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HHS Proposes New Protections for Value-Based Arrangements and Other Revisions to AKS Safe Harbors, CMP Exceptions and Stark Exceptions

Advisory

By Steven Benz, John Gould, Jeffrey L. Handwerker, Kristin M. Hicks, Ariane M. Horn, Paul M. Rudolf, MD, Allison W. Shuren, Thomas A. Gustafson, PhD, Kristine Blackwood, Rosemary Maxwell, Ashley Bender, Catherine A. Brandon, Catherine Brinkley-Talley, Neha K. Patel

On October 9, 2019, the Department of Health and Human Services (HHS) released two separate, but related, proposed rules as part of its "Regulatory Sprint to Coordinated Care." The Office of the Inspector General (OIG) released a Proposed Rule, Revisions to Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (AKS Proposed Rule),[1] and the Centers for Medicare and Medicaid Services (CMS) released a Proposed Rule, Modernizing and Clarifying the Physician Self-Referral Regulations (Stark Proposed Rule).[2] The proposed rules were published in the *Federal Register* on October 17, 2019, and comments are due December 31, 2019.[3]

In Part I of this Advisory, we describe OIG's and CMS's coordinated proposals to protect from enforcement scrutiny (i) certain value-based arrangements, and (ii) arrangements involving the donation of cybersecurity technology and services and electronic health records (EHR) systems. In Part II of this Advisory, we outline the OIG's other proposals, including new Anti-Kickback Statute (AKS) safe harbors, modifications of existing safe harbors, and a new telehealth technologies exception to the Civil Monetary Penalties (CMP) provisions related to beneficiary inducement. In Part III, we summarize CMS's proposed revisions to the Physician Self-Referral (Stark) Law regulations, including clarifications regarding certain fundamental terminology, amendments to existing exceptions, and a new exception for limited remuneration to a physician.

Understanding the scope of these proposals and their potential impact on health care delivery is critical not only to health care professionals (HCPs) and other providers and suppliers of healthcare items and services, who will be impacted directly by the rules if finalized, but also for manufacturers and other vendors who do business with the HCPs and entities.

I. CMS AND OIG COORDINATED PROPOSALS

A. Value-Based Arrangements

Overview

The stated goals of the proposed rules are to incentivize a shift away from reimbursement for healthcare items and services based on volume to payment systems where HCPs and other healthcare provider and suppliers have greater financial accountability for cost-effective, high-quality, coordinated care. To promote the evolution to value-based

[1] HHS OIG, Proposed Rule, Revisions to Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements.

[2] CMS, Proposed Rule, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations,.

[3] Comments are due 75 days after the expected *Federal Register* publication date of October 17, 2019.

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healthcare delivery and promote care coordination, CMS and OIG (together the Agencies) propose three new safe harbor protections under the AKS and three new exceptions to the Stark Law for certain remunerative arrangements between eligible participants in a "value-based enterprise" (VBE), which is a network of individuals and entities that collaborate to implement one or more value-based activities (VBAs)[4] with the intent of achieving at least one of the following four value-based goals:

1. coordinating and managing the care of a target patient population;
2. improving the quality of care for a target patient population;
3. appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; and
4. transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

In addition, the Agencies would require that the VBE set forth in a written document the purpose and activities of the VBE and establish a governing body that is responsible for monitoring the activities related to its value-based arrangements, among other things.

CMS and OIG generally propose to define a "VBE participant" to include physician practices, hospitals, post-acute providers, payors, as well as other individuals and entities, but propose to expressly exclude certain types of entities, such as pharmaceutical manufacturers; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); and laboratories.[5] The Agencies solicit comments on whether certain other entities should be excluded from protection under the proposals, such as device manufacturers, pharmacies, pharmacy benefit managers (PBMs), wholesalers, distributors. Additionally, OIG and CMS solicit comment on precluding some or all protection for arrangements between entities that have common ownership. As with the proposed safe harbors and exceptions, the Agencies intend that the definition of "VBE participant" will be aligned under each of the proposals.

The three proposed safe harbors and exceptions would provide prospective protection for and progressively greater flexibility in designing an arrangement as the VBE takes on greater downside financial risk for costs and quality of care.

At a high level, the three proposed safe harbors and exceptions protect:

1. certain in-kind and monetary arrangements where the VBE assumes full downside financial risk from a payor;
2. certain in-kind and monetary arrangements where the VBE assumes substantial downside risk from a payor; and
3. certain in-kind remuneration exchanged between qualifying VBE participants for value-based activities that are *directly connected* to care coordination and care management.

CMS and OIG are concurrently developing these proposals to address similar concerns. The Agencies coordinated closely to develop the proposals and intend to do the same with regard to the final rules, with the goal of promoting alignment and easing the compliance burden on regulated entities.

[4] "Value-based activity" is defined to include (a) the provision of an item or service; (b) the taking of an action; or (c) refraining from taking an action.

[5] For additional information on the proposed exclusions from the definition of "VBE participant" under the AKS Proposed Rule, *see* HHS OIG's Proposed Rule Revising the AKS Safe Harbors and Beneficiary Inducement CMP Rules: Information for Drug and Device Manufacturers.

Proposals (1) and (2) listed above likely would be applicable to arrangements between a healthcare entity(ies) and a payor. VBEs falling into Proposal (3) could be arrangements between a healthcare entity and a payor or between/among healthcare entities. In addition to requesting general comments, the Agencies solicit comments on a number of specific aspects of the proposals, such as the permissible types of protected remuneration; the types of safeguards needed to prevent fraud and abuse; and whether protection may be conditioned on the volume or value of referrals or of any other business generated. Below we describe the safe harbors and exceptions, focusing on the key elements of the proposals.

Full Downside Financial Risk

The Agencies propose to protect certain arrangements between VBE participants in a VBE that has assumed full financial risk for the cost of all patient care items and services for each patient in a target patient population. To be protected under the safe harbor or exception, OIG and CMS propose that the VBE must be paid on a prospectively determined basis and assume full financial risk within six months of the commencement of the VBA, and on a prospective basis for the duration of the arrangement.

Both CMS and OIG propose to require that "full financial risk" means that the contract between the VBE and the payor may not allow for any additional payments to compensate for costs incurred by the VBE in providing care to the target population. For example, OIG proposes to exclude from protection an entity that receives a partial capitated payment, be it either: (i) a capitated payment that covers a limited set of items or services or (ii) a payment arrangement where an entity receives a combination of reduced fee for service (FFS) and capitation payments for a defined set of items or services. However, CMS proposes that the proposed definition of "full financial risk" would not prohibit a payor from making payments to offset losses incurred by the VBE above those prospectively agreed to by the parties. The types of financial loss and payments CMS contemplates with its proposal are less clear, as CMS does not explain the potential types of losses a VBE could insure "above those prospectively agreed to by the parties" and does not provide examples. Both Agencies propose to permit a VBE from entering into arrangements, such as global risk adjustments, risk corridors, reinsurance, or stop loss agreements, to protect against catastrophic losses. CMS and OIG seek comment on the proposed definition of "full financial risk," including whether six months is a sufficient amount of time for parties to implement a full financial risk arrangement.

