ROPES & GRAY

ALERT

Health Care

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CMS Issues Final Payment Rules for Physicians and Hospitals

On October 30, 2015, the U.S. Department of Health and Human Services (HHS) released several final rules related to physician and hospital Medicare payments for 2016. Specifically, HHS's Centers for Medicare and Medicaid Services (CMS) finalized rules for the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System, as well as the Home Health Prospective Payment System and the End-Stage Renal Disease Prospective Payment System. In addition to various provisions related to incentive payments, public reporting, and quality measures, the final rules provided important clarifications to the Two Midnight Rule, the Stark Law, and advanced care payments.

I. Stark Law Clarifications and Exceptions

The Medicare Physician Fee Schedule and Other Revisions to Part B for 2016 final rule (PFS) (CMS-1631-FC), effective January 1, 2016, updated the physician payment rates and incorporated several provisions from recent legislation. The PFS also adopted clarifications and new exceptions to the Stark regulations, resulting largely from CMS's review of Self-Referral Disclosure Protocol (SRDP) submissions and receipt of numerous industry inquires. Speaking generally, several Stark restrictions have been loosened by, among other things, expanding exceptions relating to "technical" requirements like signatures, and creating two new exceptions that expand the universe of permissible hospital-physician relationships to include timesharing and support for recruitment of nonphysician professionals to furnish primary care. More specifically, the final rule changes to the Stark regulations include:

- **Ease the writing requirements**. Many exceptions require that arrangements, like leases and personal services arrangements, be memorialized in a writing. The historical industry standard has been in almost all cases to require traditional contracts. Through its experience in the SRDP process, CMS has seen how frequently foot-faults in this area can occur. Accordingly, CMS has formalized its operating policy. In CMS's words: "there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract. Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties," may suffice.
- **Ease the signature requirements**. Expanding the special rules for non-compliance with the signature requirement, adopted a few years ago, CMS will now allow parties to obtain signatures within 90 days after an arrangement begins, whether or not failure to have had signatures in place at the outset was inadvertent. This does, however, remain subject to the frequency limitations currently in place.
- **Ease the one-year requirements**. Many exceptions also require that arrangements have a term of at least one year. CMS affirmed that an arrangement that, in fact, is in place for at least one year will satisfy the requirement, whether or not the written documentation includes an explicit one-year (or more) term.
- **Expand holdover protection**. Consistent with the changes above (and indeed perhaps practically compelled by them), CMS has eliminated the six-month limit on holdover protection. Subject to other requirements in place, like fair market value, a holdover could extend indefinitely.
- **Further develop the "stand in the shoes" rules**. Responding to questions arising from the first iterations of the "stand in the shoes rules," CMS has confirmed the general industry understanding that physicians who stand in the shoes of their physician organizations do not need to sign all agreements between their organizations and an entity that furnishes designated health services (DHS) (like a hospital). However, when determining whether payments made between a DHS entity and a physician organization subject to stand-in-the-shoes are impermissibly volume-variable, CMS confirmed that it will look at all physicians, including

non-owners. As a result of this change, the industry now must consider whether CMS's directive to measure volume-variability of compensation paid to a physician organization subject to stand-in-the-shoes on the basis of the referrals of *all* physicians in the physician organization leaves any practical use for indirect compensation analyses for employees and contractors—while not so stated in the preamble, requiring employees and contractors to stand in the shoes for purposes of measuring volume-variability may in practice have eliminated the voluntary nature of stand-in-the-shoes with respect to any non-owner physician in a physician organization that has at least one physician owner.

- **Ease physician-owned hospitals' disclosure requirements, but change ownership calculations**. CMS provided welcome confirmation regarding disclosures required of a physician-owned hospital, excluding certain categories of websites, providing additional principles regarding whether something counts as "public advertising," and noting examples of name-based disclosures that suffice. However, CMS also made some changes—with delayed effectiveness of January 2017—to how physician-ownership levels are calculated, so that, for determining *both* the baseline level and the current level, hospitals must count *all* physician owners, not just physicians who refer.
- **Finalize methodology defining the geographic area served by FQHCs and RHCs**. CMS finalized the definition for the geographic area served by a federally qualified health center (FQHC) or rural health center (RHC) under the physician recruitment exception. As finalized, the geographic area of each of an FQHA or RHC is defined as the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis.
- **Clarify "remuneration."** In response to questions that arose from the Third Circuit's 2009 decision in *United States ex rel. Kosenske v. Carlisle HMA*, CMS confirmed that a physician's use of hospital space to provide services to the hospital's patients is not itself "remuneration," and therefore does not create a financial relationship between the hospital and the physician, if both the hospital and the physician independently bill for their respective services.

Further, to facilitate expanded access to care, CMS adopted two new exceptions to physician self-referral prohibitions:

- **Timeshare arrangements.** CMS established a new exception for qualifying timeshare arrangements between physicians and hospitals. To qualify for this exception, (i) remuneration for the use of premises, equipment, personnel, items, supplies, or services must be predominantly for the provision of evaluation and management services to patients; (ii) the arrangement cannot involve advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment; and (iii) the parties to the arrangement must be, on the one hand, a physician (or physician organization in whose shoes the physician stands) and, on the other, a hospital or a physician organization. The "standard-fare" requirements common to other exceptions also apply here. Arrangements must not be conditioned on the licensee's referral of patients to the licensor, and the compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. Further, this exception is not available to convey a possessory leasehold interest in any office space subject to the arrangement.
- **Assistance to employ nonphysician practitioners.** CMS also established a new exception for payments made by a hospital, FQHC, or RHC to a physician to assist the physician in engaging a nonphysician practitioner to furnish primary care (including mental health) services. For these purposes, "nonphysician practitioners" include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and clinical psychologists and social workers. This exception applies only to situations in which the employment agreement or contract is set out in writing and signed by the hospital, physician, and nonphysician practitioner. The purpose of the engagement must be to provide primary care services to patients of the physician practice, and the arrangement must comply with other Stark law and anti-kickback statute requirements. The exception caps the amount of remuneration at 50 percent of the nonphysician

practitioner's aggregated compensation and benefits paid by the physician during a period not to exceed the first two consecutive years of the arrangement.

