, or supply is not used solely for one or more of the permitted purposes. Although the categorical inclusion of surgical items, devices, or supplies in the definition of "remuneration" may provide a bright line test for determining which items may be furnished to physicians at reduced or no cost, it also may include certain items, device, or supplies in the definition of "remuneration" that the Congress meant to exclude in section 1877(h)(1)(C)(ii) of the Act. Nothing in the regulation compels an entity to provide any item, device, or supply to a physician below fair market value or for free. Entities concerned about

monitoring for "sole use" may elect not to give away surgical (or any other) item, device, or supply. Moreover, items, devices, and supplies that do not constitute remuneration for purposes of the physician self-referral law may nonetheless implicate the anti-kickback statute.

Similarly, our clarification of the "used solely" requirement was not intended to loosen the requirement or to create a slippery slope that will lead to abusive arrangements. Prior to the proposed rule, we received inquiries from stakeholders questioning whether the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes means that the provision of such an item, device, or supply constitutes "remuneration" under our regulations. We are adding the phrase "in fact" to the definition to clarify that this is not the case and to provide certainty to parties regarding items, devices, or supplies with potential ancillary functions outside of one or more of the permitted purposes. At the same time, as indicated in our discussion of the provision of sterile gloves, we continue to believe that, for an item, device, or supply (including surgical tools) to satisfy the "used solely" requirement, the *primary purpose* of the item, device, or supply must be one or more of the uses permitted under the statute. Sterile gloves and other multi-use items, devices, or supplies whose primary purpose is not one of the permitted purposes are not excluded from the definition of "remuneration," even if a particular physician in fact only uses the item, device, or supply for one of the permitted purposes. We do not disagree that it may be difficult for an entity to monitor how a physician "in fact" uses a multi-use item, device, or supply whose primary purpose is not one or more of the permitted purposes to ensure that the physician in fact uses the item, device, or supply exclusively for one or more of the permitted purposes. However, because the provision of multi-use items, devices, or supplies whose primary purpose is not one or more of the permitted purposes will not be carved out of the definition of remuneration.

We continue to believe that the Congress intended the carve-out at section 1877(h)(1)(C)(ii) of the Act to cover single-use items, devices, or supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens. We note that, in the

OBRA 1993 Conference Report, H.R. 103-213 pp. 818 through 819, the Congress characterized section 1877(h)(1)(C)(ii) of the Act as an "exception" for "certain minor remuneration." Although we are not finalizing a monetary limit for the carve-out, we continue to believe that the items carved out of the definition of "remuneration" must be low value. We also reaffirm that the items, devices, or supplies provided to a physician must have little or no *independent* value to the physician. In this context, it is important to note that both the statute and our regulations provide that the items, devices, or supplies provided must serve a purpose *for the entity* providing the items, devices, or supplies; for example, collecting specimens *for the entity*. We believe that the phrase "for the entity" underscores that the items, devices, or supplies must have little, if any, independent value for the physician. Lastly, we emphasize that, even if the provision of an item, device, or supply is carved out of the definition of "remuneration" under the physician self-referral law, the provision of such items, devices, and supplies implicates the anti-kickback statute.

e. Transaction (and Isolated Financial Transaction)

Section 1877(e)(6) of the Act provides that an isolated financial transaction, such as a one-time sale of property or practice, is not a compensation arrangement for purposes of the physician self-referral law if: (1) the amount of remuneration under the transaction is consistent with the fair market value of the transaction and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician; (2) the remuneration is pursuant to an arrangement that would be commercially reasonable even if no referrals were made to the entity; and (3) the transaction meets any other requirements that the Secretary imposes by regulation as needed to protect against program or patient abuse. As enacted by OBRA 1989, the statutory exception identified a one-time sale of property as an example of an isolated financial transaction. In OBRA 1993, the Congress further clarified the statutory exception by providing an additional example of an isolated transaction, namely, a one-time sale of a practice. (*See* House Conference Report at H.R. Rep. No. 213, 103d Cong., 1st

Sess. 813-815 (1993).)

In the 1992 proposed rule, we proposed an exception (ultimately codified at §411.357(f)) to mirror the statutory exception at section 1877(e)(6) of the Act for certain isolated financial transactions (both titled and together referred to as the exception for isolated transactions) (57 FR 8591). In our proposal, we included a requirement—in addition to the statutory requirements—that there be no other transactions (that is, financial relationships) between the parties for 1 year before and 1 year after the financial transaction to ensure that financial transactions excepted under section 1877(e)(6) of the Act and §411.357(f) are truly *isolated* in nature (57 FR 8599). In the 1995 final rule, we finalized an exception for isolated financial transactions at §411.357(f), and we modified the proposed 1-year requirement in response to commenters that asserted that the requirement would create substantial and unnecessary problems (60 FR 41960). We stated that a transaction would be considered an isolated transaction for purposes of §411.357(f) if there were no other transactions between the parties for 6 months after the transaction, except those transactions that are specifically excepted by another provision in §§411.355 through 411.357. We further stated that individual payments between parties generally characterize a compensation arrangement; however, debt, as described in the definition of "ownership or investment interest" at section 1877(a)(2) of the Act, can constitute an ownership interest that continues to exist until the debt is paid off (60 FR 41960). The 1995 final rule also established definitions of "transaction" and "isolated transaction" at §411.351. We defined a "transaction" as an instance or process of two or more persons doing business and an "isolated transaction" as a transaction involving a single payment between two or more persons. The regulation at §411.351 specified that a transaction involving long-term or installment payments is not considered an isolated transaction.

In the 1998 proposed rule, we proposed to revise the definition of "transaction" at §411.351 to clarify that a transaction can involve persons or entities, but did not propose any substantive changes to the exception at §411.357(f) (63 FR 1669). This definition was finalized

in Phase II, with modification to permit installment payments (and post-closing adjustments) under certain circumstances (69 FR 16098). In Phase II, we also responded to commenters that objected to the prohibition on other transactions within 6 months of the excepted transaction. We declined to modify the 6-month prohibition on other transactions, and we explained that the concept of an *isolated* transaction is incompatible with the parties routinely engaging in multiple transactions in a year or during a short period of time. In Phase III, we made no changes to the exception at §411.357(f), but updated the term "isolated transaction" at §411.351 to refer to an "isolated financial transaction," as that specific term is used in the statutory and regulatory exceptions (72 FR 51084).

Through our administration of the SRDP, work with our law enforcement partners, and interactions with stakeholders, it has come to our attention that some parties may believe that CMS' policy is that the exceptions in section 1877(e)(6) of the Act and §411.357(f) for isolated transactions are available to protect service arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time. To illustrate, assume that a hospital makes a single payment to a physician for working multiple call coverage shifts over the course of a month (or several months) and seeks to utilize the exception at §411.357(f) to avoid qualification of the payment as a financial relationship subject to the physician self-referral law's referral and billing prohibitions. That is, the parties wish to consider the single payment for multiple services an "isolated financial transaction." We have observed that parties turn to the exception for isolated transactions to protect single payments for multiple services when they discover, typically after the services have been provided, that they failed to set forth the service arrangement in writing, and thus cannot rely on the exceptions for personal service arrangements or fair market value compensation. In fact, it is our policy that the exception for isolated transactions is <u>not</u> available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services. We see no reason to unduly stretch the meaning and applicability of the exception for isolated transactions beyond

what was intended by the Congress. As described elsewhere in this final rule, our final regulations should facilitate compliance with the physician self-referral law in general and the writing and signature requirements in particular, including a 90-day period to reduce arrangements to a signed writing and an exception for limited remuneration to a physician. We believe that these final provisions will afford parties with sufficient flexibility to ensure that personal service and other compensation arrangements comply with the physician self-referral law.

To illustrate the kind of transactions that section 1877(e)(6) of the Act is meant to exempt, the Congress provided as examples a one-time sale of property and a one-time sale of a practice. In our view, a one-time sale of property or a practice is a unique, singular transaction. It is not possible for one party to repeatedly offer and sell the same property or medical practice to another party. In contrast, in service arrangements where multiple services are provided over an extended duration of time, the same services are provided on a repeated basis, even if there is only one payment for the multiple services provided. Also, in a one-time sale of property or a practice, the consideration for the transaction (that is, the transfer of ownership of the property or practice) is exchanged at the time payment is made in a single transaction (although §411.357(f) permits installment payments under certain circumstances). In contrast, if a physician provides multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date.

We remind parties that the provision of remuneration in the form of services commences a compensation arrangement at the time the services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services. Thus, the exception for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law. Our position is buttressed by the fact that

the Congress created an exception for personal service arrangements at section 1877(e)(3) of the Act and required, among other things, that the arrangement is set out in writing and signed by the parties, that the term of the arrangement is at least 1 year, and that the compensation is set in advance. We do not believe that the Congress would impose such requirements for service arrangements under this exception, and then permit parties to avoid these requirements as long as the parties made one retrospective payment for multiple services provided over an extended period of time relying on the exception for isolated transactions.

After reviewing the comments, we are finalizing the proposed independent definition of "isolated financial transaction" at §411.351, which clarifies that an "isolated financial transaction" does not include a single payment for multiple services provided over an extended period, with the following modifications: First, the final definition of "isolated financial transaction" specifies that an isolated transaction is a *one-time* transaction. Second, subparagraph (2) of the definition of "isolated financial transaction" at §411.351 and the introductory chapeau language in §411.357(f) provides as an additional example of an isolated financial transaction a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute. Third, we are clarifying at §411.357(f)(4) that an isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute. Fourth, although we did not propose further changes to the definition of "transaction" at §411.351, we are modifying the definition in response to comments to remove the phrase "or process," because the term "process" has led some stakeholders to conclude that the exception is available to protect a single payment for multiple services provided over an extended period of time. Lastly, we are finalizing corresponding revisions to the exception for isolated transactions at §411.357(f) to reference isolated financial transactions in order to align the exception text with the statutory provisions at section 1877(e)(6) of the Act. Even though the exception at §411.357(f) applies to isolated financial transactions, we did not propose and we are not finalizing a change in the title

of the exception from "isolated transactions" to "isolated financial transactions," as the title of the statutory exception is "isolated transactions."

We received the following comments and our responses follow.

Comment: Many commenters expressed concern that, given the proposed definition of "isolated financial transaction," the exception at §411.357(f) would not apply to the settlement of a *bona fide* legal dispute, especially a dispute arising from an ongoing service arrangement, may not be excepted under §411.357(f). Commenters noted that parties to a service arrangement may have a legitimate dispute concerning the amount of compensation due under a service arrangement, for example, where the terms of a contract documenting the arrangement are ambiguous. In these circumstances, a physician may have reasonable belief that he or she is owed more money under the contract, while the entity may believe in good faith that the physician is entitled to less than what the physician claims. Under such circumstances, the parties may wish to settle the matter to avoid litigation. The commenters expressed concern that the settlement could be construed as a single payment for multiple services previously provided by the physician and, therefore, the exception at §411.357(f) would be unavailable to protect the compensation arrangement arising from the settlement payment (or reduction in debt). Several commenters maintained that resolution of a *bona fide* dispute is altogether different from making a single payment for multiple services provided over an extended period of time. The commenters requested that CMS expressly include a settlement of a *bona fide* legal dispute, along with a one-time sale of a property or practice, in the definition of "isolated financial transaction," and strike language stating that an isolated financial transaction does not include a single payment for multiple services.

Response: Our policy has always been that the exception for isolated transactions at §411.357(f) is applicable to a compensation arrangement arising from the settlement of a *bona fide* dispute, even if the dispute originates from a service arrangement where multiple services have been provided over an extended period of time. To clarify our longstanding policy, we are

modifying the definition of "isolated financial transaction" at §411.351 to include in subparagraph (2) a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, and we are including similar language in the introductory chapeau language at §411.357(f). However, the exception is not applicable to the compensation arrangement that the parties dispute.

We agree with the commenters that stated that settlement of a *bona fide* dispute arising from an arrangement is fundamentally different from making a payment, including a single payment, for items or services provided under the arrangement. Although the settlement of a *bona fide* dispute may include a one-time payment made by a party (or installment payments as permitted under the exception), the cornerstone of a settlement of a *bona fide* dispute, as opposed to a payment for items or services, is that one or more of the parties forgoes a good faith claim to be paid more under the arrangement than the party actually receives. Therefore, we are describing the settlement of a *bona fide* dispute in the definition of "isolated financial transaction" and in the exception at §411.357(f) as an instance of *forgiveness* of an amount owed. We are further clarifying at §411.357(f)(4) that an isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute. Thus, a settlement of a *bona fide* legal dispute under §411.357(f) is a separate compensation arrangement from any compensation arrangement between the parties giving rise to the *bona fide* dispute, and settlement of a *bona fide* dispute under §411.357(f) does not retroactively bring the compensation arrangement that gave rise to the dispute into compliance with the physician self-referral law.

For the reasons explained above, we decline to omit from subparagraph (2) the phrase "but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated)." Parties may rely on the exception at §411.357(f) to protect an isolated financial transaction that settles a *bona fide* dispute arising from an arrangement for multiple, repeated, or ongoing services, but the exception is not

available to protect a single payment for multiple or repeated services. A single payment for multiple or repeated services is not an isolated financial transaction, but rather an ongoing, extended compensation arrangement that must satisfy the requirements of another applicable exception.

Comment: Several commenters maintained that our proposal to exclude a single payment for multiple services from the definition of "isolated financial transaction" is inconsistent with the statutory exception for isolated transactions at section 1877(e)(6) of the Act. According to the commenters' interpretation of section 1877(e)(6) of the Act, the statutory examples of isolated financial transactions, namely a one-time sale of property or a one-time sale of a practice, are illustrative only, and non-exhaustive. The commenters asserted that the exception may also be used for payments for services, noting that section 1877(e)(6) of the Act incorporates by reference certain requirements of the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships, including the requirement that the remuneration is "consistent with the fair market value of the *services*" (emphasis added). Another commenter asserted that it is reasonable to see a single payment for items or services already furnished as an isolated transaction. The commenter provided as an example a hospital's single payment to a physician for fulfilling an unanticipated need for call coverage over a weekend or holiday, where the physician performs no others services for the hospital for the previous or subsequent 6-month periods.

Response: We agree with the commenters that the examples of isolated transactions in section 1877(e)(6) of the Act are illustrative only, not exhaustive. Among other things, as noted above, we believe that a single transaction resolving a *bona fide* dispute is an example of an isolated transaction that may be protected under the exception, if all the requirements of the exception are met. What the statutory examples illustrate, however, are *one-time* transactions, where there is not only a single payment (or installment payments as permitted under the exception) but also a single exchange of value, typically occurring on a specific date, involving

consideration that is usually not the subject of repeated or frequent exchange over an extended period of time. In a sale of property or a practice, for example, there is typically a closing date when value is exchanged, and the parties ordinarily do not repeatedly transact to buy and sell the same property or practice over an extended period. The Congress' inclusion of the term "one-time" underscores that the exception is not available for transactions that are repeated over an extended period of time. In contrast to a one-time sale of property or a practice, if a physician repeatedly provides services to an entity over the course of months or years, then the physician has repeatedly provided remuneration to the entity in the form of an in-kind benefit during that timeframe. Even if the entity only makes one payment for the services, this is not a *one-time* transaction as contemplated by the statute, but rather an ongoing service arrangement. Because we interpret the exception for isolated transactions as protecting *one-time* transactions, as indicated at section 1877(e)(6) of the Act, we are modifying the definition of "isolated financial transaction" to include the term "one-time."

Under our interpretation of the statutory scheme, ongoing service arrangements, where a physician provides multiple services to an entity over an extended period of time, must satisfy all the requirements of another applicable exception, such as the exception for personal service arrangements at §411.357(d)(1) or the exception for fair market value compensation at §411.357(l). We do not believe that the Congress would have required ongoing service arrangements to meet all the requirements of section 1877(e)(3) of the Act, including writing, signature, 1-year term, and set in advance requirements, and then permit parties to sidestep these requirements by making a single, retrospective payment for multiple services relying on the exception for isolated transactions.

We agree with the commenters that not all service arrangements are *per se* excluded from protection under the exception for isolated transactions. In the proposed rule, we noted that the same services can be provided by one party and purchased by another on a repeated basis, whereas a party cannot repeatedly offer and sell the same property or medical practice to another

party (84 FR 55808). We believe that the commenters may have inferred from this statement that our policy categorically excludes services from the isolated transaction exception. This is not our policy. As noted above, the exception for isolated transactions protects *one-time* transactions. With respect to an arrangement for services, the exception is available to protect a single payment (or installment payments, as permitted by the exception) for a *one-time* service arrangement, as opposed to an arrangement where multiple or repeated services are provided over an extended period of time. Whether a one-time service arrangement constitutes an isolated financial transaction depends on the facts and circumstances of the arrangement, including whether the service (or bundle of integrally related services) is provided in its entirety during a discrete time-period of short duration, such as a 24-hour or weekend shift. We note that, under §411.357(f)(3), if parties utilize the exception for isolated transactions for a one-time service arrangement that qualifies as an isolated financial transaction, the parties would not be barred from entering into an ongoing arrangement for the same or similar services during the 6 months after the isolated financial transaction, provided that the subsequent service arrangement satisfied all the requirements of a different exception applicable to the subsequent service arrangement. The parties would, however, be barred from using the exception for isolated transactions for 6 months after the one-time service arrangement, regardless of the subject matter or consideration of the transaction.

Comment: Some commenters maintained that, under the plain language of the exception for isolated transactions and our previous guidance, the exception may be relied on to protect a single payment for multiple services. The commenters noted that "transaction" is currently defined to mean an "instance or process" of two or more persons or entities doing business, and stated that a "process" suggests an ongoing relationship such as an arrangement for repeated or multiple services provided over an extended period of time. The commenters further noted that the terms "isolated financial transaction" and "transaction" are defined together in the current regulations, and that "isolated financial transaction" is defined as a transaction involving a single

payment. Another commenter objected to CMS' statement that the proposal is a clarification of longstanding policy and stated that there is nothing in the plain language of the exception to put parties on notice that the exception cannot be used to protect a single payment for multiple services.

Response: We first introduced the concept of a "process" of two or more persons doing business in the 1995 final rule (60 FR 41979). There is very little commentary in the 1995 final rule or subsequent rulemaking on the term "process" in the definition of "transaction," though we did note in Phase II, when declining to adopt a policy allowing a certain number of transactions per year, that the concept of an isolated transaction is incompatible with parties routinely engaging in multiple transactions each year or more than one transaction during a short period of time (69 FR 16098). Moreover, in the FY 2009 IPPS final rule, we explained that all the requirements of an exception must be met at the time that a physician makes a referral, and that parties may not turn back the clock to retroactively "cure" noncompliant arrangements (73 FR 48703). Under the statute and our regulations, a compensation arrangement is formed when remuneration, including in-kind remuneration such as the provision of a service, is exchanged between a physician and an entity. Thus, once a physician begins providing services to an entity under an arrangement, a compensation arrangement is formed, and the compensation arrangement must satisfy all the requirements of an exception at that time if the physician makes referrals to the entity. The statute and our previous policy statements in Phase II and the FY 2009 IPPS final rule are the basis for the policy articulated in the proposed rule and this final rule, namely that parties may not rely on the exception for isolated transactions to protect or retroactively "cure" a service arrangement involving the provision of multiple or repeated services over an extended period of time.

We recognize, however, that stakeholders may have been under the impression, given the use of the word "process" in the definition of "transaction," that the exception for isolated transactions was available to protect service arrangements involving multiple or repeated

services provided over an extended period of time. We also acknowledge that, under the current regulations, the definition of "isolated financial transaction" is subsumed under the definition of "transaction," and, although the definition of "isolated financial transaction" requires a single payment (or installment payments, if certain requirements are met), it does not explicitly state that a single payment cannot be made for repeated or multiple services. To clarify our policy, we are deleting the term "process" from the definition of "transaction" in §411.351 and we are explicitly stating in subparagraph (2) of the definition of "isolated financial transaction" at §411.351 that an isolated financial transaction does not include a single payment for multiple or repeated services. We stress that these revisions are effective as of the date set forth in this final rule and apply prospectively only.

Comment: Many commenters maintained that our policy reduces flexibility and increases the burden of compliance with the physician self-referral law. The commenters noted that the exception for isolated transactions includes core safeguards of the physician self-referral law, such as requirements pertaining to fair market value, the volume or value of a physician's referrals and other business generated by the physician, and commercial reasonableness, and asserted that a single payment for multiple services that meets these requirements and the other requirements of §411.357(f) does not pose a risk of program or patient abuse. One commenter stated that parties often seek to rely on the isolated transaction exception to make a single payment for items or service previously furnished, where the arrangement has not been documented before payment is made, and the documentation deficiencies are not discovered until after the items or services have been furnished (which may be for a period of more than 90 days).

Several commenters asserted that the proposal, if finalized, would have an especially acute impact on hospitals located in states that prohibit the corporate practice of medicine. According to the commenters, hospitals in states without such restrictions may rely on the exception for *bona fide* employment relationships for instances in which fair market value

compensation has been paid to a physician for services provided, but the arrangement is not set out in writing and the compensation was not set in advance. The commenters noted that, in states where the employment of physicians is prohibited, the exception for *bona fide* employment relationships is not available, and the only available exception to protect the arrangement may be the exception for isolated transactions.

A few commenters, using identical language, provided an example of an arrangement that the commenters claimed should be covered by the exception for isolated transactions. In the example, an arrangement with an anesthesiology group is expiring, and despite good faith efforts to agree to the terms of a renewal arrangement, the parties disagree over the amount of compensation to be paid under the renewal. The commenters explained that the compensation formula in such a case may be very complex and take significant time to negotiate. In the commenters' example, the anesthesiology group agrees to keep providing services to patients after the previous arrangement expires while the parties continue to negotiate the terms of the renewal. The commenters contended that there is no harm to the Medicare program if, after the parties agree on compensation for the renewal, the entity relies on the exception for isolated transactions to compensate the physicians for services already furnished in the renewal term. The commenters suggested that no other exception would be available in this context, because the compensation for the renewal term was not set in advance of the services already provided, and the compensation would likely exceed the $3,500 limit under the proposed exception for limited remuneration to a physician.

Response: Our policy that the exception for isolated transactions is not available to protect a single payment for multiple or repeated services is grounded in our interpretation of the statute and the mandate under sections 1877(b)(4) and 1877(e)(6)(B) of the Act to protect only those financial relationships that do not pose a risk of program or patient abuse. We are not convinced that an ongoing service arrangement is an isolated financial transaction like a one-time sale of a property or a practice. Moreover, we do not believe that the Congress would have

required an ongoing service arrangement to satisfy all the requirements of the exception for personal service arrangements at section 1877(e)(3) of the Act, including set in advance, writing, and 1-year term requirements, and allowed the same arrangement to be excepted under the exception for isolated transactions, which does not include these requirements. The commenters' example of the anesthesiology practice illustrates our concern with the use of the exception for isolated transactions to protect an ongoing service arrangement. As explained in section II.D.5 of this final rule, the "set in advance" requirement is an important safeguard to prevent parties from adjusting, including retrospectively adjusting, the compensation under an arrangement in a manner that takes into account the volume or value of a physician's referrals. In the commenters' example, the parties would be permitted to rely on the exception for isolated transactions to compensate the physicians retroactively, thus sidestepping the "set in advance" requirement of other exceptions and opening the door to adjustments of compensation during the negotiation period that take into account the volume or value of the physicians' referrals or other business generated by the physicians.

The special rule for writing and signature requirements at final §411.354(e)(4) and the exception for limited remuneration to a physician at final §411.357(z) provide significant flexibility under our regulations while providing sufficient safeguards, including an annual monetary limit of $5,000 (as adjusted for inflation) under §411.357(z), a 90-day period for obtaining required writings under §411.354(e)(4), and the requirement under §411.354(e)(4) that the arrangement satisfy all the requirements of an applicable exception (other than the writing and signature requirement), including the "set in advance" requirement, for the first 90 days of the arrangement and thereafter. In contrast, the exception for isolated transactions does not limit the amount of compensation permissible under the arrangement, does not require the compensation arrangement to ever be in writing, and does not require compensation to be set in advance. Given the limited requirements of the exception for isolated financial transactions, we believe that excepting ongoing service arrangements under §411.357(f), which could last for

years and be worth hundreds of thousands of dollars or more, would pose a risk of program or patient abuse.

We note that, depending on the facts and circumstances, the parties in the commenters' example of an anesthesiology services arrangement could rely on the indefinite holdover provision at §411.357(d)(1)(vii) to continue the arrangement on the same terms and conditions of the original arrangement while the parties negotiate the compensation terms for the renewal arrangement. Once the parties finalize the negotiations, compensation under the arrangement could be amended under new §411.354(d)(1)(ii) (as discussed in section II.D.5. of this final rule) or the parties could enter into a new arrangement that satisfies the requirements of §411.357(d)(1) or another applicable exception to the physician self-referral law. In either case, to meet the "set in advance" requirement, the newly negotiated compensation terms may only be applied *prospectively*.

Comment: A few commenters requested that, if CMS finalizes its proposed definition of "isolated financial transaction," it should also finalize a new exception for isolated payments. The exception suggested by the commenters would permit an isolated, one-time payment for services already furnished, if: (1) the payment is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated; and (2) the remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity. Similar to the current exception at §411.357(f) for isolated transactions, there could be no additional exchanges of remuneration between the parties for 6 months after the isolated payment, except for financial relationships that satisfy all the requirements of another exception in §411.355 through §411.357. The commenters contended that their proposal incorporates the three central requirements of other compensation exceptions—fair market value compensation, commercial reasonableness of the arrangement, and compensation that is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated

by the physician—but would not require a writing or compensation set in advance.

Response: The exception suggested by the commenters does not differ substantively from the exception for isolated financial transactions at §411.357(f). For the reasons explained in response to the immediately previous comment, adopting the commenters' suggestions would pose a risk of program or patient abuse and, therefore, we cannot issue the suggested exception under the authority at section 1877(b)(4) of the Act.

3. Denial of Payment for Services Furnished under a Prohibited Referral—Period of Disallowance (§411.353(c)(1))

In the CY 2008 PFS proposed rule, we solicited comments on how to determine the period of time during which a physician may not make referrals for designated health services to an entity and the entity may not bill Medicare for the referred designated health services when a financial relationship between the parties failed to satisfy the requirements of any applicable exception (72 FR 38183). We referred to this timeframe as the "period of disallowance." We stated that, as a general matter, the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy the requirements of any applicable exception and end on the date that the financial relationship ends or is brought back into compliance (that is, satisfies all the requirements of an applicable exception). We noted, however, that it is not always clear when a financial relationship has ended. By way of example, we stated that, if a physician paid less than fair market value for the rental of office space, the below market rental payments may have been in exchange for future or anticipated referrals, so it is not clear if the financial relationship ended on the date that the lease expires. We sought comments on whether we should employ a case-by-case method for determining when a financial relationship ends or if we should, to the extent practicable, create a provision that would deem certain kinds of financial relationships to last a prescribed period of time for purposes of determining the period of disallowance. Assuming we were to prescribe a determinate amount of time for the period of disallowance in certain circumstances, we sought

comments on whether the period of disallowance could be terminated if parties returned or repaid the value of any problematic compensation under an arrangement.

In the FY 2009 IPPS proposed rule, we proposed regulations at §411.353(c)(1) pertaining to the period of disallowance (73 FR 23690 through 23692). Under that proposal, the period of disallowance would begin when the financial relationship failed to satisfy the requirements of any applicable exception. Where the noncompliance is unrelated to the payment of compensation, the period of disallowance would be deemed to end no later than the date that the financial relationship satisfies all the requirements of an applicable exception. Correspondingly, where the noncompliance is related to the payment of excess or insufficient compensation, we proposed that the period of disallowance would be deemed to end no later than the date on which the excess compensation was repaid or the additional required compensation was paid, and the arrangement satisfied all the requirements of an applicable exception. We emphasized that the proposal only prescribed an outside limit on the period of disallowance. We acknowledged that, in certain cases, a financial relationship may end before the excess compensation has been returned or the insufficient compensation paid in full, and that the period of disallowance in such cases would end when the financial relationship ended. However, we did not issue any regulations or guidance on determining when a financial relationship has ended in such cases, and we stated that the period of disallowance would have to be determined in such instances on a case-by-case basis. Lastly, we recognized that noncompliance may also arise for other reasons related to compensation, such as payments that take into account the volume or value of a physician's referrals, but we did not propose any regulations regarding how to determine the period of disallowance in such cases.

In the FY 2009 IPPS final rule, we finalized §411.353(c)(1) as proposed, without substantive modifications (73 FR 48700 through 48705). We emphasized again that the regulation only prescribed an outside date for the period of disallowance, and that parties could determine that the period of disallowance ended earlier than the outside date prescribed by the

regulation on the theory that the financial relationship ended prior to this date. We made it clear in response to commenters that the period of disallowance established at §411.353(c)(1) was not intended to extend the period of disallowance beyond the end of a financial relationship. Rather, the regulation was merely intended to give parties clear guidance on steps that could be taken to ensure that the period of disallowance had ended. In addition, we explained the application of the provisions regarding excess and insufficient compensation at §411.353(c)(1)(ii) and (iii).

In the proposed rule, noting our experience administering the SRDP and stakeholder feedback that we have received over the years, we proposed to delete in their entirety the provisions setting forth the period of disallowance at §411.353(c)(1) because we believe that, although the rules were initially intended merely to establish an outside, bright-line limit for the period of disallowance, in application, they appear to be overly prescriptive and impractical (84 FR 55809). We are finalizing this proposal. We emphasize that our action in this final rule does not permit parties to a financial relationship to make referrals for designated health services or to bill Medicare for the services when their financial relationship does not satisfy all the requirements of an applicable exception. It is a fundamental principle of the physician self-referral law that a physician may not make a referral for designated health services to an entity with which he or she (or an immediate family member) has a financial relationship, and the entity may not bill Medicare for the services, if the financial relationship between the parties does not satisfy all the requirements of an applicable exception. Nothing in this final rule affects the billing and referral prohibitions at §411.353(a) and (b). We stress that the analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship, including the operation of the financial relationship as negotiated between the parties, and it is not possible for us to provide definitive rules that would be valid in all cases.

We also emphasize that removing the period of disallowance regulations is in no way meant to undermine parties who relied on §411.353(c)(1)(ii) or (iii) in the past to establish that

the period of disallowance has ended. The general principle stated in the CY 2008 PFS proposed rule that the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy all the requirements of any applicable exception and end on the date that the financial relationship ends or satisfies all the requirements of an applicable exception remains true. And, we continue to believe that *one* way to establish that the period of disallowance has ended in such circumstances is to recover any excess compensation and bring the financial relationship back into compliance with the requirements of an applicable exception. However, we are aware that the payment of excess or insufficient compensation may complicate the question of when a financial relationship has ended or been brought back into compliance with the requirements of an applicable exception for purposes of the physician self-referral law, and believe that removing the period of disallowance regulations is the best way to ensure that what was intended as an elective "safe harbor" is not mistaken for a compulsory action required to ensure that the period of disallowance has ended.

As we stated in the proposed rule, since the publication of the FY 2009 IPPS final rule, stakeholders have questioned whether our preamble guidance was intended to state that administrative or other operational failures during the course of an arrangement, such as the erroneous payment of excess compensation or the erroneous failure to pay the full amount of compensation due during the timeframes established under the terms of an arrangement, would necessarily result in noncompliance with the physician self-referral law (84 FR 55809). Through submissions to the SRDP and other interactions with stakeholders, we are aware of questions regarding whether administrative errors, such as invoicing for the wrong amount of rental charges (that is, an amount other than the amount specified in the written lease arrangement) or the payment of compensation above what is called for under a personal service arrangement due to a typographical error entered into an accounting system, create the type of "excess compensation" or "insufficient compensation" described in our preamble guidance and the period of disallowance rules. As we stated in the proposed rule and affirm here, this was never

our intent (84 FR 55809 through 55810). However, the failure to remedy such operational inconsistencies (that is, payment discrepancies) could result in a distinct basis for noncompliance with the physician self-referral law.

In the proposed rule, endeavoring to clarify statements in the FY 2009 IPPS final rule regarding whether parties can "turn back the clock" or retroactively "cure" noncompliance, we stated that parties that detect and correct administrative or operational errors or payment discrepancies *during* the course of the arrangement are not necessarily "turning back the clock" to address past noncompliance (84 FR 55811). Rather, it is a normal business practice, and a key element of an effective compliance program, to actively monitor ongoing financial relationships, and to correct problems that such monitoring uncovers. An entity that detects a problem in an ongoing financial relationship and corrects the problem while the financial relationship is still ongoing is addressing a current problem and is not "turning back the clock" to fix past noncompliance. On the other hand, once a financial relationship has ended, parties cannot retroactively "cure" the previous noncompliance by recovering or repaying problematic compensation. Of course, to the extent that the financial relationship has ended, the period of disallowance has ended as well. We believe this policy encourages active, regular review of arrangements for compliance with the physician self-referral law. We provided an example to illustrate our policy regarding payment discrepancies in the operation of a compensation arrangement (84 FR 55810 through 55811), and believe that it is useful to repeat the example from the proposed rule here. We have modified some of the language of the example for clarity.

Assume there is a 1-year arrangement between an entity and a physician beginning January 1 for the personal services of the physician; the arrangement is memorialized at the outset in a writing signed by the parties; the amount of compensation provided for in the writing does not exceed fair market value; and the arrangement otherwise fully complies with all the requirements of an applicable exception. Assume further that the entity provides compensation to the physician in months 1 through 6 in an amount other than what is stipulated in the writing,

and the parties discover the payment discrepancy early in month 7. For purposes of this illustration, assume that a hospital pays a physician $150 per hour for medical director services when the writing evidencing the arrangement between the parties identifies $140 per hour as the physician's rate of pay. If the $150 per hour payment is due to an administrative or other operational error—that is, the payment discrepancy was unintended—the parties may, while the arrangement is ongoing during the term initially anticipated (in this example, during the year of the arrangement), correct the error by collecting the overage (or making up the underpayment, if that is the case).

We expect entities and the physicians who refer designated health services to them to operate effective compliance programs that identify administrative or operational errors and rectify them promptly. We provided this example in the proposed rule and include it in this final rule to assure parties that unintended payment discrepancies that are corrected in a timely manner do not cause a compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law during the timeframe of the erroneous operation of the arrangement. We did not state in the proposed rule, nor is it our view, that every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of an exception or that every error or mistake must be corrected in order to maintain compliance with the physician self-referral law. However, if parties identify an error that would cause the compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law, they cannot simply "unring the bell" by correcting it at some date after the termination of the arrangement. We discuss below the comments that we received regarding our statements in the proposed rule and this example.

In the proposed rule, we continued our analysis of the example provided, stating that, if the operational error—that is, payments of $150 per hour instead of the agreed upon $140 per hour—was not timely discovered and rectified, we would analyze the *actual* compensation arrangement between the parties as we would any financial relationship under the physician self-

referral law. For purposes of explaining our policies in this final rule, assume also that the payments to the physician did not revert back to the intended $140 per hour for months 7 through 12, and the hospital did not recover any of the $10 per hour paid in excess of the intended $140 per hour. Therefore, the physician was, in fact, paid $150 per hour under the parties' arrangement for the provision of medical director services. In the proposed rule, we noted that the *actual* arrangement between parties does not always coincide with the terms described in the written documentation. To properly ascertain potential noncompliance, it is important to determine whether the *actual* amount of compensation paid under the arrangement—that is, the amount the physician actually received, as opposed to the amount stipulated in the written agreement—exceeded fair market value for the services actually provided. Assuming that the *actual* amount paid ($150 per hour) did not exceed fair market value and was not determined in any manner that took into account the volume or value of the physician's referrals or other business generated for the hospital, then the potential noncompliance would relate primarily to the failure to properly document the *actual* arrangement (medical director services compensated at $150 per hour) in writing, provided that the arrangement satisfied the remaining requirements of an applicable exception. We emphasize again in this final rule that various provisions in our regulations, including those finalized in this final rule, may offer parties a means of limiting the scope of potential noncompliance when the actions of the parties differ from their documented arrangement such that they create a separate compensation arrangement that must be analyzed for compliance with the physician self-referral law. To illustrate, assume the *actual* arrangement between the parties is for the provision of medical director services compensated at $150 per hour and all the requirements of an applicable exception are satisfied except for the requirements that the compensation is set in advance, in writing, and signed by the parties. The new exception finalized at §411.357(z) for limited remuneration to a physician may be available to protect the first $5,000 paid to the physician (if the exception has not yet been utilized during the current calendar year). In addition, the parties could rely on the special rule for writing and signature

requirements finalized at §411.354(e)(3), coupled with the clarification of the writing requirement at §411.354(e)(2), to establish that the actual amount of compensation provided under the arrangement was set forth in writing within 90 consecutive calendar days of the commencement of the arrangement via a collection of documents, including documents evidencing the course of conduct between the parties. The 90-day clock would begin when the parties could no longer use (or were no longer using) the exception at §411.357(z). Thus, while the parties are relying on the exception at §411.357(z) and for up to 90 consecutive calendar days after, they would likely be developing the documentation necessary to evidence their arrangement for medical director services under which the physician is paid $150 per hour. Depending on the facts and circumstances, the parties may be able to establish that the arrangement complied with the physician self-referral law for its entire duration.

Finally, as we stated in the proposed rule, in certain instances, the failure to collect money that is legally owed under an arrangement may potentially give rise to a secondary (separate) financial relationship between the parties (84 FR 55810). In such circumstances, because forgiveness of an obligation or debt may constitute remuneration for purposes of the physician self-referral law, the parties may conclude that the only means to avoid noncompliance with the physician self-referral law is to recoup the amount owed under the arrangement. Turning back to the previous example, and assuming that the hospital corrected the error beginning in month 7 but did not collect the excess compensation from the physician, the relevant inquiry is whether the uncorrected payment errors during months 1 through 6—that is, the additional $10 per hour paid to the physician—gave rise to a secondary financial relationship (for example, an interest free loan or the complete forgiveness of debt) that must satisfy the requirements of an applicable exception.

We received the following comments and our responses follow.

Comment: Commenters generally supported the removal of the "period of disallowance" provisions from §411.353(c). One commenter stated that these provisions were cumbersome to

apply and raised questions for parties deciding whether the period of disallowance ended. The commenter further stated that removal of the provisions will help parties to establish the end of the period of disallowance on a case-by-case basis without concern of having to defend why an arrangement is believed to have ended prior to the deeming provision in the regulations. One commenter agreed with our proposal, asserting that removing the period of disallowance regulations in their entirety would offer providers more flexibility to determine when a financial relationship has ended. In contrast, two commenters requested that we replace the period of disallowance regulation to provide for a date certain by which a compensation arrangement would be deemed to end. Specifically, the commenters (in identical phrasing) suggested that the arrangement and, thus, the period of disallowance, should be deemed to end on the date that is 90 days after the physician (or immediate family member) last receives remuneration from the entity under the arrangement.

Response: As we stated in the proposed rule, although the period of disallowance provisions were initially intended to establish an outside, bright-line limit for the period of disallowance, the rules, in application, were overly prescriptive and impractical (84 FR 55809). We are finalizing our proposal to delete the provisions from §411.353(c) of our regulations. We are not persuaded to establish a rule under which the period of disallowance would end 90 days after the physician (or immediate family member) last receives remuneration from the entity under the specific arrangement. Such a rule would be inappropriate in the case of remuneration to a physician that was substantially in excess of fair market value or that was determined in a manner that took into account the volume or value of the physician's referrals to the entity. In addition, the rule suggested by the commenters could extend the period of disallowance in many cases, for instance, in a case where a lease arrangement has ended and the noncompliance was related to the parties' failure to properly document it as required by our regulations. We believe that the determination of when the period of disallowance ends is best made on a case-by-case basis taking into consideration the facts and circumstances of the specific compensation

arrangement between the parties.

Comment: Two commenters (in essentially identical comments) claimed that parties often have no way of knowing when certain types of compensation arrangements end. The commenters highlighted as particularly problematic one-time payments that are above or below fair market value and the provision of nonmonetary compensation in excess of the annual limit established in regulation. The commenter suggested that we adopt a rebuttable presumption that a compensation arrangement resulting from a one-time payment in excess or below fair market value or the payment of nonmonetary compensation above the annual limit in §411.357(k)(1) ends the earlier of 6 months after the payment and the date the value causing the one-time payment or excess nonmonetary compensation is corrected (paid or repaid) by the physician (or the physician organization in whose shoes the physician stands under §411.354(c)).

Response: One-time payments that are above or below fair market value may be an indication of a reward (that is, payment) for a physician's referrals. Referrals are not items or services (*see* section II.D.2.c. of this final rule); therefore, there is no exception available to protect the payment for referrals. A compensation arrangement that involves a one-time payment that is above or below fair market value does not lend itself to a one-size-fits-all approach. We decline to adopt the commenter's suggestion with respect to one-time payments that are above or below fair market value.

With respect to the provision of nonmonetary compensation in excess of the annual limit established in regulation, we offer the following observations. In Phase II, when explaining that the exception for temporary noncompliance does not apply to arrangements that previously complied with the exception for nonmonetary compensation at §411.357(k), we noted that, in the case of nonmonetary compensation, it is possible to be compliant in the next year, since the exception permits nonmonetary compensation up to $300 annually (69 FR 16057). In Phase III, we clarified that the aggregate limit in §411.357(k)(1) is to be calculated on a calendar year basis (72 FR 51058). Thus, on January 1 of the next calendar year, the parties would no longer be

over the limit for the current calendar year. Put another way, the period of disallowance for nonmonetary compensation overages that are not repaid in accordance with §411.357(k)(1) in most cases will end on December 31st of the year in which the excess nonmonetary compensation is provided. However, in rare instances, the period of disallowance may continue if the nonmonetary compensation is so valuable that it cannot fairly be considered the type of token of appreciation anticipated by the exception (72 FR 51059). For example, if a hospital gifts a physician an expensive new car on December 30th of a calendar year, the compensation arrangement that results from the transfer of the remuneration would not appropriately be considered to end the next day. Rather, the remuneration should be viewed as a likely exchange for the physician's future referrals. Under our final regulation at §411.351, it is clear that referrals are not items or services for which an entity may provide remuneration. In essence, with respect to the provision of nonmonetary compensation that is not a fair market value exchange for items or services and the amount of which is over the annual limit at §411.357(k)(1), there is a rebuttable presumption that the period of disallowance ends no later than December 31st of the year in which the excess nonmonetary compensation is provided. There is no need to adopt the commenter's suggestion with respect to the period of disallowance for the payment of excess nonmonetary compensation.

Comment: A large number of commenters expressed appreciation for our proposed rule guidance on remedying payment discrepancies that occur during the course of a compensation arrangement. Most of these commenters agreed that, if a party identifies an administrative or operational error or a payment discrepancy during the course of an arrangement, the parties do not fall out of compliance with the requirements of an applicable exception if the payment discrepancy is remedied prior to the end of the arrangement.

Response: As described more fully above and in our responses to other comments, an effective compliance program should enable parties to identify administrative and operational errors that result in payment discrepancies under a compensation arrangement. When payment

discrepancies are identified and rectified in a timely manner, we do not believe that the discrepancies cause a compensation arrangement to be out of compliance with the requirements of the applicable exception during the time that they existed. We are codifying in regulation at new §411.353(h) a special rule for reconciling compensation to confirm our policy view.

Comment: One commenter noted that, ideally, the impact of an effective compliance program will be the identification of payment discrepancies within the term of an arrangement, providing the parties an opportunity to cure the error. According to this commenter, however, even an effective compliance program may not identify all errors within the term of an arrangement. The commenter requested that CMS provide a grace period for correcting unintentional errors that would begin upon termination or expiration of an arrangement, expressing concern, along with other commenters, with a policy that does not allow for the correction of errors that are discovered after the termination or expiration of an arrangement. Some of these commenters asserted that it is unfair that errors discovered after several years of an ongoing multi-year arrangement could be corrected to "right the ship," while errors discovered even 1 week after the expiration of a 1-year arrangement could not. One commenter suggested that, provided that the parties to an arrangement correct any payment discrepancies within 1 year of the termination or expiration of an arrangement, we should consider the arrangement to have satisfied the requirements of the applicable exception for its entire duration. Other commenters asserted that "retroactive curing" of an arrangement (or "turning back the clock") should be permitted at any time.

Response: In Phase II, when we finalized the exception for temporary noncompliance at §411.353(f), we stated that it was applicable in those instances where an arrangement has fully satisfied the requirements of another exception for at least 180 consecutive calendar days, but has fallen out of compliance with that exception for reasons beyond the control of the entity. We also stated that parties must take steps to rectify their noncompliance or otherwise comply with the statute as expeditiously as possible under the circumstances (69 FR 16057). In regulation,

we provided that the period of time in which an entity must rectify the noncompliance must not exceed 90 consecutive calendar days. By the end of the 90-day exception period, parties must either comply with another exception or have terminated their otherwise prohibited financial relationship. We continue to believe in the importance of promptly rectifying noncompliance in those instances where the noncompliance occurs for reasons beyond the control of the entity. Our belief that parties should promptly reconcile known payment discrepancies that occur through their own administrative or operational errors in order to maintain compliance with the requirements of an exception is a logical extension of this policy. In Phase II, we also stated that the exception for temporary noncompliance is not intended to allow an entity to submit otherwise prohibited claims or bills when it purposefully takes or omits to take actions or engages in conduct that causes its financial relationship to be noncompliant with the requirements of an exception (69 FR 16057). It is our view that the knowing failure to comply with the terms of an arrangement negotiated by the parties is a purposeful or affirmative action or omission of the parties. It does not qualify as a reason beyond the control of the entity, and we are not persuaded by the commenters that we should allow a period of time for reconciliation of known payment discrepancies that exceeds the period for resolving temporary noncompliance occurring for reasons beyond the control of the entity. Specifically, permitting parties to reconcile payment discrepancies for a period of 1 year following the expiration or termination of their compensation arrangement or for an unlimited period of time would present a risk of program or patient abuse. Allowing a lengthy or unlimited period of time to correct payment discrepancies, especially in the case of significant payment discrepancies, would serve as a disincentive for parties to monitor arrangements for compliance with the physician self-referral law through an effective compliance program. Therefore, we decline to adopt the commenters' suggestions regarding the length of the reconciliation period. However, we are persuaded that a limited "grace period" to reconcile payment discrepancies following the expiration or termination of a compensation arrangement would not pose a risk of program or patient abuse. We believe that allowing the

same period of time to reconcile payment discrepancies as the period to rectify noncompliance due to reasons beyond the control of the entity—but no longer—would not pose a risk of program or patient abuse. Therefore, we are finalizing at §411.353(h) a special rule that permits an entity to submit claims or bills for designated health services and permits payment to be made to the entity for such designated health services if all payment discrepancies under the parties' arrangement (or the arrangement between the entity and the immediate family member of the physician) are reconciled within 90 consecutive calendar days of expiration or termination of the compensation arrangement, and following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement. To maintain consistency with other regulations that require remedial action within certain timeframes, the regulation specifies that the reconciliation must occur within the specified number of consecutive calendar days. Under the special rule for reconciling compensation at final §411.353(h), if the parties to a compensation arrangement reconcile all payment discrepancies in the arrangement within this timeframe, the entity may submit a claim or bill and payment may be made to the entity for designated health services referred by the physician, assuming their arrangement satisfied all the requirements of an applicable exception during the entire duration of the arrangement, after considering the reconciliation.

Comment: One commenter asserted that a result of our policy that payment discrepancies reconciled during the course of an arrangement will prevent the arrangement from being considered out of compliance with the requirements of an exception to the physician self-referral law is that parties will continue arrangements they would otherwise wish to terminate in order to keep the arrangement "live" or ongoing so that identified payment discrepancies may be reconciled.

Response: The flexibility provided under the final special rule for reconciling compensation at §411.353(h) should provide parties sufficient time to reconcile identified payment discrepancies without requiring the continuation of arrangements the parties no longer

wish to have.

Comment: A few commenters asserted that it is unfair that parties could discover an error in the first few months of a long-term arrangement but not have to correct it until the end of the arrangement, yet parties that discover an error after the termination or expiration of an arrangement would be unable to take even immediate action to cure it in order to maintain compliance with the physician self-referral law.

Response: We believe the new special rule at §411.353(h) addresses the latter part of the commenter's concern. However, the commenter's assumption that parties could discover an error in the first few months of a long-term arrangement and suffer no consequences under the physician self-referral law if they wait until the end of the arrangement to reconcile the discrepancies is incorrect. Although the new special rule for reconciling compensation at §411.353(h) allows an entity to avoid violating the billing prohibition of the physician self-referral law if the parties reconcile all payment discrepancies under their arrangement within 90 consecutive calendar days following the expiration or termination of the arrangement, parties that fail to reconcile known payment discrepancies risk establishing a second financial relationship (for example, through the forgiveness of debt or the provision of an interest-free loan) that must satisfy the requirements of an applicable exception in order to avoid the prohibitions of the physician self-referral law. If the payment discrepancy or the failure to reconcile it (that is, recover excess compensation or collect compensation owed) is significant enough to give rise to a separate financial relationship, that financial relationship must satisfy the requirements of an applicable exception once it exists. The commencement date of the second financial relationship depends on the facts and circumstances, such as the amount of excess compensation or unpaid compensation and how long the known overpayment or underpayment of the compensation has continued. For example, a large amount of excess compensation that is not recovered may give rise to a financial relationship in a shorter amount of time than a very small amount of unrecovered excess compensation or unpaid compensation. Thus, even if the

entity is deemed not to have violated the physician self-referral law's billing prohibition once the original compensation arrangement is ultimately reconciled, the entity would be prohibited from submitting a claim or bill for a designated health service referred by the physician beginning at the point where the second financial relationship exists.

Comment: One commenter suggested that we allow parties an established amount of time after the end of a financial relationship to cure noncompliance with one or more requirements of an applicable exception. The commenter did not expressly limit its suggestions to payment discrepancies due to clerical errors or other unintentional deviation from the terms of a compensation arrangement. The commenter asserted that this approach would acknowledge the realities of the rhythms of compliance programs and recognize that it can take some time to identify, quantify, and cure defects in a financial relationship with a referring physician. The commenter claimed that this approach would not absolve an entity of its responsibility to structure its financial relationships with physicians to comply with the requirements of an applicable exception or to monitor its administration of those relationships.

Response: We are not adopting the commenter's suggestion to allow the correction of any aspect of a compensation arrangement that fails to satisfy the requirement of the exception upon which the parties rely. As we understand the commenter's suggested approach, parties would be able to retroactively restructure compensation arrangements that failed to satisfy the requirements of an applicable exception for any reason. This approach would allow parties to retroactively restructure compensation terms to comply with fair market value requirements or apply a different formula for the compensation so that it does not run afoul of the volume or value standard. To the extent the commenter was suggesting this approach only with respect to the types of errors we discussed in the proposed rule, we believe our final policy addresses the commenter's concerns.

Comment: One commenter requested clarification whether a hospital that has paid a physician excess compensation due to a technical error could "cure" the error by offsetting the

amount to be recouped against future compensation over multiple years to alleviate hardship and navigate complex state employment laws related to wage recoupment and penalties charged to employees.

Response: The special rule for reconciling compensation at final §411.353(h) requires that the reconciliation of payment discrepancies occurs no later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement. The commenter's inquiry relates to an ongoing compensation arrangement between the hospital and the physician. In such circumstances, the payment discrepancy could be recovered through an offset against future compensation. However, if the parties wish to ensure that their compensation arrangement is deemed to satisfy the requirements of an applicable exception throughout its entire duration, if their compensation arrangement expires or terminates before the entire amount of the payment discrepancy is recouped, the remaining amounts must be recouped within 90 consecutive calendar days following the expiration or termination of a compensation arrangement.

Comment: One commenter expressed concern with what it interpreted as a mandate for a party to recover any excess payments it has made in order to achieve compliance with the physician self-referral law. The commenter discussed the difficulty entities face when trying to recover excess payments or collect unmade payments from physicians and physician practices. The commenter explained that disputes over whether excess payments have been made or are owed are common and contribute to the difficulty entities face recovering excess payments or underpayments in order to achieve compliance. The commenter suggested that requiring the party to which money is owed to make a "reasonable effort" to be made whole would be sufficient, with the determination of "reasonable effort" dependent on the facts and circumstances of the arrangement, such as the amount of money at issue. The commenter asserted that, if a large amount of money is at issue, a reasonable effort might very well require a hospital, for example, to sue a physician or physician practice, but a lawsuit might not be

reasonable for a dispute over a small amount of money or where the costs of the action would dwarf the amount owed. The commenter also asserted that a compromise of the amount owed may be justified if the physician or physician practice has equitable or legal defenses.

Response: As we explained in the proposed rule, the now-removed period of disallowance rules were never intended as anything more than deeming provisions so that parties could know the absolute latest date that the period of disallowance would end when the reason for the failure of their compensation arrangement to satisfy the requirements of an exception is the payment of excess compensation or the failure to pay all amounts due under the arrangement (84 FR 55809). The now-removed period of disallowance provisions never stated that a party must recover any excess payments it has made or recover any underpayment owed to it in order to achieve compliance with the physician self-referral law, nor do we adopt such a policy here. However, we reiterate the following points.

