

Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the
Comprehensive Care for Joint Replacement Model
January 1, 2018

Section 1115A(d)(1) of the Social Security Act (Act) authorizes the Secretary of Health and Human Services (Secretary) to waive certain specified fraud and abuse laws as may be necessary solely for purposes of carrying out the testing by the Center for Medicare and Medicaid Innovation (Innovation Center) of certain innovative payment and service delivery models. This Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model (2017 Notice) is issued under this authority. The Comprehensive Care for Joint Replacement (CJR) model is being tested under section 1115A(b) of the Act. The first Performance Year under the CJR model began April 1, 2016. The Secretary has determined these waivers are necessary to test the CJR model. Beginning January 1, 2018,¹ this 2017 Notice will supersede the November 16, 2015, Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model (2015 Notice).²

This 2017 Notice is composed of two parts. Part I sets forth the specific conditions that must be met to qualify for a waiver. Each waiver protects only payment arrangements and patient engagement incentives that meet all of the listed conditions and applies only to the specific laws cited in the waiver. The waivers in this 2017 Notice protect specific financial arrangements that are entered into pursuant only to the CJR model and described in the regulations governing the CJR program at 42 CFR Part 510, as amended from time to time (CJR Regulations),³ and in the applicable waiver. The waivers in this 2017 Notice do not apply to other arrangements that may be entered into by Participant Hospitals and other entities or individuals and are not applicable outside of the CJR model. A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (i) does not implicate the specific fraud and abuse law; (ii) implicates the law, but fits within an existing exception or safe harbor; or (iii) otherwise complies with the law.

Part II consists of commentary explaining the reasons that certain changes were made when establishing the requirements for waivers in this 2017 Notice, clarifying certain waiver requirements that we retained in this 2017 Notice, and describing general limitations to the waivers.

¹ We have aligned the date this 2017 Notice will supersede the 2015 Notice—January 1, 2018—with the January 1, 2018, effective date of certain CJR model regulatory changes made by the final rule published at 82 Fed. Reg. 180 (Jan. 3, 2017) and the final rule published at 82 Fed. Reg. 57,066 (Dec. 1, 2017).

² The 2015 Notice is available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf>.

³ See 80 Fed. Reg. 73,274 (Nov. 24, 2015), as amended by 82 Fed. Reg. 180 (Jan. 3, 2017) and 82 Fed. Reg. 57,066 (Dec. 1, 2017).

This 2017 Notice:

- revises the three waivers included in the 2015 Notice, namely: (i) the Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements (Payments Waiver); (ii) the Waiver for Distribution Payments from a Physician Group Practice to Practice Collaboration Agent (PGP Waiver), which this 2017 Notice renames the Waiver for Distribution Payments from a CJR Collaborator to a Collaboration Agent (Distribution Payments Waiver); and (iii) the Waiver for Patient Engagement Incentives Provided by Participant Hospitals to Medicare Beneficiaries in Episodes (PEI Waiver);
- adds a new Waiver for Downstream Distribution Payments from a Collaboration Agent to a Downstream Collaboration Agent (Downstream Distribution Payments Waiver);
- simplifies and streamlines certain requirements of the Payments Waiver and Distribution Payments Waiver, including reducing the number of regulatory provisions that are conditions of waiver protection while maintaining important safeguards against fraud and abuse;
- modifies the documentation requirements under the Payments Waiver and Distribution Payments Waiver to decrease the administrative burden on parties entering into payment arrangements for which waiver protection is sought; and
- addresses how waiver protection will terminate for arrangements involving or related to Non-Electing Hospitals that are no longer in the CJR model after the Voluntary Participation Election Period (as these terms are defined in Part I of this 2017 Notice).