Meaningful/Substantial Downside Financial Risk

The Agencies propose a safe harbor from the AKS and an exception to the Stark Law for value-based arrangements between participants in VBEs that assume meaningful/ substantial downside financial risk[6] to protect both monetary and in-kind remuneration. To be protected under the safe harbor or exception, OIG and CMS propose that the VBE must be paid on a prospectively determined basis and assume meaningful/substantial financial risk within six months of the commencement of the VBA, and on a prospective basis for the duration of the arrangement.

For purposes of the proposed AKS safe harbor, OIG proposes to define "substantial downside financial risk" as risk to the VBE in the form of:

1. shared savings with a repayment obligation to the payor of at least 40% of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

[6] In its discussion the proposed safe harbor to the AKS, OIG uses the term "meaningful downside financial risk," while in its discussion of the proposed exception to the Stark Law, CMS uses the term "substantial downside financial risk."

2. a repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20% of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;
3. a prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or
4. a partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected FFS payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the VBAs.

For purposes of the proposed Stark Law exception, CMS proposes to define "meaningful downside financial risk" as arrangement where a physician:

1. is responsible to pay the entity no less than 25% of the value of the remuneration the physician receives under the VBA; or
2. is financially responsible to the payor or the entity on a prospective basis for the cost of all or a defined set of items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

CMS elaborates that the physician must be the entity assuming the meaningful downside financial risk. CMS states that it believes that when a physician assumes downside financial risk in an arrangement, the physician has incentive to change his or her practice and referral patterns in a way that "curbs the influence of traditional FFS, volume-based payment." It seeks comment as to whether the physician would have the same behavior-modification incentives if the entity that assumes the meaningful downside financial risk is the entity furnishing DHS. Also with respect to arrangements subject to this exception to the Stark Law, CMS proposes that the methodology used to determine the amount of the remuneration is set in advance of the value-based activities for which the remuneration is paid.

No Downside Financial Risk

The Agencies also propose protections for arrangements between a VBE and one or more of its VBE participants or between VBE participants in the same VBE for the provision of at least one value-based activity for a target population, regardless of the level of risk undertaken by the VBE or any of its participants. These arrangements, however, would be limited to care coordination and care management. In other words, no entity would be required to assume downside financial risk for the exception to be applicable. The stated purpose of this proposal is to encourage physicians and physician groups that are not used to risk-sharing or are too small to absorb downside financial risk to participate in care coordination activities.

With respect to the proposed AKS safe harbor, OIG proposes to protect only in-kind, non-monetary remuneration, and that the recipient of the remuneration must pay at least 15% of the offeror's cost for the in-kind remuneration. In addition, OIG proposes and seeks comment on a requirement that the VBA participants must establish one or more specific evidence-based, valid outcome measures against which the recipient will be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population. To illustrate this arrangement, OIG describes an arrangement in which a hospital might provide a behavioral health nurse to follow designated inpatients with mental health disorders in the event of discharge to a SNF. In this example, the SNF, in turn, might provide certain staff to the hospital to help coordinate designated patients' care through the discharge planning process or might provide office

space for the behavioral health nurse. With respect to the proposed Stark exception, CMS proposes that the exception would permit both monetary and non-monetary remuneration, provided that the methodology used to determine the amount of remuneration is set in advance, but seeks comment on whether it should limit the scope of the exemption to non-monetary remuneration.

Additional Key Safeguards in the Proposed Protections for VBAs

	No Downside Risk Required	Substantial Financial Downside Risk Required	Full Financial Risk Required
Remuneration funded by, or otherwise resulting from contributions by, an individual or entity outside of the applicable VBE, is excluded.	Yes	Yes	Yes
Remuneration does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest.	No	Safe harbor only	Safe harbor only
Remuneration must not take into account volume or value of referrals of patients that are *not* part of the VBA's target population or business covered under the VBA.	Yes	Yes	Yes
The VBA is "commercially reasonable" / "objective and measurable."	Yes	No	No

	No Downside Risk Required	Substantial Financial Downside Risk Required	Full Financial Risk Required
The VBA does not limit independent decision-making or restrict referrals to a particular provider, practitioner, or supplier.	Yes	Yes	Yes
The VBA does not direct or restrict referrals to a particular provider.	Yes	Yes	Yes
The VBA does not include marketing of items or services or patient recruitment activities.	Yes	Yes	Yes
The VBA provides for an operational utilization review program and a quality assurance program.	No	No	Safe harbor only
Writing Requirement	Yes	Yes	Safe harbor only
Recordkeeping Requirement	Yes	Yes	Yes
Internal monitoring and assessment requirement	Safe harbor only	No	No
The offeror does not, and should not, know that the remuneration is likely to be diverted, resold, or used for an unlawful purpose.	Safe harbor only	No	No

1. Indirect Compensation Arrangements Applicable to Stark Exception for Value-Based Arrangements

CMS recognizes that some VBAs may not involve direct compensation arrangements between a DHS entity and the referring physician but rather there could be an indirect compensation link between the parties. To provide protection for these arrangements under the proposed VBA exceptions, CMS proposes a special rule for indirect compensation arrangements involving value-based arrangements. Specifically, CMS is proposing that, when the value-based arrangement is the link in the chain closest to the physician—that is, the physician is a direct party to the value-based arrangement—the indirect compensation arrangement would qualify as a "value-based arrangement" for purposes of applying the proposed VBA exception. The link closest to the physician must be a *compensation* arrangement that meets the definition of the VBA—it may not be an ownership interest.

Among the issues about which it seeks comment, CMS asks whether to exclude an unbroken chain of financial relationships between a DHS entity and a physician from the definition of "indirect value-based arrangement" if the link closest to the physician (that is, the VBA to which the physician is a party) is a compensation arrangement between the physician and a pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. Or, in the alternative, CMS asks whether the exception should be even more narrowly drawn by excluding an unbroken chain of financial relationships between a DHS entity and a physician from the definition of "indirect value-based arrangement" if one of these entities is a party to *any* financial relationship in the chain of financial relationships.

2. Price Transparency in Proposed Stark Exceptions

Consistent with HHS's articulated policy to increase price transparency in health care, CMS seeks comments on how to pursue transparency objectives in the context of the Stark Law, including the appropriate time for price information to be disseminated to patients and whether a price transparency requirement should be included in every exception for VBAs under the new proposal at § 411.357(aa). According to CMS, price transparency is important in a health care system that pays for value, and price and quality information is important for patients to make informed decisions when choosing care.

B. Cybersecurity and EHR Technology

Both proposed rules contain parallel regulations which would make donations of certain technology beyond the reach of the Stark Law and the AKS. Specifically, CMS and OIG propose a new cybersecurity technology exception and safe harbor, respectively, and also propose modifications to the existing EHR technology regulations. Importantly, with respect to the AKS Proposed Rule, OIG solicits comments on the types of donors who should be protected under these safe harbors, and whether the agency should revisit its historical view that only entities with "direct and primary patient care relationships," and that "provide[] services and submit[] claims," are eligible for safe harbor protection with respect to the donation of these types of technologies.

1. Proposed New Cybersecurity Technology Regulations

The new cybersecurity technology exception and safe harbor would protect donations of software or other non-hardware information technology that are "necessary and used predominantly" to "protect information by preventing, detecting, and responding to cyberattacks." CMS and OIG propose additional conditions consistent with the existing regulatory framework. Specifically, these donations must not take into account the volume or value of referrals or other business generated between the parties, the recipient must not demand the donation as a condition for doing business, and the arrangement must be documented in writing. With respect to the AKS safe harbor, OIG proposes an additional condition

for protection, i.e., the donor must not shift the cost of the donation to the federal health care programs (e.g., a donor hospital could not list the value of a donation of cybersecurity technology on the hospital cost report).

Separately, both CMS and OIG solicit comments on alternative approaches in which donations of certain hardware technology could be protected. Additionally, both agencies solicit comments on whether to require a financial contribution from the recipient of the technology, similar to the existing EHR Stark exception and AKS safe harbor.

2. Proposed Modifications to the EHR Technology Exceptions

Both agencies propose "almost identical" modifications to the parallel EHR technology regulations. Specifically, both proposed rules would update the provisions pertaining to interoperability and data lock-in, would clarify that donations of certain cybersecurity software and services are permitted, would remove the existing sunset provisions (currently set at December 31, 2021 for both rules), and would modify the definitions of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act.

Separately, both agencies solicit comments on potential modifications to the existing requirement that recipients contribute 15% of the costs of the donated technology. To this end, CMS and OIG indicate that they are considering either eliminating or reducing the percentage contribution requirement for all recipients, or alternatively, eliminating or reducing that requirement for a subset of recipients (e.g., small or rural practices). In addition, CMS and OIG solicit comments on allowing donations of replacement EHR technology.

II. ADDITIONAL AKS AND CMP PROPOSALS

A. Personal Services and Management Contracts and Outcomes-Based Payment Arrangements

OIG proposes to expand the existing safe harbor for personal services and management contracts[7] and create a new provision to protect certain outcomes-based payments. As proposed, the outcomes-based payments safe harbor would not protect arrangements that providers enter into with drug manufacturers; DMEPOS manufacturers, suppliers, and distributors; or laboratories. OIG's specific proposals are described below.

1. Proposed Changes to the Existing Safe Harbor Provisions

First, OIG proposes to replace the current safe harbor requirement that the *aggregate* compensation payable under the services arrangement be set in advance with a requirement that the "*methodology* for determining the compensation paid to the agent over the term of the agreement is set in advance." (Emphasis added.) OIG would continue to require that the compensation reflect fair market value, be commercially reasonable, and not take into account the volume or value of referrals of business otherwise generated between the parties.

Second, OIG proposes to eliminate entirely the current requirement that, if any agreement provides for services on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals. OIG believes removing these requirements will afford parties additional flexibility in designing bona fide business arrangements, including care coordination and quality-based arrangements, and that the safe harbor as amended would still provide sufficient safeguards against the manipulation of these arrangements to reward referrals.

[7] 42 C.F.R. § 1001.952(d).

2. Proposed Safe Harbor Protection for Certain Outcomes-Based Payments

Within the personal services safe harbor, OIG proposes to add a new provision to protect "outcome-based payments," made between or among parties that are collaborating to (i) measurably improve (or maintain improvement in) quality of patient care; or (ii) appropriately and materially reduce costs to, or growth in expenditures of, payors while improving, or maintaining the improved, quality of care for patients. The safe harbor would require only that the parties collaborate and does not expressly require that the arrangement include the provision of services.

a. Outcomes-Based Payments

OIG would define outcome-based payments as "payments from a principal to an agent that: (i) reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients." Such payments would exclude any payment that relates solely to the achievement of internal cost savings for the principal. For example, the proposed safe harbor would not protect arrangements that involve sharing in financial risk or gain only as it relates to prospective payment systems (e.g., acute inpatient hospitals, home health agencies, outpatient hospitals, skilled nursing facilities, etc.) because the savings under the arrangement would not accrue to the payor. OIG seeks comments on potential alternative definitions of "outcomes-based payment," such as by reference to specific types of payments, such as shared savings payments, shared losses payments, gainsharing payments, pay-for-performance payments, and episodic or bundled payments.

b. Outcome Measures

OIG proposes to require that parties to an outcomes-based payment arrangement establish one or more specific evidence-based, valid outcome measures that must be satisfied to receive the outcomes-based payment.[8] OIG notes that, for an arrangement to be protected, measures must promote improved quality or efficiencies in the delivery of care, or appropriate cost reduction. OIG acknowledges that payment for the maintenance of high quality may be low risk, but is concerned that measures that simply seek to reward the status quo are more likely to be mere payments for referrals. OIG solicits comments on whether, and if so how, it should protect arrangements that involve payments for maintaining high quality.

Related to the concern of rewarding the status quo, OIG proposes to require the parties to regularly monitor and assess the agent's performance on each outcome measure under the agreement. Parties would be required to "rebase" the benchmark or outcome measure periodically – in other words, reset the benchmark to take into account improvements already made so the arrangement does not become and "evergreen" arrangement based on referrals once performance on the performance measure has maxed out. OIG solicits comments on the definition of "rebase," whether it would be appropriate and realistic to establish a specific timeframe for requiring parties to rebase, and if so, when and how frequently rebasing should occur.

c. Payment Methodology

[8] This requirement is similar to the outcome-measure requirement in the proposed care coordination arrangements safe harbor at paragraph (ee), with an important difference. This proposed safe harbor requires satisfaction of an outcome measure to receive an outcomes-based payment, whereas the care coordination arrangements safe harbor requires monitoring and assessment related to such outcome measure. Achievement of the outcomes measure is not a prerequisite to the provision or use of in-kind remuneration under the proposed care coordination arrangements safe harbor.

Similar to the requirements in the current personal services safe harbor, OIG proposes to require that the methodology for determining the aggregate compensation (including any outcomes-based payments) paid between and among the parties over the term of the agreement is: (i) set in advance; (ii) commercially reasonable; (iii) consistent with fair market value; and (iv) not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a federal health care program.

With respect to the fair market value, OIG acknowledges that this requirement may pose challenges to the extent there are not industry standards yet developed to determine fair market value for some outcomes-based payment arrangements. Further, OIG acknowledges that some of the outcomes-based payment arrangements it proposes to protect do not necessarily correlate payments with actual services performed (and in some cases, reward not performing services). OIG states that it anticipates the industry will evolve and adapt to assess fair market value for outcomes-based payment arrangements, but does not address how parties might meet this safe harbor requirement in the interim. OIG, however, is considering whether to take a different approach, including whether to value outcomes-based payments separately from other compensation or whether to substitute the fair market value requirement with a different safeguard that would help ensure that payments are for legitimate participation in arrangements that drive value-based care and are not merely disguised payments for referrals.