First, the new special rule for reconciling compensation arrangements permits the submission of a claim or bill and the payment of the claim or bill for a designated health service even if a compensation arrangement does not operate as intended with respect to its compensation terms, provided that: (1) no later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, all remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and (2) except for the discrepancies in payments described in paragraph (h)(1), the compensation arrangement fully complies with an applicable exception. This regulation assures an entity that its claims were not prohibited under section 1877(a)(1) of the Act or our regulations at §411.353(b). However, it is a deeming provision only and does not require the entity to reconcile payment discrepancies.

Second, if payment discrepancies are not reconciled within 90 consecutive calendar days

following the expiration or termination of a compensation arrangement, the parties may not "unring the bell" on any noncompliance resulting from the payment discrepancies. In the event that the compensation arrangement failed to satisfy the requirements of an applicable exception due to discrepancies in payment as required under the terms and conditions of the arrangement, the period of noncompliance would begin at the time the payment discrepancies caused the arrangement to fail to satisfy the requirements of the exception. As described in response to other comments below, not all payment discrepancies necessarily result in noncompliance with the physician self-referral law.

Third, although recoupment of amounts due to payment discrepancies is not required to show that the period of disallowance has ended, referrals are prohibited and claims may not be submitted during the period that a financial relationship fails to satisfy the requirements of an applicable exception. If a physician was regularly paid more for services called for under an arrangement (due to an overpayment) or regularly paid less for items or services actually received (due to failure to pay all amounts owed), and the discrepancies were not reconciled during the course of the arrangement (or, under the policies finalized in this final rule, within 90 consecutive calendar days of the termination or expiration of the arrangement), from the point of the variance on, the arrangement would not satisfy the requirements of an applicable exception. Parties are free to demonstrate that a financial relationship has ended as they see fit. As always, in the absence of a financial relationship, the physician self-referral law is not implicated.

Fourth, we do not believe that "reasonable efforts" to recover excess payments or collect amounts due are equivalent to the reconciliation of payment discrepancies. A policy requiring that the parties make "reasonable efforts" would present compliance and enforcement challenges, and would not provide for the certainty that reduces burden on stakeholders. Moreover, we do not believe that the mere undertaking of "reasonable efforts" to recover excess payments or collect amounts due is sufficient to warrant a deeming provision allowing the submission of claims or bills for designated health services and the payment for such services where parties

make "reasonable efforts" to recover excess payments or collect amounts due under their compensation arrangement.

Finally, as discussed in section II.D.2.e. of this final rule, parties to a legitimate dispute regarding a compensation arrangement may utilize the exception for isolated transactions at §411.357(f) to protect the compensation arrangement that arises from the forgiveness of an obligation related to the settlement. However, the settlement of a dispute over payment discrepancies that confers remuneration on the party that is relieved of some or all of its obligation to refund excess payments or pay amounts due under the original arrangement does not retroactively return the original arrangement to compliance with the requirements of an exception.

Comment: A few commenters questioned our analysis that the *actual* activities and remuneration between parties constitutes the arrangement that must be analyzed for compliance with the physician self-referral law. These commenters argued that the "arrangement" is what the parties intended (as referenced in a written agreement or otherwise). The commenters also stated a belief that this position is unsupported by the statute. Another commenter asserted that, once the parties have memorialized in writing an arrangement that would satisfy the requirements of an applicable exception, if the arrangement satisfied all the requirements of an applicable exception at its inception, the referral and billing prohibitions of the physician self-referral law will not and cannot attach during the course of the arrangement.

Response: As we stated in Phase II and continue to believe, section 1877 of the Act is clearly intended to make entities responsible for monitoring their compensation arrangements with physicians (69 FR 16112). Unless a compensation arrangement between a physician (or immediate family member of a physician) and an entity satisfies the requirements of an applicable exception, section 1877 of the Act and §411.353(a) and (b) of our regulations prohibit a physician from making a referral for designated health services and prohibit an entity from submitting a claim to Medicare or bill any individual, third party payor, or other entity for the

designated health services furnished pursuant to a prohibited referral. As set forth in section 1877(h)(1) of the Act, the term "compensation arrangement" means any arrangement involving remuneration between a physician (or an immediate family member of such physician) and an entity. The regulation at §411.354(c) specifies that the arrangement involving remuneration may be direct or indirect, but otherwise essentially incorporates the statutory definition. Neither of these definitions limits a compensation arrangement to that described in written documentation. Although many of the exceptions to the physician self-referral law require that the arrangement between the parties is documented in writing in order to avoid the law's prohibitions, the actions of the parties, regardless of what they have documented an arrangement to be, constitute the compensation arrangement between them.

The commenters assert that, once a compensation arrangement is documented in writing and satisfies the remaining requirements of an applicable exception, the referral and billing prohibitions of the physician self-referral law will not and cannot attach from that point forward and during the course of the arrangement, even if the parties deviate from the terms and conditions—including the payment terms and conditions—of the documented arrangement. If this were the case, parties would only need to document an arrangement that, on its face, would satisfy the requirements of an applicable exception. As noted, the physician self-referral law requires that, where a compensation arrangement exists between a physician (or an immediate family member of the physician) and the entity to which the physician makes referrals for designated health services, unless the compensation arrangement satisfies all the requirements of an applicable exception, the physician is prohibited from making referrals and the entity from submitting claims for designated health services. The physician self-referral law does not permit the physician to make referrals and the entity to submit claims for designated health services merely because an arrangement they documented would comply with the requirements of an applicable exception. The actions of the parties, regardless of what they have documented an arrangement to be, constitute the compensation arrangement between them. The commenter's

assertion that the *actual* arrangement that exists between parties need not satisfy the requirements of an exception and the law's prohibitions would not apply as long as they have documentation of some arrangement they state they intended, if true, would reduce the statute to a paper tiger.

To be clear, for purposes of determining compliance with the physician self-referral law, the arrangement under which the parties operate is analyzed to determine whether it satisfies all the requirements of an applicable exception. As discussed in the responses to other commenters, a slight deviation from the terms set forth in the written documentation of an arrangement may not result in a different *actual* arrangement between the parties.

Comment: Some commenters expressed concern with a policy under which—they assumed—even a single mistake, for instance if a check for single rental payment during an arrangement was written for the wrong amount, would turn the original arrangement into a different *actual* arrangement. One of these commenters stated its disagreement that a mere mistaken payment of remuneration creates a financial relationship within the meaning of the physician self-referral law, but conceded that, if an entity discovers that it has overpaid a physician or has been underpaid by a physician and fails to make reasonable efforts to recover the excess compensation or recover the shortfall, a new financial relationship in the form of a gift (that is, the forgiveness of debt) may arise, for which there would be no applicable exception under the physician self-referral law.

Response: We did not state in the proposed rule, nor is it our view, that every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of an exception or that every error or mistake must be corrected in order to maintain compliance with the physician self-referral law. However, if parties identify an error that would cause the compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law, they cannot simply "unring the bell" by correcting it at some date after the expiration or termination of the arrangement.

Given the individual commenter's concession that the failure to make reasonable efforts to recover excess compensation or a shortfall in payment may establish a new financial relationship in the form of a gift (that is, forgiveness of debt) for which there would be no applicable exception under the physician self-referral law, we assume that commenter's assertion that a mere mistaken payment of remuneration under a compensation arrangement does not create a second, separate financial relationship within the meaning of the physician self-referral law refers to the situation in which the parties never identify the mistaken payment (or underpayment) and are, therefore, unaware of the need to reconcile any payment discrepancies. We agree that not all transfers of remuneration create compensation arrangements. (*See* 66 FR 921 and 69 FR 16113.) In addition, theft generally does not create a compensation arrangement between the thief and the victim. For example, the theft of items, the use of office space that is not included in a lease, and the use of equipment during periods outside those included in a lease would not create a compensation arrangement between the party whose assets have been coopted and the party that took them or used them without permission or payment. Further, a slight deviation from the operation of the arrangement as anticipated and documented (where written documentation is required under the applicable exception) that results in the payment of too much or too little compensation under an arrangement—for example, in the case of a single rental payment over the course of an entire lease arrangement that was paid in the wrong amount—may not require reconciliation by the party receiving the overpayment or failing to make the full payment due, especially if the parties are not aware of the discrepancy. However, where a party is aware of the mistakes (or payment discrepancies) in the operation of its arrangements, as the commenter stated, the failure to correct the mistake may indeed establish a second financial relationship between the parties, depending on the facts and circumstances.

4. Ownership or Investment Interests (§411.354(b))

a. Titular Ownership or Investment Interest (§411.354(b)(3)(vi))

In the FY 2009 IPPS final rule, we introduced the concept of titular ownership or

investment interests in the context of our rulemaking pertaining to the "stand in the shoes" provisions at §411.354(c) (73 FR 48693 through 48699). Under the provisions finalized in the FY 2009 IPPS final rule, for purposes of determining whether a compensation arrangement between an entity and a physician organization is deemed to be a compensation arrangement between the entity and the physician owners, employees, and contractors of the organization, a physician whose ownership or investment interest in the physician organization is merely titular in nature is not required to stand in the shoes of the physician organization (73 FR 48694). We explained that an ownership or investment interest is considered to be "titular" if the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment (73 FR 48694). The concept of titular ownership or investment interests set forth in the FY 2009 IPPS final rule applied only to the stand in the shoes provisions at §411.354(c) which pertain to compensation arrangements. Because we were responding to a comment on the 1998 proposed rule (and the Phase I comments thereafter) regarding the application of the exceptions for compensation arrangements, we did not propose to extend the concept of titular ownership or investment interests to the provisions at §411.354(b) pertaining to ownership or investment interests. Separately, we had previously concluded in a 2005 advisory opinion (CMS-AO-2005-08-01) that, for purposes of section 1877(a) of the Act, physician-shareholders of a group practice who did not receive any of the purchase and ownership rights or financial risks and benefits typically associated with stock ownership would not be considered to have an ownership or investment interest in the group practice.

In the proposed rule, we proposed to extend the concept of titular ownership or investment interests to our rules governing ownership or investment interests at §411.354(b). We explained that, under proposed §411.354(b)(3)(vi), ownership and investment interests would not include titular ownership or investment interests. Consistent with the FY 2009 IPPS final rule, a "titular ownership or investment interest" would be an interest that excludes the

ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. As noted in the FY 2009 IPPS final rule, whether an ownership or investment interest is titular is determined by whether the physician has any right to the financial benefits through ownership or investment (73 FR 48694). We are finalizing §411.354(b)(3)(vi) as proposed. The new regulation at §411.354(b)(3)(vi) should afford providers and suppliers with greater flexibility and certainty under our regulations, especially in states where the corporate practice of medicine is prohibited. For the reasons similar to those stated in our advisory opinion CMS-AO-2005-08-01, namely that a physician with a titular ownership in an entity does not have a right to the distribution of profits or the proceeds of sale and, therefore, does not have a financial incentive to make referrals to the entity in which the titular ownership or investment interest exists, our interpretation and revised definition of "ownership or investment interest" does not pose a risk of program or patient abuse. We are finalizing §411.354(b)(3)(vi) as proposed, without modification.

We received the following comment and our response follows.

Comment: Nearly all the commenters that addressed the proposal to revise §411.354(b)(3) supported excluding titular ownership from qualifying as an ownership or investment interest under §411.354(b). One commenter emphasized that the proposal, if finalized, would afford physicians with greater flexibility, especially in States where the corporate practice of medicine is prohibited.

Response: We have long recognized that an interest in an entity that excludes the ability or right to receive the financial benefits of ownership should not be considered to constitute an ownership or investment interest for purposes of the physician self-referral law. (*See* CMS advisory opinion CMS-AO-2005-08-01.) Our proposal at §411.354(b)(3)(vi) codifies this policy. The policy we are explicitly articulating in regulatory text at §411.354(b)(3)(vi) will provide stakeholders greater certainty under our regulations. We caution that any compensation

arrangement between a physician and an entity in which the physician or an immediate family member of the physician holds only a titular ownership or investment interest must nonetheless satisfy all the requirements of an applicable exception in §411.355 or §411.357.

b. Employee Stock Ownership Program (§411.354(b)(3)(vii))

We stated in the 1998 proposed rule that an interest in an entity arising through a retirement fund constitutes an ownership or investment interest in the entity for purposes of section 1877 of the Act (63 FR 1708). Our interpretation was based on the premise that a retirement interest in an entity creates a financial incentive to make referrals to the entity. In Phase I, we reconsidered the issue and withdrew the statement regarding retirement interests that we made in the 1998 proposed rule (66 FR 870). As finalized in Phase I, §411.354(b)(3)(i) excluded an interest in a retirement plan from the definition of "ownership or investment interest." We stated that retirement contributions, including contributions from an employer, would instead be considered to be part of an employee's overall compensation.

We made no changes to §411.354(b)(3)(i) in Phase II. However, after publishing Phase II, we received a comment stating that, contrary to our intent, some physicians were using their retirement plans to purchase or invest in other entities (that is, entities other than the entity that sponsored the retirement plan) to which the physicians were making referrals for designated health services. We made no changes to §411.354(b)(3)(i) in Phase III, but proposed in the CY 2008 PFS proposed rule to address the potential abuse described by the commenter on Phase II (72 FR 38183). After reviewing the comments received in response to that proposal, in the FY 2009 IPPS final rule, we finalized changes to §411.354(b)(3)(i) that restricted the retirement interest carve-out to an interest in an entity that arises from a retirement plan offered by the entity to the physician (or an immediate family member) through the physician's (or immediate family member's) employment with that entity (73 FR 48737 through 48738). Under the current regulation at §411.354(b)(3)(i), if, through his or her employment by Entity A, a physician has an interest in a retirement plan offered by Entity A, any interest the physician may have in Entity

A by virtue of his or her interest in the retirement plan would not constitute an ownership or investment interest for purposes of section 1877 of the Act. On the other hand, if the retirement plan sponsored by Entity A purchased or invested in Entity B, the physician would have an interest in Entity B that would not be excluded from the definition of "ownership or investment interest" for purposes of the physician self-referral law. For the physician to make referrals for designated health services to Entity B, the ownership or investment interest in Entity B would have to satisfy the requirements of an applicable exception. We explained in the FY 2009 IPPS final rule that it would pose a risk of program or patient abuse to permit a physician to own another entity that furnishes designated health services (other than the entity which employs the physician) through his or her retirement plan, because the physician could then use the retirement interest carve-out to skirt the prohibitions of the physician self-referral law (73 FR 48737 through 48738).

Since we published the 2009 IPPS final rule, stakeholders have informed us that, in certain cases, employers seeking to offer retirement plans to physician employees may find it necessary or practical, for reasons of Federal law, State law, or taxation, to structure a retirement plan using a holding company. By way of example, assume a home health agency desires to sponsor a retirement plan for its employees and elects to establish such plan using a holding company whose primary asset will be the home health agency. To effectuate the retirement plan, the home health agency's assets are transferred to or purchased by the holding company, which then employs the physicians and other staff of the home health agency. The holding company sponsors the retirement plan for its employees, offering the employees (including physician employees) an interest in the holding company. Under our current regulation at §411.354(b)(3)(i), the physician's interest in the holding company would not be considered an ownership or investment interest, because the physician is employed by the holding company, the holding company sponsors the retirement plan, and the physician's ownership interest in the holding company arises through the retirement plan sponsored by the holding company.

However, because the physician has an interest in the retirement plan that owns the holding company, and the holding company owns the home health agency, the physician has an indirect ownership or investment interest in the home health agency that would not be excluded under §411.354(b)(3)(i) and may not satisfy the requirements of an applicable exception at §411.356.

It is our understanding that a retirement plan structure involving ownership of a holding company and indirect ownership of a legally separate entity (as defined at §411.351) may be particularly advantageous or necessary in certain circumstances for the establishment of an employee stock ownership plan (ESOP). An ESOP is an individually designed stock bonus plan, which is qualified under Internal Revenue Code (IRC) section 401(a), or a stock bonus and a money purchase plan, both of which are qualified under IRC section 401(a), and which are designed to invest primarily in qualifying employer securities. It is our understanding that ESOPs must be structured to comply with certain safeguards under the Employee Retirement Income Security Act of 1974 (ERISA) (Pub. L. 93–406), including certain nondiscrimination rules and vesting rules that, among other things, do not allow an employee to receive the value of his or her employer stocks held through the retirement plan until at least 1 year after separation from the employer. Given the statutory and regulatory safeguards that exist for ESOPs, we believe that an interest in an entity arising through participation in an ESOP merits the same protection from the physician self-referral law's prohibitions as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity. We do not believe that excluding from the definition of "ownership or investment interest" an interest in an entity that arises through participation in an ESOP qualified under IRC section 401(a) poses a risk of program or patient abuse, and we are finalizing our proposal at §411.354(b)(3)(vii) to remove such interests from the definition of "ownership or investment interest" for purposes of section 1877 of the Act. To provide regulatory flexibility in structuring retirement plans, §411.354(b)(3)(vii) is not restricted to an interest in an entity that both employs the physician and sponsors the retirement plan.

To illustrate our policy, assume that a holding company is owned by its employees, including physician employees, through an ESOP, and that the holding company owns a separate legal entity that furnishes designated health services (an "entity" for purposes of section 1877 of the Act). Under §411.354(b)(3)(vii), for purposes of the physician self-referral law, the physician's interest in the ESOP will not constitute an ownership or investment interest in the holding company or the legally separate entity the holding company owns. As with the current retirement interest exclusion at §411.354(b)(3)(i), employer contributions to the ESOP on behalf of an employed physician will be considered part of the physician's overall compensation and will have to meet the requirements of an applicable exception for compensation arrangements at §411.357 or the physician's individual referrals must satisfy the requirements of an applicable exception in §411.355.

In the proposed rule, we sought comments on whether the safeguards that are imposed by ERISA are sufficient for purposes of the physician self-referral law to ensure that an ownership or investment interest in an ESOP does not pose a risk of program or patient abuse and, if not, what additional safeguards we should include to ensure that such interests do not pose a risk of program or patient abuse. To prevent the kind of abuses identified by the commenter on Phase II, we sought comment as to whether it is necessary to restrict the number or scope of entities owned by an ESOP that would not be considered an ownership or investment interest of its physician employees. It is our understanding that an ESOP is designed to invest primarily in "qualifying employer securities," but the ESOP may also invest in other securities. We sought comment on whether the exclusion from the definition of "ownership or investment interest" should apply only to an interest in an entity arising from an interest in "qualifying employer securities" that are offered to a physician as part of an ESOP. Finally, we sought comment on whether the revision to §411.354(b)(3)(vii) is necessary; that is, whether existing §411.354(b)(3)(i) affords entities furnishing designated health services sufficient regulatory flexibility to structure nonabusive retirement plans, including ESOPs or other plans that involve

holding companies (84 FR 55812).

We are finalizing §411.354(b)(3)(vii) as proposed, without modification.

We received the following comment and our response follows.

Comment: Nearly all the commenters that addressed the proposal at §411.354(b)(3)(vii) favored excluding an interest in an entity that arises by virtue of a physician's participation in an ESOP from the regulation regarding what constitutes an ownership or investment interests under §411.354(b). Commenters stated that no additional safeguards or requirements are necessary. Two commenters pointed to specific safeguards related to ESOPs that are imposed by ERISA, which they asserted are sufficient to protect against program or patient abuse. One of the commenters highlighted that ERISA requires a fiduciary to act with care, skill, prudence, and diligence under the circumstances of a prudent person acting in a similar capacity, and ESOPs are required to have an independent appraiser to establish value for all securities which are not readily tradable on a market. The other commenter emphasized that ESOPs are also regulated by the U.S. Department of Treasury. This commenter highlighted anti-abuse rules for ESOPs in section 409(p) of the Internal Revenue Code, which mandate broad-based employee ownership and establish strict repercussions for violations. According to this commenter, since their enactment, these rules have been highly effective in ensuring that ESOPs serve their intended purpose and are not subject to abuse.

Response: We are convinced by the commenters that the legal and regulatory protections applicable to ESOPs are sufficient to prevent program or patient abuse, and we are finalizing §411.354(b)(3)(vii) without any additional requirements. We remind parties that employer contributions to the ESOP are considered part of an employee's overall compensation arrangement with his or her employer (*see* 66 FR 870). Thus, when determining whether a compensation arrangement satisfies all the requirements of an applicable exception, including the requirements pertaining to fair market value and the volume or value of the physician's referrals, employer contributions to the ESOP must be considered as part of the employee's compensation

under the arrangement.

5. Special Rules on Compensation Arrangements (§411.354(e))

In the CY 2008 PFS proposed rule, we proposed an alternative method for satisfying certain requirements of some of the exceptions in §§411.355 through 411.357 (72 FR 38184 through 38186). We explained that, although we do not have the authority to waive violations of the physician self-referral law, we do have the authority under section 1877(b)(4) of the Act to implement an alternative method for satisfying the requirements of an exception. The proposed method would have required, among other things, that an entity self-disclose the facts and circumstances of the arrangement at issue and that CMS make a determination that the arrangement satisfied all but the "procedural or 'form' requirements" of an exception (72 FR 38185). We cited the signature requirement of the exception for personal service arrangements at §411.357(d)(1) as an example of a procedural or "form" requirement, and explained that the alternative method would not be available for violations of requirements such as compensation that is fair market value, set in advance, and not determined in any manner that takes into account the volume or value of a physician's referrals.

In the FY 2009 IPPS final rule, we did not finalize the alternative method proposed in the CY 2008 PFS proposed rule. Instead, relying on our authority under section 1877(b)(4) of the Act, we finalized a rule for temporary noncompliance with signature requirements at §411.353(g) (73 FR 48705 through 48709). As finalized in the FY 2009 IPPS final rule, §411.353(g) applied only to the signature requirement of an applicable exception in §411.357. We declined to extend the special rule for temporary noncompliance to any other procedural or "form" requirement of an exception (73 FR 48706) or to noncompliance arising from "minor payment errors" (73 FR 48703). The special rule at §411.353(g) permitted an entity to submit a bill and receive payment for a designated health service if the compensation arrangement between the referring physician and the entity fully complied with the requirements of an applicable exception at §411.357, except with respect to the signature requirement, and the

parties obtained the required signatures within 90 consecutive calendar days if the failure to obtain the signatures was inadvertent, or within 30 consecutive calendar days if the failure to obtain the signatures was not inadvertent (73 FR 48706). Entities were allowed to use the special rule at §411.353(g) only once every 3 years with respect to the same physician. We stated that we would evaluate our experience with the special rule at §411.353(g) and that we may propose modifications, either more or less restrictive, at a later date (73 FR 48707). Subsequently, in the CY 2016 PFS final rule, we removed the distinction between failures to obtain missing signatures that were inadvertent and not inadvertent, thereby allowing all parties up to 90 consecutive calendar days to obtain the missing signatures (80 FR 71333). As discussed in further detail in this section of the final rule, following a revision to section 1877 of the Act, in the CY 2019 PFS final rule, we removed the provision limiting the use of the special rule at §411.353(g) to once every 3 years with respect to the same physician (83 FR 59715 through 59717).

In the CY 2016 PFS final rule, we clarified that the writing requirement of various exceptions in §411.357 can be satisfied with a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties (80 FR 71314 through 71317).[11] In response to our proposals regarding satisfaction of the writing requirement, one commenter requested that CMS permit a 60- or 90-day grace period for satisfying the writing requirement of an applicable exception, stating that such a grace period is needed for last minute arrangements between physicians and entities to which they refer patients for designated health services (80 FR 71316 through 71317). In response, we noted that the special rule at §411.353(g) applied only to temporary noncompliance with the signature requirement of an applicable exception, and we declined to extend the special rule to the writing requirement of various exceptions at §411.357. We stated that a "grace period" for satisfying the writing

[11] Our guidance on the writing requirement was subsequently codified in statute in section 1877(h)(1)(D) of the Act and incorporated into our regulations at §411.354(e). *See* 83 FR 59715 through 59717.

requirement could pose a risk of program or patient abuse; for example, if the rate of compensation is not documented before a physician provides services to an entity, the entity could adjust the rate of compensation during the grace period in a manner that takes into account the volume or value of the physician's referrals (80 FR 71317). We added that an entity could not satisfy the set in advance requirement at the outset of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began. Finally, we reminded parties that, even if an arrangement is not sufficiently documented at the outset, depending on the facts and circumstances, contemporaneous documents created during the course of an arrangement may allow parties to satisfy the writing requirement and the set in advance requirement for referrals made *after* the contemporaneous documents were created (80 FR 71317).

Section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, enacted February 9, 2018) (BiBA) added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain exceptions applicable to compensation arrangements. As amended, section 1877(h)(1)(D) of the Act provides that the writing requirement in various exceptions applicable to compensation arrangements "shall be satisfied by such means as determined by the Secretary," including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Section 1877(h)(1)(E) of the Act created a statutory special rule for temporary noncompliance with signature requirements, providing that the signature requirement of an applicable exception shall be satisfied if the arrangement otherwise complies with all the requirements of the exception and the parties obtain the required signatures no later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant. In the CY 2019 PFS final rule, we finalized at §411.354(e) a special rule on compensation arrangements, which codified in our regulations the clarification of the writing requirement found at section 1877(h)(1)(D) of the Act (83 FR 59715 through 59717). In addition, we removed the 3-year

limitation on the special rule on temporary noncompliance with signature requirements at §411.353(g)(2) in order to align the regulatory provision at §411.353(g) with section 1877(h)(1)(E) of the Act. We proposed, in the alternative, to delete §411.353(g) in its entirety and to codify section 1877(h)(1)(E) of the Act in the newly created special rules on compensation arrangements at §411.354(e). However, we declined to finalize the alternative proposal in the CY 2019 PFS final rule, because we believed it would be less disruptive to stakeholder compliance efforts to amend already-existing §411.353(g).

As stated in our proposed rule, we have reconsidered our policy on temporary noncompliance with the signature and writing requirements of various compensation arrangement exceptions (84 FR 55813 through 55814). In our administration of the SRDP, we have reviewed numerous compensation arrangements that fully satisfied all the requirements of an applicable exception, including requirements pertaining to fair market value compensation and the volume or value of referrals, except for the writing or signature requirements. In many cases, there are short periods of noncompliance with the physician self-referral law at the outset of a compensation arrangement, because the parties begin performance under the arrangement before reducing the key terms and conditions of the arrangement to writing. As long as the compensation arrangement otherwise meets all the requirements of an applicable exception, and the parties memorialize the arrangement in writing and sign the written documentation within 90 consecutive calendar days, we do not believe that the arrangement poses a risk of program or patient abuse. Therefore, it is appropriate to provide entities and physicians flexibility under our rules to satisfy the writing or signature requirement of an applicable exception within 90 consecutive calendar days of the inception of a compensation arrangement.

Relying on our authority at section 1877(h)(1)(D) of the Act, which grants the Secretary the authority to determine the means by which the writing requirement of a compensation arrangement exception may be satisfied, and section 1877(h)(1)(E) of the Act, which establishes a statutory rule for temporary noncompliance with signature requirements, we proposed to create

a special rule for noncompliance with the writing or signature requirement of an applicable exception for compensation arrangements. Specifically, we proposed to delete §411.353(g) in its entirety, codify the statutory rule for noncompliance with signature requirements at section 1877(h)(1)(E) of the Act in a special rule on compensation arrangements at §411.354(e)(3), and incorporate a special rule for noncompliance with the writing requirement into the new special rule at §411.354(e)(3). In this final rule, the special rule on writing and signature requirements is designated as §411.354(e)(4) and a new rule on electronic signatures is included in our regulations at §411.354(e)(3).

Under the special rule for writing and signature requirements at §411.354(e)(4), the writing requirement or the signature requirement is deemed to be satisfied if: (1) the compensation arrangement satisfies all the requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception. A party may rely on §411.354(e)(4) if an arrangement is neither in writing nor signed at the outset, provided both the required writing and signature(s) are obtained within 90 consecutive calendar days and the arrangement otherwise satisfied all the requirements of an applicable exception. We remind readers that, as we explained in the CY 2016 PFS final rule and subsequently codified at §411.354(e)(2), a single formal written contract is not necessary to satisfy the writing requirement in the exceptions to the physician self-referral law (80 FR 71314 through 71317). Depending on the facts and circumstances, the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Thus, parties to an arrangement would have 90 consecutive calendar days to compile the collection of documents if the parties determine to show compliance with the writing requirement in this manner. We note that, because parties must compile the documents that evidence their arrangement within 90 consecutive calendar days of the commencement of the arrangement, if an

arrangement expires or is terminated before the compilation is complete or the end of the "grace period," whichever comes first, the parties may not rely on the special rule at §411.354(e)(4) to establish compliance with the physician self-referral law for their arrangement. However, depending on the facts and circumstances, the new exception for limited remuneration to a physician at §411.357(z), which does not include a writing or signature requirement, might be available to protect a short-term arrangement.

We stressed in the proposed rule and reiterate here that our proposal to permit parties up to 90 consecutive calendar days to satisfy the writing requirement of an applicable exception does not amend, nor does it affect, the requirement under various exceptions in §411.357 that compensation must be set in advance. The amount of or formula for calculating the compensation must be set in advance and the arrangement must satisfy all other requirements of an applicable exception, other than the writing or signature requirements, in order for parties to an arrangement to establish compliance with the physician self-referral law by relying on §411.354(e)(4). Section 1877(h)(1)(D) of the Act provides the Secretary with the authority to determine the means by which the writing requirement may be satisfied, but it does not provide the Secretary similar authority with respect to the set in advance requirement. Moreover, we believe that the set in advance requirement is necessary to prevent parties from retroactively adjusting the amount of compensation paid under an arrangement in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician over the course of the arrangement, including the first 90 days of the arrangement.

In the proposed rule, we did not propose to amend the special rule on compensation that is considered to be set in advance at §411.354(d)(1), though we did clarify that §411.354(d)(1) is a deeming provision, not a requirement (84 FR 55782). As explained in more detail below, in response to comments, we are finalizing certain modifications to the special rule at §411.354(d)(1), including codifying *requirements* at §411.354(d)(1)(ii) for modifying the compensation (or formula for determining the compensation) during the course of an

arrangement. The new regulation related to modifying compensation terms during the course of an arrangement requires that the modified compensation (or formula for determining compensation) is set out in writing before the furnishing of items or services for which the modified compensation is to be paid, and it specifically provides that parties do not have 90 days under §411.354(e)(4) to reduce the modified compensation terms to writing. We emphasize that the requirements in new §411.354(d)(1)(ii), including the writing requirement, apply only when the parties *modify* the compensation (or formula for determining compensation) during the course of an arrangement.

In this final rule, the current special rule at §411.354(d)(1) is redesignated as §411.354(d)(1)(i). To underscore that this rule is merely an optional "deeming provision" and not a requirement, we are replacing the phrase "is considered 'set in advance'" with "is deemed to be 'set in advance'." We are also deleting the phrase "and may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician," because the requirements for modifying the compensation are codified in this final rule at §411.354(d)(1)(ii).

Under §411.354(d)(1)(i), compensation is deemed to be set in advance if the compensation is "set out in writing before the furnishing of items or services" and the other requirements of §411.354(d)(1)(i) are met. In the proposed rule, we stated that, because the special rule on the set in advance requirement at §411.354(d)(1) is an optional deeming provision and not a requirement, in order to satisfy the set in advance requirement included in various exceptions in §411.357, it is not necessary that the parties reduce the compensation to writing before the furnishing of items or services. Given the writing requirement in the new rule at §411.354(d)(1)(ii) on modifying compensation during the course of an arrangement, we are qualifying this statement in this final rule. As finalized in this rule, compensation may be set in advance even if it is not set out in writing before the furnishing of items or services as long as the compensation is not modified at any time during the period the parties seek to show the

compensation was set in advance. For example, assume that the parties to an arrangement agree on the rate of compensation before the furnishing of items or services, but do not reduce the compensation rate to writing at that point in time. Assume further that the first payment under the arrangement is documented and that, under §411.354(e)(4), during the 90-day period after the items or services are initially furnished, the parties compile sufficient documentation of the arrangement to satisfy the writing requirement of an applicable exception. Finally, assume that the written documentation compiled during the 90-day period provides for a rate of compensation that is consistent with the documented amount of the first payment, that is, the rate of compensation was not modified during the 90-day period. Under these specific circumstances, we would consider the compensation to be set in advance. More broadly speaking, records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance. On the other hand, under §411.354(d)(1)(ii), if the parties modify the compensation (or formula for determining the compensation) during the 90-day period (or thereafter), the modified compensation (or formula for determining the compensation) must be set out in writing before the furnishing of items or services for which the modified compensation is to be paid. To the extent that our preamble discussion in the CY 2016 PFS final rule suggested that the rate of compensation must always be set out in writing before the furnishing of items or services in order to meet the set in advance requirement of an applicable exception, we are retracting that statement (80 FR 71317).

We noted in the proposed rule and reiterate here that there are many ways in which the amount of or a formula for calculating the compensation under an arrangement may be documented before the furnishing of items or services (84 FR 55815). It is not necessary that the document stating the amount of or a formula for calculating the compensation, taken by itself, satisfies the writing requirement of the applicable exception; the document stating the amount of or a formula for calculating the compensation may be one document among many which, taken

together, constitute a collection of documents sufficient to satisfy the writing requirement of the applicable exception as interpreted at §411.354(e)(2). For example, depending on the facts and circumstances, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services, may be sufficient to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of items or services. Even if the amount of or a formula for calculating the compensation is not set in advance, depending on the facts and circumstances, the parties may be able to rely on the new exception for limited remuneration to a physician at §411.357(z). Under §411.357(z), if an entity initially pays a physician for services utilizing the exception for limited remuneration to a physician and the parties subsequently decide to continue the arrangement utilizing an exception that requires the compensation to be set in advance, such as the exception for personal service arrangements at §411.357(d)(1), depending on the facts and circumstances, the parties may be able to use documentation of the initial payments made while utilizing §411.357(z) to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of services under the subsequent personal service arrangement.

In the proposed rule, we clarified our longstanding policy that an electronic signature that is legally valid under Federal or State law is sufficient to satisfy the signature requirement of various exceptions in our regulations and sought comments on whether we should codify this policy in our regulations. We also noted that the collection of writings that parties may rely on under §411.354(e)(2) to satisfy the writing requirement of our exceptions may include documents and records that are stored electronically (84 FR 55815). In response to commenters, we are codifying a new special rule for electronic signatures at §411.354(e)(3); the special rule on writing and signature requirements, which was proposed at §411.354(e)(3), will be designated as §411.354(e)(4). While we are not codifying our policy on electronic documents, we are

reaffirming in this final rule our policy that the documents that may be used to satisfy the writing requirement under §411.354(e)(2) include electronically stored documents.

After reviewing the comments, we are finalizing the special rule for writing and signature requirements without modification at §411.354(e)(4). In addition, to clarify the set in advance requirement in various exceptions and to prevent program or patient abuse, we are finalizing requirements for modifying compensation (or the formula used to calculate compensation) during the course of an arrangement at §411.354(d)(1)(ii); for modified compensation under an arrangement to be set in advance, it must satisfy these requirements. We are also finalizing a special rule for electronic signatures at §411.354(e)(3), codifying our longstanding policy that an electronic signature that is valid under Federal or State law is sufficient to satisfy the signature requirement of various physician self-referral law exceptions.

We received the following comments and our responses follow.

Comment: We received nearly unanimous support for our proposal to allow parties up to 90 consecutive calendar days to satisfy the writing and signature requirements of various physician self-referral law exceptions. Commenters stated that the proposal, if finalized, would reduce administrative burden associated with the documentation requirements of the exceptions to the physician self-referral law, provide flexibility in situations where an arrangement begins before key terms and conditions are reduced to writing, and allow entities to avoid so-called technical noncompliance that may lead to disclosures of nonabusive arrangements to the SRDP.

Response: We agree with the commenters that the policy as finalized affords greater flexibility and will reduce the administrative burden associated with the writing and signature requirements. We believe that, with the clarification of the set in advance requirement detailed below, the special rule on writing and signature requirements at §411.354(e)(4) will not pose a risk of program or patient abuse, and we are finalizing it as proposed.

Comment: Several commenters supported our proposal to allow parties additional time to obtain required writings and signatures, but encouraged us to adopt a 120- or 180-day period

instead of the proposed 90-day period for obtaining required writings and signatures. According to some commenters, if, as required under the proposed special rule, a compensation arrangement complies with all the requirements of an applicable exception except for the writing and signature requirements, a 180-day grace period for compliance with the writing and signature requirements poses a low risk of program or patient abuse. One commenter stated that a grace period of 120 days is necessary for a large health care system to obtain required writings and signatures, given the large number of contracts the system must review and the time it takes for staff to review the contracts. Another commenter stated that small practices may need up to 120 days to comply with the writing and signature requirements.

Response: We decline to extend the special rule to allow parties up to 120 or 180 days to comply with the writing and signature requirements. With respect to the signature requirement, section 1877(h)(1)(E) of the Act currently provides for a period of 90 consecutive calendar days for parties to obtain missing signatures, and we are not persuaded that we could extend the period to 120 or 180 days under section 1877(b)(4) of the Act without posing a risk of program or patient abuse. Regarding the writing requirement, we believe that the requirement is important for ensuring transparency in potentially lucrative compensation arrangements, and we believe that extending the grace period to 120 or 180 days could pose a risk of program or patient abuse.

We believe that allowing a period of 90 consecutive calendar days to satisfy the writing and signature requirements sufficiently addresses legitimate concerns regarding the administrative burden of the writing and signature requirements and inadvertent "technical" noncompliance, especially in light of the clarification of the writing requirement at §411.354(e)(2) and the new exception for limited remuneration to a physician at §411.357(z), which may be used to protect an arrangement at its inception while parties collect required documentation and signatures to satisfy the writing and signature requirements of other exceptions on a going-forward basis.

Commenter: One commenter objected on both legal and policy grounds (the policy objections are discussed in the next comment and response) to the proposal to allow parties up to 90 consecutive calendar days to document arrangements in writing, especially for personal service arrangements excepted under §411.357(d). The commenter stated that CMS lacks the legal authority to permit parties up to 90 consecutive calendar days to document an arrangement in writing. The commenter maintained that the codification of the 90-day signature rule in the BiBA expressly provides that, except for the signature requirement, an arrangement must comply with all the other requirements of an exception, including the writing requirement. The commenter concluded that the Congress did not intend that the 90-day signature rule to be expanded to include the writing requirement.

Response: Our proposal to allow parties up to 90 consecutive calendar days to document arrangements in writing does not waive the writing requirement in various statutory and regulatory exceptions, including the exception for personal service arrangements at §411.357(d). Rather, our proposal was made pursuant to section 1877(h)(1)(D) of the Act, which expressly grants the Secretary the authority to determine the means by which the writing requirement in various exceptions is satisfied. In this context, the special rule we are finalizing at §411.354(e)(4) functions as a deeming provision. As long as parties obtain the required writings and signatures within 90 consecutive calendar days (and the other requirements of an applicable exception are met), the arrangement is *deemed* to have met the writing and signature requirement, including for the first 90 days of the arrangement. Thus, with respect to the statutory special rule for signature requirements at section 1877(h)(1)(E) of the Act, if the parties obtain the required writing within 90 consecutive calendar days and the arrangement satisfies all the other requirements of an applicable exception, then the arrangement "otherwise complies with all criteria of the applicable exception" for the initial 90-day period, including the writing requirement. While it is true that the Congress did not explicitly extend the 90-day period for signature requirements in section 1877(h)(1)(E) of the Act to the writing requirement in various

exceptions, we do not believe that section 1877(h)(1)(E) of the Act limits the grant of authority in section 1877(h)(1)(D) of the Act to determine the means by which the writing requirement may be satisfied.

We note that, in addition to the authority granted to the Secretary under section 1877(h)(1)(D) of the Act, the Secretary has authority under section 1877(b)(4) of the Act to issue regulations excepting financial relationships that do not pose a risk of program or patient abuse. In the FY 2009 IPPS final rule, we explained that, although the Secretary cannot grant immunity for violations or waive requirements of the physician self-referral law, the Secretary is authorized under section 1877(b)(4) of the Act to propose alternative methods for compliance with the physician self-referral law, including amendments to our regulations that keep within the exceptions certain financial relationships that would otherwise be out of compliance with the physician self-referral law (73 FR 48707 through 48709). Relying on this authority, in the FY 2009 IPPS final rule, we finalized the special rule for temporary noncompliance with signature requirements at §411.353(g) (73 FR 48702 through 48703), which the Congress in the BiBA codified in the substantively identical special rule for signature requirements at section 1877(h)(1)(E) of the Act. As with the special rule for temporary noncompliance with signature requirements finalized in the FY 2009 IPPS final rule, the Secretary has the authority under section 1877(b)(4) of the Act to propose alternative methods for compliance with the writing requirement of various physician self-referral law exceptions, if the financial relationships ultimately protected under the exceptions do not pose a risk of program or patient abuse. Based on our administration of the SRDP and our experience working with our law enforcement partners, we conclude that an arrangement that satisfies all the requirements of an applicable exception for the duration of the arrangement, including the set in advance requirement as detailed below, but is not initially set out in writing or signed (or both) for a period of no longer than 90 consecutive calendar days, does not pose a risk of program or patient abuse. Therefore, the Secretary also has authority under section 1877(b)(4) of the Act to issue the new special rule

for writing and signature requirements at §411.357(e)(4).

Comment: In addition to the objection discussed above, one commenter objected strongly to the proposed policy to permit parties up to 90 consecutive calendar days to document personal service arrangements. According to the commenter, the proposal, if finalized, would allow parties to routinely, intentionally, and repeatedly enter into oral agreements worth thousands of dollars, without sufficient transparency to determine if the arrangements comply with all the other requirements of an exception. Specifically, the commenter expressed concern that parties would use the "grace period" to adjust compensation upward or downward based on a physician's referrals, and these adjustments would be virtually impossible to detect, because the original arrangement would not be documented. The commenter doubted whether parties that do not timely document arrangements at their inception would assiduously comply with all the other requirements of an exception.

Response: We believe that the set in advance requirement, as clarified and codified in this final rule, addresses the commenter's concern that parties will adjust the compensation under an arrangement upward or downward during the first 90 days of the arrangement in a manner that takes into account the volume or value of referrals or other business generated by the physician, and that these adjustments will be virtually impossible to detect. In the proposed rule, we emphasized that, other than the writing and signature requirements, the special rule on writing and signature requirements requires an arrangement to satisfy *all* the requirements of an applicable exception, including the set in advance requirement, for the entire term of the arrangement, including the first 90 days (84 FR 55814). Under the current special rule for compensation that is considered set in advance at §411.354(d)(1) (that is, the special rule in effect prior to the effective date of this final rule), the formula for determining compensation cannot be changed or modified during the course of an arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Thus, to the extent that compensation is adjusted upwards or downwards during the first 90 days

of an arrangement in a manner that takes into account the volume or value of referrals or other business generated, as described by the commenter, the compensation would not be considered to be set in advance under current §411.354(d)(1). However, as we explained in the proposed rule, the special rule at current §411.354(d)(1) is merely a deeming provision, not a requirement (84 FR 55814).

We share the commenter's concern regarding inappropriate and potentially undetectable changes in compensation during the first 90 days of an arrangement and thereafter. Although modifications of the compensation terms of an arrangement are permissible under the physician self-referral law (*see* 73 FR 48697), such modifications may pose a risk of program or patient abuse, because the modifications could be made—either retroactively or prospectively—in a manner that takes into account the volume or value of a physician's referrals or other business generated by the physician. We believe that, in order to prevent program or patient abuse, including abuse of the 90-day "grace period" for documenting an arrangement in writing under final §411.354(e)(4), it is necessary to codify in our regulations certain *requirements*, including a writing requirement, for modified compensation to meet the set in advance requirement of various exceptions. Unlike the deeming provision in current §411.354(d)(1), which will be redesignated as §411.354(d)(1)(i), compliance with the new set in advance rule at §411.354(d)(1)(ii) will be *required* for any modification of the compensation terms of an arrangement. The set in advance requirements at §411.354(d)(1)(ii) are based on preamble guidance in the FY 2009 IPPS final rule on the requirements for amending compensation arrangements (73 FR 48696 through 48697).

Under final §411.354(d)(1)(ii), compensation (or a formula for determining the compensation) that is modified at any time during the course of a compensation arrangement, including the first 90 days of the arrangement, satisfies the set in advance requirement of various exceptions only if all of the following conditions are met: (1) all requirements of an applicable exception in §§411.355 through 411.357 are met on the effective date of the modified

compensation (or the formula for determining the modified compensation); (2) the modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid; and (3) before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Importantly, parties will *not* have 90 days under §411.354(d)(1)(ii) to reduce the modified compensation (or the formula for determining the modified compensation) to writing. Rather, the modified compensation (or the formula for determining the modified compensation) must be set forth in writing in sufficient detail so that it can be objectively verified *before* the furnishing of items, services, office space, or equipment for which the modified compensation is to be paid. Given our program integrity concerns, as well as the concerns identified by the commenter with modifications to the compensation terms of an arrangement, we believe that the transparency afforded by a writing requirement is necessary for modifying compensation, including modifying compensation during the first 90 days of an arrangement.

Under §411.354(d)(1)(ii)(A), the amended arrangement, including the modified rate of compensation, must satisfy the requirements of an applicable exception anew. For example, suppose that an arrangement for call coverage at the rate of $500 per 24-hour shift of coverage satisfies all the requirements of the exception for personal service arrangements at §411.357(d)(1) on day 1. If, on day 70, the parties agree to modify the compensation to $600 per 24-hour shift, the arrangement *as amended* must satisfy all the requirements of the exception for personal service arrangements; thus, the compensation under the amended arrangement (that is, $600 per 24-hour shift) may not exceed fair market value for the call coverage and may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, and the other requirements of the exception for personal service arrangements must also be satisfied. In addition, as required by §411.354(d)(1)(ii)(B),

the amended compensation rate may not be retroactive (that is, the physician may not be paid at the rate of $600 per 24-hour shift for services provided from day 1 to day 69). Lastly, under §411.354(d)(1)(ii)(C), the modified compensation (or formula for determining the compensation) must be set forth sufficiently in writing *before* the furnishing of the services for which the modified compensation is to be paid. Thus, if the physician provides the first shift of call coverage at the rate of $600 per 24-hour shift on day 75, the modified rate of compensation must be set forth in writing in sufficient detail so that it can be objectively verified before the services are furnished on day 75. Under §411.354(e)(4), the parties will still have through day 90 to reduce the entire arrangement to writing and to obtain required signatures, but in order for the modified compensation (or formula for determining the compensation) to satisfy the set in advance requirement, it must be in writing before the furnishing of services on day 75. If the parties again modify the compensation terms of the arrangement effective, for example, on day 180, all the conditions for modifying the compensation under §411.354(d)(1)(ii) must be met again, and the modified compensation must be sufficiently set forth in writing before the furnishing of services on day 180. (There is no signature requirement under §411.354(d)(1)(ii), so the writing that documents the modified compensation need not be signed by the parties.)

As noted in Phase III, in certain instances, modifications to an arrangement may be material to the compensation terms of the arrangement, without directly modifying the amount of compensation under an arrangement (72 FR 51044). Returning to the example above, assume the parties modified the arrangement on day 70 to reduce the call coverage shift from 24 to 12 hours, but retained the compensation amount of $500 per shift. For purposes of the physician self-referral law, the modification is material to the compensation terms of the arrangement because it raises questions as to whether the compensation under the amended arrangement ($500 per 12-hour shift) satisfies requirements pertaining to fair market value and the volume or value of referrals or other business generated. It is our view that such an amendment is a modification of the formula for determining compensation ($500 per 12-hour shift versus $500

per 24-hour shift), and this modification must meet all conditions of §411.354(d)(1)(ii) in order to avoid the physician self-referral law's referral and billing prohibitions. On the other hand, modifications that do not affect the compensation terms of the arrangement need not meet the conditions of §411.354(d)(1)(ii); for example, if the parties amend the schedule for the provision of call coverage from Tuesdays to Thursdays but there are no other changes to their arrangement, §411.354(d)(1)(ii) would not be triggered. Lastly, reflecting our current policy, §411.354(d)(1)(ii) does not require that the modified compensation remain in place for at least 1 year from the date of amendment and there is no prohibition on the number of times the parties may modify the compensation, provided that the conditions of §411.354(d)(1)(ii) are met each time the compensation is modified. We caution against a practice of frequently or repeatedly modifying the compensation terms over the course of an arrangement and remind readers that, under §411.354(d)(1)(ii), each time the compensation is modified, the parties must establish anew that the arrangement—as modified—satisfies all the requirements of an applicable exception.

Given our clarification and codification at §411.354(d)(1)(ii) of the conditions that modified compensation must meet in order to be set in advance, we believe that our interpretation of writing and signature requirements as set forth at §411.354(e)(4) does not pose a risk of program or patient abuse. To reiterate, with the exception of the writing and signature requirements, a compensation arrangement must satisfy all the requirements of an applicable exception, including the set in advance requirement, during the initial 90 days of the arrangement (and thereafter). Any modification of the compensation terms of an arrangement during the initial 90 days (or thereafter) must meet all the conditions of §411.354(d)(1)(ii) in order for the compensation to be set in advance. If parties modify the compensation terms of an arrangement during the first 90 days (or thereafter), the modified compensation arrangement will have to satisfy all the requirements of an applicable exception, including applicable requirements pertaining to fair market value and the volume or value of referrals or other business generated

by the referring physician. In addition, under §411.354(d)(1)(ii)(C), the modified compensation (or formula for determining the compensation) must be sufficiently set forth in writing *before* the furnishing of items, services, office space, or equipment for which the modified compensation is to be paid, even if the modification occurs during the first 90 days of the arrangement. Thus, notwithstanding the 90-day period for obtaining required writings and signatures under §411.354(e)(4), parties will not be permitted to modify the compensation terms of an arrangement during the first 90 days without documenting the modification in writing, and modifications to the compensation (or formula for determining the compensation) may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

Lastly, the commenter doubted that parties that fail to document their arrangements during the first 90 days of the arrangement work diligently to ensure compliance with other requirements of applicable exceptions. Our experience administering the SRDP suggests otherwise. We have reviewed a large number of arrangements that satisfied all the requirements of an applicable exception except the writing and signature requirements. We have learned that parties neglect to document arrangements in writing and sign the writings for a variety of reasons, such as administrative oversight or personnel changes. At the same time, we continue to believe that the writing requirement functions as an important safeguard to provide transparency and prevent program or patient abuse, and we reiterate that the best practice is to document compensation arrangements in writing from the outset. We believe that §411.354(e)(4) provides sufficient flexibility for nonabusive arrangements that fully satisfy all the requirements of an exception other than the writing or signature requirement, while incenting parties to act diligently to sign and document arrangements within 90 consecutive calendar days of the commencement of their arrangement. We also stress that arrangements that fail to satisfy all the requirements of an applicable exception other than the writing and signature requirement during the first 90 days (and thereafter) would not be protected under §411.354(e)(4).

Comment: Several commenters appreciated CMS' statement that the set in advance requirement does not require parties to set out the compensation in writing in advance of the furnishing of items or services, and that the special rule on the set in advance requirement at §411.354(d)(1) is a deeming provision, not a requirement. One commenter noted that the clarification would greatly benefit hospitals that inadvertently fail to document their compensation terms prior to starting performance. Another commenter found helpful our preamble guidance regarding the set in advance requirement and the use of practice patterns, including consistent payments patterns, to establish that the rate of compensation was set in advance. The commenter stated that a grace period of more than 90 days may be necessary in some circumstances to establish an identifiable pattern of payments.

Response: As explained above, under §411.354(e)(4), other than the writing and signature requirements, a compensation arrangement must satisfy all the requirements of an applicable exception, including the set in advance requirement, for the entire duration of the arrangement, including the first 90 days of the arrangement. Thus, the compensation (or formula for calculating the compensation) must be determined before the furnishing of items or services for which compensation is to be paid. A party submitting a claim for payment for a designated health service retains the burden of proof under §411.353(c)(2) to establish that all the requirements of an applicable exception, including the set in advance requirement, if applicable, are met. The surest and most straightforward way for a party to establish that the compensation under an arrangement is set in advance is to satisfy the deeming provision at §411.354(d)(1)(i). Under §411.354(d)(1)(i), parties that document the compensation in writing prior to the furnishing of items, services, office space, or equipment in sufficient detail so that it can be verified are *deemed* to satisfy the set in advance requirement. However, we are reiterating in this final rule that the compensation (or the formula determining the compensation) does not need to be documented in writing and it does not need to be deemed to be set in advance under §411.354(d)(1)(i) in order to satisfy the set in advance requirement during the first 90 days of the

arrangement.

In order for an arrangement to meet the writing requirement of an applicable exception on an ongoing basis, the compensation (or formula for calculating compensation) must be documented in writing by the time the 90-day period under §411.354(e)(4) expires. As we explained in the CY 2016 PFS, to determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made (80 FR 71315). A reasonable person could not verify whether the compensation under an arrangement complies with an applicable fair market value requirement, for example, if the person could not determine from the documentation what the compensation was under the arrangement. Thus, by day 91, the compensation terms of the arrangement must be documented in writing in order to satisfy the writing requirement of an applicable exception. As explained above, we decline to extend the "grace period" for collecting required writings beyond the 90-day period. We believe that 90 consecutive calendar days provides sufficient time to document an arrangement to show compliance with the requirements of an applicable exception, including the set in advance requirement.

