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

November 16, 2015

Section 1115A(d)(l) 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 & Medicaid Innovation (CMMI) 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 (Notice) is issued under this authority. The Comprehensive Care for Joint Replacement (CJR) model is being tested under section 1115A(b) of the Act.

This 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 arrangements that meet all of the listed conditions. Each waiver applies only with respect to the specific laws cited in the waiver. Part II consists of commentary explaining the waiver requirements of Part I. The waivers established by this Notice apply only to the CJR model. These waivers are not applicable outside of the CJR model.

The waivers in this Notice apply to certain arrangements and beneficiary incentives described below that the Secretary has identified as necessary to test the CJR model.

Part I: CJR Model Waiver Conditions

Terms defined in the CJR final rule (Final Rule) at 42 CFR Part 510 that are also used in this Notice have the meaning set forth in the Final Rule. These terms include, but are not limited to: Alignment Payment, CJR Collaborator, Collaborator Agreement, Distribution Arrangement, Distribution Payment, Episode of Care (or Episode), Gainsharing Payment, Internal Cost Savings, Participant Hospital, Performance Year, Practice Collaboration Agent, and Sharing Arrangement.[1]

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

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the 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 distribution of Gainsharing Payments and the payment of Alignment Payments under a Sharing Arrangement between a Participant Hospital and a CJR Collaborator, provided that all of the following conditions are met:

a. All requirements of 42 CFR § 510.500 (Financial arrangements under the CJR model) are met. For purposes of this waiver, maintaining active Medicare billing privileges constitutes compliance with 42 CFR § 510.500(c)(3).

[1] We have capitalized the terms defined in the Final Rule and used in this Notice. The capitalized terms have the same meaning as the uncapitalized terms defined in the Final Rule at 42 CFR § 510.2.

b. All requirements of 42 CFR § 510.405 (Beneficiary choice and beneficiary notification) are met.

c. The Participant Hospital does not add conditions, limitations, or restrictions to the Sharing Arrangement other than those required or permitted under the Final Rule or this waiver.

d. The criteria for selecting a provider or supplier as a CJR Collaborator must include criteria related to, and inclusive of, the quality of care to be delivered by the CJR Collaborator to beneficiaries during an Episode. The Collaborator Agreement must require the CJR Collaborator to have met, or agree to meet, the quality criteria for selection.

e. The CJR Collaborator must meet quality criteria for the calendar year for which the Gainsharing Payment is determined by the Participant Hospital. The quality criteria must be established by the Participant Hospital and directly related to Episodes. The Collaborator Agreement must set forth the quality criteria established by the Participant Hospital that will be used in determining the Gainsharing Payment.

f. The methodology for determining Gainsharing Payments must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an Episode.

For the distribution of Gainsharing Payments and the payment of Alignment Payments that meet all of the preceding conditions, the waiver period will start on the date of this Notice and will end the earlier of (1) the date the Sharing Arrangement is terminated; (2) 24 months after the final Performance Year; (3) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR §§ 510.410(b)(1) and (2)(v); or (4) the date on which the Participant Hospital is required to terminate the Collaborator Agreement with the CJR Collaborator under 42 CFR §§ 510.410(b)(1) and (2)(iv).

2. Waiver for Distribution Payments from a Physician Group Practice to a Practice Collaboration Agent

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the 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 distribution of Distribution Payments from a physician group practice as used in 42 CFR § 510.505 that is a CJR Collaborator to a Practice Collaboration Agent who is entitled to receive such distribution under 42 CFR § 510.505, provided that all of the following conditions are met:

a. All requirements of 42 CFR § 510.505 (Distribution Arrangements) are met.

b. Distribution Payments are derived solely from Gainsharing Payments made by a Participant Hospital to the Physician Group Practice (PGP) pursuant to a Sharing Arrangement under the CJR model.

c. The distribution of the Gainsharing Payments from the Participant Hospital to the PGP from which the Distribution Payments are derived satisfies the requirements of the Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements set forth in this Notice.

d. Distribution Payments are made pursuant to a written Distribution Arrangement between the PGP and the Practice Collaboration Agent that sets forth the terms and conditions of the Distribution Arrangement in advance of any distribution of Distribution Payments by the PGP.

e. The PGP does not add conditions, limitations, or restrictions to the Distribution Arrangement other than those required or permitted by the Final Rule or this waiver.

For the distribution of Distribution Payments that meets all of the preceding conditions, the waiver period will start on the date of this Notice and will end the earlier of (1) the date the PGP's Sharing Arrangement with the Participant Hospital is terminated; (2) the date the written Distribution Arrangement between the PGP and the Practice Collaboration Agent is terminated; (3) 24 months after the final Performance Year; (4) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR §§ 510.410(b)(1) and (2)(v); or (5) the date on which the Participant Hospital is required to terminate the Collaborator Agreement with the PGP under 42 CFR §§ 510.410(b)(1) and (2)(iv).

3. Waiver for Patient Engagement Incentives Provided by Participant Hospitals to Medicare Beneficiaries in Episodes

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)(l) 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 during the Episode.

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. All requirements of 42 CFR § 510.515(c) (Documentation of beneficiary incentives) are met.

g. All requirements of 42 CFR §510.405 (Beneficiary choice and beneficiary notification) are met.

For items and services that meet all of the preceding conditions, the waiver period will start on the first day of the first Performance Year and will end on the earlier of (1) the end of the final Performance Year or (2) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR §§ 510.410(b)(1) and (2)(v), provided that a beneficiary may keep items received (unless otherwise specified under the Final Rule) and receive the remainder of any service initiated during the Episode.

Part II: Explanation of Waiver Requirements

Each waiver set forth in Part I of this Notice applies to arrangements that squarely meet all of the conditions pertaining to that particular waiver. A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement (1) does not implicate the specific fraud and abuse law; (2) implicates the law, but fits within an existing exception or safe harbor, as applicable; or (3) otherwise complies with the law. 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 physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), and the beneficiary inducements CMP (section 1128A(a)(5) of the Act). Failure to fit in a waiver is not, in and of itself, a violation of the law(s). If an arrangement otherwise complies with existing law, it does not need protection under a waiver.

The waivers in this Notice have been developed in consultation with CMMI, which is administering and testing the CJR model. Section 1115A(d)(1) of the Act specifies the legal standard that has guided development of these waivers. Under this standard, the physician self-referral law, the Federal anti-kickback statute, and the beneficiary inducements CMP may be waived "as may be necessary solely for purposes of carrying out the testing" of the CJR model. The Secretary has determined that the arrangements covered by these waivers are necessary to carry out the testing of the CJR model.[2]

Each waiver protects only arrangements that meet *all* of the listed conditions. 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 period for which waiver protection is sought.

The design of the waivers is premised on the expectation that the requirements of the Final Rule will mitigate risks of fraud and abuse. The goal of the waiver conditions is to ensure that

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[2] This Notice does not waive the "gainsharing" CMP (section 1128A(b)(1) and (2) of the Act). Section 512 of the Medicare Access and CHIP Reauthorization Act of 2015, 114 P.L. 10, revised the statute so that it prohibits hospitals from knowingly making payments, directly or indirectly, to induce physicians "to reduce or limit *medically necessary* services" provided to Medicare or Medicaid beneficiaries. 114 P.L. 10, *512, 129 Stat. 87 (emphasis added). Because the statute no longer prohibits payments knowingly made by hospitals to induce physicians to reduce or limit medically unnecessary services, no waiver of the gainsharing CMP is needed.

protected arrangements are consistent with the quality, care coordination, and cost reduction goals of the CJR model; are subject to safeguards designed to mitigate the risk of fraud and abuse (including, for example, risk of harms such as overutilization, underutilization, increased costs, and inappropriate patient steering); and can readily be monitored and audited. In general, the enumerated terms and conditions are those focused on accountability, transparency, compliance, and program integrity. Some waiver provisions incorporate the provisions of the Final Rule by reference. Readers are cautioned to consult the Final Rule as necessary to ensure compliance with the Final Rule and, if desired, these waivers.

Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other Federal or State laws and regulations. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the Final Rule. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required for an arrangement to be covered by these waivers.

We reserve the right to reconsider the waivers and to modify, suspend, or terminate the waivers on a prospective basis for any reason consistent with the public interest and with respect to some or all Participant Hospitals, CJR Collaborators, and Practice Collaboration Agents. The modification, suspension, or termination of part or all of the waivers does not require advance notice. If the modification, suspension, or termination applies to all Participant Hospitals, CJR Collaborators, and Practice Collaboration Agents, it shall be effective when publicly posted. If the modification, suspension, or termination of a waiver is limited to one or more specific Participant Hospital(s), CJR Collaborator(s), or Practice Collaboration Agent(s), we will publicly post a notice and provide separate notice to the parties named in the notice, and the modification, suspension, or termination shall be effective on the date of the 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.

A. Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements.

The Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements (Payments Waiver) applies to the application of the physician self-referral law and the Federal anti-kickback statute to distributions of Gainsharing Payments and payment of Alignment Payments. The Payments Waiver protects only Gainsharing Payments and Alignment Payments as defined in the Final Rule. This waiver does not protect distributions of Distribution Payments made by a PGP to a Practice Collaboration Agent; those arrangements are addressed by the PGP Waiver, described below.

To be protected by the Payments Waiver, Gainsharing Payments and Alignment Payments must meet the requirements of 42 CFR § 510.500—including, but not limited to, all requirements related to the calculation and the distribution of payments, the quality criteria for selecting CJR Collaborators and determining payments to CJR Collaborators, and the creation and retention of records (for example, Sharing Arrangement, Collaborator Agreement, and list of CJR Collaborators)—and the conditions of the Payments Waiver. The Payments Waiver protects only Gainsharing Payments from a Participant Hospital to a CJR Collaborator and Alignment Payments from a CJR Collaborator to a Participant Hospital. The Payments Waiver does not

protect any other payment made by a Participant Hospital or a CJR Collaborator or any other person or entity. Other arrangements would need to comply with existing law and may qualify for protection under an existing exception or safe harbor.

The Payments Waiver protects only Gainsharing Payments and Alignment Payments and does not protect any other arrangements that may be included in the Collaborator Agreement or any other agreement between a Participant Hospital and a CJR Collaborator. Any arrangements for the provision of items or services between Participant Hospitals and CJR Collaborators, even if such items or services contribute to care redesign, Episode spending, or quality performance within an Episode, are not protected by the Payments Waiver. In addition, to qualify for waiver protection, no additional conditions, limitations, or restrictions, other than those permitted or required by the Final Rule or the waiver, may be added to the Sharing Arrangement or the Collaborator Agreement or imposed upon receipt of a Gainsharing Payment or Alignment Payment. For example, 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 to the Participant Hospital. Similarly, 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. The Payments Waiver does not protect any payment solicited or received by a Participant Hospital for inclusion of a particular provider or supplier on the Participant Hospital's preferred provider list, nor does the Payments Waiver protect arrangements that incentivize reductions in the amount or quality of medically necessary care furnished to Medicare beneficiaries.

Under the Final Rule, and thus also for purposes of this waiver, Gainsharing Payments and Alignment Payments must be made by electronic funds transfer. This requirement increases transparency so that payments may be more readily monitored and verified. Also, this condition makes clear that payments in the form of in-kind items or services are not protected. More generally, the Payments Waiver does not protect financial arrangements other than the distribution of Gainsharing Payments and the payment of Alignment Payments, as defined in the Final Rule, such as personal services or management contracts, health information technology or other infrastructure arrangements, staffing arrangements, or others, even if the arrangements are of comparable value to the Gainsharing Payment or Alignment Payment that would otherwise be paid. Such arrangements would need to comply with existing law and may qualify for protection under existing exceptions or safe harbors.

