



***INNOVATORS’
GUIDE TO
NAVIGATING
MEDICARE***

**Version 3
2015**

TABLE of CONTENTS

OVERVIEW	3
Coverage, Coding, and Payment.....	3
CMS Relevant Components.....	5
Openness and Transparency of Processes.....	9
A Look to the Future.....	10
Contact Information.....	10
COVERAGE	11
National Coverage Determination	11
Reconsiderations and Appeals	14
National Coverage Determination Process Schematic	15
CODING	16
Statutory Authority - HIPAA.....	16
ICD-9, ICD-10, and HCPCS Coding Systems.....	17
ICD-9 and ICD-10	18
HCPCS	22
Level I HCPCS - Current Procedural Terminology.....	23
Level II HCPCS	25
Other Code Sets	29
CODE SET COMPARISON CHART	31
PAYMENT	32
Hospital Outpatient Prospective Payment System.....	38
Physician Fee Schedule.....	44
Part B Drugs in the Physician’s Office.....	46
Clinical Laboratory Services.....	48
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies	49
Inherent Reasonableness.....	51
Rulemaking Cycles of Medicare Payment Systems	52
A LOOK TO THE FUTURE	54
Value-Based Purchasing and Quality Reporting	54
Medicare Shared Savings Program.....	61
End Stage Renal Disease Prospective Payment System - Bundled Payment	62
Incentive Programs	62

OVERVIEW

With a Medicare budget of approximately \$500 billion and serving 54 million beneficiaries, the Centers for Medicare & Medicaid Services (CMS) plays a key role in the overall direction of the health care system. From the beginning of the Medicare program, one of the most important program goals for CMS has been to make “the best of modern medicine” available to Medicare beneficiaries. Over the last 50 years, significant advances in medical science have offered improved health for beneficiaries and others. Many of these advances have involved the use of new technologies, such as prescription drugs and medical devices.

CMS, through its Council for Technology and Innovation (CTI), has developed the Innovators’ Guide to Navigating Medicare to assist stakeholders in understanding the processes used to determine coverage, coding, and payment for new technologies under the Medicare fee-for-service program. This guide is only intended as a general summary. The information provided is not intended to grant rights or impose obligations. While a chapter may contain references or links to statutes, regulations, or other policy materials, it is not intended to take the place of applicable statutory law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Coverage, Coding, and Payment

In recent years, CMS has made substantial progress in defining the coverage, coding, and payment processes and how they relate to each other. In order to improve stakeholder understanding and consider how these processes might be further improved, CMS has made the requirements of these processes, including how decisions are made, more transparent and provided opportunities for public input to facilitate dialogue between CMS and interested stakeholders. This better enables stakeholders to develop a strategy for working with CMS to support timely introduction of innovative technology to the Medicare marketplace, allowing Medicare beneficiaries timely access to advances in health care.

Payment for many technological advances can be made under one of Medicare’s payment methodologies without being preceded by an explicit coverage determination, coding change, and/or payment decision by CMS. However, the Agency will specifically evaluate issues involving coverage, coding, and/or payment with respect to certain technological advances. The basic analytical framework that CMS uses for each of these issues is as follows:

1) Coverage

Medicare’s authority to cover or exclude certain items or services is governed by the Social Security Act (the Act) and implementing regulations.

- Benefit Category – Does the new technology fall into at least one defined benefit category or categories under the Act?
- Statutory Exclusion – Does the new technology involve an item or service that is specifically excluded by the Act?
- Reasonable and Necessary – Is the new technology “reasonable and necessary”

for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member?

2) **Coding**

- Clinically Different – Are changes in coding needed to accommodate the new technology? In most cases, new items and services are adequately described in existing codes. However, some new technologies may warrant differentiation through the creation of new codes.

3) **Payment**

- Payment System – Which fee-for-service payment system(s) does the new technology fit into (e.g., hospital inpatient prospective payment system, physician fee schedule)?
- Payment Amount – If the new technology warrants a new code, how will the payment amount be determined?

Coverage

CMS and its claims administration contractors, (i.e., Medicare Administrative Contractors (MACs)), have the authority to determine coverage for items or services. The Agency may choose to develop a national coverage policy to ensure that similar claims will be adjudicated under uniform criteria. Coverage policies are more likely to be developed when the item or service produces significant clinical consequences for beneficiaries, when the medical community is divided about the merits of an item or service for a particular population, or when the item or service has a significant impact on the Medicare program.

The MACs develop Local Coverage Determinations (LCDs) that apply only within the jurisdiction served by the individual contractor. CMS makes National Coverage Determinations (NCDs) that are binding policies for Federal government contractors that review and/or adjudicate claims, determinations, and /or decisions, including MACs, Quality Improvement Organizations (QIOs), Qualified Independent Contractors (QICs), the Medicare Appeals Council, and Administrative Law Judges (ALJs). An NCD that expands coverage is also binding on Medicare Advantage organizations.

Coding

Currently, CMS uses the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) and the Healthcare Common Procedure Coding System (HCPCS) for processing Medicare claims. The updated International Classification of Diseases, 10th Edition (ICD-10) is scheduled for implementation on October 1, 2015. In contrast to coverage decisions, changes to coding systems are made strictly at the national level. In many instances new technologies are adequately described by existing codes. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), contractors can no longer establish local codes, although new technologies are sometimes accommodated by ‘not otherwise classified’ codes pending determination of a new code assignment.

Payment

Payment levels for most of Medicare's fee-for-service payment systems are structured to gradually adjust to the use of a new technology, and in general do not require major modifications. For example, many institutional payment systems calculate payments based on claims and other data. As a new technology is used to treat Medicare beneficiaries, its relative use will be reflected in payment for the service using the technology.

In certain cases, payment adjustments for new technologies are appropriate. Medicare's inpatient and outpatient prospective payment systems (OPPS) include provisions designed to provide an extra payment amount for certain new technologies. To merit such additional payment, the new technology generally must represent a substantial clinical improvement relative to existing technologies and meet specific cost thresholds. However, for payment under the outpatient prospective payment system, a new service may be assigned to a New Technology Ambulatory Payment Classification (APC) group if the new service cannot appropriately be assigned to a clinical APC and a new drug may receive pass-through payment without demonstrating substantial clinical improvement.

Timing of Policy Decisions

Coverage, coding, and payment decisions are not necessarily made in any particular order. For example, a manufacturer may have secured a new code before seeking Medicare coverage. In addition, while CMS will not generally accept a coverage determination request for a device or pharmaceutical that is not approved or cleared for marketing by the Food and Drug Administration (FDA), applicants may apply for a new technology hospital inpatient add-on payment several months prior to the technology's receipt of FDA approval, as long as FDA approval is granted before CMS makes its decisions for the inpatient prospective payment system (IPPS) final rule. However, because CMS may add new services or pass-through items for payment on a quarterly (rather than annual) basis under the OPPS, OPPS applications for New Technology APCs or pass-through drugs, biologicals, or devices are not considered complete and may not be evaluated until the new technology is approved by the FDA.

Timelines for Medicare coding, coverage, and payment decisions may often span a 12 month period. A manufacturer should be cognizant of these different timeframes in order to navigate a technology's adoption through the Medicare program. Local and national coverage decisions are made under specific timeframes to accommodate public notice and comment requirements. Coding changes are commonly made on an annual basis, while some payment changes may occur quarterly. For planning purposes, this guide contains a set of charts that provide key milestones for coverage, coding, and payment decision-making processes including the many opportunities for public input.

CMS Relevant Components

In addition to understanding the various milestones, it is helpful to know which CMS components to contact regarding Medicare decisions for new technologies under the

coverage, coding and payment processes. Each component's responsibilities are described below.

Center for Clinical Standards and Quality

The Center for Clinical Standards and Quality (CCSQ) oversees national quality initiatives, develops and supports performance measurement systems that promote efficiency of care, and also includes the Coverage and Analysis Group (CAG), which is responsible for developing national coverage policy. CAG also provides oversight of Medicare contractors to ensure that the local coverage determination process is properly followed. Within CAG, coverage determinations about drugs, non-implantable devices, and laboratory and diagnostic tests are referred to the Division of Items and Devices. Other coverage topics, including surgical procedures and implantable devices, are referred to the Division of Medical and Surgical Services. The Division of Operations and Information Management provides ongoing scanning of industry developments to keep CAG staff abreast of new and developing treatments and technologies that may result in national coverage issues and maintains liaisons with other Department components, such as the FDA. This Division is also responsible for oversight of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) and public notice and comment processes.

Center for Medicare

The Center for Medicare (CM) develops payment rules, undertakes benefit category determinations, and formulates Medicare policy for the development and maintenance of new and revised codes. Within CM, the Hospital and Ambulatory Policy Group (HAPG) is responsible for refining hospital and most outpatient payment systems. This group contains four Divisions:

- The Division of Acute Care defines the scope of Medicare benefits for services provided by hospitals to inpatients, and develops, updates, and evaluates the IPPS for payments to hospitals for inpatient services and associated capital costs. This Division considers applications for temporary supplemental payments for new technologies under the IPPS. It also develops and maintains new and revised procedure codes for the ICD-9-Clinical Modification (ICD-9-CM) and ICD-10 Procedure Coding System (ICD-10-PCS) used for inpatient hospital services. The Centers for Disease Control and Prevention (CDC) develops and maintains diagnosis codes for ICD-9-CM and ICD-10-CM.
- The Division of Ambulatory Services formulates payment policies for ambulance transports, rural health clinics, federally qualified health centers, clinical laboratory services, certain blood products, and hemophilia clotting factors. This Division also develops payment policies for drugs provided under Medicare Part B including those drugs provided by physicians (e.g., injectable drugs, vaccines, chemotherapy agents), and drugs used in connection with durable medical equipment.
- The Division of Outpatient Care develops and maintains the hospital OPPS and the ambulatory surgical center (ASC) payment system. This Division considers applications

for temporary supplemental payments for new technologies and new drugs, biologicals, and radiopharmaceuticals used within a hospital outpatient department that are payable under the OPSS and may be payable under the ASC payment system including payment adjustments for new technology intraocular lenses provided in ASCs. This Division also staffs meetings of the Advisory Panel on Hospital Outpatient Payment whose purpose is to advise the Department of Health and Human Services (DHHS) Secretary and the CMS Administrator about the clinical integrity of the ambulatory payment classification (APC) groups and their associated relative payment weights among select other matters related to the OPSS.

- The Division of Practitioner Services develops, updates, and evaluates payment policies and systems for physicians and non-physician practitioners. As part of these responsibilities, the Division develops payment amounts for all services paid under the Medicare physician fee schedule. This fee schedule is used to pay physicians and many other non-physician practitioners (i.e., nurse practitioners, physician assistants, psychologists, social workers, physical and occupational therapists, audiologists, and others) for their services to Medicare beneficiaries. This fee schedule is based on the establishment of relative values for physician work, practice expense, and professional liability for each service. This Division also maintains the relative value units (that form the basis of Medicare payment for physician services), which includes reviewing the American Medical Association (AMA) recommendations through the Relative Value Update Committee (RUC).

Another group within CM, the Chronic Care Policy Group (CCPG), develops and maintains payment systems for post-acute care services (e.g., inpatient rehabilitation facilities, inpatient psychiatric facilities, skilled nursing facilities, home health agencies, and hospice care), renal dialysis, and durable medical equipment used outside of hospital outpatient departments and ambulatory surgical centers. This group contains six Divisions:

- The Division of Home Health, and Hospice, develops and evaluates Medicare policies and standards on payment for the home health and hospice programs.
- The Division of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy maintains and updates level II of the HCPCS code set. The Level II HCPCS is a national standard code set adopted under HIPAA for use by all payers (Medicare, Medicaid, and private insurers) and used primarily to identify products, supplies, and services not included in the Current Procedural Terminology, 4th Edition (CPT-4) codes. This Division also develops and evaluates Medicare policies and standards on payment methods for items and services furnished by DMEPOS suppliers and the scope of benefits for DMEPOS.
- The Division of DMEPOS Competitive Bidding is responsible for developing, implementing, and maintaining national payment and operational policies for the Medicare DMEPOS competitive bidding program.
- The Division of Institutional Post-Acute Care develops and evaluates Medicare policies,

standards on payment methods, and the scope of benefits for services provided by both skilled nursing facilities and inpatient rehabilitation facilities.

- The Division of Chronic Care Management develops, evaluates, and reviews payment policies, regulations, and instructions concerning services for renal dialysis, partial hospitalization at community mental health centers and hospitals, and religious non-medical healthcare institutions. In addition, this Division develops and evaluates Medicare policies and standards on payment methods for services provided by inpatient psychiatric facilities.
- The Division of Technical Payment Policy develops, updates, and evaluates policies designed to improve the functioning of the Medicare program, engages in activities that promote the efficiency and quality of services delivered by providers, and works on initiatives to facilitate beneficiary access to care. This Division develops policies concerning assignment and reassignment of benefits, mandatory claims submission, limiting charge, beneficiary signatures on claims, timely filing, physician self-referral law, and appeals before the Provider Reimbursement Review Board.
- The Division of Cost Reporting develops and evaluates national policies, regulations, and instructions for payment/reimbursement of the costs incurred by providers of services and other classes of facilities under the Medicare program. This Division develops policies pertaining to the use of all cost reporting forms, schedules, and related instructions necessary for paying health care institutions. This Division also is responsible for certain policies concerning reimbursement for costs claimed by organ procurement organizations (OPOs) and hospital-based OPOs.

Center for Program Integrity

The Center for Program Integrity (CPI) is responsible for the prevention and detection of fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Program integrity activities target the range of causes of improper payments, from mistakes such as incorrect coding or erroneous billing practices, to providing medically unnecessary services or intentional deception by billing for services that were never provided. CPI provides instructions to contractors carrying out these activities including; Medicare Administrative Contractors (MACs), Program Safeguard Contractors (PSCs), Zone Program Integrity Contractors (ZPICs), Medicaid Integrity Contractors (MICs), and Recovery Audit Contractors (RACs).

Center for Medicare and Medicaid Innovation (Innovation Center)

The Innovation Center was established by section 1115A of the Social Security Act (as added by Section 3021 of the Affordable Care Act). Congress created the Innovation Center for the purpose of testing “innovative payment and service delivery models to reduce program expenditures ...while preserving or enhancing the quality of care” for those individuals who receive Medicare, Medicaid, or CHIP benefits. Congress provided the Secretary of DHHS with the authority to expand the scope and duration of a model being tested through

rulemaking, including the option of testing on a nationwide basis. In order for the Secretary to exercise this authority, a model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits. These determinations are made based on evaluations performed by CMS and the certification of CMS's Chief Actuary with respect to spending.

The Innovation Center is currently focused on the following priorities:

- Testing new payment and service delivery models
- Evaluating results and advancing best practices
- Engaging a broad range of stakeholders to develop additional models for testing

Council for Technology and Innovation

The CTI was established in 2004 under Section 942(b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) to serve as a coordination point for those components of CMS that are responsible for policy development and implementation affecting new and emerging medical technology, and to coordinate the exchange of information on new technology between CMS and other entities that make similar decisions. The CTI is composed of senior CMS staff and clinicians and is chaired by an Executive Coordinator appointed by the Secretary of DHHS. CTI facilitates discussions on coverage, coding, and payment issues of unusual complexity or controversy; accelerates and improves coordination of these processes; improves supply of evidence for new medical technologies; and facilitates the exchange of information with other federal agencies to devise clinical trials or registries that better meet the evidence needs to support coverage, coding, and payment decisions.

Openness and Transparency of Processes

CMS maintains open channels of communication between outside entities and CMS components charged with making coverage, coding, and payment decisions. CMS continues to preserve liaisons with beneficiaries, provider groups, industry associations, patient organizations, medical associations, investors, and other parties that relate to their assigned subject areas.