II. Changes to the Two Midnight Rule

The final rule for the Hospital Outpatient Prospective Payment for 2016 (CMS-1633-FC and CMS-1607-F2) (OPPS) includes updates to the Two Midnight Rule, which will go into effect for calendar year 2016, regarding when inpatient admissions are appropriate for payment under Medicare Part A.

A. Increased Discretion to Allow Payment under Medicare Part A for Short Inpatient Stays

For inpatient stays not expected to cross two midnights, the new rule permits the admitting physician to exercise greater discretion in determining, on a case-by-case basis, whether an inpatient admission is appropriate under Medicare Part A. The physician's decision is subject to medical review, and the hospital must maintain supporting documentation in the medical record to substantiate that inpatient admission is necessary. Under the new rule, it will continue to be unlikely that an inpatient admission will be payable under Medicare Part A if the patient is not in the hospital for at least one overnight period. CMS will monitor the number of admissions under the new rule and will prioritize these cases for medical review.

For inpatient stays that are expected to last at least two midnights, the rule remains the same, and services provided to such patients will generally be assumed to be payable under Medicare Part A.

B. Changes to Enforcement Mechanism

Effective October 1, 2015, responsibility for the initial review of inpatient admissions under the Two Midnight Rule shifted from Medicare Administrative Contractors (MACs) and Recovery Audit Contractors (RACs) to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs will continue to review inpatient cases under the existing Two Midnight Rule criteria through the end of calendar year 2015, at which time they will begin reviewing cases under the revised criteria described in the final rule.

BFCC-QIO reviews will focus on educating providers about when inpatient hospital claims are payable under Medicare Part A in accordance with the Two Midnight Rule. The BFCC-QIO may refer the provider to a RAC if it identifies patterns of inappropriate inpatient admissions, or if the provider fails to improve its inpatient admission practices following education by the BFCC-QIO.

In addition, CMS has already implemented, or is in the process of implementing, certain changes to the RAC program that will affect the review of inpatient hospital claims:

- In order to provide hospitals with sufficient time to rebill for Medicare Part B services after the denial of a Medicare Part A claim, CMS has decreased the RAC look-back period from three years to six months from the date of service. The shorter look-back period is limited to instances where the hospital submits the claim within three months of the date of service.
- For providers that are new to RAC reviews, CMS has established limits on Additional Documentation Requests (ADRs). CMS is working to establish additional limits on ADRs based on a hospital's historical compliance with Medicare rules.
- CMS is in the process of implementing a requirement that RACs complete complex reviews within 30 days. If a RAC fails to complete a complex review within this period, it will lose any contingency fee to which it would otherwise be entitled for the affected claims.
- CMS is working to establish a 30-day waiting period before the RAC can send a claim to the MAC for adjustment. This will enable the provider to submit a discussion period request before any payment adjustments are made.

III. Other Notable Provisions

CMS stated that these final rules "advance value-based purchasing and promote program integrity." In addition to the Stark Law and Two Midnight Rule changes, the following provisions are meant to assist in achieving these lofty Medicare goals.

A. Advance Care Planning

CMS received a large number of comments supporting its proposal to allow physicians to bill for advanced care planning conversations and has finalized the provision to better assist patients and their families engaged in such planning. Advance care planning generally includes conversations between patients and their practitioners before and during treatment for a progressive illness, to determine the best present and future care plan. As such, CMS, consulting with the American Medical Association, is establishing separate payment and a payment rate for two advance care planning services provided to Medicare beneficiaries by physicians and other practitioners. This will lead to more opportunity and flexibility to utilize planning sessions at a time most appropriate for the patient.

B. EHR Advancement

CMS continues to revise the definition of certified EHR technology in accordance with new criteria intended to align with the requirements of Stage 3 of the EHR Incentive Program and clinical quality measures (CQM).

C. Modifications to Hospital Quality Reporting and PQRS

The final rules include various adjustments to the quality program measures for the hospital outpatient quality reporting program, the Physician Quality Reporting System (PQRS), and ambulatory surgical center quality reporting program, including the addition of new quality measures and the deletion of certain existing quality measures to address outstanding gaps and streamline the measure to improve its data collection.

D. OPPS Payment Policies

The final outpatient payment rule includes updates to the payment policies and rates for outpatient services, ambulatory surgery centers, and partial hospitalization services provided by Community Mental Health Centers.

E. Home Health Performance Payment

The Home Health Prospective Payment System final rule confirmed the home health payments tied to quality performance within Medicare-certified home health agencies in the nine states participating in the model program.[1] Maximum payment adjustment in the first year of the model is three percent, as opposed to the proposed five percent.

F. End-Stage Renal Disease Quality Incentive Program

Quality incentive payments will also be tied to metrics meant to improve dialysis care under the End-Stage Renal Disease Quality Incentive Program. The End-Stage Renal Disease final rule applies payment incentives to dialysis facilities to improve the quality of dialysis care and reduce dialysis facilities' payment rates for failing to meet quality measures for anemia management, infections, safety, and other patient experience elements.

If you have any questions, please contact any member of Ropes & Gray's health care practice or your usual Ropes & Gray advisor.

[1] States include: Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington.