October 23, 2019

Protecting Payment for Value – OIG and CMS Propose New AKS Safe Harbors and Stark Exceptions

On October 9, 2019, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") and Centers for Medicaid & Medicare Services ("CMS") released their long-awaited proposed rules describing potential changes to regulations implementing the federal anti-kickback statute (the "AKS"), beneficiary inducement provisions of the civil monetary penalty law (the "CMPL"), and the physician self-referral law (the "Stark Law"). OIG and CMS have described the changes as efforts to reduce barriers to the coordination and delivery of value-based care.

The proposed rulemakings each include three new provisions for value-based care arrangements presenting different financial risk profiles.

This is our executive summary of the proposed rules. Our detailed analysis is available here.

Proposals to Protect Certain Value-Based Care Arrangements

There are three distinct proposed safe harbors and exceptions that would protect remuneration between a "**value-based participant**" and a "**value-based entity**" (or "value-based enterprise") pursuant to a "**value-based arrangement**."

> **What is a value-based participant?** It's an individual or entity that engages in at least one value-based activity as part of a "value-based entity" (in OIG's words) or "value-based enterprise" (in CMS's words). OIG proposes that it *cannot include* a pharmaceutical manufacturer; manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or laboratory. OIG might also exclude pharmacies; pharmacy benefit managers; pharmaceutical wholesalers/distributors; and medical device companies. CMS is considering exclusions.
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> **What is a value-based entity?** It's a group of at least two value-based participants that collaborate to achieve a value-based purpose under a value-based arrangement. It must have an accountable body (*e.g.*, a board) and a governing document. OIG and CMS may consider further requirements, including requirements for the accountable body to have a duty of loyalty to the value-based entity.
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> **What is a value-based arrangement?** It's an arrangement providing for a value-based activity (*e.g.*, coordinating and managing care, improving quality of care, reducing costs or expenditures of payors without reducing quality of care, and transitioning to healthcare and payment mechanisms based on quality of care and cost control) for a target patient population (which must be identified in advance, and might be subject to other limitations).
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> **What would be protected?** OIG proposes that remuneration must be either (i) primarily used for value-based activities directly connected to coordination and management of care, or (ii) directly connected to one or more value-based purposes. CMS does not propose similar requirements.

The three proposals vary based on the level of risk that parties assume.

> The **care coordination** proposal would protect only in-kind remuneration under the AKS, but both in-kind and monetary remuneration under Stark. In each case, protection would be available for arrangements not involving downside financial risk. OIG would require recipients to contribute to at least some of the cost. OIG and CMS would require arrangements to be commercially reasonable for the value-based arrangement.
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> The **substantial downside risk proposal** would protect in-kind and monetary remuneration. Eligibility would require participants to bear downside risk (8% under the OIG proposal; 25% under the CMS proposal for Stark).

The **full financial risk** proposal also would protect in-kind and monetary remuneration. It would require, as implied, assumption of full financial risk.

There also is an OIG (but not CMS) proposal that would cover arrangements between parties in a CMS-sponsored model, program, or other initiative.

Other Value-Based Proposals

Modifications to EHR Safe Harbor/Exception. OIG and CMS would extend protection beyond December 31, 2021. The agencies also would cover replacement technology, and might make further changes.

Cybersecurity Technology Safe Harbor/Exception. OIG and CMS would permit donors to provide cybersecurity technology without recipient cost-sharing.

Personal Services Safe Harbor. OIG would provide safe harbor protection for arrangements with *formulas* that are set in advance, even if aggregate compensation is not. OIG also might add specific protection for outcomes-based payments (*e.g.*, gainsharing payments).

Warranties Safe Harbor. OIG might expand this safe harbor to protect warranties on bundles of related items and services—but, protection would require that all federally reimbursable items in a bundle be reimbursed under the same federal health care program, in the same payment. Protection also would be limited to the cost of the product(s) under the warranty.

Patient Engagement. OIG proposes a new safe harbor to protect certain arrangements for in-kind (not cash) patient engagement tools and support to improve quality, health outcomes, and efficiency—if furnished by VBE participants to patients in a target patient population. OIG is considering an array of revisions to this proposal.

Unrelated Changes to the Stark Law

Most changes respond to issues and arguments that CMS has encountered through the self-disclosure protocol.

Designated Health Services ("DHS"). The rule would define DHS to include *inpatient services only if* the services affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System ("IPPS").

Commercially Reasonable. Many Stark Law regulations have long required that arrangements must be commercially reasonable in the absence of referrals. CMS has proposed to define "commercially reasonable" to mean that a particular arrangement furthers a legitimate business purpose of the parties, and is on similar terms and conditions as like arrangements. CMS acknowledges in the commentary that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Fair Market Value. CMS also proposes to revise the definitions of "fair market value" and "general market value." These changes would remove current language that limits them not just to the result of *bona fide* bargaining between the parties, but to between parties "who are not otherwise in a position to generate business for the other party." However, the commentary minimizes the impact of this change.

"Volume or Value of Referrals" Standard. This would consider an arrangement to "take into account" the volume or value of referrals only when (i) the mathematical formula used to calculate the amount of compensation includes as a variable referrals or other business generated, and (ii) the amount of compensation *correlates* with the number or value of referrals generated by the physician or the generation of other business for the entity.

Group Practice Definition. One change would make clear that a profit share cannot include profits from fewer than all of the designated health services that a group provides. This is particularly relevant for groups establishing bonuses targeted for just certain lab services or DME that a group furnishes. Another change would provide some flexibility for groups to distribute revenue earned under a value-based arrangement to group members in a volume-sensitive manner.

Grace Period for Writing. CMS proposes a 90-day grace period for the writing requirement (not just the signature requirement, as exists now).

***De Minimis* Compensation.** CMS proposes a new exception for remuneration to physicians not exceeding $3,500/year (among other requirements).

Current Stark Law Policy. CMS articulates a number of points of current agency policy and interpretation.

> **Isolated Transitions.** CMS does *not* consider a "transaction" (for purposes of the isolated transactions exception) to include a single payment made for multiple services provided over an extended period of time.
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> **Mid-Course Corrections.** CMS *does* recognize that parties who detect and correct administrative or operational errors or discrepancies (*e.g.*, payment inconsistent with a contract) can cure the errors in the arrangement if it is still active (but cannot do so after the relationship has ended).
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> **Electronic Signatures.** CMS considers an electronic signature that is legally valid under federal or state law to be sufficient to satisfy any Stark Law exception signature requirements.
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> **Internal Notes.** CMS states that, depending on the circumstances, the obligation to document that a compensation formula was set in advance can be satisfied through "informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules," or documents used by physicians in similar situations.

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Comments are due 75 days from Federal Register publication.

This is our executive summary. Our full analysis is available here. We will discuss some issues during a webinar on October 23 (click here for registration or replay information).