POWERS

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MEMORANDUM

To: Clients and Friends

From: Powers

Date: December 7, 2020

Subject: Final Physician Self-Referral (Stark) Regulations

On December 2, 2020, the Centers for Medicare and Medicaid Services(CMS) published a Final Rule titled, "Modernizing and Clarifying the Physician Self-Referral Regulations," that makes a number of modifications to the regulations implementing the physician self-referral or "Stark" law (42 U.S.C. 1395nn).[1] The Final Rule follows closely the proposed changes published by CMS in November of 2019. Most of the Final Rule's changes are effective January 1, 2021, with certain amendments of 42 CFR § 411.352(i) being delayed until January 1, 2022. (See "Profit Distributions in Group Practices" on page 6.)

Overview

The publication of the Final Rule is consistent with CMS' previous statement in its proposed rule that it intended to finalize the rule sometime in 2020. The Final Rule is part of the Department of Health and Human Services' (HHS') "Regulatory Sprint to Coordinated Care" initiative and is intended to address obstacles posed by Stark regulations to value-based care. The Final Rule establishes three new exceptions for compensation paid as part of a value-based care arrangement, but with important changes from the originally proposed language. The exceptions are designed to protect payments to referring physicians from a provider of Stark covered designated health services (DHS) that advance certain value-based objectives and which, for a variety of reasons, cannot be protected under previously existing exceptions in the statute and regulations.

CMS also attempts, with varying degrees of success, to provide clarity surrounding terms that are at the core of multiple Stark law exceptions and which have bedeviled providers trying to structure compliant arrangements. They include "commercial reasonableness," "fair market value," and what it means to "take into account" the "volume or value of referrals" and "other business generated."

CMS also finalized two additional new exceptions: one for donations of cybersecurity technology and the other for items or services valued at less than $5000 per year. Finally, the Final Rule makes a number of technical changes designed to further clarify the regulations. Overall, despite the attempted

[1] 85 Fed. Reg. 77,492 (Dec. 2, 2020).

clarification, we see little here that remedies the Stark law's well-deserved reputation as one of the most complex and impenetrable areas of health care law.

This memorandum addresses specific parts of the Final Rule that we believe will be of most significance to physicians and other providers; it does not attempt to examine every aspect of the finalized changes.

Collaborative Care - Value-Based Exceptions

CMS has finalized three new exceptions for "arrangements that facilitate value-based health care delivery and payment" and several new definitions critical to understanding the scope of the exceptions. These definitions remain largely unchanged from the proposed rule.

Definitions

All three exceptions require, as a threshold matter, a "**value-based purpose**," defined as

1. Coordinating and managing the care of a *target patient population;*
2. Improving the quality of care for a *target patient population;*
3. Appropriately reducing the costs to, or growth in expenditures of payers without reducing the quality of care for a *target patient population;* or
4. Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a *target patient population.*

A ***target patient population*** is defined as an identified patient population selected by a *value-based enterprise* (VBE) or its VBE *participants* based on legitimate and verifiable criteria that:

(1) Are set out in writing in advance of the commencement of the *value-based arrangement*; and
(2) Further the *VBE's value-based purpose(s)*.

The new exceptions are intended to protect compensation relationships related to "*value based arrangements*" that provide "at least one *value-based activity* for a *target patient population*." A ***"value based activity***" is any of the following activities if reasonably designed to achieve at least *one value-based purpose* of *the VBE.*

(i) The provision of an item or service;
(ii) The taking of an action; or
(iii) The refraining from taking an action.

A "***value based arrangement***" means one for the provision of a *value-based activity* for a *target patient population* that is between or among the *VBE* and one or more of its *participants*; or between and among *VBE participants* in the same *VBE*.

A ***VBE*** must consist of two or more participants that:

(1) Collaborate to achieve at least one *value-based purpose*
(2) Where each is party to a *value-based arrangement* with the other or with at least one other *VBE participant* in the same *VBE.*
(3) Have an accountable body or person responsible for financial and operational oversight, and
(4) Have a governing document that describes the *value-based enterprise* and how the VBE participants intend to achieve its *value-based purpose(s).*

Significantly, a VBE need not be a separate corporate entity; it could exist through contractual arrangements.

In the proposed rule, CMS stated that it was considering excluding from the definition of *VBE participants* durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) manufacturers, distributors, and suppliers, pharmaceutical manufacturers and distributers, pharmacy benefit managers, wholesalers, and distributors. However, this proposal was not adopted. This means that compensation relationships between physicians and these entities may qualify for protection under the new value-based exceptions.

