POWERS

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ATTORNEYS AT LAW

MEMORANDUM

To: Clients and Friends

From: Powers

Date: November 11, 2019

Subject: Proposed Changes to the Physician Self-Referral (Stark) Regulations

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On October 17, 2019, the Centers for Medicare and Medicaid Services(CMS) published a Notice of Proposed Rulemaking (NPRM) ("Proposal or Proposed Rule") that would make a number of modifications to the regulations implementing the physician self-referral or "Stark" law (42 U.S.C. 1395nn).[1] Comments on the NPRM are due on December 31, 2019. CMS states that it intends to finalize the rule sometime in 2020.

Overview

The NPRM 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 the Stark law to the health care industry's shift to value-based care and payment. The proposal would establish three new exceptions for compensation paid as part of a value-based care arrangement. 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 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."

In addition, CMS proposes two additional new exceptions: one for donations of cybersecurity technology and the other for items or services valued at less than $3500 per year. Finally, the NPRM offers a number of technical changes designed to further clarify the regulations. Overall, while the proposed new exceptions and changes to existing regulations are well-intended and sometimes beneficial, 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.

[1] 54 Fed. Reg. 55766 (October 17, 2019).

This memorandum addresses specific parts of the proposed rule that we believe will be of most significance to physicians and other providers; it does not attempt to examine every aspect of CMS' lengthy proposal.

Collaborative Care - Value-Based Exceptions

CMS proposes 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.

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 *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) Are party to a *value-based arrangement* with the other or 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.

CMS is 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. This would prevent compensation relationships between physicians and these entities from being protected under the new value-based exceptions.

Value-Based Exceptions

All three 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,
(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 the VBE to 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*.

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

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.

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 is defined as being meaningful if either:

(1) 25% 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; or
(2) The physician is at risk prospectively for all or a portion of patient care items or services for the *target population* for a defined period of time.

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. The criteria for this exception are, in addition to the 4 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 25% 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 recent enforcement actions.[3] Unfortunately, despite some minor clarifications, the proposed rule does not appear to give the provider community the certainty it needs.

The first proposed change would define 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) the arrangement **may** be commercially reasonable even if not profitable to one or more parties.

Second, CMS proposes to tweak 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 proposes 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 compensation from (or to) the DHS entity includes **as a variable** the physician's referrals to (or other business generated for) the entity, resulting in an increase or decrease in compensation **that**

[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).

correlates positively (if the compensation flows to the physician and negatively if from the physician to the entity) with the number or value of the referrals or other business generated; or,

(2) There is a predetermined direct correlation between the physician's prior referrals (or other business generated) and the prospective rate of compensation to the physician.

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 Distribution by Group Practices

CMS is proposing in the preamble—but not in the regulatory text of the proposed rule—a narrowing of the special rules for profit sharing that would reduce flexibility that was widely thought to exist in this area. In brief, the commentary casts doubt on specialty, subspecialty or department specific methods of distributing profits from ancillary services generated in or through referrals from subgroups within group practices. The regulation at 42 CFR § 411.352(i) permits distribution of profits to "sub-groups" of five or more physicians.

This has been used by groups with multiple specialties or subspecialties to distribute ancillary service profits to the group that is primarily responsible for the referrals. However, in the preamble to the proposed rule, CMS takes the position—apparently for the first time—that a group practice cannot distribute profits from one line of DHS using a different methodology than another line and also cannot distribute profits for one line of DHS to one subset of physicians and distribute profits of a different line to a different subset of physicians.

In the example given, 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. Unless CMS backs off of this language in the final rule, this could disrupt a number of existing physician group practice compensation arrangements.

New Exception for De Minimis Remuneration to a Physician

CMS is proposing a new exception for cash compensation of up to $3,500 per year 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.

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.

New Exception for Cybersecurity, Technology, and Related Services

CMS is proposing a broad new exception for nonmonetary remuneration for certain software technology related to cybersecurity. The exception applies if:

(1) It is necessary and used predominantly for cybersecurity;
(2) It does not include hardware;
(3) Eligibility for the technology and the amount is not determined in a manner that directly takes into account volume or value of referrals or other business generated;
(4) Receipt of technology is not a condition for doing business with the donor; and,
(5) It is documented in writing.

The recipient is not required to contribute to the cost and a formal contract is not required. CMS is soliciting comments on whether to expand the exception to include hardware.

Changes to EHR Exception

CMS proposes to make a number of changes to the existing compensation exception for electronic health records (EHR). These include:

(1) 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;
(2) Revising the protections against data blocking;
(3) Including cybersecurity software and related services in the protected class; and,
(4) Deleting (or extending) the current sunset date of December 31, 2021.

In addition to these specific proposals, CMS is seeking comments on possible changes to, or even elimination of the current 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. One option under consideration is to treat rural or small practices differently from urban or larger practices. CMS also asks for comment on the elimination of the 15% match for updates to previously furnished EHR.

Finally, CMS is proposing to eliminate from the exception the current prohibition on using it to subsidize replacement of EHR technology already owned by the practice.

Definition of DHS – Clarification

CMS is proposing 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). Since hospitals are paid by Medicare under a DRG system, ordering additional tests or other services is unlikely to impact the DRG and the rate of payment. Thus, the referral is essentially the admission, and not what happens during the stay.

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For further information, please contact Rebecca Burke (rebecca.burke@powerslaw.com) or the Powers attorney with whom you usually work.