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Self-Referral and Anti-Kickback Proposed Rules

OVERVIEW

On October 9th, the Centers for Medicare and Medicaid Services (CMS) released two proposed rules that, if finalized, would reduce some of the regulatory requirements and create new exceptions for the Physician Self-Referral law, also known as the Stark Law, and the Federal Anti-Kickback Statute and Civil Monetary Penalty (CMP) Law. The changes are intended to clarify and expand exceptions for providers engaged in value-based arrangements, in which payment is based at least partially on meeting targets for the cost of care. While the two rules are coordinated, they do not line up in all particulars (for example, in the criteria for "meaningful" or "substantial" downside risk).

This document summarizes several major provisions of each rule. The Stark Law proposed rule is available here, and the Federal Anti-Kickback Statute and CMP Law proposed rule is available here.

REVISIONS TO THE PHYSICIAN SELF-REFERRAL REGULATIONS

The Stark Law prohibits a physician from making referrals for designated health services to entities that the physician has a financial relationship with, and prohibits filing claims for those services. The scope of the law includes services paid for through federally-funded health insurance, including Medicare, Medicaid, TRICARE and Affordable Care Act plans. The proposed rule aims to advance value-based healthcare delivery and payment by defining value-based arrangements, activities, enterprises, participants, and purposes that qualify for exceptions to Stark prohibitions. Major provisions of the rule are described below.

Full Financial Risk Exception

CMS is proposing to clarify an exception to the Stark law that applies to participants in a value-based enterprise (VBE) that have taken on "full financial risk" for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For Medicare beneficiaries, CMS would interpret this requirement to mean that the value-based enterprise is responsible for all items and services covered under Parts A and B. The exception would allow VBE participants to direct referrals to specific providers within the VBE, resulting in an increase in revenue. The individual clinicians would not need to be paid prospectively and be at risk - only the entity in which they participate. This could provide revenue opportunities through both increased attributions and per-member-per-month payments for specialists or groups, and through increased fee-for-service revenue for individuals, so long as they are part of a VBE taking on full financial risk. This exception would essentially allow VBEs to direct care similar to health plans.

A VBE would not have to be a separate legal entity with the ability to contract on its own. Instead, VBE participants could jointly or separately sign the contract for the VBE to assume full financial risk, or

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VBE participants could confer the VBE with the authority to bind all VBE participants into a contract, similar to physicians in an independent practice association (IPA) model. The VBE would be financially responsible within six months following the commencement date of the value-based arrangement. Full financial risk would be prospective, and could take the form of either capitation payments or global budget payments. Remuneration would have to be for, or result from, items or services provided by the recipient of the remuneration for patients in the target patient population, and could not be conditioned on referrals of patients who are not part of that population or designed as an inducement to reduce or limit medically necessary services. Finally, records of the methodology for determining the amount of remuneration and the actual amount of remuneration paid under the arrangement would need to be retained for at least six years.

Defining "Full Financial Risk"

CMS is seeking comments regarding the proposed definition of "full financial risk." Specifically, CMS is seeking comment on whether a VBE should be considered to be at full financial risk if it is responsible for the cost of only a defined set of patient care services for a target patient population, as opposed to the total cost of care, and whether CMS should require a minimum period of time during which the VBE is at full financial risk. CMS is also seeking comment on whether to revise the definition of a "value-based arrangement" to require care coordination and management.

Meaningful Downside Risk Exception

CMS is proposing to define an exception for value-based arrangements in which providers are at "meaningful downside financial risk" for failure to achieve the value-based purposes of a VBE, set at a risk threshold of 25% for referral services and remuneration exchanged in a value-based arrangement. Under the proposal, a physician must be at meaningful downside financial risk for the entire term of an arrangement, rather than only part of an arrangement, in order to prevent any gaming that could occur.

Similar to the full financial risk exception and previous safe harbor language, CMS proposes to include requirements that the remuneration is for or results from items or services provided by the recipient of the remuneration for patients in the target patient population, and could not be conditioned on referrals of patients who are not part of that population or be an incentive to reduce or limit medically necessary items or services. The records of the methodology for determining the amount of the remunerations and the actual amount of remuneration paid under the value-based arrangement would also need to be maintained for at least six years. Unlike the full financial risk exception, CMS is proposing a requirement that the methodology used to determine the amount of remuneration in a meaningful downside risk arrangement is set in advance.

Defining "Meaningful Downside Risk"

CMS is seeking comment on how to define meaningful downside financial risk, specifically whether the proposed 25% threshold is appropriate and sufficient enough to curb any gaming that could occur, and

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whether downside risk for 25% of smaller amounts of remuneration would be enough to curb the influence of traditional fee-for-service, volume-based payments. CMS is also seeking comment on whether to only reference costs under the scope of specific arrangements in question in the 25% threshold, as opposed to the total cost of care. Similar to the full financial risk exception, CMS is proposing to make VBEs under the meaningful downside risk exception financially responsible within six months following the commencement date of the value-based arrangement, but is seeking comment about whether six months is an appropriate amount of time under this exception.

Value-Based Arrangement Exception

CMS is proposing an exception that protects remuneration paid under an upside-only risk value-based arrangement. Similar to the prior two exceptions, the remuneration would have to be for value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, the remuneration could not be an incentive to reduce or limit medically necessary items or services, the remuneration could not be conditioned on referrals of patients who are not part of the target patient population, and records of the methodology for determining the amount of remuneration and the actual amount of remuneration paid under the arrangement must be retained for at least six years. Further, a document describing the remuneration must be set in advance and signed by all parties to the VBE requiring an exception. The agreement must include all reference to all of the following:

- How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;
- The target patient population for the arrangement;
- The type or nature of the remuneration;
- The methodology used to determine the amount of the remuneration; and
- The performance or quality standards against which the recipient of the remuneration will be measured, if any.

Similar to the previous proposed exception, a remuneration arrangement may take into account the potential for shared savings (and avoided shared losses) that result from changes in the volume and value of services delivered through the value-based relationship, as long as it does not "condition on" the volume or value of referrals. For the upside-only value-based arrangement, this means that even within the target population the compensation formula cannot explicitly take into account the volume or value of referrals. CMS is proposing an alternative safeguard for this exception, specifically that remuneration could not be conditioned on the volume or value of referrals of *any* patients, or the volume or value of *any other* business generated, for an entity protected by this exception.

CMS is seeking comment on the interplay of this additional requirement and the longstanding policy that a *bona fide* employee, independent contractor, or party of a managed care contract with the entity may direct the physician's referrals to a particular provider, practitioner, or supplier, as long as the compensation arrangement meets specified conditions designed to ensure that it is in patients' best medical interests, that it protects patients' choice, and that it avoids interfering in an insurer's operations.

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CMS is considering whether this requirement would impede a value-based arrangement if the entity cannot direct referrals as historically permitted. CMS is also considering whether to limit the scope of this exception to nonmonetary remuneration only.

Electronic Health Records (EHR) and Cybersecurity Exceptions

CMS is proposing to revise, or soliciting comment on potential revisions to, a number of exceptions regarding the donation of EHR and cybersecurity technology. These include:

- Modify or eliminate the requirement that recipients of EHR technology contribute at least 15% of the donor's cost of the technology for certain classes of providers (such as small physician practices).
- Excluding nonmonetary remuneration of EHR software, information technology, or training services.
- Update requirements related to interoperability and data lock-in by prohibiting donors from engaging in information blocking practices as defined by the Public Health Service Act.
- Modify the definitions of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act.
- Remove the sunset provision, as the EHR exception is scheduled to expire on December 31st, 2021.

CMS is also requesting comments for an alternative proposal that would allow donations of cybersecurity hardware (rather than only software and services) to occur if a cybersecurity risk assessment has established that the hardware is reasonably necessary to protect both the donor and the recipient.

Limited Remuneration to a Physician Exception

CMS is proposing to create an exception for limited remuneration to a physician for items or services provided by a physician where the remuneration does not exceed a total of $3,500 as long as certain requirements are satisfied. CMS is seeking comment on whether the $3,500 limit is appropriate to accommodate non-abusive compensation arrangements for the provision of items or services by a physician.

Revised Definitions of "Commercially Reasonable" and "Fair Market Value"

CMS is proposing to alter or remove existing requirements that an arrangement be commercially reasonable and reflect fair market value for services delivered. CMS proposes to remove the requirement that an arrangement be profitable in order to be considered "commercially reasonable." CMS is also revising the definition of "fair market value" to eliminate the connection to the volume or value standard, and to provide for a definition of general application, in addition to a definition applicable to the rental of equipment and office space.

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In short, CMS is proposing to focus on the broader relationship between providers and the effect of the value-based arrangement on overall care outcomes (including quality and utilization patterns) rather than only on the specific features of the remuneration transaction. Considered narrowly, a remuneration from one provider to another may not be profitable or reflect fair market value, but in the wider scope of utilization changes brought about by the referral relationship, and attending shared savings, the arrangement may be considered fair, profitable and reasonable.

Group Practice and Profit Sharing

In response to questions about the application of rules related to profit sharing within a group practice, CMS is proposing to clarify the definition of a group practice and requirements for profit sharing. For a group practice, the profits from all the designated health services of the practice (or a component of at least five physicians in the practice) must be aggregated and distributed, with profit shares not determined in a manner that directly takes into account the volume or value of a physician's referrals, or that splits profit distributions on a service-by-service basis. In addition, due to inconsistencies in the existing regulatory language with respect to Medicaid, CMS is proposing to remove reference to Medicaid in the definition of overall profits from designated health services.

Price Transparency Objectives

CMS is interested in comments regarding transparency objectives in the context of the physician self-referral law, specifically regarding the availability of pricing information and out-of-pocket costs to patients, the burden associated with a requirement to provide information about the factors that may affect the cost of services for which a patient is referred, and the appropriate timing for the dissemination of that information. CMS is also seeking comment on whether the inclusion of a price transparency requirement in a value-based exception would provide additional protections against program or patient abuse through the active participation of patients in selecting their health care providers and suppliers.

Compliance Requirements

CMS is proposing to separate Stark Law compliance from Anti-Kickback Statute compliance, as the Stark Law is a strict liability statute and the Anti-Kickback Statute requires intent. CMS reasons that many of the Stark Law's exceptions require compliance with the Anti-Kickback Statute, which adds an "intent" element to overall compliance, but does not require compliance with Anti-Kickback intent as one of the compliance conditions within the self-referral regulations. CMS is proposing to remove these compliance requirements within the self-referral regulations and treating intent as an independent consideration for Anti-Kickback compliance.

REVISIONS TO THE ANTI-KICKBACK AND CMP RULES

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In coordination with the aforementioned changes, HHS Office of the Inspector General (OIG) is also proposing revisions to safe harbor protections under the Anti-Kickback Statute and CMP Law. The proposed rule would add safe harbor protections for certain coordinated care and value-based arrangements, telehealth technologies offered to patients receiving in-home dialysis, and donations of cybersecurity technology. The proposed rule would also revise existing safe harbors for EHR arrangements, warranties, local transportation, and personal services and management contracts.

Value-Based Arrangement Safe Harbors

The proposed rule would create three proposed new safe harbors for remuneration exchanged between participants in a value-based arrangement:

- *Care coordination arrangements to improve quality, health outcomes, and efficiency* – The first value-based arrangement safe harbor would protect in-kind remuneration exchanged between VBE participants in value-based arrangements, requiring that the remuneration is commercially reasonable, put in writing, and establishes one or more specific evidence-based outcome measures. The remuneration must also be non-monetary, primarily used to engage in value-based activities that are directly connected to care of the target patient population, and cannot either induce the affiliated parties to provide medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient. The value-based arrangement would have directly and explicitly connect to the coordination and management of care for the target patient population, and could not limit parties' abilities to make decisions in the best interests of their patients. This safe harbor would not protect value-based arrangements that include marketing items or services to patients or patient recruitment activities. Additionally, any remuneration provided by parties outside of the applicable VBE, and remuneration in which the offeror knows or should know that it is likely to be diverted, resold, or used by the recipient for an unlawful purpose would not be protected under this safe harbor. Finally, OIG is proposing a recipient contribution requirement of at least 15% of the total cost of the remuneration, and annual monitoring and assessment of the VBE.
- *Value-based arrangements with substantial downside financial risk* – The second value-based arrangement safe harbor would protect VBEs that assume substantial downside risk. This safe harbor would protect both monetary and in-kind remuneration and would offer more flexibility than the safe harbor for care coordination. OIG is proposing that substantial downside financial risk would be defined as shared savings with a repayment obligation of at least 40% of any shared losses, a repayment obligation under an episodic or bundled payment arrangement of at least 20% of any total loss, a prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, or a partial capitated payment for a set of items and services for the target patient population where the capitated payment reflects a discount equal to at least 60% of the total expected fee-for-service payments. This safe harbor would protect arrangements during the six months before the date that the VBE assumes financial risk. This safe harbor would not protect an ownership or investment interest in the

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VBE, and would not protect any remuneration funded by an individual or entity outside of the VBE.

- *Value-based arrangements with full financial risk* – The third value-based arrangement safe harbor would protect VBEs that assume full financial risk for the prospectively paid cost of all items and services for each patient in a target patient population. This proposed safe harbor would include more flexible conditions than both the care coordination and substantial downside financial risk safe harbors. The term of the value-based arrangement must be for a period of at least one year, and this safe harbor would not protect an entity that receives a partial capitated payment, or any remuneration funded an individual or entity outside of the applicable VBE, but OIG is considering whether to should protect ownership or investment interests in VBEs that assume full financial risk.