CMS periodically hosts Open Door Forums or Town Hall Meetings in order to better hear from and interact with those providers, beneficiaries, manufacturers, and other stakeholders interested in coverage, coding, payment, and other issues. These forums encourage dialogue between CMS officials and stakeholders about policies under development or issues that arise with existing procedures. Notice of Town Hall Meetings is published in the *Federal Register* and specific information about Open Door Forums can be found on the CMS website at: <http://www.cms.hhs.gov/opendoorforums/>.

Many CMS policies are developed with the assistance of advisory committees or in collaboration with outside groups. Meetings of these groups are usually held in a public forum and interested parties may be invited to participate or comment. These groups include,

but are not limited to, the Medical Evidence Development & Coverage Advisory Committee (MEDCAC), the Advisory Panel on Hospital Outpatient Payment (HOP Panel), the National Committee on Vital and Health Statistics (NCVHS), and the American Hospital Association Editorial Advisory Board for the Coding Clinic. Activities of these and other groups that help CMS develop policies for new health care technologies and ways that interested parties may stay informed of their activities are described in more detail in subsequent chapters of this guide.

Coordination with Outside Entities

CMS is strengthening its ties to health care technology stakeholders by developing collaborations with organizations that facilitate health care innovation. Collaborations help provide early insights into emerging technologies that may play a major role in reducing disease burden or improving health in the future.

CMS is working to speed Medicare beneficiary access to new and innovative medical products through closer coordination with the U.S. Food and Drug Administration (FDA). The Agencies are also exploring ways to ensure that when CMS needs to make coverage, coding, and/or payment decisions, it has access to timely and accurate FDA information regarding the technology at issue.

Increased Beneficiary Involvement

CMS has taken steps to encourage communication with beneficiary advocates in order to inform policy decisions. In June 2005, CMS appointed six patient advocates to the MEDCAC as voting members, at least one of whom sits on each MEDCAC panel. Industry representatives maintain their non-voting status and also participate in the MEDCAC reviews.

A Look to the Future

CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost. Our vision of future success in fulfilling this charge is moving from a fee-for-service payment system towards a value-based payment system. The last chapter of this guide provides a brief description of several Medicare programs designed to promote and measurably improve care and population health by transforming Medicare into an integrated and accountable delivery system that continuously improves care, reduces unnecessary costs, and promotes health.

Contact Information

Information on CTI initiatives and activities is located on the CMS website at http://www.cms.hhs.gov/CouncilonTechInnov/01_overview.asp . Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want guidance about how they can navigate these processes, can contact the Council at CTI@cms.hhs.gov .

COVERAGE

➤ *For information on Coverage:*

- <http://www.cms.gov/CoverageGenInfo/>
- <http://www.cms.gov/center/coverage.asp>

Medicare covers items and services when specifically required by Congress or by using several policy options that include national coverage determinations (NCDs), local coverage determinations (LCDs), rulemaking, and claim-by-claim adjudication. In general, in order for an item or service to be considered for Medicare coverage, the item or service must fall within at least one benefit category established in the Act, the item or service must not be specifically excluded by the Act, and the item or service must be “reasonable and necessary” (R&N). This chapter provides general and historical information concerning the NCD process, and summarizes the LCD process.

National Coverage Determination

NCDs are developed by CMS to describe the nationwide conditions for Medicare coverage for a specific item or service. NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under §1862(a)(1) of the Act or other applicable provisions of the Act. NCDs are issued as program instructions. Once published in a CMS program instruction, an NCD is binding on all Medicare Administrative Contractors (MACs), Quality Improvement Organizations (QIOs), Qualified Independent Contractors (QICs), Administrative Law Judges (ALJs), and the Medicare Appeals Council.¹ Similarly, an NCD is binding on Program Safeguard Contractors (PSCs).²

Medicare Advantage (Part C) health plans are required to cover all items and services that are offered under Part A and Part B. Thus, plans must cover items and services that are covered under an NCD. NCDs do not apply to Part D plans.

NCD Process

➤ *For information on the NCD process, including information on submitting an NCD request:*

<http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html>

The NCD process consists of three major steps: 1) initiation, 2) review, and 3) completion. CMS initiates the NCD process by “opening” the NCD. This is announced to the public by posting a “tracking sheet” on the CMS coverage web site. NCD reviews pertain to reviews of particular items and services to determine whether they meet the statutory requirements. Development of a complete, formal request for an NCD can be initiated either by an outside party or internally by CMS staff.

¹ See 42 CFR §405.732, 42 CFR §405.860, and 42 CFR §405.1060

² See Program Integrity Manual, Chapter 13, §13.1.1

Time Frames

Time frames required for the NCD process are statutory, as mandated by the MMA. The time frame does not begin until CMS formally accepts an NCD request. In the event that CMS has a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources. Once a completed request is accepted, CMS notifies the requester and posts a tracking sheet announcing the NCD review on the CMS coverage website.

For NCD requests not requiring an external technology assessment (TA) or Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) review, CMS must post a proposed decision no later than six months after the date CMS accepts the completed formal request. For NCDs that require either a TA or MEDCAC review, or both, the proposed decision must be posted no later than nine months after the date CMS accepts the completed request. The NCD process timeline is illustrated in a schematic located at the end of this chapter and also at <http://www.cms.hhs.gov/DeterminationProcess/Downloads/8a.pdf>.

Technology Assessments

Technology Assessments (TAs) are systematic reviews of evidence, conducted and coordinated by CMS staff to review relevant evidence and inform a determination if the item or service is reasonable and necessary. To minimize bias, systematic reviews emphasize a comprehensive search of all potentially relevant medical and scientific articles and use explicit, reproducible criteria in the selection of articles for review. Primary research designs and study characteristics are appraised in accordance with a hierarchy of medical evidence. Data are summarized and the evidence is appraised to assess its validity (how credible it is), clinical relevance (its applicability in real health care settings), and weight (magnitude of effect).

CMS staff generally performs TAs internally but may contract with an external party to perform a TA. A guidance document on the CMS website describes the factors CMS considers in commissioning external TAs, posted at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=7>

Medicare Evidence Development & Coverage Advisory Committee

- *For information on MEDCAC:*
<http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html>

For coverage topics that are highly controversial or have a major potential impact on the Medicare program or its beneficiaries, CMS may draw on the expertise of the MEDCAC. The primary role of the MEDCAC is to provide independent, expert advice to assist CMS in making sound coverage decisions for the topic under review. The MEDCAC reviews and evaluates medical literature and TAs, listens to testimony, deliberates, and provides CMS with recommendations as to the strength of the evidence reviewed.

The CMS website contains an overview of the MEDCAC; a guidance document entitled *Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee*; the MEDCAC's charter; the 1998 *Federal Register* notice that established the MEDCAC (formerly known as the MCAC); the current roster of MEDCAC members; and other informational materials.

Decision Memoranda

CMS posts on its website proposed and final decision memoranda. The decision memoranda inform interested parties of CMS' analysis, describe the clinical position that CMS intends to implement, and provide background on how CMS reached its decision.

NCD Implementation

The NCD is the formal instruction to the Medicare claims processing contractors regarding how to process claims (e.g., when to pay, when not to pay, pay only when certain clinical conditions are met). Appropriate payment or other changes to accommodate the coverage decision are effective at the time a final decision is posted to the CMS website. In most instances CMS implements an NCD through the change management process and provides detailed coding and billing instructions. The instructions specify appropriate coding and detail how the NCD criteria are to be implemented in the claims processing systems. Those instructions have a specific effective date dictating when claims will be processed according to the new criteria. The contractors implement the NCD within their own jurisdictions and may subsequently develop LCDs or policy articles to supplement the NCD.

Coverage with Evidence Development

- *For information on Coverage with Evidence Development:*
<http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>

Coverage with Evidence Development (CED) is a coverage decision made through an NCD. These NCDs require additional data collection, such as data collected in a clinical trial, as a condition of coverage. The purpose of CED is to provide Medicare coverage for a particular item or service and to develop evidence of its impact on the health of Medicare beneficiaries. Examples of NCDs that require CED are Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnea and NaF-18 Positron Emission Tomography to Identify Bone Metastasis of Cancer.

Local Coverage Determination

The term 'local coverage determination' means a determination by a Medicare Administrative Contractor (MAC) under Part A or Part B, as applicable, regarding whether or not a particular item or service is covered on a contractor-wide basis under such parts, in accordance with 1862(a)(1)(A). LCDs may be developed in the absence of an NCD or as a

supplement to an NCD as long as the LCD policy does not conflict with national policy.

Local Coverage Determination Time Frames

Unlike the NCD time clock that begins with the acceptance of a formal request to open an NCD, the time clock for an LCD begins with the initiation of a minimum 45-day comment period following publication of a new draft LCD or a revision to a LCD that makes a substantial change. During this time, comments on the draft LCD must be solicited from several outside parties, including affected health professionals, other contractors, providers, and QIOs. In addition to the draft LCD comment period, contractors provide open meetings for the purpose of discussing draft LCDs prior to presenting the policy to the Contractor Advisory Committee (CAC). Once the contractor has considered all the comments and developed the final LCD, a minimum notice period of 45 days is required prior to the effective date of implementation.

Reconsiderations and Appeals

Reconsiderations of NCDs and LCDs

Any interested party may request a reconsideration of the benefit category determination or any provision of an existing NCD or LCD by submitting a formal request in writing to CMS or the local contractor, respectively. A formal request for reconsideration must include either (1) new information that was not considered during the initial determination, or (2) arguments that the NCD or the LCD decision materially misinterpreted the applicable statutory provisions, the applicable regulatory provisions, or the existing evidence at the time the determination was made. Contractors must consider all LCD reconsideration requests from beneficiaries residing or receiving care in the contractor's jurisdiction; providers doing business in the contractor's jurisdiction; and any interested party doing business in the contractor's jurisdiction. A reconsideration request – once accepted– goes through the same process as an initial NCD or LCD. The reconsideration process permits experts to re-evaluate the evidentiary basis for a decision.

Appeals of NCDs and LCDs

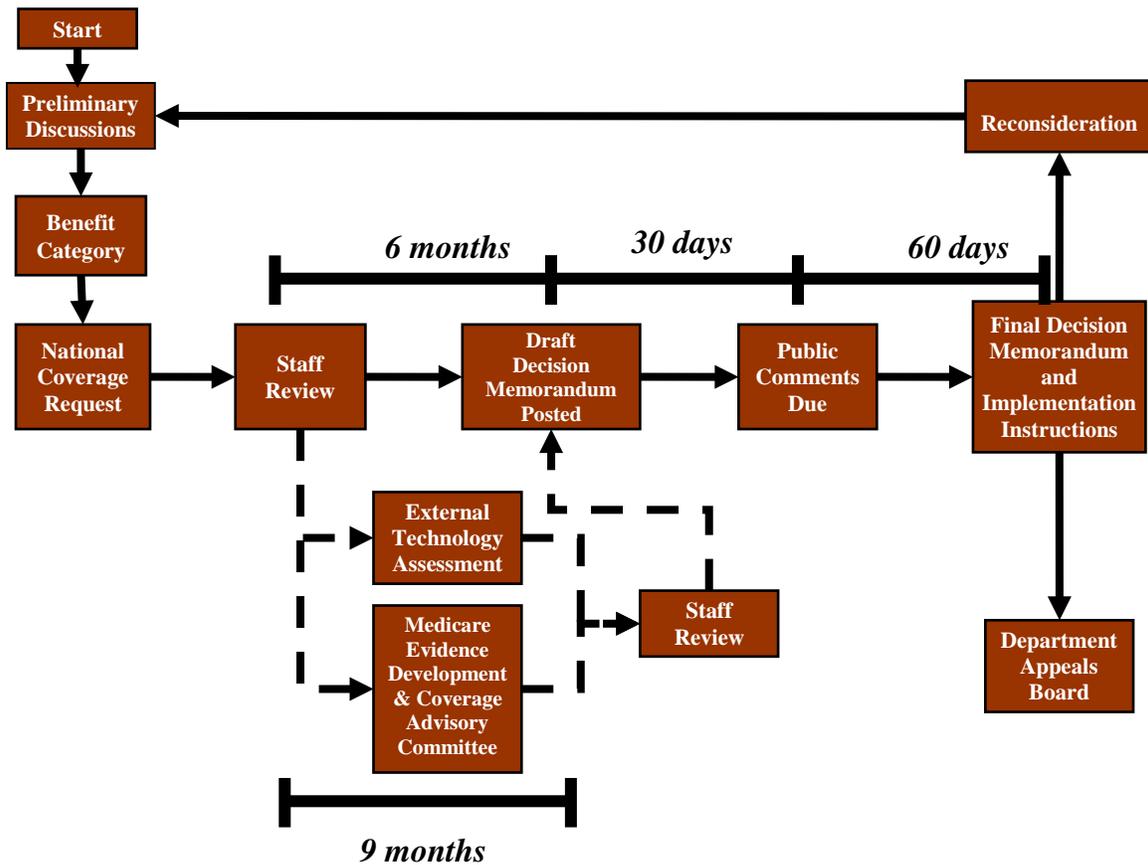
Distinct from reconsiderations of NCDs and LCDs or appeals of claims denials, section 1869(f) of the Act creates a process of independent review for beneficiaries to challenge NCDs and LCDs. These independent reviews are subject to strict limitations. Only an aggrieved party may seek review of an NCD or LCD. An "aggrieved party" is a beneficiary (or the estate of a beneficiary) who is entitled to Part A benefits, enrolled under Part B, or both, and is in need of coverage for an item or service that is denied based on the applicable NCD or LCD (regardless of whether or not the item or service was received) and has received written documentation from the treating physician of the need for the item or service.³ Regulations governing the review of NCDs and LCDs are established at 42 CFR Part 426.

³ The aggrieved party may also be the estate of such a beneficiary who filed a timely complaint prior to death.

Appeals of Claim Denials

Any beneficiary has the right to appeal a claim denial. This process, established at 42 CFR Part 405, Subpart I, results in the review of an individual claim denial, but it does not include a review of the validity or underlying evidentiary basis for an NCD and LCD.

National Coverage Determination Process Schematic



CODING

➤ *For information on Coding:*

- <http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/>
- <http://www.cms.hhs.gov/MedHCPCSGenInfo/>
- <http://www.cms.hhs.gov/ICD10/>

The Medicare program accounts for about 20 percent of all health care spending in the United States. Use of standardized coding systems is essential for Medicare and other health insurance programs to ensure that claims are processed in an orderly and consistent manner. Standardized coding systems provide a uniform language for nationwide communication of medical, surgical, and diagnostic items and services for use in medical education, research, and development of guidelines for medical care review.

A major goal of an effective code set is to strike a balance that sufficiently identifies and differentiates items and services, and also results in a manageable system that health care professionals and administrative staff can efficiently use in submitting claims. Regular and other planned updates that accommodate new technology and changes in medical practice, without the administrative burden to health care providers of sporadic updates, increases confidence that the most current code sets are utilized.

Coding is distinct from coverage of a new technology; assignment of a new code does not automatically imply coverage by any payer. However, for items and services newly covered by Medicare, CMS may assign either an existing code that describes a similar item or service, a miscellaneous code (e.g., a not elsewhere classified code or a not otherwise specified code), or a new code for payment purposes, whichever is appropriate based upon HCPCS coding criteria as applied to the individual technology.

This chapter discusses the coding systems used on Medicare claims; the statutory authority for coding use; general principles for coding updates; and a description of the ICD-9-CM and HCPCS code sets, including how to request a coding change, operational guidance, and a look to the implementation of ICD-10 on October 1, 2015. A chart that compares the application cycles for new and revised code sets is located at the end of this chapter.

