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HEALTH LAW DISPATCH

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## Special Edition

On October 9, 2019, as part of its Regulatory Sprint to Coordinated Care, the U.S. Department of Health and Human Services ("HHS") announced the long-awaited proposed regulations seeking to update and clarify the regulations implementing the Physician Self-Referral Law (commonly referred to as the "Stark Law") and the Federal Anti-Kickback Statute. The proposed rules issued by the Centers for Medicare & Medicaid Services (CMS) modifying the Stark Law regulations and those issued by the Office of Inspector General (OIG) modifying the regulations under the Federal Anti-Kickback Statute and Civil Monetary Penalties law were published in the Federal Register on October 17, 2019. The proposed regulations are part of the HHS's efforts to reduce regulatory barriers and advance the transition to value-based care and promote coordination of care among providers.

While we believe the proposed regulations are important enough to warrant a special edition of the *Health Law Dispatch*, it's also important to note that these regulations are not yet final and the comment period for the proposed regulations ends on December 31, 2019. The proposed regulations are extensive and far-reaching. As such, it would not be practical to attempt to summarize all of the proposed changes in this edition of the *Health Law Dispatch*. Rather, this special edition of the Schenck Price Health Care Law Practice Group's Health Law Dispatch seeks to identify and highlight specific aspects of the proposed regulations we believe to be important to our clients.

## CMS Proposes Revisions to Stark Law for Value-Based Care

*By Meghan V. Hoppe, Esq.*

In October, the Centers for Medicare & Medicaid Services ("CMS") released proposed regulations ("Proposed Rule") that include changes aimed at modernizing the federal physician self-referral statute (42 U.S.C. § 1395nn) and its associated regulations (42 C.F.R. § 411.350 et seq.) (collectively, the "Stark Law"). Unless an exception applies, the Stark Law prohibits a physician from referring a Medicare patient for designated health services to an entity with which the physician, or a member of the physician's immediate family, has a financial relationship. See 42 U.S.C. § 1395nn. The Proposed Rule creates three new Stark Law exceptions that would permit certain remuneration among participants in qualifying value-based arrangements.

First, CMS introduced the Full Financial Risk exception for value-based arrangements between VBE participants (defined below) assuming "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. See 84 Fed. Reg. 55779. The VBE participant(s) would need to take on full financial risk on a prospective basis (i.e., prior to providing any patient care items and services covered by the applicable payor). CMS elaborated that full financial risk may take the form of capitation payments (fixed, pre-determined payments agreed upon by contract) or global budget payments from a payor that compensates the value-based enterprise for providing all patient care items and services for a target patient population.

The second new exception is for Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician. See 84 Fed. Reg. 55781. CMS has proposed that "meaningful downside" occur when a physician is responsible for at least 25 percent of the value of remuneration received under the value-based arrangement. This exception could also include situations where the physician takes on "full financial risk" and is prospectively responsible for the cost of all or a defined set of patient care services for the target patient population.

This exception would require that the nature and extent of the physician's downside financial risk be set forth in writing and that the physician be at meaningful downside financial risk for the entire term of the value-based arrangement.

Lastly, CMS proposed a general exception for Value-Based Arrangements. See 84 Fed. Reg. 55783. This exception broadly addresses compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise or any of its "VBE participants," and permits both monetary and nonmonetary remuneration between the parties.

Importantly, the Proposed Rule establishes six new definitions at 42 C.F.R. § 411.351 to implement the value-based exceptions. A "VBE participant" is defined as an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. CMS is considering whether to exclude from this definition certain healthcare entities such as pharmaceutical manufacturers, manufacturers and distributors of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), pharmacy benefit managers, wholesalers and distributors. A "value-based enterprise" or "VBE" would mean two or more VBE participants (i) collaborating to achieve at least one value-based purpose; (ii) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (iii) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (iv) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). The Proposed Rule also ascribes specific meanings to "value-based activity," "value-based arrangement," "value-based purpose" and "target patient population".

