Medicare Physician Fee Schedule Final Rule for Calendar Year 2016 Makes Changes in Stark Law Regulatory Provisions and Contains Important Updates of Medicare Payment Policies

Executive Summary, November 2015

Sponsored by the Physician Organizations Practice Group. Co-sponsored by the Academic Medical Centers and Teaching Hospitals; Business Law and Governance; Health Care Liability and Litigation; Hospitals and Health Systems; Fraud and Abuse; In-House Counsel; Medical Staff, Credentialing, and Peer Review; and Regulation, Accreditation, and Payment Practice Groups; and the Children’s Hospital and Physician In-House Counsel Affinity Groups.

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On November 16, 2015, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year 2016 Medicare Physician Fee Schedule Final Rule with Comment Period (Final Rule). With the exception of the change to the definition of “ownership or investment interest” as it relates to physician-owned hospitals, which is effective January 1, 2017, the Final Rule is effective January 1, 2016. The Final Rule provides updates to payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2016. The Final Rule includes updates to the regulations under the physician self-referral law (Stark Law), including two new exceptions to the self-referral prohibition, changes to the requirements for physician-owned hospitals, and several “clarifications” to existing self-referral regulations. CMS commented that it believes these new exceptions will improve access to care across all areas and will be particularly helpful in rural and underserved areas. In its press release announcing the Final Rule, CMS said the Final Rule is one of several reflecting a broader administration-wide strategy to create a health care system that results in better care, smarter spending, and healthier people. The Final Rule also is the first PFS Final Rule since the repeal of the Sustainable Growth Rate formula by the Medicare Access and CHIP Reauthorization Act of 2015.

Physician Self-Referral Updates

The Stark Law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and prevents the DHS entity from filing claims with Medicare for those services furnished as a result of a prohibited referral. In formulating the Final Rule, CMS stated that it learned from stakeholder inquiries, review of the relevant literature, and self-disclosures submitted to the Self-Referral Disclosure Protocol (SRDP) that additional clarification of certain provisions of the law would be

helpful. In addition to clarifying certain existing regulations, CMS also announced its intent to expand access to needed health care services through the establishment of two new exceptions.

New Stark Exceptions

The Final Rule establishes a new exception to permit payment by hospitals, Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs) to physicians for the purpose of recruiting and compensating non-physician practitioners under certain conditions. The requirements for the exception are similar to the requirements for the physician recruitment exception. The Final Rule permits contractual arrangements as well as employment relationships, but agreements with a staffing agency are not covered. Clinical social workers and clinical psychologists were added to the list of non-physician personnel who are covered by the exception. The non-physician practitioner must supply a minimum amount of primary care services in the physician's office to qualify for the exception. The financial assistance can be up to an amount that does not exceed 50% of the aggregate compensation, signing bonus, and benefits paid to the non-physician practitioner and the amount must not exceed fair market value (FMV) of the patient care services furnished by the non-physician practitioner to patients of the physician’s practice.

The Final Rule also establishes a new exception to permit time-share arrangements for the use of office space, equipment, personnel, items, supplies, and other services. Such arrangements have been common, particularly for hospitals providing specialty clinics for physicians on a part-time basis. They were analyzed under a variety of Stark Law exceptions, including FMV, space rental, equipment rental, and personal service arrangement exceptions. Under the new exception, physicians are permitted to enter into “turnkey” arrangements with hospitals or physician organizations for office space, equipment, furnishings, waiting areas, and necessary support staff. Similar to the office space and equipment rental exceptions, the arrangement must be in writing; must be signed by the parties; and must specify the premises, equipment, personnel, items,
supplies, or services covered by the arrangement. The compensation must be set in advance, must be consistent with FMV, and must not take into effect the volume or value of referrals. The arrangement must be commercially reasonable and not violate the Anti-Kickback Statute or any other federal or state law or regulation. In structuring the arrangement and setting the compensation, the 2000 U.S. Department of Health and Human Services Office of Inspector General Special Fraud Alert on rental of space in physician offices by suppliers to whom the physician refers patients may be instructive. Arrangements under the new exception are characterized as license agreements rather than leases. The physician (licensee) must furnish predominantly evaluation and management services and “advanced imaging equipment” (such as MRI or CT) may not be used in the space. Certain per-unit-of-service and percentage compensation methodologies are prohibited.

**Physician-Owned Hospital Requirements**

The Affordable Care Act established new restrictions on physician-owned hospitals, including setting a baseline physician ownership percentage that cannot be exceeded and requiring physician-owned hospitals to state on their websites and in their advertising that they are owned by physicians. CMS updated the regulations to clarify that a broad range of actions comply with the website and advertising requirements. CMS also finalized changes that provide that baseline and future calculations of a hospital’s physician ownership percentage include all physicians, not just those physicians who refer to the hospital. The physician ownership changes take effect on January 1, 2017.

**Clarifications to Existing Stark Exceptions**

After reviewing reports made through the SRDP, CMS determined that certain Stark clarifications could be made to reduce perceived or actual Stark violations without increasing the risk of federal program abuse. The clarifications are as follows:
• “Writing” required by many Stark Law exceptions can be a collection of documents rather than a single formal contract.

• The term of a lease or personal services agreement may continue indefinitely on the same terms for a holdover period (which was previously limited to six months).

• Parties have a 90-day grace period to obtain missing signatures on a written document, regardless of whether the failure to obtain the signatures was inadvertent.

• A split-billing arrangement does not create a Stark Law financial relationship when both the hospital and the physician bill independently for their services.

• Compensation to a physician organization cannot take into account referrals of any physician in the physician organization, including referrals of employees and independent contractors who do not “stand in the shoes” of the physician organization. Employed physicians and independent contractor physicians who do not stand in the shoes of the physician organization do not need to sign the writing between the DHS entity and the physician organization.

Other Payment Provisions Impacted by the Final Rule

As is customary, the Final Rule impacts and updates a number of payment provisions. Some of the significant payment provisions impacted by the Final Rule as are follows:

• Incident to Services—The physician who bills for “incident to” services must also be the physician who directly supervises the auxiliary personnel who provide the incident to services. CMS made this change to ensure that incident to services furnished to Medicare patients are an integral, although incidental, part of the physician’s personal professional service that is billed to Medicare.

• Payment for Advance Care Planning Services—CMS finalized its proposal to assign Current Procedural Terminology codes, separate payment, and a
payment rate for two advance planning services provided to Medicare beneficiaries by physicians and other practitioners. Prior to the Final Rule, Medicare only paid for advance care planning services when the beneficiary first enrolled in the Medicare program.

- The Final Rule establishes the same criteria for satisfactory reporting established for the 2017 Physician Quality Reporting System payment adjustment, which generally requires the reporting of nine measures covering three National Quality Strategy Domains.

- The Value-Based Modifier provides for different payments to physicians, physician groups, and other eligible professionals based on quality and cost of care. In 2016, CMS will apply the modifier to non-physician practitioners who are solo practitioners in the 2018 payment adjustment period.

- Misvalued Code Changes—CMS is finalizing a proposed change in the utilization rate assumption used to determine per-minute cost of equipment used for radiation therapy, and it is revising codes for lower gastrointestinal endoscopy services in line with the Relative Value Scale Utilization Committee recommendations.

The Physician Organizations Practice Group will publish a Member Briefing that will more fully describe the changes adopted in the Medicare Physician Fee Schedule Final Rule.

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