The Payments Waiver requires contemporaneous documentation that identifies key information related to the Gainsharing Payments and Alignment Payments for which waiver protection is sought, consistent with the Final Rule at 42 CFR § 510.500, including contemporaneous documentation of the payment and receipt of such payments.

For distributions of Gainsharing Payments and the payment of Alignment Payments that meet all of the prescribed conditions of the Payments Waiver, the waiver period will start on the date of this Notice and will end the earlier of (1) the date the Sharing Arrangement is terminated; (2) 24 months after the final Performance Year; (3) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR §§ 510.410(b)(1) and (2)(v); or (4) the date on which the Participant Hospital is required to terminate the Collaborator Agreement with the CJR

Collaborator under 42 CFR §§ 510.410(b)(1) and (2)(iv). These end dates are intended to align with the Performance Years and the period of the Sharing Arrangement between the Participant Hospital and the CJR Collaborator and to allow, where necessary, a period after the end of the final Performance Year for certain post-participation operations, including Centers for Medicare & Medicaid Services' (CMS) reconciliation processes under the Final Rule and the calculation and distribution of final Gainsharing Payments and Alignment Payments.

B. Waiver for Distribution Payments from a Physician Group Practice to Practice Collaboration Agent

Waiver for Distribution Payments from a Physician Group Practice to Practice Collaboration Agent (the PGP Waiver) applies solely to Distribution Payments, as defined in the Final Rule, made by PGP that is a CJR Collaborator to a Practice Collaboration Agent as defined in the Final Rule. The Practice Collaboration Agent must be eligible to receive a Distribution Payment from the PGP under the Final Rule. The Distribution Payment must be derived solely from a Gainsharing Payment made by a Participant Hospital to the PGP under the CJR model, and the distribution of the Gainsharing Payment must also comply with the Payments Waiver described above. The intent of the PGP Waiver is to allow for situations in which a PGP that is also a CJR Collaborator seeks to distribute all or a portion of the Gainsharing Payment it has received from a Participant Hospital to a Practice Collaboration Agent. Distribution of Distribution Payments from the PGP to Practice Collaboration Agents is subject to conditions in the waiver, including compliance with relevant provisions of the Final Rule.

The Distribution Payments must be made pursuant to a written Distribution Arrangement between the PGP and the Practice Collaboration Agent that sets forth the terms and conditions of the Distribution Arrangement. The terms and conditions must be set in advance of any payments being made by the PGP to the Practice Collaboration Agent. In no event would a Distribution Payment be protected if that Distribution Payment, or the Gainsharing Payment from which it is derived, is earned by reducing the amount or quality of medically necessary care provided to Medicare beneficiaries.

The PGP Waiver does not protect any other arrangements directly or indirectly between the PGP and Practice Collaboration Agents, nor any arrangements between Practice Collaboration Agents and other individuals or entities. As with the Payments Waiver, no conditions, limitations, or restrictions may be added to the Distribution Arrangement other than those required or permitted by the Final Rule or the waiver. For example, the PGP may not condition receipt of Distribution Payments on the number of referrals made or business generated for the PGPs or other Practice Collaboration Agents by the Practice Collaboration Agent. The PGP Waiver does not protect financial arrangements between the PGP and Practice Collaboration Agents other than Distribution Payments under the Final Rule, such as employment, personal services, or management contracts; returns on investment to PGP owners; or health information technology or other infrastructure arrangements, even if the arrangements are of comparable value to the Distribution Payment that would otherwise be paid. Such arrangements would need to comply with existing law and may qualify for protection under other exceptions or safe harbors.

For the same reasons stated above for the Payments Waiver, distributions of Distribution Payments must be made by electronic funds transfer. As with the Payments Waiver, the PGP Waiver requires compliance with the documentation requirements of 42 CFR § 510.505.