CMS noted that these new exceptions need fewer "traditional" requirements to ensure the arrangements do not pose a risk of program or patient abuse because a value-based system inherently provides safeguards, such as overutilization, care stinting, patient steering and negative impacts on the medical marketplace.

As noted, stakeholders in the healthcare industry have an opportunity to influence the final regulations by providing comments on the Proposed Rule during the public comment period.

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## OIG Proposes New Anti-Kickback Safe Harbors for Value-Based Care Arrangements

*By Divya Srivastav-Seth, Esq.*

As part of the federal government's ongoing effort to shift reimbursement for services and items provided under federal programs from fee for service to fee for value, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") has proposed new rules excluding certain types of remuneration as prohibited under the Federal Anti-Kickback Statute 42 U.S.C. § 1320a-7b ("AKS"). See 84 Fed. Reg. 55694. The AKS prohibits any person from knowingly receiving or soliciting remuneration in order to induce or reward the referral of business reimbursable under any of the federal health care programs. Remuneration is defined to include any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind.

The OIG's proposed rules recognize that the key driver to achieving value-based, coordinated care arrangements is to allow for economies of scale based on large health populations to exist in the federal payer market. However, reimbursement based on the size of a health population and the savings (or lack thereof) runs directly counter to entrenched AKS regulatory prohibitions against arrangements premised on the volume or value of referrals. Such prohibitions were designed to prevent the over-utilization of services or items that were paid for by federal programs. The OIG's new rules cross this divide by, *inter alia*, providing new safe harbors for certain "legitimate" value-based care coordination arrangements depending on the amount of financial risk assumed by these value-based enterprises ("VBE") and their participants.

Under the proposed rules, prohibited remuneration under the AKS would not include payments or anything of value exchanged pursuant to a value-based arrangement if the VBE participants and/or the VBE assumes either substantial downside or complete financial risk. The remuneration must be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE or VBE participant is at financial risk. In addition, the remuneration must be directly connected to one or more stated value-based purposes, at least one of which must be the coordination and management of care for the target patient population. See 84 Fed. Reg. 55763.

In order to qualify for the safe harbor, all arrangements must be set forth in writing in advance of, or contemporaneous with, the commencement of the value-based arrangement or any material change to the value-based arrangement. The writing must state all material terms of the value-based arrangement, including: a description of the nature and extent of the financial risk attributable to a target patient population; a description of the manner in which the recipient of the remuneration meaningfully shares in the financial risk; the value-based activities; and the target patient population. Further, the remuneration cannot include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest, or be funded by, or otherwise result from the contributions of, any individual or entity outside of the value-based arrangement. As additional safeguards, the remuneration cannot induce the VBE participants to reduce or limit medically necessary items or services furnished to any patient and must not be based on the volume or value of referrals of patients who are not part of the target patient population or on business not covered under the value-based arrangement. Also, the remuneration must not limit a patient's freedom of choice to select his or her own provider or limit a provider's decisions that are made in the best interests of the patient. Remuneration will not be exempt if it is related to any patient recruitment activities. See 84 Fed. Reg. 55763-64; 42 C.F.R. § 1001.952(ff) and 42 C.F.R. § 1001.952(gg).

The OIG's proposed rules also provide a safe harbor for remuneration exchanged in value-based care coordination arrangements that do not share risk but limits this exception to in-kind remuneration only. The proposed rules provide similar requirements, as applicable, for risk sharing arrangements but also require that the participants set forth in writing both the offeror's cost of the in-kind remuneration and the percentage of cost contributed by the recipient, which must be a minimum of 15%. In addition, a reasonable person or a governing authority must monitor the progress toward coordinated care and terminate the arrangement if it is determined that there is a likelihood that goals for value-based care will not be achieved. See 84 Fed. Reg. 55762; 42 C.F.R. § 1001.952(ee).