Statutory Authority - HIPAA

Recognizing the increasing role of electronic transactions between providers and insurers and the confusion and inefficiencies resulting from diverse ways of handling these transactions, the Congress required, in the administrative simplification title of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), adoption and use of national standards governing the nature and content of electronic transactions. This guide will focus on the HIPAA requirements related to national code sets, including associated operational guidelines.

To meet the HIPAA requirements for the adoption of transaction and code set standards, the

Secretary of DHHS, in a final rule issued in the August 17, 2000 *Federal Register*, designated six code sets as national standard code sets for use in standard electronic transactions throughout the United States:

- International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM) Volumes 1 and 2 (tabular list and alphabetic index, respectively, of diseases);
- ICD-9-CM, Volume 3, (tabular list and alphabetic index of procedures);
- Healthcare Common Procedure Coding System (HCPCS);
- Current Procedural Terminology (CPT), 4th Edition
- National Drug Codes (NDC); and
- Code on Dental Procedures and Nomenclature.

All entities covered by the HIPAA administrative simplification requirements, including health plans and health care providers, were required to be in compliance with the electronic transactions code set standards by October 16, 2003.

The HIPAA requirements were updated to implement ICD-10 as a replacement of ICD-9-CM for services provided on or after October 1, 2014. This issue was described in a final rule in the September 5, 2012 *Federal Register*: <http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf>. The Protecting Access to Medicare Act of 2014, delayed implementation one year. The HIPAA requirements were updated to implement ICD-10 as a replacement of ICD-9-CM for services provided on or after October 1, 2015 in the August 4, 2014 *Federal Register*: <http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf>.

ICD-9, ICD-10, and HCPCS Coding Systems

The following standardized coding systems are used for processing Medicare claims:

- ICD-9-CM (replaced by ICD-10 effective October 1, 2015); and
- HCPCS. HCPCS is divided into two principal subsystems:
 - Level I, comprised of CPT codes
 - Level II

ICD-9-CM and ICD-10-CM consist of codes for diagnoses and for hospital inpatient procedures. HCPCS consists of codes for items and services furnished in settings other than hospital inpatient, such as hospital outpatient departments, physicians' offices, and patients' homes.

General Principles for Coding Updates

The ICD and HCPCS code sets are updated at least annually and in some cases more frequently. Each code set has a standardized, open process for developing new, unique codes as necessary. In most instances new technologies can be adequately described by existing

codes, but in other cases new or revised codes may be warranted. The frequency of updates reflects a balance between the desire to rapidly recognize new technology within code sets and the need to provide users of the code sets with a stable, predictable update and business cycle. When code sets are updated, the updates must be disseminated, coding manuals revised, and medical records, billing software, and other systems changed to accommodate the new and revised codes. Coders must be educated on and prepared for changes in codes to ensure they are accurately utilizing the codes to best describe the diagnoses identified and the items and services delivered. Planned update cycles allow providers to prepare for and manage the necessary changes in coding practices and systems. The process for requesting updates to each code set is described in greater detail below. Also, refer to the Code Set Comparison Chart at the end of this chapter for a timetable of key milestones for each code set.

ICD-9 and ICD-10

- *For information on ICD-9-CM:*
<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/>

- *For information on ICD-10:*
 - <http://www.cms.hhs.gov/ICD10/>
This page provides annual updates to ICD-10-CM and ICD-10-PCS as well as official coding guidelines.
 - http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/ICD9ProviderDiagnosticCodes/03_meetings.asp

The ICD-9-CM is a modified version of the ICD-9 system developed by the World Health Organization. CM refers to a “clinical modification” developed for the United States, where it has been in use since 1979. ICD-9-CM contains three volumes of information. Volume 1 contains the diagnosis codes that every health care provider needs for billing. Volume 2 is an alphabetical index of Volume 1. Volume 3 contains procedure codes, which are used for billing inpatient hospital stays in the Medicare Severity-Diagnosis Related Group (MS-DRG)⁴ payment system. ICD-9-CM procedure codes describe the procedure performed and may also indicate insertion of a device, such as a pacemaker or hip replacement. Procedure codes do not specifically describe all the devices and products used during a procedure, such as wound closing devices, specific catheters, or surgical tools.

Effective on October 1, 2014 (for FY 2015), the ICD-9-CM code set includes 14,567 diagnosis codes and 3,882 procedure codes, or a total of 18,449 codes. The ICD-9-CM code updates effective on October 1, 2014 were the last updates to ICD-9-CM. As stated earlier, on October 1, 2015, ICD-10 will replace ICD-9-CM.

Responsibility for maintaining the ICD-9-CM and ICD-10 is divided between two agencies in HHS: (1) the National Center for Health Statistics (NCHS) within the Centers for Disease

⁴ MS-DRGs are discussed in greater detail in the Payment chapter and also in the Acute Inpatient Prospective Payment System Fact Sheet located on the CMS website:
<http://www.cms.hhs.gov/MLNProducts/downloads/AcutePaymtSysfetsht.pdf>.

Control and Prevention for maintenance of the classification of diagnoses, and (2) the CMS for maintenance of the classification of procedures. Since the federal government maintains the ICD-9-CM and ICD-10 code set, it is in the public domain, and providers, insurers, and others can use the system without paying user fees.

The ICD-10 Coordination and Maintenance Committee

- *For information on the ICD-10 Coordination and Maintenance Committee, addenda, and summary reports:*
 - <http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html>
 - http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

The ICD-10 Coordination and Maintenance (C&M) Committee (formerly the ICD-9-CM C&M Committee), co-chaired by representatives from NCHS and CMS, considers requests to create new ICD-10-CM (diagnosis) and ICD-10-PCS (procedures) codes or to revise codes for greater utility. The C&M Committee holds public meetings twice a year, generally in March and September, to discuss proposed revisions. The C&M Committee's role is advisory, and no decisions are made at these meetings. The Director of NCHS and the Administrator of CMS make all final diagnosis and procedure coding decisions, respectively.

Information on the C&M Committee meetings is posted on the CMS and CDC websites. The agenda for upcoming meetings is posted approximately one month prior to the meeting. Official code revision packages, which are referred to as addenda, and summary reports are available on the CMS website for procedure codes and the NCHS website for diagnosis codes. Summary reports from the most recent meeting include the deadline for comments, the scheduled dates for the next meeting, the deadline for receipt of modification proposals, and the mailing address and e-mail address to submit either modification proposals or comments on proposals.

Process for Requesting a Revision to ICD-10 Codes

- *For information on how to request new/revised ICD-10 codes:*
 - <http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/newrevisedcodes.html>
 - http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

Interested parties are instructed to submit recommendations for ICD-10 modification to the C&M Committee two months prior to a scheduled meeting. Proposals for new codes should include a description of the requested code and the rationale for why the new code is needed. [See side box.] Supporting references and literature may also be submitted. Proposals should be consistent with the structure and conventions of the classification system.

Upon review of the request, a decision is made on whether to include the topic on the meeting agenda. If included, a lead coding analyst is assigned and will contact the requestor to discuss the submitted proposal. A background paper, including CMS recommendations on proposed coding revisions, is shared with the requestor prior to the meeting. The requestor is

given the opportunity (or may select a speaker) to make a presentation on the clinical nature of the procedure at the upcoming C&M meeting. Speakers are allowed approximately 20 minutes to present the topic. The lead coding analyst then leads a discussion of possible code revisions, including alternative suggestions for consideration. No decisions are made at the meeting.

Public comments are encouraged both at the meetings and in writing. The meeting participants are encouraged to ask questions concerning the clinical and coding issues and to offer recommendations. A summary report is posted on the CMS website within approximately one month of the meeting. The public is offered an opportunity to make additional written comments by mail or e-mail before the end of the comment period imposed by the C&M Committee.

Recommendations and comments are carefully reviewed and evaluated before any final decisions are made by NCHS or CMS. Finalized code revisions and proposed MS-DRG assignments are published in the IPPS notice of proposed rulemaking (NPRM) on or around April 1 of each year. The public may not comment on the listed codes because they are final, but may comment on the proposed MS-DRG assignments during the IPPS NPRM comment period. Due to timing constraints, proposals from the Spring C&M meeting may not be finalized for inclusion in the IPPS proposed rule.

The IPPS final rule, published on or about August 1 of each year, includes the finalized MS-DRG assignments and repeats the finalized codes. The codes that were finalized after the spring publication of the proposed IPPS rule appear in the final rule with an asterisk by the code number. Beginning with the implementation of ICD-10 on October 1, 2015, the FY 2016 IPPS final rule will include finalized MS-DRGs assignments for new and revised ICD-10-CM and ICD-10-PCS codes. Publishers and vendors then prepare ICD-10-CM and ICD-10-PCS coding books, software, and other publications. The revised codes are implemented on October 1 of each year to coincide with the updating of the IPPS.

New technology coding topics presented during the Fall C&M Committee meeting are considered for an April 1 implementation if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the IPPS new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are

Request for an ICD-10 Procedure Code

A request should include:

- Background information on the procedure
- Patients on whom the procedure is performed
- Outcomes and any complications
- Manner in which the procedure is currently coded
- Discussion of reasons the existing ICD-10-PCS codes do not adequately capture the procedure
- Recommended options for new or revised code titles

Examples of procedure code papers can be found in C&M meeting materials of previous meetings located on the CMS website at <http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html?DLSort=0&DLEntries=10&DLPages=1&DLSortDir=descending>

provided an opportunity to comment on the expedited request. The April 1 implementation exception for new technology, though available since 2004, has not yet been utilized.

ICD-9 and ICD-10 Coding Guidance

The official ICD-9 and ICD-10 coding guidelines are posted on the National Center for Health Statistics (NCHS) website at: <http://www.cdc.gov/nchs/icd.htm>

Operational coding advice and guidelines for ICD are published quarterly by the American Hospital Association (AHA) in the *Coding Clinic*. The Editorial Advisory Board (EAB) for *Coding Clinic* consists of representatives of AHA, the American Health Information Management Association (AHIMA), NCHS, CMS, the American Medical Association (AMA), the American College of Surgeons, and other hospital coders and physicians. Four of those parties (AHA, AHIMA, NCHS, and CMS) are identified as Cooperating Parties for *Coding Clinic*. The Cooperating Parties must agree on the coding guidance before it can be published in the *Coding Clinic*. Anyone may send issues to AHA for EAB discussion. Information on submitting coding questions can be found at <http://www.ahacentraloffice.org/ahacentraloffice/shtml/RequestCodingAdvice.shtml>

The official ICD-10-CM coding guidelines are posted on CDC's website at <http://www.cdc.gov/nchs/icd/icd10cm.htm>. The ICD-10-PCS coding guidelines are posted with the annual updates to ICD-10-PCS on CMS' website at <http://www.cdc.gov/nchs/icd/icd10cm.htm>

AHA supplies copies of the *Coding Clinic* to the Recovery Audit Contractors (RACs) for use as official coding advice in reviewing the accuracy of coding for Medicare claims submitted by hospitals. Copies for a fee are also available on the AHA website: www.ahacentraloffice.org.

Managing the Transition from ICD-9 to ICD-10

ICD-9-CM, which is over 36 years old, exhibited technical obsolescence. One aspect of this problem was a significant limitation on the availability of new codes to accommodate new technology and changes in medical practice. On January 16, 2009, DHHS issued regulations through notice and comment rule-making to replace ICD-9-CM as a national standard code set with an updated version called ICD-10-CM for identifying diagnoses and the ICD-10-Procedure Coding System (PCS) for identifying procedures. The effective date was March 17, 2009. The compliance date for these provisions was originally October 1, 2013; however, as stated earlier, it was changed to October 1, 2015 through formal rulemaking.

The ICD-10-PCS/CM encompasses an updated hierarchical structure and uses seven-character alphanumeric codes permitting a more detailed and flexible inpatient coding system. The following summary describes specific information about the timeline for the partial code freeze for ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) as the transition to ICD-10 (ICD-10-CM and ICD-10-PCS) begins. For the FY 2015 draft there were 69,823 ICD-10-CM diagnosis codes and 71,924 ICD-10-PCS codes.

Partial Code Freeze for ICD-9-CM and ICD-10 from October 1, 2012 through October 1, 2015

The ICD-9-CM Coordination and Maintenance Committee implemented a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10 on October 1, 2015. There was considerable support for this partial freeze. The partial freeze was implemented as follows:

- The last regular, annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014, there were only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108-173.
- On October 1, 2015, there will be only limited code updates to ICD-10 code sets to capture new technologies and diagnoses as required by section 503(a) of Pub. L. 108-173. There will be no updates to ICD-9-CM, as it will no longer be used for reporting.
- On October 1, 2016, regular updates to ICD-10 will begin.

HCPCS

- *For information on HCPCS:*
<http://www.cms.gov/MedHCPCSGenInfo/>

HCPCS⁵ is the standard code set for items and services furnished in settings other than hospital inpatient, such as physicians' offices, hospital outpatient departments, and patients' homes. The HCPCS code set is divided into two principal subsystems, referred to as Level I and Level II. Level I consists of the CPT, an alpha-numeric coding system maintained by the AMA to identify medical services and procedures furnished by physicians and other health care professionals. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the Level II HCPCS codes were established for use in submitting claims for these items. Level II codes are maintained and distributed by CMS, taking into consideration input from all insurers including Medicare, Medicaid, and private payer organizations.

⁵ Prior to 2001, this code set was called the HCFA Common Procedure Coding System after the previous name of the Agency. In 2001, the former Health Care Financing Administration (HCFA) became the Centers for Medicare & Medicaid Services.

Level I HCPCS - Current Procedural Terminology

The AMA developed the Current Procedural Terminology (CPT) in 1966, and the version currently in use is the fourth edition. There are three categories of CPT codes:

- Category I codes consist of five numeric digits and represent procedures and services performed by physicians, other health care professionals, and facilities. Category I codes are divided into six sections: Evaluation and Management; Anesthesiology; Surgery; Radiology; Pathology and Laboratory; and Medicine. Each section is further divided into subsections based on anatomic system, procedure or condition.
- Category II codes are performance measurement codes that support data collection for services that are generally agreed to contribute to positive health outcomes. Category II codes have five characters – four numbers and then the letter F.
- Category III codes are emerging technology codes that support data collection for services that do not yet have FDA approval or are not widely used. Category III codes have five characters – four numbers followed by the letter T.⁶

Requesting a Revision to Level I HCPCS (CPT)

➤ *For information on how to apply for a CPT code:*

<http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page>

Proposals to add, modify, or delete CPT codes are considered by the CPT Editorial Panel, a 17-member group comprised of representatives from the AMA, private health insurers, the American Hospital Association, the Health Care Professionals Advisory Committee, and CMS. The CPT Editorial Panel is supported in its efforts by the CPT Advisory Committee, which is made up of representatives of more than 90 medical specialty societies and other health care professional organizations.

The CPT Editorial Panel meets regularly, at least three times a year. Applications for new codes are accepted on a rolling basis but proposed CPT changes must be received at

CPT Coding Request

The AMA recommends that parties interested in requesting a CPT code answer several questions before submitting a request:

- Is the suggestion a fragmentation of an existing procedure/service?
- Can the suggested procedure / service be reported by using two or more existing codes?
- Does the suggested procedure / service represent a distinct service?
- Why aren't the existing codes adequate?

Source: AMA website

⁶ Unlike Category I codes, the AMA Relative Value Update Committee (RUC) does not make recommendations for relative values relation to resource use for Category II and Category III Codes. (The AMA RUC provides information on resource use to be used in establishing relative weights under the Medicare Physician Fee Schedule, which is described in the Payment chapter.)

least four months in advance for consideration at the next meeting. An application form and directions to request changes to CPT are available on the AMA website.

Category I CPT codes are updated annually to reflect changes in medical technology and practice. Coding changes are effective for use on January 1 of each year. The AMA prepares each annual update so that the new CPT books are available in the fall of each year preceding their effective date to allow for implementation.

Level I HCPCS – Early Release

Category I vaccine product codes, Molecular Pathology, and Category III codes are typically “early released” for reporting either January 1 or July 1 of a given CPT cycle and become effective six months subsequent to the date of release, e.g., codes released on January 1 are effective July 1, allowing 6 months for implementation, and codes released on July 1 are effective January 1.

Category II codes are typically "early released" for reporting three times yearly approximately 3 weeks following approval of the Panel minutes after each CPT Editorial Panel Meeting. The effective dates for these codes are three months subsequent to the date of release, e.g., codes released by April 1 are effective July 1, allowing 3 months for implementation.

CPT Coding Guidance

- *For information on CPT coding guidance:*
<http://catalog.ama-assn.org/Catalog/home.jsp?checkXwho=done>

The AMA produces a number of CPT manuals and publications. A catalog of their products is available on the AMA website. CPT is copyrighted by the AMA. The AMA requires a license to use CPT in a product or publication. Information on the licensing agreement is available on the AMA website.

In 2005, the AHA and CMS entered into an agreement for the establishment of a Clearinghouse to handle inquiries on established HCPCS usage and to publish the results of those inquiries to assist providers in properly using established HCPCS codes. The purpose of the Clearinghouse is to provide interpretation and explanation on the proper use of Level I HCPCS (CPT-4) codes for hospital providers and certain Level II HCPCS codes for hospitals, physicians, and other health professionals who bill Medicare.

CMS works closely with the AHA and the AMA to promote consistency of interpretation of the basic principles of HCPCS coding by institutional providers, and to prevent any wide divergence between HCPCS coding by institutional providers and the recommendations made by the AMA’s CPT-4 advisory panel for the physician community. The AHA Clearinghouse is supported by the HCPCS Editorial Advisory Board (EAB) and functions in a manner similar to the Coding Clinic for ICD-9-CM. Coding guidance provided by the HCPCS EAB is published quarterly by the AHA in the *Coding Clinic for HCPCS*. CMS is

working with the AHA, AHIMA, and other members of the HCPCS EAB to develop the Clearinghouse into the kind of valuable resource for users of HCPCS that the Coding Clinic has become for ICD-9-CM users.

Level II HCPCS

Level II HCPCS codes are used primarily to identify products and services not included in the CPT codes, such as drugs and biologicals, or DMEPOS used in settings other than hospital inpatient, such as hospital outpatient departments, physicians' offices, and patients' homes. The development and use of Level II of the HCPCS began in the 1980's. Level II HCPCS codes are also referred to as alpha-numeric codes because they consist of a single alphabetical letter followed by four numeric digits.

Currently, Level II HCPCS codes represent approximately 5,500 separate categories of like items or services that encompass millions of products from different manufacturers. A descriptor is assigned to a code that provides the definition of the items and services that can be billed using that code. To avoid any appearance of endorsement of a particular product through HCPCS, brand or trade names generally are not used to describe the products represented by a code unless brand distinction is deemed necessary in order to facilitate compliance with Section 1847A of the Social Security Act, (e.g., as it pertains to single-source drugs).

Level II HCPCS are in the public domain and a free, downloadable file is available on the CMS HCPCS website at www.cms.gov/Medicare/Coding/medhcpcsgeninfo. Tape or disk versions can be purchased from the National Technical Information Service (NTIS) by phone at 703-487-4650 or by e-mail at orders@ntis.fedworld.gov. Paper copies can be purchased through the Government Printing Office (GPO). The American Dental Association (ADA) maintains and copyrights the Current Dental Terminology (CDT) code sets. CMS does not have an agreement with the ADA to include and publish CDT codes or dental codes (D codes) in the HCPCS Level II code set.

Permanent National HCPCS

Level II HCPCS includes several types of codes that have different purposes. The permanent national HCPCS code set is distributed and maintained by CMS. The CMS HCPCS Workgroup considers each coding request and recommends whether a change to the national permanent codes is warranted. Recommendations for a revision to the HCPCS are reviewed at regularly scheduled meetings of the CMS HCPCS Workgroup. CMS makes final HCPCS coding decisions. The HCPCS Decision Tree, developed by the CTI, is a helpful tool for determining if a new technology warrants a unique code and is posted on the CMS website at:

http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS_Decision_Tree_and_Definitions.pdf.

Permanent national codes are updated once a year on January 1. Codes are broken down into general categories that include a series of codes for drugs⁷, orthotics and prosthetics, vision services, etc. A list of the categories of permanent national codes appears in the side box.

Temporary National HCPCS

Like permanent national HCPCS codes, temporary national HCPCS codes are distributed and maintained by CMS. Temporary codes allow CMS the flexibility to establish codes that are needed to meet the national program operating needs of a particular insurer, (i.e., Medicare, Medicaid, private insurance sector), before the next January 1 annual update for permanent national codes or until consensus can be achieved on a permanent national code. Temporary codes are intended to meet the national program operational needs of a particular insurer (Medicare, Medicaid, or the private insurance sector) that are not addressed by an already existing national code. They are developed based on programmatic needs and cannot be requested by other parties. The CMS HCPCS Workgroup has set aside certain sections of the HCPCS code set for temporary codes for specific items or types of insurers (for example, G codes are used by Medicare to identify professional health care procedures and services that would otherwise be coded in CPT but for which there are no suitable CPT codes). [See side box.]

Temporary codes do not have established expiration dates. Although temporary codes may be established to meet the programmatic needs of specific payers, other payers may elect to use these codes.

Types of Permanent Level II HCPCS Codes*

- A codes** Ambulance, medical and surgical supplies, administrative, miscellaneous, and investigational
 - B codes** Enteral and parenteral nutrition
 - D codes** Current Dental Terminology (CDT) codes
 - E codes** Equipment
 - J codes** Drugs that are not self-administered and generally not administered orally, inhalation solutions, chemotherapy drugs
 - L codes** Orthotics and prosthetics
 - M codes** Other Medical Services
 - P codes** Pathology and laboratory services, and blood products
 - R codes** Diagnostic radiology services
 - U codes** Modifiers (There are currently no codes in this section.)
 - V codes** Vision Services (e.g., lenses), audiology, and speech-language pathology
- *"Miscellaneous" and "Not Otherwise Classified" codes exist in almost every alphabetic code section.

⁷ Medicare uses the 5 character alphanumeric HCPCS to identify Part B drugs rather than the 11-digit National Drug Codes (NDCs). NDCs are used by retail pharmacies and by state Medicaid agencies to identify drugs, and in Medicare Parts C and D. Some billing systems used by professional and institutional providers do not use NDC codes.

Temporary codes can be added, changed, or deleted on a quarterly basis. Once established, temporary codes for Medicare are usually implemented within 90 days, the time needed to prepare and issue policy and implementation instructions, enter the new code into the claims processing computer systems, and initiate user education. Quarterly updates to the Level II HCPCS codes can be found on the CMS HCPCS website.

Code Modifiers

In some instances, insurers instruct providers and suppliers that a HCPCS code must be accompanied by a code modifier to provide additional information regarding the service or item identified by the HCPCS code. Modifiers are used when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may

apply to an item or service and that may have implications for the level of or conditions of payment for a particular insurer. For example, a UE modifier is used when the DME item identified by a HCPCS code is "used equipment," a NU modifier is used for "new equipment." The level II HCPCS modifiers are either alpha-numeric or two letters.

Miscellaneous Codes

The absence of a specific code for a distinct category of products does not preclude a provider's or supplier's ability to submit claims to private or public insurers and does not affect patient access to products. Miscellaneous codes are available for assignment by insurers when there is no existing national code that adequately describes the item or service for billing. Miscellaneous codes allow providers and suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the FDA, even though there may be no distinct code that describes the service or item. A miscellaneous code may be

Types of Temporary Level II HCPCS Codes

- C codes** Items and services for outpatient use, including pass-through devices, pass-through drugs and biologicals, brachytherapy sources, and new technology and certain other services.
- G codes** Professional health care procedures and services that would otherwise be coded in CPT but for which there are no CPT codes.
- H codes** Mental health services for which State Medicaid agencies are mandated by State law to establish separate codes.
- K codes** Used by the DME MACs when permanent national codes do not include codes needed to implement a medical review policy.
- Q codes** Drugs, biologicals and other medical equipment or services not identified by national Level II codes, but for which codes are needed for Medicare claims processing.
- S codes** Used primarily by private insurers to report drugs, services, and supplies for which there are no permanent national codes, but for which codes are needed to implement policies, programs, or claims processing. Also may be used by Medicaid program, but typically not payable by Medicare.
- T codes** Used primarily by State Medicaid agencies for items for which there are no permanent national codes and for which codes are necessary to meet a national Medicaid program operating need. Typically not used by Medicare but can be used by private insurers.

assigned by an insurer for use while a request for a new code is being considered under the HCPCS review process, permitting establishment of a claims history to support the need for a national permanent code. The use of miscellaneous codes also helps avoid the inefficiency and administrative burden of assigning distinct codes for items or services that are rarely furnished or for which insurers expect to receive few claims.

Except for hospital outpatient claims, Medicare claims with miscellaneous codes are generally manually reviewed by the claims contractors. The provider must provide a clear description of the billed item or service, pricing information, and documentation to explain why the item or service is needed by the beneficiary. In most cases, under the hospital OPPS, unlisted procedure codes are assigned to the lowest level APC within the clinical category that includes the unlisted code. The assignment of an unlisted code to the lowest level APC in the clinical category in which the code falls provides a reasonable means for interim payment until such time as there is a code that specifically describes the services being performed and paid. It encourages the creation of codes where appropriate and mitigates against overpayment of services that are not clearly identified on the bill. For new technologies that encompass complete services but may not have yet been granted a specific HCPCS code, the New Technology APC payment mechanism is available under the OPPS, which is described in the Payment chapter.

Before using a miscellaneous code on a claim form, a provider or supplier should check with the entity that will receive the claim to determine whether there is a specific code that should be used rather than a miscellaneous code. Interested parties that believe a unique code is warranted should submit a request to modify the HCPCS in accordance with the established process.

Requesting a Modification to the Level II HCPCS Code Set

- *For information on the HCPCS application process:*
http://www.cms.gov/Medicare/Coding/MedHCPCSApplication_Form_and_Instructions.html

Any interested party may submit a request to modify the HCPCS Level II national code set. Detailed information regarding the process and the format for submitting a request is available on the CMS HCPCS website. In addition to the information requested in this format, a requestor should submit any descriptive material, including the manufacturer's product literature and information that is helpful in understanding the medical features of the item.

The HCPCS coding review process is an ongoing, continuous process. Requests may be submitted at any time throughout the year. Requests that are received and complete by January 3 of the current year (or by the following Monday if January 3 falls on a weekend) are considered for inclusion in the next annual update, with implementation, January 1 of the following year. Requests received or completed after January 3, and requests received earlier that require additional evaluation, are included in a later HCPCS review cycle.

Three types of coding revisions may be requested:

- Addition of a permanent code
- Revision of the language used to describe an existing code
- Discontinuation of an existing code

The CMS website includes a list of all public requests for modifications to the code set submitted in the current coding cycle along with CMS' preliminary coding decision and rationale. Interested parties may submit comments regarding these code requests and preliminary decisions to the CMS HCPCS Workgroup by sending an e-mail via the HCPCS website. CMS hosts a series of annual HCPCS public meetings that provide an open forum for interested parties to make oral presentations or submit written comments in response to the preliminary HCPCS coding decisions. Comments regarding code requests, received by the date of the public meeting at which the code request is discussed, are included as part of the Workgroup's review when it reconvenes to reconsider all requests on the public meeting agendas. Notice of HCPCS Public Meetings is published in the *Federal Register* each year.

HCPCS Level II Coding Guidance

➤ *The following resources are available on the CMS HCPCS website at:*

<http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/>

- HCPCS decision tree and definitions,
- current HCPCS, Quarterly and Annual Updates,
- alphabetical index of HCPCS codes by type of service or product,
- alphabetical table of drugs for which there are Level II codes,
- newly established temporary codes, and their effective dates,
- HCPCS Level II coding process information and criteria,
- HCPCS Level II code modification application and instructions,
- summaries of code applications,
- public meeting agendas and summaries, and
- HCPCS coding decision spreadsheets.

Other Code Sets

National Drug Code

➤ *For information on the NDC:*

<http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>

The National Drug Code (NDC) is a code set that identifies the vendor (manufacturer), product, and package size of all drugs and biologics recognized by the FDA. It is maintained and distributed by the FDA, in collaboration with drug manufacturers.

Code on Dental Procedures and Nomenclature

➤ *For information on the CDT:*

<http://www.ada.org/en/publications/cdt/>

Code on Dental Procedures and Nomenclature (CDT) is a separate category of national codes maintained and copyrighted by the American Dental Association (ADA). It lists codes for billing dental procedures and supplies. Decisions regarding the revision, deletion, or addition of CDT codes are made by the ADA and not the CMS HCPCS Workgroup. CDT manuals are available for purchase on the ADA website. Users of CDT codes must enter an agreement with the ADA.

CODE SET COMPARISON CHART							
CODE SET	Timing			Volume	Transparency		
	Application Deadline	Effective Date	Length of Cycle	Average Number of Applications in Cycle	Provide Detailed Application Summaries	Publish Preliminary Decisions	Public Input
HCPCS II	January 3	January 1 of the following year	12 months + Quarterly Updates	150	Yes – published at least 4 weeks prior to Public Meetings	Yes	Public Meetings Spring of each year
CPT	3 months prior to May, October, or February meeting see www.ama-assn.org	Cat. I: codes released Fall, eff Jan 1 ----- Cat I vaccine, MoPath, or III codes: Jan 1 or July 1 ----- Cat II codes: Feb 15, Jun 15, or Oct 15	15 months + Quarterly Updates	200 (Review is divided into committees and sub-committees, who report back to 1 group)	No	No	Public may attend voting meeting. Votes are silent.
CDT	November 1	Jan 1 of second year following receipt of application	14 to 17 months	120	Yes	No	Public may attend voting meeting. Votes are known.
ICD-9 And ICD-10	January (2 months prior to meeting)	October 1 of the following year	7 months	CMS processes 10 – 25 procedure applications NCVHS processes 25 diagnosis applications	Yes – provided at public meeting	No	Public Meeting March
	July (2 months prior to meeting)	October 1 of the following year (codes for New Tech can be implemented in following April)	13 months	CMS processes 10 – 25 procedure applications NCVHS processes 25- 35 diagnosis applications	Yes – provided at public meeting	No	Public Meetings September

PAYMENT

➤ *For information on Medicare FFS payment systems:*

- <http://www.cms.hhs.gov/home/medicare.asp>
- <http://www.cms.hhs.gov/center/provider.asp>
- <http://www.medpac.gov/-documents-/payment-basics>

Medicare is the single largest payer for health care services in the United States. The majority of beneficiaries, approximately 70 percent in FY 2014, are enrolled in Medicare Parts A and B, which provide fee-for-service (FFS) insurance. Medicare contracts with Medicare Administrative Contractors (known as MACs or Medicare contractors) to process more than 1.2 billion FFS claims from over 1.5 million providers, totaling over \$367 billion in FY 2014.

Medicare pays for most items and services on a prospective rather than cost basis. A prospective, fixed payment system allows for better resource planning by providers, offers bundled services or items for care management, and provides incentives for efficiencies.