Value-Based Exceptions: Core Requirements

All three of the new exceptions for *value-based arrangements* include certain core requirements:

(1) The payments, which can be in cash or in-kind, are for or result from value-based activities undertaken by the recipient for patients in the target population;
The remuneration is not an inducement to reduce medically necessary care;
(2) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or other business outside of the value-based arrangement;
(3) If remuneration to the physician is conditioned on the physician referring to a particular provider, the arrangement must satisfy the requirements of 42 CFR § 411.354(d)(4)(iv)[2]; and,

[2] 42 CFR § 411.354(d)(4)(iv) requires that the arrangement be set out in writing, signed by the parties, and the directed referral does not apply if the patient expresses a preference for a different provider, or if the choice of provider is determined by the patient's insurer, or if it is not in the patient's best medical interests.

(4) Records of the methodology for determining and the amount of remuneration paid under the VB arrangement must be maintained for at least 6 years and made available upon request.

Value-Based Exception No. 1: Full Financial Risk Exception

The full financial risk exception requires, in addition to the core requirements outlined above, that the VBE assume **full financial risk** from the payer. This means that the *VBE* must be financially responsible on a prospective basis for the cost of all patient care items and services covered by the payer for each patient in the *target population*. Although this is similar to the prepaid plans exception already in the statute and regulations, it does not require the entity to have a contract with CMS (*e.g.,* Medicare Advantage) or on the enrollment status of the patients. It appears designed for hospital-physician collaborations that contract with a private payer on either a capitated or global budget basis. The exception covers not just the period during which the VBE is fully at risk, but also a "pre-risk" period of 12 months (extended from six months in the 2019 proposed rule).

Value-Based Exception No. 2: Meaningful Downside Financial Risk

The second new exception is for **value-based arrangements with meaningful downside risk to the physician** and is measured at the physician level—not at the VBE level. In addition to the 4 core requirements above, it also requires that:

(1) The physician be at meaningful downside risk for failure to achieve the *value-based purposes* of the *VBE* during the entire duration of the *value-based arrangement*;
(2) A description of the nature and extent of the physician's risk is set forth in writing; and,
(3) The methodology used to determine the amount of the remuneration is set in advance.

Risk, for this purpose, is defined as 10% (down from 25% in the proposed rule) of the value of the remuneration received under the value-based arrangement is subject to "claw back" for failure to achieve the value-based purposes of the VBE.

This exception could be used to protect physicians in a VBE that are taking sub-capitated payments from a payer through the VBE or other intermediary but is more likely to apply in partial risk arrangements where the physician is paid on a modified fee for service basis with built in performance incentives.

Value-Based Exception No. 3: Other Value-Based Arrangements

The third new value-based exception is the easiest to meet. It does not require downside risk nor does it prohibit arrangements that take into account the volume or value of referrals. Some of the other criteria for this exception include, in addition to the core requirements above:

(1) The arrangement must be in writing, signed by the parties, and describe:
   - the value-based activities and how they further value-based purposes of the enterprise;
   - The target patient population;
   - The nature of the remuneration;
   - The methodology used to determine the remuneration; and,
   - The performance standards against which the recipient will be measured, if any;

(2) If performance standards are used, they must be objective and measurable and changes must only be made prospectively; and,
(3) The remuneration methodology must be set in advance.

This exception could be used for full or partial risk arrangements (whether above or below the 10% threshold) but is also available and intended to apply to other VB-related payments physicians may get from a DHS provider to which the physician refers Medicare patients. In particular, it may protect employment and personal service arrangements that would not qualify for the other Stark exceptions because of the fair market value, commercial reasonableness, and taking into account the volume or value of referrals limitations.

Changes to Key Terminology

The proposed definitional changes to key Stark law terms may be the most significant aspects of the proposed rule. CMS is attempting to provide greater clarity with respect to three key terms:

- commercial reasonableness;
- fair market value; and,
- taking into account the volume or value of referrals.

These terms appear in multiple exceptions throughout the Stark statute and regulations but have been poorly understood resulting in multiple high profile enforcement actions.[3] Unfortunately, despite some minor clarifications, the proposed rule does not appear to give the provider community the certainty it needs.

[3] e.g., *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.,* 792 F.2d 364 (4th Cir. 2015) and *U.S. ex. rel. J. William Bookwalter, III M.D., et al v. UPMC et. al.* (3rd Cir. 2019).

In the final rule, CMS has modified the proposed change to the definition of the term "**commercially reasonable"** to mean:

(1) an arrangement that furthers a legitimate business purpose and is on similar terms as like arrangements; and,
(2) is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.

CMS also explicitly notes that an arrangement **may** be commercially reasonable even if not profitable to one or more of the parties.

Second, CMS has tweaked its existing regulatory definitions of "**fair market value**" and "general market value" (which is part of the definition of fair market value). However, it is not at all clear that the new wording will provide additional clarity to this term.