This 2017 Notice will supersede the 2015 Notice as of January 1, 2018. New arrangements entered into on or after January 1, 2018, must meet all of the conditions of the applicable waiver in this 2017 Notice to receive waiver protection. Any arrangement entered into on or before December 31, 2017, that qualifies for waiver protection because it satisfies all of the specific conditions of the Payments Waiver or the PGP Waiver in the 2015 Notice will also be able to meet the conditions of the Payments Waiver or Distribution Payments Waiver, respectively, as set forth in this 2017 Notice and receive ongoing waiver protection until the date the waiver period ends as set forth below. **Such arrangements do not require restructuring or modifications to receive continued waiver protection because this 2017 Notice streamlines and simplifies certain conditions of the Payments Waiver and the PGP Waiver. We intend for waiver protection to be seamless and for the Payments Waiver and Distribution Payments Waiver set forth in Part I of this Notice to function as an effective continuation of the Payments Waiver and PGP Waiver, respectively, as set forth in the 2015 Notice.** However, parties to an arrangement seeking waiver protection under the Payments Waiver or Distribution Payments Waiver may elect to modify an arrangement entered into on or before December 31, 2017, to comply with the simplified waiver conditions once they go into effect.

To receive waiver protection for in-kind items or services provided to Medicare beneficiaries on or before December 31, 2017, the arrangement must satisfy all of the conditions of the PEI Waiver as set forth in the 2015 Notice, provided that a beneficiary may keep items received (unless otherwise specified under the CJR Regulations) and receive the remainder of any service initiated on or prior to December 31, 2017.

This 2017 Notice also applies to arrangements entered into on or before December 31, 2017, related to Non-Electing Hospitals; however, this Notice establishes some different periods of waiver protection for these arrangements. In instances where arrangements related to Non-Electing Hospitals may have different periods for waiver protection, Part I below explicitly references those different dates. For example, the Payments Waiver includes a date for waiver protection that ends 24 months after the Participant Hospital's final Performance Year, or in the case of a Non-Electing Hospital, December 31, 2019. This provision recognizes that Non-Electing Hospitals will leave the CJR model one month into Performance Year 3, and their last reconciliation under the CJR model would relate to Performance Year 2 (i.e., calendar year 2017). The December 31, 2019, date for when waiver protection may end for Non-Electing Hospitals is consistent with the 24-month waiver protection period applicable to other Participant Hospitals because it is 24 months after the last Performance Year for which the Non-Electing Hospital would be subject to reconciliation. Parallel provisions are in the Distribution Payments Waiver and the Downstream Distribution Payments Waiver.

For the PEI Waiver, the waiver period for a Non-Electing Hospital will end on the earlier of January 31, 2018, or the date on which a Participant Hospital is terminated by CMS under 42 CFR § 510.410(b)(2)(v) (regarding compliance enforcement), provided that a beneficiary may keep items received (unless otherwise specified under the CJR Regulations) and receive the remainder of any service initiated on or prior to January 31, 2018.

I: The Waivers and Applicable Requirements

Terms defined in the CJR Regulations that are also used in this 2017 Notice have the meaning set forth in the CJR Regulations. These terms include, but are not limited to: Alignment Payment, CJR Collaborator, Collaboration Agent, Distribution Arrangement, Distribution Payment, Downstream Collaboration Agent, Downstream Distribution Arrangement, Downstream Distribution Payment, Episode of Care (or Episode), Gainsharing Payment, Internal Cost Savings, Low-Volume Hospital, Mandatory MSA, Participant Hospital, Performance Year, Rural Hospital, Sharing Arrangement, and Voluntary MSA.⁴ For the purposes of this 2017 Notice, we also use the terms Non-Electing Hospital, Voluntary Participation Election Letter, and Voluntary Participation Election Period, each as defined below.

“Non-Electing Hospital” means a hospital that was a Participant Hospital in a Voluntary MSA, a Rural Hospital, or a Low-Volume Hospital that does not make an election to continue participation in the CJR model through the submission of a Voluntary Participation Election Letter during the Voluntary Participation Election Period.

“Voluntary Participation Election Letter” means the letter described in 42 CFR § 510.115(c).

“Voluntary Participation Election Period” means the period described in 42 CFR § 510.115(b).

⁴ We have capitalized the terms defined in the CJR Regulations and used in this Notice. The capitalized terms have the same meaning as the uncapitalized terms defined in the CJR Regulations at 42 CFR § 510.2.

1. Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements (Payments Waiver)

The intent of this Payments Waiver is to provide protection for the payment and receipt of Gainsharing Payments and Alignment Payments pursuant to a Sharing Arrangement between a Participant Hospital and a CJR Collaborator that squarely meets all of the conditions set forth below.

