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Waivers of Certain Fraud and Abuse Laws Permitted in CJR Model

On Nov. 16, 2015, the U.S. Centers for Medicare & Medicaid Services (CMS) issued a Final Rule implementing a new Medicare program in which acute care hospitals in certain geographic areas will be responsible for a retrospective bundled payment for episodes of care to beneficiaries admitted for all lower extremity joint replacements. This new payment bundling program, named the Comprehensive Care for Joint Replacement (CJR), goes into effect April 1, 2016. The CJR permits providers to enter into certain agreements that allow them to share in both cost-savings and overpayments anticipated by the bundling program. These types of sharing arrangements, though, would typically run afoul of certain fraud and abuse laws. Therefore, in conjunction with the implementation of the Final Rule, the Secretary of Health and Human Services has determined that waivers of the Ethics in Patient Referrals Act of 1989 (Stark) (SSA § 1877), the Federal Anti-Kickback Statute (AKS) (SSA § 1128B(b)) and Anti-Inducement provisions of the Civil Monetary Penalty Law (CMP) (SSA § 1128A(a)(5)) are required to carry out the goals of the CJR. Waivers are applicable only within the CJR model and if all stated conditions are met. The waiver period begins immediately and ends no later than the 24 months after the final performance year of the CJR model. The Final Rule and corresponding waivers are discussed below.

The CJR Retrospective Bundling Model

Created under the authority of the Center for Medicare & Medicaid Innovation (CMMI), the CJR will be tested over a five-year demonstration period and is intended to reduce Medicare expenditures and improve the efficiency and quality of care for beneficiaries undergoing knee and hip replacements. The episode of care begins with the hospital admission and covers all related care within 90 days of the hospital discharge. The total episode payment will be calculated at the end of a performance year and then be compared to a regional target price. If the episode payment exceeds the regional target price, the hospital will be responsible for Repayment to Medicare, and if it is less than the established target price, the hospital will be paid a Reconciliation payment.

Sharing Arrangements Permitted

Since the acute care hospitals will be accepting the financial risk for the entire episode, the CJR model permits Sharing Arrangements with CJR "Collaborators," who are defined as the non-hospital providers during the 90-day episode of care, such as orthopedic surgeons, physician group practices (PGP), skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, and providers and suppliers of therapy services. Under these Sharing Arrangements, the CJR will permit Gainsharing and Alignment Payments between a participant hospital and a CJR Collaborator. A Gainsharing Payment is defined as a payment from a participant hospital to a CJR Collaborator, when the hospital receives a Reconciliation payment. An Alignment Payment is a payment from a CJR Collaborator to a participant hospital, when Repayment to Medicare is required. The CJR also permits a PGP that is a CJR Collaborator to distribute to its PGP members Gainshairing Payments, which are defined as Distribution Payments made pursuant to a Distribution Arrangement. In addition to this payment sharing among providers, the CJR also permits participant hospitals to provide certain in-kind patient engagement incentives directly to the beneficiaries undergoing hip and knee replacements.

Waivers of Fraud and Abuse Laws

Under most circumstances, these Gainsharing, Alignment and Distribution Payments, as well as the beneficiary incentives would violate Stark, and implicate both the AKS and Anti-Inducement Act. Therefore, in conjunction with the CJR bundling payment model, these fraud and abuse laws are being waived, subject to certain conditions, because it is believed that the CJR will reduce the normal risks of fraud and abuse. There are three categories of waivers that have been established: (1) Gainsharing and Alignment Payments between a participant hospital and a CJR Collaborator ("Payments Waiver"); (2) Distribution Payments from PGP to PGP members ("PGP Waiver"); and (3) Patient engagement incentives provided by participant hospitals to Medicare beneficiaries during the episodes ("PEI Waiver"). Each waiver protects only those arrangements that meet all of the listed conditions, as set forth below, and are not applicable outside of the CJR model. Failure to satisfy a waiver is not, in and of itself, a violation of the law(s). Arrangements that do not meet a waiver have no special protection and will be evaluated on a case-by-case basis.