While the methodologies for determining the payment rates vary by setting, in most cases the payments are based on a statutory formula that calculates the relative relationship between the average cost for performing a service and the average cost of performing all services in the same setting. The relative cost for a service is represented by a number called the relative weight. To determine the payment, the relative weight is generally multiplied by a fixed dollar amount or rate.

Under most FFS payment systems, changes to the relative weights are budget-neutral such that increasing the relative weight (and payment) for one item or service will decrease payments for all other items and services under that system. Updates to the fixed dollar amount or rate for inflation or other factors that result in a change in total expenditures are not generally budget-neutral.

Each FFS payment system is usually updated annually. CMS proposes payment rates and policy changes for the following year and those rates and changes are open for public comment. In some instances, CMS also holds public meetings to gather additional input.

This chapter focuses on the payment systems for acute and ambulatory care settings that are most likely to see the introduction of new technology – inpatient acute care hospitals, hospital outpatient departments, and physician offices. This chapter also describes the payment mechanisms for specific items such as the limited drugs covered under Part B, clinical laboratory tests, and DMEPOS, including information on the competitive bidding program for certain DMEPOS.

Payment systems for other settings such as skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term care hospitals, end-stage renal disease facilities, ambulatory surgical centers, and ambulance suppliers are

similar in their prospective nature and general design to the payment systems profiled in this chapter. A chart of the rulemaking cycles for the profiled FFS payment systems is located in this chapter.

CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost. Our vision of future success in fulfilling this charge is moving from a fee-for-service payment system towards a value-based payment system by paying providers based on the quality rather than the quantity of services. At the end of this chapter are brief descriptions of several programs designed to promote and measurably improve care and population health by transforming fee-for-service Medicare into an integrated and accountable delivery system that continuously improves care, reduces unnecessary costs, and promotes health.

Inpatient Prospective Payment System

➤ *For information on the IPPS:*

- <http://www.cms.hhs.gov/AcuteInpatientPPS/>
- <http://www.medpac.gov/documents/payment-basics/hospital-acute-inpatient-services-payment-system-14.pdf?sfvrsn=0>

IPPS Payments

➤ *For information on determining IPPS payment:*

- http://www.cms.hhs.gov/AcuteInpatientPPS/02_stepspps.asp#TopOfPage

The hospital IPPS makes payments to acute care hospitals for each Medicare patient, or case, treated. Hospitals are paid based on the average national resource use for treating patients in similar circumstances, not the specific cost of treating each individual patient. With few exceptions, Medicare does not pay separately for individual items or services.⁸ Physicians and hospital staff determine the appropriate course of treatment, and hospitals receive a bundled payment for the covered inpatient facility services provided to the Medicare patient. Hospitals receive one IPPS payment per Medicare case at discharge that equates to the total Medicare payment for the facility costs of caring for that Medicare patient. Physicians are paid separately under the Physician Fee Schedule (PFS) for their professional services provided during the inpatient stay.

Medicare Severity – Diagnosis Related Groups

➤ *For information on MS-DRGs:*

- <http://www.cms.hhs.gov/reports/downloads/WR434Z1.pdf>

Under the IPPS, each case is categorized into a Medicare Severity – Diagnosis Related

⁸ Certain costs are paid outside of the IPPS. For example, heart, liver, lung and kidney acquisition costs incurred by an approved transplant facility are paid on a reasonable cost basis.

Group (MS-DRG) depending on the patient's diagnosis, the procedures performed, complicating conditions, age, and discharge status. Each MS-DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that MS-DRG compared to the cost of cases in other MS-DRGs. The weights are recalibrated annually. For FY 2008, CMS revised the DRG payment system by adopting 745 Medicare Severity (MS)-DRGs to replace the previously existing 538 DRGs to better recognize severity of illness. For FY 2015 there are 753 MS-DRGs. The changes did not result in cost savings to Medicare but increased payment amounts to hospitals treating more severely ill and costlier patients, and decreased payment amounts to hospitals treating less severely ill patients.

Standardized Amounts

➤ *For information on wage index:*

http://www.cms.hhs.gov/AcuteInpatientPPS/03_wageindex.asp

The base payment unit for IPPS is called the standardized amount. The standardized amount is based on hospital charges per Medicare discharge that are adjusted to account for differences in certain hospital costs, such as the patient case-mix and wage rates. These payment amounts are increased annually by an update factor. Update factors are set by Congress and are intended to account for annual inflation while maintaining incentives for hospitals to be efficient.

The standardized amount is divided into labor-related and non-labor-related shares. After the labor-related share is adjusted by a wage index applicable to the area where the hospital is located, it is added back to the non-labor-related share.⁹ This wage-adjusted standardized amount is then multiplied by the MS-DRG relative weight to determine the payment for the case. The standardized amount is subject to other adjustments that may be applied to each case that a qualifying hospital treats or applied only to specific cases as described below.

Add-on Payments – DSH

➤ *For information on DSH:*

http://www.cms.hhs.gov/AcuteInpatientPPS/05_dsh.asp#TopOfPage

If a hospital treats a high percentage of low-income patients, it receives a percentage add-on payment applied to the wage-adjusted base payment rate of the MS-DRG for each case it treats. This add-on, known as the disproportionate share hospital (DSH) adjustment, varies depending on several factors, including the percentage of low-income patients served. In addition, the ACA requires that part of this payment be made on the basis of uncompensated care.

⁹ If the hospital is located in Alaska or Hawaii, the non-labor share is also adjusted by a cost of living adjustment factor.

Add-on Payments – IME

- *For information on IME:*

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Indirect-Medical-Education-IME.html>

If the hospital trains residents in an approved medical residency program, it receives a percentage add-on payment for each case, known as the indirect medical education (IME) adjustment. This payment varies with the number of residents the hospital is training and the hospital's number of inpatient beds. Teaching hospitals also receive a separate payment outside the IPPS, based on the number of residents, for Medicare's share of the hospital's direct cost of medical education.

Outlier Payment

- *For information on outlier payments:*

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html>

Case-specific adjustments are made for high cost cases called outliers. The outlier payment is designed to protect the hospital from large financial losses due to unusually expensive cases, which can reflect the use of advanced technology. The costs of a new technology are included in the determination of whether a case qualifies for an outlier payment. The outlier payment is determined by comparing the total cost of caring for a particular case to the MS-DRG payment for that case, including DSH or IME payments and payments for new medical services and technologies, plus a fixed dollar amount that is set in regulation.¹⁰ The outlier payment is added to the wage-adjusted base payment rate for the MS-DRG, plus any DSH or IME adjustments and any applicable add-on payment for new technologies, as described below.

Add-on Payments – New Technology

- *For information on IPPS new technology add-on payments, including the deadline to submit an application:*

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>

The IPPS is designed to adapt to changing technology through year-to-year adjustments in MS-DRG weights based on historical cost data. In theory, if new technologies lead to better

¹⁰ The costs are determined by applying the hospital's cost-to-charge ratio (CCR) – the percentage of charges that costs have represented for the hospital in the past -- to the hospital's charges for the case. Those costs are compared to a MS-DRG-specific fixed loss threshold, which is the sum of the MS-DRG payment for the case, including any add-on payments (new technology, indirect medical education, disproportionate share adjustment), plus a fixed loss amount. CMS sets the fixed loss amount each year at a level projected to generate outlier payments equal to 5.1 percent of total payments under the IPPS. Medicare then pays 80 percent of hospitals' costs above the fixed loss threshold.

care but are more expensive, or if they lead to more efficient care and are less expensive, hospitals will eventually receive appropriate payment as the MS-DRG weights are adjusted over time to reflect the impact of fluctuating costs. In practice, however, there are concerns that the system may be slow to react to rapidly evolving technological advancements. Hospitals may experience a financial disadvantage as they provide more expensive products and services to Medicare beneficiaries while waiting for MS-DRG payments to reflect the higher costs. As an incentive for hospitals to adopt new technologies during the period before their costs are recognized in the MS-DRG weights, certain new medical services or technologies may be eligible for new technology add-on payments. The new technology add-on payment policy provides additional payments for eligible high cost cases without significantly eroding the incentives provided by a payment system based on averages.

To qualify for add-on payments, a service or technology must be new, represent a substantial clinical improvement over predecessor technology, and be high cost relative to the MS-DRG payment that would normally be paid. Since it can take two to three years for reflection of cost data in the calculation of the MS-DRG weights, technologies generally are considered new for two to three years after they become available. Applicants must demonstrate that their product offers substantial clinical improvement, relative to technologies previously available, in the diagnosis or treatment of Medicare beneficiaries. Applicants must submit a formal request including a full description of the clinical applications of the technology, the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, and data to demonstrate that the technology

Items Qualifying for New Technology Add-on Payments

Item	Condition Treated	Add-on Years
Xigris®	Severe sepsis	FY2003 FY2004
InFuse™ Bone Graft	Spinal fusion	FY2004 FY2005
Kinetra® Implantable Neurostimulator	Essential tremor and Parkinson's disease	FY2005 FY2006
Cardiac Resynchronization Therapy with Defibrillation	Chronic, moderate to severe heart failure	FY2005
Endovascular Graft Repair of the Thoracic Aorta (GORE TAG)	Thoracic aorta aneurysms	FY2006 FY2007
Restore® Rechargeable Implantable Neurostimulator	Chronic, intractable pain	FY2006 FY2007
X STOP Interspinous Process Decompression System	Back and leg pain (lumbar spinal stenosis)	FY 2007
Cardiwest™ Temporary Artificial Heart System (TAH-t)	Bridge heart transplant	FY 2009 FY 2010 FY 2011
Spiration IBV Valve	Prolonged respiratory air leak	FY 2010 FY 2011
AutoLITT™	Glioblastoma Multiforme	FY 2011 FY 2012

meets the high cost threshold, which is published in the IPPS final rule.

The side box represents items approved for new technology add-on payment since 2003 and the years for which the add-on payments were effective. Half of all submitted applications were disapproved either because the applications were not substantially different from older technologies or because they failed to meet the criteria for substantial clinical improvement or high cost.

The high cost threshold for eligible items is the lesser of:

- 75 percent of the standardized payment amount, increased based on the national case-weighted ratio of costs to charges,
- or -
- 75 percent of one standard deviation of the geometric mean standardized charge for cases in the MS-DRG involved with the technology, or the case-weighted average of all relevant MS-DRGs, if the new technology could be assigned to many different MS-DRGs.

Although any interested party may submit an application for a new technology add-on payment, applications often come from the manufacturer of a new drug or device. A preliminary discussion on whether or not new technologies qualify for add-on payments is published in the IPPS proposed rule and is open to public comment. CMS posts the deadlines for submittal of the applications on its web site well in advance of the expected IPPS proposed rule publication to allow time for receipt and careful consideration of the applications. CMS will generally accept

Items Qualifying for New Technology Add-on Payments (continued)

Item	Condition Treated	Add-on Years
Voraxaze	Renal Impairment Secondary to Toxic MTX Concentration.	FY 2013 FY 2014 FY 2015
Dificid	Clostridium Difficile Associated Diarrhea	FY 2013 FY 2014
Kcentra	Replacement Therapy for Fresh Frozen Plasma	FY 2014 FY 2015
Zilver Drug Eluting Peripheral Stent	Peripheral Artery Disease	FY 2014 FY 2015
Zenith Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft	Abdominal Aortic Aneurysm	FY 2013 FY 2014 FY 2015
Argus® II Retinal Prosthesis System	Retinitis Pigmentosa	FY 2014 FY 2015
Implantable Hemodynamic Monitor System (IHMS) (CardioMEMS, Inc.)	Congestive Heart Failure	FY 2015
Responsive Neurostimulator System (RNS)® System (Neuropace)	Epilepsy	FY 2015
MitraClip® System (Abbott Vascular)	Mitral Valve Regurgitation	FY 2015

partial or Phase I applications if some of the necessary information (e.g., FDA approval) is expected but has not been obtained by the initial deadline. The deadline for completed or Phase II applications is generally at the end of the calendar year for add-on payments effective October 1 of the following year.

The actual add-on payments are based on the cost to hospitals for the new technology. A new technology add-on payment is made if the total covered costs of the patient discharge exceed the MS-DRG payment of the case (including adjustments for IME and DSH, but excluding outlier payments). The total covered costs are calculated by applying the cost-to-charge ratio (that is used for inpatient outlier purposes) to the total covered charges of the discharge.

If the costs of the discharge exceed the full MS-DRG payment, the additional payment amount equals the lesser of the following:

- 50 percent of the costs of the new medical service or technology; or
- 50 percent of the amount by which the total covered costs of the case (as determined above) exceed the standard MS-DRG payment, plus any applicable outlier payments if the costs of the case exceed the MS-DRG, plus adjustments for IME and DSH.

Hospital Outpatient Prospective Payment System

➤ *For information on the OPSS:*

- <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>
- <http://www.medpac.gov/documents/payment-basics/outpatient-hospital-services-payment-system.pdf?sfvrsn=0>

Bundled Payments

Under the hospital OPSS, hospitals are generally paid for each covered service they provide to Medicare beneficiaries at prospectively established rates based on the national median cost of performing similar services. As under the IPPS, the payment received for each service is generally a bundled payment for a group that reflects the total facility cost of providing the service. The payment bundle includes most implantable devices and low cost drugs, as well as supplies and equipment integral to performing a service. Therefore, OPSS group payments typically include the costs of the supportive and ancillary services required to perform the specific hospital outpatient service, which are incorporated into the OPSS cost-based payment group weight. However, while the IPPS makes one bundled payment for all care provided during the inpatient stay, a hospital may receive multiple OPSS payments for a single outpatient encounter if multiple separately payable services are provided during that encounter. Physicians are paid separately under the Medicare PFS for their professional services provided during outpatient encounters.

Ambulatory Payment Classifications

All items and services paid separately under the OPSS are assigned to payment groups called Ambulatory Payment Classifications (APCs), which are intended to group together items and services that are similar in clinical characteristics and cost. APC relative payment weights are based on estimated cost. There are several types of APCs that represent types of items or services paid under the OPSS:

- Procedure or visit APCs (clinical APCs),
- Partial hospitalization services APCs,
- Pass-through drug, biological, or device APCs,
- Nonpass-through drug APCs,
- Brachytherapy source and blood product APCs, and
- New Technology APCs

Items, services, procedures, and supplies under the OPSS are reported on claims with CPT codes and Level II HCPCS codes (see Coding chapter). For a reference, please see 74 FR 60431. Payment for these codes may be either paid separately or packaged. As noted above, OPSS cost-based relative payment weights reflect the packaged costs of items and/or services that are usually supportive and ancillary to a separately payable service. Services in each clinical APC are similar clinically and in terms of the resources they require. By law, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to use of resources if the highest geometric mean cost for an item or service in the APC group is more than 2 times greater than the lowest geometric mean cost for an item or service within the same APC group (often referred to as the 2 times rule). Each year CMS reviews and adjusts, as necessary, the APC groupings and updates the relative payment weights to ensure that they are consistent with clinical practice and comport with the requirements of the 2 times rule. Exceptions to the 2 times rule may be made for low volume services or other special cases.

Advisory Panel on Hospital Outpatient Payment (HOP Panel)

➤ *For information on the HOP Panel:*

<http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>

CMS holds meetings of the Advisory Panel on Hospital Outpatient Payment (HOP Panel), a federal advisory committee comprised of hospital representatives with expertise as clinicians or in hospital administration, coding, and billing. The HOP Panel meetings are open to the public, with notification of upcoming meetings published in the *Federal Register*. The meetings provide input into the development of the proposed and final OPSS rules for the following calendar year. The HOP Panel hears presentations from the public about the need for changes in the structure of the APCs, and reviews data on the utilization and cost of the services in question, and evaluates requests for changes in the supervision level for therapeutic services. The Panel makes recommendations to CMS about potential changes in

APCs. CMS addresses these recommendations during the annual rulemaking cycle.

APC Payment Rates

Hospital-specific overall and hospital-specific departmental cost-to-charge ratios (CCRs) are applied to a hospital's charges for services in the most recent full year hospital claims data to determine estimated costs per service for purposes of rate setting. The costs are standardized on each claim to reflect the labor costs in the geographic area in which the hospital is located using the IPPS pre-reclassification hospital wage index. The geometric mean cost, including packaged costs, of all services assigned to each clinical APC is then calculated. CMS calculates an unscaled APC weight that reflects the relative geometric mean cost of the services within the APC compared to the geometric mean cost of a clinic visit, which is then scaled to maintain the total payment weight under the prospective payment system. The scaled relative weight for the APC is multiplied by a base payment unit called the conversion factor to determine the APC payment rate. The conversion factor is updated annually for changes in hospital operating input costs. The conversion factor also is adjusted annually to account for anticipated outlier payments and pass-through payments and incorporates budget neutrality adjustments for the wage index and rural adjustment.

All items within an APC have the same payment rate, although there are policies, such as the multiple surgical procedure reduction, that may result in two procedures in the same APC being paid different amounts. Separately payable drugs and biologicals are paid based upon the statutory default, which is the average sales price (ASP) + 6 percent.

Clinical Diagnostic Laboratory Tests

- *For information on Clinical Diagnostic Laboratory Tests:*
<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2845CP.pdf>.

Since the inception of the OPSS, OPSS hospitals were paid separately for clinical diagnostic laboratory tests or services (laboratory tests) provided in the hospital outpatient setting at Clinical Laboratory Fee Schedule (CLFS) rates. Beginning in CY 2014, payment for most laboratory tests (except for molecular pathology tests) is packaged under the OPSS. There are limited circumstances in which hospitals can separately bill for laboratory tests. It will be the hospital's responsibility to determine when laboratory tests may be separately billed under the limited exceptions.

Outlier Payments

In addition to the APC payment, hospitals may receive outlier payments for high cost services. To receive an outlier payment, the hospital's charges, adjusted to cost by application of its overall CCR, must exceed the OPSS payment for the service by both a fixed threshold (\$2,775 for CY 2015) and by 1.75 times (for CY 2015) the APC payment. The fixed loss threshold exists to ensure that outlier payments are made for unusually high costs that are incurred in providing care to the most costly patients receiving expensive and

complex services. When a service meets the criteria for outlier payment, the hospital receives an outlier payment that equals 50 percent of the difference between its costs and 1.75 times the APC payment amount. For CY 2015, the OPSS sets the criteria to limit the outlier payments to 1 percent of the estimated total payments made under the OPSS.

Transitional Outpatient Payments

Certain cancer hospitals and children's hospitals receive additional transitional outpatient payments that make up any difference between what the hospital receives under the OPSS and what it would have received under the cost reimbursement methodology that existed prior to implementation of the OPSS. These hospitals are permanently held harmless from a decline in payments below their pre-Balanced Budget Act of 1997 (BBA) amount as a result of the implementation of the OPSS.

Rural Sole Community Hospital Adjustment

The MMA instructed the Secretary to conduct a study comparing urban and rural hospital costs and provided the authority to adjust OPSS payments to rural hospital payments by January 1, 2006, if rural hospital costs were determined to be greater than urban hospital costs. Based on an analysis of rural and urban hospital costs that showed that rural sole community hospitals were the only class of rural hospitals that were significantly more costly than urban hospitals, CMS implemented a budget neutral 7.1 percent payment increase for rural sole community hospitals in CY 2006, which has been continued to date and includes the small number of hospitals classified as essential access community hospitals.

New Technology APCs

- *For information on the New Technology APC application process:*
<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/newtechapc.pdf>

New technology services, including surgical procedures, diagnostic tests, and other procedures, may be assigned to a New Technology APC. Assignment to a New Technology APC allows CMS to gather actual cost data about the service before it is placed in an APC with other clinically similar services. The predetermined New Technology APC payment is based on CMS's best estimated cost of the new service.

New Technology APCs provide payment for complete services or procedures that cannot be appropriately reported under an existing HCPCS code or combination of codes. Components or items that are part of a more comprehensive service are not eligible for placement in a New Technology APC. Although any interested party may apply to have a new service assigned to a New Technology APC, most applications are received from manufacturers. To qualify for assignment to a New Technology APC, among other criteria, the service must not be adequately represented in the claims data being used for the most current annual OPSS payment update, may not qualify for transitional pass-through payment and may not be able to be assigned to a clinical APC.

Applications for a New Technology APC assignment can be submitted at any point in the year and are considered for inclusion in a quarterly update that is at least four months away from the date of submission to allow time for analysis, decision-making, and systems changes. For example, to be considered for the July 1 update, applications must be received by the first business day in March. The time period for a determination may be extended if an application is incomplete, if further information is required, or if a more extensive evaluation is required to determine eligibility.

The table below indicates the earliest date that New Technology APC status could be implemented once a completed application and all additional information are received.

CMS Must Have Complete Application and All Necessary Information by the First Business Date in . . .	Earliest Possible Effective Date For a New Technology APC Assignment . . .
March	July 1
June	October 1
September	January 1
December	April 1

Assignment to a New Technology APC is temporary. Services and procedures are moved from a New Technology APC to a clinical APC once sufficient claims data are available for the technology to appropriately place it with services that are clinically similar and have similar resource use. The transition from a New Technology APC to a clinical APC is done through the rulemaking process, where the proposed clinical APC assignment is open to public comment.

Transitional Pass-Through Payments

To develop an appropriate APC payment for a procedure, CMS must be able to determine the costs to the hospital of performing the procedure, including the cost of drugs, biologicals, and devices that may be used in the respective procedure. Prior to the implementation of the OPPS in 2000, there was concern that CMS did not have sufficient hospital cost data to determine the appropriate cost for some items. Transitional pass-through payments may provide additional payment for new devices, drugs, and biologicals for two to three years while CMS gathers additional data on the cost of those items. These new items are used in existing procedures, and those procedures are assigned to existing APCs. As noted above, complete new procedures do not

qualify for transitional pass-through payments but may be considered for placement in a New Technology APC.

Pro-Rata Reduction

By law, the total projected amount of pass-through payments in a year is limited to a percentage of projected total payments under the OPPS. For 2000 through 2003, the pass-through limit was 2.5 percent of total projected payments. In 2004 and future years, the limit is 2.0 percent of total projected payments. If CMS estimates that pass-through payments will exceed that limit, a uniform (pro-rata) reduction to all pass-through payments is required. Pro-rata reductions apply only to transitional pass-through payments for a particular year. To date, 2002 is the only year in which a pro-rata reduction has been necessary.

Transitional Pass-Through Payments: Devices

- *For information on the transitional pass-through device application process, including eligibility criteria and the complete list of established device categories:*
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html

Subject to any budget neutrality reduction, the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment for the device. The pass-through device cost is determined by adjusting a hospital's charges for the item to cost using its overall CCR. The cost of similar devices, if any, which are identified in the procedural APC with which the pass-through device is associated, is then subtracted from the device's cost to determine the pass-through payment amount for the device.

As with applications for assignment to New Technology APCs, applications for pass-through status can be submitted at any point in the year and are considered for inclusion in a quarterly update that is at least four months away from the date of submission. The time period for a determination may be extended if an application is incomplete, if further information is required, or if a more extensive evaluation is required to determine eligibility. To qualify, an item must have costs that are not insignificant compared with APC payments that would otherwise be made, including the costs of similar items. Applications for new devices must also demonstrate a substantial clinical improvement in the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Transitional pass-through payments for devices are based on categories of devices. CMS can create a new category of pass-through devices to include an item only if that item cannot be described by any current or previous pass-through device category. Comments received during past rulemaking cycles indicated that some of the previous and existing category descriptors were thought by some observers to be overly broad and may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment. In response to this concern CMS modified the regulations to permit, beginning in CY 2006, creation of an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where an existing or previously existing category descriptor does not appropriately describe the new type of device. Creation of an additional category may require clarification or refinement of the descriptors of previous categories. A determination regarding the revision of category descriptors is made on a case-by-case basis and implemented prospectively.

Transitional Pass-Through Payments: Drugs and Biologicals

- *For information on transitional pass-through drug payments:*
<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/drugapplication.pdf>

The purpose of transitional pass-through payments for new drugs and biologicals is to enable beneficiaries' access to technologies that are too new to be captured in the data used to determine APC payment rates. Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount is the amount by which the amount determined under section 1842(o) (referring to payment under the average sales price (ASP) methodology) exceeds the otherwise applicable payment for the drug or biological. Payment for drugs and biologicals with pass-through status is made at ASP+6 percent, which is the same payment rate for separately paid drugs and biologicals without pass-through status. Approval of a drug or biological for a transitional pass-through payment under the OPSS is not contingent on prior assignment of a national HCPCS code. New drugs and biologicals that receive transitional pass-through status are typically assigned a product-specific HCPCS code.

For new drugs and biologicals for which a HCPCS code has not been assigned, the MMA requires CMS to pay hospital outpatient departments at 95 percent of its average wholesale price (AWP). To implement the MMA provision, CMS instructed hospitals to bill for a new drug or biological using a new HCPCS code, C9399 (unclassified drug or biological), and the National Drug Code (NDC) for the product. The OPSS payment system flags the code for manual pricing by the Medicare contractor. The contractor sets the payment rate at 95 percent of AWP using the Red Book. Contractors notify CMS of drugs and biologicals being reported under HCPCS code C9399.

Physician Fee Schedule

➤ *For information on the PFS:*

- <http://www.cms.hhs.gov/PhysicianFeeSched/>
- <https://www.cms.gov/apps/physician-fee-schedule/overview.aspx>
- <http://www.cms.hhs.gov/center/physician.asp>
- <http://www.medpac.gov/documents/payment-basics/physician-and-other-health-professionals-payment-system-14.pdf?sfvrsn=0>

Payments per Service

Medicare pays for services furnished by physicians (e.g., surgery, office visits, and other professional services) and services furnished by many other non-physician practitioners under a payment system known as the Medicare Physician Fee Schedule (PFS). The PFS includes payments for the professional services as well as the direct expenses (i.e., clinical staff, medical equipment, and disposable supplies) and office overhead expenses used to furnish a specific service (e.g., supplies, equipment, clinical and administrative staff, and other expenses).

PFS payments are the product of the national relative value units for a service, the geographic practice cost indexes (GPCIs) for the area where the service is furnished, and the single “dollar” conversion factor. The conversion factor for physicians' services is updated annually by a formula specified in law.

Relative Value Units

➤ *For information on RVUs:*

- http://www.cms.hhs.gov/PFSlookup/03_PFS_Document.asp#TopOfPage
- <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html>

Each of the over 7,000 services paid under the PFS is divided into three components for purposes of establishing its relative value:

- work – reflecting the practitioner’s time and intensity in furnishing the service.,
- practice expense – direct costs in clinical labor, medical equipment, and disposable supplies, and indirect costs including office expenses, administrative labor and other costs, and
- malpractice insurance premiums.

Generally, each component of each physician service is assigned a uniform national relative value unit (RVU), a numerical value used to quantify the relative amount of resources used in furnishing each service under the PFS. The law prohibits any differential in payment for a service based upon the specialty of the physician performing the service.

The initial work RVUs used at the inception of the PFS were based primarily on a study of physician work conducted for CMS by the Harvard School of Public Health. The study valued each service on the basis of the relative physician work--time, effort, and skill--required to perform the service. Practice expense RVUs for a service are based on the typical resources required to perform each service including the direct practice expense inputs for the type and amount of clinical staff time, disposable supplies, and medical equipment. Malpractice RVUs are based on malpractice premium data for the top 20 Medicare physician specialties. For each service, the malpractice RVU amount is the weighted average of the premiums for specialties that perform the service using the proportion of the total services provided by the specialty as the weight.

AMA RUC

In establishing RVUs for new, revised, and potentially misvalued codes, CMS takes into consideration the recommendations of a committee sponsored by the American Medical Association (AMA) and national medical specialty societies. The Relative Value Update Committee (RUC) provides recommendations for work RVUs, and through the work of its Practice Expense Sub-committee, provides recommendations for practice expense resource inputs. Voting members of the RUC include representatives from medical specialties. The AMA RUC recommendations are subject to review by CMS staff and the public through notice and comment rulemaking.

The multi-specialty feature of this system is important since the PFS, like the IPPS and OPFS, is a relative value payment system and not a cost-based reimbursement system. Increased payments for a service result in decreased payments for all other services.

Geographic Practice Cost Indexes

- *For information on GPCIs:*

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/AlternativeGPCIReview.html>

Payments under the PFS are adjusted for geographic variation in costs across 89 payment areas. A geographic practice cost index (GPCI) specific to the payment locality where the service is furnished is applied to each of the three relative value components of the PFS. The GPCIs are required by law to measure area cost differences compared to the national average for each of the three fee schedule relative value components.

Update to the PFS Conversion Factor

- *For information on section 101 of MACRA:*

<https://www.congress.gov/bill/114th-congress/house-bill/2/text#toc-H8707FE64FFCF4CE2A98F9C4CCCD16645>

The annual update to the PFS conversion factor is set out in statute in section 101 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The law permanently repeals the sustainable growth rate (SGR) formula and replaces it with statutorily prescribed physician payment updates and provisions.

Contractor-Priced Services

In some instances, an item or service coverable in a physician's office does not have a national payment rate under the PFS. In those cases, the Medicare contractor is required to determine the appropriate payment rate for the locality it serves. Most of the contractor-priced codes represent low volume items or services, or new items or services that are not accurately described by established procedure codes and therefore billed using not otherwise classified (NOC) codes. In setting the payment rate for a service represented by a contractor-priced code, the contractor medical director (CMD) typically gathers evidence on the relative amount of physician work and other physician resources used in furnishing the service.

Part B Drugs in the Physician's Office

- *For information on Part B drugs:*

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/McrPartBDrugAvgSalesPrice/>

Note: Links to drug pricing files are in the navigation pane located on the left side of the webpage.

Medicare Part B covers a limited number of drugs, for example, drugs provided as part of (or incident to) a physician service, certain drugs specified by law, and drugs furnished for use with covered durable medical equipment. Many Part B covered drugs are infused or injected by physicians such as oncologists, rheumatologists, and urologists. However, other examples

of Part B drugs include certain pharmacy-dispensed drugs, such as immunosuppressives, oral anti-cancer drugs, and oral anti-nausea drugs as well as influenza vaccine, pneumococcal pneumonia vaccine, hepatitis B vaccine for high and intermediate risk patients, and intravenous immune globulin that is administered in the home to patients with primary immune deficiency. Medicare pays the physician or pharmacy for the drug provided to the beneficiary and does not pay pharmaceutical manufacturers directly.

Average Sales Price

The MMA specified that beginning in 2005, certain Part B covered drugs must be paid based on average sales prices that are submitted to CMS quarterly by manufacturers and that the payment amount would be 106 percent of the average sales price (ASP). The MMA also requires that drug payment amounts be updated quarterly based on the most recent manufacturers' data. During a given quarter, CMS calculates the next quarter's payment amounts based on the last quarter's manufacturer data. Therefore, many describe this process as having a two quarter lag.

Supplying Fee

Medicare Part B pays supplying and dispensing fees in very limited circumstances. The MMA requires Medicare to pay a supplying fee as determined appropriate by the Secretary to pharmacies for providing immunosuppressive drugs, certain oral anticancer drugs and certain oral antiemetic drugs. Currently, the supplying fee is \$24 for the first prescription and \$16 for all subsequent prescriptions within each 30-day period. A one-time supplying fee of \$50 for the first immunosuppressive prescription after a beneficiary has received a transplant is also available.

Dispensing Fee

Medicare also pays a dispensing fee for nebulized inhalation drugs that are furnished for use with covered DME. Effective January 1, 2006, Medicare pays a fee of \$57 for the initial 30-day supply of inhalation drugs furnished for use with DME, then a monthly fee of \$33 thereafter. Medicare pays a fee of \$66 if a beneficiary receives a 90-day supply of these drugs. Additional information on supplying fees and inhalation drug dispensing fees is found on the CMS website at:

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3990.pdf>

Furnishing Fee

Medicare pays a furnishing fee for items and services related to Medicare Part B covered blood clotting factor products. The furnishing fee payment amount for years after CY 2005 is increased annually by the percentage increase in the consumer price index for medical care for the 12 month period ending with June of the previous year. Additional information on the Medicare blood clotting factor furnishing fee, including the fee paid per unit of clotting factor is found on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee.html>

Clinical Laboratory Services

➤ *For information on clinical laboratory services:*

- <http://www.cms.hhs.gov/ClinicalLabFeeSched/>
- <http://www.cms.hhs.gov/center/clinical.asp>
- <http://www.medpac.gov/documents/payment-basics/clinical-laboratory-services-payment-system-14.pdf?sfvrsn=0>

Generally, Medicare pays for clinical diagnostic laboratory tests at the lesser of three amounts: the actual charge for the test submitted by the laboratory; the local fee schedule amount; or the national limitation amount (NLA). The local fee schedules were originally based on 60 percent of the prevailing charges for tests in each contractor locality for services rendered on or after July 1, 1984. The NLA is a percentage of the median value of all local fees for each test. The NLA is set at 74 percent of the median of the local fees for tests for which NLAs were established before January 1, 2001 and at 100 percent of the median for tests Medicare first paid for on or after January 1, 2001. Unlike the IPPS, the OPSS, and the PFS, the clinical laboratory fee schedule has no provision to permit routine changes in relative payment rates to reflect technological advances and other changes over time.

Fee schedule amounts are generally updated each year by the change in the consumer price index. However, legislation by Congress can modify the update to the fees. The annual update to the local clinical laboratory fees for CY 2015 is (-0.25) percent. The annual update to local clinical laboratory fees for CY 2015 reflects an additional multi-factor productivity adjustment and a (-1.75) percentage point reduction as described by the ACA. Beneficiaries do not pay cost-sharing for clinical laboratory services as they do for most other Medicare services.

The statute does not specify how to calculate fees for new tests. The MMA required CMS to establish procedures for determining payment for new lab test codes to be included in the annual update of the clinical laboratory fee schedule. For a clinical laboratory test that is assigned a new or substantially revised code in a particular year, CMS notifies the public that a new code has been created and invites the public to present comments on the appropriate basis for establishing a payment amount for the new code. CMS considers the comments presented at the public meeting and makes a list of its proposed determinations. The proposed determinations, the reasons for the determinations, and the data on which the determinations were based are made available to

Public Meetings Regarding New Products

CMS holds public meetings on proposed payment determinations for certain new codes representing both clinical laboratory and DME items. The meetings provide an opportunity for CMS to obtain industry and public reaction to preliminary recommendations regarding payment methodology for these codes.

Each public meeting is announced in the *Federal Register* 30 days prior to the meeting date. A detailed agenda and summary of the meeting is posted on the CMS website. [See Coding Chapter]

the public. The public is given an opportunity to submit comments. CMS then issues a list of final determinations for each new test.

Crosswalking and Gapfilling

Depending on the nature of a new test, CMS uses one of two bases to determine payment. The first basis, called crosswalking, is used for a new test that is comparable to an existing test code, multiple existing test codes, or a portion of an existing test code. The new test code is assigned the existing local fee schedule amount and the existing NLA for the related test. Payment for the new test code is made at the lesser of the local fee schedule amount or the NLA. The second method, called gapfilling, is used when no comparable, existing test is available. Gapfilling requires each local contractor to develop a payment amount based on charges, costs, and other relevant factors for its locality. Local payment amounts are established from the gapfill amounts and become the basis for establishing the NLA for a new test code, multiple existing test codes, or a portion of an existing test code.

The public may request CMS to reevaluate its decision of whether a code should be priced by crosswalking or gapfilling. This reconsideration process, effective for new or substantially revised HCPCS codes assigned on or after January 1, 2008, provides the public with an additional opportunity to comment on CMS payment determinations.

A Look to the Future

Section 1834A of the Act, as added by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), requires significant changes to the process for pricing clinical diagnostic laboratory tests under the CLFS. Under the new legislation, CMS is required to collect data from laboratories on the prices that they receive from private payers. With certain designated exceptions, the payment amount for a test on the CLFS furnished on or after January 1, 2017, will be equal to the weighted median of private payer rates reported for the test, based on data about private payer payment rates and volumes of each test collected from laboratories. CMS is also required to consult with an expert outside advisory panel for input on the establishment of payment rates for new clinical diagnostic tests and on coverage and payment processes for new clinical diagnostic laboratory tests. CMS is currently engaged in rulemaking and setting up an advisory panel.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

- *For information on DMEPOS*
 - <http://www.cms.hhs.gov/DMEPOSFeeSched/>
 - <http://www.cms.hhs.gov/center/dme.asp>

Medicare payment for most durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including surgical dressings, therapeutic shoes, and parenteral and enteral nutrition, is based on the lower of the actual charge for the item or a fee schedule amount. The law specifies that the fee schedule amounts for each category of DMEPOS (inexpensive or other routinely purchased items, items requiring frequent and substantial servicing,

customized items, oxygen and oxygen equipment, and other items of DME) are to be based on average payments made under the previous reasonable charge methodology in a base year¹¹. The fee schedule amounts are updated by annual covered item updates. The law also sets various ceiling and floor limits on the fee schedule for different DMEPOS categories. The fee schedule amounts for DME and surgical dressings are statewide fee schedule amounts. The fee schedule amounts for prosthetic devices, prosthetics, orthotics, and therapeutic shoes are regional fee schedule amounts that are the weighted average of the state fee schedule amounts in each of 10 CMS regions. The fee schedule amounts for parenteral and enteral nutrition are national fee schedule amounts. In addition, the law establishes special payment rules for certain items and services.

As with clinical laboratory services, the law does not specify how to calculate fee schedule amounts for new DME technology. Generally, gapfilling is used to calculate new DME fee schedule amounts by using either:

- Fee schedule amounts for comparable items; or
- Supplier or retail prices.

In cases where retail pricing information is used, the DME gapfilling methodology approximates historic reasonable charges by using current prices decreased by a deflation factor to approximate the base year price. The deflation factors are based on the percentage change in the consumer price index for urban consumers (CPI-U). Once this amount is determined, the amount is inflated to the current price using a percentage increase and the cumulative covered item update. The covered item updates are set in law and are often, but not always, the CPI-U.

DMEPOS Competitive Bidding Program

- *For information on DMEPOS Competitive Bidding*
<http://www.cms.gov/DMEPOSCompetitiveBid/>

Section 302 of the MMA established requirements for a new competitive bidding program for certain DMEPOS items and services. The statute requires that “single payment amounts” replace the current Medicare DMEPOS fee schedule payment amounts for selected DMEPOS items in certain areas of the country. The single payment amounts are determined by using bids submitted by DMEPOS suppliers. The program is intended to set more appropriate DMEPOS payment amounts, which will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality items and services.

There are currently competitive bidding programs in 100 Metropolitan Statistical Areas (MSAs) throughout the United States. Items and services phased in under the programs thus

¹¹ The actual months from 1986 and 1987 included in the base year vary across different types of DME according to time periods specified in the law. Payment for surgical dressing fees is an exception and is calculated using a 1992 base period.

far include:

- Oxygen Supplies and Equipment
- Standard (Power and Manual) Wheelchairs, Scooters, and Related Accessories
- Enteral Nutrients, Equipment and Supplies
- Continuous Positive Airway Pressure (CPAP) Devices, Respiratory Assist Devices, and Related Supplies and Accessories
- Hospital Beds and Related Accessories
- Walkers and Related Accessories
- Support Surfaces (Group 2 Mattresses and Overlays)
- Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories

In addition, a national mail order program has been implemented for replacement of supplies such as test strips and lancets used with home blood glucose monitors. By law, the single payment amounts established under this program are also used to pay claims for these supplies when they are picked up at local pharmacies.

Finally, the statute requires that the fee schedule amounts for items phased in under the program be adjusted by no later than January 1, 2016, based on the prices established under the competitive bidding programs. This is to ensure that payment for items and services furnished in areas outside the 100 MSAs where competitive bidding is in effect is at the amounts established under the competitive bidding programs. This allows savings for the program and all beneficiaries without having to establish competitive bidding programs throughout the entire United States.

Inherent Reasonableness

Inherent reasonableness (IR) is the authority provided to CMS to correct grossly excessive or deficient Medicare payment amounts for specific items and services under Part B that are not paid under the Physician Fee Schedule or a prospective payment system. Therefore, payments for DME, clinical laboratory services, and other Part B services other than those noted above may be adjusted using IR. By law, IR determinations revise inherently unreasonable payment amounts when factors, including the following, result in grossly deficient or excessive payment amounts: Medicare and Medicaid are the sole or primary source of payment for a category of items or services; the payment amounts do not reflect changing technology, increased facility costs associated with that technology, or changes in acquisition or production costs; or the payment amounts are grossly higher or lower than payment amounts made by other purchasers in comparable localities. Factors that may be considered in establishing a revised payment are the price markup, the differences in charges to Medicare and to other payers, and the cost necessary to produce the item or service.

Both CMS and the Medicare contractors may make IR determinations. The IR determinations made by CMS apply nationally. CMS will publish proposed and final notices in the *Federal Register* before adopting a new payment amount. The notice will provide the criteria and circumstances, if any, under which a contractor may grant an exception to the IR-

adjusted amount.

IR adjustments made by contractors are limited to a 15 percent increase or decrease in any given year. If a contractor is establishing a special payment limit using the inherent reasonableness authority, the contractor must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors considered in determining that amount. Contractors must also solicit comment on the proposed amount and evaluate those comments. Contractors must submit in writing any proposed IR adjustment to CMS. The adjustment may not be imposed until CMS informs the contractor that notification of the proposed adjustment has been received and the contractor has informed the affected suppliers and State Medicaid agencies of any limits it establishes. This policy is designed to make sure that full consideration is given to pertinent factors before limitations are set locally.

Rulemaking Cycles of Medicare Payment Systems

As described earlier, CMS refines Medicare payment policy through annual rulemaking and responds to changes in clinical practice and industry operations. CMS is interested in public input on areas that need improvement at all stages of the rulemaking process but it is most helpful to receive recommendations as we develop the proposed rules to allow for full consideration of potential changes.

Calendar Year (CY) Cycle: January 1 – December 31

- Hospital Outpatient Prospective Payment System
- Ambulatory Surgical Center Payment System
- Physician Fee Schedule including Part B Drugs
- Home Health Agency Prospective Payment System
- End-Stage Renal Disease Prospective Payment System

CY Rulemaking Phase	Approximate Timeframe
Proposed rule development	Winter/spring
Proposed rule publication	Summer (June/July)
Comment period	Late summer - early fall
Final rule publication	On or about November 1
Final rule effective date	January 1

Fiscal Year (FY) Cycle: October 1 - September 30

- Inpatient Prospective Payment System /Long-term Care Hospital Prospective Payment System
- Skilled Nursing Facility Prospective Payment System
- Inpatient Rehabilitation Facility Prospective Payment System
- Inpatient Psychiatric Facility Prospective Payment System
- Hospice Wage Index

FY Rulemaking Phase	Approximate Timeframe
Proposed rule development	Fall/winter
Proposed rule publication	Late spring (April/May)
Comment period	Late spring - early summer
Final rule publication	On or about August 1
Final rule effective date	October 1

A LOOK TO THE FUTURE

CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost. Our vision of future success in fulfilling this charge is moving from a fee-for-service payment system towards a value-based payment system by paying providers based on the quality, rather than the quantity of services. Below are brief descriptions of several programs designed to promote and measurably improve care and population health by transforming fee-for-service Medicare into an integrated and accountable delivery system that continuously improves care, reduces unnecessary costs, and promotes health.

Value-Based Purchasing and Quality Reporting

Medicare is rapidly transforming its payment systems by linking payment to the quality and efficiency of care provided. For many payment systems, collecting and reporting quality data is an important part of incentivizing high quality care for beneficiaries and providing public information for quality driven decision making. CMS has several programs that link quality measure reporting and performance to payment.

Hospital

Hospital Value-Based Purchasing (VBP) Program

- *For information on the Hospital VBP program:*
<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772039937>

The Hospital VBP Program is an important part of Medicare's transformation from a system that rewards volume of care to one that rewards value, outcomes, and innovation. Established by Section 3001 of the ACA, which added section 1886(o) to the Act, the Hospital VBP Program affects hospitals' payments, based on their performance on a subset of the Hospital Inpatient Quality Reporting Program quality measures.

Hospital-Acquired Condition-Present on Admission Indicator (HAC-POA) Program

- *For information on the HAC payment provision, including the current list of HAC categories included in the program:*
http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp#TopOfPage

Section 1886(d)(4)(D) of the Act requires the Secretary to identify conditions that are: (a) high cost or high volume or both, (b) result in the assignment of a case to a MS-DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. The selected conditions include serious preventable events.

Hospital-Acquired Condition Reduction Program (HAC RP)

- *For information on HAC RP including:*
 - *details of the measures and scoring methodology:*
<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774189166>.
 - *HAC RP scores for individual hospitals found on Hospital Compare:*
 - <http://www.medicare.gov/hospitalcompare/HAC-reduction-program.html>
 - <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html>

Effective October 1, 2014, the Hospital-Acquired Condition Reduction Program, mandated by Section 3008 of the ACA, requires CMS to measure and publicly report on hospital acquired conditions, including infections. In addition, the HAC RP reduces total Medicare payments under the IPPS by 1 percent for hospitals that are in the worst performing quartile with regard to hospital-acquired conditions. Hospitals are ranked based on their Total HAC score which is calculated using data from the applicable period and two domains or sets of risk-adjusted quality measures. For FY 2015, Domain 1 (i.e., Patient Safety) is weighted at 35 percent of the Total HAC score and Domain 2 (i.e., Hospital-Acquired Infection) is weighted at 65 percent of the Total HAC score. The conditions included in this provision include those already selected for the Deficit Reduction Act Hospital-Acquired Conditions Program payment policy and any other conditions acquired during a hospital stay that the Secretary deems appropriate.

Hospital Readmission Reduction Program (HRRP)

- *For information on HRRP:*
<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html>

Effective October 1, 2012, the Hospital Readmission Reduction Program (HRRP), mandated by section 3025 of the ACA requires CMS to reduce payments to IPPS hospitals that experience readmission rates for a variety of conditions within 30 days of discharge that is greater than expected based on a hospital's calculated excess readmission ratio. The maximum reduction increases from 1 percent of hospitals' base DRG payment in 2013, to 2 percent in 2014, and to 3 percent in 2015 and beyond. The readmission ratio quantifies a hospital's expected readmissions rate based on the measure of a hospital's readmission performance compared to the national average for the hospital's set of patients with that applicable condition.