Third, CMS has finalized its proposal to standardize its approach to assessing whether a compensation relationship **"takes into account the volume or value of referrals or other business generated."** In brief, the new rules would provide that neither is present unless:

(1) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with changes in the number or value of the physician's referrals to the entity. or,

(2) Compensation from an entity furnishing designated health services to a physician (or immediate family member) takes into account the volume or value of other business generated only if the formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

This proposal is the most useful and may be as close to a bright line test as is possible. It should be helpful to medical practices in structuring a variety of arrangements with hospitals and others and avoid the difficulties encountered by providers in *Tuomey* and *UPMC,* cited in footnote 3 above.

Profit Distributions in Group Practices

The Stark law and regulations have long restricted compensation paid to physicians inside group practices to ensure that group members are not financially rewarded for overutilizing ancillary services

provided by the group. There is a threshold prohibition on any member receiving compensation, directly or indirectly, based on the volume or value of his or her DHS referrals. Exceptions to this prohibition are then provided for certain permissible profit sharing or productivity bonus payments. As previewed last year in the preamble to the proposed rule, the Final Rule now attempts to narrow permissible profit sharing methodologies.

The existing regulation at 42 CFR § 411.352(i) permits distribution of profits related to "the group's entire profits derived from DHS" to "sub-groups" of five or more physicians. This has been used by groups with multiple specialties, subspecialties, or locations to distribute various ancillary service profits to subgroups that are primarily responsible for the referrals. CMS now takes the position that the existing rule language does not clearly state the agency's intent—evidenced for the first time in the proposed rule's preamble—that a group practice cannot distribute profits from one line of DHS to one subset of physicians and distribute profits of a different line of DHS to a different subset of physicians.

In the example given in the preambles to both the proposed and final rules, CMS states that a practice will not qualify as a "group practice" if it distributes clinical laboratory service profits to one subset of physicians and distributes diagnostic imaging to a different subset. CMS attempts to effectuate this clarification going forward by changing the language of the regulation from "entire profits derived from DHS" to "profits derived from all the designated health services of any component of the group" that includes at least five physicians (or all of the physicians of the group if fewer than five).

This change requires that all profit tied to any DHS services provided specifically by the group or sub-group must be aggregated prior to distribution. This clarification will almost certainly require many existing physician group practice compensation arrangements to be amended. Apparently recognizing the potential to disrupt group compensation planning, CMS has delayed the effective date for this provision until January 1, 2022. However, for those group practices affected, it may be prudent to amend the impacted compensation arrangements sooner given CMS' assertion that the new language more accurately reflects the agency's intent.

New Exception for De Minimis Remuneration to a Physician

CMS has finalized a new exception for cash compensation of up to $5,000 per year (increased from $3,500 in the proposed rule) adjusted for inflation, paid to a physician for services provided by the physician to the entity provided the compensation does not take into account volume or value of referrals, does not exceed fair market value, and is commercially reasonable. Significantly, the arrangement need not be in writing and signed by the parties, and compensation need not be set in advance. The rule also allows the physician to provide the services through employees hired for the purpose of performing the services, a wholly owned entity, or locum tenens physicians.

CMS refers to this as the "things happen" exception and states that it intends to address situations in which the parties do not have time to work out all the details of an arrangement and prepare the

necessary written documents. This is a forgiving exception that might also be characterized as the "oops" exception. It should be modestly helpful in protecting minor and mostly short term payments that otherwise would constitute technical violations of Stark and subject participants to substantial penalties and claims disallowances.

New Exception for Cybersecurity, Technology, and Related Services

CMS is proposing a broad new exception for nonmonetary remuneration for certain software technology and services necessary and used predominantly to implement, maintain, or reestablish cybersecurity if the following conditions are met:

(1) Eligibility for the technology and services and the amount thereof is not determined in a manner that directly takes into account volume or value of referrals or other business generated;
(2) Receipt of technology and services is not a condition for doing business with the donor; and
(3) The donation arrangement is documented in writing.

For purposes of this exception, "technology" means any software or other types of information technology. CMS has not limited the types of entities that can be donors and donations may also include training services. This exception is separate from the pre-existing exception for electronic health records.

Changes to EHR Exception

CMS has made changes to the existing compensation exception for electronic health records (EHR). These include:

(1) Adding cybersecurity software and services to the types of eligible nonmonetary remuneration;
(2) Updating interoperability requirements and related definitions to provide consistency with amendments made to the Public Health Service Act (PHSA) as part of the 2016 CURES legislation;
(3) Revising the protections against data blocking; and
(4) Deleting the current sunset date of December 31, 2021.

CMS has not eliminated the requirement that physicians contribute at least 15% of the costs when EHR is being subsidized by a hospital or other entity to which the physicians refer. Finally, CMS has modified the exception to permit donations of replacement EHR technology already owned by the practice.

Definition of DHS – Clarification

CMS has finalized its proposal to redefine services furnished to hospital inpatients to exclude referrals for services that do not affect the amount of Medicare payment to the hospital under the inpatient prospective payment system (IPPS).

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