The waiver period for the PGP Waiver will start on the date of this Notice and will end the earlier of (1) the date the PGP's Sharing Arrangement with the Participant Hospital is terminated; (2) the date the written Distribution Arrangement between the PGP and the Practice Collaboration Agent is terminated; (3) 24 months after the final Performance Year; (4) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR §§ 510.410(b)(1) and (2)(v); or (5) the date on which the Participant Hospital is required to terminate the Collaborator Agreement with the PGP under 42 CFR §§ 510.410(b)(1) and (2)(iv). As noted for the Payments Waiver, this waiver period allows for a period of time after the end of the final Performance Year to accommodate post-participation operational issues and payment distributions. The PGP Waiver is coterminous with the Payments Waiver. If the Payments Waiver is no longer in effect for the PGP at the time of the distribution, then the PGP and the Practice Collaboration Agent are not covered by the PGP Waiver.

C. Waiver for Patient Engagement Incentives Provided by Participant Hospitals to Medicare Beneficiaries in Episodes

This waiver (the Patient Engagement Incentives or PEI Waiver) protects certain items or services provided to a Medicare beneficiary during an Episode that promote beneficiary engagement with managing his or her care. Each condition enumerated in the waiver must be met for the waiver to apply. The PEI Waiver applies to the Federal anti-kickback statute and the Beneficiary Inducements CMP, and includes certain safeguards designed to mitigate the risk of fraud and abuse. This waiver is intended to protect beneficiary incentives generally described at 42 CFR § 510.515, provided they meet all the conditions of this waiver. To be protected, an item or service must meet all conditions of the waiver. The waiver does not protect any items or services provided to Medicare beneficiaries outside of an Episode (except as provided for certain services that occur after termination of the waiver) or any other Federal health care program beneficiaries.

Consistent with the CJR model, the PEI Waiver protects only items and services provided by the Participant Hospital directly or through an agent who is under the hospital's direction and control. Consistent with the Final Rule, it does not protect an item or service if a reasonable beneficiary would perceive the item or service as being from the agent, rather than from the Participant Hospital. (Nothing in this Notice prevents Participant Hospitals or CJR Collaborators from providing, or structuring arrangements to provide, items or services to beneficiaries if they can do so in a manner that complies with existing law.)

The PEI Waiver is intended to allow Participant Hospitals to offer and provide to Medicare beneficiaries preventive items and care services, as well as items and services that advance the clinical goals by engaging patients in managing their care as set forth in the program rules and the waiver. The clinical goals are beneficiary adherence to drug regimens, beneficiary adherence to a care plan, reduction of readmissions and complications resulting from lower-extremity joint replacement procedures, and management of chronic diseases and conditions that may be affected by the lower-extremity joint replacement procedure.

All items and services must be provided in-kind. Gift cards, coupons, cash, or other cash equivalents 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, or public transportation fare cards or tokens. Beneficiaries may be given 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.

The item or service must be reasonably related to medical care provided to a Medicare beneficiary during an Episode. For example, technology in the form of a device to monitor and transmit medical indications and symptoms could be reasonably related to medical care provided during an Episode, but a device that solely plays games would not be. Similarly, transportation to medical appointments or to pick up prescriptions could be protected, but transportation to entertainment or recreational events would not be.

For items or services that meet all of the prescribed conditions of the PEI Waiver, the waiver period will start on the first day of the first Performance Year and will end on the earlier of (1) the end of the final Performance Year or (2) the date on which the Participant Hospital is terminated from the CJR model under 42 CFR §§ 510.410(b)(1) and (2)(v), provided that a beneficiary may keep items received (unless otherwise specified under the Final Rule), and receive the remainder of any service initiated during the Episode. The PEI Waiver period does not include a "tail" period after the end of the final Performance Year because items or services can be offered only during an Episode. We have included provisions to ensure continuity of care for beneficiaries who may be receiving items or services during an Episode in the event that the model year ends or the Participant Hospital is terminated from the model during an Episode.

As to section 1877(a) of the Act:

Dated: [November 16, 2015]

/Andrew M. Slavitt/

Andrew M. Slavitt
Acting Administrator,
Centers for Medicare & Medicaid Services

As to section 1128A(a)(5), and sections 1128B(b)(l) and (2) of the Act:

Dated: [November 16, 2015]

/Daniel R. Levinson/

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