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to Gainsharing Payments and Alignment Payments made and received under a Sharing Arrangement between a Participant Hospital and a CJR Collaborator, provided that all of the following conditions are met:

- a. The following requirements of 42 CFR § 510.500 are satisfied:
 - i. (a)(1) & (3) (relating to Gainsharing Payment and Alignment Payment requirements and the selection of individuals and entities to be CJR Collaborators);
 - ii. (b)(2), (6), & (8) (relating to Sharing Arrangement requirements); and
 - iii. (c)(1)(i), (c)(1)(iii), (c)(1)(iv), (2), (3)(i), (5)-(7), (10), (11), (14), (15), & (16) (relating to Gainsharing Payment, Alignment Payment, and Internal Cost Savings conditions and restrictions).
- b. The Participant Hospital does not add conditions, limitations, or restrictions to the Sharing Arrangement other than those required or permitted under the CJR Regulations or this waiver.
- c. The Participant Hospital has entered into a Sharing Arrangement with a CJR Collaborator, and the financial or economic terms of any Gainsharing Payments and Alignment Payments are specified in writing.
- d. The Participant Hospital maintains documentation of (i) the Sharing Arrangement; (ii) the payment of any Gainsharing Payments, including any recoupment of all or a portion of a CJR Collaborator's Gainsharing Payment; and (iii) the receipt of any Alignment Payments. The Participant Hospital must retain such documentation for at least ten (10) years following the last Gainsharing Payment or Alignment Payment and make such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneously with the correlating event (e.g., documentation of the Participant Hospital's payment of a Gainsharing Payment must be created contemporaneously with the distribution of such payment).
- e. Neither the Participant Hospital nor the CJR Collaborator restricts Medicare beneficiaries' ability to choose any Medicare-enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.
- f. The requirements of 42 CFR § 510.405(a)(2) (prohibiting the charging and acceptance of fees for inclusion on a list of preferred providers or suppliers) are satisfied.

For the payment and receipt of Gainsharing Payments and Alignment Payments that meet all of the preceding conditions, the waiver period will start on January 1, 2018, and will end on the earlier of (i) the effective date of termination or expiration of the Sharing Arrangement; (ii) 24 months after the Participant Hospital's final Performance Year or, in the case of a Non-Electing Hospital, December 31, 2019; (iii) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR § 510.410(b)(2)(v); or (iv) the date on which the Participant Hospital is required to terminate the Sharing Arrangement with the CJR Collaborator under 42 CFR § 510.410(b)(2)(iv).

2. Waiver for Distribution Payments from a CJR Collaborator to a Collaboration Agent (Distribution Payments Waiver)

The intent of this Distribution Payments Waiver is to provide protection for the payment and receipt of Distribution Payments pursuant to a Distribution Arrangement between a CJR Collaborator and a Collaboration Agent that squarely meets all of the conditions set forth below.

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to Distribution Payments made and received under a Distribution Arrangement between a CJR Collaborator and a Collaboration Agent that is entitled to receive such distribution under 42 CFR § 510.505, and the receipt of such Distribution Payments, provided that all of the following conditions are met:

- a. The following requirements of 42 CFR § 510.505 are satisfied:
 - i. (a)(1) (Distribution Payment made in accordance with a Distribution Arrangement); and
 - ii. (b)(2), (4)-(7), (9)-(12), & (14) (relating to Distribution Arrangement requirements).
- b. Distribution Payments are derived solely from Gainsharing Payments made by a Participant Hospital to the CJR Collaborator pursuant to a Sharing Arrangement under the CJR model.
- c. The CJR Collaborator does not add conditions, limitations, or restrictions to the Distribution Arrangement other than those required or permitted by the CJR Regulations or this waiver.
- d. The CJR Collaborator has entered into a Distribution Arrangement with a Collaboration Agent, and the financial or economic terms of any Distribution Payments are specified in writing.
- e. The CJR Collaborator maintains documentation of the Distribution Arrangement and the payment of any Distribution Payments; retains such documentation for at least ten (10) years following the last Distribution Payment; and makes such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneously with the correlating event (e.g., documentation of the CJR Collaborator's payment of a Distribution Payment must be created contemporaneously with the distribution of such payment).