OIG states that it recognizes that, to incentivize care coordination and appropriate behavior changes through outcomes-based payments, parties may need to establish payment methodologies that at least indirectly take into account the volume and value of referrals or other business generated between the parties. Thus, OIG proposes to require that the compensation methodology for determining the outcomes-based payment not be determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. This requirement would differ from the existing personal services safe harbor provision (as proposed to be amended), which does not allow the parties to take into account referrals or business generated between the parties, whether directly or indirectly, in determining an arrangement's compensation methodology.

d. Contract Requirements and Documentation

OIG proposes that parties make outcomes-based payments pursuant to a written agreement signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the arrangement. The term of the agreement may not be less than one year. OIG further proposes to require that the written agreement include the outcomes measure(s), the evidence-based data or information upon which the parties relied to select the outcome measure(s), and the schedule for the parties to regularly monitor and assess the outcome measure(s). If specific services are to be performed, the agreement must specify all of the services the parties perform (or refrain from performing) to qualify for the outcomes-based payment.

In addition to these writing requirements, OIG suggests that parties may consider documenting and retaining such documentation necessary to demonstrate compliance with each prong of the safe harbor (e.g., documentation of payments and data showing the agent's achievement of the outcome measure(s)).

e. Additional Safeguards

In addition to the safeguards described above, the safe harbor would require that the arrangement "neither limits any party's ability to make medically appropriate decisions for patients, nor induces the reduction of medically necessary services" and that the "services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law."

f. Excluded Entities

As in its approach to the proposed safe harbors to protect VBAs, OIG proposes to exclude pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories from the safe harbor for outcomes-based payments. OIG is also considering excluding pharmacies (including compounding pharmacies), PBMs, wholesalers, and distributors from the new safe harbor protections. OIG is also considering whether to more specifically target the safe harbor on outcomes-based payments arrangements that further value-based care or care coordination by limiting protection for outcomes-based payment arrangements to VBE participants. OIG is soliciting comments about these proposed exclusions, including illustrative examples of beneficial or problematic arrangements that might be excluded or included if OIG finalizes some or all of these exclusions.

B. Arrangements for Patient Engagement and Support

OIG proposes a new safe harbor to protect certain arrangements for patient engagement tools and supports intended to improve quality, health outcomes, and efficiency. Under the proposed safe harbor, in-kind patient engagement tools or supports, furnished directly by a VBE participant to a patient in a target patient population, would not be considered "remuneration" for purposes of the AKS if directly connected to the coordination and management of care, provided all of the conditions of the safe harbor are met.[9] OIG proposes that the tool or support must advance one or more specifically enumerated goals: (1) adherence to a treatment regiment, drug regiment, or follow-up care plan as determined by the patient's provider; (2) management of a disease or condition, as directed by the patient's provider; (3) improvement in measurable evidence-based measurable health outcomes for a patient or the target patient population; or (4) ensuring patient safety. OIG intends for this new safe harbor to protect the provision of appropriate patient engagement tools and supports that promote patient engagement with their individual care and adherence to their treatment regimes.

1. Types of Remuneration

OIG further proposes to restrict the types of renumeration eligible for protection under this safe harbor to certain items, goods, and services:

- *Preventive items, goods, or services*. OIG declines to define "preventive services" in its proposal and would instead permit protection for tools and supports that a VBE participant reasonably determines, within the medical judgment of the patient's provider, to be preventive care.
- *Items, goods, or services such as health-related technology and patient health-related monitoring tools and services*. OIG envisions that this category of remuneration might include wearable monitoring devices, such as a smart watch or tracker designed to collect information and transmit data to a patient's physician for treatment or monitoring.
- *Supports and services designed to identify and address a patient's "social determinants of health*." OIG notes that substantial evidence indicates that unmet needs for some "health-related nonmedical" items, goods, and services play a critical role in determining health outcomes and expenditures. As examples, OIG cites transportation to medical appointments and nutrition education to address clinical conditions, and it seeks public input on which items, goods, and services might be covered by the safe harbor as social determinants.

[9] OIG notes that a practice permissible under the AKS is also excepted from the beneficiary inducements civil money penalty provisions.

With a limited exception for certain patients who lack financial resources, the aggregate retail value of the tool or support would not be permitted to exceed $500 a year. Alternatively, OIG is also considering alternative values and configurations of this limit.

OIG clarifies that the in-kind limitation requires the patient to receive the actual tool or support (and not funds to purchase the tool or support). Accordingly, cash, cash equivalents, and gift cards would be excluded from the safe harbor. However, based on feedback citing the efficacy of such remuneration in maintaining patient engagement and reinforcing positive behavioral change, OIG is considering (for possible inclusion in the final rule) whether to protect patient incentives and supports in the form of cash, cash equivalents, and gift cards in limited, defined circumstances.

2. Proposed Safeguards

OIG proposes a number of additional safeguards as a condition of safe harbor protection:

- OIG would require the tool or support to be furnished directly to the patient by a VBE participant, though OIG is considering whether to permit the tool or support to be furnished through someone acting on the VBE participant's behalf and under the VBE participant's direction (e.g., a nurse employed by the VBE).
- OIG would prohibit outside entities from funding or otherwise contributing to the cost of patient engagement tools or supports furnished by a VBE participant.
- The remuneration would not be permitted to include any item or service used for patient recruitment or marketing for additional items or services to patients, though OIG solicits comment on permitting targeted marketing or similar outreach to the target population for the purposes of engaging them in evidence-based prevention or wellness activities.
- The tool or support would be prohibited from resulting in medically unnecessary or inappropriate items or services.
- OIG would require the tool or support to be recommended by the patient's licensed healthcare provider.
- OIG would decline protection for the remuneration where the VBE participant knows or should know that the tool or support is likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the patient engagement tool or support is provided.
- OIG would require VBE participants to make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the safe harbor.

3. Potential Safeguards

OIG is also considering imposing a number of additional safeguards, including:

- prohibiting VBE participants from billing payors, including federal healthcare programs, for the tool or support; claiming the value of the tool or support as bad debt; or otherwise shifting the burden of the value of the tool or support onto payors, including federal health care programs.
- requiring VBE participants to provide the same patient engagement tools or supports to an entire target patient population, or otherwise offering tools and supports to all patients based on uniform criteria.
- requiring VBE participants to use "reasonable efforts" to monitor the effectiveness of the tool or support in achieving the intended benefit.

- requiring VBE participants to engage in reasonable efforts to retrieve an item or good from a patient in certain circumstances.
- prohibiting the VBE participant from publicly advertising the patient engagement tool or support to patients or others who are potential referral sources.

C. CMS-Sponsored Model Arrangements and Patient Incentives

This proposed AKS safe harbor would protect certain remunerative arrangements between or among "parties" to a CMS-sponsored model "for which CMS has determined that the safe harbor is available" and protect "participants" that furnish certain incentives to patients in such a model.[10] "CMS-sponsored model" means: (1) a Phase I or Phase II Center for Medicare and Medicaid Innovation (CMMI) model; or (2) the Medicare Shared Savings Program.[11] OIG seeks comments on broadening this term to include CMS initiatives "under other sections of the Act with statutory authority to waive the fraud and abuse laws." The purpose of this proposed safe harbor is to "reduce the need for model-by-model waivers of fraud and abuse laws."

Under the proposed safe harbor, arrangements between parties to a CMS-sponsored model for which the safe harbor is available are protected if:

1. the parties reasonably determine that their arrangement will advance one or more of the model's goals;
2. the arrangement does not induce providers or suppliers either to furnish medically unnecessary care or to reduce or limit medically necessary care to any patient;
3. the parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program business outside of the CMS-sponsored model;
4. the parties document their arrangement (including the activities to be undertaken and the remuneration to be exchanged) in a writing signed by the time the arrangement begins;
5. the parties provide to CMS upon request "all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the [safe harbor] conditions"; and
6. the parties satisfy any "programmatic requirements" CMS imposes in connection with use of the safe harbor.

The safe harbor also would protect patient incentives (unless CMS decides a certain type of patient incentive is prohibited) furnished by "participants" to a CMS-sponsored model for which CMS has decided the safe harbor is available,[12] if:

1. the participant reasonably determines that the patient incentive will advance one or more of the model's goals;
2. the patient incentive has a "direct connection to the patient's healthcare";

[10] "Participants" means an individual or entity that is "subject to, and is operating under, participation documentation to participate in a CMS-sponsored model." "Parties" are participants plus other individuals/entities "who the participation documentation specifies may enter into a CMS-sponsored model arrangement." "Participation documentation" means the "participation agreement, cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that: (i) is currently in effect, and (ii) specifies the terms of a CMS-sponsored model."

[11] Currently HHS specifies AKS waivers relating to CMMI models on a model-specific basis. HHS has authority under the CMMI statute to waive the AKS (and other specified statutory provisions) "as may be necessary solely for purposes of carrying out [the CMMI statute] with respect to testing models described in section (b) [Phase I models]." The new proposed safe harbor essentially would expand the power to waive the AKS to Phase II CMMI models.

[12] E.g., the incentives might be a range of incentives such as transportation, nutrition support, home monitoring technology, and gift cards, provided CMS did when determined by CMS to be appropriate to be appropriate and not prohibited by the participation documentation.

3. the participant provides 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] conditions"; and
4. the participant satisfies any "programmatic requirements" CMS imposes in connection with the use of the safe harbor.

D. Modifications to the Warranties Safe Harbor

The warranties safe harbor protects the exchanges of value pursuant to a warranty agreement "provided by a manufacturer or supplier of an item to a buyer (such as a health care provider or beneficiary)," as long as certain conditions are met. The proposed rule would make four changes to the safe harbor:

- Update the definition of "warranty;"
- Expand the safe harbor to encompass warranty arrangements for one or more items (i.e., bundled items) and related services, where certain conditions are met;
- Introduce additional safeguards and requirements as a condition of safe harbor protection; and
- Exclude beneficiaries from the reporting requirements applicable to buyers of products with warranties.

Although the safe harbor now can protect warranties for products providers purchase from manufacturers or suppliers, it does not shield any warranties for services a manufacturer or supplier furnishes to a provider. OIG is considering expanding the current proposal to include warranties covering only services, but it has not specifically addressed whether it might extend this safe harbor to warranted services offered by *providers*. Instead, OIG describes certain risks associated with physician warranties, such as the potential for sham warranty payments to induce physician selection, particularly where the warranted outcome is not easily achievable.

1. Definition of Warranty

The warranty safe harbor currently defines the term "warranty" through reference to the definition of "written warranty" in the Magnuson-Moss Act.[13] OIG proposes to remove this cross reference, and instead define "warranty" directly, using language similar to the Magnuson-Moss Act definition. OIG states that the new definition would continue to include agreements promising that warranted items or services "will meet a specified level of performance over a specified period of time," which OIG interprets to include arrangements conditioned on clinical outcome guarantees (provided the arrangements meet all of the safe harbor's requirements). OIG intends this proposal to clarify that the safe harbor applies to FDA-approved drugs and devices.

2. Bundled Warranties

OIG interprets the current safe harbor as limited to warranties on single items, and not covering bundled items or services.[14] OIG proposes to extend protection to warranty arrangements that apply to one or more items and related services, provided that the warranty covers at least one item. However, OIG warns that the proposal "would not protect free or reduced-price items or services that sellers provide either as part of a bundled warranty or ancillary to a warranty agreement." OIG notes that items or related services with an independent value to the buyer would require the protection of a different safe harbor should they be offered to the buyer for free or at a discounted price in connection with a warranty, and cites laboratory testing and medication adherence services as potential examples:

[13] 15 U.S.C. § 2301(6).
[14] *See* OIG, Advisory Opinion No. 18-10 (September 17, 2018).

> [L]aboratory testing required for patient care may be necessary to determine if a warranted outcome was achieved, but the laboratory test would have independent value to the buyer. A seller's provision of laboratory testing for free or at a reduced charge as part of a warranty agreement would implicate the anti-kickback statute. Additionally, the provision of medication adherence services for free or below fair market value would implicate the anti-kickback statute. In contrast, if sellers provide items and services with no independent value to a buyer, other than to determine whether the conditions of a warranty have been satisfied, the items and services may not constitute remuneration under the anti-kickback statute, and thus, may not implicate the statute.

Regarding medication adherence services, OIG further notes:

> Using medication adherence services offered by drug manufacturers as an example, we are concerned that manufacturers may promote patients' adherence to prescribed medications, even when a patient is experiencing harmful side effects, or the medication is not achieving the purpose for which it was prescribed. Because manufacturers have financial incentives for patients to use and reorder their medications but do not have the medical expertise the prescribing physicians have to determine whether continued use of medications is clinically appropriate for a specific patient, medication adherence services offered by manufacturers, such as phone or message communications directing patients to take their medications, could result in patient harm or inappropriate utilization of drugs.

Additionally, while the proposal would not protect warranties covering only services, although OIG is considering extending protection to such arrangements if sufficient safeguards exist.

Finally, OIG would also condition protection for bundled warranties on the requirement that all federally reimbursable items and services subject to the warranty are reimbursed (1) by the same federal health care program, *and* (2) *in the same payment* (e.g., where items or services are reimbursed by Medicare Part A in the same DRG payment). However, OIG is considering modifying this proposal to protect items and services reimbursed under the same payment *methodology*. OIG is also considering permitting warranties where the bundled items are reimbursed under the same payment by Medicare but reimbursed separately by Medicaid. OIG seeks examples of circumstances that merit an exception to the proposed same-program, same-payment requirement.

3. Additional Safeguards and Reporting Requirements

First, OIG proposes to continue its requirement limiting remuneration provided under a warranty to the cost of the items and services subject to that warranty. Additionally, OIG proposes to prohibit manufacturers and suppliers from conditioning warranties on either the exclusive use of one or more items and services or on minimum purchase requirements.

OIG also proposes to exclude beneficiaries from the reporting requirements applicable to other buyers of products under warranty, since beneficiaries do not report costs to the government. Further, OIG seeks input on whether the current reporting requirements keep buyers from receiving warranty payments over several years, and recognizes the need for delayed reporting if,

E. Modifications to the Local Transportation Safe Harbor

OIG seeks information regarding expanding the scope of protected transportation covered by the safe harbor for local transportation finalized in 2016 as well as expanding its protection to transportation services offered in the context of VBE programs. Specifically, the OIG seeks comments on (1) expanding the distance which residents of rural areas may be transported from 50 miles to 75 miles and (2) eliminating any mileage limitation on transportation of a patient at discharge

from a health care facility following an inpatient stay. The Proposed Rule also makes clear that the OIG did not intend for ride-sharing services to be excluded from the existing safe harbor.

The OIG has particular interest in public comment on the following issues:

- Expansion of Mileage Limit
    - Whether an increase to a 75 mile limit is sufficient;
    - What data or information exists demonstrating that patients in certain communities or service areas cannot obtain care within the existing 50 mile distance limitation; and
    - Whether the protection of transportation beyond the 50 mile limit should require a demonstration of medical, financial or transportation need.
- Elimination of Distance Limit for Discharged Patients
    - Whether safe harbor protection should be expanded to encompass transportation to any location of the discharged patient's choice, including another health care facility;
    - Whether safe harbor protection should be granted to situations where the patient has not discharged from an inpatient stay, such as from and ambulatory surgery center or emergency room;
    - Whether the protection of transportation for discharged patient beyond the current limit should require a demonstration of medical, financial or transportation need; and
    - Whether an increase in the mile limit for patients in rural areas remains necessary if the discharge limit is eliminated.

Lastly, the OIG asks for comments on whether the transportation safe harbor should cover rides for health-related, but non-medical purposes, such as trips to a food bank, social service facility or chronic disease support group. The Agency notes that the safe harbor proposed for patient engagement tools and supports for VBEs would cover transportation for non-medical services, and, therefore, seeks to understand whether similar protections should cover like programs offered by non-VBEs.

F. ACO Beneficiary Incentive Program

Accountable Care Organizations (ACOs) in certain two-sided risk models may operate CMS-approved beneficiary incentive programs, intended to encourage beneficiaries to obtain medically necessary primary care services. These beneficiary incentive programs operate under section 1899(m) of the Social Security Act (SSA); CMS finalized regulations implementing this provision in December 2018. OIG's proposed rule would codify in regulations a statutory exception to the definition of "remuneration" in the AKS, which provides that remuneration does not include an incentive payment made to a Medicare fee-for-service beneficiary by an ACO's beneficiary incentive program.

OIG proposes to adopt language nearly identical to that in the statute, with two exceptions apparently designed to sharpen the focus. First, OIG proposes that the new exception would apply only to incentive payments made by the ACO to the ACO's assigned beneficiaries. Second, OIG proposes a wording change apparently intended to insure that for an incentive payment to satisfy the statutory exception and thus to qualify for the corresponding proposed safe harbor, all of the requirements enumerated in SSA §1899(m) and those alone, must be satisfied.

G. CMP Exception for Telehealth Technologies

In 2018, Congress amended the Social Security Act to permit an individual with end state renal disease (ESRD) receiving home dialysis to elect to receive their monthly ESRD-related clinical assessment via telehealth if certain other conditions are met.[15] Concurrently, Congress created a new statutory exception to the definition of "remuneration" in the beneficiary inducement CMP for the provision of telehealth technology.[16] In the Proposed Rule, CMS proposes to codify this exception in regulation, proposes additional safeguards, and solicits comments on other safeguards it is considering.

CMS proposes to define telehealth technologies as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider. Telephones, facsimile machines, and electronic mail systems are not telehealth technologies." CMS solicits comments on this definition, including whether the definition should include technologies such as software, webcams, data plans, and internet access that facilitate the telehealth encounter. CMS is also considering additional limitations such as a cap on the retail value of the telehealth technology.

The proposed exception would exclude from the definition of remuneration telehealth technologies provided by a provider of services or a renal dialysis facility to an individual with ESRD, who is receiving in-home dialysis payable under Medicare Part B, if telehealth technologies: (i) are furnished by the provider or renal dialysis facility that is currently providing the in-home dialysis, telehealth visits, or other ESRD care to the patient; (ii) are not offered as part of any advertisement or solicitation; (iii) contribute substantially to the provision of telehealth services, is not of excessive value, and is not duplicative of technology that the individual already owns if that technology is adequate for the telehealth purpose; and (iv) 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 telehealth technologies as a bad debt for payment purposes under a federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a federal health care program, other payors, or individuals.

Due to its concerns that the provision of telehealth technology with substantial independent value might induce beneficiaries to choose a particular provider, CMS is considering a number of additional requirements that might mitigate the risk of inducement, such as requiring that the provider retain ownership of any hardware (i.e., only loan hardware to beneficiaries) or requiring that the person who furnishes the telehealth technology take reasonable steps to limit the use of the technology to telehealth services. CMS also solicits comment on the following topics related to the telehealth technologies exception:

- Whether the exceptions should apply to suppliers in addition to providers of services and renal dialysis facilities.
- Whether CMS should include a non-discrimination requirement which would require providers to provide the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis, or to otherwise consistently offer telehealth technologies to all patients to satisfy a uniform criteria.

[15] SSA § 1881(b)(3).

[16] BBA § 1128A(i)(6)(J) ("The provision of telehealth technologies (as defined by the Secretary) on or after January 1, 2019, by a provider of services or a renal dialysis facility (as such terms are defined for purposes of title XVIII) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if: (i) the telehealth technologies are not offered as part of any advertisement or solicitation; (ii) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end stage renal disease; and (iii) the provision of the telehealth technologies meets any other requirements set forth in regulations promulgated by the Secretary.")

- Whether to include a condition to the final rules requiring providers and facilities to: (1) provide written notice to the patient for the reason for the technology and any potential hidden costs associated with the services; and (2) advise patients that they retain the freedom to choose any provider or supplier of dialysis services and to receive dialysis in any appropriate setting.

III. ADDITIONAL STARK LAW PROPOSALS

A. Group Practices—Distribution of Revenue Related to Participation in VBE

CMS is proposing a new rule to address downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relates to the physician's participation in a VBA.

CMS' current special rules for the profit shares and productivity bonuses paid to physicians in a group practice prohibit calculation methodologies that directly take into account the volume or value of the recipient physician's referrals to the group practice. CMS is proposing to add regulation text at §411.352(i)(3), which is a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. Under this proposal, when such profits are distributed to the participating physician, they would be deemed not to directly take into account the volume or value of the physician's referrals.

If finalized, this means that a group practice could distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician's participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration would be deemed not to directly take into account the volume or value of the physician's referrals.

CMS is seeking comment regarding whether it should permit the distribution of "revenue" from designated health services or "profits" from designated health services (as proposed) in order to effectuate the goals described in the Proposed Rule.

B. Guidance Regarding Fundamental Terminology and Requirements

In addition to proposing new and modified regulatory exceptions to the Stark Law, CMS also proposes clarifications to "fundamental terminology," that is, terminology used in many of the existing exceptions. According to CMS, its overall intention with respect to these proposals is to "reduce the burden of compliance" with the Stark Law. Specifically, CMS proposes, in some instances, new or modified regulatory definitions under 42 C.F.R. § 411.351 (i.e., for "commercially reasonable" and for "fair market value"), and in other instances by creating new special rules for compensation under 42 C.F.R. § 411.354(d) (i.e., for the "volume or value" and the "other business generated" standards, and for patient choice and directed referrals).