Comment: One commenter requested additional guidance from CMS on the interim systems and documents that may be relied upon to satisfy the requirement that rental rates are set in advance during the 90-day grace period. Specifically, the commenter asked whether a scheduling platform that tracks leasing arrangements and allocates leased square footage, scheduling actual space utilization and rent, would be sufficient to satisfy the set in advance requirement.

Response: The determination as to what constitutes sufficient documentation to establish that compensation under the arrangement is set in advance depends on the facts and circumstances in each case. Therefore, we cannot opine on whether the scheduling platform

described by the commenter would be sufficient to establish that the set in advance requirement was met. We discussed in the proposed rule (and repeated above) the various documents that, depending on the facts and circumstances, may be used to establish that compensation is set in advance. We are clarifying the types of documents that, individually or taken together and depending on the facts and circumstances, may establish that compensation is set in advance. These documents include informal communications via email or text, internal notes to file, similar payments between the same parties for similar items or services under prior arrangements, generally applicable fee schedules, or, where no formal generally applicable fee schedule exists, other documents showing a pattern of payments to or from other similarly situated physicians for the same or similar items or services. This list is illustrative only and is not exhaustive. To avoid being overly prescriptive, we are not providing more determinant rules for establishing that compensation is set in advance.

Comment**:** Several commenters stated that, even if the proposed special rule is finalized, there would be continuing uncertainty regarding how parties can establish that compensation is set in advance if there is no signed writing and no steady, consistent stream of payments. Commenters noted that informal writings between the parties may not be detailed enough to satisfy the set in advance requirement and that, in certain instances, the compensation may only have been determined through in-person conversations, with no paper trail. The commenters also noted that fee schedules and comparisons to other arrangements may not be useful for compensation arrangements where the payment methodology is more complicated or customized to the specific financial relationship. Given these difficulties, the commenters requested that compensation be deemed to comply with all the requirements of an applicable exception, except the writing and signature requirements, if the parties certify in the signed writing documenting the arrangement that the arrangement met all the elements of the exception as of the commencement date of the arrangement. The commenters noted that this requirement would provide an additional safeguard, because a false certification could expose a person to potential

liability under the False Claims Act, because it would be useful evidence of scienter.

A second group of commenters suggested that, to provide additional flexibility, CMS should create another special rule on the set in advance requirement at §411.354(d). Under the commenters' proposal, compensation would be considered set in advance if: (1) the parties agree in advance that compensation under the arrangement will be fair market value and not determined in any manner that takes into account the volume or value of the physician's referrals prior to the commencement of the arrangement; (2) the parties work with reasonable diligence to establish the specific compensation amount or methodology; (3) the parties, in fact, establish the specific compensation amount or methodology within 90 days of the commencement of the arrangement; and (4) the resulting compensation is fair market value and commercially reasonable without taking into account the volume or value of referrals or other business generated by the physician. The commenters asserted that, as long as the compensation is ultimately fair market value and the arrangement is commercially reasonable, then there is no risk of program or patient abuse. The commenters further asserted that their proposal would be helpful for practices located in States that prohibit the corporate practice of medicine, because providers in those States cannot rely on the exception for *bona fide* employment relationships, which does not include a set in advance requirement. One commenter stressed that the special rule is especially needed if CMS finalizes its proposed definition of "isolated financial transaction," as parties may have relied on this exception in the past to compensate physicians for services furnished prior to the parties setting the compensation under the arrangement.

Response: We decline to adopt the deeming provision suggested by the first commenters and the new special rule recommended by the second commenters. The set in advance requirement is a statutory requirement and, in our view, both proposals are inconsistent with the statutory requirement that the compensation is set *in advance.* In addition, as explained above, the set in advance requirement is an important safeguard to prevent program or patient abuse, including abuse of the 90-day grace period under §411.354(e)(4). We believe that both

proposals would be subject to the kinds of abuses described by the commenter above, namely undocumented and potentially undetectable adjustments of the compensation during the first 90 days of the arrangement that take into account the volume or value of referrals or other business generated by the physician. Even with a requirement that compensation is, in fact, fair market value, we believe that the proposals could be subject to abuse. Typically, fair market value is a range of values, and parties could use the 90-day period to adjust compensation upwards or downwards within this range. Therefore, we do not believe that we have the authority under section 1877(b)(4) of the Act to waive the set in advance requirement for 90 days. In addition, although the Secretary has authority under section 1877(h)(1)(D) of the Act to determine how the writing requirement of various exceptions may be satisfied, we do not believe that this authority does not extend to the set in advance requirement.

With respect to the first commenters' proposal, parties documenting an arrangement after it has begun, as is permitted under §411.354(e)(4), may choose to include memoranda or other notes describing earlier agreements, including verbal agreements or agreements made by informal communications that set the compensation (or formula for determining the compensation) in advance. The memoranda would not be sufficient for the compensation to be deemed to be set in advance under §411.354(d)(1)(i), but, depending on the facts and circumstances, the memoranda could be used as evidence to help establish that the compensation was set in advance. We emphasize that there is no requirement under the physician self-referral law that parties create or retain such memoranda. As illustrated by our earlier discussion in this section II.D.5., there are a variety of ways to establish that compensation is set in advance, and, other than the deeming provision in §411.354(d)(1)(i), we are not prescribing or recommending any particular approach.

With respect to the second commenters' proposed special rule, we note that the new rule for modifying compensation at §411.354(d)(1)(ii) provides stakeholders certainty regarding the requirements that must be met in order for modified compensation to satisfy the set in advance

requirement. Parties to an arrangement are permitted to enter into an arrangement that satisfies all the requirements of an applicable exception, including the set in advance requirement, and later modify the compensation terms of the arrangement, provided that the modified compensation is not retroactive and all the other conditions of §411.354(d)(1)(ii) are met. This policy, coupled with the new exception for limited remuneration to a physician at §411.357(z), which does not require compensation to be set in advance, should provide sufficient flexibility for all providers, including providers located in States that prohibit the corporate practice of medicine.

Comment: Some commenters stated that, if finalized, the proposed 90-day grace period and the clarification of the set in advance requirement, coupled with the newly proposed exception for limited remuneration to a physician, which does not require the compensation to be set in advance, would accommodate situations where a physician's services are needed on an urgent basis, and the compensation arrangement commences before the parties can set the compensation in advance or document the compensation.

Response: We agree with the commenters that, depending on the facts and circumstances, parties that do not have an opportunity to set compensation in advance may utilize the exception for limited remuneration to a physician at §411.357(z) to protect an arrangement at its outset. If the parties decide to continue the arrangement on an ongoing basis, the parties may utilize another applicable exception without an annual limit, such as the exception for fair market value compensation at §411.357(l). Depending on the facts and circumstances, records of payments made while utilizing the exception at §411.357(z) may establish that the compensation under the ongoing arrangement satisfied the set in advance requirement of §411.357(l). Parties that utilize the exception at §411.357(l) (or another exception that requires the arrangement to be in writing and signed by the parties) for the ongoing arrangement have 90 consecutive calendar days to satisfy the writing and signature requirements under §411.354(e)(4) once the parties begin to utilize that exception (or another

applicable exception that requires the arrangement to be in writing and signed by the parties).

Comment; Several commenters urged us to finalize regulatory text, clearly stating CMS' policy that electronic signatures that are legally valid under Federal or State law are sufficient to satisfy the signature requirement of various exceptions. Some commenters also specifically asked that the regulatory text clarify that assent transmitted by email may satisfy the signature requirement. Other commenters recognized that CMS has declined in the past to specify what qualifies as a signature for purposes of the physician self-referral law, because CMS does not wish to be overly prescriptive. Nevertheless, the commenters requested that we explicitly confirm that a signature includes a sender's typed or printed name on an email or letterhead stationary that is one of the contemporaneous writings documenting an arrangement under §411.354(e)(2).

Response: Our longstanding policy is that an electronic signature that is valid under applicable Federal or State law is sufficient to satisfy the signature requirement in various physician self-referral law exceptions. To provide greater clarity and certainty to stakeholders, we are codifying this policy at §411.354(e)(3). We believe that what constitutes a valid signature that is sufficient to satisfy the signature requirement of various exceptions to the physician self-referral law depends on the facts and circumstances. We decline to provide a general rule regarding whether a sender's typed or printed name on an email or letterhead stationary would satisfy the requirement that an arrangement is signed by the parties. However, we note that, if an individual's typed or printed name on an email sent by that individual constitutes an electronic signature for purposes of applicable Federal or State law, then it qualifies as a "signature" for purposes of the physician self-referral law. Similarly, if the individual whose name is printed on the letterhead of the document being relied upon to satisfy the signature requirement of an applicable exception is also the sender of the document and the document would be considered signed by the individual under applicable Federal or State law, then it qualifies as a "signature" for purposes of the physician self-referral law. While a hand-

written "wet" signature is the paradigmatic example of a signature, there is no requirement under the physician self-referral law that parties sign a document by hand, nor is there a requirement that electronic signatures be scanned copies of hand-written signatures. Any electronic signature that is valid under applicable Federal or State law is sufficient to satisfy the signature requirement under the physician self-referral law.

6. Exceptions for Rental of Office Space and Rental of Equipment (§411.357(a) and (b))

Section 1877(e)(1) of the Act establishes an exception to the physician self-referral law's referral and billing prohibitions for certain arrangements involving the rental of office space or equipment. Among other things, sections 1877(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act require the office space or equipment to be used exclusively by the lessee when being used by the lessee. The exclusive use requirements are incorporated into our regulations at §411.357(a)(3) and (b)(2).

In the 1998 proposed rule, we stated our belief that the exclusive use requirement in the statute was meant to prevent "paper leases," where payment passes from a lessee to a lessor, even though the lessee is not actually using the office space or equipment (63 FR 1714). In Phase II, we further explained our interpretation of the exclusive use requirement (69 FR 16086). We stated that, after reviewing the statutory scheme, we believe that the purpose of the exclusive use requirement is to ensure that the rented office space or equipment cannot be shared with the lessor when it is being used or rented by the lessee (or any subsequent sublessee). In other words, a lessee (or sublessee) cannot "rent" office space or equipment that the lessor will be using concurrently with, or in lieu of, the lessee (or sublessee). We added that we were concerned that unscrupulous physicians or physician groups might attempt to skirt the exclusive use requirement by establishing holding companies to act as lessors. To foreclose this possibility, we modified the exclusive use requirements at §411.357(a)(3) and (b)(2), to stipulate that the rented office space or equipment may not be "shared with or used by the lessor or any person or entity related to the lessor" when the lessee is using the office space or equipment.

Disclosures to the SRDP have included several arrangements where multiple lessees use the same rented office space or equipment either contemporaneously or in close succession to one another, while the lessor is excluded from using the premises or equipment. At least one entity disclosed that it had invited a physician who was not the lessor into its office space to treat a mutual patient for the patient's convenience. The disclosing parties assumed that the arrangements violated the physician self-referral law, because, based on their understanding of the exceptions at §411.357(a) and (b), the arrangements did not satisfy the exclusive use requirement of the applicable exception. As noted in the 1998 proposed rule and in Phase II, the purpose of the exclusive use rule is to prevent sham leases where a lessor "rents" space or equipment to a lessee, but continues to use the space or equipment during the period ostensibly reserved for the lessee. We do not interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prevent multiple lessees from using the rented space or equipment at the same time, so long as the lessor is excluded, nor do we interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prohibit a lessee from inviting a party other than the lessor (or any person or entity related to the lessor) to use the office space or equipment rented by the lessee. Moreover, we do not believe it would pose a risk of program or patient abuse for multiple lessees (and their invitees) to use the space or equipment to the exclusion of the lessor, provided that the arrangements satisfy all the requirements of the applicable exception for the rental of office space or equipment, and any financial relationships between the lessees (or their invitees) that implicate the physician self-referral law likewise satisfy the requirements of an applicable exception. Therefore, relying on the Secretary's authority under section 1877(b)(4) of the Act, we proposed to clarify our longstanding policy that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment under §411.357(a)(3) and 411.357(b)(2). Specifically, we proposed to add the following clarification to the regulation text: For purposes of this exception, exclusive use means that the lessee (and any other lessees of the same office space or equipment) uses the office space or equipment to the exclusion of the lessor

(or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or the equipment.

After reviewing the comments, we are finalizing the proposal without modification.

We received the following comments and our responses follows.

Comment: Several commenters supported our clarification of the exclusive use requirement in §411.357(a)(3) and (b)(2) as proposed. Commenters explained that as physician practices evolve to meet the rising costs of health care, the uncertainty regarding "exclusive use" is challenging when multiple physicians use the same space or equipment, a practice which the commenter stated is common; for example, a physician may invite a guest physician into the premises in order to coordinate and jointly treat a mutual patient. Commenters stated it would not pose a risk of program or patient abuse to allow multiple parties to use space or equipment concurrently.

Response: We agree with the commenters that the clarification of the exclusive use requirement in the exception for the rental of office space at §411.357(a)(3) and the exception for the rental of equipment at §411.357(b)(2) offers flexibility and certainty to providers, and that it does not pose a risk of program or patient abuse to permit multiple lessees (and their invitees) to use space or equipment concurrently, provided that all the other requirements of the exception are satisfied and that the lessor (or any person or entity related to the lessor) is excluded. We remind readers that the exceptions for the rental of office space and equipment both require, among other things, that the rental charges are consistent with fair market value, that the space or equipment that is rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement, and that the lease arrangement would be commercially reasonable even if no referrals were made between the lessee and lessor. If a lessor collects rental payments from multiple lessees for concurrent use of office space or equipment, these requirements and all the other requirements of §411.357(a) or (b) must still be satisfied.

Comment: Multiple commenters requested that CMS update the new proposed language to permit lessors to use their own space or equipment along with lessees, especially when the lease provides access to space or equipment on a part-time basis. One commenter further explained that lessors should have the opportunity to utilize or lease such space to other lessees when it is not utilized as long as the leasing arrangements are properly administered and that any allocations of space, costs, or flow of funds can be audited, monitored and otherwise objectively verified to ensure accountability. Another commenter stated that, if a hospital leases space to a physician practice, the practice should be permitted to sublease back an exam room to the hospital for use by a hospital-employed physician or technician, in order to coordinate care. The commenter stated that if CMS is concerned about the risk of abuse, CMS could provide that space subleased back to the lessor must be at the same rate that the lessor leases the space to the tenant.

Response: Both the statute and our regulations require that leased office space or equipment is used exclusively by the lessee when it is being used by the lessee. We believe that the commenters' proposal would render this requirement meaningless. In addition, the exclusive use requirement is an important safeguard to prevent sham or "paper" leases, where a lessor collects rent from a lessee while continuing to use the leased office space or equipment during periods of time that are ostensibly reserved for the lessee. We also note that, under §411.357(a)(3) and §411.357(b)(2), rented office space or equipment may not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement. We question if a lease arrangement satisfies this requirement if the lease includes space or equipment that is consistently not used by the lessee. For example, assume a physician owns a medical office building, a hospital leases the entire building from the physician, the hospital (sublessor) subleases an office suite to the physician (sublessee), and the remainder or a significant portion of the medical office building remains unused and unoccupied. On these facts, the amount of spaced leased by the hospital (that is, the entire medical office building) likely exceeds that

which is reasonable and necessary for the legitimate business purposes of the lease arrangement.

We note that, as amended in this final rule, the exception for fair market value compensation at §411.357(l) may be used for office space and equipment lease arrangements. The exception for fair market value does not include an exclusive use requirement. Rather, the exception includes as a substitute the requirement that the arrangement not violate the anti-kickback statute. Depending on the facts and circumstances, the arrangements described by the commenters may be permitted under the exception for fair market value compensation at §411.357(l). We note, however, that the arrangements would have to satisfy the commercial reasonableness requirement at §411.357(l)(4) and the remaining requirements of the exception for fair market value compensation.

7. Exception for Physician Recruitment (§411.357(e))

Section 1877(e)(5) of the Act established an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. The exception at section 1877(e)(5) of the Act authorizes the Secretary to impose additional requirements on recruitment arrangements as needed to protect against program or patient abuse. The 1995 final rule incorporated the provisions of section 1877(e)(5) of the Act into our regulations at §411.357(e). As finalized in the 1995 final rule, §411.357(e) requires the recruitment arrangement to be in writing and signed by both parties, that is, the recruited physician and the hospital.

In Phase II, we substantially modified §411.357(e). Relying on our authority under section 1877(b)(4) of the Act, we expanded the exception at §411.357(e)(4) to address remuneration from a hospital (or a federally qualified health center (FQHC), which was added as a permissible recruiting entity under Phase II) to a physician who joins a physician practice. There, we established requirements for recruitment arrangements under which remuneration is provided by a hospital or FQHC indirectly to a physician through payments made to his or her physician practice as well as directly to the physician who joins a physician practice (69 FR

16094 through 16095). When payment is made to a physician indirectly through a physician practice that the recruited physician joins, the practice is permitted to retain actual costs incurred by the practice in recruiting the physician under §411.357(e)(4)(ii), and, in the case of an income guarantee made by the hospital or FQHC to the recruited physician, the practice may also retain the actual additional incremental costs attributable to the recruited physician under §411.357(e)(4)(iii). Under the Phase II regulation, if a recruited physician joined a physician practice, §411.357(e)(4)(i) required the party to whom the payments are directly made (that is, the physician practice that the recruited physician joins) to sign the written recruitment agreement (69 FR 16139).

In Phase III, we responded to a commenter that requested clarification with respect to who must sign the writing documenting the physician recruitment arrangement (72 FR 51051). The commenter's concern was that §411.357(e)(4)(i) could be interpreted to require that the recruiting entity (in the commenter's example, a hospital), the physician practice, and the recruited physician all had to sign one document. The commenter asserted that this would be unnecessary and would add to the transaction costs of the recruitment. The commenter suggested that we require a written agreement between the hospital and either the recruited physician or the physician practice to which the payments would be made or, in the alternative, that we should permit the hospital and the physician practice receiving the payments to sign a written recruitment agreement and require the recruited physician to sign a one-page acknowledgment agreeing to be bound by the terms and conditions set forth in that agreement. We responded that the exception for physician recruitment requires a writing that is signed by all parties, including the recruiting hospital (or FQHC or rural health clinic, which was added as a permissible recruiting entity under Phase III), the recruited physician, and the physician practice that the physician will be joining, if any, and explained that nothing in the regulations precluded execution of the agreement in counterparts.

We have reconsidered our position regarding the signature requirement at

§411.357(e)(4)(i). In the SRDP, we have seen arrangements in which a physician practice that hired a physician who was recruited by a hospital (or FQHC or rural health clinic) did not receive any financial benefit as a result of the hospital and physician's recruitment arrangement. Examples of such arrangements include arrangements under which: (1) the recruited physician joined a physician practice but the hospital paid the recruitment remuneration to the recruited physician directly; (2) remuneration was transferred from the hospital to the physician practice, but the practice passed all of the remuneration from the hospital to the recruited physician (that is, the practice served merely as an intermediary for the hospital's payments to the recruited physician and did not retain any actual costs for recruitment, actual additional incremental costs attributable to the recruited physician, or any other remuneration); and (3) the recruited physician joined the physician practice after the period of the income guarantee but before the physician's "community service" repayment obligation was completed. In each of the arrangements disclosed to the SRDP, the arrangement was determined by the disclosing party not to satisfy the requirements of the exception at §411.357(e) solely because the physician practice that the recruited physician joined had not signed the writing evidencing the arrangement. We do not believe, however, that, under the circumstances described by parties disclosing to the SRDP, there exists a compensation arrangement between the physician practice and the hospital (or FQHC or rural health clinic) of the type against which the statute is intended to protect; that is, the type of financial self-interest that impacts a physician's medical decision making. Because the physician practice is not receiving a financial benefit from the recruitment arrangement, we do not believe it is necessary for the physician practice to also sign the writing documenting the recruitment arrangement between the recruited physician and the hospital (or FQHC or rural health clinic) in order to protect against program or patient abuse. We also believe that eliminating the signature requirement for a physician practice that receives no financial benefit under the recruitment arrangement would reduce undue burden without posing a risk of program and patient abuse. For these reasons, we proposed to modify the signature requirement at

§411.357(e)(4)(i). We proposed to require the physician practice to sign the writing documenting the recruitment arrangement, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

After reviewing the comments, we are finalizing the proposal without modification.

We received the following comment and our response follows.

Comment: Several commenters supported our proposal to modify the signature requirement at §411.357(e)(4)(i) to require a physician practice to sign the writing documenting a recruitment arrangement between a physician and a hospital only if remuneration is provided to the physician indirectly through payments made to the physician practice and the physician practice does not pass directly through to the physician all the remuneration from the hospital. One commenter stated that eliminating the signature requirement for a physician practice would reduce burden without posing a risk of program and patient abuse.

Response: We agree with the commenters that the proposal will reduce the burden of compliance with the physician self-referral law without posing a risk of program or patient abuse. Therefore, we are finalizing the modification of the exception as proposed. We note in this context that a "physician practice" under §411.357(e)(4) includes a sole practice consisting of only one physician. (*See*, for example, the definition of "entity" at §411.351). Under the definition of "physician" at §411.351, a physician and the professional corporation of which he or she is a sole owner are the same for purposes of the physician self-referral law. Thus, if a recruited physician joins an existing sole physician practice, and the recruited physician receives remuneration indirectly through payments made to the sole physician practice and the sole physician practice does not pass directly through to the recruited physician all the remuneration from the hospital, then the physician in the sole physician practice or someone authorized to sign on behalf of the physician's professional corporation must sign the writing documenting the arrangement.

8. Exception for Remuneration Unrelated to the Provision of Designated Health Services (§411.357(g))

Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician does not create a compensation arrangement for purposes of the physician self-referral law, if the remuneration does not relate to the provision of designated health services. The statutory exception is codified in our regulations at §411.357(g). Because our prior rulemaking regarding §411.357(g) was based in part on an interpretation of legislative history, we reviewed the legislative history of section 1877(e)(4) of the Act and certain provisions that preceded it in the proposed rule.

As originally enacted by OBRA 1989, the referral and billing prohibitions of the physician self-referral law applied only to clinical laboratory services. OBRA 1989 created three general exceptions for both ownership and compensation arrangements at sections 1877(b)(1) through (3) of the Act, and granted the Secretary the authority at section 1877(b)(4) of the Act to create additional exceptions. Section 42017(e) of OBRA 1990 (Pub. L. 101-508) redesignated section 1877(b)(4) as 1877(b)(5) of the Act, and added an exception at section 1877(b)(4) of the Act for financial relationships with hospitals that are unrelated to the provision of clinical laboratory services. (To avoid confusion between the exception added by OBRA 1990 at section 1877(b)(4) of the Act and section 1877(b)(4) of the Act as it currently exists, the exception for financial relationships unrelated to the provision of clinical laboratory services enacted by OBRA 1990 is referred to herein as the "OBRA 1990 exception.") The OBRA 1990 exception applied to both ownership or investment interests and compensation arrangements, and excepted financial relationships between physicians (or immediate family members of physicians) and hospitals that did not relate to the provision of clinical laboratory services. OBRA 1993 eliminated the OBRA 1990 exception, but the Social Security Act Amendments of 1994 (Pub. L. 103-432) (SSA 1994) reinstated the exception through January 1, 1995.

In place of the OBRA 1990 exception, OBRA 1993 added a new exception at section

1877(e)(4) of the Act. Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician that does not relate to the provision of designated health services is not considered a compensation arrangement for purposes of the referral and billing prohibitions. Although there are certain similarities between section 1877(e)(4) of the Act and the OBRA 1990 exception, the exception at section 1877(e)(4) of the Act is narrower than the OBRA 1990 exception in several important respects: (1) the OBRA 1990 exception excepts both ownership interests and compensation arrangements between hospitals and physicians, whereas section 1877(e)(4) of the Act applies only to compensation arrangements under which remuneration passes from the hospital to the physician; (2) the OBRA 1990 exception protects a broad range of financial relationships that are unrelated to the provision of clinical laboratory services, whereas section 1877(e)(4) of the Act has a narrower application, applying only to remuneration unrelated to the provision of designated health services; and (3) the OBRA 1990 exception applies to financial relationships between entities and physicians or their immediate family members, whereas section 1877(e)(4) of the Act applies only to compensation arrangements with physicians.

In the 1998 proposed rule, we proposed to revise our regulation at §411.357(g) to reflect our interpretation of section 1877(e)(4) of the Act (63 FR 1702). (The prior regulation at §411.357(g) was based on former sections 1877(b)(4) and (e)(4) of the Act as they were effective on January 1, 1992 (63 FR 1669).) We stated that, for remuneration from a hospital to a physician to be excepted under §411.357(g), the remuneration must be "completely unrelated" to the furnishing of designated health services. We clarified that the remuneration could not in any direct or indirect way involve designated health services, and further that the exception would not apply in any situation involving remuneration that might have a nexus with the provision of, or referrals for, a designated health service (63 FR 1702). We further stated that the remuneration could in no way reflect the volume or value of a physician's referrals, and that payments to physicians that were "inordinately high" or above fair market value would be presumed to be related to the furnishing of designated health services. We provided the

following examples of remuneration that might be completely unrelated to the furnishing of designated health services and excepted under §411.357(g): (1) fair market value rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member; and (2) compensation for teaching, general utilization review, or administrative services.

In Phase II, we finalized the exception at §411.357(g) with modifications (69 FR 16093 through 16094). As finalized, in addition to requiring that the remuneration does not in any way take into account the volume or value of the physician's referrals, §411.357(g) requires that the remuneration is wholly unrelated (that is, neither directly nor indirectly related) to the furnishing of designated health services. The regulation stipulates that remuneration relates to the furnishing of designated health services if it: (1) is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; (2) is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or (3) otherwise takes into account the volume or value of referrals or other business generated by the referring physician. We stated that we incorporated cost reporting principles in the regulation in order to provide the industry with bright-line rules to determine whether remuneration is related to the furnishing of designated health services (69 FR 16093). At the same time, we retracted the statement from the 1998 proposed rule that general utilization review or administrative services might not be related to the furnishing of designated health services. We justified our narrow interpretation of section 1877(e)(4) of the Act on the legislative history of the exception, noting that, initially, under the original statute, the exception was necessary to insulate a hospital's relationships with physicians that were unrelated to the provision of clinical laboratory services, a very small element of a hospital's practice. We continued that, since 1995, however, all hospital services are designated health services and a narrower interpretation of the exception is required to prevent abuse (69 FR 16093). We have made no changes to §411.357(g)

since Phase II. Commenters on Phase II stated that the Congress intended hospitals to be able to provide any amount of remuneration to physicians, provided that the remuneration did not *directly* relate to designated health services. In Phase III, based on our interpretation of the legislative history at that time, we reaffirmed our narrow interpretation of section 1877(e)(4) of the Act (72 FR 51056).

Based on our review of the statutory history of the OBRA 1990 exception and section 1877(e)(4) of the Act, and comments we received on our CMS RFI, we proposed certain modifications to the exception at §411.357(g) to broaden the application of the exception. In the proposed rule, we stated that we continued to agree with the statement in Phase II that the exception at section 1877(e)(4) of the Act is significantly narrower than the OBRA 1990 exception. There are many financial relationships between hospitals and physicians that would be permissible under the OBRA 1990 exception because they do not relate, directly or indirectly, to the provision of clinical laboratory services. On the other hand, insofar as the exception at section 1877(e)(4) of the Act requires the remuneration to be unrelated to the provision of designated health services, and OBRA 1993 defines this term to include inpatient and outpatient services, the scope of protected compensation arrangements under section 1877(e)(4) of the Act is much narrower than that of the OBRA 1990 exception. Generally speaking, most financial relationships between hospitals and physicians relate to the furnishing of designated health services, in particular, inpatient or outpatient hospital services. That being said, we also considered in the proposed rule that OBRA 1993 did not merely strike the term "clinical laboratory services" in the OBRA 1990 exception and substituted the term "designated health services." Rather, OBRA 1993 eliminated the OBRA 1990 exception and created a new (albeit somewhat similar) exception at section 1877(e)(4) of the Act. In light of this statutory history, in the proposed rule we stated that the most accurate interpretation of section 1877(e)(4) of the Act is not as a carryover of the 1990 OBRA exception into the significantly revised statutory regime established by OBRA 1993, but rather as a new exception that was intentionally created by the

Congress in OBRA 1993, the very same legislation in which the Congress expanded the referral and billing prohibition of the physician self-referral law to inpatient and outpatient hospital services. We stated in the proposed rule that, in creating a new exception for remuneration unrelated to the provision of designated health services *and* expanding the definition of "designated health services" to include inpatient and outpatient hospital services, we believe that the Congress intended the exception to apply to a narrow—but not empty—subset of compensation arrangements between hospitals and physicians.

In the proposed rule, we reconsidered what remuneration, if any, is permissible under the exception if the exception does not apply to any item, cost, or service that could be allocated to Medicare or Medicaid under cost reporting principles, or to remuneration that is offered in any preferential or selective manner whatsoever based on comments received to the CMS RFI. We stated that we agreed with the commenters that the current exception is too restrictive and that the current §411.357(g) has an extremely limited application (84 FR 55818).

To give appropriate meaning to the statutory exception at section 1877(e)(4) of the Act, we proposed to delete the current provisions at §411.357(g)(1) and (2) in their entirety and to remove the phrase "directly or indirectly" from the regulation text. In place of existing §411.357(g)(1) and (2), we proposed language that incorporates the concept of patient care services as the touchstone for determining when remuneration for an item or service is related to the provision of designated health services. In particular, we proposed regulation text to clarify that remuneration from a hospital to a physician does not relate to the provision of designated health services if the remuneration is for items or services that are not related to patient care services. We noted that section 1877(e)(4) of the Act specifically excepts remuneration unrelated to the *provision* of designated health services. For purposes of applying the exception at section §411.357(g), we interpreted section 1877(e)(4) of the Act to except remuneration unrelated to the act or process of providing designated health services, a concept which is not as all-encompassing as remuneration that is unrelated in any manner whatsoever to designated

health services. We stated our belief that patient care services provided by a physician, when the physician is acting in his or her capacity as a medical professional, are integrally related to the act or process of providing designated health services, regardless of whether such services are provided to patients of the hospital; thus, payment for such services relates to the provision of designated health services. Likewise, we proposed that items that are used in the act or process of furnishing patient care services are integrally related to the provision of designated health services, and payments for such items relate to the provision of designated health services. On the other hand, we also stated our belief that remuneration from a hospital to a physician for services that are not patient care services or items that are not used in the act or process of providing designated health services does not relate to the *provision* of designated health services and would, therefore, not be prohibited under section 1877(e)(4) of the Act or our regulations at proposed §411.357(g) (provided that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals).

In the proposed rule, we stated our belief that the concept of patient care services would provide a determinant and practicable principle for applying §411.357(g) to compensation arrangements between hospitals and physicians. We also noted that the proposed regulation at §411.357(g) retained the requirement that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals. Remuneration that is determined in any manner that takes into account the volume or value of a physician's referrals clearly relates to the provision of designated health services, regardless of the nature of the item or service for which the physician receives remuneration. Thus, the proposed provisions at §411.357(g)(2) and (g)(3), which were intended to clarify when remuneration does not relate to the provision of designated health services, would not have applied to remuneration that is determined in any manner that takes into account the volume or value of a physician's referrals (84 FR 55816 through 55817).

In the proposed rule, we stated that remuneration from a hospital to a physician that

pertains to the physician's patient care services is the paradigm of remuneration that relates to the provision of designated health services. Most obviously, when a physician provides patient care services to hospital patients, the physician's patient care services are directly correlated with the provision of designated health services. Thus, remuneration from the hospital to the physician for such services is clearly related to designated health services. However, we noted in the proposed rule that there does not have to be a direct one-to-one correlation between a physician's services and the provision of designated health services in order for payments for the service to be related to the provision of designated health services. For example, payment for emergency department call coverage relates to the furnishing of designated health services, even if the physician is not as a matter of fact called to the hospital to provide patient care services, because the hospital is paying the physician to be available to provide patient care services at the hospital. Similarly, medical director services typically include, among other things, establishing clinical pathways and overseeing the provision of designated health services in a hospital. Under our proposal, payments for such services would relate to the furnishing of designated health services for purposes of applying the exception at proposed §411.357(g). We also stated that utilization review services are closely related to patient care services, and for this reason, we considered remuneration for such services to be related to the furnishing of designated health services (84 FR 55818).

In contrast to the services described above, in the proposed rule we stated that the administrative services of a physician pertaining solely to the business operations of a hospital are not related to patient care services. Thus, under our proposal, if a physician were a member of a governing board along with persons who were not licensed medical professionals, and the physician received stipends or meals that were available to the other board members, we would not have considered the remuneration provided to the physician to relate to the provision of designated health services, provided that the physician's compensation for the administrative services was not determined in a manner that takes into account the volume or value of his or her

referrals. In this instance, we stated that the dispositive factor in determining that a physician's services are not related to the provision of designated health services is that the services are also provided by persons who are not licensed medical professionals, and the physician is compensated on the same terms and conditions as the non-medical professionals. Because the services could be provided by persons who are not licensed medical professionals, we concluded that the services were not patient care services. To provide clarity for stakeholders, we proposed a general principle at §411.357(g)(3) for determining when remuneration for a particular service, when provided by a physician, is related to the provision of designated health services. We stated that, if a service can be provided legally by a person who is not a licensed medical professional and the service is of the type that is typically provided by such persons, then payment for such a service is unrelated to the provision of designated health services and may be protected under proposed §411.357(g), provided that it is not determined in a manner that takes into account the volume or value of the physician's referrals. We noted in this context that "licensed medical professional" would include, but would not be limited to, a licensed physician. That is, if a service could be provided legally by both a physician and a medical professional who is not a physician, such as a registered nurse, but the service could not be provided by a person who is not a licensed medical professional, it would still be considered a patient care service under §411.357(g)(3) as proposed. Thus, we proposed that remuneration provided by a hospital to a physician for the service would not be excepted under §411.357(g), notwithstanding the fact that the service does not have to be performed by a *physician* (84 FR 55818 through 55819).

In the proposed rule, we stated that with respect to remuneration from a hospital for items provided by a physician, typical examples of remuneration that is related to the provision of designated health services include the rental of medical equipment and purchasing of medical devices from physicians. Because these items are used in the provision of patient care services, and patient care services may be designated health services or be directly correlated with the

provision of designated health services, we concluded that remuneration for such items clearly relates to the provision of designated health services. We also stated that rental of office space where patient care services are provided, including patient care services that are not necessarily designated health services, is remuneration related to the provision of designated health services. In contrast, we stated that, if a physician who joins another practice sells the furniture from his or her medical office to a hospital, and the hospital places the furniture in the hospital's facilities, as long as the payment is not determined in a manner that takes into account the physician's referrals, the remuneration would not be considered to be related to the provision of designated health services under our proposal. Also, we stated our continued belief that, as first stated in the 1998 proposed rule, §411.357(g) is available to except rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member. To provide stakeholders with greater clarity, we proposed to stipulate in regulation that remuneration provided in exchange for any item, supply, device, equipment, or office space that is used in the diagnosis or treatment of patients, or any technology that is used to communicate with patients regarding patient care services, is presumed to be related to the provision of designated health services for purposes of §411.357(g) (84 FR 55819).

In the proposed rule, we stated our belief that §411.357(g)(2) and (3) would provide clarity regarding when payments for items and services relate to the provision of designated health services, and also give the meaning to the statutory exception. We stated that the requirement pertaining to the volume or value of a physician's referrals at §411.357(g)(1) would ensure that payments to a physician for items or services that are ostensibly not related to patient care services are not in fact disguised payments for the physician's referrals. We sought comments on our proposals, as well as other possible ways for distinguishing between remuneration that is related to the provision of designated health services and remuneration that is unrelated to the provision of designated health services. Specifically, we sought comment as to whether we should limit what we consider to be "remuneration related to the provision of

designated health services" to remuneration paid explicitly for a physician's provision of designated health services to a hospital's patients (84 FR 55819).

We received the following comment and our response follows.

Comment: Commenters on the proposal generally supported our efforts to restore utility to the statutory exception, but a few commenters expressed valid concerns that the expansion of the exception, especially without substantial guidance and examples of its application, would risk program or patient abuse. One commenter noted that "patient care services" is a defined term under our regulations, and it is not clear whether the term "patient care services" as used in §411.357(g) was intended to have the same meaning as "patient care services" as defined at §411.351. Many commenters, citing uncertainty in applying the proposed exception, requested codification of specific remuneration that would be deemed not to relate to the provision of designated health services.

Response: Given the concerns raised by commenters, we are not finalizing our proposed revision to §411.357(g) at this time. We are continuing to evaluate the best way to restore utility to the statutory exception, and we may finalize revisions to the exception for remuneration unrelated to the provision of designated health services in future rulemaking.

9. Exception for Payments by a Physician (§411.357(i))

Section 1877(e)(8) of the Act excepts payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services, or to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value. The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at §411.357(i). In the 1998 proposed rule, we proposed to interpret "other items and services" to mean any kind of item or service that a physician might purchase (that is, not limited to "services" for purposes of the Medicare program in §400.202 of this Chapter), but not including clinical laboratory services or those items or services that are specifically excepted by another provision in §§411.355 through 411.357 (63

FR 1703). We stated that we did not believe that the Congress meant the exception for payments by a physician to protect financial relationships that were covered by more specific exceptions with specific requirements, such as the exceptions for rental arrangements at section 1877(e)(1) of the Act.

In Phase II, we responded to commenters that disagreed with our position that the exception for payments by a physician is not available for arrangements involving any items or services excepted by another exception (69 FR 16099). We reiterated the statutory interpretation from the 1998 proposed rule, explaining that the determination that items and services addressed by another exception should not be covered in this exception is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception for payments by a physician from negating the statute (69 FR 16099; *see also* 72 FR 51057). As a result, we made no changes to the regulation at §411.357(i) in Phase II. Thus, as finalized in Phase II, the exception for payments by a physician at §411.357(i) stated that the exception could not be used for items or services that are specifically *excepted* by another exception in §§411.355 through 411.357, with a parenthetical clarifying that this included the exception for fair market value compensation at §411.357(l). However, at that time, the exception for fair market value compensation applied only to the provision of items or services *by* physicians *to* entities; the exception did not apply to items or services provided by entities to physicians.

Following the publication of Phase II, commenters complained that neither §411.357(i) nor §411.357(l) were available to protect many arrangements wherein physicians purchased items and services from entities, because: (1) the exception for payments by a physician was limited to the purchase of items and services not specifically excepted by another exception in §§411.355 through 411.357 (including §411.357(l)); and (2) the exception for fair market value compensation did not apply to items or services provided by an entity to a physician (72 FR 51057). In response to the commenters, we expanded §411.357(l) in Phase III to include both items and services furnished by physicians to entities *and* items and services furnished by entities

to physicians (72 FR 51094 through 51095). However, Phase III did not modify the exception for payments by a physician,[12] including the parenthetical indicating that §411.357(i) could not be used for items or services specifically excepted under §411.357(l). We acknowledged that the expansion of the exception for fair market value compensation to items or services furnished by entities to physicians would require parties in some instances to rely on §411.357(l) instead of §411.357(i). We concluded, however, that upon further consideration, we believe that the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse (72 FR 51057). We also emphasized in Phase III that the exception for payments by a physician could not be used to protect office space leases (72 FR 51044 through 51045). We explained that we did not believe that the lease of office space is an "item or service" and that parties seeking to protect arrangements for the rental of office space must rely on §411.357(a) (72 FR 51059). In 2015, when we finalized the exception at §411.357(y) for timeshare arrangements, we reaffirmed our position that the exception for payments by a physician is not available for arrangements involving the rental of office space (80 FR 71325 through 71327).

Commenters on the CMS RFI stated that our interpretation of the exception for payments by a physician, especially our determination that the exception is not available if any other exception would apply to an arrangement, unreasonably narrowed the scope of the statutory exception. Commenters also noted that compliance with other exceptions is generally more burdensome than compliance with the statutory exception for payments by a physician, and urged us to conform the language of the exception at §411.357(i) to the statutory language at section 1877(e)(8) of the Act. As noted in the proposed rule, we found the CMS RFI comments

[12] In the September 5, 2007 **Federal Register**, the regulation text of the exception for payments by a physician was modified in error. Phase II stated that §411.357(i) is limited to payments for items or services that are "not specifically excepted by another provision in §§411.355 through 411.357" (69 FR 16140). The September 5, 2007 **Federal Register** replaced "excepted" with "addressed" (72 FR 51094). The original language of the exception was restored in a correction notice to Phase III and published in the December 4, 2007 **Federal Register** (72 FR 68076).

regarding the narrowing of the statutory exception persuasive and, as a result, we reconsidered our position regarding the availability of the exception for payments by a physician for certain compensation arrangements (84 FR 55820).

To explain our proposal and the policies we are setting forth in this final rule regarding the availability of the exception at §411.357(i), it is important to distinguish between the statutory exceptions found at section 1877(e) of the Act (codified at §411.357(a) through §411.357(i) of our regulations) and the regulatory exceptions (codified at §411.357(j) *et seq*.) issued using the Secretary's authority under section 1877(b)(4) of the Act.[13] We continue to believe that the exception for payments by a physician at section 1877(e)(8) of the Act was not meant to apply to compensation arrangements that are specifically excepted by other *statutory* exceptions in section 1877 of the Act. Given the placement of the exception for payments by a physician as the final statutory exception at section 1877(e) of the Act, we believe that this exception functions as a catch-all to protect certain legitimate arrangements that are not covered by the exceptions at sections 1877(e)(1) through (7) of the Act. As a matter of statutory construction, the catch-all exception at section 1877(e)(8) of the Act does not supersede the previous exceptions. With respect to arrangements for the rental of office space or the rental of equipment, in particular, we note that the statutory exceptions for such arrangements at section 1877(e)(1) of the Act include requirements that are specific to rental arrangements, as well as general requirements that the arrangements are commercially reasonable, that rental charges are fair market value, and that compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. We do not

[13] Section 1877(b)(5) of the Act directs the Secretary to establish a regulatory exception for electronic prescribing, but does not provide any statutory text or specific requirements for the exception. Pursuant to this authority, we established an exception for electronic prescribing items and services at §411.357(v). Although §411.357(v), unlike all the other exceptions at §411.357(j) *et seq.*, was not issued using the Secretary's authority under section 1877(b)(4) of the Act, for purposes of our interpretation of the exception for payments by a physician, we treat §411.357(v) as a regulatory exception. In particular, we interpret section 1877(b)(5) of the Act as a grant of authority for the Secretary to issue a regulatory exception; it is not itself a statutory exception, just as section 1877(b)(4) of the Act grants the Secretary authority to create exceptions, but is not an exception in its own right.

believe that the Congress would have imposed these particularized requirements at section 1877(e)(1) of the Act, but also allowed parties to sidestep them by relying on the exception for payments by a physician to protect rental arrangements.

Although we maintain our policy with respect to the statutory exceptions, we no longer believe that the regulatory exceptions should limit the scope of the exception for payments by a physician. Thus, we proposed to remove from §411.357(i)(2) the reference to the regulatory exceptions, including the parenthetical referencing the exception for fair market value compensation. We also proposed that the exception at §411.357(i) would not be available to protect compensation arrangements specifically addressed by one of the statutory exceptions, codified in our regulations at §411.357(a) through (h). Under the proposal, parties would generally be able to rely on the exception at §411.357(i) to protect fair market value payments by a physician to an entity for items or services furnished by the entity, even if a regulatory exception at §411.357(j) *et seq*. may be applicable. However, for the reasons noted previously in this section II.D.9., §411.357(i) would not be applicable to arrangements for the rental of office space or equipment.[14] That is, we believe that, as a matter of statutory construction, the exception for payments by a physician is not available to protect any type of arrangement that is specifically addressed by another statutory exception at section 1877(e) of the Act, including arrangements for the rental of office space or the rental of equipment.

We are retracting our prior statements that office space is neither an "item" nor a "service." We made these statements, in significant part, to emphasize that we do not believe that the exception for payments by a physician should be available to protect the type of arrangement for which the Congress established a specific exception in statute. In this final rule, we have more clearly explained this position and no longer believe it is necessary to preclude office space from the categories of "items" and "services." (We note that we have not made

[14] Elsewhere in this final rule, we are finalizing our proposal to extend §411.357(l) to arrangements for the rental of office space, including rentals of less than 1 year, provided that all the requirements of the exception are satisfied.

prior similar statements regarding equipment.) As such, and because the exception at §411.357(i) is unavailable to protect an arrangement for the rental of office space or equipment, parties seeking to protect an arrangement for the rental of office space or equipment must structure the arrangement to satisfy the requirements of §411.357(a), §411.357(b), §411.357(l) (for direct compensation arrangements), or §411.357(p) (for indirect compensation arrangements). Although we are retracting our statement that office space is not an "item or service," parties may not rely on the exception for personal service arrangements at §411.357(d)(1) to protect arrangements for the rental of office space. We noted that §411.357(i) may be available to protect payments by a physician for the lease or use of space that is *not* office space, such as storage space or residential real estate.

We also proposed to remove from §411.357(i)(2) the reference to exceptions in §§411.355 and 411.356. As noted previously, we interpret the exception at section 1877(e)(8) of the Act for payments by a physician to function in the statutory scheme as a catch-all, to apply to compensation arrangements for the furnishing of other items or services by entities that are not specifically addressed at sections 1877(e)(1) through (7) of the Act. Therefore, we no longer believe that the exception should be limited by the exceptions at sections 1877(b) and (c) of the Act or the regulatory exceptions codified in §§411.355 and 411.356.

Lastly, "items or services" furnished by the entity under the exception for payments by a physician may not include cash or cash equivalents. That is, the physician may not make in-kind "payments" to the entity in exchange for cash from the entity. We believe that cash provided by an entity to a physician poses a risk of program or patient abuse, and that the Congress would have included additional safeguards at section 1877(e)(8) of the Act if the exception were designed to cover such arrangements. At the same time, we note that, if a physician pays an entity $10 in cash for a gift card worth $10, we do not believe that this would constitute a financial relationship for purposes of the physician self-referral law. Likewise, in cases where a physician or an entity acts as a pure pass-through, taking money from one party and passing the

exact same amount of money to another party, we do not believe that the pass-through arrangement is a financial relationship for purposes of the physician self-referral law.

After reviewing the comments, we are finalizing our proposal at §411.357(i) without modification.

We received the following comments and our responses follow.

Comment: Most commenters that addressed this issue supported our proposed interpretation of the statutory payments by a physician exception and the proposed regulatory changes to implement the interpretation. One commenter asserted that our previous interpretation of the statute inappropriately narrowed the utility of the exception. Other commenters emphasized that finalizing our proposal would increase flexibility and reduce the cost and burden of compliance with the physician self-referral law. Commenters generally agreed that the exception should be available to protect an arrangement even if the arrangement is addressed by a regulatory exception, but not if another statutory exception, such as the exception for the rental of office space, is applicable to the arrangement. One commenter agreed that the exception for payments by a physician functions in the statutory scheme as a "catch-all" exception that applies only to arrangements that are not otherwise addressed in a statutory exception.

Response: We agree with the commenters and are finalizing our revisions to §411.357(i) as proposed.

Comment: Several commenters supported our retraction of our previous policy that office space is neither an item nor a service. The commenters recognized that, under the regulatory scheme of the physician self-referral law, retraction of the policy is key to making the exception for fair market value compensation at §411.357(l) applicable to arrangements for the rental of office space.

Response**:** In this final rule, we are reiterating the retraction of our previous policy that office space is neither an item nor a service. Given our interpretation of the exception for

payments by a physician within the statutory scheme of exceptions applicable only to compensation arrangements, we no longer believe that it is necessary to distinguish office space from items or services in order to ensure that the exception at §411.357(i) may not be used for rental of office space arrangements. As recognized by the commenters and explained in section II.D.10 of this final rule, parties may now use the exception for fair market value compensation at §411.357(l) to except arrangements for the rental of office space. At the same time, we are taking this opportunity to clarify that office space is not a service, and therefore the exception for personal service arrangements at §411.357(d)(1) is not available to protect arrangements for the rental of office space or timeshare arrangements.

10. Exception for Fair Market Value Compensation (§411.357(l))

In the 1998 proposed rule, we proposed an exception at §411.357(l) for fair market value compensation (63 FR 1699). We noted that the statutory exceptions at section 1877(e) of the Act apply to specific categories of financial relationships and do not address many common and legitimate compensation arrangements between physicians and the entities to which they refer designated health services. The exception for fair market value compensation was proposed as an open-ended exception to protect certain compensation arrangements that may not be specifically addressed in the statutory exceptions. Among other things, we stated that the exception might be used to protect arrangements for the sublease of office space (63 FR 1714). We suggested that parties could use the exception for fair market value compensation if they had any doubts about whether they met the requirements of another exception in §411.357.

In Phase I, we finalized §411.357(l), stating that parties could use the exception, even if another exception potentially applied to an arrangement (66 FR 919). We explained our belief that the safeguards incorporated into the exception for fair market value compensation were sufficient to cover various compensation arrangements, including arrangements covered by other exceptions. In Phase II, we responded to commenters that requested that the exception at §411.357(l) be made available to protect arrangements for the rental of office space, including

arrangements where space is rented *by* entities *to* physicians (69 FR 16111). We declined to extend §411.357(l) to arrangements for the rental of office space, and emphasized that §411.357(l) applied only to payments *from* an entity *to* a physician for items and services furnished by the physician. We modified our policy in Phase III and extended the application of the exception at §411.357(l) to payments *from* a physician *to* an entity for items or services provided by the entity, but continued to decline to make §411.357(l) applicable to an arrangement for the rental of office space (72 FR 51059 through 51060). We explained our policy at that time that the rental of office space is not an "item or service." We added that, because arrangements for the rental of office space had been subject to abuse, we believe that it could pose a risk of program or patient abuse to permit parties to protect such arrangements relying on §411.357(l). In the CY 2016 PFS final rule, we reaffirmed our position that the exception for fair market value compensation does not apply to arrangements for the rental of office space (80 FR 71327).

We have reconsidered our policy regarding the application of §411.357(l). Through our administration of the SRDP, we have seen legitimate, nonabusive arrangements for the rental of office space that could not satisfy the requirements of §411.357(a) because the term of the arrangement was less than 1 year, and could not satisfy the requirements of §411.357(y) because the arrangement conveyed a possessory leasehold interest in the office space. To provide flexibility to stakeholders to protect such nonabusive arrangements, we proposed and are now finalizing modifications to §411.357(l) to permit parties to rely on the exception for fair market value compensation to protect arrangements for the rental or lease of office space.

As discussed in many of our previous rulemakings and most recently in the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), we are concerned about potential abuse that may arise when rental charges for the lease of office space or equipment are determined using a formula based on: (1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business

generated in the office space (a "percentage-based compensation formula"); or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (a "per-click compensation formula"). We continue to believe that arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. To address this risk, in the FY 2009 IPPS final rule, we included in the exceptions for the rental of equipment, fair market value compensation, and indirect compensation arrangements restrictions on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of equipment. Because the exception at §411.357(l), to date, has not been applicable to arrangements for the rental of office space, it does not include a prohibition on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of office space. (The exceptions for the rental of office space and indirect compensation arrangements currently include the prohibitions as they relate to the determination of rental charges for the lease of office space.) We remain concerned about the potential abuse related to percentage-based compensation and per-click compensation formulas for determining the rental charges of both office space and equipment. Therefore, we proposed to incorporate into the exception at §411.357(l) prohibitions on percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for the lease of office space, similar to the restrictions found in §411.357(a)(5)(ii) and §411.357(p)(1)(ii).

Unlike the exception for the rental of office space at §411.357(a), the exception for fair market value compensation does not require a 1-year term. Therefore, short-term arrangements for the rental of office space of less than 1 year will be permissible under the exception. However, as with other compensation arrangements permitted under §411.357(l), the parties will be permitted to enter into only one arrangement for the rental of the same office space during the course of a year. The parties will be able to renew the arrangement on the same terms and

conditions any number of times, provided that the terms of the arrangement and the compensation for the same office space do not change. Parties are not required to renew their arrangement in writing. Renewals effectuated through course of conduct or by verbal agreement are permitted under the exception for fair market value compensation. However, parties retain the burden of proof under §411.353(c)(2) to establish that the terms of the arrangement and the compensation for the same items, office space, or services did not change during the renewal arrangement. Although we believe that, in most cases, parties seeking to lease office space prefer leases with longer terms—for instance, to justify expenses spent on property improvements—as described by commenters, some parties, especially parties in rural areas, would prefer or find necessary the flexibility of a short-term rental of office space. Given the requirements of the exception for fair market value compensation, including the requirement that parties enter into only one arrangement for the leased office space over the course of a year and the requirement that the arrangement does not violate the anti-kickback statute, which, as explained below and in section II.D.1. of this final rule, is not being removed from §411.357(l)(5) in the final rule, we do not believe that short-term arrangements for the rental of office space that satisfy all the requirements of §411.357(l) pose a risk of program or patient abuse. We remind readers that, as explained in section II.D.9. of this final rule, the exception for payments by a physician at §411.357(i) is not available to protect any leases of office space, including short-term leases.