For the payment and receipt of Distribution Payments that meet all of the preceding conditions, the waiver period will start on January 1, 2018, and will end on the earlier of (i) the effective date of termination or expiration of the Distribution Arrangement between the CJR Collaborator and the Collaboration Agent; (ii) 24 months after the final Performance Year or, in the case of a Distribution Payment derived from a Sharing Arrangement between the CJR Collaborator and a Non-Electing Hospital, December 31, 2019; (iii) 12 months after the effective date of termination or expiration of the Sharing Arrangement between the CJR Collaborator and the applicable Participant Hospital; (iv) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR § 510.410(b)(2)(v); or (v) the date on which the Participant Hospital is required to terminate the Sharing Arrangement with the applicable CJR Collaborator under 42 CFR § 510.410(b)(2)(iv).

3. Waiver for Downstream Distribution Payments from a Collaboration Agent to a Downstream Collaboration Agent (Downstream Distribution Payments Waiver)

The intent of this Downstream Distribution Payments Waiver is to provide protection for the payment and receipt of Downstream Distribution Payments pursuant to a Downstream Distribution Arrangement between a Collaboration Agent and a Downstream Collaboration Agent that squarely meets all of the conditions set forth below.

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to the payment and receipt of Downstream Distribution Payments pursuant to a Downstream Distribution Arrangement between a Collaboration Agent and a Downstream Collaboration Agent who is entitled to receive such distribution under 42 CFR § 510.506, provided that all of the following conditions are met:

- a. The following requirements of 42 C.F.R. § 510.506 (Downstream Distribution Arrangements) are satisfied:
 - i. (a)(1) (Downstream Distribution Payment made in accordance with a Downstream Distribution Arrangement); and
 - ii. (b)(2), (4)-(7), (9)-(12), & (14) (relating to Downstream Distribution Arrangement requirements).
- b. Downstream Distribution Payments are derived solely from Distribution Payments made by a CJR Collaborator to a Collaboration Agent pursuant to a Distribution Arrangement under the CJR model.
- c. The Collaboration Agent does not add conditions, limitations, or restrictions to the Downstream Distribution Arrangement other than those required or permitted by the CJR Regulations or this waiver.
- d. The Collaboration Agent has entered into a Downstream Distribution Arrangement with a Downstream Collaboration Agent, and the financial or economic terms of any Downstream Distribution Payments are specified in writing.
- e. The Collaboration Agent maintains documentation of the Downstream Distribution Arrangement and the payment of any Downstream Distribution Payments; retains such documentation for at least ten (10) years following the last Downstream Distribution Payment; and makes such documentation available to the Secretary upon

request. All documentation must be created in advance of or contemporaneously with the correlating event (e.g., documentation of the Collaboration Agent's payment of a Downstream Distribution Payment must be created contemporaneously with the distribution of such payment).

For the payment and receipt of Downstream Distribution Payments that meet all of the preceding conditions, the waiver period will start on January 1, 2018, and will end on the earlier of (i) the effective date of termination or expiration of the Downstream Distribution Arrangement; (ii) 24 months after the final Performance Year or, in the case of a Downstream Distribution Payment derived from a Sharing Arrangement between the CJR Collaborator and a Non-Electing Hospital, December 31, 2019; (iii) 12 months after the effective date of termination or expiration of the Distribution Arrangement between the CJR Collaborator and Collaboration Agent; (iv) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR § 510.410(b)(2)(v); or (v) the date on which the Participant Hospital is required to terminate the Sharing Arrangement with the applicable CJR Collaborator under 42 CFR § 510.410(b)(2)(iv).

4. Waiver for Patient Engagement Incentives Provided by Participant Hospitals to Medicare Beneficiaries in Episodes (PEI Waiver)

The PEI Waiver is intended to allow Participant Hospitals to offer and provide to Medicare beneficiaries preventive care items and care services, as well as items and services that advance certain clinical goals of the CJR model by engaging patients in managing their care as set forth in the CJR Regulations.

Pursuant to section 1115A(d)(l) of the Act, section 1128A(a)(5) of the Act (relating to the beneficiary inducements Civil Monetary Penalty Law (CMP)) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided to a Medicare beneficiary in an Episode if all of the following conditions are met:

- a. The item or service is provided directly by a Participant Hospital or by an agent of the Participant Hospital under the Participant Hospital's direction and control.
- b. The item or service is in-kind.
- c. The item or service is provided to a Medicare beneficiary who is in an Episode at the time the item or service is furnished.
- d. The item or service is reasonably connected to the medical care provided to the Medicare beneficiary during the Episode, and
 - i. Is for preventive care; or
 - ii. Advances any of the following clinical goals by engaging the beneficiary in better managing his or her own health:
 - A. Beneficiary adherence to drug regimens;
 - B. Beneficiary adherence to a care plan;
 - C. Reduction of readmissions and complications resulting from lower-extremity joint replacement procedures; or
 - D. Management of chronic diseases and conditions that may be affected by the lower-extremity joint replacement procedure.

- e. The item or service is not tied to the receipt of items or services outside the Episode.
- f. The requirements of 42 CFR § 510.515(d) (documentation of beneficiary incentives) are satisfied.
- g. Neither the Participant Hospital nor its agent restricts Medicare beneficiaries' ability to choose any Medicare-enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.

For items and services that meet all of the preceding conditions, the waiver period will start on January 1, 2018, and will end on the earlier of (i) the end of the Participant Hospital's final Performance Year or, for Non-Electing Hospitals, January 31, 2018, or (ii) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR § 510.410(b)(2)(v), provided that a beneficiary may keep items received (unless otherwise specified under the CJR Regulations) and receive the remainder of any service initiated during the Episode.

II: Explanation of Certain Waiver Requirements and General Limitations

The waivers set forth in this 2017 Notice have been developed in consultation with the Innovation Center, which is administering and testing the CJR model. In accordance with section 1115A(d)(1) of the Act, the Secretary has determined that these waivers are necessary to test the CJR model. The objectives of the waiver conditions are to ensure that protected arrangements: (i) are consistent with the model; (ii) are subject to safeguards designed to mitigate the risk of fraud and abuse; and (iii) can be readily monitored and audited. In addition to the conditions set forth in these waivers, the CJR Regulations include further requirements that are designed to promote program integrity and lessen the risk of fraud and abuse within the CJR model.

The Department has had the benefit of almost 2 years' experience with the CJR model and the 2015 Notice. The Department has also received feedback from entities participating in the CJR model about various challenges encountered when implementing financial arrangements that comply with the waivers set forth in the 2015 Notice. Based on this experience and feedback, we simplified and streamlined the waivers to reduce burden on providers and suppliers seeking to structure arrangements to satisfy the conditions of an applicable waiver while maintaining a focus on program integrity. For example, the prior Payments Waiver incorporated 42 CFR § 510.500 in its entirety. That is no longer the case for this 2017 Notice. Instead, the 2017 Notice only incorporates certain provisions from the CJR Regulations. The Payments Waiver set forth in this 2017 Notice also aims to significantly reduce the burden of documentation requirements for purposes of the waiver by, for example, providing that only one party—not both—must maintain the required documentation.

As in the 2015 Notice, some waiver requirements in this 2017 Notice incorporate certain provisions of the CJR Regulations by reference. Readers are cautioned to consult the CJR Regulations as necessary to ensure compliance with the CJR Regulations and, if desired, these waivers.

