SWEEPING PROPOSALS ISSUED BY OIG TO MAKE CHANGES TO THE ANTI-KICKBACK STATUTE SAFE HARBORS AND ADD AN EXCEPTION TO THE CIVIL MONETARY PENALTY LAW GOVERNING BENEFICIARY INDUCEMENTS

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On October 9, 2019, the Department of Health and Human Services (the "Department") Office of Inspector General ("OIG") issued a sweeping set of proposed regulations, which were published in the Federal Register (available here) on October 17, 2019 (the "Proposed Regulations"), as part of the Department's "Regulatory Sprint to Coordinated Care" (the "Regulatory Sprint"). The Regulatory Sprint is a large initiative to modernize many health care regulations. The proposed regulatory changes under the Regulatory Sprint are aimed at reducing barriers to care coordination and value-based arrangements in order to help accelerate the transformation of the nation's health care system to one that incentivizes providers to focus on improved quality, better health outcomes and increased efficiency in health care delivery. Dorsey & Whitney's health care attorneys have been closely tracking the Regulatory Sprint, and more information and links to Dorsey publications on the Regulatory Sprint can be found here.

The Proposed Regulations introduce significant new proposed value-based terminology, propose six entirely new safe harbors to the Anti-Kickback Statute ("AKS"), propose changes to four existing AKS safe harbors and propose a new exception to the Civil Monetary Penalty Law governing inducements provided to Medicare and Medicaid beneficiaries ("CMPL").

The OIG issued the Proposed Regulations following an August 2018 Request for Information about ways the OIG could modify the AKS and CMPL in order to reduce barriers to patient care coordination and value-based arrangements, which we wrote about here. In response, the OIG received 359 comments from stakeholders, which it addressed in the Proposed Regulations and the corresponding preamble text.

This article summarizes each of the OIG's proposals, in four sections numbered as follows:

(I) Six new AKS safe harbors;
(II) Changes to four existing AKS safe harbors;
(III) Codification of a statutory exception under the Medicare Shared Savings Program ("MSSP"); and
(IV) A new exception to the CMPL.

The Proposed Regulations were published contemporaneously with proposed regulations from the Centers for Medicare & Medicaid Services ("CMS") that would make numerous significant changes to the federal physician self-referral law ("Stark Law"). Our summary of the proposed changes to the Stark Law will be posted here. Although the Stark Law is a civil, strict liability payment law whose regulatory provisions are promulgated by CMS, and the AKS is an intent-based, criminal law whose regulatory provisions are promulgated by OIG, both agencies worked together in the process of developing these sweeping regulatory proposals. The agencies jointly recognize the need to modernize and clarify the Stark Law and AKS, which are often analyzed in tandem. There are a number of differences between the Stark Law and AKS proposals. However, where there are similar proposals from CMS, the authors of this article have listed those proposals adjacent to our summary of the OIG's proposals.

As a word of caution, the OIG makes clear in the preamble to the Proposed Regulations that it is not sure whether the Proposed Regulations strike the correct balance between the goals of clarity/objectivity/flexibility/ease of use, on the one hand, and adequate safeguards against health care fraud and abuse/ensuring accountability and transparency, on the other hand. The preamble provides a detailed discussion of each proposal, and is rich with examples, proposed additional and alternative considerations under review by the OIG and repeated requests for specific stakeholder comments to help the OIG determine if their proposals "got it right." Thus, there may be significant changes to the Proposed Regulations once they are published in final form.

Comments to the Proposed Regulations are due by December 31, 2019 and can be submitted here. Please contact the authors or your regular Dorsey attorney if you would like assistance with submitting comments. Dorsey attorneys will continue to closely monitor the status of these Proposed Regulations as we await final rules from the OIG.

The following is a summary of the OIG's Proposed Regulations:

I. Six New AKS Safe Harbors

Value-Based Terminology and Care Coordination Safe Harbor

The OIG has proposed a set of safe harbors to protect from challenge under the AKS remuneration exchanged among certain types of entities to achieve certain value-based purposes. In understanding the proposed new safe harbors for value-based arrangements, it is critical to carefully review the proposed new defined terms that form the basis for safe harbor protection, certain of which are described below.

A value-based purpose would mean: (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) reducing payor costs or expenditures 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 or services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

The Proposed Regulations would create safe harbors that address arrangements in which participants in a value-based enterprise ("VBE") engage in value-based activities reasonably designed to achieve at least one of these value-based purposes ("VBE Participants"). As proposed, a VBE must be comprised of at least two of a wide range of potential individual or entity participants, including: clinicians, hospitals, suppliers, payors, post-acute providers, disease management companies, and social service organizations. However, due to perceived fraud and abuse concerns, the OIG's proposal precludes pharmaceutical manufacturers, laboratories, or manufacturers, distributors or suppliers of durable medical equipment, prosthetics, orthotics, or supplies ("DMEPOS") from being VBE Participants. The OIG is also considering whether to exclude additional categories of entities, such as pharmacy benefit managers ("PBMs").

The VBE must have two or more VBE Participants collaborating to achieve a value-based purpose, and must have either a person, entity or a board of directors or other governing body that is responsible for the financial and operational oversight of the enterprise. The VBE does not need to be a separate legal entity. The OIG intends that one of the VBE Participants can act as the responsible person or entity, and that the responsible person or entity need not have interests independent of the participants. In addition, the VBE must have a governing document that describes the enterprise and how the participants intend to achieve their value-based purposes. The governing document can be a written contract or protocol among the participants, and need not be formal bylaws or in any other specific format, so long as it describes the enterprise and how the participants intend to achieve its value-based purposes.

While there are many similarities, there are also some differences between the OIG and CMS proposed definitions related to value-based arrangements. For example, the CMS and OIG definitions of "value-based enterprise" (or VBE), "value-based purpose," "value-based activities," "value-based arrangement," and "target patient population" are aligned. However, OIG has a more restrictive proposed definition of "value-based enterprise participant" (or VBE Participant) than CMS. As described above, the OIG would exclude from this definition pharmaceutical manufacturers, laboratories or DMEPOS manufacturers, distributors or suppliers, which is unlike CMS. Further, the OIG proposes to define certain terms that CMS has not defined, such as "coordination and management of care," which is required for protected remuneration under several of the OIG's new value-based safe harbors.

Three New Safe Harbors for Value-Based Arrangements

1. **New Safe Harbor for Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (42 C.F.R. § 1001.952(ee))**

The first of the proposed safe harbors for value-based arrangements applies to participants who collaborate to promote value-based care and care coordination without assuming financial risk. It would protect non-monetary, in-kind compensation exchanged among VBE Participants to achieve value-based purposes.

An example of a value-based arrangement that falls within this care coordination safe harbor is an arrangement between a hospital and a skilled nursing facility ("SNF") in which the hospital provides the SNF with the services of a behavioral health nurse to follow hospital inpatients with certain mental health disorders for a one-year period following discharge from the hospital while such patients receive care at the SNF.

Many requirements must be met in order for the in-kind remuneration among VBE Participants to receive safe harbor protection.

First, the Proposed Regulations require that the VBE Participants set out specific, evidence-based, valid outcome measure(s) against which the recipient of the in-kind remuneration would be measured and that the participants reasonably anticipate would advance the coordination and management of care of the target patient population.

Second, the value-based arrangement must be set out in writing and signed, at or prior to the beginning of the arrangement. The contract must state: (1) the value-based activities to be undertaken; (2) the term of the arrangement; (3) the target patient population; (4) a description of the remuneration; (5) the cost of providing the remuneration; (6) the percentage of that cost to be contributed by the recipient(s) and the schedule of contribution payments; and (7) the specific evidence-based, valid outcome measure(s) against which the recipient would be assessed.

Third, the value-based arrangement must be directly connected to coordination and management of care of the target patient population and must not: (1) limit any participant's ability to make decisions in the best interests of their patients; (2) direct or restrict referrals, if that direction or restriction is contrary to patient or payor preference or applicable law; or (3) include marketing to patients or patient recruitment.

Fourth, the VBE or the responsible person or entity must monitor and assess, and report, at least annually, on: (1) the coordination and management of care for the target population; (2) any deficiencies in the delivery of quality care under the value-based arrangement; and (3) progress toward the arrangement's evidence-based, valid outcome measure(s). In addition, the parties must terminate the arrangement within sixty days of the responsible person's or entity's determination that the value-based arrangement is unlikely to achieve its intended outcome measure(s) or further the coordination and management of care for the target patient population, or has resulted in material deficiencies in quality of care.

Lastly, the remuneration provided under the value-based arrangement must satisfy certain requirements. As noted, the remuneration must be in-kind and non-monetary in nature. But it must also be used primarily for value-based activities directly connected to coordination and management of care for the target patient population, must not induce the participants to furnish medically unnecessary care or withhold medically necessary care, and must not be funded by, or result from, the contributions of any person or entity outside of the VBE.

The arrangement must be commercially reasonable, and the remuneration must not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population or any business not covered under the value-based arrangement.

The recipient of the in-kind remuneration must contribute at least fifteen percent (15%) of the cost of the remuneration back to the person or entity paying for the in-kind items or services. And finally, the person or entity paying the remuneration does not, and should not, know that the remuneration is likely to be diverted, resold or used by the recipient for an unlawful purpose.

The corresponding Stark proposal protecting value-based arrangements that focuses on care coordination is found at proposed 42 C.F.R. § 411.357(aa)(3), and it includes some variations from the proposed AKS safe harbor described above.

2. New Safe Harbor for Value-Based Arrangements with Substantial Downside Financial Risk (42 C.F.R. § 1001.952(ff))

For the payments made by a VBE to a VBE Participant to be protected under this proposed new safe harbor, the VBE must, among other requirements, agree to assume substantial downside financial risk from a payor for providing or arranging for services for a target patient population for the entire term of the value-based arrangement. VBE Participants who contract with the VBE must "meaningfully participate" in the aforementioned substantial downside financial risk (as discussed in more detail below), and the arrangement must not limit patient choice.

In an attempt to define "substantial downside financial risk," the OIG has published four examples where the OIG would consider the arrangements to have acceptable financial risk:

1) repayment to the payor of 40% of shared losses;
2) repayment to the payor under an episodic or bundled payment of at least 20% of total losses;
3) a prospective payment from the payor for a target population and a subset of total cost of care; or
4) a partial capitated payment for a target population that is a discount of at least 60% of the expected fee-for-service ("FFS") payments.

In all of these examples, payments (and in the case of the fourth example above, the FFS amounts) would be calculated based on historical expenditures, or, if unavailable, evidenced-based expenditures.

The OIG proposed to define "meaningfully shares" as compensation where:

1) the VBE Participants are at risk for 8% of the VBE's risk under its arrangement with the payor;
2) partial or full capitated payment (with some exclusions, such as prospective payment systems for certain facilities); or
3) payment to a physician VBE Participant that meets the requirements of the proposed Stark Law exception for value-based arrangements with meaningful downside financial risk, at proposed 42 C.F.R. § 411.357(aa)(2).

The safe harbor requires that remuneration paid from the VBE to the VBE Participant must primarily be used for value-based activities, directly connected to the services provided to the target population (and therefore included in the calculation of the substantial downside financial risk) and further coordination and management of care for such target patient population. The remuneration must not be conditioned on patient referrals that are outside of the patient population or business not covered by the value-based arrangement.

This safe harbor includes several materially notable exclusions. The safe harbor would only protect payments made directly between a VBE and a VBE Participant, and thus, would not protect payments made to downstream contractors of the VBE Participant or payments made for marketing or patient recruitment activities. The safe harbor also would not offer protection for ownership of investment interests in a VBE, or any distributions thereof. Importantly, as previously noted, the OIG has proposed to carve out from those able to take advantage of the safe harbor protection pharmaceutical manufacturers, DMEPOS manufacturers, distributors and suppliers, and laboratories (as these entities are proposed to be excluded from the definition of "VBE Participant").

The OIG notes a concern that value-based arrangements may result in providers limiting medically necessary services to achieve a more efficient outcome, but result in adverse patient care. As such, the OIG is proposing a requirement that the remuneration from the VBE to the VBE Participant not induce VBE Participants to limit medically necessary items or services furnished to any patient.

3. New Safe Harbor for Value-Based Arrangements with Full Financial Risk (42 C.F.R. § 1001.952(gg))

Finally, the OIG proposes a safe harbor protecting arrangements whereby a VBE has agreed to assume from a payor "full financial risk" for an identified target patient population for at least one year. In arrangements where a VBE is willing to accept the highest level of financial risk, the OIG sees less threat of fraud and abuse, and wants to promote innovation in care delivery and coordination. The OIG proposes to define "full financial risk" as a VBE that is "financially responsible for the cost of all items and services covered by [the payor] for each patient in the target patient population and [prospectively paid] by [the payor]." This includes a fully capitated payment model without an allowance for retrospective reconciliation, but would not cover payment for coverage of some (either type of service or temporal limitation) but not all services for a target patient population. The VBE Participant would also be prohibited from seeking additional or separate reimbursement from the payor for services provided under the value-based arrangement. In addition, the VBE must maintain a utilization review program and quality assurance program in order to fall within the safe harbor protection.

The safe harbor proposal requires that remuneration paid from the VBE to the VBE Participant is primarily used for value-based activities, directly connected to the services provided to the target population (and therefore

included in the calculation of the financial risk) and further coordination and management of care for such target patient population. The remuneration must not be conditioned on patient referrals that are outside of the patient population or business not covered by the value-based arrangement.

Similar to the proposed safe harbor for value-based arrangements with substantial downside financial risk, this safe harbor includes several materially notable exclusions. The safe harbor would only protect payments made directly between a VBE and a VBE Participant, and thus, would not protect payments made to downstream contractors of the VBE Participant or payments made for marketing or patient recruitment activities. The safe harbor also would not offer protection for ownership of investment interests in a VBE, or any distributions thereof. Importantly, as discussed earlier, the OIG has proposed to carve out from those able to take advantage of the safe harbor protection pharmaceutical manufacturers, DMEPOS manufacturers, distributors and suppliers, and laboratories (as these entities are proposed to be excluded from the definition of "VBE Participant").

The OIG notes a concern that value-based arrangements may result in providers limiting medically necessary services to achieve a more efficient outcome, but result in adverse patient care. As such, the OIG proposed a requirement that the remuneration from the VBE to the VBE Participant not induce VBE Participants to limit medically necessary items or services furnished to any patient.

The corresponding Stark proposal protecting value-based arrangements that take on full financial risk is found at proposed 42 C.F.R. § 411.357(aa)(1), and it includes some differences from the proposed AKS safe harbor described above.

New Safe Harbor for Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency (42 C.F.R. § 1001.952(hh))

This new proposed safe harbor would protect remuneration provided by a VBE Participant in the form of a patient engagement tool or support to improve quality, health outcomes and efficiency. This safe harbor would require that the tool/support be furnished directly to the patient and that no individual or entity outside of the applicable VBE funds or contributes to it, and the aggregate value does not exceed $500 on an annual basis (with an exception for patient financial need).

Additionally, the tool/support would need to be an "in-kind" preventative item, good or service (such as health-related technology and patient health-related monitoring tools and services) with a direct connection to care coordination and management for the target patient population. The OIG explained in preamble text that the "in-kind" requirement means that the patient needs to be given the actual tool/support rather than funds to purchase or reimbursement for purchasing it, but the OIG would consider a voucher for a particular tool/support to satisfy this requirement.

Further, the tool/support cannot be a gift card, cash or cash equivalent, or anything used for patient recruitment or marketing. Among many other areas for which the OIG is soliciting comments, the OIG is soliciting comments on whether to protect patient incentives in the form of cash and cash equivalents in certain circumstances, subject to an annual monetary cap and other safeguards. Further still, the OIG is considering whether to include protection for gift cards in limited circumstances, such as when they are provided to patients with specified conditions as part of an evidence-based treatment program.

Next, the proposed safe harbor would require that the tool/support does not result in medically unnecessary or inappropriate items or services reimbursable by a Federal health care program and would need to be recommended by the patient's provider. It would also need to advance adherence to a treatment, drug regimen or follow-up care plan, management of a disease, improvement in measurable outcomes, and/or ensure patient safety. In the preamble, the OIG gave examples of tools that would advance these goals, including a smart pill bottle and free childcare during medical appointments, but stated that offering a reward for compliance with a treatment regimen, such as movie tickets, would not advance these goals, and thus would not be protected

under the safe harbor. The proposed safe harbor would also require that "the offeror does not, and should not, know" that the tool/support would be likely to be used for a purpose other than the express purpose for which it is provided.

The OIG is also considering a safe harbor that would likely include similar conditions to those at proposed 42 C.F.R. § 1001.952(hh) for waivers of small beneficiary cost-sharing amounts, such as for care management and remote monitoring.

CMS-sponsored model arrangements and CMS-sponsored model patient incentives safe harbor (42 C.F.R. § 1001.952(ii))

In order to reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored value-based models, the OIG has proposed a new safe harbor to (a) permit remuneration between and among parties to arrangements (e.g., distribution of capitated payments, shared savings or losses distributions) under a model or other initiative being tested or expanded by the CMS Innovation Center; and (b) to permit remuneration in the form of incentives and supports provided by CMS model participants and their agents under a CMS-sponsored model to patients covered by such model.

The objective of the proposed safe harbor is to standardize and simplify AKS compliance for CMS-sponsored model participants in models for which CMS has determined participants should have the protection under the safe harbor by applying uniform conditions across all models or initiatives sponsored by CMS. OIG did note that the proposal does not extend to commercial and private insurance arrangements that may operate alongside, but outside, a CMS-sponsored model, but indicated that nothing in the proposed safe harbor would prevent commercial and private insurers from implementing arrangements that cover both public and private patients given that such arrangements could be structured to meet one of the other proposed safe harbors.

Conditions of CMS-Sponsored Model Arrangements

As used in section 1128B of the Act, "remuneration" would not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement in a model for which CMS has determined that this safe harbor is available if all of the following conditions are met:

(i) The CMS-sponsored model participants reasonably determine that the CMS-sponsored model arrangement would advance one or more goals of the CMS-sponsored model.

(ii) The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services furnished to CMS-sponsored model patients.

(iii) The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for or to induce or reward any Federal health care program referrals or other Federal health care program business generated outside the CMS-sponsored model.

(iv) The terms of the CMS-sponsored model arrangement are set forth in a writing in advance of or contemporaneously with the commencement of the arrangement. The writing must specify, at a minimum, the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement.

(v) The parties to the CMS-sponsored model arrangement make available to the Secretary of the Department materials and records sufficient to establish whether the remuneration was exchanged between the parties in a manner that meets the conditions. The OIG noted that the parties would have flexibility to determine what type of documentation would memorialize the arrangement such that they could demonstrate safe harbor compliance to CMS or OIG upon request.

(vi) The CMS-sponsored model parties must satisfy such other programmatic requirements as may be imposed by CMS in connection with the use of the safe harbor.

Conditions for CMS-Sponsored Model Patient Incentives

Additionally, "remuneration" would not include a CMS-sponsored model patient incentive under a model for which CMS has determined that this safe harbor is available if:

(i) The CMS-sponsored model participant must reasonably determine that the patient incentive the CMS-sponsored model participant furnishes to its patients under the CMS-sponsored model would advance one or more goals of the CMS-sponsored model.

(ii) The patient incentive must have a direct connection to the patient's healthcare both from a healthcare perspective and a financial perspective.

(iii) The CMS-sponsored model participant makes available to CMS, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was distributed in a manner that meets the safe harbor.

(iv) The CMS-sponsored model participant satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(v) A patient may retain any incentives received prior to the termination or expiration of the participation documentation of the CMS-sponsored model participant.

OIG noted in its commentary that a model participant could use this safe harbor to provide its patients with free or below-fair-market-value incentives that advance the goals of the CMS-sponsored model, such as preventative care, adherence to a treatment regimen, or management of a disease or condition; such incentives could include nutrition support, home monitoring technology and gift cards, as determined by CMS through the CMS-sponsored model's design. Certain CMS-sponsored models or future models might permit waivers of cost-sharing amounts (for example, copayments and deductibles) or cash incentives to certain patients to promote certain clinical goals of a CMS-sponsored model.

Finally, in its commentary regarding the proposed rule, OIG noted that the safe harbor protects the last payment or exchange of value made by or received by a CMS-sponsored model party following the final performance period that the CMS-sponsored model participant that is a party to the arrangement participates in the CMS-sponsored model.

In an American Health Lawyers Association webinar on October 24, 2019, Lisa Ohrin Wilson, Senior Technical Advisor in the Chronic Care Policy Group at CMS, stated that CMS did not propose a parallel Stark exception to the proposed AKS safe harbor for CMS-sponsored model arrangements because the proposed Stark Law value-based arrangements exception (which would be added at 42 C.F.R. § 411.357(aa)(3)) could apply to CMS-sponsored models.

New Safe Harbor for Cybersecurity Technology Related Services (42 C.F.R. § 1001.952(jj))

The OIG proposes the creation of a safe harbor to protect donations of certain cybersecurity technology and related services. As stated in the preamble to the Proposed Regulations, "[t]he digitization of the healthcare delivery system and related rules designed to increase interoperability and data sharing in the delivery of healthcare create numerous targets for cyberattacks. The healthcare industry and the technology used to deliver healthcare have been described as an interconnected 'ecosystem' where the 'weakest link' in the system can compromise the entire system. Given the prevalence of protected electronic health information and other personally identifiable information stored within these systems, as well as the processing and transmission of

this information, the risks associated with cyberattacks may be most immediate for the 'weak links' but have implications for the entire healthcare system." With this in mind, the OIG has proposed a safe harbor that would protect from regulatory scrutiny health care organizations that assist providers and suppliers in the acquisition of cybersecurity technology either through donation or subsidy.

Before cybersecurity technology may be donated, the arrangement must meet certain defined conditions. The most notable condition under this safe harbor is that the donated technology must be shown to be necessary and used predominately to implement and maintain effective cybersecurity. By way of example, the types of technology may include malware prevention software, software security measures to protect endpoints that allow for network access control, business continuity software that mitigates the effect of cyberattacks, data protection and encryption, and email traffic filtering. The technology donation must not directly take the volume or value of referrals into account, nor be a condition of doing business, the arrangement must be set forth in a written agreement, and there may not be cost shifting to any Federal health care program.

Importantly, the safe harbor only allows the donation of ***software*** and related services, to the explicit exclusion of ***hardware*** (with limited exceptions), the intent being to be agnostic to specific types of non-hardware cybersecurity technology and reduce the chance that one purpose of a donation would be to solicit referrals. The OIG stated that hardware is more likely to have multiple purposes, so donations of hardware are more likely to be suspect. Hardware can be included in a cybersecurity donation only if it has been determined to be reasonably necessary based on a risk assessment of both the donor and recipient party.

The corresponding Stark proposal protecting the donation of cybersecurity technology and related services is found at proposed 42 C.F.R. § 411.357(bb), and is generally aligned with the OIG's proposed AKS safe harbor described above (with some exceptions).

II. Changes to Four Existing AKS Safe Harbors

Changes Proposed to the Safe Harbor for Donation of Electronic Health Records Items and Services (42 C.F.R. § 1001.952(y))

The OIG proposes to further modify the electronic health records ("EHR") software safe harbor created in 2006 and first modified in 2013 in order to build in consistency with the 21st Century Cures Act, specifically related to the "deeming" provision and "information blocking" condition.

"Deeming" is the process by which relevant parties may demonstrate their arrangement for EHR software fits the safe harbor by showing that such software ***has been*** certified. The OIG proposes to modify this language to require a showing that such software ***is*** certified. In other words, the certification must be current as of the date of the donation, as opposed to the software having been certified at some point in the past but no longer maintaining certification on the date of the donation.

The "information blocking" condition currently prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of items or services with other electronic prescribing or EHR systems. The OIG has not proposed any rules that would substantively change this condition. Instead, the OIG has proposed changes that would better align this condition with the 21st Century Cures Act by, for example, updating definitions for consistency.

Finally, the OIG proposed to clarify that certain cybersecurity software and services are protected under this safe harbor. Furthermore, the sunset provision created in 2013, which states that this safe harbor would sunset in 2021, is proposed to be removed. The OIG is also considering three additional rules, including updating the current fifteen percent (15%) recipient contribution requirement, allowing replacement technology, and expanding the scope of donors protected by this safe harbor.

CMS has also proposed a nearly identical exception under the Stark Law (under proposed modifications to

existing 42 C.F.R. § 411.357(w)), and comments received on the CMS proposal may impact the final version of the OIG's proposed AKS safe harbor described above.

Changes Proposed to the Personal Services and Management Contracts Safe Harbor, Including Protection for Outcomes-Based Payment Arrangements (42 C.F.R. § 1001.952(d))

The OIG is proposing to revise the existing safe harbor for personal services and management contracts. Two of these proposed revisions aim to align this safe harbor with the personal service arrangements exception under Stark. Specifically, the OIG proposes to remove the requirement that ***aggregate*** compensation be set in advance and instead require only that the ***methodology for determining*** the compensation paid over the term of the agreement be set in advance. This change would remove a key hurdle for many existing arrangements that currently do not qualify for protection under the safe harbor because the aggregate compensation under the arrangement is not set in advance. The OIG states in preamble text that the intention of this proposal is to provide enhanced flexibility to undertake innovative arrangements, while still mitigating the risk of adjusting compensation to reward referrals or unnecessary utilization. The proposed revisions also include removing the requirement that, if services are provided on a part-time basis, the agreement must specify the exact schedule of such intervals, their precise length and the charge for them.

Next, the proposed revisions add a new provision to this safe harbor that would protect remuneration for "outcomes-based payments" that meet specified parameters. Such a payment would need to be made from a principal to an agent to reward the agent for improving (or maintaining improvement in) patient or population health by achieving outcome measure(s) that coordinate care ***across care settings*** (rather than in just one care setting such as a hospital) or that achieve outcome measure(s) that appropriately reduce payor costs and improve or maintain improved quality of patient care. Protected payments would not include any payments made by a pharmaceutical manufacturer, a DMEPOS manufacturer, distributor or supplier, or a laboratory, and the OIG is considering also excluding payments made by pharmacies, PBMs, wholesalers and distributors, as well as limiting the safe harbor only to outcomes-based payment arrangements of VBE Participants.

Protected payments would not include these payments that relate solely to achieving internal cost savings for the principal (as opposed to the payor). As an example, the OIG states that a payment arrangement between a hospital and physician group relating only to sharing financial risk or gain with respect to items/services reimbursed to the hospital under the Medicare inpatient hospital prospective payment system would not be protected, but an arrangement where such parties share risk or gain ***across care settings*** would be protected. It is likely that many in the industry will provide comments on protection that is needed for internal cost savings (i.e., gainsharing arrangements that a hospital has with its physicians solely for care provided in the hospital setting), rather than just savings that accrue to a payor.

Among many other proposed requirements to qualify for safe harbor protection, such as commercial reasonableness, amounts paid to be set in advance, written agreement, etc., the outcome measure(s) used for the outcomes-based payments would need to be selected based on clinical evidence or credible medical support, and the agent must satisfy these measures in order to receive an outcomes-based payment. Neither party can be limited in making decisions in their patients' best interests nor induced to reduce or limit medically necessary items or services (which, the OIG recognizes, is already prohibited under the gainsharing Civil Monetary Penalty Law, at 1128A(b)(1) of the Social Security Act, for payments from hospitals to physicians, and is included here in recognition that parties other than hospitals and physicians may seek safe harbor protection). Further, the parties would need to regularly monitor and assess the agent's performance, including the impact on patient quality of care, and periodically rebase during the term of the agreement (i.e., reset the benchmark used for determining whether to make a payment in order to account for improvements that have already been made). Finally, the compensation methodology cannot ***directly*** take into account the volume or value of referrals

or business otherwise generated, and the OIG recognizes in preamble text that parties may need to establish payment methodologies that ***indirectly*** do so.

Changes to the Warranties Safe Harbor (42 C.F.R. § 1001.952(g))

The Proposed Regulations would expand the safe harbor for warranties to protect warranties for bundled items and services, such as product support services. The OIG also proposes modifying the reporting requirements to exclude beneficiaries, and seeks comments on what other modifications would reduce reporting burdens. The OIG is also considering permitting warranties applying only to services, and seeks comments on the potential fraud and abuse risks this expansion may create and what safeguards are needed to mitigate those risks.

Changes to the Local Transportation Safe Harbor (42 C.F.R. § 1001.952(bb))

The OIG proposed expanding the local transportation safe harbor, created in 2016 (as Dorsey wrote about here), to increase mileage limits for patients residing in rural areas from fifty to seventy-five miles. The OIG seeks comments on whether that increase is sufficient. The OIG also clarifies that ridesharing services are permissible under this safe harbor. The Proposed Regulations would also remove any mileage limits on transportation of a patient from a health care facility to their residence after the patient has been discharged. The OIG also seeks comments on whether the safe harbor should be extended to protect transportation for non-medical purposes that may nevertheless improve or maintain health, such as transportation to grocery stores, social services facilities or gyms.

III. *Codification of a Statutory Exception under the MSSP: The ACO Beneficiary Incentive Program Safe Harbor (42 C.F.R. § 1001.952(kk))*

The Proposed Regulations codify the Accountable Care Organization ("ACO") Beneficiary Incentive Program statutory exception to the definition of "remuneration" passed in the Bipartisan Budget Act of 2018. As modified, the safe harbor would protect patient incentives provided by and among parties participating in CMS-approved MSSPs. The safe harbor would emphasize that an ACO may only furnish incentive payments to assigned beneficiaries but does not include any additional conditions for the safe harbor to apply. The OIG seeks comments on whether any additional conditions should be included.

IV. *New Exception to the CMPL for Telehealth Technologies Donated to Existing ESRD Patients for In-Home Dialysis (42 C.F.R. § 1003.110)*

Finally, the OIG proposed to add a new exception to the definition of prohibited "remuneration," codifying amendments that were enacted in the Bipartisan Budget Act of 2018. The exception states that "remuneration" does not include the provision of telehealth technologies by a provider of services or a renal dialysis facility to an individual with end stage renal disease ("ESRD") who is receiving in-home dialysis payable under Medicare Part B as long as:

(1) the telehealth technologies are furnished to the individual by the provider of services or the renal dialysis facility that is ***currently*** providing the in-home dialysis, telehealth visits, or other ESRD care to the patient (in order to avoid steering patients to select new providers);
(2) the telehealth technologies are not offered as part of any advertisement or solicitation (again, to avoid steering);
(3) the telehealth technologies contribute substantially to the provision of telehealth services related to the individual's ESRD, are not of excessive value, and are not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes; and

(4) the provider of services or a renal dialysis facility does not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the technologies as bad debt for payment purposes under Federal health care programs, or otherwise shift the burden of the value of the telehealth technologies onto Federal health care programs, other payors, or individuals.

Note that the definition of "telehealth technologies" means multimedia communications equipment that includes, at a minimum, A/V equipment permitting two-way, real-time interactive communication between the patient and a distant site provider used in the patient's diagnosis, intervention, or ongoing care management. Telephones, fax machines and e-mail systems do not count as telehealth technologies.