In the proposed rule, we proposed to remove the requirement at §411.357(l)(5) that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submissions. As explained in section II.D.1. of this final rule, with respect to the exception for fair market value compensation, we are finalizing this proposal with respect to Federal or State laws or regulations governing billing or claims submissions, but we are not finalizing the proposal with respect to the requirement that the arrangement does not violate the anti-kickback statute. We believe that the requirement that the arrangement does not

violate the anti-kickback statute in §411.357(l)(5) functions as an important safeguard that substitutes for certain requirements included in certain statutory exceptions but omitted from §411.357(l), including the exclusive use requirement in the exceptions for the rental of office space and equipment. We did not propose to remove §411.357(l)(6), which requires that any services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. However, we solicited comments on whether this requirement is necessary to protect against program or patient abuse or should be removed from the exception, and whether substitute safeguards such as those included in many of the statutory or regulatory exceptions to the physician self-referral law would be appropriate. As explained below, in this final rule we are not removing or modifying §411.357(l)(6).

In this final rule, we are taking the opportunity to reorganize the exception at §411.357(l) to distinguish the writing requirement of the exception for fair market value compensation from other requirements. As the exception is currently organized, §411.357(l)(1) requires the arrangement to be in writing and requires the writing to specify the items or services covered by the arrangement; §411.357(l)(2) requires the timeframe of the arrangement to be in writing, and also contains substantive requirements pertaining to timeframe of the arrangement and rules governing the frequency with which parties can enter into an arrangement for the same items or services; §411.357(l)(3) requires the compensation of the arrangement to be in writing, and also contains substantive requirements pertaining to the compensation under the arrangement. We are placing the writing requirement from these various provisions in §411.357(l)(1). Specifically, §411.357(l)(1) will require the arrangement to be in writing and signed by the parties; while §411.357(l)(i) through §411.357(l)(iii) will list the information that must be specified in writing, as follows: the items, services, office space, or equipment covered by the arrangement (§411.357(l)(1)(i)); the compensation that will be provided under the arrangement (§411.357(l)(1)(ii)); and timeframe of the arrangement (§411.357(l)(1)(iii)). These

organizational modifications are intended to clarify the exception and do not affect or modify the requirements of the exception in any way.

In addition to the organizational changes explained above, after reviewing the comments, we are finalizing our proposal to permit arrangements for the lease of office space under §411.357(l) with certain modifications to clarify the exception and to protect against program or patient abuse. First, we are clarifying in the introductory chapeau language that the exception may be used for the *lease* of office space and not only for the *use* of office space. Second, we are no longer requiring at §411.357(l)(5) that the arrangement not violate any Federal or State law or regulation governing billing or claims submission, but we are not finalizing our proposal to remove the requirement for compliance with the anti-kickback statute. Third, we are adding the phrase "even if no referrals were made between the parties" to the commercially reasonable requirement in §411.357(l)(4). Fourth, as explained in section II.E.1. of this final rule, we are modifying the requirement at §411.357(l)(2) to permit parties to rely on §411.357(l) and §411.357(z) to protect an arrangement for the same items, services, office space, or equipment during the course of a year. Lastly, as explained in section II.B.4, we are requiring at §411.357(l)(7) that any arrangement that includes a directed referral requirement must satisfy all the conditions of §411.354(d)(4).

We received the following comments and our responses follow.

Comment: Commenters generally supported our proposal to allow parties to rely on the exception for fair market value compensation at §411.357(l) to protect arrangements for the rental of office space. Commenters recognized the flexibility afforded by the proposal, especially for office space leases with a term of less than one year. One commenter noted that the proposal would be helpful for rural providers, where short-term rentals may be necessary to address community needs, such as the need to relocate a physician due to facility demands or renovations. Another commenter stated that the exception could be helpful for situations where a laboratory leases space from a physician for a temporary patient service center for specimen

collections while a permanent space is renovated or constructed.

Response: We agree with the commenters that the proposal, once finalized, will afford greater flexibility for short-term leases of office space. Under the current regulations, an arrangement for the *lease* of office, which involves the transfer of dominion and control of the leased premises to the lessee, must have a term of at least 1 year. On the other hand, arrangements for the use of space, where dominion and control over the space are not transferred to the party making use of the space, are permitted for durations of less than 1 year under the exception for timeshare arrangements at §411.357(y). (*See* 80 FR 71325 through 71326). However, the exception at §411.357(y) includes several requirements not found in the exception for the rental of office space at §411.357(a), such as a requirement at §411.357(y)(2) that the arrangement is between a physician and a hospital or a physician organization and the requirement at §411.357(y)(3)(i) that the premises covered by the arrangement is used predominantly for evaluation and management services to patients. Given the latter restrictions, an arrangement such as that identified by the commenter, under which a laboratory compensates a physician for space used on a short-term basis for specimen collections, would not be permissible under either §411.357(a) or §411.357(y). As modified in this final rule, the exception for fair market value compensation at §411.357(l) may be used to except such an arrangement, provided that all the requirements of the exception are satisfied. To clarify that the exception at §411.357(l) may be used for *leases* of office space, where dominion and control are transferred to the lessee, we are modifying the chapeau language of the exception to include the phrase "lease of office space."

Comment: Commenters generally opposed inclusion of a requirement for compliance with the anti-kickback statute in regulatory exceptions, including the exception for fair market value compensation at §411.357(l). One commenter that addressed our request for comments on §411.357(l)(6), which prohibits services furnished under an arrangement from involving the counseling or promotion of a business arrangement or other activity that violates a Federal or

State law, specifically objected to including a requirement for compliance with the anti-kickback statute in the exception for fair market value compensation.

Response: As explained in section II.D.1 of this final rule, we are not removing the requirement for compliance with the anti-kickback statute from the exception for fair market value compensation at §411.357(l)(5). We believe that the requirement that the arrangement does not violate the anti-kickback statute in §411.357(l)(5) functions as an important substitute safeguard for requirements that are included in certain statutory exceptions but omitted from §411.357(l), including the exclusive use requirement in the exceptions for the rental of office space and equipment. For similar reasons, we are also not removing the requirement at §411.357(l)(6), which requires that the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. This requirement applies to service arrangements and is carried over from the statutory exception for personal service arrangements, codified in our regulations at §411357(d)(1)(vi). We are concerned that, if we remove the requirement at §411.357(l)(6), we would need to include additional safeguards to substitute for the statutory requirements in order to ensure that excepted service arrangements under §411.357(l) do not pose a risk of program or patient abuse.

Comment: One commenter supported removing the phrase "and furthers the legitimate business purpose of the parties" from §411.357(l)(4), but requested either that the term "commercially reasonable" be defined to include a requirement that the arrangement must be commercially reasonable *even if no referrals were made between the parties* or that §411.357(l)(4) be modified to require an arrangement to be commercially reasonable "even if no referrals were made between the parties."

Response: As we discussed in section II.B.2, we are not including the "even if no referrals were made" requirement in the definition of "commercially reasonable" at final §411.351. Most exceptions that include a commercial reasonableness requirement, including

exceptions that apply to arrangements that could also be excepted by §411.357(l), stipulate that the arrangement must be commercially reasonable "even if no referrals" were made between the parties. We are adopting the second approach advocated by the commenter and are revising the requirement at §411.357(l)(4) to clarify that the arrangement must be commercially reasonable "even if no referrals were made between the parties." Without this modification, some stakeholders may believe that the standard articulated at §411.357(l) is a different and less demanding standard than the requirement in other exceptions.

Comment: One commenter supported our proposal at §411.357(l)(3) to prohibit the use of percentage-based or per-unit-of service based compensation formulas for determining the compensation for the rental of office space under the exception for fair market value compensation.

Response: We are finalizing this proposal. We believe that it is a necessary safeguard for the reasons stated in the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534).

Comment: One commenter requested that CMS permit indefinite holdovers for arrangements under the exception for fair market value compensation, similar to the indefinite holdover provisions in the exceptions for rental of office space, rental of equipment, and personal service arrangements. The commenter noted that an arrangement may be for any period of time under §411.357(l), and the exception permits the arrangement to be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change. The commenter interpreted the renewal provision under §411.357(l) to require written documentation that the renewed arrangement was on the same terms and conditions, while there is no such requirement under the indefinite holdover provisions.

Response: We believe that the commenter misunderstood the renewal provision in §411.357(l)(2). Under §411.357(l)(2), parties are permitted to renew an arrangement any number of times if the terms of the arrangement and the compensation for the same items,

services, office space, or equipment do not change. Likewise, the indefinite holdover provisions at §411.357(a)(7), §411.357(b)(6), and §411.357(d)(1)(vii) require the holdover arrangement to continue on the same terms and conditions. Neither the indefinite holdover provisions in the latter exceptions nor the renewal provision in §411.357(l)(2) require the holdover arrangement or renewal arrangement to be documented in a formal writing. To be sure, parties renewing an arrangement under §411.357(l)(2) retain the burden of proof under §411.353(c)(2) to establish that the renewal arrangement is on the same terms and conditions as the previous arrangement, but parties to a holdover arrangement under one of the indefinite holdover provisions have a similar burden. In sum, with respect to documentation and writing requirements, there is no substantive difference between the indefinite holdover provisions and the renewal provision in §411.357(l)(2). Therefore, we are not including an indefinite holdover provision in §411.357(l).

11. Electronic Health Records Items and Services (§411.357(w))

Relying on our authority at section 1877(b)(4) of the Act, on August 8, 2006, we published a final rule (the 2006 EHR final rule) that, among other things, established an exception at §411.357(w) for certain arrangements involving the donation of interoperable electronic health records software or information technology and training services (the EHR exception) (71 FR 45140). The EHR exception was initially set to expire on December 31, 2013. On December 27, 2013, we published a final rule (the 2013 EHR final rule) modifying the EHR exception by, among other things, extending the expiration date of the exception to December 31, 2021, excluding laboratory companies from the types of entities that may donate electronic health records items and services under the exception, and updating the provision under which electronic health records software is deemed interoperable (78 FR 78751).

Although we did not specifically request comments on the EHR exception in the CMS RFI, we received several comments related to the exception. In addition, in its August 27, 2018 request for information described in section I.B.1. of this final rule, OIG requested comments on the safe harbor at 42 CFR 1001.952(y), which is substantively similar to the EHR exception at

§411.357(w) (*see* 83 FR 43607). After reviewing comments related to the EHR exception and safe harbor submitted in response to the CMS RFI and the OIG's request for information, as well as recent statutory and regulatory developments arising from the 21st Century Cures Act (Pub. L. 114-255, enacted on December 13, 2016) (Cures Act), in the proposed rule, we proposed to update provisions in the EHR exception pertaining to interoperability (§411.357(w)(2)) and data lock-in (§411.357(w)(3)), clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the sunset provision at §411.357(w)(13), and modify the definitions of "electronic health record" and "interoperable" at §411.351 to ensure consistency with the Cures Act (84 FR 55822). We also proposed to modify the requirement at §411.357(w)(4) that a physician contributes at least 15 percent of the cost of the donated electronic health records items and services and permit certain donations of replacement electronic health records items and services (84 FR 55822).

As discussed more fully below, in this final rule we are finalizing certain of our proposals to revise the EHR exception. Despite the fundamental differences in the statutory structure, operation, and penalties of the respective underlying statutes, we have worked closely with OIG to ensure consistency between our revised EHR exception and the policies finalized by OIG related to its safe harbor and discussed elsewhere in this issue of the **Federal Register**.

a. Requirements Regarding Interoperability

Currently, the requirements at §411.357(w)(2) and (3) require donated software to be interoperable and prohibit the donor (or a person on the donor's behalf) from taking action to limit the interoperability of the donated items or services. In the proposed rule (84 FR 55822), we proposed changes that would impact §411.357(w)(2) and (3) based on the Cures Act and the Office of the National Coordinator for Health Information Technology (ONC), HHS Notice of Proposed Rulemaking, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (ONC NPRM), which proposed to implement key

provisions in Title IV of the Cures Act.[15] Among other things, the ONC NPRM proposed Conditions and Maintenance of Certification requirements for health IT developers under the ONC Health IT Certification Program (certification program) and proposed to define reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the Public Health Service Act (PHSA). We discuss our specific proposals and our final policies and regulations pertaining to §411.357(w)(2) and (3) below in subsections (1) and (2), respectively.

(1) The "Deeming Provision" (§411.357(w)(2))

The existing regulation at §411.357(w)(2) requires that software donated under the EHR exception is interoperable. The deeming provision at §411.357(w)(2) provides certainty to parties that donated software satisfies the interoperability requirement at §411.357(w)(2). Specifically, §411.357(w)(2) currently provides that software is deemed to be interoperable if it has been certified under ONC's certification program to electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. In the 2013 EHR final rule, we modified the deeming provision to reflect developments in the ONC certification program and to track ONC's anticipated regulatory cycle. By relying on ONC's certification program and related updates of criteria and standards, we stated that the deeming provision would meet our objective of ensuring that software is certified to the current required standard of interoperability when it is donated (78 FR 78753). In the proposed rule, we proposed to retain this general construct for the updated EHR exception, but proposed two clarifications to the deeming provision at §411.357(w)(2) (84 FR 55823). Our current regulation at §411.357(w)(2) specifies that the software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We proposed to modify this

[15] 84 FR 7424 (March 4, 2019). At the time our proposed rule was published on October 17, 2019, ONC had not yet issued its final rule implementing the Cures Act. ONC published its final rule on May 1, 2020 (85 FR 25642).

language to replace the phrase "has been certified" with the phrase "is certified" (84 FR 55823). The proposed modification was intended to clarify that the certification must be current as of the date of the donation, as opposed to the software having been certified at some point in the past (and potentially no longer maintaining certification on the date of the donation). We also proposed to remove the reference to "an edition" of certification criteria to align with changes to ONC's certification program (84 FR 55823). As we describe in more detail below, we proposed and are finalizing an updated definition of "interoperable" (84 FR 55824 through 55825). Although the revised definition would not require a change to the text of §411.357(w)(2), the revision would impact the deeming provision, and we solicited comments regarding this update to the definition of "interoperable" (84 FR 55823). We emphasized in the proposed rule and reaffirm here that an arrangement for the donation of software that met the definition of interoperable and that satisfied the requirements of §411.357(w) at the time the donation was made will not cease to be protected by the exception, even though we are finalizing certain changes to these provisions (84 FR 55823).

After reviewing comments on our proposal, we are finalizing our clarifying revisions to the deeming provision at §411.357(w)(2) as proposed, with one modification to the regulation text. We are removing the phrase "electronic health record" preceding "certification criteria" because the phrase "electronic health records certification criteria" has been removed from 45 CFR part 170 as of June 30, 2020.

We received the following comments and our responses follow.

Comment: Commenters generally agreed with our proposal to clarify that software would be deemed to be interoperable under §411.357(w)(2) if, on the date it is donated, it "is" certified by a certifying body authorized by ONC, rather than "has been certified." Some commenters had questions about our removal of the phrase "an edition" before "the electronic health record certification criteria" and inquired whether we should specify that the criteria are the "latest" or "current" certification criteria. One commenter recommended that we modify the

deeming provision to state that the certification must be current as of the date that the donor has entered into a binding agreement with the recipient or the electronic health records vendor. This commenter stated that a reasonable time limit, such as 1 year, could be applied in order to prevent potential fraud or abuse.

Response: We are finalizing our proposal to modify §411.357(w)(2) to specify that the donated software "is" certified on the date that it is donated, as opposed to "has been certified" on that date, and to delete the phrase "an edition." We agree that the certification criteria should be the latest or current criteria; that is, current as of the date of donation. However, we believe that our proposal, which provides that the software must be certified to the "then-applicable" version of 45 CFR part 170, already includes this requirement, and we are finalizing the regulation text as proposed. As noted above, we are removing the phrase "electronic health record" before "certification criteria" in §411.357(w)(2), because the phrase "electronic health records certification criteria" has been removed from 45 CFR part 170 as of June 30, 2020. We note that the latter change does not alter the scope of the remuneration to which the EHR exception applies. The exception continues to apply only to donations of items or services that are necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records. We also decline to adopt the commenter's suggestion that the certification must be current on the date that the donor has entered into a binding agreement with the recipient. To help ensure that donations of health information technology will further the policy goal of fully interoperable health information systems (71 FR 45149), we believe that parties that enjoy the benefit of donated software being deemed to be interoperable must ensure that it is certified to the current certification criteria on the date it is donated. However, depending on the facts and circumstances, donations that do not satisfy the requirements of the deeming provision may still satisfy the requirement at §411.357(w)(2) that the donated software is interoperable.

Comment: One commenter opposed the concept of an "optional" deeming provision, asserting that it is critical to require that software be certified by a certifying body authorized by

ONC to further support the goal of value-based arrangements. In contrast, another commenter was concerned that the EHR exception applies only to donations of software that has been certified by ONC.

Response: Although we agree that the interoperability of software is a critical requirement of the EHR exception, we disagree with the first commenter that certification by a certifying body authorized by ONC should be the only way of meeting this requirement. This certification provides donors and recipients with assurance that the electronic health records software donated under their arrangement is interoperable for purposes of the EHR exception, but such certification is not required under the exception. We emphasize that the exception does not require that donated software is certified as interoperable by a certifying body authorized by ONC; rather, the exception requires that donated software is interoperable. We believe that requiring only that donated software is interoperable—allowing parties to demonstrate that donated software is interoperable even if it is not certified as interoperable by a certifying body authorized by ONC—coupled with the optional method for assuring that software is interoperable through satisfaction of the deeming provision at §411.357(w)(2), affords parties sufficient flexibility under the exception for donations of electronic health records items or services.

Comment: One commenter suggested that the proposed change to the deeming provision creates compliance uncertainty in the context of an ongoing software donation. In particular, the commenter was concerned that the proposed wording change would mean that, if at any time after the initial software donation the electronic health records software loses its certification, the continued provision of the software, including maintenance, would implicate the fraud and abuse laws. Other commenters supported the proposal to require that software is certified at the time it is provided to a recipient, with one commenter noting that any updates to donated systems should also need to be certified to the most recent standards. Another commenter requested that we provide for a 5-year grace period under the interoperability deeming provision so that physicians

not participating in the Quality Payment Program could continue to use donated electronic health records software certified to the 2015 edition.

Response: As we explained in response to the comment immediately above, the deeming provision is optional. Certification of donated electronic health records software by a certifying body authorized by ONC is not required to satisfy the requirement at §411.357(w)(2) that the software is interoperable, as defined at § 411.351; the exception merely requires that the software is interoperable at the time it is provided to the recipient. Regardless of whether the physician recipient participates in the Quality Payment Program, electronic health records software is not required to satisfy the deeming provision at §411.357(w)(2) in order to be "interoperable" as defined at §411.351. With respect to ongoing donations of maintenance, updates, or other items or services in connection with previously donated electronic health records software, we note the following. If the electronic health records software loses its certification, then new donations of that electronic health records software, including updates and patches of that software, will not be *deemed* to be interoperable under the deeming provision in §411.357(w)(2). However, if the electronic health records software is still interoperable (as defined at §411.351), then the EHR exception will remain available to protect ongoing donations of such electronic health records software, including updates and patches, provided that all other requirements of the exception are satisfied. If, on the other hand, software that loses its certification is no longer interoperable (as defined at §411.351), then new donations of such electronic health records software, including updates and patches of the software, would not be protected under the EHR exception.

(2) Information Blocking and Data Lock-in (§411.357(w)(3))

The current requirement at §411.357(w)(3) prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health IT applications, products, or services). Beginning with the 2006 EHR final rule and reaffirmed in the 2013 EHR final rule,

§411.357(w)(3) has been designed to: (1) prevent the misuse of the exception that results in data and referral lock-in; and (2) encourage the free exchange of data (in accordance with protections for privacy) (78 FR 78762). Since the publication of the 2006 EHR final rule and 2013 EHR final rule, significant legislative, regulatory, policy, and other Federal government action further defined the data lock-in problem (now commonly referred to as "information blocking") and established penalties for certain types of individuals and entities that engage in information blocking. Most notably, the Cures Act added section 3022 of the PHSA, known as "the information blocking provision," which defines conduct that constitutes information blocking by health care providers, health IT developers of certified health IT, health information exchanges, and health information networks. Section 3022(a)(1) of the PHSA defines "information blocking" in broad terms, while section 3022(a)(3) of the PHSA authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the PHSA. The ONC NPRM included proposals to implement the statutory definition of "information blocking," define certain terms related to the statutory definition of "information blocking," and establish exceptions to the definition of "information blocking." ONC published its final rule on May 1, 2020 (85 FR 25642).

In the proposed rule, we proposed modifications to §411.357(w)(3) to recognize these significant updates since the 2013 EHR final rule (84 FR 55823). Specifically, we proposed at §411.357(w)(3) to prohibit the donor (or any person on the donor's behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the PHSA, in connection with the donated items or services. We stated that, should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, we would incorporate such regulations into the requirement at §411.357(w)(3) for purposes of the physician self-referral law, if we finalized the proposals described in the proposed rule (84 FR 55823).

We noted in the proposed rule that the current requirements of the EHR exception, while not using the term "information blocking," already include concepts similar to those found in the

Cures Act's prohibition on information blocking (84 FR 55823). For example, in prior rulemaking, we stated our concern about donors (or those on the donor's behalf) taking steps to limit the interoperability of donated software to lock in or steer referrals (*see*, for example, 71 FR 45156 and 78 FR 78762 through 78763). We stated in the proposed rule that the proposed modifications of §411.357(w)(3) were not intended to change the underlying purpose of this requirement, but instead further our longstanding goal of preventing abusive arrangements that lead to information blocking and referral lock-in through modern understandings of those concepts established in the Cures Act (84 FR 55823).[16] We solicited comments on aligning the requirement at §411.357(w)(3) with the PHSA information blocking provision and the information blocking definition in 45 CFR part 171.

After reviewing comments on our proposal, we are not finalizing the proposed modification of §411.357(w)(3). Rather, based on the comments and for the reasons explained below, we are removing §411.357(w)(3) from our regulations.

We received the following comments and our responses follow.

Comment: We received a number of comments about incorporating the "information blocking" prohibitions from the Cures Act or the ONC NPRM into the EHR exception at §411.357(w)(3). Several commenters supported aligning the EHR exception with the concepts of interoperability and information blocking from the Cures Act and the ONC NPRM, including our proposal to expressly prohibit information blocking at §411.357(w)(3). One commenter agreed with CMS' assessment that the incorporation of the concept of information blocking into the regulation does not change the underlying purpose of the existing interoperability requirements. Another commenter that supported the prohibition on information blocking asserted that large health systems can control referrals and increase market share by limiting access to patients' records to specific providers on the same health information network, thereby

[16] We recognized in the proposed rule that the ONC NPRM was not a final rule and was subject to change (84 FR 55823). However, we based our proposals on both the statutory language and the language in ONC's NPRM for purposes of soliciting public input on our proposals.

shutting out independent providers and negatively impacting patient care. Other commenters did not disagree that information blocking should be prohibited, but raised a number of questions and concerns regarding how such a provision would work in the EHR exception. For example, a number of commenters expressed concern about relying on the ONC NPRM, which was not yet final at the time our proposed rule was published. Some commenters were particularly concerned about the array of exceptions to the definition of "information blocking" and incorporation of the definition of "electronic health information" as proposed in the ONC NPRM.

Some commenters asked that we clarify which party is responsible to ensure that information blocking does not occur, asserting that a donor cannot control what happens to software after it is donated. Several commenters recommended removing or revising the requirement in the EHR exception that a donor (or any person on a donor's behalf) does not engage in a practice constituting information blocking, explaining that a vendor may engage in information blocking without the donor's knowledge. Another commenter expressed concern that, if a determination of information blocking against either a donor or recipient occurs at some time after the donation, the recipient may be vulnerable to unexpected costs or loss of access to its health information technology if the arrangement suddenly ends. Another commenter asserted that the incorporation of ONC's proposals into the exception at §411.357(w)(3) would introduce an intent-based requirement into the strict-liability framework of the physician self-referral law.

A few commenters suggested that, rather than including a prohibition on information blocking (as that term is defined in the Cures Act or in 45 CFR part 171) as a requirement of the EHR exception, CMS should assume that information blocking will not be tolerated and will be enforced through other authorities. One commenter explained that, when the EHR exception was first issued in 2006, interoperability was in its infancy, and there was no separate regulatory guidance on interoperability and information blocking, whereas now these concepts are

separately addressed and regulated by ONC. Given these changes, the commenters maintained that incorporation of information blocking provisions into the EHR exception is duplicative and unnecessary.

Response: Based on the comments and after assessing the final rule published by ONC, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (ONC final rule),[17] we are removing the requirement at §411.357(w)(3) in its entirety. This requirement, when originally implemented in the 2006 EHR final rule, was intended to "help ensure that donations of health information technology will further the policy goal of fully interoperable health information systems and will not be misused to steer business to the donor." (71 FR 45156). The 2013 EHR final rule also explained that the Department was considering other policies to improve interoperability and noted that those policy efforts are "better suited than this exception to consider and respond to evolving functionality related to the interoperability of electronic health record technology" (78 FR 78763). At that time, the Department had few other authorities to directly address information blocking. However, there are now other enforcement authorities designed to address information blocking. For example, the Cures Act gave ONC and OIG more direct authority to address information blocking. Additionally, CMS has separate authority to address providers that information block, and OCR has authorities related to patient access.

The Cures Act and the ONC final rule recognize that certain practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information may nonetheless be reasonable and necessary. That is why the Cures Act directed the Secretary to identify exceptions to the definition of information blocking. The ONC final rule implements eight exceptions that apply to practices likely to interfere with the access, exchange, or use of electronic health information provided that the practice meets the conditions of an exception. However, §411.357(w)(3), as implemented by the 2006 EHR final rule, required that a party not

[17] 85 FR 25642 (May 1, 2020).

take "any action to limit or restrict the use, compatibility, or interoperability" of the donated electronic health records items or services. The requirement did not account for actions that may be reasonable and necessary, such as implementing privacy and security measures.

Recognizing the developments since 2013, we agree with the commenter that newer and separate authorities are better suited than a requirement of an exception to the physician self-referral law to deter information blocking and hold individuals and entities that engage in information blocking appropriately accountable. We also agree with commenters that a recipient is unlikely to have the capabilities to determine if a donor (or someone on the donor's behalf) engaged in information blocking, which includes a level of intent set by statute, or met an exception to information blocking as set forth in the ONC final rule. Given these potential issues with the proposed modifications to §411.357(w)(3) and limitations of the original requirement at §411.357(w)(3) discussed above, we no longer believe that the requirement is an effective way to achieve the policy goals that served as its original basis. Removing the requirement at §411.357(w)(3) should sufficiently address the concerns of the commenters that had questions about the scope of information blocking practices, how CMS would determine the party responsible, and how the information blocking knowledge standards in the Cures Act and ONC final rule would be assessed in context of this exception and the strict-liability framework of the physician self-referral law. We emphasize that we are maintaining the interoperability requirement at §411.357(w)(2). We believe that this requirement and the optional deeming provision at §411.357(w)(2) will ensure that donations of items and services under §411.357(w) that satisfy all the requirements of the EHR exception further the Department's policy goal of an interoperable health system and prevent donations of items and services intended to lock in referrals by limiting the flow of electronic health information.

Comment: One commenter requested that we include in the EHR exception a requirement that donors must also provide access to electronic health records to pharmacists. The commenter stated that some health information technology systems block pharmacists'

visibility into relevant clinical information from other health care providers.

Response: The EHR exception does not limit the scope of permissible donors to those donors that grant access to electronic health records to a specified set of providers or suppliers. However, for a donation to be permissible under the EHR exception, among other things, the software must be interoperable and should not inappropriately interfere with, prevent, or materially discourage legally permissible access, exchange, or use of relevant clinical information. We encourage parties to report concerns regarding potential information blocking to https://healthit.gov/report-info-blocking.

b. Cybersecurity

We proposed to amend the EHR exception to clarify that the exception is applicable (and always has been applicable) to certain cybersecurity software and services,[18] and to more broadly protect the donation of software and services related to cybersecurity (84 FR 55823). Currently, the exception at §411.357(w) protects electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. We proposed to modify this language to expressly include software that "protects" electronic health records, and to expressly include software and services related to cybersecurity.

In the 2006 EHR final rule, we emphasized that software and information technology and training services donated under §411.357(w) must create, maintain, transmit, or receive electronic health records, and those functions must predominate (71 FR 54151). We stated that the core functionality of the items and services must be the creation, maintenance, transmission, or receipt of individual patients' electronic health records, but, recognizing that electronic health records software is commonly integrated with other features, we also stated that arrangements in which the software package included other functionality related to the care and treatment of

[18] For instance, a secure log-in or encrypted access mechanism included with an EHR system or EHR software suite would be cybersecurity features of the EHR items or services that may be protected under the existing EHR exception.

individual patients would be protected (71 FR 45151). Under our proposal, the same criteria would apply to cybersecurity software and services, provided that the predominant use of the software or services is cybersecurity associated with the electronic health records.

In section II.E.2. of this final rule, we discuss the new exception at §411.357(bb), which applies specifically to arrangements involving the donation of cybersecurity technology and related services (the cybersecurity exception), and the definition of "cybersecurity" at §411.351 that will apply to both the EHR exception and the cybersecurity exception at §411.357(bb). As finalized, the cybersecurity exception at §411.357(bb) is broader and includes fewer requirements than the EHR exception as applied to cybersecurity software and services that are necessary and used predominantly to protect electronic health records. Among other things, the cybersecurity exception at final §411.357(bb) does not require recipients to contribute to the cost of the donated cybersecurity technology or services, while the EHR exception retains the cost contribution requirement at §411.357(w)(4) for donations of electronic health records items or services. In the proposed rule, we solicited comments on whether it is necessary to modify the EHR exception to expressly include cybersecurity, given our proposed addition of a standalone exception for cybersecurity technology and related services at §411.357(bb), and we stated that a party seeking to protect an arrangement involving the donation of cybersecurity software and services only needs to comply with the requirements of one applicable exception (84 FR 55824).

After reviewing the comments on our proposed rule, we are finalizing our proposal to expand the EHR exception to expressly include cybersecurity software and services so that it is clear that an entity donating electronic health records software and providing training and other related services may also utilize the EHR exception to protect donations of related cybersecurity software and services to protect the electronic health records, provided that all the requirements of the EHR exception are satisfied. In the final exception, we removed the word "certain" before "cybersecurity software and services" in the introductory chapeau language to avoid ambiguity regarding the scope of the EHR exception.

We received the following comments and our responses follow.

Comment: A number of commenters supported stating in regulation text that the EHR exception applies to donations of cybersecurity software and services that protect electronic health records. These commenters stated that the proposal, if finalized, would clarify the regulations, and one of the commenters also noted that the revision would reduce administrative overhead by avoiding real or perceived disparities between donations of electronic health records items and services and cybersecurity donations. One commenter supported our proposal to include certain cybersecurity donations under the EHR exception, as well as in proposed §411.357(bb). The commenter appreciated our statement that cybersecurity donations only need to satisfy one of the exceptions, and noted that having two exceptions available allows a donor to tailor its donation strategy.

Response: We are finalizing our proposal to expressly permit donations of cybersecurity software and services that protect electronic health records under the EHR exception. We agree with the commenter that having two exceptions available to protect donations of cybersecurity software and services increases flexibility under our regulations.

Comment: A few commenters expressed concern that the proposal related to cybersecurity software and services with respect to the EHR exception and the separately proposed cybersecurity exception at §411.357(bb) overlap significantly and could lead to confusion if both are finalized. The commenters stated that, if CMS finalizes a separate cybersecurity exception at §411.357(bb), the proposed cybersecurity-related clarifications to the EHR exception would not be necessary. One of the commenters questioned how the cost contribution requirement under the EHR exception at §411.357(w)(4) would apply to donations of cybersecurity software under §411.357(w), given that there is no cost contribution requirement in the cybersecurity exception at proposed §411.357(bb), and also asked whether the electronic health records or cybersecurity function must predominate in software that includes both electronic health records and cybersecurity functions. A different commenter requested

that, if we finalize protection for certain cybersecurity software and services under the EHR exception, we also clarify that the predominant purpose of the software or service must be cybersecurity associated with electronic health records. Another commenter suggested that creating separate exceptions for electronic health records items and services and cybersecurity technology and related services is taking a piecemeal approach to tools that must work together for care coordination.

Response: We recognize that there is a certain amount of overlap between the cybersecurity exception established in this final rule at §411.357(bb) and the EHR exception, as amended by this final rule, although we do not agree that this overlap will result in the type of confusion suggested by the commenter. The revision to the introductory language of §411.357(w) merely confirms in regulation text that the EHR exception has always been applicable to (and remains applicable to) arrangements that include the donation of cybersecurity software and services that have a predominant purpose of protecting electronic health records. In application, if a party is donating electronic health records items and services under the EHR exception, and the donation includes cybersecurity software or services that are necessary and used predominantly to protect electronic health records, the parties may structure their entire arrangement to satisfy the requirements of the EHR exception, instead of structuring the arrangement to satisfy two different exceptions. We believe that having this option available will reduce administrative burden for some parties. Other parties may wish to structure such donations as two separate arrangements that each satisfy the requirements of the respective exception at §411.357(w) and §411.357(bb). As noted in the proposed rule and reiterated above, parties seeking to protect an arrangement involving the donation of cybersecurity software and services only need to satisfy the requirements of one applicable exception (84 FR 55824).

Regarding the requirement in the EHR exception that a physician recipient must contribute 15 percent of the donor's cost of the donated items and services, under this final rule, the EHR exception retains the 15 percent cost contribution requirement at §411.357(w)(4), but

there is no cost contribution requirement under the standalone cybersecurity exception at §411.357(bb). Thus, if parties rely on the exception at §411.357(w) to protect an arrangement for a donation that includes both electronic health records items and services and related cybersecurity software or services, the physician recipient must contribute 15 percent of the donor's cost for the cybersecurity software or services under §411.357(w)(4). If parties structure such a donation to satisfy the requirements of §411.357(w) and §411.357(bb) respectively, then the physician does not have to pay the 15 percent cost contribution for the cybersecurity software and services if the arrangement related to the cybersecurity software and services satisfies all the requirements of §411.357(bb).

We reiterate here that, with respect to cybersecurity technology and related services, the scope of the EHR exception is more limited than the standalone cybersecurity exception at §411.357(bb). Arrangements for the donation of standalone cybersecurity hardware or items or services that are not used predominantly to protect electronic health records (but are used predominantly to implement, maintain, or reestablish cybersecurity) are not excepted under the EHR exception, but may be protected under the cybersecurity exception if all the requirements of §411.357(bb) are satisfied.

Comment: Some commenters requested that CMS broaden the application of the EHR exception to additional cybersecurity technology and services, for example, to cybersecurity hardware, such as network appliances. One commenter requested that we make the EHR exception applicable to donations of cybersecurity hardware, software, infrastructure and services, without exception and without a requirement that the recipient contribute 15 percent of the donor's cost for the items or services. Another commenter suggested that, if the expanded exception does not protect hardware, CMS should permit donors to place cybersecurity hardware at the recipient's location as long as the donor retains title to or a leasehold interest in the equipment.

Response: By including the word "protect" in the introductory chapeau language of

§411.357(w), we are clarifying that the scope of the EHR exception applies to cybersecurity software or other information technology and training services that are necessary and used predominantly to protect electronic health records. We decline to expand the EHR exception to apply to additional services or hardware, including hardware that is donated or loaned to a recipient. There is a separate, standalone exception at final §411.357(bb) that applies to broader cybersecurity donations, including donations of cybersecurity hardware, and that exception does not include a contribution requirement.

c. The Sunset Provision

The EHR exception originally was scheduled to expire on December 31, 2013. In the 2006 EHR final rule, we stated that the need for an exception for donations of electronic health records items and services should diminish substantially over time as the use of electronic health records technology becomes a standard and expected part of medical practice. In our 2013 proposal to revise the EHR exception (78 FR 21308), we recognized that, although the adoption of electronic health records had risen dramatically, its use was not yet universal nationwide. Because continued adoption of electronic health records remained an important goal of the Department, we solicited comments regarding an extension of the EHR exception (78 FR 21311 through 21312). In response to those comments, in the 2013 EHR final rule, we extended the sunset date of the exception to December 31, 2021, a date that corresponds to the end of the electronic health records Medicaid incentives (78 FR 78755 through 78757). We stated our continued belief that, as progress on the goal of nationwide electronic health records adoption is achieved, the need for an exception for donations should continue to diminish over time. Nonetheless, commenters on the CMS RFI and on OIG's request for information requested that we make the EHR exception and safe harbor permanent.

Although widespread (though not universal) adoption of electronic health records largely has been achieved at this time, we no longer believe that the need for an exception for arrangements involving the donation of electronic health records items and services will diminish

over time or completely disappear. The continued availability of the EHR exception provides certainty with respect to the contribution costs related to donations of electronic health records items and services for recipients, facilitates adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an electronic health records system, and helps preserve the gains already made in the adoption of interoperable electronic health records technology (84 FR 55824). Therefore, in the proposed rule, we proposed to eliminate the sunset provision at §411.357(w)(13) (84 FR 55824). In the alternative, we considered an extension of the sunset date. We sought comment on whether we should extend the sunset date instead of making the exception permanent, and if so, the duration of any such extension. Based on the comments we received on the proposed rule, we are finalizing our proposal to make the EHR exception permanent by removing the sunset provision at §411.357(w)(13).

We received the following comment and our response follows.

Comment: We received almost unanimous support to remove the sunset date in the EHR exception. Commenters asserted that the elimination of the sunset date would provide certainty regarding the availability of an exception to the physician self-referral law for ongoing donations of electronic health records items and services. Commenters also agreed with our statement in the proposed rule that the exception will remain necessary after 2021, given new entrants, aging electronic health records technology at existing practices, and emerging and improved technology. In contrast, one commenter suggested that, after 2021, the exception should only be available to rural providers and to physicians entering into solo practice in a health professional shortage area or medically underserved area. According to the commenter, making the current exception permanent could incentivize entities to reward high referring physicians with new electronic health records systems or updates.

Response: We are finalizing our proposal to make the EHR exception permanent by removing the sunset date. We note that, as finalized, the exception continues to require at

§411.357(w)(6) that neither the eligibility of a physician to receive items or services nor the amount or nature of the items or services may be determined in any manner that directly takes into account the volume or value of the physician's referrals or other business generated between the parties. Given this requirement, as well as the other requirements of the exception, we do not believe that making the EHR exception permanent poses a risk of program or patient abuse.

d. Definitions

In the proposed rule, we proposed to modify the definitions of "electronic health record" and "interoperable" (84 FR 55824 through 55825). We adopted definitions for these terms in the 2006 EHR final rule based on contemporaneous terminology, the emerging standards for electronic health records, and other resources cited by commenters at that time. Our proposed modifications to these definitions were largely based on terms and provisions in the Cures Act that update or supersede terminology we used in the 2006 EHR final rule (84 FR 55824 through 55825). We discuss our specific proposals and our final policies and regulations pertaining to definitions of "electronic health record" and "interoperable" below in subsections (1) and (2), respectively.

(1) "Electronic health record"

The term "electronic health record" is defined at §411.351 as a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions. We proposed to revise this definition so that "electronic health record" would mean a repository that includes electronic health information that: (1) is transmitted by or maintained in electronic media; and (2) relates to the past, present, or future health or condition of an individual or the provision of health care to an individual (84 FR 55824). We proposed the modifications to reflect the term "electronic health information" that is used throughout the Cures Act and that is central to the definition of interoperability at section 3000(9) of the PHSA and the information blocking provisions at section 3022 of the PHSA. We based our proposed modifications, in part, on ONC's proposed definition of "electronic health

information" in the ONC NPRM (84 FR 7513), which reflects more modern terminology used to describe the type of information that is part of an electronic health record. We solicited comments on this updated definition (84 FR 55824).

After reviewing the comments on our proposed definition of "electronic health record," we are not finalizing our proposal to modify the definition. Rather, we are retaining the current definition of "electronic health record" at §411.351.

We received the following comments and our responses follow.

Comment: Several commenters expressed general support for our proposed revision to the definition of "electronic health record," particularly to the extent that the definition would align with the definition included in the Cures Act. Some commenters supported our proposal to incorporate the term "electronic health information," which ONC proposed to define in the ONC NPRM. According to one commenter, the broad definition of "electronic health information" in the ONC NPRM would ensure that data related to medical imaging, such as electronic orders and referrals for radiology services, would be subject to the information blocking provisions. The commenter suggested that, if ONC does not finalize a broad definition of "electronic health information," CMS should retain the term "consumer health status information" in the definition of "electronic health record." Another commenter maintained that, to further the agency's price transparency goals, CMS should explicitly define "electronic health record" to include electronic health information that relates to the past, present, or future payment for the provision of health care to an individual.

In contrast, several other commenters objected to the inclusion of the term "electronic health information" in the definition of "electronic health record." Noting that, at the time we issued our proposed rule, ONC had not finalized its definition of "electronic health information," these commenters maintained that the definition proposed by ONC is overly broad. For example, one commenter asserted that, under the proposed definition, a patient's computer or mobile telephone could be considered an electronic health record if the patient obtained a copy

of his or her health record through electronic transmittal. Some commenters specifically stated that the proposed definition of "electronic health record" was too broad because, as proposed, it would have included financial information pertaining to payment for the provision of health care to an individual. Several commenters also made suggestions to limit the scope of "electronic health information."

Response: As stated in the proposed rule and reiterated above, our proposal to modify the definition of "electronic health information" was meant to update terminology that we adopted in the 2006 EHR final rule (84 FR 55824). We did not intend for our proposed modifications to the definition of "electronic health record" to make a substantive change to the scope of the exception at §411.357(w). We agree with commenters that our proposed changes might have inadvertently introduced undesirable complexity. To remain true to our intent, we are not finalizing any of the proposed changes to the definition of "electronic health record," and we are retaining the existing definition in our regulations. We also note that ONC published its final definition of "electronic health information" in the Federal Register on May 1, 2020, well after the comment period for our proposed rule closed on December 31, 2019, and the final definition of "electronic health information" (85 FR 25955) differs from the definition that ONC proposed (84 FR 7601). Among other things, as ONC explained in its final rule, the definition of "electronic health information" in ONC's final rule does not expressly include or exclude price information (85 FR 25804). Given that ONC's final definition differs from the definition in the ONC NPRM, which we cited in our proposed rule, and that ONC's final rule was published after the comment period for our proposed rule closed, we are concerned that the public may have not had sufficient information to comment on our proposal to incorporate the concept of "electronic health information" in the definition of "electronic health record." Finally, although CMS remains committed to the price transparency initiative, at this time, we do not believe that modifying the definition of "electronic health record" with the resulting impact on the scope and requirements of the EHR exception is the best means to achieve this goal.

(2) "Interoperable"

The term "interoperable" is currently defined at §411.351 to mean able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purposes and meaning of the data are preserved and unaltered. This definition of "interoperable" was based on 44 U.S.C. 3601(6) (pertaining to the management and promotion of electronic Government services) and several comments we received in response to our 2005 rulemaking proposing exceptions for certain electronic prescribing and electronic health records arrangements (70 FR 59182) that referenced emerging industry definitions and standards related to interoperability (71 FR 45155 through 45156).

In the proposed rule, we proposed to update the definition of "interoperable" to align with the statutory definition of "interoperability" added by the Cures Act to section 3000(9) of the PHSA (84 FR 55824 through 55825). Consistent with section 3000(9) of the PHSA, we proposed to define "interoperable" to mean: (i) able to securely exchange data with and use data from other health information technology without special effort on the part of the user; (ii) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (iii) does not constitute information blocking as defined in section 3022 of the PHSA (84 FR 55824 through 55825). We stated that, should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, and if we finalize our proposed definition of "interoperable," we would incorporate the final ONC regulations into the definition of "interoperable" at §411.351 by referencing 45 CFR part 171 instead of section 3022 of the PHSA (84 FR 55825).

We also noted in the proposed rule that the statutory definition of "interoperability" includes concepts similar to the existing definition of "interoperable" at §411.351 (for example, the ability to securely exchange data across different systems or technology) (84 FR 55825). Two new concepts in the statutory definition were included in our proposed modification of the

definition: (1) interoperable means the ability to exchange electronic health information without special effort on the part of the user; and (2) interoperable expressly does not mean information blocking (Section 3000(9) of the PHSA; (42 U.S.C. 300jj(9)). We stated that, as a practical matter, we believe that these two concepts are not substantively different from the existing definition and only reflect an updated understanding of interoperability and related terminology, and solicited comments on a definition that would align the definition of "interoperable" at §411.351 (for purposes of the physician self-referral law) with the statutory definition "interoperability" at 3000(9) of the PHSA (84 FR 55825).

As an alternative proposal, we considered revising our regulations to eliminate the term "interoperable" and instead define the term "interoperability" by reference to section 3000(9) of the PHSA and 45 CFR part 170 (if finalized) (84 FR 55825). In conjunction, we would revise the EHR exception to incorporate the term "interoperability" and remove the term "interoperable." We sought comment regarding whether using terminology identical to the PHSA and ONC regulations would facilitate compliance with the requirements of the EHR exception and reduce any regulatory burden resulting from the differences in the agencies' varying terminology related to the singular concept of interoperability (84 FR 55825). We are not finalizing this alternative proposal.

After reviewing the comments on our proposals, we are revising the definition of "interoperable," but omitting the provision related to information blocking and deleting the phrase "without special effort on the part of the user" from proposed subparagraph (1). Specifically, at revised §411.351, "interoperable" means: (1) able to securely exchange data with and use data from other health information technology; and (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

We received the following comments and our response follows.

Comment: We received general support for our effort to align the definition of

"interoperable" with the statutory definition of "interoperability" in the Cures Act. However, citing uncertainty regarding the proposals in the ONC NPRM, one commenter requested that CMS not define "interoperable" with reference to ONC's proposed definition. The commenter also requested that CMS not replace the definition of "interoperable" with a definition of "interoperability" that cites ONC's proposed definition at 45 CFR 170.102. One commenter supported including a provision pertaining to information blocking in the definition, while several other commenters raised questions about the incorporation of information blocking in the definition of "interoperable." For example, these commenters asked when the test for interoperability occurs and whether a prior donation of electronic health records items or services would cease to satisfy the requirements of the EHR exception if there was a finding of information blocking sometime after the donation. One commenter asked for further clarification of the phrase "without special effort on the part of the user."

Response: As we explain above in the discussion of our proposal to include the concept of "information blocking" in the exception at §411.357(w)(3), we believe that newer and separate authorities are better suited than the EHR exception to deter information blocking and hold individuals and entities that engage in information blocking appropriately accountable. We are concerned that, if we include the phrase "does not constitute information blocking" in the definition of "interoperable" at §411.351, then §411.357(w)(2), which requires that the donated software is interoperable, could be interpreted to prohibit parties from engaging in practices that constitute "information blocking" but that might not be prohibited under ONC rules. Therefore, we are not including the phrase "does not constitute information blocking" in the definition of "interoperable" at §411.351.

With respect to the phrase "without special effort on the part of the user," we note that, the phrase is used in the definition of "interoperability" at section 4003(a)(2) of the Cures Act and the partial phrase "without special effort" is used in the conditions of certification at section 4002(a) of the Cures Act. As explained above, although software certified by ONC is deemed to

be interoperable for purposes of the physician self-referral law, certification is not required for compliance with §411.357(w)(2). To avoid any implication that we are incorporating a certification requirement into the definition of "interoperable" at §411.351, we are removing the phrase "without special effort on the part of the user" from the definition.

e. Additional Proposals and Considerations

(1) 15 Percent Recipient Contribution (§411.357(w)(4))

In the 2006 EHR final rule, we agreed with a number of commenters that suggested that cost sharing is an appropriate method to address some of the program integrity risks inherent in unlimited donations of electronic health records items and services (71 FR 45160 through 45161). Accordingly, we incorporated a requirement at §411.357(w)(4) that, before the receipt of the items or services, the physician pays 15 percent of the donor's cost of the items or services. We stated our belief that the 15 percent cost sharing requirement is high enough to encourage prudent and robust electronic health records arrangements without imposing a prohibitive financial burden on recipients. Moreover, we stated that this approach requires recipients to contribute toward the benefits they may experience from the adoption of interoperable electronic health records software (for example, a decrease in practice expenses or access to incentive payments related to the adoption of electronic health records technology).

We received a number of comments in response to the CMS RFI, and OIG received similar comments in response to its request for information, asserting that the 15 percent contribution requirement of the EHR exception has been burdensome to some recipients and acts as a barrier to adoption of electronic health records. Some commenters on the requests for information asserted that this burden may be particularly acute for small and rural practices that cannot afford the contribution. Other suggested that applying the 15 percent contribution requirement to upgrades and updates to electronic health records software is restrictive and cumbersome and similarly acts as a barrier.

In the proposed rule, we considered and solicited comments on two alternatives to the

existing requirement at §411.357(w)(4) as outlined below, but did not propose specific regulation text along with the proposals (85 FR 55825). First, we considered eliminating the contribution requirement or reducing the percentage that small or rural physician organizations would be required to contribute. In conjunction with this proposal, we solicited comments on how we should define "small or rural physician organization." We also solicited comments on whether "rural physician organization" should be defined as a physician organization located in a rural area, as that term is defined at §411.351, or defined in line with the definition of "rural provider" at §411.356(c)(1). We also solicited comments on other subsets of potential physician recipients for which the 15 percent contribution is a particular burden. As an alternative, we proposed to reduce or eliminate the 15 percent contribution requirement in the EHR exception for all physician recipients. We solicited comments regarding the impact this might have on the use and adoption of electronic health records technology, as well as any attendant program integrity concerns. We solicited comments requesting specific examples of any prohibitive costs associated with the 15 percent contribution requirement, both for the initial donation of electronic health records items and services, and subsequent upgrades and updates to previously donated electronic health records items and services.

Finally, in the proposed rule, we also considered modifying or eliminating the contribution requirement for updates to previously donated electronic health records software or services, regardless of whether we determined to retain the 15 percent contribution requirement or reduce that contribution requirement for some or all physician recipients (85 FR 55825). We solicited comments on this approach as well as what such a modification should entail. For example, we considered requiring a contribution for the initial donation only, as well as any new electronic health records software modules, but not requiring a contribution for any update of the software already donated. We solicited comments on these alternatives, or another similar alternative that would still involve some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update of the software

already donated.

After reviewing the comments, we are retaining the 15 percent cost contribution requirement for all physician recipients. However, in response to comments, we are revising §411.357(w)(4) as it pertains to the timing of payments. Under revised §411.357(w)(4)(i), a physician must pay the required cost contribution amount before receiving an initial donation of electronic health records items and services or a donation of replacement items and services. However, with respect to items or services donated after the initial donation or the replacement donation, final §411.357(w)(4)(ii) requires that the cost contribution amount must be paid at reasonable intervals. Specifically, as finalized, §411.357(w)(4)(i) and (ii) require that: (i) before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services; and (ii) except as provided in subparagraph (i), with respect to items or services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals. We are not modifying §411.357(w)(4)(iii), which requires that the donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

We received the following comments and our responses follow.

Comment: A large number of commenters recommended that we remove the 15 percent contribution requirement for all donations and for all recipients or, in the alternative, reduce the contribution requirement to 5 percent of the donor's cost for the items and services. Commenters provided a number of reasons in support of their request to remove the contribution requirement. One commenter noted that the contribution requirement may pose a barrier to physicians who have not yet adopted electronic health records software, and added that, even if the contribution requirement is eliminated, physicians would still be required to bear other costs related to electronic health records implementation, such as hardware, staff time, and other resources. A

few commenters stated that the contribution requirement may be an unreasonable constraint on how health systems and hospitals finance the needed infrastructure to implement new value-based payment models and promote coordination of care. One of these commenters asserted that a common electronic health records system across a network of hospitals and physicians fosters a higher degree of integrated care, better and more timely access to services through coordinated systems, alignment of quality standards across all participating providers, and a more structured approach to optimizing utilization, thus contributing to higher quality and more affordable care. However, according to the commenter, small and independent practices typically cannot afford the electronic health records systems used by a larger health care system, even at a discount, which leads to a network of disjointed care and service offerings. Other commenters cited the added burden involved in setting the contribution amount in writing and the necessary, ongoing monitoring to ensure compliance. One of these commenters also highlighted that eliminating the requirement would align the EHR exception with the proposed cybersecurity exception at §411.357(bb), which does not include a contribution requirement. Several commenters that supported eliminating the contribution requirement as a requirement of the EHR exception suggested that CMS should still allow the donor to require a contribution. One of the commenters suggested that any contribution requirement should be left up to market forces and negotiation between the parties, and another suggested that the contribution amount should be at the discretion of the donor, as long as the donor consistently and fairly applies its policy to all recipients.

In contrast, some commenters raised concerns about eliminating the contribution requirement. One of these commenters maintained that physician adoption and use of an electronic health records system is improved when physicians have a certain level of buy-in and share in the financial cost. Similarly, other commenters suggested that 15 percent represents a fair contribution amount, the contribution requirement serves as a reasonable safeguard to reduce wasteful spending, and it is important for recipients to have a stake in the purchased technology.