Patient Engagement and Support Safe Harbors

The proposed rule would create safe harbors for certain tools and supports provided under patient engagement and support arrangements to improve quality, health outcomes, and efficiency. The patient engagement tools and supports would have to be provided by a VBE participant to a patient in the target patient population, and limited to in-kind donations of items, goods, or services intended to prevent or reduce deterioration of health or acute events. The tools and supports would need to be designed to identify and address a patient's social determinants of health, and must show a direct connection to the coordination and management of care of the target patient population. VBE participants would not include pharmaceutical manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, and supplies, or laboratories.

CMS-Sponsored Models Safe Harbor

The proposed rule would create a new safe harbor for certain remuneration provided in connection with CMS-sponsored models. The safe harbor would allow remuneration in the form of incentives and supports between parties under any model or other initiative being tested or expanded by the CMS Innovation Center, where the "parties" may include both participating providers and patients attributed under the model. This safe harbor would not extend to commercial and private insurance arrangements that operate alongside a CMS-sponsored model, but those arrangements could qualify for other safe harbor protections described in the proposed rule.

EHR Safe Harbor Modifications

The proposed rule would modify existing safe harbor for EHR items and services to add protections for certain cybersecurity technology included as part of an EHR arrangement. The revisions are similar to the Stark Rule EHR changes, essentially proposing that donated items and services would need to be interoperable and could not limit compatibility or interoperability of other electronic prescribing or EHR systems. The proposed rule would also update provisions regarding interoperability, and would remove the December 31st, 2021 sunset date.

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Cybersecurity Technology and Services Safe Harbor

The proposed rule would create a new safe harbor for nonmonetary remuneration in the form of donations of cybersecurity technology and services. In general, and similar to the CMS proposed rule, OIG has not included hardware in its technology and services safe harbors, as OIG believes it poses a higher risk of constituting disguised payments for referrals. OIG is, however, considering adding limited protection for specific hardware that is necessary for cybersecurity, is stand-alone, and serves only cybersecurity purposes. The donor and recipient would be required to enter into a signed, written agreement that must include a general description of the cybersecurity technology and services to be provided over the term of the agreement and a reasonable estimate of the value of the donation.

In-Home Dialysis Telehealth Safe Harbor

The proposed rule would create a new safe harbor for beneficiary incentives for telehealth technologies provided to certain in-home dialysis patients. The safe harbor would protect the provision of telehealth by a provider of services or a renal dialysis facility to individuals with end stage renal disease who receive home dialysis, payable by Medicare Part B, if the telehealth technologies are not offered as part of any advertisement or solicitation.

Personal Services and Management Contracts Safe Harbor Modifications

The proposed rule would modify the existing safe harbor for personal services and management contracts to add flexibility with respect to outcomes-based payments and part-time arrangements. In particular, the rule would substitute a requirement that the methodology for determining compensation must be set in advance, eliminate the requirement that part-time basis contracts must specify the schedule, length, and the exact charge of an agreement, and protect certain outcomes-based payments that measurably improve quality of patient care and reduce costs while maintaining quality.

Warranty Safe Harbor Modifications

The proposed rule would modify the existing safe harbor for warranties by revising the definition of a "warranty" to clarify that the safe harbor applies to FDA-regulated drugs and devices, provides protection for bundled warranties for one or more items and related services, and excludes beneficiaries from the reporting requirements applicable to buyers. Bundled warranties would need to be reimbursed by the same federal health care program and in the same payment form as the items and services subject to the arrangement. A manufacturer or supplier could not pay for any expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty, and they could not condition bundled warranties on exclusive use or impose minimum purchase requirements. Remuneration for any medical, surgical, or hospital expense incurred by a beneficiary would be limited to the cost of the items and services subject to the warranty. OIG is considering prohibiting direct patient outreach by a seller offering a warranty, and is soliciting comments on the potential fraud and abuse risks that may arise if the safe harbor is expanded to include services-only warranties.

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Transportation Safe Harbor Modifications

The proposed rule would revise the existing safe harbor for local transportation to expand and modify mileage limits for rural areas and for transportation for discharged patients. Specifically, the rule would expand the allowable transportation distance for residents of rural areas to 75 miles, and would remove any mileage limit on transportation of a patient from a healthcare facility to a patient's residence. OIG is seeking comments on the most appropriate distance, how entities would provide transportation over distances in excess of 50 miles, and whether the final rule should protect transportation in excess of the current limits only where there is a demonstration of financial, medical, or transportation need. OIG is also considering including non-medical purposes in the final safe harbor.