1. New Definitions Under 42 C.F.R. § 411.351

a. Commercially Reasonable

With respect to the proposed new definition for "commercially reasonable," CMS reiterates its position that the key question to ask is "whether the arrangement makes sense as a means to accomplish the parties' goals," and underscores that commercial reasonableness does not turn on whether the arrangement is profitable for the parties. To that end, CMS proposes two possible definitions: either that the particular arrangement "furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements," or in the alternative, 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." CMS solicits comments on which definition is more appropriate.

b. Fair Market Value

CMS proposes modifications to the existing regulatory definition of "fair market value." As a preliminary matter, CMS clarifies that the "fair market value" requirement is separate and distinct from the "volume or value" or "other business generated" standards. As such, in order to satisfy the requirements of any exception in which these concepts appear, compensation must satisfy each of these conditions independently.

The proposed modified definition of "fair market value" is restructured to separately address a general definition, as well as certain specific definitions (i.e., for rental of equipment and for rental of office space). CMS indicates that this proposed structure merely "reorganizes for clarity," but does not differ significantly from the statutory definition of "fair market value." There are, however, some substantive modifications to the various definitions.

The most notable proposed change to the definition of "fair market value," which requires the value to be consistent with "general market value," is that CMS proposes substantive modifications to its definition of "general market value." Specifically, the proposed revisions are designed to align the regulatory definition of "general market value" with the valuation industry term "market value," which considers *only* the subject transaction (and not any other business the parties to the transaction may have with one another). CMS indicates that it views the concept of "fair market value" as relating to a *hypothetical* transaction, and the concept of "general market value" as relating to an *actual* transaction, between actual parties that is set to occur within a specific timeframe. CMS uses physician compensation by hospital systems as an example to illustrate that "general market value" would consider the specific circumstances of the employment (e.g., cost of living in the geographic area of the hospital, the professional qualifications and characteristics of the physician, the hospital's economic position), and as such, makes the determination of what constitutes "general market value" a fact-specific inquiry that may provide the relevant parties more flexibility in determining fair market value.

2. New Special Rules Under § 42 C.F.R. § 411.354(d)

a. The Volume or Value and the Other Business Generated Standard (§ 411.354(d)(5) and (6))

CMS' stated purpose with respect to this proposed special rule for compensation is to provide clear, objective tests for determining whether compensation takes into account the volume or value of referrals, or the value of other business generated by the physician. CMS proposes what it represents to be a "bright-line rule" that considers whether the mathematical formula used to calculate the amount of compensation includes as a variable referrals or other business generated, and whether the resulting amount of compensation correlates with the volume or value or referrals or business generated.

CMS sets forth two separate special rules for non-fixed compensation: § 411.354(d)(5) addresses compensation from a DHS entity to a physician, whereas § 411.354(d)(6) addresses compensation to a DHS entity from a physician. For compensation *from* a DHS entity to a physician, the compensation only will be deemed to take into account the volume or value of referrals or business generated if the compensation *positively correlates* with the volume or value of the referrals or business generated (i.e., the physician receives additional compensation as referrals or business generated increase). Inversely, for compensation to a DHS entity from a physician, the compensation will only be deemed to take into account the volume or value of referrals or business generated if the compensation *negatively correlates* with the volume or value of referrals or business generated (i.e., the physician pays less to the DHS entity as referrals or business generated increase).

For both types of compensation (i.e., *from* the DHS entity, and *to* the DHS entity), CMS proposes additional policies that outline narrowly-defined circumstances in which fixed-rated compensation could be deemed to take into account the

volume or value of referrals or other business generated. That is, if the fixed-rate compensation (e.g., a fixed annual salary) is set using a predetermined tiered approach that considers the volume or value of past referrals or business generated in determining the fixed-rate compensation, the compensation will be deemed to take into account the volume or value of referrals or other business generated.

CMS notes that although these proposals are "special rules," rather than definitions, CMS intends to interpret these rules in the same manner as definitions, such that if the methodology used to determine compensation does not squarely fit within these defined circumstances, CMS will not view the compensation as taking into account the volume or value of referrals or business generated.

b. Patient Choice and Directed Referrals (§ 411.354(d)(4))

Currently, § 411.354(d)(4) of the Stark regulations provide that for certain compensation arrangements under which compensation is conditioned on referrals from the physician to the DHS entity, CMS may nonetheless deem the compensation arrangement to not take into account the volume or value of referrals, if certain conditions are met. In the Stark proposed rule, CMS proposes to include compliance with the § 411.354(d)(4) conditions as a new affirmative requirement for certain other regulatory exceptions (i.e., for academic medical centers at § 411.355(e), for bona fide employment relationships at § 411.357(c), for personal services arrangements at § 411.357(d)(1), for physician incentive plans at § 411.357(d)(2), for group practice arrangements with a hospital at § 411.357(h), for fair market value compensation at § 411.357(l), and for indirect compensation arrangements at § 411.357(p)).

In addition, CMS proposes revision to the § 411.354(d)(4) conditions. Namely, CMS clarifies that the physician's compensation, or a formula for determining the compensation, must be set in advance for the duration of the arrangement, and that any changes in compensation (or the formula for determining compensation) must be made prospectively.

C. "Recalibration" of Existing Regulations

CMS also re-examines the existing Stark regulations and proposes a number of revisions to the existing provision, including deleting certain existing requirements. CMS proposes these revisions based off experience in administering the Self-Referral Disclosure Protocol (SRDP),[17] stakeholder comments and interactions, and CMS' interactions with law enforcement partners.

1. Decoupling Stark Law from AKS and Other Laws

CMS proposes to "decouple" the Stark Law from the AKS and other Federal and State laws or regulations governing billing or claims submission. Many of the Stark exceptions include a requirement that the arrangement at issue not violate any the AKS or any Federal or State law or regulation governing billing or claims submission. CMS explains that it has come to agree, in collaboration with law enforcement officials, that including a requirement for compliance with the AKS is misplaced in a Stark exception because it introduces an intent-based requirement into a strict liability statute. Historically, commenters expressed concern regarding the difficulty this created for entities to meet their burden of proof that an arrangement does not violate the Stark Law. CMS reiterates and underscores, however, that the proposal does not affect parties' liability under any of these laws and further clarifies that if a financial relationship complies with an exception to the Stark Law, it does not mean that it does not violate the AKS. CMS notes that, if this proposal is accepted, the Secretary would monitor the impact of this change and would retain the authority to reinstate the deleted requirements.

[17] CMS notes that it has received more than 1100 SRDP submissions since the inception of the program in 2010.

2. Definitions

CMS proposes revisions to the following existing definitions at 42 C.F.R. § 411.351:

- Designated Health Services (DHS)
- Physician
- Referral
- Remuneration
- Transaction

We highlight below the key proposed revisions to these existing definitions.

Notably, CMS proposes to revise the definition of DHS to clarify that a service that otherwise meets the definition of DHS when provided by a hospital to an inpatient does not constitute DHS captured by the Stark Law if the furnishing of the service does not affect Medicare's payment to the hospital under the inpatient prospective payment system (IPPS). CMS seeks comment on whether this should be extended to analogous services when a hospital is not paid under the IPPS.