1. Explanation of Certain Waiver Requirements

- To qualify for protection under the Payments Waiver, Distribution Payments Waiver, and the Downstream Distribution Payments Waiver, no additional conditions, limitations, or restrictions (other than those permitted or required by the CJR Regulations or the waiver) may be added to a financial arrangement receiving waiver protection. For example:
 - For an arrangement to receive protection under the Payments Waiver, a Participant Hospital that makes a Gainsharing Payment to a CJR Collaborator may not condition receipt of that Gainsharing Payment on the CJR Collaborator's satisfaction of any additional conditions or criteria related to the number of expected or future referrals from the CJR Collaborator, a Collaboration Agent, or a Downstream Collaboration Agent to the Participant Hospital. Additionally, a CJR Collaborator may not condition an Alignment Payment to a Participant Hospital on the number of the Participant Hospital's expected or future referrals to the CJR Collaborator.
 - For an arrangement to receive protection under the Distribution Payments Waiver, a CJR Collaborator may not condition receipt of Distribution Payments on the number of referrals made or business generated by a Collaboration Agent or a Downstream Collaboration Agent.
 - For an arrangement to receive protection under the Downstream Distribution Payments Waiver, a Collaboration Agent may not condition receipt of Downstream Distribution Payments on the number of referrals made or business generated by a Downstream Collaboration Agent.
- The Payments Waiver, Distribution Payments Waiver, and Downstream Distribution Payments Waiver do not protect the provision or receipt of in-kind remuneration.
- For the PEI Waiver, all items and services must be provided in-kind. Gift cards, cash, or other cash equivalents (instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards) are not covered by the PEI Waiver. Waivers of cost-sharing amounts (for example, copayments and deductibles) also are not protected by the waiver. The in-kind requirement means that the beneficiary must receive the actual item or service and not funds to purchase the items or services. For example, beneficiaries may not be given cash reimbursements for transportation costs such as bus or taxi fare or gasoline. Beneficiaries may be given transportation, including, for example, prepaid vouchers redeemable solely for transportation services for them and any caregivers accompanying them under a contractual arrangement between the Participant Hospital and the transportation provider acting as an agent of the Participant Hospital.
- For the PEI Waiver, in-kind items and services may be provided to a Medicare beneficiary who is in an Episode at the time the item or service is furnished without regard to whether that Episode is subsequently cancelled by CMS pursuant to 42 CFR § 510.210(b).
- The PEI Waiver does not protect any items or services provided to Medicare

beneficiaries outside of an Episode (except as provided for certain services initiated during the Episode) or any other Federal health care program beneficiaries.

- The end dates of each waiver are intended to allow, where necessary, a period after the end of the final Performance Year for certain post-participation operations, including the Innovation Center's reconciliation processes under the CJR Regulations and the calculation and distribution of Gainsharing Payments, Alignment Payments, Distribution Payments, and Downstream Distribution Payments for the final Performance Year.

2. General Limitations

The following are general limitations that apply to this 2017 Notice:

- The waivers set forth in Part I of this 2017 Notice apply to arrangements that squarely meet all of the conditions pertaining to the particular waiver. If an arrangement does not meet all of the waiver conditions, it does not qualify for waiver protection.
- Waivers do not provide retrospective protection; an arrangement must meet all of the waiver conditions during the entire period for which waiver protection is sought. For example, for an arrangement entered into on or before December 31, 2017, to receive waiver protection through December 31, 2017, such arrangement must have satisfied the applicable waiver's conditions as set forth in the 2015 Notice, and continue to satisfy the applicable waiver's conditions as set forth in the 2015 Notice through December 31, 2017. As of January 1, 2018, that arrangement would receive waiver protection if it continues to satisfy the applicable waiver's conditions as set forth in this 2017 Notice.
- Apart from meeting applicable waiver conditions, no special action (such as submission of an application for a waiver) is required by parties to be covered by these waivers. Parties need not apply for a waiver.
- Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Federal physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (sections 1128B(b)(1) and (2) of the Act), or any other applicable law.
- Nothing in this 2017 Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other applicable Federal or State laws and regulations, including, but not limited to, any anti-fraud laws, other than those specified above. Nothing in this 2017 Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the CJR Regulations.
- We reserve the right to reconsider any waiver and, where the public interest requires, to modify, suspend, or terminate a waiver on a prospective basis with respect to some or all Participant Hospitals, CJR Collaborators, Collaboration Agents, or Downstream Collaboration Agents. The modification, suspension, or termination of part or all of a waiver does not require advance notice. We anticipate, however, that the circumstances

under which no advance notice would be provided would be limited to egregious conduct that poses an imminent risk of harm to programs or patients.

As to section 1877(a) of the Social Security Act:

Dated: [December 05, 2017]

/Seema Verma/

Seema Verma
Administrator
Centers for Medicare & Medicaid Services

As to sections 1128B(b)(1) and (2) of the Social Security Act:

Dated: [December 05, 2017]

/Daniel R. Levinson/

Daniel R. Levinson
Inspector General
Department of Health and Human Services