In 2009, CMS began publicly reporting hospital readmission rates on the Hospital Compare website. The HRRP measures used to determine the payment reduction for FY 2013 and 2014 focus on readmission rates following hospitalizations for acute myocardial infarction (AMI), pneumonia (PN), and heart failure (HF). In 2014, the measures finalized for FY 2015 Payment Determination include the previous measures and two additional measures: readmission rates following hospitalization for chronic obstructive pulmonary disease

(COPD), and elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA).

Hospital Inpatient Quality Reporting (IQR)

➤ *For information on Hospital IQR:*

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1138115987954>

In accordance with the Deficit Reduction Act (DRA) of 2005, the IPPS pays hospitals that treat Medicare beneficiaries a financial incentive, in addition to making data publicly available. This incentive, referred to as the Annual Payment Update (APU), is authorized by the MMA. The APU is offered to hospitals that meet CMS's requirements to collect and submit accurate, complete, and timely quality measure data. The intent is to encourage hospitals to adopt evidence-based, outcomes-driven health care delivery practices. Beginning with FY 2015, the reduction in the applicable percentage increase for hospitals that fail to submit quality information under rules established by the Secretary is one quarter of the applicable percentage increase (prior to the application of statutory adjustments under sections 1886(b)(3)(B)(ix), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act) or one quarter of the applicable market basket update.

Physician

Physician Value-Based Payment Modifier (Value Modifier) Program

➤ *For information on the Physician Value Modifier:*

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>

Section 1848(p) of the Act requires that Medicare establish a Value Modifier that provides for differential payment under the Medicare PFS based upon the quality of care furnished compared to cost during a performance period. The statute requires that the Value Modifier be applied to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. The statute also requires the Value Modifier to be budget neutral. CMS' overall approach to implementing the Value Modifier is based on participation in the Physician Quality Reporting System (PQRS).

In accordance with the MACRA, the Value Modifier will no longer be applied as a separate payment adjustment after the 2018 payment year. Instead, the program will be combined with other quality reporting and quality performance programs into a single Merit-Based Incentive Payment System (MIPS). With stakeholder input, the MIPS program and policies will be developed over the coming years through notice and comment rulemaking.

Physician Feedback Reporting Program

- *For information on how to access the 2013 QRUR:*
<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html>

Section 1848(n) of the Act requires CMS to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare fee-for-service beneficiaries and authorizes CMS to include information on the quality of care furnished to these beneficiaries. Quality and Resource Use Reports (QRURs) are confidential feedback reports provided to physicians and groups of physicians under the Medicare Physician Feedback Program. CMS has provided QRURs to an increasing number of physician groups since 2012. In September 2014, CMS made available the 2013 QRURs to every physician group practice and physician solo practitioner nationwide. The reports provide physicians information about the resources used and the quality of care furnished to their Medicare fee-for-service (FFS) patients. Physicians and groups of physicians can use these QRURs to see how they compare with other groups of physicians caring for Medicare patients. For physicians and groups of physicians who may be subject to the Value Modifier starting in 2015, the QRURs will provide information on how the group's quality and cost performance affect their Medicare payments in 2015 through the application of the Value Modifier.

Physician Quality Reporting System (PQRS)

- *For information on PQRS measures and additional information about the PQRS program, including the various reporting options and reporting methods, and the criteria for satisfactory reporting to avoid a negative payment adjustment:*
<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>

As a VBP strategy for Medicare Part B services, CMS launched on July 1, 2007, the Physician Quality Reporting Initiative (PQRI), which was later renamed to the Physician Quality Reporting System or PQRS. The PQRS provided bonuses through program year 2014 for physicians and other health professionals who satisfactorily reported on quality measures to CMS. Beginning in calendar year 2015 (based on 2013 quality measure reporting) and moving forward, eligible professionals who do not satisfactorily meet the PQRS reporting requirements set forth by CMS will receive a negative payment adjustment. CMS intends the PQRS to be a first step toward performance-based payment reform and public reporting of performance information for Part B providers. Since the launch of the PQRS program in 2007, additional quality measures have been added which allows most eligible professionals (as defined by the statute) to participate in the program.

Physician Compare Public Reporting

- *For information on Physician Compare:*
<http://www.medicare.gov/physiciancompare/>

Consistent with Section 10331(a) of the ACA, CMS is phasing in quality measures on Physician Compare over the next several years. The 2012 PFS final rule indicated that the first measures available for public reporting on Physician Compare would be the 2012 PQRS Group Practice Reporting Option (GPRO) measures collected via the Web Interface. CMS publicly reported the first set of measure data, which was a sub-set of the 2012 GPRO measures collected under PQRS through the Web Interface, in February 2014 for the 66 group practices and 141 Accountable Care Organizations (ACOs). In December 2014, the next phase of public reporting included posting a sub-set of 2013 PQRS GPRO Diabetes Mellitus and Coronary Artery Disease measures collected via the Web Interface for 139 group practices and 214 Shared Savings Program and 23 Pioneer ACOS. In addition, Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACO summary survey measure data were added to Physician Compare.

For 2014 data, all PQRS GPRO measures collected via the Web Interface, as well as a sub-set of measures reported via registry or electronic health record (EHR) are available for public reporting on Physician Compare. All measures reported by Shared Savings Program and Pioneer ACOs are also available for public reporting. CMS will continue to publicly report 2014 CAHPS for ACOs and will publish the first set of CAHPS for PQRS measures for groups of 100 or more eligible professionals (EPs) who participate in PQRS GPRO and for group practices of 25-99 EPs reporting via a certified CAHPS vendor. In addition, twenty individual measures reported by EPs under the 2014 PQRS via claims, EHR, or registry are available for public reporting. All 2014 data are targeted for publication in late 2015.

For 2015 data, at the group practice level, all 2015 PQRS GPRO measures reported via the Web Interface, registry, or EHR are available for public reporting. In addition, the summary surveys for 2015 CAHPS for PQRS and CAHPS for ACO measures are available for public reporting for group practices of 2 or more EPs and ACOs reporting via a CMS-approved certified survey vendor. At the individual EP level, all 2015 PQRS measures reported via registry, EHR, or claims are available for public reporting. In addition, individual EP-level 2015 Qualified Clinical Data Registry (QCDR) measures, which include PQRS and non-PQRS data, will be available for public reporting on Physician Compare in 2016.

Physician Compare only publicly reports comparable, valid, reliable, and accurate data. In addition, only those measures that resonate with consumers and are deemed to be relevant to consumers are included on the profile pages of the website. All other comparable, valid, reliable, and accurate measures are included in a publicly available downloadable database on <https://data.medicare.gov>.

Other Quality Reporting Programs

Hospital Outpatient Quality Reporting Program (OQR)

➤ *For information on OQR:*

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier1&cid=1192804525137>

The Hospital OQR Program, modeled on the Hospital IQR Program, was mandated by the Tax Relief and Health Care Act of 2006 and is a pay-for-reporting program implemented by CMS for hospital outpatient services. By making quality-of-care data publicly available, CMS enables consumers to make more informed decisions about their health care and encourages providers to improve the quality of outpatient care. Outpatient care can refer to numerous types of health services provided to those who visit hospitals or other health care facilities (e.g., emergency department services, observation services, outpatient surgical services, lab tests, and medical imaging services). The Hospital OQR Program uses a variety of methods to stimulate and support significant improvement in the quality of hospital outpatient care. It aims to refine and standardize hospital outpatient data collection, data transmission, and performance measures. Hospitals paid under the OPSS that meet administrative, data collection and submission, validation, and reporting requirements are eligible to receive an APU or financial incentive intended to encourage adoption of evidence-based care practices. OPSS hospitals not meeting these requirements are subject to a two percentage point reduction in their APU. The data submitted for the Hospital OQR Program are used by CMS to calculate hospital outpatient process measures which are posted on the Hospital Compare website along with other types of measures.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program

➤ *For information on ASCQR:*

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier1&cid=1138115987249>

The ASCQR Program is a quality measure data reporting program implemented by CMS for care provided in the ASC setting. Under this program, quality data reporting requirements for care rendered in the ASC setting were implemented starting with claims submitted for services beginning October 1, 2012 for calculating the first payment update effective for CY 2014. ASCs that meet program requirements during a given CY receive their full annual payment update for the upcoming CY; ASCs that do not participate or fail to meet those requirements may receive a two percent reduction of their annual payment update. To participate in the program, an ASC submits quality measure data; once an ASC submits any quality measure data under the ASCQR Program, the ASC is considered to be participating in the program.

Inpatient Psychiatric Facility (IPF) Quality Reporting Program

➤ *For information on IPF QR:*

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier1&cid=1228772862944>

The ACA requires the implementation of a quality reporting program for the inpatient psychiatric facilities (IPF) and units that were paid under Medicare's IPF FFS payment system. As required under section 340 – (F) of the ACA, a prospective payment system took effect in FY 2010. In 2012, six psychiatric care performance measures were chosen for inclusion. The measures were grouped into three domains: patient safety, clinical quality of

care, and care coordination. All of the selected measures had been available as trial measures under the Joint Commission's ORYX program since October 2008. The criteria that CMS established to select the quality measures were aligned with the criteria being used for other federal quality reporting programs – measures should be endorsed by NQF, they should support HHS National Quality Strategy's three-part aim, and they should balance the work-flow and ensure information is collected across the full spectrum of quality performance. Effective FY 2014, non- participating hospitals and units began incurring a two percent reduction for non-compliance, based on performance measured over a six-month period spanning Q4 of CY 2012 through Q1 of 2013. CMS began publishing results on four of the measures on the Hospital Compare website in April 2014.

Prospective Payment System-Exempt Cancer Hospitals Quality Reporting (PCHQR)

➤ *For information on PCHQR:*

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier1&cid=1228772862874>

Section 3005 of the ACA requires the CMS to establish a Cancer Hospital Quality Reporting Program (CHQRP, also known as PCHQR), and to publish no later than October 1, 2012, the measures selected with respect to fiscal year 2014. Facilitated by the NQF, the Commission on Cancer (CoC), the American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN) agreed to synchronize their developed measures to ensure that a unified set were put forth to the public. Eligible hospitals are described in section 1886(d)(1)(B)(v) of the Act and referred to as a PPS-Exempt Cancer Hospital or PCH. These hospitals are excluded from payment under the IPPS.

Home Health Quality Reporting Program

➤ *For information and a link to Home Health Compare:*

- <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html>
- <https://www.medicare.gov/homehealthcompare/>

Since 1999, CMS has required Medicare-certified home health agencies to collect and transmit Outcome and Assessment Information Set (OASIS) data for all adult patients whose care is paid by Medicare and Medicaid, with the exception of patients receiving pre- or postnatal services only. OASIS data are used for multiple purposes including calculating several types of quality reports which are provided to home health agencies to help guide quality and performance improvement efforts. Beginning in 2007, home health agencies that did not comply with the requirement to submit OASIS quality data were subject to a two-percent decrease in their home health market basket percentage increase. The quality measures for each home health provider are reported on Home Health Compare.

Hospice Quality Reporting Program (HQRP)

- *For information on HQRP:*

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/>

Section 3004 of the ACA requires the Secretary to publish, no later than October 1, 2012 the selected quality measures that must be reported by Hospice programs. The ACA requires that CMS use nationally endorsed quality measures, but also allows CMS to specify measures that are not already endorsed if a feasible and practical measure in the area determined appropriate by the Secretary has not been endorsed. For fiscal year 2014, and each subsequent year, failure to submit required quality data shall result in a 2 percentage point reduction to the market basket percentage increase for that fiscal year.

The Hospice Quality Reporting Program is currently “pay-for-reporting,” meaning it is the act of submitting data that determines compliance with HQRP requirements. Performance level is not a consideration when determining market basket updates/APU.

Long-term Care Hospital Quality Reporting Program (LTCH QRP)

- *For information on LTCH QRP:*

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/>

Section 3004 of the ACA directs the Secretary to establish quality reporting requirements for LTCHs. For fiscal year 2014 and each subsequent year, failure to submit required quality data shall result in a 2 percent reduction in the annual payment update. For FY 2014, LTCHs that failed to report incurred a 2 percent reduction for non-compliance, based on quality data submitted for 3-month period spanning Q4 of calendar year 2012. For FY 2015, LTCHs that failed to report incurred a 2 percent reduction for non-compliance, based on quality data submitted for 12-month period spanning calendar year 2013.

Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)

- *For information on IRF QRP:*

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/>

Section 3004 of the ACA directs the Secretary to establish quality reporting requirements for Inpatient Rehabilitation Facilities (IRFs). For fiscal year 2014 and each subsequent year, failure to submit required quality data shall result in a 2 percent reduction in the annual payment update.

Medicare Shared Savings Program

Established by Section 3022 of the ACA, which added section 1899 to the Act, the Medicare Shared Savings Program (Shared Savings Program) is designed to improve beneficiary

outcomes and increase value of care by promoting accountability for the care of Medicare FFS beneficiaries, requiring coordinated care for all services provided under Medicare FFS, and encouraging investment in infrastructure and redesigned care processes. In 2012, CMS established the Shared Savings Program to facilitate coordination and cooperation among providers to improve the quality of care for Medicare FFS beneficiaries and reduce unnecessary costs by creating Accountable Care Organizations (ACOs). Under the program regulations, provider participation is purely voluntary. For those that choose to participate, Medicare continues to pay individual providers and suppliers for specific items and services as it currently does under the Medicare fee-for-service payment systems. Eligible providers, hospitals, and suppliers participate in the Shared Savings Program by creating or participating in an ACO which provides a framework for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Shared Savings Program will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care.

End Stage Renal Disease Prospective Payment System - Bundled Payment

On January 1, 2011, CMS implemented a fully bundled PPS for renal dialysis services furnished to Medicare beneficiaries for the treatment of End Stage Renal Disease (ESRD). The ESRD Prospective Payment System (PPS) provides a case-mix and facility-adjusted, per treatment bundled payment for dialysis, including drugs, laboratory services, equipment and supplies, and capital related costs. Future considerations include determining when a product is no longer oral-only, developing a drug designation process by which to include new injectable and intravenous products into the bundled payment, and reviewing the case-mix payment adjustments to determine if refinements are necessary. Finally, in accordance with the Achieving a Better Life Experience Act of 2014 (ABLE), the implementation of oral only ESRD-related drugs into the ESRD PPS is delayed until 2025.

Incentive Programs

ESRD Quality Incentive Program

Effective for services furnished on or after January 1, 2012, CMS implemented an ESRD quality incentive program for renal dialysis services.

Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

The Medicare and Medicaid EHR Incentive Programs provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology. Eligible professionals can receive up to \$44,000 over five years through the Medicare EHR Incentive Program and up to \$63,750 over six years through the Medicaid EHR Incentive Program. Beginning in 2015, eligible professionals who do not demonstrate meaningful use by October of the previous year may be subject to a downward payment adjustment.

Electronic Prescribing (e-Rx) Incentive Program

- *For information on e-Rx Incentive Program:*
<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ERxIncentive/index.html>

In 2009, CMS launched the Electronic Prescribing (e-Rx) Incentive Program and began accepting data regarding eligible professional's use of e-Rx. Similar to PQRS, eligible professionals could have earned an incentive payment for having a qualified electronic prescribing system and reporting whether or not it was used for at least 50 percent of their eligible reporting instances. Beginning in 2012 eligible professionals who were not satisfactory e-prescribers (in the prior year) were subject to a downward payment adjustment. 2013 was the final program year for participating and reporting in the eRx Incentive Program. The 6-month 2014 eRx payment adjustment reporting period, which began on January 1, 2013 and ended on June 30, 2013, was the final reporting period to avoid the 2014 eRx payment adjustment. However, electronic prescribing via certified EHR technology is still a requirement for eligible professionals in order to achieve meaningful use under the Medicare and Medicaid EHR Incentive Programs.