Notably, the OIG and Centers for Medicare & Medicaid Services ("CMS") coordinated closely in drafting their respective proposed rules, where appropriate, to include consistent terminology for value-based arrangements. However, the OIG commentary for the proposed rules mentions that although certain arrangements may be protected by the less restrictive, civil, strict liability physician self-referral law, AKS measures are necessarily more restrictive to serve as back-stop protection, since the AKS is a criminal intent-based statute. See 84 Fed. Reg. 55696. Accordingly, the risk allocation under AKS safe harbors requires additional downside risk to be shared between the VBE, the VBE participant and a payer. The CMS and OIG rules also differ in that the full financial risk requirement for AKS safe harbor protection must be carried for a fixed one (1) year term, while CMS has not yet specified a defined time period for its similar exception.

The OIG repeatedly mentions in its commentary that the rules are still fluid because of the relative novelty of risk sharing value-based arrangements, and any final OIG rule should be reviewed in combination with the final CMS rules to understand the full regulatory landscape. See Id. Of course, the OIG has invited comment about value-based care coordination arrangements from interested stake holders through the public comment period and has said that these proposed rules may change in their final form.

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## CMS Proposed Rule to Change and Clarify Fundamental Stark Law Terminology

### *By Daniel O. Carroll, Esq.*

An important aspect of the proposed regulations ("Proposed Rule") issued by Centers for Medicare & Medicaid Services ("CMS") announced on October 9, 2019 and published in the Federal Register on October 17, 2019, relating to the federal physician self-referral statute (42 U.S.C. § 1395nn) and related regulations (42 C.F.R. § 411.350, et seq.)(collectively, the "Stark Law"), is the change to clarify certain fundamental Stark Law terminology and concepts. Notably, the Proposed Rule includes a definition for the term "commercially reasonable," a core requirement of many Stark Law exceptions. The Proposed Rule also proposes to codify special rules to define the volume or value standard and the other business generated standard used throughout the Stark Law exceptions. Moreover, CMS seeks to revise the regulatory definitions of "fair market value" and "general market value" to provide clarity and guidance in the application of these concepts when analyzing compensation arrangements.

The Proposed Rule will finally define the core requirement of commercial reasonableness. CMS is proposing two alternative definitions for the term "commercially

reasonable," in an effort to recognize that it is not a determination of valuation, but rather a determination of whether the arrangement makes sense as a way for the parties involved to accomplish their goals. The first definition defines commercially reasonable to mean that "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements." The second definition defines commercially reasonable to mean that "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty." Finally, the Proposed Rule will clarify that an arrangement may be commercially reasonable even if it is not profitable for one or both parties. See 84 Fed. Reg. 55790.

While many of the Stark Law exceptions require compensation to not be determined in a manner that takes into account the volume or value of referrals by the physician in the arrangement and certain Stark Law exceptions require compensation to not be determined in a manner that takes into account other business generated between the parties, there are no regulations defining or interpreting the foregoing standards. The Proposed Rule attempts to do so. CMS believes its Proposed Rule creates an objective bright-line approach with special rules to determine whether or not compensation is determined in a manner that takes into account the value or volume of referrals or other business generate between the parties. Only if the formula used to calculate compensation includes referrals or other business generated as factors that correlate to increases or decreases in compensation, is the compensation arrangement considered to have taken volume or value of such factors into consideration. See 84 Fed. Reg. 55792-93.

A third change to Stark Law terminology modifies the structure of the definition of "fair market value" to provide "a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space." In addition to the structural change in the definition of "fair market value," CMS proposes a change to the definition of "general market value" within the definition of "fair market value." Significantly, the proposed definition of "general market value" is intended to equate to and be consistent with the valuation industry's term "market value." Accordingly, and of note, CMS recognized that the hypothetical value of a transaction may diverge from the market value of the actual transaction under consideration and expressly stated that "[e]xtenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject the transaction." 84 Fed. Reg. 55799.

Whether or not these modifications to fundamental Stark Law terminology achieve the clarity and establish the bright line standards that CMS sought to provide is still to be determined, but the Proposed Rule does provide added guidance that will impact (and may alter) current interpretations of Stark Law requirements.

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## OIG and CMS Propose Rulemaking on Cybersecurity and EHR Donations

***By Deborah A. Cmielewski, Esq.***

As part of the Regulatory Sprint to Coordinated Care, on October 9, 2019, the Office of Inspector General ("OIG") of the Department of Health and Human Services and the Centers for Medicare & Medicaid Services ("CMS") issued important rulemaking designed to facilitate coordinated and value-based care and to support innovation in the delivery of health care services in the United States. Important elements of the proposed rulemaking deal with cybersecurity technology and services as well as electronic health records ("EHR"), key items necessary to modernizing the health care delivery system that contain inherent risks of fraud and abuse.

First, the OIG has proposed a new safe harbor for the donation of cybersecurity technology and services. See 84 Fed. Reg. 55733. With this new safe harbor, the OIG seeks to eliminate a real or perceived prohibition in the existing regulations that will enable parties to engage in practices that deter the growing threat of cybercrime involving health care records. It is hoped that the proposed new safe harbor will advance cyberhygiene and promote the interoperability of systems, while deterring arrangements that improperly influence clinical decision-making.

Proponents of the new safe harbor expressed overwhelming support in response to the OIG Request for Information, citing mounting cyberattacks and data breaches that jeopardize the health care delivery system. They noted that the rising cost of cybersecurity technology and services can prohibit health care providers and suppliers with limited resources from investing in adequate protections. In that regard, the OIG elected not to include a requirement that recipients of cybersecurity technology and services

contribute to a portion of the donor's costs. The OIG hopes that such cost savings may enable providers with limited resources to use their own resources to invest in additional safeguards not protected by the safe harbor.

Important conditions of the proposed new safe harbor include the following:

- The donated technology and services must be necessary and used predominantly to implement and maintain effective cybersecurity
- Donations cannot be conditioned on the present or future volume or value of referrals or other business between the parties
- A potential recipient cannot explicitly or implicitly demand a donation as a condition for doing business with the donor
- The donor and recipient must enter into a written and signed agreement
- Donors are prohibited from shifting the costs of donations to Federal health care programs

While it is clear that, consistent with current regulations, hardware is excluded from the proposed safe harbor, the OIG is considering including an alternative to protect hardware donations if the parties choose to meet the five (5) listed conditions as well as an additional safeguard that the donor has determined the donation is reasonably necessary based on a risk assessment of both the donor and recipient. See 84 Fed. Reg. 55735-5739.

OIG coordinated with CMS to ensure consistency of the proposed safe harbor with proposed modifications to the physician self-referral law. In a similar vein, CMS is proposing an exception to the physician self-referral law relating to cybersecurity donations. See 84 Fed. Reg. 55734 and 84 Fed. Reg. 55823.

Both the OIG and CMS have also recognized that the donation of valuable EHR technology could be deemed to incentivize providers to make improper referrals. Consistent with the proposed rulemaking concerning cybersecurity technology and services donations, OIG and CMS are also proposing changes in the area of EHR donations.

First, the OIG has proposed changes to the existing safe harbor for EHR items and services. Some of the salient features of the proposal include the following: (i) modification to the safe harbor to include the requirement that software must be certified to the current required standard of interoperability at the time that it is donated; (ii) alignment of the condition that prohibits a donor from limiting or restricting the use compatibility or interoperability of items or services with other electronic prescribing or electronic health record systems with the proposed definition of information blocking and related exceptions; (iii) clarification that certain cybersecurity software and services are and have always been protected under the EHR safe harbor; and (iv) a requirement that an entity donating EHR software and related services may also donate related cybersecurity software and services in order to safeguard EHR. The OIG is also seeking comment on the possible modification or elimination of the sunset provision of the safe harbor as well as the potential expansion of protected donors. See 84 Fed. Reg. 55739-55744.

Importantly, the OIG is also considering separate comment on the potential elimination, reduction or modification to the provision of the EHR safe harbor that requires a recipient to pay 15% of the donor's cost of the donated technology. See 84 Fed. Reg. 55743.

CMS is proposing similar changes to the exception to the physician self-referral law relating to EHR. See 84 Fed. Reg. 55822. Once again, although the underlying statutes differ, both agencies intend to coordinate as much as possible to ensure consistency in the regulatory provisions.

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