Section 1877(h)(1)(C)(ii) of the SSA carves out from the definition of "remuneration" the furnishing of items, devices, or supplies used solely for the collection, transportation, processing, storage of specimens or for the ordering of tests or communicating results of tests. CMS previously clarified through regulation and advisory opinions that surgical items, devices and supplies were not included among the excepted products because they could be used for functions other than those enumerated. CMS now proposes to remove exclusion of surgical items, devices or supplies, recognizing that it is not the fact that a product might have the capability to be used in a surgical function but rather how the device is "in fact" being used by the recipient. If finalized, CMS would replace the "surgical" qualifier with a requirement that such items are "in fact, used solely" for one or more of the six specified purposes.

CMS also proposes to create a stand-alone definition for "isolated financial transaction," separate from the definition of "transaction" to clarify that this term does not include a payment for multiple services provided over an extended period, even when there is only one lump sum payment for such services.

3. Period Of Disallowance

CMS proposes to entirely remove the rules on the period of disallowance (42 C.F.R. § 411.353(c)(1)). The period of disallowance is the period of time during which referrals are prohibited. Under the current rule, this period begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than upon the happening of one of three events. CMS acknowledges that the period of disallowance, which was initially created in an attempt to create a bright-line rule, is not always practical or clear cut. Rather, in order to establish when a financial relationship has ended, each relationship should be looked at on a case-by-case basis.

CMS also clarifies statements from the FY 2009 IPPS rule regarding whether parties can retroactively cure noncompliance. CMS acknowledges, and desires to encourage, that it is normal business practice to actively monitor and correct administrative and operational errors or discrepancies during the course of "live financial relationships." However, once a financial relationship has been ended, CMS notes that parties have lost the ability to retroactively correct or "cure" noncompliance.

4. Ownership or Investment Interests

While CMS' proposals focus largely on compensation arrangements between DHS entities and physicians, the agency puts forth for comment two changes to the types of ownership or investment interests outlined in 42 C.F.R. § 411.354(b).

First, CMS proposes to exclude titular ownership or investment interest from the reach of the self-referral prohibition, CMS defines "titular ownership or investment interest" to be "an interest that excludes the ability or right to receive the financial benefits of ownership or investment, including but not limited to the distribution of profits, dividends, proceeds of sale, or similar returns on investment." CMS states that because a physician with only titular ownership or investment interest does not have any rights to the financial benefits, there is not incentive to make referrals to the entity in which the physician has such ownership or investment interest.

Next, CMS proposes to exclude any interest in an entity which arises from participation in an employee stock ownership plan (ESOP). CMS notes that safeguards are already in place due to the requirements of ESOPs under the Employee Retirement Income Security Act of 1973.

Regarding the exception for ESOPs, CMS seeks comments on:

- Whether the safeguards imposed on ESOPs are sufficient protection to ensure that there is no risk of program or patient abuse; and
- Whether it is necessary to restrict the number or scope of entities owned by an ESOP that would be considered an ownership or investment interest of its physician employees.

5. Exceptions

CMS proposes revisions to the following existing exceptions:

- Rental of Office Space (42 C.F.R. § 411.357(a))
- Rental of Equipment (42 C.F.R. § 411.357(b))
- Physician Recruitment (42 C.F.R. § 411.357(e))
- Remuneration Unrelated to the Provision of Designated Health Services (42 C.F.R. § 411.357(g))
- Payments by a Physician (42 C.F.R. § 411.357(i))
- Fair Market Value Compensation (42 C.F.R. § 411.357(l))
- Assistance to Compensate a Nonphysician Practitioner (42 C.F.R. § 411.351(x))

We highlight below the key types of revisions that CMS proposes to these existing exceptions.

a. Writing Requirement

CMS proposes the creation of a "grace period" of 90 days in order to satisfy the writing requirement included in many exceptions under § 42 C.F.R. § 411.357, including the exceptions for the rental of office space, the rental of equipment, personal service arrangements, and fair market value compensation. Specifically, the writing requirement would be satisfied if: (1) the compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirements; and (2) the parties obtain the required writing or signatures within 90 consecutive calendar days of when the arrangement failed to satisfy the requirements of the applicable exception. The first requirement includes any requirement under an exception that compensation be set in advance. CMS notes that any formula for calculating the compensation under the arrangement should be documented in some way before the start of the arrangement. Such documentation can include informal communication, internal notes, fee schedules, or similar payments between the parties from prior arrangements.

CMS notes this rule would not be available for short term arrangements that are for 90 days or less. Such short term arrangements may be addressed by the proposed limited remuneration to a physician exception, discussed below.

b. Office Space and Equipment Leases

CMS seeks to clarify the "exclusive use" requirement for office space and equipment leases. CMS proposes adding language to clarify that the exclusive use requirement does not bar multiple lessees from using a rented space or equipment at the same time when the lessor is excluded from the premise. CMS also notes that for the purposes of the exception, the lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the space or equipment rented pursuant to the exception.

c. Fair Market Value Compensation

CMS proposes to expand the arrangements permitted under the fair market value compensation exception to protect arrangements for the rental or lease of office space. Historically, CMS has specifically disallowed reliance on the fair market value compensation exception for office space lease arrangements.

The fair market value compensation exception differs from the rental of office space exception in two key areas: (1) it does not require a one-year term and (2) it requires that arrangements do not involve counseling or promotion of a business arrangement or other activity that violates a federal or state law.

Regarding the lack of 1-year term requirement, CMS notes that the parties would only be allowed to enter into one arrangement for rental space during the course of a year, although the arrangement could be renewed "on the same terms and conditions any number of times."

CMS does note a continued concern about compensation which is determined using either a percentage-based compensation formula or per-click compensation formulas. CMS, therefore, proposes adding a prohibition on such formulas for determining rental charges for office spaces.

D. New Exception for Limited Remuneration to a Physician

CMS proposes a new exception that would allow for limited financial arrangements with physicians. CMS states that it had been made aware of multiple arrangements where limited remuneration was paid by an entity to a physician, such as arrangements where services were furnished sporadically or for a low compensation rate.

CMS proposes an exception where (1) the arrangement is for items or services actually provided by the physician; (2) the amount of the remuneration to the physician is limited; (3) the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements; (4) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (5) the remuneration does not exceed the fair market value for the item or services. Under the proposed exception, remuneration cannot exceed an aggregated amount of $3,500 per year. CMS clarifies that when an entity has multiple undocumented, unsigned compensation arrangements, the parties are considered to have only one compensation arrangement for all items and services under this exception.

CMS solicits comments on the following topics related to the proposed limited remuneration exception:

- Whether the $3,500 limit is appropriate;
- Whether it is necessary to limit the applicability of the exception to services that are personally performed by the physician and items provided by the physician; and
- Whether there should be a requirement that the arrangement not violate the AKS or other federal or state law.

* * *

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the authors of this Advisory.

**Alana Reid and Jessica Morris contributed to this Advisory.*

Ms. Reid is a graduate of the University of Virginia School of Law and is employed at Arnold & Porter's Washington, DC office. Ms. Reid is admitted only in Texas. She is not admitted to the practice of law in Washington, DC.

Ms. Morris is a graduate of American University Washington College of Law and is employed at Arnold & Porter's Washington D.C. office. Ms. Morris is admitted only in New York. She is not admitted to the practice of law in Washington, DC.