The "Payments" Waiver

Stark and AKS are waived with respect to the distribution of Gainsharing Payments and the Alignment Payments under a Sharing Arrangement between a participant hospital and a CJR Collaborator, provided that all of the following conditions are met:

1. All requirements of the Sharing Arrangements as set forth in the Final Rule are met;
2. All requirements of beneficiary choice and beneficiary notification are met;
3. The participant hospital does not add conditions (such as the number of expected or future referrals), limitations, or restrictions to the Sharing Arrangement other than those required or permitted under the Final Rule or this waiver;
4. 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;
5. The CJR Collaborator must meet quality criteria for the calendar year. The Collaborator agreement must set forth the quality criteria established by the participant hospital and be directly related to episodes; and,
6. 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.

Gainsharing and Alignment Payments must be made by electronic funds transfer to allow for transparency and easier monitoring and verification. Payments in the form of in-kind items or services are not protected. The Payments Waiver also does not protect financial arrangements, such as personal services or management contracts, health information technology or other infrastructure arrangements, staffing arrangements, even if the arrangements are of comparable value to the Gainsharing or Alignment Payments that would otherwise be paid. Such arrangements would need to comply with existing law or qualify for protection under existing exceptions or safe harbors.

The PGP Waiver

The intent of the PGP Waiver is to allow for situations in which a PGP desires to distribute all, or a portion of, the Gainsharing Payment it has received from a participant hospital to its members. Stark and AKS will be waived with respect to these Distribution Payments, if a PGP is a CJR Collaborator and the following conditions are met:

1. All requirements of Distribution Arrangements as set forth in the Final Rule are met;
2. Distribution Payments are derived solely from Gainsharing Payments made by a participant hospital to the PGP pursuant to a Sharing Arrangement under the CJR model;
3. The distribution of the Gainsharing Payments from the participant hospital to the PGP satisfies the requirements of the Payments Waiver described above;
4. Distribution Payments are made pursuant to a written Distribution Arrangement between the PGP and the PGP member that sets forth the terms and conditions in advance; and,
5. 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.

As with the Payments Waiver, Distribution Payments must be made by electronic funds transfer. The Final Rule does not require a PGP to make a Distribution Payment, and the PGP is free to retain some or all of the Gainsharing Payment it receives from a participant hospital.

The PEI Waiver

The PEI Waiver is intended to allow participant hospitals to offer and provide Medicare beneficiaries preventative items and care services, as well as items and services that advance clinical goals. The Anti-Inducement provision of the CMP and the AKS are waived with respect to items or services provided to a Medicare beneficiary in an episode if all of the following conditions are met:

1. 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;
2. The item or service is in-kind;
3. The item or service is provided during the episode;
4. The item or service is reasonably connected to the medical care provided to the Medicare beneficiary, is for preventative care, and advances outlined clinical goals by engaging the beneficiary in better managing his or her own health;
5. The item or service is not tied to the receipt of items or services outside the episode;
6. All requirements of documentation of beneficiary incentives as set forth in the Final Rule are met; and,
7. All requirements of beneficiary choice and notification as set forth in the Final Rule are met.

As set forth in the waiver, all items and services must be provided in-kind. Thus, gift cards, coupons, cash or other cash equivalents are not covered by the PEI Waiver. Waivers of cost-sharing amounts (for example, copayments and deductible) also are not protected by the waiver. The in-kind requirement means 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 public transportation fare cards or tokens. However, prepaid vouchers redeemable for transportation services are permissible.

Waiver Period

The waivers of the above fraud and abuse laws are limited to the CJR model and therefore, only apply during the 5-year demonstration period. These waivers go into effect immediately, and end when arrangements are terminated or when a provider or participant hospital is terminated from the CJR model. An exception is made for the Payments and PGP Waivers to extend beyond the demonstration model for 24 months after the final performance year of the CJR Model, or into 2022. Because the bundling payment model is retrospective, and the calculation of Reconciliation and Repayments is

done after a performance year, this extension will accommodate post-participation payment distributions under the sharing arrangements between providers.

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