Response: After careful consideration, we continue to believe that the contribution requirement is an important safeguard to protect against program or patient abuse. When recipients of valuable remuneration have some responsibility to contribute to the cost of the items or services, they are more likely to make economically prudent decisions and accept only items and services that they need. As described below, we are revising the requirement at §411.357(w)(4) to increase flexibility in connection with administering the contribution requirement. We note that, depending on the facts and circumstances, donations of electronic health records items and services may be permissible under the new exceptions for arrangements that facilitate value-based health care delivery and payment at §411.357(aa). There is no requirement in the exceptions at final §411.357(aa)(1), (2), or (3) that recipients of the electronic health records items or services contribute to the donor's cost for the items or services.

Comment: Many commenters suggested that, if CMS determines not to eliminate the 15 percent contribution requirement for all physician recipients, it should eliminate the requirement for at least a subset of recipients, such as small, rural, or tribal physician practices; free and charitable clinics; physicians with demonstrable financial need; or physician practices located in underserved areas, including urban practices serving low-income Medicaid populations. Several commenters stated that the contribution requirement presents a significant financial barrier for these physician practices that could negatively impact patient care, and one commenter maintained that the contribution requirement "prices out" physicians in small, rural, or underserved practices, while another stated that the 15 percent contribution requirement is "too steep" for many small practices. Another commenter believed that the contribution requirement could be lowered for small and rural physician organizations, provided that the donor is still permitted to decide the cost sharing amount required.

Some commenters that favored eliminating the contribution requirement for a subset of physician practices, such as small or rural practices and practices in underserved areas, provided a variety of definitions for small, rural, and underserved practices, including definitions based on

the Quality Payment Program; the anti-kickback statute safe harbor for local transportation; the North American Industry Classification System for small businesses; and the Secretary's designation of medically underserved areas and primary health care geographic health professional shortage areas. Some commenters expressed concern that different contribution requirements for different sets of physician practices may be difficult to administer and increase burden and, therefore, supported removing the contribution requirement for all physicians.

Response: As we explained in response to the immediately previous comment, we are retaining the 15 percent contribution requirement for all recipients seeking to protect donations of electronic health records items and services under the EHR exception. We agree with the commenters that identified the challenges of defining subgroups of entities to exempt from this requirement. Even if we were to adopt definitions for the categories of physician recipients who would be exempted from the contribution requirement—whether by adopting definitions existing in other regulations or definitions suggested by commenters—we are cognizant that qualification under a designation can change over time (for example, a physician practice may qualify as a "small practice" at some points in time but not at others, depending on staffing changes), resulting in significant compliance challenges when such a change occurs. In addition, the program integrity risks associated with donations of electronic health records items and services apply regardless of the geography or size of the donation recipient. Again, we note that, to the extent that the donation of electronic health records items and services is made under a value-based arrangement (as defined at §411.351), no recipient contribution is required, provided that the arrangement satisfies all the requirements of an applicable exception at final §411.357(aa).

Comment: A number of commenters asked that, if CMS retains a contribution requirement on the initial donation of electronic health records items and services, the contribution requirement be eliminated for updates to the original donation. Commenters noted that updates may ensure that an electronic health records donation continues to function as needed and to meet current Federal standards for data exchange. One commenter stated that it is

not uncommon for a donor's electronic health records system to be linked to a recipient's system, and the two systems must be in sync if they share an "instance" of electronic health records software. According to the commenter, updates to the donor's system must also be passed on to the recipient's electronic health records system, even if the recipient does not need, want, or use the updates. The commenter contended that, with respect to such updates, the 15 percent cost contribution requirement functions as a tax that damages the financial stability of small practices. Another commenter recommended that CMS consider retaining a contribution requirement only for the provision of replacement software while eliminating it for the initial donation and any updates to that initially donated system.

Response: As explained in response to comments above, we are retaining the contribution requirement for all electronic health records donations, including updates. We recognize that updates are crucial for the continuing functionality of an electronic health records system; however, we do not believe that it is appropriate to retain a contribution requirement for certain donations and eliminate it for others. We are concerned about gaming under such a regulatory scheme; for example, the parties could structure the "initial" donation to consist of a functionality with a low cost, and consequently, a small required contribution, with the most valuable functionality provided later as an "update" with no required contribution. For this reason, we believe that a cost contribution requirement is appropriate for all donations, including updates. However, as explained in our response to comments below, for updates to previously donated electronic health records items or services, we are no longer requiring that the contribution be made before the receipt of items and services.

Comment: Some commenters addressed other aspects of the contribution requirement at §411.357(w)(4). For example, one commenter expressed concern about the requirement that the physician recipient must pay the required contribution before the items or services are received. This commenter noted that recipients may unintentionally fail to satisfy this requirement due to inadvertent late payments and requested that CMS add a remedy period for mistakes to be

corrected. Another commenter recommended eliminating the requirement that the physician make the required contribution payment prior to the receipt of services and recommended instead that CMS require that the parties have in place a commercially reasonable collections process.

Response: We are aware that assessing a contribution for each update could create compliance challenges and increase administrative burden. We recognize that updates may need to take place quickly to remedy security or other problems in an electronic health records system, and we understand the commenter's concern about inadvertent late payments under such circumstances. We do not believe that it would pose a risk of program or patient abuse to permit a physician to pay required contribution amounts after receipt of an update, provided that payments are made at reasonable intervals. In contrast, with respect to an initial donation of items or services, or a donation that will replace existing items or services, we believe that parties can effectively plan the donation, with all expenses known in advance. Thus, there does not exist the same administrative burden or potential for inadvertent late payments that may exist with the timing of payments for periodic updates. In light of this, we are modifying the requirement at §411.357(w)(4) to permit payments of the cost contribution for items and services received after the initial donation or replacement donation at reasonable intervals, rather than in advance of the receipt of the items and services. Of course, parties remain free to require advance payments under their electronic health records donation arrangement. The regulation continues to require that the physician recipient pays the cost contribution amount for the initial donation of items or services or the donation of replacement items or services before the items or services are received. We note that the EHR exception does not require a specific billing method, but the contribution amounts must actually be paid by the physician and be paid at reasonable intervals. A donor could choose to bill a recipient separately for each update or could bill the recipient monthly or quarterly to combine the contribution payments for all updates during a select period of time. Given the modifications to §411.357(w)(4) that we are finalizing here, we do not believe that it is necessary to add a remedy period for mistakes to be corrected,

as suggested by the commenter.

Comment: One commenter recommended that we not require a 15 percent contribution for cybersecurity donations under the EHR exception. The commenter noted that some organizations will only permit practices to use their electronic health records systems if the practice has certain cybersecurity protections, and thus the commenter suggested that the party requiring the cybersecurity protection should pay any costs associated with it.

Response: We are not finalizing separate requirements for different types of donations within this exception. If a party seeks to protect a donation of cybersecurity software or services under the EHR exception, then a contribution toward the cost of the items and services is required. However, as explained in our response to comments above, a physician need not pay the 15 percent cost contribution for cybersecurity technology and services donated in conjunction with electronic health records items and services if the donation of the cybersecurity technology or services satisfies all the requirements of final §411.357(bb).

Comment: One commenter stated that donations of items and services under the EHR exception are typically made to a physician practice, as opposed to an individual physician. However, the cost contribution requirement at §411.357(w)(4) requires the physician to pay 15 percent of the donor's cost. The commenter stated that, given this language, it is unclear whether individual physicians or the physician practice must pay the cost contribution. The commenter requested that CMS clarify that donations may be made to a physician organization as the sole contracting party and as the sole contributor to the donor's cost.

Response: Because the physician self-referral law is implicated when a financial relationship exists between a physician (or an immediate family member of a physician) and an entity, the exception for electronic health records items or services at §411.357(w) is structured to apply to remuneration from an entity to a physician. The commenter correctly notes that the cost contribution requirement at §411.357(w)(4) requires the physician to pay 15 percent of the donor's cost. The required contribution amount may be paid by the physician or on behalf of the

physician by his or her physician organization.

With respect to donations to physicians in a physician organization consisting of more than one physician, we note the following. We acknowledge, as the commenter stated, that donations of items and services under the EHR exception are often made to a physician organization, as opposed to an individual physician. When an arrangement for the donation of electronic health records items and services is between the donor entity and a physician organization, under our regulation at §411.354(c)(1), each physician who stands in the shoes of the physician organization is deemed to have the same compensation arrangement as the physician organization. Thus, the donation of the electronic health records items and services to the physician organization is deemed to establish a direct compensation arrangement between each physician who stands in the shoes of the physician organization and the entity donating the electronic health records items and services. Each of those "deemed direct" compensation arrangements must satisfy the requirements of an applicable exception in order to avoid the physician self-referral law's referral and billing prohibitions. However, unlike many other forms of nonmonetary compensation, the cost of electronic health records items and services is oftentimes capable of being allocated on a per-user basis. Thus, when a donor entity divides the cost of electronic health records items and services among physician recipients in an appropriate manner (for example, per capita or by estimated usage based on their portions of the physician organization's patient universe or visits), the donation of electronic health records items and services to the physicians in a physician organization is properly viewed as a direct compensation arrangement between the donor entity and each recipient physician, rather than "deemed direct" compensation arrangements that result from applying the "stand in the shoes" provisions at §411.354(c)(1). In such circumstances, each physician recipient would be required to contribute 15 percent of the cost of the electronic health records items and services specifically allocated to him or her, rather than the cost of the entire suite of electronic health records items and services provided to the physician organization as a whole. The required

contribution amount may be paid by each individual physician or on behalf of the physicians by the physician organization.

To illustrate, assume that a donor entity wishes to provide licenses for the physicians in a physician organization to access and utilize electronic health records items and services, and the cost of the license is $100,000 per year for 25 licenses. The donor entity may divide the cost of the 25 licenses among the potential licensees, and allocate $4,000 to each physician recipient. Thus, if the donor entity provided 10 licenses to a physician organization, it could allocate $4,000 per physician recipient, establishing a direct compensation arrangement with each physician recipient. In these circumstances, each physician recipient must pay 15 percent (or $600) of the cost of the license before receipt of the license in order to satisfy the requirement at §411.357(w)(4). In contrast, assume that a donor entity provides information technology and training services that are not readily or appropriately divisible by any particular number of licensees or users. If the cost of the items and services provided to a physician organization cannot readily and appropriately be divided among the individual physician recipients of the items and services, under the regulation at §411.354(c)(1), the entirety of the items and services are deemed to be provided to each physician who stands in the shoes of the physician organization.

(2) Equivalent Items and Services (§411.357(w)(8))

In the 2013 EHR final rule, we highlighted a commenter's assertion that the prohibition on donating equivalent items or services currently included in the exception at §411.357(w)(8) locks physician practices into a vendor, even if they are dissatisfied with the donated items or services, because the recipient must choose between paying the full amount for a new electronic health records system and continuing to pay 15 percent of the cost of the substandard system (78 FR 78766). That commenter asserted that the cost differential between these two options is high enough to effectively locks physician practices into electronic health records technology vendors. In the 2013 EHR final rule, we responded that we continued to believe that items and services

are not necessary if the recipient already possesses the equivalent items or services. We noted that providing equivalent items and services confers independent value on the physician recipient and stated our expectation that physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

We appreciate that advancements in electronic health records technology are continuous and rapid. According to commenters on the CMS RFI and OIG's request for information, in some situations replacement electronic health records items or services are appropriate but prohibitively expensive. In the proposed rule, we proposed to permit donations of replacement electronic health records items or services under the EHR exception (84 FR 55826). We specifically sought comment as to the types of situations in which the donation of replacement items and services would be appropriate. We further solicited comment as to how we might safeguard against donors inappropriately offering, or physician recipients inappropriately soliciting, unnecessary items and services instead of upgrading their existing technology for appropriate reasons. Based on our review of the comments, we are finalizing our proposal to permit donations of replacement items and services by removing the requirement at §411.357(w)(8) that the donor does not have actual knowledge of, or and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor, which we have historically interpreted as a prohibition on the donation of replacement technology.

We received the following comment and our response follows.

Comment: Commenters broadly supported removing the requirement at §411.357(w)(8) that effectively prohibits a donor from donating replacement items and services under the EHR exception. Commenters provided a number of reasons for their support of the elimination of this requirement, highlighting that, because they cannot afford the full cost to replace their electronic health records systems, some physician practices may work with an electronic health records system that no longer meets their needs, is outdated, or is otherwise substandard. Similar to the

commenter on the 2013 EHR proposed rule, a few commenters maintained that the prohibition on replacement items and services locks a physician recipient into a particular vendor, even if the physician is not satisfied with its current electronic health records system, because the cost for a new system is significantly higher than continued payment of a 15 percent contribution for updates to the physician's current electronic health records software. One commenter stated that one of its clinically integrated networks operates with more than two dozen electronic health records systems. The commenter explained that, although it has developed a system to aggregate all patient information, the diverse electronic health records systems made the solution less than optimal. The commenter explained that, if the restriction on donations of replacement items and services were lifted, it could achieve greater efficiency and care coordination by migrating the network to one unified electronic health records system. A different commenter recommended that CMS eliminate the requirement at §411.357(w)(8) but require a documented rationale for the need of replacement items and services, while another commenter suggested that donations of replacement items and services should be permitted only if the recipient contributes 15 percent of the cost of the replacement software and services and demonstrates in writing, accompanied by documentation from an objective third party, that the recipient's current electronic health records system is substandard such that it poses a threat to patient safety. Similarly, one commenter suggested that donations of replacement software should only be permitted if the software that the physician is currently using no longer meets certification criteria.

Response: We are removing the requirement at §411.357(w)(8) from the EHR exception. We recognize that there may be valid business or clinical reasons for a physician recipient to replace an entire electronic health records system rather than update existing items and services, even if the existing software meets current certification criteria and does not pose a threat to patient safety. Under the revised EHR exception, replacement items and services are treated the same as a new donation and arrangements for the donation of replacement electronic health records items and services would need to satisfy all the requirements of the exception to avoid

the referral and billing prohibitions of the physician self-referral law. For example, under §411.357(w)(4)(i), a recipient of replacement items and services would be required to pay at least 15 percent of the donor's cost for the items and services before receiving them. We believe that treating a donation of replacement items and services the same as a new donation strikes an appropriate balance between making necessary replacements financially feasible for recipients and maintaining safeguards to protect against program or patient abuse, such as recipients inappropriately soliciting or accepting unnecessary electronic health records items and services.

12. Exception for Assistance to Compensate a Nonphysician Practitioner (§411.357(x))

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified in our regulations at §411.357(e). In Phase III, we declined one commenter's request to expand §411.357(e) to cover the recruitment of nonphysician practitioners (NPPs) into a hospital's service area, including into an existing physician practice, stating that the exception for physician recruitment at §411.357(e) applies only to payments made directly (or, in some circumstances, passed through) to a recruited physician (72 FR 51049). Recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. We further stated that payments made by a hospital to subsidize a physician practice's costs of recruiting and employing NPPs would create a compensation arrangement between the hospital and the physician practice for which no exception would apply, and that these kinds of subsidy arrangements pose a substantial risk of fraud and abuse. Following the publication of Phase III, we reconsidered our position. There have been significant changes in our health care delivery and payment systems, as well as projected shortages in the primary care workforce. To address this changed landscape, in the CY 2016 PFS final rule, we finalized a limited exception at §411.357(x) for hospitals, FQHCs, and

rural health clinics (RHCs) to provide remuneration to a physician to assist with the employment of (or other compensation arrangement with) an NPP (80 FR 71301 through 71311).

The exception at §411.357(x) applies to remuneration provided by a hospital to a physician to compensate an NPP to provide patient care services. As we noted in the proposed rule, we have received several inquiries regarding the meaning of the term "patient care services" as it relates to an NPP. The inquiries generally concentrate on the requirement at §411.357(x)(1)(v)(B) that the NPP has not, within 1 year of the commencement of his or her compensation arrangement with the physician, been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital. Often, prior to becoming an NPP, an individual may have been a registered nurse (or some other health care professional) and may have provided services to patients that are similar to the services provided by an NPP. For purposes of the exception at §411.357(x), the question presented by stakeholders is whether the services provided by the individual before the individual became an NPP constitute "patient care services."

As we explained in the proposed rule, the definition of "patient care services" found at §411.351 relates to tasks performed by a physician only (84 FR 55826). To clarify the meaning of "patient care services" for purposes of the exception for assistance to compensate an NPP, we proposed to revise §411.357(x) to change the references to "patient care services" to "NPP patient care services" and include a definition of the term "NPP patient care services" in the exception at §411.357(x)(4)(i). We proposed to define "NPP patient care services" to mean direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement. Under the definition of "NPP patient care services," services provided by an individual who is not an NPP (as the term is defined at §411.357(x)(3)) at the time the services are provided, are not NPP

patient care services for purposes of §411.357(x). Thus, if an individual worked in the geographic area served by the hospital providing the assistance (for example, as a registered nurse) for some period immediately prior to the commencement of his or her compensation arrangement with the physician or physician organization in whose shoes the physician stands, but had not worked as an NPP in that area during that period, the exception at §411.357(x) would be available to protect remuneration from the hospital to the physician to compensate the NPP to provide NPP patient care services, provided that all the requirements of the exception are satisfied. In this example, the registered nursing services would not be considered NPP patient care services when determining whether the arrangement satisfies the 1-year restriction at §411.357(x)(1)(v) (84 FR 55826).

We also proposed conforming changes to the term "referral" as defined at §411.357(x)(4) for purposes of the exception. Specifically, we proposed to revise §411.357(x) to change references to "referral" when describing the actions of an NPP to "NPP referral" and revise §411.357(x)(4) accordingly. We stated, and affirm here, that it is unnecessary to have a general definition of "referral" at §411.351 that is applicable throughout our regulations and a different definition of the same term ("referral") that applies only for purposes of the exception at §411.357(x). We did not propose substantive changes to the definition itself; however, we proposed to move the definition to §411.357(x)(4)(ii) in order to accommodate the inclusion of the related definition of "NPP patient care services" within section §411.357(x)(4) (84 FR 55826).

We also proposed a related change to §411.357(x)(1)(v)(A). As drafted, §411.357(x)(1)(v)(A) requires the NPP to not have practiced in the geographical area served by the hospital within 1 year of the commencement of the compensation arrangement with the physician. According to stakeholders that requested guidance on the scope of the exception, the word "practiced" may be interpreted to include the provision of NPP patient care services (as we proposed to define the term here) and other services, for example, services provided by a health

care professional who is not an NPP at the time the services are furnished. To resolve any potential stakeholder confusion, we proposed to replace the term "practiced" with "furnished NPP patient care services." Under the proposal, a hospital would not run afoul of §411.357(x)(1)(v)(A) if the hospital provided remuneration to a physician to compensate an NPP, and the individual receiving compensation from the physician furnished services in the hospital's geographic service area within 1 year of the commencement of his or her compensation arrangement with the physician, provided that the services furnished by the individual during the 1-year period were not NPP patient care services, as we proposed to define the term at §411.357(x)(4)(i) (84 FR 55826 through 55827).

In addition to the inquiries related to the meaning of the terms "patient care services" and "practice," we noted our awareness of stakeholder uncertainty regarding the timing of arrangements that may be permissible under §411.357(x). Specifically, stakeholders have inquired whether an NPP must begin his or her compensation arrangement with the physician (or physician organization in whose shoes the physician stands) on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician, noting that the exception includes no explicit prohibition on an entity providing assistance to a physician to reimburse the physician for the compensation, signing bonus, or benefits paid to an NPP already employed or contracted by the physician prior to the date of the commencement of the physician's compensation arrangement with the hospital, FQHC, or RHC. As we stated when finalizing the exception at §411.357(x), our underlying goal is to increase access to needed care (80 FR 71309). Permitting a hospital, FQHC, or RHC to simply reimburse a physician for overhead costs of current employees or contractors already serving patients in the geographic area served by the hospital, FQHC, or RHC does not support this goal. Nonetheless, as stakeholders pointed out, there is no express requirement regarding the timing of the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) in §411.357(x). To ensure that compensation arrangements

protected under the exception do not pose a risk of program or patient abuse, we proposed to amend §411.357(x)(1)(i) to expressly require that the compensation arrangement between the hospital, FQHC, or RHC and the physician commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement with the NPP (84 FR 55827). Put another way, the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) must commence on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician.

We received a number of comments in support of our clarifying proposals. Although we received a few comments addressing issues outside the scope of our proposals, we did not receive any comments objecting to our proposals or suggesting alternatives for clarifying the requirements of the exception for assistance to compensate a nonphysician practitioner. We are finalizing the proposed revisions to §411.357(x) without modification.

We received the following comments and our responses follow.

Comment: Most commenters that commented on our proposal supported the proposed modifications to clarify the terminology used in the exception and that the exception cannot be used to reimburse physicians for compensation, signing bonus, and benefits expenses related to NPPs who were employed or contracted before the commencement of the compensation arrangement between the hospital and the physician.

Response: As discussed above, we are finalizing our clarifying revisions in the exception for assistance to compensate a nonphysician practitioner at §411.357(x). We believe that the revisions finalized here will provide the clarity sought by stakeholders prior to the proposed rule.

Comment: Two commenters requested that CMS revise the exception at §411.357(x) to remove any limits on the practice specialties of nonphysician practitioners for whom physicians may receive assistance. One of the commenters asserted that surgery, neurology, urology, and many other specialty services are areas of acute need for many communities. The commenter

also recommended that we not limit the medical specialties of physicians who may receive assistance under the exception to physicians who provide "primary care services or mental health services." The other commenter asserted that, although most nurse practitioners provide primary care or behavioral health services, nurse practitioners practice in nearly all practice specialties, and these medical practices are also in need of nurse practitioners, particularly in rural and underserved communities. This commenter suggested that CMS align the exception for assistance to compensate a nonphysician practitioner with the exception for physician recruitment, noting that the former exception is limited to nonphysician practitioners who, for the most part, provide primary care or behavioral health services, while no similar restriction applies to physician recruitment.

Response: The exception for assistance to compensate a nonphysician practitioner was proposed in the CY 2016 PFS proposed rule (80 FR 41686) and finalized in the CY 2016 PFS final rule (80 FR 70866). In the CY 2016 PFS proposed rule, we stated that our goal in proposing (and ultimately finalizing) the exception was to promote the expansion of access to primary care services, but sought comment regarding whether there was a compelling need to expand the scope of the exception to nonphysician practitioners who provide services that are not considered primary care services (80 FR 41911). In response, commenters requested that we broaden the scope of the exception. Commenters that suggested an expansion to mental health services provided convincing evidence of the compelling need for access to mental health care services throughout the country (80 FR 71306). However, commenters that requested the expansion of the exception to any other specialty services provided no documentation or other evidence of the compelling need for such an expansion (80 FR 71306 through 71307).

We did not propose to expand the scope of the exception for assistance to compensate a nonphysician practitioner in the proposed rule, and make no attempt to finalize such a regulatory modification in this final rule. However, we note that the commenters that made the requests for expansion of the scope of the exception, like those that commented on the CY 2016 PFS

proposed rule, failed to provide any documentation or other evidence of the compelling need for such an expansion at this time. With respect to the commenter that suggested the exception for assistance to compensate a nonphysician practitioner at §411.357(x) should be aligned with the exception for physician recruitment at §411.357(e), we note that the exception for physician recruitment is statutory and covers only remuneration from a hospital to a physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital to become a member of the hospital's medical staff. In contrast, the underlying purpose of the exception to assist a physician to compensate a nonphysician practitioner is to promote expansion of access to primary care and mental health care services. There is no reason for the two exceptions to have identical requirements and scope.

13. Updating and Eliminating Out-of-Date References

a. Medicare+Choice (§411.355(c)(5))

Section 1877(b)(3) of the Act and §411.355(c) of the physician self-referral regulations set forth exceptions for designated health services furnished by various organizations to enrollees of certain prepaid health plans. When the Medicare+Choice program was established in the Balanced Budget Act of 1997 (Pub. L.105–33) (BBA), the Congress failed to update section 1877(b)(3) of the Act to except the designated health services furnished under Medicare+Choice coordinated care plans. Based on our belief that this was an oversight, in the June 26, 1998 interim final rule with comment period (Medicare Program; Establishment of the Medicare+Choice Program (63 FR 34968)), we revised §411.355(c) to accommodate the creation of the Medicare+Choice program and, relying on the Secretary's authority to create new exceptions under section 1877(b)(4) of the Act, we included Medicare+Choice coordinated care plans in §411.355(c)(5) of our regulations (63 FR 35003 through 35004). (We declined to include Medicare+Choice medical savings account plans and Medicare+Choice private FFS plans due to the risk of patient abuse related to financial liability for premiums and cost sharing, which were not limited by the BBA.) We included Medicare+Choice coordinated care plans at

§411.355(c)(5), in part, to avoid contradiction with the BBA's establishment of provider-sponsored organization (PSO) plans as coordinated care plans. PSOs are defined in the BBA as entities that must be organized and operated by a provider (which may be a physician) or a group of affiliated health care providers (which may include physicians). The BBA requires that the providers have at least a majority financial interest in the entity and share a substantial financial risk for the provision of items and services. If such ownership was not excepted, the physician owners of PSOs would not be permitted to refer enrollees for designated health services furnished by the coordinated care plan (or its contractors and subcontractors). Subsequently, in 1999, the Congress amended section 1877(b)(3) of the Act to create a similar statutory exception for Medicare+Choice at section 1877(b)(3)(E) of the Act (Pub. L. 106-113).

Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003) (MMA) renamed the Medicare+Choice program as the Medicare Advantage program and provided that any statutory reference to "Medicare+Choice" was deemed to be a reference to the Medicare Advantage program. In reviewing our regulations for out-of-date references, including references to Medicare+Choice, as part of this rulemaking, it came to our attention that the language of §411.355(c)(5) may be inconsistent with other program regulations. Current §411.355(c)(5) excepts designated health services furnished by an organization (or its subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and Part 422 of Title 42, Chapter IV of the Code of Federal Regulations. For consistency with the MMA directive and to ensure the accuracy of our regulations, we proposed to revise §411.355(c)(5) to more accurately reference Medicare Advantage plans. Under this proposal, §411.355(c)(5) would reference designated health services furnished by an organization (or its contractors or subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under

section 1857 of the Act and part 422 of this chapter. This proposal does not represent a change in our policy.

The Medicare Advantage program varies from the Medicare+Choice program in ways other than its name and has matured in the years since passage of the MMA. More than 20 years have passed since we determined to protect designated health services furnished to enrollees of coordinated care plans and exclude medical savings account plans and private FFS plans from the scope of §411.355(c)(5). In light of this, we sought comments regarding whether §411.355(c)(5) is broad enough to protect designated health services furnished to enrollees in the full range of Medicare Advantage plans that exist today and that do not pose a risk of program or patient abuse. Specifically, we were interested in commenters' views on which, if any, other Medicare Advantage plans we should include within the scope of §411.355(c)(5).

We received the following comment and our response follows.

Comment: Multiple commenters supported the proposed updates and elimination of references to "Medicare+Choice." We did not receive any comments opposing these changes.

Response: We are finalizing the changes as proposed.

b. Web site

We proposed to modernize the regulatory text by changing "Web site" to "website" throughout the physician self-referral regulations to conform to the spelling of the term in the Government Publishing Office's Style Manual and other current style guides.

After reviewing the comments, we are finalizing our proposal to change "Web site" to "website" wherever the term appears in our regulations.

We received the following comment and our response follows.

Comment: Multiple commenters supported the proposed updates and elimination of references to "Web site." We did not receive any comments opposing these changes.

Response: We are finalizing the changes as proposed.

E. Providing Flexibility for Nonabusive Business Practices

1. Limited Remuneration to a Physician (§411.357(z))

In the 1998 proposed rule, we proposed an exception for *de minimis* compensation in the form of noncash items or services (63 FR 1699). In Phase I, using the Secretary's authority at section 1877(b)(4) of the Act, we finalized the proposal at §411.357(k) and changed the name of the exception to nonmonetary compensation, noting that, although free or discounted items and services such as free samples of certain drugs, chemicals from a laboratory, or free coffee mugs or note pads from a hospital fall within the definition of "compensation arrangement," we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits (66 FR 920). The exception for nonmonetary compensation at §411.357(k) permits an entity to provide compensation to a physician in the form of items or services (other than cash or cash equivalents) up to an aggregate amount of $300 per calendar year, adjusted annually for inflation and currently $423 per calendar year, provided that the compensation is not solicited by the physician and is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. The exception does not require that the physician provide anything to the entity in return for the nonmonetary compensation, nor does it require that the arrangement is set forth in writing and signed by the parties.

We also recognized in Phase I that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the exception at §411.357(c) for *bona fide* employment relationships because most members of a hospital's medical staff are not hospital employees, nor would they qualify for the exception at §411.357(l) for fair market value compensation because, to the extent that the medical staff membership is the only relationship between the hospital and the physician, there is no written agreement between the parties to which these incidental benefits could be added. We acknowledged that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its patients; for example, free computer and Internet access benefits the hospital and its patients

by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information (66 FR 921). To address this, using the Secretary's authority under section 1877(b)(4) of the Act, we finalized a second exception for noncash items or services provided to a physician. The exception at §411.357(m) for medical staff incidental benefits permits a hospital to provide noncash items or services to members of its medical staff when the item or service is used on the hospital's campus and certain conditions are met, including that the compensation is reasonably related to the provision of (or designed to facilitate) the delivery of medical services at the hospital and the item or service is provided only during periods when the physician is making rounds or engaged in other services or activities that benefit the hospital or its patients (66 FR 921). In addition, the compensation may not be offered in a manner that takes into account the volume or value of referrals or other business generated between the parties. Under the exception, permissible noncash compensation is limited on a per-instance basis, and the current limit is $36 per instance. Like the exception at §411.357(k) for nonmonetary compensation, the exception at §411.357(m) for medical staff incidental benefits does not impose any documentation or signature requirements.

Through our administration of the SRDP, we have been made aware of numerous nonabusive arrangements under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician's provision of items and services to the entity. In some instances, the arrangements were ongoing service arrangements under which services were provided sporadically or for a low rate of compensation; in others, services were provided during a short period of time and the arrangement did not continue past the service period. For example, one submission to the SRDP disclosed an arrangement with a physician for short-term medical director services while the hospital was finalizing the engagement of its new medical director following the unexpected resignation of its previous medical director. Despite the hospital's need for the services and compensation that was fair market value and not determined in any manner that took into account the volume or value of the referrals or other business

generated by the physician, the arrangement could not satisfy all the requirements of any applicable exception because the compensation was not set in advance of the provision of the services and was not reduced to writing and signed by the parties. Under arrangements such as this, insofar as the hospital paid the physician in cash, the exception at §411.357(k) for nonmonetary compensation would not apply to the arrangement. Similarly, the exception at §411.357(l) for fair market value compensation would not protect the arrangement if it was not documented in contemporaneous signed writings and the amount of or formula for calculating the compensation was not set in advance of the provision of the items or services, even if the compensation did not exceed fair market value for actual items or services provided and was not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician.

In the proposed rule, we stated that, based on our review of numerous arrangements in the SRDP, we believe that the provision of limited remuneration to a physician would not pose a risk of program or patient abuse, even in the absence of documentation regarding the arrangement and where the amount of or a formula for calculating the remuneration is not set in advance of the provision of items or services, if: (1) the arrangement is for items or services actually provided by the physician; (2) the amount of the remuneration to the physician is limited; (3) the arrangement is commercially reasonable (4) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (5) the remuneration does not exceed the fair market value for the items or services. We stated that, under these circumstances, remuneration that is held within reasonable limits is unlikely to cause overutilization or similar harms to the Medicare program. Therefore, relying on the Secretary's authority under section 1877(b)(4) of the Act, we proposed an exception for limited remuneration from an entity to a physician for items or services actually provided by the physician (84 FR 55828 through 55829).

We proposed that the exception for limited remuneration to a physician would apply only

when the remuneration does not exceed an aggregate of $3,500 per calendar year, which would be adjusted for inflation in the same manner as the annual limit on nonmonetary compensation and the per-instance limit on medical staff incidental benefits; that is, adjusted to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. We stated our belief that an annual aggregate remuneration limit of $3,500 would be sufficient to cover the typical range of commercially reasonable arrangements for the provision of items and services that a physician might provide to an entity on an infrequent or short-term basis. We also proposed that the exception would not be applicable to payments from an entity to a physician's immediate family member or to payments for items or services provided by the physician's immediate family member. We sought public comment on whether the $3,500 annual aggregate remuneration limit is appropriate, too high, or too low to accommodate nonabusive compensation arrangements for the provision of items or services by a physician. We also sought comments regarding whether it is necessary to limit the applicability of the exception to services that are personally performed by the physician and items provided by the physician in order to further safeguard against program or patient abuse. In keeping with our proposal to decouple exceptions issued under our authority at section 1877(b)(4) of the Act from the anti-kickback statute, we did not propose to include a requirement under §411.357(z) that the arrangement must not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission. However, we solicited comment regarding whether such a safeguard is necessary here in light of the absence of requirements for set in advance compensation and written documentation of the arrangement. We also proposed that the remuneration may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician or exceed fair market value for the items or services provided by the physician, and the compensation arrangement must be commercially reasonable. Finally, we proposed limits on the percentage-based and per-unit compensation formulas for the lease of office space, the lease of equipment,

and the use of premises, equipment, personnel, items, supplies, or services (84 FR 55829).

After reviewing the comments, we are finalizing the exception for limited remuneration to a physician at §411.357(z) with several modifications. First, we are setting the annual aggregate remuneration limit to the physician at $5,000 instead of at $3,500, adjusted annually for inflation and indexed to the CPI-U. Second, the exception permits the physician to provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice). Third, we are requiring that the arrangement is commercially reasonable even if no referrals were made between the parties. Fourth, to address our concerns regarding the preservation of patient choice, we are requiring compliance with the special rule at §411.354(d)(4) if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier. Lastly, we are modifying the per-click and percentage-based compensation provisions at §411.357(z)(1)(v), to clarify that these provisions only apply to timeshare arrangements for the use of premises or equipment.

Given the relatively low annual aggregate remuneration limit of the exception and the other safeguards of the exception, we believe that the exception for limited remuneration to a physician, as finalized, does not pose a risk of program or patient abuse. However, when the remuneration a physician receives from an entity for items or services exceeds the annual aggregate remuneration limit of $5,000, as adjusted annually for inflation, the additional safeguards of other applicable exceptions are necessary to protect against program or patient abuse. For example, for long-term arrangements for items or services provided on a more routine or frequent basis, where the aggregate annual compensation exceeds the annual aggregate remuneration limit of the exception at new §411.357(z), the requirement that compensation is set in advance before the provision of the items or services is necessary to ensure that various payments made over the term of the arrangement are not determined retrospectively to reward

past referrals or encourage increased referrals from the physician. We note that the annual aggregate remuneration limit for the exception at §411.357(z) is higher than the annual limit for the exception for nonmonetary compensation at §411.357(k) because the exception for limited remuneration to a physician would protect a fair market value exchange of remuneration for items or services actually provided by a physician, while the exception for nonmonetary compensation does not require a physician to provide actual items or services in exchange for the nonmonetary compensation.

The final exception at §411.357(z) for limited remuneration to a physician applies to the provision of both items and services by a physician. In the proposed rule, we retracted our prior statements that office space is neither an "item" nor a "service." Thus, the exception for limited remuneration to a physician is available to protect compensation arrangements involving the lease of office space or equipment from a physician. For the reasons articulated in section II.D.10. of this final rule and the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), the exception at §411.357(z) incorporates prohibitions on percentage-based and per-unit of service compensation to the extent the remuneration is for the use or lease of office space or equipment, similar to the provisions at existing §411.357(p)(1)(ii) for indirect compensation arrangements and §411.357(y)(6)(ii) for timeshare arrangements.

We explained in the proposed rule and reaffirm here our policy that, in determining whether payments to a physician under the exception for limited remuneration to a physician exceed the annual aggregate remuneration limit in §411.357(z), we will not count compensation to a physician for items or services provided outside of the arrangement, if the items or services provided are protected under an exception in §411.355 or the arrangement for the other items or services fully complies with the requirements of another exception in §411.357. To illustrate, assume an entity has an established call coverage arrangement with a physician that fully satisfies the requirements of §411.357(d)(1) or §411.357(l). Assume further that the entity later

engages the physician to provide supervision services on a sporadic basis during the same year but fails to document the arrangement in a writing signed by the parties. In determining whether the supervision arrangement satisfies the requirements of the exception for limited remuneration to a physician, we will not count the compensation provided under the call coverage arrangement towards the annual aggregate remuneration limit in §411.357(z). However, if an entity has multiple undocumented, unsigned arrangements under which it provides compensation to a physician for items or services provided by the physician, we consider the parties to have a single compensation arrangement for various items and services, and the aggregate of all the compensation provided under the arrangement may not exceed the annual aggregate remuneration limit of §411.357(z) during the calendar year in order for the exception to protect the remuneration to the physician. To illustrate, assume the entity in the previous example also engages the physician to provide occasional EKG interpretations during the course of the year, and that the aggregate annual compensation for the supervision services and the EKG interpretation services *taken together* exceeded the annual aggregate remuneration limit.[19] Assuming neither arrangement satisfies the requirements of any other applicable exception, the exception for limited remuneration to a physician will not protect either arrangement (which, as noted, we treat as a single arrangement for multiple services) after the annual aggregate remuneration limit is exceeded during the calendar year.

As we explained in the proposed rule, the exception for limited remuneration to a physician may be used in conjunction with other exceptions to protect an arrangement during the course of a calendar year in certain circumstances (84 FR 55830). To illustrate, assume that an entity engages a physician to provide call coverage services, and that the arrangement is not documented or the rate of compensation has not been set in advance at the time the services are first provided. Further, assume that, after the services are provided and payment is made, the

[19] As noted, compensation paid under the call coverage arrangement would not be included when determining whether the annual aggregate remuneration limit was exceeded, because the call coverage arrangement in this example fully complies with an applicable exception.

parties agree to continue the arrangement on a going forward basis and agree to a rate of compensation. Assume also that the parties have no other arrangements between them. Depending on the facts and circumstances, the parties may rely on the exception at §411.357(z) to protect payments to the physician up to the $5,000 annual aggregate remuneration limit, provided that all the requirements of the exception are satisfied. For the ongoing compensation arrangement, the parties could rely on another applicable exception, such as §411.357(d)(1), to protect the arrangement once the compensation is set in advance and the other requirements of that exception are satisfied. (We remind readers that, under §411.354(e)(4), the parties would have up to 90 consecutive calendar days to document and sign the arrangement.)

In the proposed rule, we noted that §411.357(d)(1)(ii) requires that the personal service arrangement covers all the services provided by the physician (or an immediate family member of the physician) to the entity (or incorporate other arrangements by reference or cross-reference a master list of contracts) and §411.357(l)(2) requires that parties enter into only one arrangement for the same services in a year. As we stated in the proposed rule, for purposes of §411.357(d)(1)(ii), we will not require an arrangement for items or services that satisfies all the requirements of the final exception for limited remuneration to a physician to be covered by a personal service arrangement protected under §411.357(d)(1) or listed in a master list of contracts (84 FR 55830). Likewise, with respect to the restriction in the exception for fair market value compensation at §411.357(l)(2), we will not consider an arrangement for items or services that is protected under the exception at §411.357(z) to violate the prohibition on entering into an arrangement for the same items and services during a calendar year.

The vast majority of commenters supported our proposal, stating that the exception would increase flexibility under our regulations and reduce the burden of compliance without posing a risk of program or patient abuse. After reviewing the comments, we are finalizing the proposed exception for limited remuneration to a physician at §411.357(z) with certain modifications, as noted above. We are also making certain modifications to the exception for

personal service arrangements at §411.357(d)(1) and the exception for fair market value compensation at §411.357(l) to ensure that §411.357(z) may be used in conjunction with these exceptions.

We received the following comments and our response follows.

Comment: We received numerous comments regarding who may provide items and services and to whom the payments for items and services under the new exception at §411.357(z) may be made. Many commenters requested that we not limit the exception at §411.357(z) to items or services that are personally provided by physicians. One commenter suggested that the exception should be available for payments to a physician for items or services provided by someone at the direction of and under the control of the physician through a contract or employment arrangement. In contrast, one commenter expressed concern that the exception, as proposed, is subject to abuse and urged CMS to limit the applicability of the exception to items or services that are personally provided by the physician. One commenter suggested that the exception should apply to payments to a group practice for the services of a midlevel practitioner employed by the group or to a physician's immediate family members for items or services provided by the immediate family members.

Response: In the 1998 proposed rule, we interpreted the exception for personal service arrangements at §411.357(d)(1) to permit physicians to provide services through employees (63 FR 1701). In Phase II, we added that a physician may provide services under §411.357(d)(1)(ii) through a wholly owned entity or a *locum tenens* physician, but we declined to permit physicians to provide services under the exception through independent contractors (69 FR 16090 through 16093). We explained that, if physicians were permitted to provide services through independent contractors, a physician could enter into a broad range of service arrangements and take a fee as a middleperson without performing any actual service. In contrast, when a physician provides services through an employee or a wholly owned entity, the relationship evidences a *bona fide* business operated by the physician to provide the services. We find this

reasoning to be convincing and applicable to the exception for limited remuneration to a physician, and therefore we are clarifying at §411.357(z)(2) that a physician may provide items or services through an employee, a wholly owned entity, or a *locum tenens* physician, but not through an independent contractor. With respect to items, office space, or equipment provided by a physician through a physician's employee, wholly-owned entity, or *locum tenens* physician, we stress that the items, office space, or equipment provided must be the items, office space, or equipment *of* the physician.

For purposes of determining whether payments comply with the annual aggregate remuneration limit, any payments for items, office space, equipment, or services provided through a physician's employee, wholly owned entity, *or locum* tenens physician would be counted towards the annual aggregate remuneration limit applicable to the physician. In other words, there are not separate limits for a physician and his or her employees. For example, if an entity pays a physician $1,000 for personally performed services, $400 for services provided through the physician's employee, and $150 for items provided through the physician's employee, assuming no other previous payments for the calendar year, the sum of $1,550 is counted towards the annual aggregate remuneration limit applicable to the physician. (See below for a discussion of payments to a group practice or physician organization, and the application of the physician "stand in the shoes" rules at § 411.354(c) under the exception for limited remuneration to a physician.) Given our clarification that payments to a physician for items or services provided through a physician's employee, wholly owned entity, *or locum* tenens physician count towards the physician's annual aggregate remuneration limit and the other requirements of the exception, including the low annual compensation limit and requirements pertaining to fair market value, the volume or value of referrals and other business generated, and commercial reasonableness, we do not believe that our final policy poses a risk of program or patient abuse.

We are not convinced that the exception at §411.357(z) should be applicable to payments

to a physician's immediate family member for items or services provided by the family member. As explained above, the limited remuneration to a physician exception is designed in part to allow entities to compensate physicians for short-term or infrequent arrangements, many of which commence under exigent circumstances, with little time to reduce the arrangement to writing or set the compensation in advance. We do not believe that such situations typically arise with respect to physicians' immediate family members. In addition, if each immediate family member had a separate annual aggregate remuneration limit under the exception, the sum total of remuneration to a physician and his or her immediate family members could be substantial, depending on the number of immediate family members. We believe that such a policy may pose a risk of program or patient abuse. We note that an entity is permitted under the exception to compensate a physician for services provided through the physician's immediate family member if the family member is an employee of the physician acting at the direction of the physician, provided that all the requirements of the exception are met. However, as noted above, any payments to the physician for such services would be counted towards the physician's annual aggregate remuneration limit.

Comment: A significant number of commenters supported the proposed exception, but requested that the limit be higher than $3,500 per calendar year, as adjusted for inflation. Many commenters asserted that the proposed limit of $3,500 could be easily exceeded in a day or a weekend, for example, if a hospital has a sudden and immediate need to secure emergency on-call coverage in an area with high labor costs or a shortage of physicians. Other commenters suggested that a higher annual aggregate remuneration limit would better reflect what they consider the typical range of commercially reasonable arrangements that physicians might enter into with entities on a short-term or infrequent basis. Most commenters requested an annual aggregate remuneration limit of either $5,000, $7,000, or $10,000. A few commenters requested limits over $10,000, such as $35,000 per calendar year or 10 percent of the physician's total cash compensation from an entity (or its affiliates) over the most recent fiscal year. One commenter

stated that, as an alternative to raising the annual aggregate remuneration limit, CMS could cap the amount of remuneration per episode of service during a defined period of time, such as 2 or 3 months. In contrast, one commenter urged us to not raise the annual aggregate remuneration limit above $3,500.

Response: In establishing the appropriate annual aggregate remuneration limit in the final exception for limited remuneration to a physician at §411.357(z), we relied on our experience administering the SRDP and working with law enforcement, as well as comments we received on our proposed rule. In light of the comments we received, we are convinced that the proposed limit of $3,500 per calendar year, as adjusted for inflation, is not high enough to accommodate the broad range of nonabusive infrequent or temporary arrangements that an entity and a physician might enter into over the course of a year. Given the other requirements of the finalized exception, an annual aggregate remuneration limit of $5,000 for items or services actually provided by a physician to an entity does not pose a risk of program or patient abuse. We believe that an annual amount of remuneration greater than $5,000 per calendar year, as adjusted for inflation, may be high enough in certain instances to improperly incent physicians and affect medical decision-making. Without transparency safeguards that require an arrangement to be set forth in writing and signed by the parties and the safeguard of requiring that compensation is set in advance of the provision of items or services under the arrangement, we do not believe that an annual aggregate remuneration limit greater than $5,000 is appropriate. We believe that the per-episode methodology suggested by the commenter would increase burden, be difficult to administer and enforce, and could easily result in failure to comply with the requirements of the exception if parties do not meticulously track payments to the physician. For these reasons, we are finalizing a limit of $5,000 per calendar year, as adjusted for inflation.

Comment: One commenter requested clarification whether the annual aggregate remuneration limit on remuneration applies to an individual physician or a physician practice comprised of more than one physician. Another commenter suggested that the annual aggregate

remuneration limit, when applied to physicians in physician organizations, should apply to physicians individually, as opposed to the entire physician organization.

Response: Because the physician self-referral law is implicated when a financial relationship exists between physicians and entities that furnish designated health services, the exception for limited remuneration to a physician at §411.357(z) is structured to apply to remuneration from an entity to a physician. We did not propose, nor are we finalizing, an exception that permits a specific amount of remuneration from an entity to a physician organization under the conditions outlined in the new exception at §411.357(z).

Under our regulations at §411.354(c), remuneration from an entity to a physician organization would be deemed to be a direct compensation arrangement between the entity and each physician who stands in the shoes of the physician organization. A "deemed" direct compensation arrangement must satisfy the requirements of an applicable exception if the physician makes referrals to the entity and the entity bills the Medicare program for designated health services furnished as a result of the physician's referrals. The exception for limited remuneration to a physician is available to protect a direct compensation arrangement between an entity providing remuneration to an individual physician, as well as a "deemed" direct compensation arrangement between an entity and a physician who stands in the shoes of the physician organization to which the entity provides the remuneration. If an entity that makes payment to a physician organization relies on new §411.357(z), under §411.354(c)(1), the payment will create a "deemed" direct compensation arrangement with each physician who stands in the shoes of the organization. That is, each physician who stands in the shoes of the physician organization will be deemed to have the same compensation arrangement with the entity making the payment to the physician organization. Compensation received by the physician organization under such circumstances is counted towards the annual aggregate remuneration limit of *each* physician who stands in the shoes of the physician organization. For example, if an entity pays a physician organization $1,000 under §411.357(z) for lease of the

physician organization's equipment, and the physician organization consists of two owners (Drs. A and B) who stand in the shoes of the organization, then $1,000 is counted towards the annual aggregate remuneration limit of both Drs. A and B. The $1,000 payment would not count toward the annual aggregate remuneration limit of other physicians in the physician organization who are not required to stand in the shoes of the physician organization and are not treated as permissibly standing in the shoes of the physician organization.

Remuneration from an entity to a physician under a direct compensation arrangement between the entity and the individual physician (as opposed to a "deemed direct" compensation arrangement under the stand in the shoes rules) is counted only towards the individual physician's annual aggregate remuneration limit under §411.357(z). Returning to the example earlier in this response, if, in a direct compensation arrangement under §411.354(c)(1)(i), the entity paid Dr. A $500 for her services relying on §411.357(z), assuming no other payments during the calendar year relying on §411.357(z), the amount counted towards Dr. A's annual aggregate remuneration limit for payments received from the entity under §411.357(z) would be $1,500; that is, $500 for the services provided under the direct compensation arrangement and $1,000 for the equipment rental arising from the "deemed" direct compensation arrangement with the physician organization. Importantly, the $500 paid under the direct compensation arrangement between the entity and Dr. A would not be counted towards the annual aggregate remuneration limit of Dr. B or any other physician in the physician organization.

Under certain circumstances, a payment from an entity to a physician organization may be considered to be a payment directly to the physician who provided the items or services to the entity, with the physician organization only passing the remuneration through from the entity to the physician. What constitutes a direct compensation arrangement with an individual physician under §411.354(c)(1)(i), as opposed to an arrangement with a physician organization that creates a "deemed direct" compensation arrangement with a physician standing in the shoes of the organization under §411.354(c)(ii) or (iii), depends on the facts and circumstances of each

arrangement. Important factors include, but are not limited to, whether the physician (or the physician's employee, wholly owned entity, or *locum tenens* physician) provides the services under the arrangement, as opposed to the services being provided by another physician in the physician organization (or the physician organization's employee, wholly owned entity, or *locum tenens* physician); whether any items, office space, or equipment provided by the physician under the arrangement are owned or leased by the individual physician (as opposed to being owned or leased by the physician organization); and whether payment is made directly to the individual physician or, if payment is made to the physician organization, whether the physician organization acts as a pure go-between or middleman, transferring all of the compensation received from the entity under the arrangement to the physician who provided the items or services. (See section II.D.9. of this final rule for a discussion of our policy on pure "pass-through" payments.) Payments made to and retained by a physician organization for services provided through an employee of the physician organization are permitted under §411.357(z), but the payment amount would be counted toward the annual aggregate remuneration limit of each physician who stands in the shoes of the organization.

Comment: A number of commenters requested clarification whether, if compensation exceeds the proposed annual aggregate remuneration limit in a given calendar year (as adjusted for inflation), the entity can rely on the exception up to the point immediately prior to when the remuneration exceeded the limit. The commenters also requested clarification on how the exception would apply when remuneration straddles a calendar year. Specifically, the commenter asked if the remuneration limit resets at the beginning of each calendar year, or whether CMS would apply the exception for a different period, such as a 12-month period beginning with the commencement of the compensation arrangement.

Response: An entity may rely on the exception at §411.357(z) up to the point in a calendar year immediately prior to when the annual aggregate remuneration limit is exceeded. After that point, if the arrangement does not fit into another applicable exception, the physician

is not permitted to make referrals to the entity for designated health services, and the entity may not bill Medicare for such improperly referred services. For example, if the aggregate payments from an entity to a physician exceed the annual aggregate remuneration limit on April 1 of a given year, the exception is available to protect referrals from January 1 to March 31, but not for referrals from April 1 to December 31. We stress, however, that structuring arrangements to satisfy the requirements of an applicable exception that does not impose a cap on the amount of remuneration paid to the physician under the arrangement (other than the requirement that compensation is fair market value for the items and services provided by the physician) is a best practice and the best way to avoid exceeding the annual aggregate remuneration limit imposed at §411.357(z)(1).

The annual aggregate remuneration limit on remuneration under §411.357(z) resets each calendar year. As explained in section II.D.2.e. of this rule, the provision of remuneration in the form of items or services commences a compensation arrangement at the time the items or services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services. Thus, for arrangements that straddle a calendar year, remuneration should be allocated to the annual aggregate remuneration limit of a calendar year based on the date that the items or services are provided. To illustrate, assume that an entity engages a physician to present at an educational program series held periodically throughout an academic year spanning September 2020 through May 2021. Assume also that, on December 15, 2020, the entity pays the physician $2,000 for services provided during the fall semester and, on May 15, 2021, the entity pays the physician $4,000 for services provided during the spring semester. The $2,000 paid under the arrangement for the fall semester is counted toward the annual aggregate remuneration limit for 2020 and the $4,000 paid for the spring semester is counted toward the annual aggregate remuneration limit for 2021.

It is possible that the services for which the physician is paid will more directly straddle

the change from one calendar year to the next. For example, assume a physician is engaged to provide a single weekend of emergency call coverage and is paid $2,000 for coverage provided on December 31, 2021 and January 1, 2022, and the physician is paid for the services on January 31, 2022. Assuming no unusual circumstances that would require the payment to be weighted for one day over another, $1,000 would be counted towards the physician's 2021 annual aggregate remuneration limit and $1,000 would be counted towards the physician's 2022 annual aggregate remuneration limit.

Comment: One commenter requested that CMS clarify whether the exception for limited remuneration to a physician can apply to multiple types of services or arrangements.

Response: During any given calendar year, the exception at §411.357(z) may be applied to the provision of different types of items or services, including office space and equipment. The annual aggregate remuneration limit on remuneration from an entity to a physician is determined by adding compensation for all of the various items and services provided by the physician. For example, if, in a calendar year, a physician is paid $500 for one service, $350 for a separate service, $150 for certain items, and $400 for a short-term lease of equipment, the amount allocated to the annual aggregate remuneration limit under §411.357(z) for that year is $1,400. As explained above, if the parties had additional arrangements in the same calendar year that fully satisfied all the requirements of an applicable exception other than §411.357(z), the remuneration under those arrangements would not be counted towards the physician's annual limit under §411.357(z).

Comment: One commenter expressed concern that the exception for limited remuneration to a physician may allow for business arrangements that the commenter deemed "questionable" and asserted are subject to abuse. This commenter urged CMS to include additional safeguards in the exception, including a requirement that the arrangement does not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission. Other commenters objected to including any additional requirements

pertaining to the anti-kickback statute or Federal or State laws or regulations governing billing or claims submissions. These commenters stressed that parties already have an independent obligation to not violate these other laws and expressed concern that the introduction of the intent-based anti-kickback statute into the strict liability framework of the physician self-referral law would increase the burden of compliance without affording any additional safeguards to protect against program or patient abuse.

Response: As explained in sections II.D.1. and II.D.10. of this final rule, we generally believe that certain regulatory exceptions need not include requirements pertaining to the anti-kickback statute or other Federal or State laws or regulations governing billing or claims submissions in order to ensure that financial relationships to which the exceptions apply do not pose a risk of program or patient abuse. Even so, we believe that a requirement for compliance with the anti-kickback statute is appropriate in certain instances, particularly where both a regulatory and statutory exception could apply to an arrangement and the regulatory exception does not contain all of the requirements or safeguards that are included in the statutory exception. For example, as explained in section II.D.10, the requirement in the regulatory exception for fair market value compensation at §411.357(l) that the arrangement does not violate the anti-kickback statute acts as a *substitute* safeguard for certain requirements that are included in the statutory exception for the rental of office space but omitted in the regulatory exception, such as the exclusive use requirement at section 1877(e)(1)(A)(ii) of the Act and §411.357(a)(3) of our regulations. With respect to the final exception for limited remuneration to a physician at §411.357(z), the regulatory exception omits certain requirements that are found in many statutory exceptions that are potentially applicable to arrangements excepted under §411.357(z), such as the set in advance, writing, and signature requirements. However, the low annual cap on aggregate remuneration under the exception provides a strong and sufficient substitute safeguard for the omitted requirements. Therefore, we are not requiring under §411.357(z) that the arrangement not violate the anti-kickback statute or other Federal or State law or regulation

governing billing or claims submissions. Nonetheless, we agree with the commenter that certain additional safeguards are necessary to prevent program or patient abuse, especially in light of our final policy to raise the annual aggregate remuneration limit under the exception from $3,500 to $5,000.

As proposed, the exception for limited remuneration to a physician required the compensation arrangement to be commercially reasonable. As explained elsewhere in this final rule, we believe that the requirement that an arrangement is commercially reasonable is uniformly interpreted wherever it appears. Most exceptions that include a commercial reasonableness requirement, including exceptions that apply to arrangements that could also be excepted by §411.357(z), stipulate that the arrangement must be commercially reasonable "even if no referrals were made" between the parties. We are modifying the requirement at §411.357(z)(1)(iii) to clarify that the arrangement must be commercially reasonable "even if no referrals were made between the parties." We are concerned that, without this modification, some stakeholders may believe that the commercial reasonableness standard in §411.357(z) is a different and less demanding standard than the commercial reasonableness requirement in other exceptions.

Because we do not have the same transparency into arrangements protected under the finalized exception at §411.357(z) and, as explained elsewhere in this final rule, because we prioritize the protection of patient choice, we are also requiring at §411.357(z)(1)(vi) that, if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy all the conditions of §411.354(d)(4). As revised in this final rule, §411.354(d)(4) provides that, if a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, then certain conditions must be met, including that the compensation is set in advance for the duration of the arrangement; the requirement to make referrals to a particular provider, practitioner, or

supplier is set out in writing and signed by the parties; and neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier. As explained in section II.B.4. of this final rule, the conditions in §411.354(d)(4) play an important role in preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization. Furthermore, prior to our interpretation of the volume or value standard in this final rule, a service arrangement that included a directed referral requirement would have had to comply §411.354(d)(4) in order to be deemed not to take into account the volume or value of a physician's referrals to the entity. Given our final rules interpreting the volume or value standard and other business generated standard, to ensure that arrangements excepted under §411.357(z) protect patient choice and the physician's professional medical judgement and avoid interfering in the operation of a managed care organization, we are requiring compliance with §411.354(d)(4) for arrangements that condition a physician's compensation on referrals to a particular provider, practitioner, or supplier.

We stress that, under §411.357(z)(1)(vi), the conditions of §411.354(d)(4), including the set in advance and writing requirement, must be satisfied only if the arrangement to be excepted under §411.357(z) conditions a physician's compensation on referrals to a particular provider, practitioner, or supplier. To be excepted under §411.357(z), an arrangement need not satisfy the conditions of §411.354(d)(4) if compensation under the arrangement to be excepted is not conditioned in this manner, even if the parties have other, separate arrangements that condition a physician's compensation on referrals to a particular provider, practitioner, or supplier. Likewise, if the parties begin an arrangement relying on §411.357(z) and the arrangement at its outset does not condition compensation on referrals to a particular provider, practitioner, or supplier, then the arrangement need not comply with §411.354(d)(4) at its outset. However, if the entity later requires the physician to refer to a particular provider, practitioner, or supplier,

the parties must set the compensation and document the referral requirement in writing in advance of the applicability of the requirement.

Although we are not including a requirement for compliance with the anti-kickback statute in §411.357(z), we reiterate here that, to the extent that remuneration implicates the anti-kickback statute, nothing in our proposals or this final rule affects the parties' obligation to comply with the anti-kickback statute, and compliance with the exception for limited remuneration to a physician does not necessarily result in compliance with the anti-kickback statute. As we stated in Phase I, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that particular referrals and claims are not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive (66 FR 879).

Comment: One commenter requested that we limit the applicability of the exception for limited remuneration to a physician to service arrangements and not permit use of the exception for the rental of office space or equipment or for timeshare arrangements. The commenter stated that such arrangements carry a heightened risk and, therefore, should be documented in writing so that they can be audited, monitored, and objectively verified.

Response: Although we appreciate the importance of ensuring that an exception issued by the Secretary under his authority at section 1877(b)(4) of the Act does not undermine the integrity of the Medicare program, we believe that the safeguards incorporated in final §411.357(z), including the annual aggregate remuneration limit capping the total remuneration permissible under the exception at a relatively low level and the requirement that the remuneration is for items or services actually provided by the physician, are sufficient to protect against program or patient abuse even with respect to arrangements for the rental of office space or equipment and timeshare arrangements. Therefore, the final exception for limited remuneration to a physician at § 411.357(z) is not limited to arrangements for items and services that are not office space or equipment. The prohibitions on percentage-based compensation and

per-unit of service ("per-click") fees for the rental or use, as modified in this final rule, of office space and equipment serve to protect against certain abusive arrangements.

Comment: Some commenters requested that CMS not finalize the proposed prohibition on certain percentage-based and per-unit of service compensation formulas for the use of premises, equipment, personnel, items, supplies, or services under a timeshare arrangement. The commenter assumed that the proposed requirement is apparently intended to address timeshare arrangements and other arrangements similar to traditional lease of office space and equipment, but asserted that the requirement, as drafted, is so broad that its scope is unclear.

Response: The commenter is correct that the requirement prohibiting a compensation formula under a timeshare arrangement that is based on percentage of revenue or per-unit of service fees that are not time-based relates to the use of premises (including office space), and equipment protected under final §411.357(z). Under timeshare arrangements, where dominion and control are not transferred for the use of premises, equipment, personnel, items, supplies, or services, we believe that prohibitions on percentage-based compensation and per-unit of service fees are required to ensure that excepted timeshare arrangements do not pose a risk of program or patient abuse. (*See* 80 FR 71331 through 71332). Therefore, we are not convinced that §411.357(z)(1)(v) should be removed. However, we agree that the requirement, as proposed, could have an unintended impact on arrangements other than timeshare arrangements, and we are revising the requirement to address our specific concern. Under final §411.357(z)(1)(v), compensation for the use of premises (including office space) or equipment may not be determined using a formula based on: (1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises (including office space) or equipment; or (2) per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises (including office space) or equipment.

Comment: Several commenters supported our policy that the exception for limited

remuneration to a physician be used in conjunction with other exceptions during the course of a calendar year, noting that the exception, if finalized, would provide relief for parties that begin an arrangement for items or services before the arrangement squarely fits in another exception. One commenter requested that we finalize certain modifications to the exceptions for personal service arrangements at §411.357(d) and fair market value compensation at §411.357(l) to ensure consistency with our policy regarding the application of §411.357(z). Specifically, the commenter requested that we revise §411.357(d)(1)(ii) to explicitly provide that an arrangement that satisfies all the requirements of §411.357(z) need not be covered by a personal service arrangement protected under §411.357(d)(1) or be listed on a master list of contracts. Similarly, the commenter requested that we revise §411.357(l)(2) to explicitly provide that, if an arrangement for items or services fully satisfied the requirements of §411.357(z), the parties could also rely on §411.357(l) to except an arrangement for the same items and services during a calendar year.

Response: As explained in the proposed rule and in this final rule, the exception at §411.357(z) may be used during the course of a calendar year in conjunction with other exceptions to the physician self-referral law. The commenters are correct that the exception for limited remuneration to a physician may be used in succession with another applicable exception to protect an ongoing arrangement. For example, if parties do not initially document an arrangement or set the compensation in advance, the arrangement may be excepted under §411.357(z) if all its requirements are satisfied, including that the remuneration does not exceed the annual aggregate remuneration limit established at final §411.357(z)(1). If the parties continue the arrangement, they may rely on another applicable exception to protect the arrangement on a going forward basis, provided that all the requirements of the other applicable exception are met, including any writing, signature, and set in advance requirements. All the requirements of the other applicable exception, including the set in advance requirement, would have to be met beginning on the date that the parties rely on the other exception, except that the

parties would have up to 90 consecutive calendar days to document and sign the arrangement under §411.354(e)(4). Remuneration provided to a physician for items or services provided prior to the date that the arrangement satisfies all the requirements of an applicable exception other than §411.357(z) would be counted towards the annual aggregate remuneration limit in §411.357(z)(1).

The provision at §411.357(d)(1)(ii) requires that the personal service arrangement covers all the services provided by the physician (or an immediate family member) to the entity, and states that this requirement is met if all the separate arrangements between the entity and the physician (or immediate family member) incorporate each other by reference or if they cross list a master list of contracts. We share the commenter's concern that this requirement could undermine the applicability and utility of the exception for personal service arrangements if the parties to an arrangement concurrently rely on the new exception at §411.357(z) to protect a separate arrangement for the provision of personal services. Therefore, we are modifying §411.357(d)(1)(ii) to state that a personal service arrangement excepted under §411.357(d)(1) does not have to cover personal services that are provided by a physician under an arrangement that satisfies all the requirement of §411.357(z). Without this modification, there may be confusion as to whether the exception for limited remuneration to a physician may be used for one service arrangement while the parties concurrently use §411.357(d)(1) for a separate personal service arrangement. Insofar as personal services provided under an arrangement that satisfies all the requirements at §411.357(z) are excluded from the "covers all services" requirement in §411.357(d)(1)(ii), it is not necessary to incorporate a personal service arrangement excepted under §411.357(z) by reference or list it on a master list of contracts.

The exception for fair market value compensation provides at §411.357(l)(2) that the parties may enter into only one arrangement for the same items or services during the course of a year. We share the commenter's concern that this requirement could undermine the utility of the exception for fair market value compensation if parties first rely on the new exception at

§411.357(z) to protect an arrangement for the same items or services during a single year. (We note that a "year" for purposes of the exception at §411.357(l) is not defined as a "calendar year" and refers, instead, to any 365-day period.) We are modifying this provision to state that, other than an arrangement that satisfies all the requirements of §411.357(z), the parties may not enter into more than one arrangement for the same items and services during the course of a year. With this modification, parties may use the exception for limited remuneration to a physician to protect an arrangement for the provision of items and services, and, during the course of a year, also rely on §411.357(l) to protect an arrangement for the same items and services.

Comment: One commenter asked for clarification as to whether the proposed exception for limited remuneration to a physician could be relied on by an entity to provide continuing medical education (CME) to physicians for free or at a reduced cost. The commenter characterized our proposal as "increasing the limit from $300 to $3,500 per year."

Response: We believe that the commenter is confusing the new exception for limited remuneration to a physician at §411.357(z) with the exception for nonmonetary compensation at §411.357(k), which has an annual limit of $300, adjusted annually for inflation. There are significant differences between these exceptions. Among other things, the exception for limited remuneration to a physician protects compensation that does not exceed fair market value for items or services *actually* provided by the physician. Unlike the exception for nonmonetary compensation at §411.357(k), the new exception at §411.357(z) does not permit entities to provide remuneration to a physician, including valuable in-kind remuneration such as free or reduced cost CME, without a fair market value exchange for items or services actually provided by the physician. The exception for nonmonetary compensation permits an entity to gift (or otherwise provide) a physician a limited amount of noncash remuneration during the course of a calendar year, not to exceed $300, as indexed to inflation and currently $423 per year, in the aggregate. No exchange of items or services from the physician is required. An entity may provide CME to a physician under the exception at §411.357(k), provided that the value of the

CME does not exceed the annual limit on nonmonetary compensation when aggregated with any other nonmonetary compensation provided to the physician during the same calendar year.

2. Cybersecurity Technology and Related Services (§411.357(bb))

Relying on our authority under section 1877(b)(4) of the Act, in the proposed rule, we proposed an exception at §411.357(bb) (the cybersecurity exception) applicable to arrangements involving the donation of cybersecurity technology and related services (84 FR 55830). We believe that establishing such an exception will help improve the cybersecurity posture of the health care industry by removing a perceived barrier to donations of technology and services that address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of health care. The OIG is establishing a similar safe harbor to the anti-kickback statute elsewhere in this issue of the **Federal Register**. Despite the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between the exception to the physician self-referral law and the safe harbor to the anti-kickback statute.

In recent years, both CMS and OIG have received numerous comments and suggestions urging the creation of an exception and a safe harbor, respectively, applicable to donations of cybersecurity technology and related services.[20] The digitization of health care delivery and rules designed to increase interoperability and data sharing in the delivery of health care create abundant targets for cyberattacks. For instance, a large health system with over 400 locations was recently the victim of a system-wide cyberattack that took medication, medical record, and other patient care systems offline.[21] The health care industry and the technology used in health care delivery have been described as an interconnected ecosystem where the weakest link in the

20 *See*, for example, U.S. Department of Health and Human Services, Office of Inspector General, *Semiannual Report to Congress*, Apr. 1, 2018-Sept. 30, 2018, at 84.

21 "Cyberattack hits major hospital system, possibly one of the largest in U.S. History," NBC News, September 28, 2020, available at https://www.msn.com/en-us/news/us/cyberattack-hits-major-hospital-system-possibly-one-of-the-largest-in-u-s-history/ar-BB19vtPQ?li=BBnbcA1.

system can compromise the entire system.[22] Given the prevalence of electronic health record storage, as well as the processing and transit of health records and other critical protected health information (PHI) between and within the components of the health care ecosystem, the risks associated with cyberattacks that originate with "weak links" are borne by every component of the system.

Although we did not specifically request comments on cybersecurity, numerous commenters on the CMS RFI requested that we establish an exception to protect the donation of cybersecurity technology and related services. In response to its request for information specifically related to cybersecurity, OIG received overwhelming support for a safe harbor to protect the donation of cybersecurity technology and related services. Many commenters on both requests for information highlighted the increasing prevalence of cyberattacks and other threats. These commenters noted that cyberattacks pose a fundamental risk to the health care ecosystem and that data breaches result in high costs to the health care industry and may endanger patients. Moreover, disclosures of PHI through a data breach can result in identity fraud, among other things.

The Health Care Industry Cybersecurity (HCIC) Task Force, created by the Cybersecurity Information Sharing Act of 2015 (CISA),[23] was established in March 2016 and is comprised of government and private sector experts. The HCIC Task Force produced its HCIC Task Force Report in June 2017.[24] The HCIC Task Force recommended, among other things, that the Congress "evaluate an amendment to [the physician self-referral law and the anti-kickback statute] specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either

22 *See*, for example, Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry*, June 2017 (HCIC Task Force Report), *available at* https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.
23 Pub. L. 114-113, 129 Stat. 2242.
24 HCIC Task Force Report, *available at* https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.

donation or subsidy," and noted that the regulatory exception to the physician self-referral law for EHR items and services and the safe harbor to the anti-kickback statute for EHR items and services could serve as a template for a new statutory exception.[25]

Based on responses to OIG's request for information and our proposed rule, we understand that the cost of cybersecurity technology and related services has increased dramatically, to the point where many providers and suppliers are unable to invest in and, therefore, have not invested in, adequate cybersecurity measures. As previously noted, the risks associated with a cyberattack on a single provider or supplier in an interconnected system are ultimately borne by every component in the system. Therefore, an entity wishing to protect itself by preventing, detecting, and responding to cyberattacks has a vested interest in ensuring that the physicians with whom the entity exchanges data are also able to prevent, detect, and respond to cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity, which inherently present higher risk than connections that permit physicians "read-only" access to the entity's data systems. We believe that a primary reason that an entity would provide cybersecurity technology and related services to a physician is to protect itself from cyberattacks; however, we recognize that donated cybersecurity technology and services may have value for a physician recipient insomuch as the recipient would be able to use his or her resources for needs other than cybersecurity expenses. Even so, it is our position that allowing entities to donate cybersecurity technology and related services to physicians will lead to strengthening of the entire health care ecosystem. We believe that, with appropriate safeguards, arrangements for the donation of cybersecurity technology and related services will not pose a risk of program or patient abuse, provided that they satisfy all the requirements of the exception at final §411.357(bb). In addition, we believe that the exception established in this final rule will promote increased security for interconnected and interoperable health care IT systems without protecting potentially abusive arrangements.

[25] *Id.* at 27.

In the proposed rule, we proposed that the exception at §411.357(bb) would be applicable to nonmonetary remuneration in the form of certain types of cybersecurity technology and related services (84 FR 55831). In an effort to foster beneficial cybersecurity donation arrangements without permitting arrangements that pose a risk of program or patient abuse, we proposed the following requirements for cybersecurity donations made under §411.357(bb): the technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity; neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties; neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor; and the arrangement is documented in writing. After reviewing comments on our proposed rule, we are finalizing the exception for cybersecurity donations and related services at §411.357(bb) with certain modifications related to the types of nonmonetary remuneration permitted under the exception, as well as nonsubstantive modifications to the text of the regulation.

We received the following general comments and our responses follow.

Comment: The majority of commenters generally supported the proposed exception for cybersecurity technology and related services. Commenters noted that cybersecurity is necessary to enable secure and effective exchange of health information and thus is crucial for care coordination and improved health outcomes. One commenter explained that patient safety is the most critical concern when cyberattacks occur, especially when the cyberattacks impact the patient's electronic health records and medical devices. The commenter added that cyberattacks can result in disclosure of sensitive patient information and can alter the treatment a patient is prescribed, among other negative consequences. One commenter highlighted the trend in health care towards greater interconnectivity, even as costs for cybersecurity rise, and concluded that

cybersecurity donations make sense from affordability, efficiency, and social responsibility standpoints. Another commenter stated its belief that health care providers are insufficiently prepared to meet cybersecurity challenges that arise in an increasingly digitized health care delivery system. The commenter stated that the proposed cybersecurity exception would help address these challenges and be part of a national strategy to improve the safety, resilience, and security of the health care industry.

Response: We believe that the exception as finalized at §411.357(bb) will remove real and perceived barriers to beneficial cybersecurity technology donations, addressing an urgent need to improve cybersecurity hygiene in the health care industry and protect patients and the health care ecosystem overall. With respect to care coordination, we note that, depending on the facts and circumstances, an arrangement for the donation of cybersecurity technology and services may qualify as a value-based arrangement (as defined at final §411.351) to which the new exceptions at §411.357(aa)(1), (2), and (3) for arrangements that facilitate value-based health care delivery and payments may be applicable.

Comment: A few commenters generally objected to the proposed cybersecurity exception. One commenter expressed concern that the requirements of the proposed exception are inadequate because, according to the commenter, they are difficult to monitor and less stringent than the requirements of the EHR exception. Another commenter asked CMS to reconsider the exception and whether cybersecurity technology and arrangements involving the donation of such technology are understood sufficiently at this time to warrant an exception. Some commenters expressed concern that the exception could be used to support anti-competitive behavior. One of the commenters maintained that, while health IT donations by large health care entities appear to advance interoperability, the actual result is that physician recipients lose their autonomy as independent providers, the lack of competition increases the costs of health care, and smaller providers are closed by the larger health system when they do not create a profit. Instead of finalizing the proposal, the commenter urged CMS to fund a

program that would allow small or rural providers to gain access to cybersecurity technology. Another commenter expressed concern that the proposed cybersecurity exception could inadvertently bolster information blocking, as some providers cite cybersecurity as a reason for not sharing data or providing data access to physicians.

Response: We do not understand the basis for the commeners' assertions that the provision of cybersecurity items and services to protect information by preventing, detecting, and responding to cyberattacks would limit physician autonomy or lead to inappropriate information blocking. Although we are concerned, in general, about anti-competitive behavior, we believe that an exception for arrangements involving the donation of cybersecurity technology and related services is a necessary and critical tool to assist the health care industry in addressing the prevalent and increasing cybersecurity threats facing the industry, which, among other things, can negatively impact the quality of care delivered to beneficiaries.[26] The cybersecurity exception incorporates many of the core requirements of the EHR exception, including the requirements that: (1) the remuneration is necessary and used predominantly for the purposes outlined in the exception; (2) neither the eligibility of the physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties; (3) neither the physician recipient nor the physician's practice makes the receipt of the technology or services or the amount or nature of the technology or services a condition of doing business with the donor entity; and (4) the arrangement is documented in writing. In addition, as explained above, we believe that many donors will make cybersecurity donations as a self-protective measure. Given these safeguards, we do not believe that the cybersecurity exception, as finalized, permits financial relationships that pose a risk of program

[26] *See*, for example, Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry*, June 2017 (HCIC Task Force Report), *available at* https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf. (recommending an exception for cybersecurity donations).

or patient abuse.

a. Covered Technology and Services

In the proposed rule, we proposed to limit the applicability of the cybersecurity exception to nonmonetary remuneration consisting of technology or services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity (84 FR 55832).[27] We explained that our goal is to ensure that donations are made for the purposes of addressing legitimate cybersecurity needs of donors and recipients; therefore, the core function of the donated technology or service must be to protect information by preventing, detecting, and responding to cyberattacks (84 FR 55832). As proposed, the exception at §411.357(bb) would apply to the provision of a wide range of technology and services that are predominantly used for the purpose of, and are necessary for, ensuring that donors and recipients have cybersecurity.

We are taking a neutral position with respect to the types of technology to which the final cybersecurity exception is applicable, including the types and versions of software that an entity may provide to a physician recipient when all the requirements of the exception are satisfied. We did not propose to distinguish, and the cybersecurity exception as finalized here does not distinguish, between cloud-based software and software that must be installed locally (84 FR 55832). The types of technology to which the cybersecurity exception is applicable include, but are not limited to, software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software, data protection and encryption, and email traffic filtering (84 FR 55832). As we stated in the proposed rule, these examples are indicative of the types of technology that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity (84 FR 55832). In addition, as explained in section II.E.2.b. below, the cybersecurity exception as finalized also applies to hardware that is necessary and used predominantly to implement, maintain, or

[27] In the proposed rule, the "necessary and used predominantly" condition was included in the proposed regulations at §411.357(bb)(1)(i). As explained at the end of this section, in the final rule, this condition appears in the chapeau of the exception at §411.357(bb)(1).

reestablish cybersecurity. We solicited comments on the scope of the technology to which the cybersecurity exception should be applicable, as well as whether we should expressly include (or exclude) other technology or categories of technology in the exception.

We also proposed that the cybersecurity exception would apply to a broad range of services (84 FR 55832). We stated that such services could include—

- Services associated with developing, installing, and updating cybersecurity software;
- Cybersecurity training services, such as training recipients on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology (for example, "help desk" services specific to cybersecurity);
- Cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue during and after a cybersecurity attack;
- "Cybersecurity as a service" models that rely on a third-party service provider to manage, monitor, or operate cybersecurity of a recipient;
- Services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; or
- Services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.

We stated further that these types of services are indicative of the types of services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity, and solicited comments on the scope of the services to which the cybersecurity exception should be applicable, as well as whether we should expressly include (or exclude) other services or categories of services (84 FR 55832). We noted in the proposed rule and reiterate here that, in all cases, the technology and services provided by an entity must be nonmonetary.

With respect to both technology and services, we emphasize that, although donated technology or services may have multiple uses, the cybersecurity exception only applies to

technology and services that are necessary and used predominantly to implement, maintain, and reestablish cybersecurity. The exception does not apply to technology or services that are otherwise used predominantly in the normal course of the recipient's business (for example, general help desk services related to use of a practice's IT). We solicited comment on whether this limitation would prohibit the donation of cybersecurity technology and related services that are vital to improving the cybersecurity posture of the health care industry.

With respect to the requirement that the technology or services are necessary to implement, maintain, or reestablish cybersecurity, we considered, and sought comment on, whether to deem certain arrangements to satisfy this requirement (84 FR 55832). We explained in the proposed rule that such a deeming provision, if adopted, would not affect the requirement that the technology or services are used predominantly to implement, maintain, or reestablish cybersecurity. We emphasized that parties would have to show on a case-by-case basis that the "used predominantly" requirement is met (84 FR 55832). In the proposed rule, we stated that, if we adopted a deeming provision for the purpose of applying the "necessary" requirement at proposed §411.357(bb)(1)(i), we would deem donors and recipients to satisfy the requirement if the parties demonstrated that the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards (84 FR 55832). Examples of such frameworks and sets of standards include those developed or endorsed by the National Institute for Standards and Technology (NIST), another American National Standards Institute-accredited standards body, or an international voluntary standards body such as the International Organization for Standardization. As explained below in response to comments below, we are not adopting this proposed deeming provision.

We are finalizing our proposal to limit the applicability of the cybersecurity exception to technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. However, in the final cybersecurity exception as established here, we

state the scope of the exception in the chapeau of the exception at §411.357(bb)(1) instead of including a requirement in the exception that the technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. (The remaining requirements of the exception are redesignated to account for this organizational change; for example, proposed §411.357(bb)(1)(ii) is finalized at §411.357(bb)(1)(i), and so forth). We are also removing the phrase "certain types of" before "cybersecurity technology and services" from the chapeau to avoid ambiguity regarding the scope of the exception. Most exceptions to the physician self-referral law are structured such that the chapeau delineates the scope of remuneration that may be provided under the exception, provided that the requirements enumerated under the chapeau language are satisfied. The chapeau of an exception contains specific pre-conditions that must be satisfied in order for the exception to be available to except a particular arrangement. The "necessary and used predominantly" condition in the cybersecurity exception serves this function. The remuneration that may be provided under the cybersecurity exception is limited to nonmonetary compensation, consisting of technology and services, that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. In addition, the structural reorganization of the final cybersecurity exception creates greater consistency with the EHR exception. As finalized, the chapeau of the cybersecurity exception mirrors the chapeau in the EHR exception at §411.357(w)(1), which provides that donated items or services must be necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records. Inclusion of the "necessary and used predominantly" condition in the chapeau of the cybersecurity exception underscores that "necessary and used predominantly" has the same meaning in both the EHR and cybersecurity exceptions. We believe this consistency is especially important insofar as cybersecurity software may be donated under both exceptions.

We received the following comments and our responses follow:

Comment: One commenter urged CMS to permit, with appropriate safeguards, the

donation of both nonmonetary remuneration consisting of cybersecurity technology and services and monetary remuneration to be used for the purchase of cybersecurity technologies and services. The commenter asserted that permitting monetary remuneration in appropriate circumstances could help alleviate what the commenter characterized as the cybersecurity exception's unintended adverse effects on competition, such as a situation where a donor wished to supply cybersecurity technology to two competing small providers and one of the small providers had already purchased the technology but the other had not. The commenter asserted that protecting monetary reimbursement to the first provider and an in-kind donation to the second provider would be fairer than permitting a donation to one competitor and not the other.

Response: We decline to permit reimbursement of previously incurred cybersecurity expenses, as well as the provision of cash remuneration to a physician that is intended to be used for the future purchase of cybersecurity technology and services. We believe that this would pose a risk of program or patient abuse, as the former would simply be a subsidy of practice expenses that a physician—rather than the donor entity—determined to incur, and the latter involves the provision of cash, some or all of which could be used to offset other practice expenses without ultimately enhancing the cybersecurity posture of the donor entity or the health care ecosystem as a whole. We also highlight that the example provided by the commenter likely would not satisfy the other conditions of this exception even if the exception permitted an entity to provide monetary remuneration. For instance, if a physician has already obtained cybersecurity technology or services, the provision of remuneration in the form of reimbursement would not be necessary to implement, maintain, or reestablish cybersecurity.

Comment: A number of commenters supported the requirement at proposed §411.357(bb)(1)(i) that the technology and related services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. One of the commenters suggested that this provision would ensure the legitimacy of donations and help differentiate the technology and services that may be donated under the cybersecurity exception from technology

and services that have multiple uses beyond cybersecurity. Another commenter urged CMS to require a clear nexus between the cybersecurity donation and the business relationship between the donor and recipient. The commenter explained that the cybersecurity technology should be necessary for the provision of the services involved, such as where a hospital donates cybersecurity technology to a physician to ensure the secure transfer of personal health information and thus improve care coordination for shared patients. The commenter stated that the cybersecurity exception should not protect donations that are used as a way to entice new business. A different commenter suggested that, provided that donated cybersecurity technology and services substantially further the interests of strengthening cybersecurity for the end user, their donation should be permissible. The commenter agreed with CMS that donors should have the discretion to choose the amount and nature of cybersecurity technology and services they donate to physicians based on a risk assessment of the potential recipient or based on the risks associated with the type of interface between the parties.

Response: As explained above, the cybersecurity exception is limited to technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. However, we are including this limitation in the chapeau of the final cybersecurity exception rather than as a separate requirement of the exception as we proposed. The change in the organization of the exception does not affect or alter the meaning, scope, or application of the requirement that donated technology and services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity, as that requirement was explained in the proposed rule (84 FR 55831).

The "necessary and used predominantly" language at final §411.357(bb)(1) delineates the scope of the exception and will ensure that donations are made to address legitimate cybersecurity needs of donors and recipients. With respect to technology and services with multiple uses or functions other than cybersecurity, we note the following. In the 2006 EHR final rule, we acknowledged that electronic health records software is often integrated with other

software and functionality, but we explained that such software may still be necessary and used predominantly to create, maintain, transmit, or receive electronic health records if the electronic health records functions predominate (71 FR 45151). We added that the "core functionality" of the technology must be the creation, maintenance, transmission, or receipt of electronic health records. The same principle applies to technology (as defined at §411.357(bb)(2)) and services donated under the cybersecurity exception. While donated technology and services may include functions other than cybersecurity, the core functionality of the technology and services must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate. Such technology and services must also be necessary for implementing, maintaining, or reestablishing cybersecurity. Although we are not adopting the "clear nexus" standard suggested by the commenter, we question whether donated technology or services would be necessary for the donor or recipient to implement, maintain, or reestablish cybersecurity if the technology or services are not connected to the underlying services furnished by either party. We note also that we are finalizing a requirement that a donor may not directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for donated technology or services, or when determining the amount or nature of the donated technology or services. This requirement addresses the concern expressed by the commenters regarding parties that improperly use the exception for donations to entice new business. With respect to the last comment, we decline to adopt the commenter's proposal that donations should be permitted under the cybersecurity exception if the donated technology or services "substantially further the interests of strengthening cybersecurity for the end user." We believe that stakeholders are familiar with the "necessary and used predominantly" condition from the EHR exception, and, insofar as the EHR exception applies to cybersecurity software and services, we believe that it reduces administrative burden to use a similar standard for both the EHR and cybersecurity exceptions.

Comment: Most commenters recommended that we finalize an exception that covers a

broad range of cybersecurity technology and services, and some requested specific language or clarifications. In particular, several commenters asked CMS to consider how the proposed exception would apply to cloud-based and subscription-based products and services. One commenter supported many of the examples from the proposed rule of services that could be covered under the cybersecurity exception, while other commenters requested that CMS provide clarity related to the scope of potentially permissible donations through additional examples of the types and amounts of technology and services allowed. Specifically, commenters asked CMS to clarify whether the exception is applicable to the following services: assurance, assessment, and certification programs that allow physicians to assess their own cybersecurity and demonstrate that they are trusted participants in health care data exchange; risk assessment and gap analysis services; consulting services to work with a physician to develop and implement specific cybersecurity policies and procedures; subscription fees required by vendor security products that assist physicians in developing policies and procedures in support of a risk assessment; implementation, management, and remediation services; and provision of a full-time cybersecurity officer. Some commenters noted that a cybersecurity-specific help desk may not be realistic and recommended that CMS permit donations of general help desk services, whether through the donor's IT department or the vendor's help desk services.

Although many commenters expressed concern about the utility of the exception if it does not apply to a broad enough scope of technology and services, other commenters recommended limiting the scope of cybersecurity technology and services that may be provided to a physician under the exception. One of these commenters cautioned against permitting donations of "cybersecurity as a service." The commenter asserted that the "cybersecurity as a service" model, where a third-party manages, monitors, or operates the cybersecurity of a recipient, goes beyond what is reasonable for donated cybersecurity, but did not provide further detail as to how "cybersecurity as a service" would pose a risk of program or patient abuse.

Response: As finalized, the exception protects donations of a broad range of technology

and services. Cybersecurity technology and services include both locally installed cybersecurity software and cloud-based cybersecurity software. As explained in section II.E.2.b. below, the exception also applies to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. We provided multiple examples of items and services to which the cybersecurity exception would apply in the preamble to the proposed rule (84 FR 55832), which is repeated above in this final rule. We continue to believe that the cybersecurity exception is applicable to the examples provided in the proposed rule. We also stated in the proposed rule and reiterate here that "cybersecurity as a service" may be protected, including third-party services managing and monitoring the cybersecurity of a recipient. Other than a general statement of caution, the commenter that addressed "cybersecurity as a service" did not provide any specific reasons why such a service presents a risk of program or patient abuse, and we see no reason why this cybersecurity format requires a different analysis than cybersecurity installed locally or should be excluded from the scope of the cybersecurity exception. All of the examples provided in the proposed rule are illustrative only, and the list of examples in the proposed rule is not exhaustive. We intend the exception to be applicable to technology and services that are currently available, as well as technologies and services that will be developed in the future. Donated technology and services, however, must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. To the extent that the services described by commenters are necessary and used predominantly to implement, maintain, or reestablish cybersecurity, they may be donated under the cybersecurity exception (if all the remaining requirements of the exception are also satisfied).

We recognize that cybersecurity functionality is often incorporated into software or other information technology whose primary use and functionality is not cybersecurity and, further, that certain services may be useful for implementing, maintaining, or reestablishing cybersecurity while also generally serving purposes other than cybersecurity (for example, general IT services that include a cybersecurity component). However, in order for technology

or services to be donated under the cybersecurity exception, the core functionality of the technology or services must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate. For instance, depending on the facts and circumstances of a particular arrangement, donating a virtual desktop that includes access to programs and services beyond cybersecurity software likely would not be protected because the technology would include functions not necessary and predominantly used to implement, maintain, or reestablish cybersecurity, such as, for example, word processing or claims and billing applications. Similarly, the exception is likely not applicable to general IT help desk services, because the services would not be used predominantly for cybersecurity. However, we are aware of cybersecurity-specific software and services that include customer service and help desk features for cybersecurity assistance. The cybersecurity exception is applicable to such help desk services if all the requirements of the exception are satisfied. The cybersecurity exception could also be applicable to services provided through an entity's primary help desk, if the services are necessary and used predominantly for cybersecurity (for example, to report cybersecurity incidents). The provision of a full-time cybersecurity officer in a physician recipient's practice must be necessary, the cybersecurity officer's services must be used predominantly to implement, maintain, or reestablish cybersecurity, and all other requirements of the exception at final §411.357(bb) must be satisfied in order to avoid violation of the physician self-referral law.

Comment: Several commenters interpreted our discussion in the proposed rule of the difficulty of collecting cost contribution amounts for patches and updates to mean that donations of patches or updates to previously donated technology would not fall within the scope of the cybersecurity exception. The commenters highlighted that patching and updates are critical to managing cybersecurity risks and prohibiting their donation could neutralize any benefits resulting from the cybersecurity exception. One of these commenters noted that, given the fast-paced nature of developments in cybersecurity, it is likely that new tools will need to be deployed on at least an annual basis. The commenters asked that we ensure that the

cybersecurity exception, if finalized, applies to ongoing cybersecurity software updates and other patches. Another commenter requested clarification regarding whether the provision to a physician of a routine or critical update would cause an arrangement to fail to satisfy all the requirements of the cybersecurity exception, noting that patching is sometimes given to physicians for free (because it is built into the contracts with vendors), and some patches may be focused on security while others may be more general. A different commenter asked CMS to provide greater clarity regarding donations of replacement technology in light of the rapid development of new cybersecurity technology.

Response: Constant vigilance is required to maintain the cybersecurity of the health care ecosystem, and we agree with the commenters that patching and updates are critical to managing cybersecurity risks. As we discussed in response to previous comments, we are not excluding any particular type of technology or services—including patches and updates—from the application of the final cybersecurity exception. The ongoing donation of cybersecurity patches and updates will not result in noncompliance with the physician self-referral law, provided that all the requirements of the cybersecurity exception (or another applicable exception) are satisfied at the time of their donation. We note that the written documentation evidencing the arrangement for the donation of cybersecurity technology or services may account for the future provision of patches and updates, relieving the parties from developing additional documentation each time a patch or update is issued. Also, as described below in section II.E.2.d., the exception at final §411.357(bb) does not require a financial contribution from the recipient. Therefore, routine patches and upgrades provided to recipients at no cost will not cause the arrangement between the parties to fall out of compliance with the physician self-referral law, provided that all the requirements of the exception are satisfied at the time of their issuance.

Regarding donations of cybersecurity technology or services to physicians who already have some technology or services, the final exception at §411.357(bb) does not prohibit the donation of replacement technology; however, an arrangement for the provision of cybersecurity

technology and services must satisfy all the requirements of the exception. We note that donating replacement technology could satisfy the requirement that the technology or services are necessary to implement, maintain, or reestablish cybersecurity if, for example, the technology that is replaced is outdated or poses a cybersecurity risk.

Comment: One commenter recommended that CMS clarify the scope of the intended "object" to be protected by the cybersecurity technology and services; for example, cybersecurity to protect electronic health records, medical devices, or other IT that uses, captures, or maintains individually identifiable health information. The commenter noted that the proposed cybersecurity exception was silent as to the "object" of the cybersecurity protection, and asserted that an explicit statement setting broad parameters about the purpose of donated cybersecurity technology and services would provide guidance and potentially cover future technology advances. Another commenter encouraged CMS to specifically permit donations of technology and services related to medical device cybersecurity.

Response: We decline to set parameters or requirements for the intended "object" (or "subject") of the cybersecurity protection because we are concerned that this could unintentionally limit the scope of the technology and services to which the cybersecurity exception is applicable. If all the requirements of the exception are satisfied, the exception is applicable to cybersecurity technology and services that, among other things, protect electronic health records, medical devices, or other IT that uses, captures, or maintains individually identifiable health information.

Comment: One commenter objected to what it considered to be CMS' "piecemeal" approach to health care technology, with different exceptions for different types of technology (for example, EHR and cybersecurity) that the commenter asserted must work together to drive care coordination. The commenter urged CMS to broaden the scope of the cybersecurity and EHR exceptions to ensure flexibility to protect technology that can help facilitate the transition to a value-based health care delivery and payment system. The commenter specifically

recommended that we make any final cybersecurity exception applicable to data analytics and reporting functionalities. The commenter provided as an example predictive data analytics tools that allow a hospital to identify and decrease the number of high-risk heart failure patients presenting for admission to the hospital or emergency room.

Response: We are not extending the scope of the cybersecurity exception at final §411.357(bb) to all data analytics and reporting functionality specifically designed to facilitate the transition to a value-based health care delivery and payment system, as requested by the commenter. As illustrated by the commenter's example, the use and purpose of data analytics and reporting functionality may differ significantly from those of cybersecurity technology and services. The cybersecurity exception at §411.357(bb) is limited to technology and services that are necessary and used predominantly to implement, maintain, and reestablish cybersecurity, and its requirements of the exception at §411.357(bb) are not designed to adequately protect against Medicare program or patient abuse where data analytics and reporting functionality are provided at no cost (or reduced cost) to a physician. Other exceptions to the physician self-referral law address the items and services described by the commenter. We believe that the requirements of those exceptions are appropriate to protect the Medicare program and its patients from abuse when such remuneration is provided by an entity to a physician (or vice versa). With respect to the commenter's concern regarding a piecemeal approach to exceptions under the physician self-referral law, we note that parties seeking to except an arrangement for the donation of technology are not required to utilize multiple exceptions if the separate functions of the technology and the donation satisfy the requirements of a single exception.

Comment: One commenter that generally opposed the cybersecurity exception maintained that effective cybersecurity protection could require a whole suite of services, such as active management, monitoring, and developing an effective response system if an issue arises, and it may not be possible for an outside entity to provide such a broad range of services. The commenter asserted that more limited donations of cybersecurity technology or services, on the

other hand, may not provide effective cybersecurity protection for the recipients and may expose the donor to liability in case of a cyberattack.

Response: As described in our responses to other comments, the final cybersecurity exception applies to a wide range of technology and services that implement, maintain, or reestablish cybersecurity (as defined at final §411.351). Although we established the cybersecurity exception to address real or perceived barriers to improving the cybersecurity posture of the health care industry, the exception does not apply to all remuneration that may be relevant to cybersecurity needs. The final cybersecurity exception permits technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. The protection afforded under the exception is not limited to cybersecurity that is "effective." In the strict liability context of the physician self-referral law, we are concerned that requiring "effective" cybersecurity at §411.357(bb)(1) may chill otherwise beneficial cybersecurity donations, as donors and recipients may lack the expertise to understand and determine what constitutes "effective" cybersecurity or there may be disagreement as to whether cybersecurity measures are "effective." Although donor liability is outside the scope of this rulemaking, we note that nothing in the cybersecurity exception prohibits donors and recipients from addressing such issues through contracts or other agreements.

Comment: A number of commenters supported the inclusion of a deeming provision that would allow donors or recipients to demonstrate that the compensation arrangement satisfies the requirement that the technology or services are "necessary" if the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework, such as those developed by NIST, or guidelines developed by the Department of Health and Human Services Office for Civil Rights (OCR) in collaboration with ONC. One commenter recommended that, in cases where cybersecurity is built into software that gives physicians access to a hospital's computer system, the technology should be deemed to be necessary and used predominantly for cybersecurity. The commenter

explained that such a deeming provision is warranted because, as noted in the proposed rule (84 FR 55831), a hospital that has granted physicians access to its system has a vested interest in ensuring that the physicians with whom it shares information are also protected from cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity. A different commenter recommended that any deeming provision remain voluntary, while another commenter supported a deeming provision when the cost of the donation of technology and services exceeds a specified monetary limit. One commenter supported the inclusion of a deeming provision but only if the parties to the donation arrangement, through an independent third party, demonstrate and certify that the donation ensures compliance with a written cybersecurity program or framework that conforms to NIST standards. In contrast, several commenters objected to the inclusion of any deeming provision, maintaining that it would add unnecessary burden without providing any meaningful protection against program and patient abuse. One of these commenters stated that physicians may struggle to understand what "reasonable conformance" looks like or when a cybersecurity framework or standard is considered "widely recognized."

Response: We are not including a deeming provision for establishing compliance with the condition that donated technology and services are necessary for cybersecurity in the final rule. We are concerned that any deeming provision that is specific enough to address our program integrity concerns will be of limited or no utility for stakeholders. We also agree with the commenter that parties may struggle to understand what "reasonable conformance" looks like or when a framework or standard is considered "widely recognized." Without selection of one or more specific frameworks, any deeming provision could be challenging to understand and difficult to enforce. Regarding the commenter's suggestion that software that grants access to a hospital's system should be deemed to be necessary and used predominantly for cybersecurity, we agree that the type of connection between a donor and a physician (bidirectional read-write connection versus unidirectional read-only access) is an important factor in determining whether

particular technology or services are necessary for cybersecurity. However, we do not believe that any software or other information technology should be deemed to be necessary for cybersecurity simply because the technology permits a physician to access a hospital's computer system. Moreover, the determination of whether technology or services are used predominantly to implement, maintain, or reestablish cybersecurity depends on how the donated technology or services are used in fact and, therefore, not appropriate for a deeming provision. Although technology or services donated under the cybersecurity exception may have uses or functions other than cybersecurity (for example, software that allows a physician to access a hospital's computer system), the cybersecurity use must in fact predominate.

b. Definitions of "Cybersecurity" and "Technology"

In the proposed rule, we proposed to define the term "cybersecurity" to mean the process of protecting information by preventing, detecting, and responding to cyberattacks and to define the term "technology" to mean any software or other type of information technology, other than hardware (84 FR 55831). Because the term "cybersecurity" also appears in the EHR exception at §411.357(w), which expressly applies to the donation of cybersecurity software and services, we proposed to include the definition of "cybersecurity" in our regulations at §411.351. Because the term "technology," as used in the new exception for cybersecurity technology and related services, would be defined solely for purposes of the exception at §411.357(bb), we proposed to include its definition at §411.357(bb)(2) (84 FR 55831). We note that the term "technology" is included in several instances in our regulations as part of the term "information technology" and at §411.357(w)(6)(iv) to describe one of the ways in which the determination of the eligibility of a physician for a donation of EHR items or services, or the amount or nature of the items or services, would be deemed not to be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. The proposed definition of "technology" was not intended to affect the meaning of the term "information technology" or the interpretation of §411.357(w)(6)(iv).

In the proposed rule, we proposed a broad definition of "cybersecurity" derived from the NIST Framework for Improving Critical Infrastructure,[28] a framework that does not apply specifically to the health care industry, but applies generally to any United States critical infrastructure (84 FR 55831). We proposed a broad definition of "cybersecurity" to avoid unintentionally limiting donations by relying on a narrow definition or a definition that might become obsolete over time, although we solicited comments whether a definition tailored to the health care industry would be more appropriate (84 FR 55831). We proposed a similarly broad definition of "technology" that is neutral with respect to the types of cybersecurity technology to which the exception applies (84 FR 55831). We explained in the proposed rule that the definition of "technology" is broad enough to include cybersecurity software and other IT, such as an Application Programming Interface (API)—which is neither software nor a service, as those terms are generally used—that is available now, as well as technology that may become available as the industry continues to develop. As proposed, "technology" would have excluded hardware. We explained our concern in the proposed rule that donations of valuable multiuse hardware could pose a risk of program or patient abuse (84 FR 55832).

In the proposed rule, we also considered two alternative proposals that would allow for the donation of certain cybersecurity hardware (84 FR 55831 through 55832). Under the first alternative proposal, the cybersecurity exception would cover certain hardware that is necessary for cybersecurity, provided that the hardware is stand-alone (that is, is not integrated within multifunctional equipment) and serves only cybersecurity purposes (for example, a two-factor authentication dongle). We solicited comments on what types of hardware might meet these criteria and whether such hardware should fall within the scope of the exception. Under the second alternative proposal, parties would be permitted to make more robust donations of cybersecurity hardware if the donor had a cybersecurity risk assessment that identifies the

[28] Appendix B, Version 1.1 (April 16, 2018) *available at* https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.

recipient as a risk to its cybersecurity, and the recipient had a cybersecurity risk assessment that provided a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a risk assessment (84 FR 55834).

We noted in the proposed rule and reiterate here that the exception at §411.357(bb), both as proposed and finalized, covers only items and services that qualify as cybersecurity technology and services (84 FR 55832). It does not extend to other types of cybersecurity measures outside of technology or services. For example, the exception does not apply to donations of installation, improvement, or repair of infrastructure related to physical safeguards, even if they could improve cybersecurity (for example, upgraded wiring or installing high security doors). Donations of infrastructure upgrades are extremely valuable and have multiple benefits in addition to cybersecurity, and, thus, permitting an entity to provide such services at no cost to the physician recipient would present a risk of program or patient abuse.

As explained in more detail below, in response to comments we are finalizing the definition of "cybersecurity" as proposed, and finalizing the definition of "technology" without the phrase "other than hardware."

We received the following comments and our responses follow.

Comment: Several commenters agreed with the proposed industry-neutral definition of "cybersecurity," derived from the NIST Cybersecurity Framework (NIST CSF), and most commenters generally agreed that the final rule should include a broad definition of "cybersecurity" to provide sufficient flexibility for future changes, adaptations, and variations in the dynamic world of cybersecurity. One commenter was generally supportive of the proposed definition of "cybersecurity" but believed it should include the process of protecting information through "identifying" and "recovering" from cyberattacks in order to account for the entire lifecycle of a cyberattack. The commenter presumed that the addition of "recovering" would protect "back-up services" that support reestablishing cybersecurity and reduce the impact of ransomware extortion. Another commenter supported the definition of "cybersecurity" for being

fairly broad and including donations of APIs, but requested that we modify the definition to account for what the commenter identified as the three pillars of information security: confidentiality of information, integrity of information, and availability of information.

Response: We agree with the commenters that we should adopt a broad, industry-neutral definition of "cybersecurity." Consequently, we are finalizing a definition derived from the NIST CSF. The NIST CSF is industry-neutral and widely accepted across public and private sectors and international organizations, and it applies to any critical infrastructure in the United States, which includes health care. It provides a commonly understood language for donors and recipients seeking to use the cybersecurity exception to improve their cybersecurity posture. We are not adopting a definition of "cybersecurity" that would incorporate specific technology solutions for cyberattacks. We are concerned that, as new cybersecurity technologies are developed and implemented, a definition that incorporates specific technology solutions for cyberattacks could become obsolete. We believe that the final definition of "cybersecurity" at §411.351 provides sufficient flexibility while also permitting parties a clear understanding of the technology to which the exception is applicable. Although the cybersecurity exception does not require compliance with the NIST CSF, we encourage potential donors and recipients to ensure a comprehensive, systematic approach to identifying, assessing, and managing cybersecurity risks.

We decline to add the terms "identifying" and "recovering" to the definition of "cybersecurity," as suggested by the commenter, and we noted that these terms also appear in the NIST CSF. The NIST CSF organizes basic "cybersecurity activities" into five functions: identify, protect, detect, respond, and recover. The exception at final §411.357(bb) applies to donations of cybersecurity technology and services that are necessary and used predominantly for one or more of these five functions and the related subfunctions and cybersecurity outcomes that are part of the NIST CSF. We are not persuaded to adopt a more specific definition of cybersecurity by incorporating additional terminology from the NIST CSF and are finalizing the definition of "cybersecurity" at §411.351 as proposed. With respect to recovering from

cyberattacks in particular, we stress that, although the cybersecurity exception applies to donations of nonmonetary remuneration consisting of technology and services that are necessary and used predominantly for reestablishing cybersecurity, "reestablishing" cybersecurity does not include payment by an entity of any ransom on behalf of a physician recipient in response to a cyberattack (or to reimburse a physician for a ransom paid by the physician). Moreover, the payment or reimbursement of a ransom would not be nonmonetary remuneration.

We also decline to modify the definition of "cybersecurity" to expressly include the three pillars of information security, as requested by the last commenter. We agree that the concepts described by the commenter as the "three pillars" of confidentiality, integrity, and availability of information are fundamental aspects of cybersecurity. The NIST CSF similarly recognizes these concepts; an outcome category under the "protect" function of cybersecurity includes management of data "consistent with the organization's risk strategy to protect the confidentiality, integrity, and availability of information." Therefore, the final definition of "cybersecurity" at §411.351, which includes "the process of protecting information," accounts for these principles while also providing flexibility and certainty to donors as to the scope of the cybersecurity exception.

Comment: One commenter stated that the proposed definition of "cybersecurity" seems oversimplified and not comprehensive. The commenter suggested that the definition of "cybersecurity" should be inclusive of any unauthorized use, even without deliberate criminal activity or a specific cyberattack, and recommended broadening the definition accordingly. A different commenter maintained that the proposed definition of "cybersecurity" fails to capture all aspects of security controls relevant to patient information, systems processing, or retention of patient information. The commenter recommended that we define "cybersecurity" to mean: (1) the prevention of damage to, protection of, and restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication, including information contained therein, to ensure its availability,

integrity, authentication, confidentiality, and nonrepudiation; (2) the prevention of damage to, unauthorized use of, exploitation of, and—if needed—the restoration of electronic information and communications systems, and the information they contain, in order to strengthen the confidentiality, integrity and availability of these systems; or (3) the process of protecting information by preventing, detecting, and responding to attacks.

Response: We decline to modify the definition of "cybersecurity" as suggested by the first commenter. We disagree with the commenter's characterization of the definition, and do not believe that the final definition of "cybersecurity" at §411.351 has the effect of limiting donations of cybersecurity technology and services to only those that prevent criminal misconduct. The definition of "cybersecurity" adopted in this final rule is unrelated to the intent—criminal or otherwise—of an "unauthorized user." We believe that the definition adopted in this final rule is broad enough to address the commenter's concerns about unauthorized users.

We are also not adopting the definition suggested by the second commenter. The principles underlying the commenter's definition, which the commenter stated are derived from NIST and other Federal government sources, are already generally included in the definition of "cybersecurity." Moreover, we are concerned that some of the language suggested by the commenter would greatly expand the scope of the cybersecurity exception and the donation of such technology and services could pose a risk of program or patient abuse. For example, "restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication," could be lead parties to mistakenly believe that the cybersecurity exception applies to donations of technology and services that are not necessary and used predominantly to implement, maintain, or reestablish cybersecurity, such as donations of entire communication systems.

Comment: Most commenters that commented on the proposed definition of "technology" generally agreed with using the NIST CSF as a basis for the definition. However,

many of these commenters requested that we permit donations of certain cybersecurity hardware under the exception and delete the phrase "other than hardware" in the proposed definition of "technology." In support, some commenters asserted that the lines between hardware, software, services, and other technology that is neither hardware, software, nor a service, are increasingly blurred, and noted that such technologies are often packaged together as a bundle. Other commenters suggested that hardware donations are a foundational requirement to operationalize cybersecurity best practices. These commenters asserted that including hardware within the definition of "technology" would allow for more aggressive data security and excluding hardware from the definition is shortsighted and could limit the use of effective cybersecurity measures. A few commenters highlighted that certain cybersecurity software requires specific hardware and requested that we expand the scope of the exception to cover donations of such hardware. For example, a commenter noted that firewalls involve the use of both hardware and software, and suggested that many clinicians would not have the technical knowledge to configure the firewalls. This commenter recommended that we permit the donation of low-cost hardware, potentially up to a dollar threshold that could not be exceeded for the total donation.

Other commenters that supported permitting the donation of hardware under the cybersecurity exception asserted that failing to extend the application of the exception to donations of multifunctional cybersecurity hardware (or software) would limit the utility of the exception because cybersecurity technology often is not standalone in nature. Some of these commenters provided examples of multifunctional hardware they deemed beneficial to cybersecurity hygiene, such as encrypted servers, encrypted drives, network appliances, locks on server closet doors, upgraded wiring, physical security systems, fire retardant or warning technology, and high security doors. Some of these commenters stated that any program integrity concerns with hardware donations are adequately addressed by the requirement that donated technology and services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. In contrast, a few commenters generally supported our

proposal to exclude hardware from the definition of technology, citing program integrity concerns.

Response: We are modifying the definition of "technology" to remove the phrase "other than hardware." Thus, the cybersecurity exception at final §411.357(bb) is applicable to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. We agree with the commenters that our program integrity concerns regarding donations of valuable multifunctional hardware are adequately addressed by making the exception available only to donated technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity, and we do not believe that a monetary cap is necessary. As explained in section II.E.2.a. above, donated technology, including hardware, may include other functionality or uses besides cybersecurity. However, the cybersecurity use must predominate and the core functionality of the hardware must be implementing, maintaining, or reestablishing cybersecurity. The hardware must also be necessary for cybersecurity.

Certain of the examples offered by commenters, including locks on doors, upgraded wiring, physical security systems, fire retardant or warning technology, and high security doors do not qualify as "technology" under §411.357(bb)(2) because they are physical infrastructure improvements, not software or other information technology. Therefore, the cybersecurity exception is not applicable to these items. The cybersecurity exception is applicable to hardware such as encrypted servers, encrypted drives, and network appliances, but only if the hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. If, for example, an encrypted server is used predominantly to host the computer infrastructure of a recipient, it would not satisfy the necessary and used predominantly requirement of §411.357(bb)(1), even if the encrypted server has ancillary cybersecurity uses and functionality.

Comment: A number of commenters suggested that CMS expand the proposed cybersecurity exception to apply to single-function hardware technologies that have limited or no

functionality outside of cybersecurity, such as computer privacy screens, two-factor authentication dongles and security tokens, facial recognition cameras for secure access, biometric authentication, secure identification card and device readers, intrusion detection systems, data backup systems, and data recovery systems. One commenter asserted that the sole purpose of most cybersecurity hardware is to maintain the security of patient data.

Response: The final definition of "technology" does not preclude hardware and should address the commenters' concerns. We agree that certain hardware is limited to cybersecurity uses. Provided that all the requirements of the exception are satisfied, including the requirement that the donated hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity, the exception at §411.357(bb) will permit the donation of single-use or standalone cybersecurity hardware, including the types described by the commenters.

Comment: We received several comments on our alternative proposal to permit more robust donations of cybersecurity hardware, provided that both the donor and the recipient obtain risk assessments which provide a reasonable basis to determine that the donated cybersecurity hardware is necessary. A number of commenters generally favored the proposal. Some of these commenters asserted that, because the donation is based on the results or recommendations of a risk assessment, there should be no cap or limit on the type or amount of hardware that may be donated and no requirement that a recipient contribute to the cost of donated hardware. Other commenters favored allowing robust donations of cybersecurity hardware, but opposed the requirement in the alternative proposal that both the donor and the recipient first obtain a risk assessment supporting the donation. One commenter stated that the alternative proposal could pose a risk of program abuse, while a different commenter found the alternative proposal to be too limiting, and suggested that hardware donations be permitted if the hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

Response: We are not adopting a policy that permits the donation of cybersecurity hardware only when the donor has a cybersecurity risk assessment that identifies the recipient as

a risk to its cybersecurity, and the recipient has a cybersecurity risk assessment that provides a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a risk assessment. We believe that our expansion of the definition of "technology" to include hardware, coupled with the requirement that any donated hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity, provides sufficient flexibility for cybersecurity hardware donations while protecting against program or patient abuse. Although we are not finalizing this alternative proposal, parties remain free, and are encouraged, to perform risk assessments to determine donor and recipient vulnerability to cyberattacks and to assist in creating their own cybersecurity programs.

Comment: One commenter explained that, typically, entities do not purchase the actual software that provides cybersecurity. Rather, entities purchase the right to use the software, which is accomplished through licensing, and donate a license to use the software to recipients. In these circumstances, the software itself is not donated. The commenter also recommended that we include installment and repairs among the types of technology and services that may be donated under the exception.

Response: We recognize that, in some instances, entities purchase the right to use cybersecurity software, which is accomplished through licensing, and donate that use or license rather than the software itself. The donation of a license to use cybersecurity software may be permissible under the final exception at §411.357(bb) in the same way that donating software would be permissible, if all the requirements of the exception are satisfied. We agree with the commenter that installment and repairs should be included among the technology and services to which the cybersecurity exception is applicable, and the final cybersecurity exception is applicable to such services.

c. Requirement for Donors (§411.357(bb)(1)(i))[29]

In the proposed rule, we proposed a requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties (84 FR 55833). It is our understanding that the purpose of donating cybersecurity technology and related services is to guard against threats that come from interconnected systems, and we expect that a donor would provide the cybersecurity technology and related services only to physicians that connect to its systems, which includes physicians that refer to the donor. However, this requirement would prohibit the donor from directly taking into account the volume or value of a physician's referrals or the other business generated by the physician when determining: (1) whether to make a donation of cybersecurity technology or services; or (2) how much or the nature of the donated technology or services. We are including this requirement as proposed; however, it is designated in the final regulation at §411.357(bb)(1)(i).

Nothing in the requirements of the final cybersecurity exception is intended to require a donor to donate cybersecurity technology and related services to every physician that connects to its system. Donors are permitted to select recipients in a variety of ways, provided that neither a physician's eligibility, nor the amount or nature of the cybersecurity technology or related services donated, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For example, a donor could perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation or the scope of a donation. If the donor is a hospital, it might choose to limit donations to physicians on the

[29] In the proposed rule, the requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties was designated as §411.357(bb)(1)(ii). However, this requirement is designated as §411.357(bb)(1)(i) in this final rule.

hospital's medical staff. Or, the donor might select recipients based on the type of actual or proposed interface between them. For example, an entity may elect to provide a higher level of cybersecurity technology and services to a physician with whom it has a higher-risk, bi-directional read-write connection than the entity would provide to a physician with whom it has a read-only connection to a properly implemented, standards-based API that enables only the secure transmission of a copy of the patient's record to the physician.

As discussed in the proposed rule, in contrast to the similar requirement in the EHR exception at §411.357(w)(6), the cybersecurity exception does not include a list of selection criteria which, if met, would be deemed not to directly take into account the volume or value of referrals or other business generated by the physician (84 FR 55833). We solicited comments on whether we should include deeming provisions in the exception for cybersecurity donations that are similar to the provisions at §411.357(w)(6), and any other requirements or permitted conduct that we should enumerate in the cybersecurity exception (84 FR 55833). As explained below, we are not adopting deeming provisions for determining compliance with final §411.357(bb)(1)(i).

We did not propose to restrict the types of entities that may make cybersecurity donations under the cybersecurity exception (84 FR 55833). Although receiving donated cybersecurity technology and related services would relieve a physician of a cost that he or she otherwise would incur, the program integrity risks associated with arrangements for the donation of technology and related services intended to promote cybersecurity are different than those associated with arrangements for the donation of other valuable technology, such as EHR items and services. However, we solicited comments on whether we should narrow the scope of entities that may provide remuneration under the cybersecurity exception as we have done in other exceptions, such as the EHR exception. As explained in section II.E.2.e. below, we are not limiting the types of entities that are permitted to make donations under final §411.357(bb).

Based on the comments, we are finalizing the requirement that neither the eligibility of a

physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties, although it is designated in the final exception at §411.357(bb)(1)(i). Final §411.357(bb)(1)(i) is identical to proposed §411.357(bb)(1)(ii). As noted above and explained more fully below in response to comments, we are not adopting deeming provisions that would allow parties to demonstrate compliance with final §411.357(bb)(1)(i), and we are not restricting the types of entities that may make donations under the final cybersecurity exception at §411.357(bb).

We received the following comment and our response follows.

Comment: Commenters generally supported the requirement at final §411.357(bb)(1)(i) that neither the eligibility of a physician for cybersecurity technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. However, a number of these commenters opposed our proposal to establish a deeming provision, similar to the deeming provision in the EHR exception at §411.357(w)(6), under which certain selection criteria would be deemed to satisfy the requirement at final §411.357(bb)(1)(i). One commenter maintained that it would create a risk of program or patient abuse to permit a donor to choose recipients who will receive donations of cybersecurity through a deeming provision. In contrast, other commenters supported the establishment of a deeming provision to provide clarity and guidance with respect to how parties may determine the eligibility of a physician recipient for cybersecurity technology or services, or the nature and amount of such services, without violating the physician self-referral law.

Response: We are finalizing the requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties, but are not including a list of selection criteria that, if utilized,

would be deemed not to directly take into account the volume or value of referrals or other business generated between the parties. As we explained in the proposed rule, deeming provisions for selection criteria that pertain to a prohibition on taking into account the volume or value of referrals or other business generated between parties are sometimes interpreted as prescriptive requirements, especially in the context of a new exception that applies to emerging and rapidly evolving arrangements such as the cybersecurity exception (84 FR 55833). In this context, we are concerned that a deeming provision may cause the parties to an arrangement to forgo legitimate and acceptable selection criteria, thus limiting the scope and utility of the cybersecurity exception. Because we do not want to inhibit appropriate cybersecurity donations that are made using selection criteria that are not expressly deemed to be permissible under the cybersecurity exception, we are not finalizing any deeming provisions pertaining to the requirement at final §411.357(bb)(1)(i).

d. Requirement for Recipients (§411.357(bb)(1)(ii))[30]

In the proposed rule, we proposed to include in the cybersecurity exception a requirement that neither the physician, nor the physician's practice (including employees or staff members), makes the receipt of cybersecurity technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor (84 FR 55833). This requirement mirrors a requirement in the EHR exception at §411.357(w)(5). At final §411.357(bb)(1)(ii), we are finalizing the requirement as proposed.

We did not propose and, thus, are not including in the final cybersecurity exception a requirement that the physician recipient of cybersecurity technology or services must contribute to the cost of the technology or services. As explained earlier in this section II.E.2., with this exception, we seek to remove a barrier to donations that improve cybersecurity throughout the

[30] In the proposed rule, the requirement that neither the physician, nor the physician's practice (including employees or staff members), makes the receipt of cybersecurity technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor was designated at §411.357(bb)(1)(iii). However, this requirement is designated as §411.357(bb)(1)(ii) in this final rule.

health care industry in response to the critical cybersecurity issues identified in the HCIC Task Force Report, by commenters to the CMS RFI and OIG request for information, and elsewhere. We proposed to include only those requirements under the exception that we believe are necessary to ensure that the arrangements do not pose a risk of program or patient abuse. In the case of cybersecurity technology and related services, we do not believe that requiring a minimum contribution to the cost by the recipient is necessary or, in some cases, practical. We recognize that the level of services for each recipient might vary, and might be higher or lower each year, each month, or even each week, resulting in the inability of certain physician practices, especially solo practitioners or physician practices in rural areas, to make the required contribution, which, in turn, risks the overall cybersecurity of the health care ecosystem of which the practices are a part. Similarly, donors may aggregate the cost of certain services across all recipients, such as cybersecurity patches and updates, on a regular basis, which may result in a contribution requirement becoming a barrier to widespread, low-cost improvements in cybersecurity because of the amount allocated to each recipient. Moreover, if physicians are not required to utilize resources to contribute to the cost of cybersecurity that benefits both the donor and the physician, they will instead have the flexibility to contribute to the overall cybersecurity of the health care ecosystem by using available resources for otherwise unprotected cybersecurity-related hardware that is core to their business, including updates or replacements for outdated legacy hardware that may pose a cybersecurity risk.

Importantly, although the final cybersecurity exception does not require a recipient to contribute to the cost of donated cybersecurity technology or related services, donors are free to structure donation arrangements under §411.357(bb) to require that recipients contribute to the cost of cybersecurity technology and related services. However, if a donor gave a full suite of cybersecurity technology and related services at no cost to a high-referring practice but required a low-referring practice to contribute 20 percent of the cost, then the donation could violate the requirement at §411.357(bb)(1)(i).

Based on the comments, we are finalizing the requirement that neither the physician, nor the physician's practice (including employees or staff members), makes the receipt of cybersecurity technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor as proposed.

We received the following comments and our responses follow.

Comment: Several commenters supported the proposed requirement that neither the physician who receives the cybersecurity technology nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor. One of these commenters requested that CMS align its provision on conditioning business on the receipt of cybersecurity technology or services with OIG's safe harbor condition at proposed 42 CFR 1001.952(jj)(3), while another commenter requested that the requirement in the cybersecurity exception mirror the similar requirement in the EHR exception at §411.357(w)(5).

Response: As proposed and finalized, the prohibition on making the receipt of cybersecurity technology or services a condition of doing business with the donor at final §411.357(bb)(1)(ii) is substantively identical to the OIG's safe harbor condition at proposed 42 CFR 1001.952(jj)(3) and the similar requirement in the EHR exception at §411.357(w)(5). Variation in the wording of the regulations reflect differences in the underlying statutes, with respect to the anti-kickback safe harbor, and differences in the application of the EHR and cybersecurity exceptions, with respect to the similar provision in the EHR exception at §411.357(w)(5).

Comment: Many commenters agreed that we should not require a recipient of cybersecurity technology and services to contribute to the overall cost of the technology and services. Commenters variously asserted that a contribution requirement in the context of cybersecurity may act as a barrier to donations of technology and services because calculations of the cost of technology and services may be imprecise, it may be administratively burdensome

to calculate or track contributions, and contributing to the cost of cybersecurity technology and services may be impossible for some physician recipients. In contrast, several commenters supported a contribution requirement, although one of these commenters suggested that a contribution requirement less than what is required under the EHR exception would be appropriate because, according to the commenter, a 15 percent contribution toward cybersecurity technology and services may be too high for some physicians. A few commenters that supported a contribution requirement suggested that small and rural providers, those in medically underserved areas, and federally qualified health centers should be exempt from any such requirement. A few other commenters suggested that entities should have the choice whether to require a contribution from recipients, with one of these commenters supporting a prohibition on determining the amount of the contribution from the physician recipient in any manner that takes into account the volume or value of the physician's referrals or the other business generated by the physician.

Response: We did not propose and, thus, are not including a contribution requirement in the final cybersecurity exception at §411.357(bb). For the reasons stated in the proposed rule (84 FR 55833 through 55834), as well as those identified by commenters, we do not believe that it is necessary or advisable to require the physician recipient of cybersecurity technology or services to contribute to the cost of the technology or services. The exception, as finalized, includes sufficient safeguards against program or patient abuse, and it is not necessary to include a contribution requirement that might undermine our goal of facilitating improvement and maintenance of the cybersecurity of the health care ecosystem. As we stated in the proposed rule (84 FR 55834), donors are free to require recipients to contribute to the costs of donated cybersecurity technology and services; however, we caution that the determination of the amount of the required contribution may not take into account the volume or value of the physician recipient's referrals or other business generated between the parties.

e. Written Documentation (§411.357(bb)(1)(iii))[31]

We proposed to require that the arrangement for the provision of cybersecurity technology and related services is documented in writing (84 FR 55834). We stated that, although we would not interpret this requirement to mean that every item of cybersecurity technology and every potential related cybersecurity service must be specified in the documentation evidencing the arrangement, we expect that the written documentation evidencing the arrangement identifies the recipient of the donation and includes the following: a general description of the cybersecurity technology and related services provided to the recipient over the course of the arrangement, the timeframe of donations made under the arrangement, a reasonable estimate of the value of the donation(s), and, if applicable, the recipient's financial responsibility for some (or all) of the cost of the cybersecurity technology and related services that are provided by the donor (84 FR 55834). We did not propose and, thus, we are not including a requirement in the final cybersecurity exception at §411.357(bb) that the parties sign the documentation that evidences the arrangement or that the parties document their arrangement in a formal signed contract, because we believe that this requirement may lead to inadvertent violation of the physician self-referral law, especially in situations where donors need to act quickly and decisively—prior to obtaining the signature of each physician who is considered a party to the arrangement—to provide needed cybersecurity technology or related services to physician recipients. In the proposed rule (84 FR 55834), we solicited comments on whether we should specify in regulation which terms are required to be in writing. We also sought comment regarding whether we should include a signature requirement in the cybersecurity exception.

Based on the comments, we are finalizing the writing requirement as proposed. It is designated at final §411.357(bb)(1)(iii). We are not including regulatory text that specifies which terms of the arrangement must be in writing. Rather, we believe that the appropriate

[31] In the proposed rule, the requirement that the arrangement is documented in writing was designated at §411.357(bb)(1)(iv). However, this requirement is designated as §411.357(bb)(1)(iii) in this final rule.

standard, as described in the CY 2016 PFS, is that the writing requirement of the exception is satisfied if contemporaneous documents would permit a reasonable person to verify compliance with the exception at the time that a referral is made (80 FR 71315).

We received the following comments and our responses follow.

Comment: Most commenters supported a writing requirement that provides parties with flexibility in compiling the documentation necessary to satisfy the requirement. However, a few commenters supported the inclusion of a requirement to document the arrangement in a formal written agreement, noting that this would provide transparency with respect to the cybersecurity donation process, especially in the case of hardware donations. Another commenter opined that requiring a formal written agreement between the donor and the recipient would be a reasonable safeguard, as long as the requirements for the written agreement are limited in scope. The commenter asked CMS to require documentation only of the technology or services to be donated, commercial terms as necessary to satisfy the requirements of the cybersecurity exception, and warranties by both parties to use the technology in compliance with applicable laws and regulations. The commenter also suggested that, if CMS requires a formal written agreement between the parties, to facilitate compliance, CMS should make available on the CMS website a template agreement with standard terms. In contrast, one commenter requested that CMS not impose "burdensome" writing requirements on the parties. The commenter asserted that, although donors have a vested interest in more robust documentation, for example, requiring recipients to acknowledge applicable security rules, CMS should not mandate the documentation of specific information in order for parties to avail themselves of the cybersecurity exception.

Response: We believe that the writing requirement at final §411.357(bb)(1)(iii) is reasonable in scope, and provides for adequate transparency to protect against program or patient abuse without imposing undue burden. In the proposed rule (84 FR 55834), we stated that written documentation of the arrangement should include a general description of the

cybersecurity technology and related services provided to the recipient over the course of the arrangement, the timeframe of donations made under the arrangement, a reasonable estimate of the value of the donation(s), and, if applicable, the recipient's financial responsibility for some (or all) of the cost of the cybersecurity technology and related services that are provided by the donor (84 FR 55834). We are not persuaded to specify which terms of a cybersecurity donation arrangement must be in writing, and we decline to provide a template cybersecurity donation agreement or standard cybersecurity donation terms, as suggested by the commenter. We remind stakeholders that the relevant inquiry for determining compliance with the writing requirement at final §411.357(bb)(iii) is whether contemporaneous documents pertaining to the arrangement would permit a reasonable person to verify compliance with the cybersecurity exception at the time that a referral is made (80 FR 71315). We believe that providing parties with the flexibility to document their arrangements in any manner that meets this standard is preferable to detailed mandates that could result in noncompliance with the physician self-referral law due to even a slight departure from the documentation requirement. Of course, parties are free to include additional terms in a written agreement related to a cybersecurity donation beyond those required under the exception at §411.357(bb).

Comment: One commenter requested that CMS address the differences between the documentation and signature requirements in the cybersecurity exception and OIG's cybersecurity safe harbor. The commenter highlighted that the writing requirement in the exception requires that the arrangement is documented in writing but does not require a formal written agreement that is signed by the parties, whereas the corresponding requirement in the OIG's proposed cybersecurity safe harbor requires that the arrangement is set forth in a written agreement that is signed by the parties and describes the technology and services being provided and the amount of the recipient's contribution, if any (84 FR 55765). Another commenter suggested that a signed agreement should be a necessary requirement of the exception, as it would ensure that both the donor and recipient understand what is being donated and the terms of

the donation. A different commenter asserted that it is rare that the need for cybersecurity is so pressing that there is not time for parties to prepare and sign an agreement, and supported the inclusion of a signature requirement in the cybersecurity exception.

Response: We are not persuaded to add a requirement that the arrangement is set forth in a single written agreement that is signed by the parties. Although it is a best practice to reduce the key terms of an arrangement to a writing that is signed by the parties, we are concerned that a signature requirement, in particular, could delay an entity's ability to provide necessary and beneficial cybersecurity technology and services to a physician. The physician self-referral law is a strict liability statute, which requires all the requirements of an exception to be satisfied at the time a referral is made. The failure to fully satisfy even a single requirement of an exception triggers the physician self-referral law's referral and billing prohibitions where a financial relationship exists between a physician and an entity that furnishes designated health services. We are concerned that a detailed writing requirement or a signature requirement may result in inadvertent violations. We believe that our current standard for written documentation, which requires contemporaneous documents that would permit a reasonable person to verify compliance with the exception at the time a referral is made, provides sufficient transparency and facilitates compliance (80 FR 71315). For the same reasons, we are not persuaded to include a signature requirement in the cybersecurity exception.

e. Miscellaneous comments

In addition to the comments discussed above, we received several comments unrelated to our specific proposals and our responses follow.

Comment: One commenter generally supported the proposed cybersecurity exception, but suggested that CMS adopt the same prohibition on cost-shifting that was proposed in the cybersecurity safe harbor. The commenter stated that, although a hospital's own cybersecurity costs could be an administrative expense on its cost report, hospitals should not be permitted to include donations of cybersecurity technology or services to physicians as an administrative

expense on the hospital's cost report.

Response: We do not believe that a prohibition on cost-shifting is necessary in the cybersecurity exception. As explained above, we believe that cybersecurity donations are often self-protective in nature, and thus do not pose the same level of risk as donations of EHR items and services. There is no prohibition on cost-shifting in the EHR exception, and we do not believe that such a prohibition is necessary in the cybersecurity exception. We note also that Medicare payment rules and regulations that apply to claims for reimbursement address inappropriate cost-shifting by hospitals through other mechanisms. We believe that, as with the EHR exception, the requirements of the cybersecurity exception, coupled with other Medicare rules and regulations pertaining to cost reports, are sufficient to protect against abusive donations of cybersecurity technology and related services.

Comment: One commenter worried that cybersecurity donations could be used as a gift or financial incentive and maintained that cybersecurity donations should be based on risk assessments of the donor's own software, systems, or networks. In addition, the commenter suggested that cybersecurity donations should be made available to all recipients with similar risk assessments and without regard to business relationships or affiliations. For example, the commenter stated that a donation would be appropriate if the level of connectivity between the donor and recipient created a vulnerability that could be targeted and exploited by malicious actors.

Response: Although donors are permitted under the cybersecurity exception to perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation or the scope of a donation, we decline to require donors to base cybersecurity donations on a risk assessment of either the donor or the recipient. We believe that this requirement would be impractical, and it may lead potential donors to not make otherwise beneficial cybersecurity donations. We also believe it is impracticable that donors would make donations available to all similar recipients with similar

risk assessments, independent of the specific cybersecurity needs inherent in connecting to the specific systems with which the donor interacts.

Comment: Several organizations representing individuals and entities in the laboratory industry recommended excluding laboratories from utilizing the cybersecurity exception to provide cybersecurity technology and services to physicians. One commenter opined that the concerns CMS discussed in the 2013 EHR final rule regarding the provision of EHR items and services by laboratory companies similarly apply to cybersecurity donations by these entities. According to another commenter, during the period when laboratories were permitted to donate EHR items and services under the exception at §411.357(w), physicians implicitly or explicitly conditioned referrals on EHR donations, and EHR vendors encouraged physicians to request costlier EHR software and services from laboratories, putting laboratories in an untenable position. This commenter expressed concern that the same could happen with cybersecurity donations if laboratories are permitted to make donations under the cybersecurity exception, if finalized as proposed. The commenters stated that the proposed requirements of the exception, including both the requirements at §411.357(bb)(1)(i) and §411.357(bb)(1)(ii), would not be sufficient to curb the risk of program or patient abuse.

Response: Although we acknowledge the unique perspective and concerns of the commenters representing the laboratory industry, particularly in light of the laboratory industry's experience with the EHR exception, the final cybersecurity exception does not exclude any type of entity from utilizing the exception. All individuals and entities, including laboratories, play a role in protecting the health care ecosystem from cybersecurity threats. As described in section II.E.2.d., we are finalizing a requirement at §411.357(bb)(1)(ii) that prohibits a physician (and the physician's practice, including employees and staff members) from making the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor. This requirement is similar to the requirement in the EHR exception at §411.357(w)(5) and operates in the same manner. We believe that the requirements

of the final cybersecurity exception are sufficient to ensure against program or patient abuse. Therefore, we are not categorically excluding laboratory companies from the cybersecurity exception.

Comment: Several commenters requested that CMS permit cybersecurity donations to physicians from organizations that do not furnish designated health services, such as clinical data registries, manufacturers of medical products, and medical technology companies. The commenters stated that medical technology companies play a central role in the delivery of health care, and that such entities should be permitted to make donations that directly relate to the safe and effective use of the registry or the product the entity manufactures. Another commenter requested confirmation that donations made to physicians by organizations that do not furnish designated health services, such as technology firms, do not implicate the physician self-referral law, and that donations made by entities that do furnish designated health services to individuals other than physicians (or immediate family members of physicians) similarly do not implicate the physician self-referral law.

Response: The physician self-referral law's referral and billing prohibitions apply when there is a financial relationship between a physician (or an immediate family member of a physician) and an entity that furnishes designated health services. Financial relationships include direct compensation arrangements between an entity that furnishes designated health services and a physician (or an immediate family member of a physician), as well as indirect compensation arrangements between such parties. Indirect compensation arrangements exist where, among other things, between an entity furnishing designated health services and a physician (or an immediate family member of a physician) there is an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them. An organization that does not furnish designated services, such as a technology firm, or an individual who is not a physician may be a "link" in such an unbroken chain of financial relationships. If all the conditions of §411.354(c)(2), as revised in this final rule, exist, there

would be an indirect compensation arrangement that implicates the physician self-referral law. If an organization that does not furnish designated health services donates cybersecurity technology or services to a physician (or an immediate family member of a physician), but the donation does not result in an indirect compensation arrangement between that physician (or immediate family member) and an entity that does furnish designated health services, the donation does not implicate the physician self-referral law. However, the provision of such remuneration may implicate the anti-kickback statute. Similarly, donations by an entity that furnishes designated health services directly to a person or organization that is not a physician (or the immediate family member of a physician), such as a nonprofit organization or free or charitable clinic, would not create a direct compensation arrangement that implicates the physician self-referral law. However, if the recipient of the cybersecurity technology or services has a financial relationship with a physician, there would exist an unbroken chain of financial relationships that must be analyzed to determine whether there exists an indirect compensation arrangement that implicates the physician self-referral law.

F. Nonsubstantive Changes and Out-of-Scope Comments

1. Nonsubstantive Changes

We are making some nonsubstantive revisions to our regulation text for consistency with longstanding stated policy and to ensure conformity between the text of similar regulations (for example, changing "can" to "may" at §411.357(d)(1)(ii) for conformity between the exceptions for personal service arrangements and limited remuneration to a physician). We are also updating language to reflect the agency's current lexicon (for example, changing "through" to "under" in paragraph (2) of the definition of "designated health services" at §411.351). Finally, we made revisions to improve the grammar and clarity of certain regulations (for example, changing "not including any designated health services" to "does not include any designated health services" in the exception for assistance to compensate a nonphysician practitioner at §411.357(x)(4)(ii)).

From time to time, changes in the conventions for regulations published in the Code of Federal Regulations necessitate nonsubstantive revisions of existing regulations. In this final rule, we are providing the entire text of §§411.351 through 411.357 to aid the regulated industry with compliance efforts. Because of this, we are taking the opportunity to update or include new citations to chapters, section, and paragraphs that are referenced in certain of our regulations in these sections. For example, we included precise paragraph references in §411.357(t). In addition, we are including headers for certain paragraphs within our regulations, for example, §411.354(d)(1) through (6).

2. Out-of-Scope Comments

We received several comments that are outside the scope of this rulemaking, for example, comments requesting revisions to the exception for in-office ancillary services, suggesting policy changes related to physician-owned hospitals, and making recommendations for statutory changes to section 1877 of the Act. In addition, some of the commenters described their interpretations of various physician self-referral issues or asked questions about existing regulations that are not included in this rulemaking.

We appreciate these commenters taking the time to present these issues; however, these comments are beyond the scope of this rulemaking and are not addressed in this final rule. The out-of-scope issues raised by these commenters may be addressed in future rulemaking. We express no view on these issues, and our silence should not be viewed as an affirmation of any commenter's interpretations or views.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, the Paperwork

Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires that we solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Exceptions to the Physician Self-Referral Law Related to Compensation (§411.357)

We are finalizing new exceptions for compensation arrangements that facilitate value-based health care delivery and payment in a value-based enterprise (§411.357(aa)). A value-based enterprise is required to have a governing document that describes the enterprise and how its VBE participants intend to achieve the value-based purposes of that enterprise (*see* the definition of "value-based enterprise" at §411.351). The exception for value-based arrangements with meaningful downside financial risk to the physician at §411.357(aa)(2) requires a description of the nature and extent of the physician's downside financial risk to be set forth in writing. The exception for value-based arrangements at §411.357(aa)(3) requires the arrangement to be set forth in writing and signed by the parties. All exceptions at §411.357(aa) require records of the methodology for determining and the actual amount of remuneration paid under the arrangement to be maintained for a period of at least 6 years. We also added a new exception for cybersecurity technology and related services (§411.357(bb)), and arrangements under this new exception have to be documented in writing. Finally, we have streamlined the parties that must sign the writing in the exception for physician recruitment (§411.357(e)). The

burden associated with writing and signature requirements is the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements is the time and effort necessary to compile and store the records.

While the writing, signature, and record retention requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature and record retention requirements should be considered usual and customary business practices.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

IV. Regulatory Impact Statement (or Analysis) (RIA)

A. Statement of Need

This final rule aims to remove potential regulatory barriers to care coordination and value-based care created by the physician self-referral law. Currently, certain beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors may be impermissible under the physician self-referral law. Industry stakeholders have informed us that, because the consequences of noncompliance with the physician self-referral law are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce global health system efficiencies, and lower costs (or slow their rate of growth). This final rule addresses this issue by establishing three new

exceptions that protect certain arrangements for value-based activities between physicians and entities that furnish designated health services in a value-based enterprise. These exceptions provide enhanced flexibility for physicians and entities to innovate and work together while continuing to protect the integrity of the Medicare program.

Commenters on the CMS RFI told us that they currently invest sizeable resources to comply with the physician self-referral law's referral and billing prohibitions and avoid substantial penalties related to noncompliance with this and related laws, including the Federal False Claims Act. Commenters on the proposed rule echoed the significant cost burden of complying with the physician self-referral law. The proposals finalized in this final rule that do not directly address value-based arrangements seek to balance program integrity concerns against the stated considerable burden faced by the regulated industry. These finalized provisions reassess our regulations to ensure that they appropriately reflect the scope of the statute's reach, establish exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services, and provide guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral law. We believe that these reforms will significantly reduce compliance burden by providing additional flexibility to enable parties to enter into nonabusive arrangements and by making physician self-referral law compliance more straightforward.

B. Overall Impact

1. Executive Orders and the Regulatory Flexibility Act

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on

Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is considered to be economically significant. Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. 804(2).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. For purposes of the RFA, most hospitals and most other providers and suppliers are considered small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. We anticipate that a large portion of affected entities are small based on these standards. The specific affected entities are discussed later in this section. Individuals and states are not included in the definition of a "small entity." HHS considers a rule to have a significant impact on a substantial number of small entities if it has an impact of at least three percent of revenue on at least five percent of small entities. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

We determined that this final rule does not have a significant impact on small businesses because it will likely reduce, not increase, regulatory burden. This final rule will not require existing compliant financial relationships to be restructured. Instead, it will provide important new flexibilities to enable parties to create new arrangements that advance the transition to a

value-based health care system and remove regulatory barriers to certain beneficial and nonabusive arrangements, such as the donation of cybersecurity technology and services. It will also reduce burden by clarifying certain key provisions found in current regulations. Also, although we expect entities to incur costs, these costs are estimated to be less than $1,000 per entity. These costs are unlikely to have an impact of three percent of revenue, and we expect they will be offset by savings resulting from this rule. Overall, this final rule is accommodating to legitimate financial relationships while reducing regulatory burden and continuing to protect against program and patient abuse.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The impact of this rule on small rural hospitals is minimal. In fact, several provisions of the rule benefit small rural hospitals by giving them more flexibility to maintain operations and participate in innovative arrangements that enhance care coordination and advance the transition to a value-based health care system. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $156 million. This rule imposes no mandates on state, local, or tribal governments, or on the private sector, and reduces regulatory burden on health care providers and suppliers.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule is a deregulatory action.

2. Expected Outcomes and Benefits

a. Value-based Health Care Delivery and Payment

A 2019 study of 70 participants—including 62 health plans, seven Medicaid FFS states, and Traditional Medicare—accounting for nearly 226.5 million Americans, or 77 percent of the covered U.S. population, highlighted the continued move away from a FFS system that pays only on volume and towards value-based health care delivery and payment models.[32] The study showed that, in calendar year 2018, 39.1 percent of health care dollars were traditional FFS or other legacy payments not linked to quality, 25.1 percent of health care dollars were FFS payment linked to quality and value (described as pay-for-performance or care coordination fees), 30.7 percent of health care dollars were a composite of shared savings, shared risk, and bundled payments in alternative payment models built on a FFS architecture, and 5.1 percent of health care dollars were population-based payments (that is, capitation, global budget, or percent of premium payments).[33] Although the study showed that payors made the majority of 2018 payments on a FFS basis (or in models built on a FFS architecture), the 2018 payments represent a 4.6 percent decline in FFS

[32] APM Measurement: Progress of Alternative Payment Model; Health Care Payment Learning & Action Network, October 2019; *see* https://hcp-lan.org/apm-measurement-effort/ and http://hcp-lan.org/workproducts/apm-methodology-2019.pdf.
[33] *Id*.

payments not linked to quality from such payments in 2017 (from 41 percent in 2017 to 39.1 percent in 2018), and a 34.2 percent increase in population-based payments over such payments in 2017 (from 3.8 percent in 2017 to 5.1 percent in 2018).[34]

In sections I.B. and II.A.1. of this final rule, we described the current landscape of health care delivery and payment both within and outside the Medicare program. We explained that the application of the physician self-referral law to all financial relationships between entities and the physicians who refer to them (or the immediate family members of such physicians) has inhibited a more rapid advancement toward a health care system that pays for outcomes rather than procedures. Based on stakeholder responses to numerous CMS requests for information, including the CMS RFI that is part of the Department's Regulatory Sprint, we proposed regulatory revisions to address barriers to innovative care coordination and value-based health care delivery and payment (84 FR 55766). After considering the comments on the proposed rule, we are finalizing policies intended to facilitate the transition to value-based health care delivery and payment by permitting appropriate compensation arrangements that further the goals of a value-based system without posing a risk of program or patient abuse. Specifically, as described in section II.A. of this final rule, we designed and are finalizing new exceptions for value-based arrangements at final §411.357(aa)—with safeguards intended to: (1) protect against program or patient abuse that could lead to increased expenditures; and (2) maximize the potential of value-based care delivery and improved care coordination in reducing waste and program expenditures. The new exceptions are also applicable to those indirect compensation arrangements between an entity and a physician that involve a value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party.

Although existing exceptions utilized by parties to protect financial relationships that exist outside of value-based health care delivery and payment systems also include safeguards

[34] *Id*.

designed to protect against program or patient abuse, they do not promote the potential for improvements in quality and reductions in expenditures the way that that the new exceptions set forth in this final rule may. By making available the new exceptions for value-based arrangements established in this final rule, we expect to achieve significant progress in reducing program expenditures without sacrificing program integrity. However, we are unable to quantify with certainty the overall net costs, including net expenditures of the Medicare program, related to changes in industry behavior that we can reasonably expect following the effective date of this final rule. Even so, we believe that our final policies are reasonably likely to permit, if not encourage, behavior that will reduce waste in the U.S. health care system, including Medicare and other Federal health programs, and that these changes will result in lower costs for both patients and payors, and generate other benefits, such as improved quality of patient care and lower compliance costs for providers and suppliers.

(1) Expectation of Value-Based Arrangements

As discussed in section II.A. of this final rule, compensation arrangements that qualify as value-based arrangements may take a variety of forms. Those that implicate the physician self-referral law will be directly or indirectly between an entity that furnishes designated health services and a physician who refers to that entity (or the immediate family member of a physician who refers to that entity). Although some compensation arrangements that qualify as value-based arrangements may satisfy the requirements of a "traditional" exception to the physician self-referral law, most do not. These include arrangements that: (1) involve the provision of free or reduced cost items and services; (2) tie compensation to the ordering or furnishing of designated health services; (3) tie compensation to the refraining from ordering, delaying the order of, or furnishing designated health services; or (4) involve the sharing of profits or losses such that compensation does not directly relate to the items or services actually provided by a physician. Based on our experience administering the Shared Savings Program and Innovation Center models, information provided by commenters on the CMS RFI and the

proposed rule (including payors that supported the establishment of the exceptions at final §411.357(aa)), and information shared publicly by providers, suppliers, practitioners, health plans, and others, following the issuance of this final rule—and, specifically, once the exceptions at final §411.357(aa) for value-based arrangements are available—we reasonably expect parties to enter into arrangements such as the following:

- Providing staff and other resources to physicians at below fair market value to help with patient education, pre-admission evaluations, and post-procedure follow-up and monitoring.
- Shared savings and shared loss arrangements under which the entity and the physician share financial risk for achievement of the value-based purpose(s) of the value-based enterprise or the outcome measures against which the recipient of the remuneration is assessed.
- Arrangements that enhance patient care by providing items at no cost to physicians. We note that an important piece of ensuring good outcomes and fewer complications is patient education. Hospitals are often better-positioned or willing to develop video or print materials to prepare surgical patients for what to expect pre- and post-surgery, but are not in direct contact with patients until the day of surgery. Under the new exceptions, hospitals could provide those materials at no charge to physicians for use in their practices, benefiting both hospitals and physicians, as well as surgical patients.
- Providing free telehealth equipment to physicians for use while treating patients in their office locations. The technology could be utilized for consults with a donor hospital to avoid unnecessary ambulance transports, ER visits, and exposing the patient to greater risk when emergencies or complications occur in the physician office, or could be used by primary care physicians to obtain immediate input from specialists while a patient is present in the primary care physician's office.

- Provision of data analytics services. A specialty physician practice (or other entity) may wish to provide free data analytic services to a primary care physician practice with which it works closely. The data analytics could, for example, identify practice patterns that deviate from evidence-based protocols or determine whether follow-up care recommended by the specialty physician practice is being sought by patients. In turn, the identification of deviant practice patterns and when follow up care is recommended could lead to better, more effective care for patients and reduced costs to Federal health care programs.

We cannot, however, predict the form of all potential value-based arrangements or which entities and physicians will enter into value-based arrangements and what form their specific arrangements will take. More specifically, based on comments submitted by stakeholders, our understanding of currently existing value-based arrangements and care coordination arrangements, and our assumption that there will be continued innovation, we expect significant heterogeneity in the arrangements for which the new exceptions at final §411.357(aa) will be utilized.

(2) Potential Outcomes and Benefits of Value-Based Arrangements

As described above, we can reasonably predict that our final policies and the exceptions at final §411.357(aa) will result in changes in stakeholder behavior. Entities and physicians may increase their participation in beneficial nonabusive value-based arrangements, including care coordination arrangements, that implicate the physician self-referral law. In this regard, and with respect to the intended outcomes and benefits related to this final rule, we anticipate that the policies in this final rule may: (1) remove barriers to robust participation in value-based health care delivery and payment systems, including those administered by CMS and non-Federal payors; (2) facilitate arrangements for patient care coordination among affiliated and unaffiliated health care providers, practitioners, and suppliers; (3) provide certainty for participants in the Shared Savings Program that wish to establish compensation arrangements outside of the Shared

Savings Program similar to those among providers and suppliers in Shared Savings Program ACOs; and (4) provide certainty for participants in Innovation Center models that wish to continue compensation arrangements established while participating in an Innovation Center model following the model's conclusion or establish similar arrangements outside of the model. Associated benefits that we anticipate will arise from these intended outcomes are: (1) better care coordination for patients, including Medicare beneficiaries, resulting in the reduction in costs to payors and patients from poorly coordinated, duplicative care; (2) improved quality of care and outcomes for patients, including Medicare beneficiaries; (3) substantial reduction in compliance costs to providers and suppliers to which the physician self-referral law's prohibitions apply; and (4) reduction in administrative complexity and related waste from continued progress toward interoperability of data and electronic health records.

(3) Cost Impact of Value-Based Arrangements

A. General

As noted above, we are unable to quantify with certainty the overall net costs, including net expenditures of the Medicare program, related to the changes in industry behavior that we can reasonably expect following the effective date of this final rule. However, based on the studies and reported experiences of payors, providers, suppliers, and patients that we discuss in this section IV.B. of this final rule, we believe that value-based arrangements such as those described in section IV.B.2.a.(1). of this final rule have great potential to reduce waste in the U.S. health care system, lower costs for both patients and payors, and generate other benefits such as improved quality of patient care and lower compliance costs for providers and suppliers.

A recent review of literature from January 2012 to May 2019 focusing on unnecessary spending, or waste, in the U.S. health care system (2019 Waste in U.S. Health Care Study) indicates that waste related to the failure of care coordination alone results in annual costs of $27

billion to $78 billion.[35] Much of the research on waste and improvement reviewed in the 2019 Waste in U.S. Health Care Study was conducted in Medicare populations. The 2019 Waste in U.S. Health Care Study noted compelling empirical evidence that interventions, such as aligning payment models with value or supporting delivery reform to enhance care coordination, safety, and value, can produce meaningful savings and reduce waste by as much as half. The 2019 Waste in U.S. Health Care Study also identified waste from administrative complexity (resulting from fragmentation in the health care system) as the greatest contributor to waste in the U.S. health care system at an estimated $266 billion annually, and highlighted the opportunity to reduce waste in this category from enhanced payor collaboration with health care providers and clinicians in the form of value-based payment models. According to the 2019 Waste in U.S. Health Care Study, as value-based care continues to evolve, there is reason to believe that such interventions can be coordinated and scaled to produce better care at lower cost for all U.S. residents. Moreover, in value-based arrangements, improvements could reduce waste related to overtreatment and low-value care, a separate category of waste in the U.S. health care system. Other recently published peer-reviewed articles also suggest that value-based arrangements can reduce costs.[36]

A case study targeted at determining the specific factors that reduce Medicare payments and lead to hospital savings in bundled payment models for lower extremity joint replacement

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[35] William H. Shrank, MD, MSHS, et al., *Waste in the US Health Care System, Estimated Costs and Potential for Savings*, 322(15) Journal of the American Medical Association 1501 (2019), available at https://jamanetwork.com/journals/jama/fullarticle/2752664.

[36] Brian W. Powers, et al., *Impact of Complex Care Management on Spending and Utilization for High-Need, High-Cost Medicaid Patients*, American Journal of Managed Care, 26(2), e57-e63 (Feb. 2020), *available at* https://doi.org/10.37765/ajmc.2020.42402 (a study of a complex care management program implemented in Tennessee for high-need, high-cost Medicaid patients, which found that the program reduced total medical expenditures by 37 percent and inpatient utilization by 59 percent); and Shreya Kangovi, et al., *Evidence-Based Community Health Worker Program Addresses Unmet Social Needs and Generates Positive Return on Investment*, Health Affairs, 39(2), 207-13 (Feb. 2020), *available at* https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00981 (a study that found that every dollar invested in the Individualized Management for Patient-Centered Targets (IMPaCT) intervention, which is "a standardized community health worker intervention that addresses socioeconomic and behavioral barriers to health in low-income populations," yielded a return of $2.47 from the perspective of a Medicaid payer. This return was realized within a single fiscal year).

surgeries (which provide a lump sum payment to be shared among providers for an episode of care instead of payment for every service performed) in one Texas health system found that, between July 2008 and June 2015, the system's five hospitals were able to reduce total Medicare spending per episode of care by $5,577, or 20.8 percent, in cases without complications, and by $5,321, or 13.8 percent, in cases with complications.[37] The hospitals also recognized $6.1 million in internal cost savings, along with slight decreases in emergency room visits and readmission rates, and a decrease in cases with a prolonged length-of-stay admission. Over half of the internal cost savings were attributable to reduced implant costs.[38] We note that the product standardization incentive programs that contribute to such internal cost savings involve compensation arrangements between hospitals and physicians which, depending on their structure, may not satisfy the requirements of any current exceptions to the physician self-referral law, but to which the new exceptions for value-based arrangements apply. Relatedly, in 2018, a large health plan announced that it was expanding a bundled payment program for spinal surgeries and hip/knee replacements to new markets, after finding savings of $18,000 per procedure,[39] and a health network reported over $10 million in savings in 2017 with more anticipated savings in 2018.[40]

B. Medicare Expenditures

We cannot predict with certainty how many and which parties will avail themselves of the new and revised exceptions or the changes in provider and supplier behaviors that could result. Influence on provider and supplier behavior could either reduce or increase overall

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[37] Amol Navathe, et al., *Cost of Joint Replacement Using Bundled Payment Models, JAMA Intern Med.* 2017;177(2):214–222. doi:10.1001/jamainternmed.2016.8263, *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2594805.

[38] *See* Vera Gruessner, *3 Ways Bundled Payment Models Brought Hospital Cost Savings Down*, Health Payer Intelligence (Jan. 2017), *available at* https://healthpayerintelligence.com/news/3-ways-bundled-payment-models-brought-hospital-cost-savings.

[39] *See* David Muhlestein, et al., *Recent Progress in the Value Journey: Growth of ACOs and Value-Based Payment Models in 2018*, Health Affairs (Aug. 2018) *available at* https://www.healthaffairs.org/do/10.1377/hblog20180810.481968/full/.

[40] *See* Shane Wolverton, *Providers Partner with Payers for Bundled Payments*, Becker's Hospital Review (May 2018), *available at* https://www.beckershospitalreview.com/payer-issues/providers-partner-with-payers-for-bundled-payments.html.

program spending, although the literature described in this section IV.B.2. of this final rule indicates great potential for waste reduction and cost savings across the U.S. health care system, including the Medicare program. We note that any short-term increase in expenditures could result from appropriate utilization of services as patients seek and accept medically indicated care that they may have forgone in the absence of care coordination efforts and value-based arrangements for which exceptions were previously unavailable, and that appropriate utilization could prevent greater expenditures and other negative results to life over the longer term. Because of this uncertainty, we cannot quantify any impact on Medicare expenditures. We are confident that the regulations established or revised in this final rule include sufficient and appropriate safeguards to protect against program or patient abuse, including inappropriate utilization due to a physician's financial self-interest. We believe that our final policies fall squarely within the Secretary's authority under section 1877(b)(4) of the Act to establish exceptions for financial relationships that do not pose a risk of program or patient abuse and, therefore, anticipate no increased spending due to inappropriate utilization. We will continue to assess the impact of our final policies on program expenditures. As noted in more detail later in this RIA, our view of the beneficial anticipated effects that will result from the policies in this final rule remains largely unchanged from the proposed rule.

As noted above, we are not able to provide quantitative estimates of overall savings to or expenditures of the Medicare program that will result from this final rule. However, with respect to parties currently participating in the Shared Savings Program and Innovation Center models, we have determined that this final rule would not significantly alter the conditions upon which such providers and suppliers operate. Although we do not know which new value-based models or programs will be implemented in the future, such programs and models will be associated with an estimated impact *at the time they are implemented*. Thus, we have determined that the policies set forth in this final rule will have no impact with regard to Medicare expenditures under the Shared Savings Program and Innovation Center models.

C. Commercial Sector and other Federal Payors

A recent survey of over 100 commercial payors showed that, in 2018, "pure FFS" payment—where each medical service is billed and paid for separately—accounts for only 37.2 percent of commercial payor reimbursement, and is expected to drop to 26 percent by 2021.[41] According to the payors surveyed, payors that adopted value-based health care delivery and payment models reduced health care costs by an average of 5.6 percent, improved provider collaboration, and created more impactful member engagement. Although we cannot make any quantitative estimates regarding cost savings or expenditures that may result from this final rule, we are aware of the success of certain innovative value-based arrangements that resulted in cost savings for third-party payors, improvements in quality of care, or both. The reported success of some of these programs exemplifies the promising nature of value-based health care delivery and payment.

There are numerous reported examples of successful value-based health care delivery and payment programs developed and implemented by commercial health plans. For example, one health plan recently reported that it saved $1 billion through avoided costs in 3 years of its recent primary care pay-for-value program that offers primary care practices rewards for their performance on quality, cost, and utilization measures, while also improving outcomes for its members.[42] According to this health plan, members treated by a primary care provider in the program had 11 percent fewer emergency room visits in 2017 than members treated by a primary care physician not in the program. The health plan also stated that members with a primary care physician in the program experienced 16 percent fewer inpatient admissions in 2017 compared to members seeing a primary care physician not in the program, potentially saving the health plan $224 million in

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[41] *Finding the Value in Value-Based Care: The State of Value-Based Care in 2018*; a Signature Research Report commissioned by Change Healthcare (June 2018); *see also*, Thomas Beaton, *Value-Based Payment Adoption Drives 5.6% Reduction in Care Costs*, Health Payer Intelligence (June 2018) *available at* https://healthpayerintelligence.com/news/value-based-payment-adoption-drives-5.6-reduction-in-care-costs.

[42] *See* Press Release, Highmark, Inc., *Highmark saves more than $1 billion in avoided cost with True Performance program* (Oct. 5, 2020), *available at* https://www.highmark.com/newsroom/press-releases.html#!release/highmark-saves-more-than-1-billion-in-avoided-cost-with-true-performance-program.

inpatient care costs.[43]

A collaboration between a physician-led ACO and a health plan in North Carolina similarly reduced costs while improving quality of care.[44] Specifically, a June 2020 study concluded that the 47 primary care practices that participated in the collaboration: (1) reduced the total cost of care by 4.7 percent for commercial patients; (2) reduced the total cost of care by 6.1 percent for Medicare Advantage patients; and (3) improved their Medicare star ratings, on average, from 3 to 4.5 stars. Another study, in 2020, by a different health plan analyzed the plan's Medicare Advantage enrollees and network primary care physician practices. This health plan determined that primary care physicians paid under global capitation improved certain patient outcomes related to preventive care and chronic conditions, such as higher screening rates for colorectal and breast cancer, higher rates of medication review, and higher controlled blood sugar levels.[45]

There are also studies that suggest that improved care coordination may decrease costs and enhance health outcomes. One randomized, controlled trial evaluated the cost-effectiveness of a home-based care coordination program that targeted older adults with problems self-managing their chronic illnesses.[46] Study participants in the test group received care coordination services from a nurse. They also received a pill organizer. The results of this study showed that, for those beneficiaries who participated in the study for more than 3 months, total Medicare costs were $491 lower per month than in the control group. Another study conducted

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[43] *See* Press Release, Highmark, Inc., *Highmark's True Performance Program Avoided Health Care Costs by More Than $260 Million in 2017* (June 26, 2018), *available at* https://www.highmark.com/newsroom/press-releases.html#!release/highmarks-true-performance-program-avoided-health-care-costs-by-more-than-260-million-in-2017.

[44] *See* Press Release, Blue Cross and Blue Shield of North Carolina, *Primary Care ACOs from Blue Cross NC and Aledade Show Significant Savings and Quality Improvements* (July 20, 2020), *available at* https://mediacenter.bcbsnc.com/news/primary-care-acos-from-blue-cross-nc-and-aledade-show-significant-savings-and-quality-improvements.

[45] *See* Press Release, UnitedHealth Group, *Physicians Provide Higher Quality Care Under Set Monthly Payments Instead of Being Paid Per Service, UnitedHealth Group Study Shows* (Aug. 11, 2020), *available at* https://www.unitedhealthgroup.com/newsroom/2020/uhg-study-shows-higher-quality-care-under-set-monthly-payments-403552.html.

[46] Karen Dorman Marek et al., *Cost analysis of a home-based nurse care coordination program*, J. Am. Geriatr. Soc. 2014;62(12):2369-2376.

by the Centers for Disease Control demonstrated that certain interventions, such as team-based or coordinated care, increase patient medication adherence rates.[47] Specifically, in a 2015 study, patients assigned to team-based care—including pharmacist-led medication reconciliation and tailoring, pharmacist-led patient education, collaborative care between pharmacist and primary care provider or cardiologist, and two types of voice messaging—were significantly more adherent with their medication regimen 12 months after hospital discharge (89 percent) compared with patients not receiving team-based care (74 percent).

D. Conclusion

We believe that the experience of the payors and organizations described in this section IV.B.2. of this final rule highlight the potential for eliminating a significant amount of unnecessary expenditures (waste) in the U.S. health care system, including in the Medicare program. As noted earlier, the 2019 Waste in U.S. Health Care Study indicates annual costs of $27 billion to $78 billion from the failure of care coordination alone.[48] This study identified $266 billion in annual costs from administrative complexity in the furnishing of care and compliance with laws and regulations. We cannot predict with absolute certainty whether value-based arrangements that parties enter into as a result of our final policies will reduce these annual costs, but we believe that it is likely that innovative value-based arrangements and payment for value-based health care delivery will continue to achieve the results described above in this section IV.B.2. We are also unable to provide quantitative estimates of the impact on costs that such arrangements will have. However, we believe there is great potential for reducing the expense of waste in the U.S. health care system through improved care coordination and reduced administrative complexity.

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[47] Andrea B. Neiman, et al., *CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities*, 66 Weekly 45 (Nov. 17, 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm.

[48] William H. Shrank, MD, MSHS, et al., *Waste in the US Health Care System, Estimated Costs and Potential for Savings.*

b. Clarifying Revisions and New Exceptions for Nonabusive Financial Relationships

(1) Key Terminology, the Application and Scope of the Physician Self-Referral Law, and New Exception for Limited Remuneration to a Physician

A. Summary of the Final Regulations

In addition to the final regulations discussed in subsections 2.a. and 2.b.(2). of this section IV.B., this final rule revises numerous current regulations and establishes new regulations, including a new exception at final §411.357(z) for limited remuneration to a physician, intended to clarify the scope of the prohibitions of the physician self-referral law and simplify compliance with the exceptions to the law's referral and billing prohibitions. To this end, this final rule: (1) establishes a definition of the term "commercially reasonable" at §411.351; (2) establishes special rules at §411.354(d)(5) and (6) that identify the universe of compensation formulas that are considered to be determined in a manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician; (3) revises the definition of "fair market value" at §411.351; (4) clarifies CMS policy regarding the permissible methodologies for distributing profits from designated health services within a group practice; (5) clarifies CMS policy regarding compensation formulas that will be deemed not to directly take into account the referrals of a physician in a group practice; (6) recognizes the independent obligation to comply with the anti-kickback statute and governmental billing and claims submission rules by removing from most exceptions to the physician self-referral law the requirements that the financial relationship between the entity and the physician (or immediate family member of the physician) does not violate the anti-kickback statute and does not violate any Federal or state law or regulation governing billing or claims submission; (7) revises the definition of "designated health services" at §411.351 to, in effect, remove inpatient hospital services ordered after a patient's admission to the hospital when such services are ordered by a physician who is not the physician who made the referral for the inpatient admission; (8) revises the definition of "physician" at §411.351 to limit the physician referrals to which the law's prohibitions apply to only those physicians who qualify as a "physician" under section 1861(r) of

the Act; (9) revises the definition of "remuneration" at §411.351 to clarify that the provision of certain items, devices, and supplies from an entity to a referring physician does not establish a compensation arrangement when those items, devices, or supplies are, in fact, used solely by the physician for the purpose(s) established in the statute and regulation; (10) revises the definition of "transaction" and establishes a new definition of "isolated financial transaction" at §411.351 to clarify CMS policy regarding the types of compensation arrangements to which the exception at §411.357(f) is applicable; (11) alleviates confusion reported by stakeholders regarding the period of disallowance for referrals and billing following a violation of the physician self-referral law; (12) permits parties to reconcile payment discrepancies in compensation arrangements without running afoul of the physician self-referral law; (13) removes certain interests held by a physician from qualifying as an ownership or investment interest that implicates the physician self-referral law; (14) clarifies when compensation is considered to be "set in advance" for purposes of satisfying the requirements of the exceptions to the physician self-referral law; (15) revises CMS policy regarding modifications to the financial terms of a compensation arrangement to eliminate specific timeframe limitations for such modifications; (16) clarifies CMS policy regarding the circumstances under which an entity may direct a physician's referrals to a particular provider, practitioner, or supplier; (17) expressly prohibits an entity from conditioning the existence of a compensation arrangement or the amount of a physician's compensation on the number or value of the physician's referrals to a particular provider, practitioner, or supplier; (18) clarifies that required signatures may be electronic or in any other form that is valid under applicable Federal or state law; (19) allows parties 90 consecutive calendar days to obtain documentation necessary to satisfy the writing requirement of an applicable exception; (20) clarifies the requirement for exclusive use of office space or equipment under the exceptions at §411.357(a) and (b); (21) clarifies the circumstances under which a physician practice must sign the documentation of a recruitment arrangement between a hospital and a physician; (22) clarifies and expands the application of the exception at

§411.357(i) for payments by a physician (or immediate family member of a physician) to an entity; (23) expands the application of the exception at §411.357(l) to fair market value payments for the rental of office space, even where the duration of the arrangement is less than 1 year; (24) makes permanent the EHR exception; (25) clarifies the scope of the EHR exception to permit donations of cybersecurity software and services that are necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records; (26) allows for flexible scheduling of physician contribution payments for electronic health records items and services following the initial donation of such items and services; (27) permits donations of replacement electronic health records items and services, even if the physician already possesses equivalent items or services; (28) clarifies timing issues related to arrangements between a physician and NPP where the physician receives assistance from a hospital to compensate the NPP; (29) updates and eliminates out-of-date references to bolster clarity of the scope and application of the physician self-referral regulations; (30) establishes a new exception for limited remuneration to a physician that does not require contemporaneous documentation of the terms of the arrangement or that the compensation is set in advance of the provision of the physician's services; and (31) modifies other exceptions that apply to arrangements for the personal services of physicians to ensure applicability on a going-forward basis following the commencement of an arrangement that satisfies the requirements of the new exception for limited remuneration to a physician.

B. Expectation of Industry Behavior

Following the effective date of our final policies, we anticipate a reduction in disclosures to the SRDP of potential or actual violations of the physician self-referral law because stakeholders will have a clearer understanding of the scope and application of the physician self-referral law, as well as CMS' interpretation of the law's provisions. We anticipate that entities will continue to provide electronic health records items and services to physicians with the same scope and frequency as the industry has observed since the issuance of the EHR exception in 2006. We also anticipate that parties that made submissions to the SRDP that have not yet been

settled may withdraw all or portions of their disclosures, similar to what occurred following clarifications of physician self-referral policies in the CY 2016 PFS final rule. Although we expect that entities will utilize the new exception at §411.357(z) for limited remuneration to a physician, as explained in section II.E.1. of this final rule, we anticipate that the exception's greatest utility will come during retrospective review of compliance with the physician self-referral law. As we noted in section III.A. of this final rule, we believe that, for normal business operations purposes, entities document their financial arrangements with physicians and others in order to identify and be able to enforce the legal obligations of the parties. Thus, we believe that the exception will be utilized more often by parties that did not fully document an arrangement in writing or set compensation in advance than by parties that affirmatively choose not to document their arrangement in writing or set physician compensation in advance when developing a new arrangement for physician services. Finally, we anticipate that some physician practices will revise their compensation methodologies with respect to the distribution of profits from designated health services furnished by the group in order to ensure compliance with the clarifying regulations at §411.352(i) that become effective January 1, 2022 and continued qualification as a "group practice" under the regulations at §411.352.

C. Potential Outcomes, Benefits, and Costs of Final Policies Related to Key Terminology, the Application and Scope of the Physician Self-Referral Law, and New Exception for Limited Remuneration to a Physician

According to commenters, one of the most significant benefits of this final rule is the establishing of clear boundaries for parties in setting the financial terms of compensation arrangements that do not qualify as value-based arrangements. We are unable to quantify with certainty the impact of our clarifications, expanded flexibilities, and the new exception at final §411.357(z) on costs to the regulated industry; however, we believe that most entities that have financial relationships with physicians to which the physician self-referral law applies will see some level of reduced expenditures.

Many of the entities whose financial relationships with physicians are subject to the

requirements of the physician self-referral law are hospitals and physician groups. An October 2017 study of 190 hospitals in 31 states across the United States revealed that an average community hospital (defined as 161 beds) annually dedicates 2.3 full-time equivalent employees to, and spends almost $350,000 on, compliance with Federal fraud and abuse laws, defined in the study as including the physician self-referral law, the anti-kickback statute, and laws and protocols requiring returning overpayments.[49] This study affirms commenter statements included in a 2015 Senate Finance Committee report that noted the high cost and difficulty of complying with the physician self-referral law.[50] We expect that the clarifications and regulatory revisions of this final rule will significantly reduce the costs to the regulated industry. (See section IV.C. of this final rule for further discussion of this study and the anticipated effects of this final rule on the burden identified in the study.)

CMS publishes aggregate SRDP settlement data on its website at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements. To date, we have received over 1200 disclosures to the SRDP. As of December 31, 2019, we have settled 335 disclosures by collecting an aggregate of $31.8 million from disclosing parties. Although we cannot estimate the number of compensation arrangements included in the pending disclosures that would be affected by the clarifications in this final rule, it is our observation that a substantial portion of the conduct already settled through the SRDP involved the failure of a compensation arrangement to satisfy the writing or signature requirements of an applicable exception, with many of those failures lasting for only a short period of time. Many disclosures involved the disclosing party's incorrect interpretation or misapplication of the physician self-referral law or CMS policy. Therefore, we believe that the

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[49] American Hospital Association, *Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Care Providers* (October 2017), *available at* https://www.aha.org/sites/default/files/regulatory-overload-report.pdf.

[50] Senate Finance Committee Majority Staff Report, *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovated Payment Models* (2015), *available at* https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf.

clarifications in this final rule will reduce the perceived need for disclosure to the SRDP and allow parties to avoid the costs—including costs of compliance professionals, attorneys, market valuation experts, and accountants—of preparing and submitting a disclosure to the SRDP. As noted above, we also expect that some entities may withdraw a portion of or their entire SRDP disclosures following the issuance of this final rule. However, we are unable to quantify the avoidance of costs to the industry related to refraining from or withdrawing disclosures. We note that recoveries from SRDP settlements may also diminish, but this does not represent a cost to the Medicare program or trust fund. Where there is no violation of the physician self-referral law's referral and billing prohibitions, there is no refund due to the government under section 1877(g) of the Act for Medicare payments made to the entity.

Finally, we believe that the clarifications and revisions to the EHR exception, and the permanency of the exception, will facilitate the continued adoption and use of electronic health records, especially in small physician practices, by making permanent the exception for the donation of such items and services.

(2) New Exception for Cybersecurity Items and Services

The average breached health care organization faces $8 million dollars in costs as a result of the breach, or $400 per patient record involved.[51] One hospital reported spending $10 million to recover from a cyberattack, instead of paying a $30,000 ransom demanded by hackers,[52] while another hospital paid a $55,000 ransom to hackers, despite having backup copies of the affected files.[53] A cyberattack on a hospital in Germany is the suspected cause of the death of at least one patient.[54] A September 2020 cyberattack on a large health care system in the United States

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[51] *See* Health Sector Cybersecurity Coordination Center, *A Cost Analysis of Healthcare Sector Data Breaches* (Apr. 4, 2019), *available at* https://www.hhs.gov/sites/default/files/cost-analysis-of-healthcare-sector-data-breaches.pdf

[52] *See* Naveen Goud, *ECMC Spends $10 Million to Recover from a Cyberattack*, Cybersecurity Insiders, *available at* https://www.cybersecurity-insiders.com/ecmc-spends-10-million-to-recover-from-a-cyber-attack/.

[53] *See* Samm Quinn, *Hospital pays $55,000 Ransom; No Patient Data Stolen*, Greenfield Daily Reporter (Jan. 15, 2018), *available at* http://www.greenfieldreporter.com/2018/01/16/01162018dr_hancock_health_pays_ransom/.

[54] *See* Patrick Howell O'Neill, *A patient has Died After Ransomware Hackers Hit a German Hospital*, MIT Technology Review (Sept. 18, 2020), *available at* https://www.technologyreview.com/2020/09/18/1008582/a-patient-has-died-after-ransomware-hackers-hit-a-german-hospital/.

affected nearly 400 facilities, causing hospitals to divert ambulances during the initial stages of the attack.[55] In addition, staff reported that some lab test results were delayed. The system responded by suspending user access to its information technology applications related to operations across the United States, requiring the use of back-up processes, including paper medical record charting and labeling medications by hand, for nearly three weeks.

According to the Health Sector Cybersecurity Coordination Center (HC3), health care organizations should consider implementing strong risk management practices to help prevent data breaches and minimize any disruptions or loss if a breach occurs.[56] HC3 highlights that adequate prevention and preparation for data breaches will protect patients, minimize direct and indirect costs, and allow for more efficient operations of a health care organization.[57] Separately, the HCIC Task Force's 2017 report, among other things, highlighted its review of many concerns related to potential constraints imposed by the physician self-referral law and the Federal anti-kickback Statute. The report encouraged the Congress to evaluate an amendment to these laws specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy.[58] The HCIC Task Force noted that the existing regulatory exception to the physician self-referral law (§ 411.357(w)) and the safe harbor to the Federal anti-kickback statute (42 CFR 1001.952(y)) applicable to certain donations of EHR items and services could serve as a perfect template for an analogous cybersecurity provision.[59] In 2018, the American Medical Association surveyed

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[55] *See* Jeff Lagasse, *Universal Health Services Hit with Cyberattack that Shuts Down IT Systems*, Healthcare Finance (Sept. 2020), *available at* https://www.healthcarefinancenews.com/news/universal-health-services-hit-cyberattack-shuts-down-it-systems-1; Jessica Davis, *UHS Health System Confirms all US Sites Affected by Ransomware Attack*, Health IT Security (Oct. 2020), *available at* https://healthitsecurity.com/news/uhs-health-system-confirms-all-us-sites-affected-by-ransomware-attack; Jessica Davis, *3 Weeks After Ransomware Attack, All 400 UHS Systems Back Online*, Health IT Security (Oct. 2020), *available at* https://healthitsecurity.com/news/3-weeks-after-ransomware-attack-all-400-uhs-systems-back-online; and Press Release, Universal Health Services, *Statement from Universal Health Services* (Oct. 29, 2020), *available at* https://www.uhsinc.com/statement-from-universal-health-services/.

[56] *See* Health Sector Cybersecurity Coordination Center, *A Cost Analysis of Healthcare Sector Data Breaches*.

[57] *Id*.

[58] *See* HCIC Task Force Report, *available at* https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[59] *Id*.

over 1,300 physicians in a cybersecurity-related survey. Approximately 83 percent of the participants reported having experienced some sort of cybersecurity attack.[60] The study also highlighted that 50 percent of the surveyed physicians wished they could receive donations of security-related hardware and software from other providers, and recommended that we develop an exception to permit it.

As described in section II.E.2 of this final rule, we received overwhelming support from across the health care industry in response to our proposal to establish the new exception for cybersecurity items and services, and we anticipate significant expansion of cybersecurity efforts through donations following the effective date of this final rule, similar to the expanded adoption of EHR items and services reported by stakeholders following the establishment of the EHR exception in 2006. Support for the new cybersecurity exception came from many well-resourced organizations that are potential future donors of cybersecurity technology, such as health plans and large health systems, as well as from likely recipients of donations and trade groups representing practitioners. (We note that not all of the potential donors and recipients are entities and physicians to which the physician self-referral law applies.) Because of the cost of cybersecurity attacks to organizations that wish to donate or receive cybersecurity technology and services, and the general support among donors and recipients for the new cybersecurity exception, we anticipate significant investment in improvements to the cybersecurity hygiene of the health care industry. An organization's cybersecurity posture is only as strong as its weakest link, including weaknesses of downstream providers, suppliers, and practitioners that wish to receive donations; thus, donors are incented to protect themselves by donating cybersecurity technology and services that improves their cybersecurity.

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[60] *See* American Medical Association, *Tackling Cyber Threats in Healthcare*, *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/medical-cybersecurity-findings.pdf and https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/infographic-medical-cybersecurity.pdf.

We expect that the flexibilities afforded by the cybersecurity exception will facilitate the enhancement of protection against the corruption of or access to health records and other information essential to the safe and effective delivery of health care, as well as reduce the impacts of cybersecurity attacks, including the improper disclosure of PHI. This could ultimately reduce overall costs associated with cybersecurity attacks, including ransom payments, costs to patients whose PHI is improperly disclosed, and costs to providers and suppliers to reestablish cybersecurity. However, there are a variety of factors integral to determining the extent of the impact of the cybersecurity exception on the cybersecurity hygiene of the health care industry that remain too speculative to support a quantitative estimate of the impact of this final rule. For example, we cannot predict with certainty: (1) how many entities or physicians will donate cybersecurity technology or services for which the parties may seek protection under the cybersecurity exception; (2) how such donations will improve the cybersecurity hygiene of recipients, donors, and the health care ecosystem as a whole; or (3) external factors—such as other policies promoting cybersecurity within the health care industry, how hackers will proliferate and develop new hacking strategies, or how cyberattack recovery costs and ransom costs will change—that could enable or hinder improved cybersecurity hygiene and potentially result in increased or decreased costs associated with cyberattacks. Thus, we cannot predict the specific quantitative impact of the flexibility afforded by the new cybersecurity exception on the costs or benefits to the Medicare program, or other Federal health care programs, beneficiaries, or the health care industry as a whole. Nonetheless, we expect that the flexibility to donate cybersecurity technology and services will benefit the health care ecosystem as a whole, improve cybersecurity across the industry, and reduce costs associated with cyberattacks (by reducing successful cyberattacks, and consequently, ransom fees and recovery costs).

3. Comment and Response

We sought comment on the economic impact of this final rule, including any potential increase or decrease in utilization, any potential effects due to behavioral changes, or any other potential cost savings or expenses to the Government as a result of this rule.

We received the following comment and our response follows.

Comment: One commenter requested that we provide detailed estimates of changes in Medicare program spending that CMS expects to result from the proposed new exceptions and other regulatory changes. The commenter asserted that certain successful value-based programs produce limited savings and many value-based programs produce no savings or even increase spending.

Response: We are unable to provide the detailed estimates requested by the commenter. It is impossible for CMS to provide quantitative estimates of savings to or expenditures of the Medicare program that will result from the establishment of the new exceptions at §411.357(z), (aa), or (bb), or from clarification of key terms integral to the physician self-referral law and other regulatory revisions. However, we emphasize that we engaged in the Regulatory Sprint to facilitate the transition to value-based health care delivery and payment and realize the potential cost savings that come from improved quality and care coordination. Although we cannot estimate the precise dollar amount of impact, as described throughout this section IV.B.2. of this final rule, the potential for reduced program expenditures is significant, and the policies set forth in this final rule are intended to maximize this potential.

C. Anticipated Effects

This final rule will affect entities that furnish designated health services payable by Medicare and the physicians with whom they have financial relationships. The following items or services are designated health services: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and

supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services. We do not have data on the number of entities and physicians that have financial relationships, but we believe a substantial fraction of Medicare-enrolled physicians, group practices, hospitals, clinical laboratories, and home health agencies are affected by the physician self-referral law. We anticipate that this final rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system.

To estimate the number of entities directly affected by this rule, we use Medicare enrollment data. According to this data, there were 2,265 single or multispecialty clinics or group practices, 3,159 clinical laboratories (billing independently), 2,016 outpatient physical therapy/speech pathology providers, 2,739 independent diagnostic testing facilities, 11,317 home health agencies, 6,072 inpatient hospitals, 4,402 rural health clinics, 172 comprehensive outpatient rehabilitation facilities, 8,836 federally qualified health centers, and 9,403 medical supply companies enrolled in Medicare in 2018.[61] In addition, we estimate that 400 physician practices unassociated with single or multispecialty clinics or group practices will independently review this final rule. We requested public comment on the entities affected by the rule.

We anticipate that directly affected entities will review this final rule in order to determine whether to explore newly permissible value-based arrangements and to take advantage of burden-reducing clarifications provided by the rule. We estimate that all directly affected entities described above that will be eligible to use the final rule will review the rule. In the proposed rule, we estimated that reviewing the final rule would require an average of 3 hours of time each from the equivalent of a compliance officer and a lawyer (84 FR 55837). The final rule responds to numerous comments received on the proposals discussed in the proposed rule, and includes significantly more information than the proposed rule. Although we did not receive

[61] CMS Program Statistics, https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-providers

any comments on our proposed estimate of three hours, in light of the increase in length from the proposed rule to the final rule, we have adjusted our estimate for the time required to review the final rule. We estimate that reviewing the final rule will require an average of 6 hours of time each from the equivalent of a compliance officer and a lawyer, and note that parties may review only the portions of the final rule that are applicable to their specific circumstances and needs. For example, parties that do not wish to participate in value-based health care and delivery at this time may not review sections I.B. and II.A. of this final rule.

To estimate the costs associated with this review, we use a 2019 wage rate of $35.03 for compliance officers and $69.86 for lawyers from the Bureau of Labor Statistics,[62] and we double those wages to account for overhead and benefits. As a result, we estimate total regulatory review costs of $64 million in the first year following publication of the final rule. We sought public comment on these assumptions.

In developing this final rule, we took great care to ensure that the safeguards against program and patient abuse in our new exceptions impose the minimum burden possible while providing robust protection against improper utilization and other harms against which the physician self-referral law is designed to protect. For example, we believe a value-based enterprise would ordinarily develop a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s), so our requirement does not impose any additional burden beyond what we anticipate parties would ordinarily develop. We also believe that parties to an arrangement under which remuneration is paid already keep business records necessary for a variety of purposes, such as income tax filings, records of compliance with state laws (including fee splitting laws), and, for nonprofit entities, justification of tax-exempt status. Therefore, we do not believe the requirement to maintain records of the methodology for determining and the actual amount of remuneration paid

[62] U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States, https://www.bls.gov/oes/current/oes_nat.htm

under a value-based arrangement for a period of at least 6 years imposes additional burden. In addition, we believe that physicians and entities routinely document their financial arrangements in writing as a common good business practice so that arrangements can be enforced. For example, we believe that an entity would ordinarily ensure that the details of a shared loss repayment agreement are documented in writing to ensure that the arrangement can be enforced under state law. Similarly, we believe that entities working together to achieve a purpose would routinely monitor their operations to confirm that their plans are working as intended. We sought comments on these assumptions.

The new exceptions for arrangements intended to facilitate the transition to value-based health care delivery and payment have numerous potential benefits that will reduce costs and improve quality, not only for Medicare and its beneficiaries, but for patients and the health care system in general. For example, the final exceptions provide important new flexibility for physicians and entities to work together to improve patient care and reduce costs. This increased flexibility will provide new opportunities for the private sector to develop and implement cost-saving, quality-improving programs that previously may have been impermissible. We anticipate that implementation of improvements and efficiencies, such as care redesign protocols resulting from private sector innovation, could have a beneficial effect on the care provided to Medicare beneficiaries and thereby result in savings for beneficiaries and the Trust Funds. We believe that these new exceptions will also increase participation in Innovation Center models because, unlike the fraud and abuse waivers that have been issued for certain Innovation Models, the exceptions will not expire and are not narrowly designed to apply solely to one specific model, allowing parties to enter into value-based arrangements of their own design and to continue such arrangements beyond expiration of fraud and abuse waivers. We also believe that applying the new exceptions will make compliance more straightforward for physicians and entities participating in Innovation Center models, thus resulting in cost savings for these parties. In addition, we believe that the new exceptions for arrangements intended to facilitate the

transition to value-based health care delivery and payment will ensure that the physician self-referral law continues to provide meaningful protection against overutilization and other harms, thus preventing increased Medicare expenditures and associated beneficiary liability. We lack data to quantify these effects and sought public comment on these impacts.

We believe that the clarifications and regulatory revisions of key terminology (specifically, the terms "commercially reasonable" and "fair market value," the volume or value standard, and the other business generated standard) discussed in section II.B. of this final rule will have significant, ongoing benefits to all physicians and entities affected by the physician self-referral law. These terms are used throughout the physician self-referral regulations. Commenters on the proposed rule indicated that additional guidance on these terms is necessary to reduce the complexity of structuring financial arrangements to comply with the physician self-referral law.

We anticipate that the changes to decouple the physician self-referral law regulations from the anti-kickback statute and federal and state laws or regulations governing billing or claims submission will reduce burden by making compliance more straightforward for physicians and entities. We stress that the anti-kickback statute and billing laws remain in full force and effect, so those laws will continue to protect against program and patient abuse. We anticipate that our changes to the definitions of "designated health services," "physician," and "remuneration" and the changes to the ownership and investment interest provisions in §411.354(b) will reduce compliance burden by appropriately applying the physician self-referral law's prohibitions and providing protection for nonabusive financial relationships. Our changes for the exceptions for fair market value payments by a physician and fair market value compensation will make these exceptions available to protect financial arrangements that must currently meet more complicated and burdensome requirements of other exceptions. We anticipate that this added flexibility will provide substantial burden reduction through reduced compliance costs.

We have also finalized numerous other changes that, while relatively minor in scope, are intended to collectively reduce burden. For example, the new special rules on the set in advance requirement clarifies the requirements for modifying compensation terms during the course of an arrangement and correct a common misperception among stakeholders that parties may only modify the compensation terms of an arrangement once during the course of a year. We anticipate that our changes relating to isolated transactions, the period of disallowance, the special rules on compensation arrangements, the exceptions for rental of office space and rental of office equipment, the exception for physician recruitment, and the exception for assistance to compensate a nonphysician practitioner will also have a beneficial impact by reducing the existing burden on physicians and entities through the provision of additional guidance and clarifications. We lack data to quantify these effects and sought public comment on these impacts.

As we stated in the proposed rule, the American Hospital Association estimated compliance costs faced by hospitals.[63] It estimated $350,000[64] in annual costs for an average hospital to comply with fraud and abuse regulations, which include the physician self-referral law. To estimate aggregate fraud and abuse compliance costs, we multiply this figure by the number of Medicare enrolled hospitals, which implies $2.1 billion in total annual costs across these hospitals. Based on CMS RFI comments, compliance with the physician self-referral regulations comprises a substantial fraction of these costs. we anticipate that clarifications provided in this final rule may substantially reduce the complexity of compliance for affected entities. As a result, we expect this rule will substantially reduce net fraud and abuse compliance burden for affected entities, although we lack data to quantify these estimates. We note that hospitals represent a fraction of entities affected by this final rule, and burden is likely to decline substantially for other categories of entities affected by this rule. We sought public comment on

[63] https://www.aha.org/sites/default/files/regulatory-overload-report.pdf
[64] Note that the figure is adjusted for inflation between 2017 and 2018.

the extent to which this rule will reduce compliance burden for hospitals and entities other than hospitals.

Our final modifications to the EHR exception are modest and clarify that the exception applies to certain cybersecurity technology that is included as part of an electronic health records arrangement, make the exception permanent, and clarify that contribution requirements collected from physicians for updates to previously donated technology need only be collected at reasonable intervals. The EHR exception will continue to be available to physicians and entities other than laboratories. We expect that the same entities that currently use the EHR exception will continue to use the exception. We anticipate that our final policies will result in an incremental reduction in compliance burden.

In section II.E. of this final rule, we discuss new exceptions for limited remuneration to a physician and the provision of cybersecurity technology and related services. We anticipate that the new exception for limited remuneration to a physician will ease compliance burden because it allows entities to compensate a physician for items or services provided by the physician without being subject to all the documentation and certain other requirements of existing exceptions to the physician self-referral law. We believe that this new exception will also provide additional flexibility where these arrangements are not covered by an existing exception. We anticipate that the cybersecurity exception will be widely used by physicians, group practices, and hospitals. We believe that this exception will help to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the safe and effective delivery of health care. We lack data to quantify these effects and sought public comment on these impacts.

We received the following comments and our responses follow.

Comment: The vast majority of commenters supported our proposals, noting generally that the proposed provisions will facilitate compliance with the physician self-referral law and achieve the reduced burden CMS anticipates, although no commenters provided data or other

detail that would allow us to quantify the anticipated effects.

Response: We appreciate commenters' feedback confirming our assessment that this final rule will ease compliance with the physician self-referral law and reduce burden on hospitals and other entities.

Comment: A few commenters asserted that the establishment of the accountable body or person and the development of the governing document would require the expenditure of significant resources, including legal expenses, and questioned whether adding this burden was necessary.

Response: As discussed in detail in section II.A.2.a. of this final rule, we continue to believe that a value-based enterprise would ordinarily develop a governing document and that this final rule will not result in additional burden in that regard. In addition, we have provided additional guidance about these requirements, including that we are not dictating the format or content of the governing document or the structure or composition of the accountable body. Each value-based enterprise has the flexibility to develop and implement the necessary infrastructure to effectively oversee its financial and operational activities commensurate with the size and structure of the value-based enterprise.

Comment: One commenter expressed concern that the revised definition of "remuneration" would increase the burden on parties to monitor the use of items, devices, or services to ensure that physicians are in fact using the items, devices, or services for one or more of the permitted purposes under the statute.

Response: As we mentioned in section II.D.2.d. of this final rule, we believe that it would be impossible for an entity to monitor how a physician "in fact" uses a multi-use item, device, or supply whose primary purpose is not one or more of the permitted purposes to ensure that the physician in fact uses the item, device, or supply exclusively for one or more of the permitted purposes. However, we believe that the final definition of "remuneration" will not increase the burden of monitoring, because the provision of multi-use items, devices, or supplies

whose primary purpose is not one or more of the permitted purposes will not be carved out of the definition of "remuneration."

Comment: Many commenters maintained that the proposed amendment to clarify the definition of "transaction" at §411.351 would reduce flexibility and increase the burden of compliance.

Response: We discussed this policy in section II.D.2.e. of this final rule and explained that the revision simply clarifies an existing policy that the exception for isolated transactions is not available to protect a single payment for multiple or repeated services. This longstanding policy is based on our interpretation of the statute and our mandate under sections 1877(b)(4) and 1877(e)(6)(B) of the Act to permit only those financial relationships that do not pose a risk of program or patient abuse. We do not believe that clarifying existing policy will result in additional burden, particularly in light of new flexibilities included in this final rule.

D. Alternatives Considered

This final rule contains a range of policies. The preceding preamble presents rationale for our policies and, where relevant, alternatives that were considered. We carefully considered the alternative of maintaining the status quo and not pursuing regulatory action. However, we believe that the transition to a value-based health care delivery and payment system is urgently needed due to unsustainable costs inherent in the current volume-based system. We believe this final rule addresses the critical need for additional flexibility that is necessary to advance the transition to value-based health care and improve the coordination of care among providers in both the Federal and commercial sectors.

We also considered proposing to limit the new exceptions for arrangements that facilitate the transition to value-based health care delivery and payment to CMS-sponsored models or establishing separate exceptions with different criteria for arrangements that exist outside CMS-sponsored models. However, we believe that, in their current state, the physician self-referral regulations impede the development and adoption of innovative approaches to delivering health

care, across all patient populations and payor types, and over indefinite periods of time. In addition, we considered establishing an exception to protect care coordination activities performed outside of a value-based enterprise. We rejected this alternative due to program integrity concerns that could exist without the incentives and protections inherent in a value-based enterprise and value-based arrangement, as defined at final §411.351.

We considered including provisions in the exceptions for value-based arrangements that would require compensation to be set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated between the parties. We are concerned, however, that the inclusion of such requirements would conflict with our goal of dismantling and addressing regulatory barriers to value-based care transformation. We further believe that the disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the value-based definitions will operate in tandem with the requirements included in the exceptions and be sufficient to protect against program and patient abuse. We also considered whether to exclude laboratories and DMEPOS suppliers from the definition of "VBE participant." We stated in the proposed rule that it was not clear to us that laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. As discussed in Section II.A.2.a. of this final rule, we have not excluded any entities from the final definition of "VBE participant."

Through our own experience administering the physician self-referral regulations and our thorough analysis of comments, we recognize the urgent and compelling need for additional guidance on the physician self-referral law. In preparing this rule, we conducted an in-depth review of our existing regulations to identify those matters that might benefit from additional guidance. We took great care to provide this guidance in the clearest, most straightforward

manner possible. For example, we considered addressing the need for guidance on the applicability of the physician self-referral law to referrals for inpatient hospital services after admission through modifying the definition of "referral" rather than the definition of "designated health services." We are concerned that modifying the definition of "referral" could have a broader effect and would not be as clear, and declined to adopt that approach. We have also carefully weighed each proposal to ensure that it does not pose a risk of program or patient abuse. For example, we considered whether to eliminate the requirement that a physician must pay 15 percent of the cost of donated electronic health records items and service, but are concerned that doing so would pose a risk of program or patient abuse. We sought comments on these regulatory alternatives. As discussed in section II.D.11.e. of this final rule, the EHR exception maintains the 15 percent contribution requirement.

We received no comments specific to the alternatives considered section of the proposed rule.

E. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), we have prepared an accounting statement. The following table provides estimated annualized costs through 2029.

ACCOUNTING STATEMENT: ESTIMATED ANNUALIZED COSTS

Category	Primary Estimate	Low Estimate	High Estimate	Year Dollar	Discount Rate	Period Covered
Costs						
Annualized Monetized ($millions/year)	4.3	0.0	0.0	2018	7%	2020-2029
	3.6	0.0	0.0	2018	3%	2020-2029
Annualized Quantified	0.0	0.0	0.0		7%	
	0.0	0.0	0.0		3%	

Qualitative	

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

DISCLAIMER: Based on the tight time constraints and the need to expedite the clearance process to ensure timely publication, OSORA will continue to work with CM to ensure that regulations text is in compliance with the Office of the Federal Register standards and guidance.

List of Subjects in 42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 411 as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

2. Subpart J is amended by revising §§ 411.350 through 411.357 to read as follows:

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

Sec.

* * *

§411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the

entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§424.80 of this chapter);

(2) The rules regarding purchased diagnostic tests (§414.50 of this chapter);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§410.26 of this chapter); or

(4) Any other applicable Medicare laws, rules, or regulations.

§411.351 Definitions.

The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart. As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical,

immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not a clinical laboratory service for purposes of this subpart.

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Cybersecurity means the process of protecting information by preventing, detecting, and

responding to cyberattacks.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)(i) Clinical laboratory services.

(ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are paid by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable under a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):

(i) Acute Care Hospital Inpatient (IPPS);

(ii) Inpatient Rehabilitation Facility (IRF PPS);

(iii) Inpatient Psychiatric Facility (IPF PPS);

or (iv) Long-Term Care Hospital (LTCH PPS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title, "Exceptions";

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, "Advisory Opinions by the OIG"; or

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—

(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under §1001.952 of this title; or

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.

Downstream contractor means a "first tier contractor" as defined at §1001.952(t)(2)(iii) of this title or a "downstream contractor" as defined at §1001.952(t)(2)(i) of this title.

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and §414.202 of this chapter.

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical

conditions.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or

(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with §424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under §424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, “entity” does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with §414.50 of this chapter and

Fair market value means—

(1) *General*. The value in an arm's-length transaction, consistent with the general market value of the subject transaction.

(2) *Rental of equipment*. With respect to the rental of equipment, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) *Rental of office space*. With respect to the rental of office space, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) *Assets*. With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) *Compensation*. With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) *Rental of equipment or office space*. With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Home health services means the services described in section 1861(m) of the Act and part

409, subpart E of this chapter.

Hospital means any entity that qualifies as a "hospital" under section 1861(e) of the Act, as a "psychiatric hospital" under section 1861(f) of the Act, or as a "critical access hospital" under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

"*Incident to" services* or *services "incident to"* means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, §410.26 of this chapter, and Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4

Inpatient hospital services means those services defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. "Inpatient hospital services" do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. "Inpatient hospital services" also do not include dialysis furnished by a hospital that is not certified to provide end-

stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. "Inpatient hospital services" include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. "Inpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Interoperable means—

(1) Able to securely exchange data with and use data from other health information technology; and

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

Isolated financial transaction—(1) Isolated financial transaction means a one-time transaction involving a single payment between two or more persons or a one-time transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the Federal Register, and is posted on the CMS website at *http://www.cms.hhs.gov/PhysicianSelfReferral/11__List__of__Codes.asp#TopOfPage*.

Locum tenens physician (or substitute physician) means a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes "patient care services" to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an "employee" under this section).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. "Outpatient hospital services" do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. "Outpatient hospital services" include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. "Outpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or D, except for those drugs that are "covered ancillary services," as defined at §416.164(b) of this chapter, for which separate payment is made to an ambulatory surgical center.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to

pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and outpatient speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or outpatient speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or outpatient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services*, meaning those outpatient physical therapy services described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive

devices, and adaptive equipment; or

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services.

(2) *Occupational therapy services,* meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(3) *Outpatient speech-language pathology services*, meaning those services as described in section 1861(ll)(2) of the Act that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under §411.352(g) (or the contract must satisfy the

requirements of the personal service arrangements exception in §411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in §424.80(b)(2) of this chapter (*see* also Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in §411.353(a), and the group practice is subject to the limitation on billing for those referrals in §411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Physician organization means a physician, a physician practice, or a group practice that complies with the requirements of §411.352.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics,* meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics,* meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices,* meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract

surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies,* meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and §410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§410.32 and 410.34 of this chapter, but do not include—

(1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology or certain other imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT/HCPCS codes as a radiology or certain

other imaging service and is performed—

(i) Immediately prior to or during the medical procedure; or

(ii) Immediately following the medical procedure when necessary to confirm placement of an item placed during the medical procedure.

(3) Radiology and certain other imaging services that are "covered ancillary services," as defined at §416.164(b), for which separate payment is made to an ASC.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of referrals.

Rural area means an area that is not an urban area as defined at §412.62(f)(1)(ii) of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the “same building” does not include a mobile vehicle, van, or trailer.

Specialty hospital means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(1) Patients with a cardiac condition;

(2) Patients with an orthopedic condition;

(3) Patients receiving a surgical procedure; or

(4) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital.

A "specialty hospital" does not include any hospital—

(1) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(2) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(3) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(4) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(5) That meets such other requirements as the Secretary may specify.

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

Transaction means an instance of two or more persons or entities doing business.

Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means any of the following:

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.

§411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of

the group (whether employees or direct or indirect owners), as defined at §411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at §411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3) through (6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. *Patient care services* must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this *substantially all* test and related supportive documentation must be made available to the Secretary upon request.

(3) The *substantially all* test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at §411.351.

(4) For a group practice located outside of a HPSA (as defined at §411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the *substantially all* test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the *start up* period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the *substantially all* test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under §411.357(e)(2) would result in the existing group practice not meeting the *substantially all* test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the *substantially all* test if the new member is not counted as a member of the group for purposes of §411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the

following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(2) Overall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or

value of the physician's referrals of DHS. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(3) A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in §414.22 of this chapter.)

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

(4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

§411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment for services furnished under a prohibited referral.* (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(2) When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed—

(i) The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral); and

(ii) The burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors during the course of the appellate proceeding, depending on the evidence presented by the claimant.

(d) *Refunds.* An entity that collects payment for a designated health service that was

performed pursuant to a prohibited referral must refund all collected amounts on a timely basis, as defined at §1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2) through (4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under §411.355, §411.356, or §411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception; and

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship

previously complied was §411.357(k) or (m).

(g) [Reserved]

(h) *Special rule for reconciling compensation*. An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and

(2) Except for the discrepancies in payments described in paragraph (h)(1) of this section, the compensation arrangement fully complies with an applicable exception in this subpart.

§411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships*—(1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest in the entity

may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in paragraph (b)(3)(ii) of this section, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An “under arrangements” contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS “under arrangements” with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section);

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a

compensation arrangement as defined in paragraph (c) of this section);

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

(4) An ownership or investment interest that meets an exception set forth in §411.355 or §411.356 need not also meet an exception for compensation arrangements set forth in §411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An *indirect ownership or investment interest* exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the

referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term "remuneration" at §411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if—

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(2) An *indirect compensation arrangement* exists if all of the conditions of paragraphs (c)(2)(i) through (iii) of this section exist:

(i) Between the referring physician (or a member of his or her immediate family) and the

entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link).

(ii)(A) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the individual unit of compensation received by the physician (or immediate family member)—

(*1*) Is not fair market value for items or services actually provided;

(*2*) Includes the physician's referrals to the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or

(*3*) Includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(B) For purposes of applying paragraph (c)(2)(ii)(A) of this section, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(C) If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be

measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)).

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to "stand in the shoes" of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who "stands in the shoes" of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §§411.355 and 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the "parties to the arrangements" are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who "stands in the shoes" of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of §411.357(p) as of September 5, 2007 (see 42 CFR parts 400-413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of §411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in §411.357 (other than §411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of §411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(4)(i) *Exceptions applicable to indirect compensation arrangements–General*. Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) *Special rule for indirect compensation arrangements involving a MCO or IPA and a referring physician*. Only the exceptions at §§411.355, 411.357(n), and 411.357(p) are applicable in the case of an indirect compensation arrangement in which the entity furnishing DHS described in paragraph (c)(2)(i) of this section is a MCO or IPA.

(iii) *Special rule for indirect compensation arrangements involving value-based*

arrangements. When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined at §411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party—

(A) Only the exceptions at §§411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is not a MCO or IPA; and

(B) Only the exceptions at §§411.355, 411.357(n), 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is a MCO or IPA.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

(1) *Set in advance.* (i) Compensation is deemed to be "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified.

(ii) Notwithstanding paragraph (d)(1)(i) of this section, compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is "set in advance" if all of the following conditions are met:

(A) All requirements of an applicable exception in §§411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation).

(B) The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.

(C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Paragraph (e)(4) of this section does not apply for purposes of this paragraph (d)(1)(ii)(C).

(2) *Unit-based compensation and the volume or value standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. This paragraph (d)(2) does not apply for purposes of paragraphs (d)(5)(i) and (6)(i) of this section.

(3) *Unit-based compensation and the other business generated standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered "other business generated" by the referring physician). This paragraph (d)(3) does not apply for purposes of paragraphs (d)(5)(ii) and (d)(6)(ii) of this section.

(4) *Directed referral requirement.* If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.

(i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for

determining the compensation) must be made prospectively.

(ii) The compensation is consistent with the fair market value of the physician's services.

(iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at §411.355 or §411.357.

(iv) The compensation arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(5) *Compensation to a physician.* (i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account

the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if the formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at §411.357(m), (s), (u), (v), (w), and (bb).

(6) *Compensation from a physician.* (i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other

business generated only if the formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at §411.357(m), (s), (u), (v), (w), and (bb).

(e) *Special rule on compensation arrangements*—(1) *Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(3) *Signature requirement*. In the case of any signature requirement in this subpart, such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law.

(4) *Special rule on writing and signature requirements*. In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception (that is, the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them).

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined at §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of this paragraph (a), “physician services” include only those “incident to” services (as defined at §411.351) that are physician services under §410.20(a) of this chapter.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) *Individual who furnishes the service.* They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) *Location where service is furnished.* They are furnished in one of the following locations:

(i) The same building (as defined at §411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), *or* (b)(2)(i)(C) of this section are satisfied:

(A)(*1*) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(*2*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(*1*) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(*1*) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section *or* the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section;

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at §411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at §411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) *Billing of the service.* They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a “physician in the group practice” (as defined at §411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of §424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) *Durable Medical Equipment.* For purposes of this paragraph (b), DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in §424.57(c) of this chapter.

(v) [Reserved]

(vi) All other requirements of the in-office ancillary services exception in this paragraph

(b) are met.

(5) *Furnishing a service.* A designated health service is "furnished" for purposes of this paragraph (b) in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(7) *Disclosure requirement for certain imaging services.* (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as "radiology and certain other imaging services" on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined at §400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the

physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart

D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A "component" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at §411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or

clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

(D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(2) The “academic medical center” for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at paragraph (e)(3) of this section);

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph (e)(2)(iii), a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under §416.65 of this chapter.

(3) [Reserved]

(4) [Reserved]

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs.* EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph (g)(1), "EPO and other dialysis-related drugs" means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and "furnished" means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) [Reserved]

(3) [Reserved]

(4) The exception set forth in this paragraph (g) does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.* Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) [Reserved]

(3) [Reserved]

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in §§410.36(a)(2)(ii) and 414.228 of this chapter, respectively.

(2) [Reserved]

(3) [Reserved]

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at §411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation

time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

§411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. “Stockholder equity” is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in

section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at §411.351 of this part) by the provider. A "rural provider" is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of §411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in §411.362 not later than September 23, 2011.

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment.

(3) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new

lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of this paragraph (b) if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(d) *Personal service arrangements*—(1) *General*. Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) Except for services provided under an arrangement that satisfies all of the conditions of paragraph (z) of this section, the arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member may "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or

through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at §411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

(viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as

defined at §411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at §422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §§422.208 and 422.210 of this chapter.

(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The amount of remuneration under the arrangement is not determined in any manner

that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with §411.354(d)(4)).

(2)(i) *Geographic area served by the hospital—defined.* The "geographic area served by the hospital" is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) *Noncontiguous zip codes.* With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at §411.351), the "geographic area served by the hospital" may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) *Relocation of medical practice.* A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial “start up” year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph (e), provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a

significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice

restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

(5) Recruitment of a physician by a hospital located in a rural area (as defined at §411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The "geographic area served" by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, or a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, if all of the following conditions are met:

(1) The amount of remuneration under the isolated financial transaction is—

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an arrangement that would be commercially

reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in §§411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician.

(4) An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as "unrelated," remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services—

(i) That are furnished at a price that is consistent with fair market value; and

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

(3) For purposes of this paragraph (i), "services" means services of any kind (not merely those defined as "services" for purposes of the Medicare program in §400.202 of this chapter).

(j) *Charitable donations by a physician. Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are

satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10__CPI-U__Updates.asp*.

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an

amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) This paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(l) *Fair market value compensation*. Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services or for the lease of office space or equipment by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment. The writing specifies—

(i) The items, services, office space, or equipment covered under the arrangement;

(ii) The compensation that will be provided under the arrangement; and

(iii) The timeframe for the arrangement.

(2) An arrangement may be for any period of time and contain a termination clause. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Other than an arrangement that satisfies all of the conditions of paragraph (z) of this section, the parties may

not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year.

(3) The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act).

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the

same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets the “on campus” requirement of this paragraph (m).

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10__CPI-U__Updates.asp*.

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) [Reserved]

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation paid directly or indirectly by a MCO or an IPA to a physician pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) for services provided by the physician to enrollees of a health plan. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings set forth in §1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that the training is held in the local community or service area. For purposes of this paragraph (o), "compliance training" means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, "compliance training" includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at §411.354(c)(2), if all of the following conditions are satisfied:

(1)(i) The compensation received by the referring physician (or immediate family member) described in §411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(2) The compensation arrangement described in §411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) [Reserved]

(4) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in §411.354(c)(2)(ii) satisfies the conditions of §411.354(d)(4).

(q) *Referral services.* Remuneration that meets all of the conditions set forth in §1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration that meets all of the conditions of paragraph (r)(1) or (2) of this section.

(1) Remuneration that meets all of the conditions set forth in §1001.952(o) of this title.

(2) A payment from a hospital, federally qualified health center, or rural health clinic that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

(i)(A) The physician's medical practice is located in a rural area, a primary care HPSA, or

an area with demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, or rural health clinic providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, or rural health clinic and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, or rural health clinic providing the payment.

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with §411.354(d)(4)).

(vi) The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).

(vii) The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(viii) The insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.

(ix)(A) For each coverage period (not to exceed 1 year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance

during the prior period (not to exceed 1 year)—

(*1*) Resided in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(*2*) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will—

(*1*) Reside in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(*2*) Be part of a medically underserved population.

(3) For purposes of paragraph (r)(2) of this section, *costs of malpractice insurance premiums* means:

(i) For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

(ii) For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided—

(A) In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed 1 year) resided in a medically underserved area or were part of a medically underserved population.

(s) *Professional courtesy.* Professional courtesy (as defined at §411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need; and

(t) *Retention payments in underserved areas*—(1) *Bona fide written offer.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of

employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this setion are satisfied.

(2) *Written certification from physician.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A statement that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this section are satisfied.

(3) *Additional requirements*. Remuneration provided under paragraph (t)(1) or (2) of this section must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(4) *Waiver of relocation requirement*. The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph (t).

(5) *Application to other entities*. This paragraph (t) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of

items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at §411.352) to a physician who is a member of the group (as defined at §411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and

services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:

(1) The items and services are provided to a physician by an entity (as defined at §411.351) that is not a laboratory company.

(2) The software is interoperable (as defined at §411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) [Reserved]

(4)(i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services.

(ii) Except as provided in subparagraph (i), with respect to items and services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor’s cost for the items and services at reasonable intervals.

(iii) The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's

medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) [Reserved]

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(x) *Assistance to compensate a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met:

(i) The arrangement—

(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's NPP referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by—

(*1*) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(*2*) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—

(A) Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under §411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), “nonphysician practitioner” means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined at §410.71(d) of this subchapter.

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) “NPP patient care services” means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task

performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

(ii) "NPP referral" means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, "geographic area served by the hospital" has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a "compensation arrangement" between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands)

within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The "geographic area served" by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements*. Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are

furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(8) [Reserved]

(9) The arrangement does not convey a possessory leasehold interest in the office space

that is the subject of the arrangement.

(z) *Limited remuneration to a physician*. (1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $5,000 per calendar year, as adjusted for inflation in accordance with paragraph (z)(3) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises or equipment covered by the arrangement to the party to which the permission is granted.

(vi) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of

§411.354(d)(4).

(2) A physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).

(3) The annual aggregate remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(aa) *Arrangements that facilitate value-based health care delivery and payment*—(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

(3) *Value-based arrangements*. Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The outcome measures against which the recipient of the remuneration is assessed, if any.

(ii) The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support.

(iii) Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

(iv) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(v) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(vi) The arrangement is commercially reasonable.

(vii)(A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor:

(*1*) Whether the parties have furnished the value-based activities required under the arrangement;

(*2*) Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and

(3) Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise—

(*1*) For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or

(*2*) For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

(viii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(ix) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(x) If the remuneration paid to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(xi) Records of the methodology for determining and the actual amount of remuneration

paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(xii) For purposes of this paragraph (aa)(3), "outcome measure" means a benchmark that quantifies:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

(bb) *Cybersecurity technology and related services*. (1) Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met:

(i) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(ii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iii) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology.

3. Effective January 1, 2022, § 411.352 is further amended by revising paragraph (i) to read as follows:

§411.352 Group practice.

*****

(i) *Special rules for profit shares and productivity bonuses*—(1) *Overall profits*. (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals.

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to directly relate to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) *Productivity bonuses*. (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is not directly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of the physician's referrals if the referrals are for services "incident to" the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician.

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) *Value-based enterprise participation*. Notwithstanding paragraph (g) of this section, profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at §411.351, may be distributed to the participating physician.

(4) *Supporting documentation*. Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

Dated: Novemeber 17, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.