

## WHITE PAPER: UNDERSTANDING THE FINAL RULES TO REVISE THE ANTI-KICKBACK STATUTE AND BENEFICIARY INDUCEMENT CIVIL MONETARY PENALTY REGULATIONS

Authors: Alissa Smith, Laura B. Morgan, Ross C. D'Emanuele, Randall Hanson, Carson Lamb, Claire H. Topp and Charis Zimmick  
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On November 20, 2020, the Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) issued a sweeping set of final rules to amend the safe harbors under the Federal anti-kickback statute (“AKS”)<sup>1</sup> and to amend the civil monetary penalty law (“CMP”) by codifying a revision to the definition of “remuneration.”<sup>2</sup> These final rules were published in the *Federal Register* (available [here](#)) on December 2, 2020 (the “Final Regulations” or “Final Rules”). The Final Regulations are part of HHS’s “Regulatory Sprint to Coordinated Care” (the “Regulatory Sprint”), which is a large initiative to modernize many health care regulations. The 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](#).

<sup>1</sup> As used herein, the term “AKS” may refer to the Federal anti-kickback statute at 42 U.S.C. 1320a-7b(b) and/or the anti-kickback regulations at 42 C.F.R. 1001.952 *et seq.*

<sup>2</sup> As used herein, the term “CMP” refers to the Federal Beneficiary Inducements CMP at 42 U.S.C. 1320a-7a(a)(5) and 42 U.S.C. 1320a-7a(i)(6) and/or the CMP regulations at 42 C.F.R. 1003.110.

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The Final Regulations were issued just over a year from when OIG published its proposed rules to revise the AKS and CMP on October 17, 2019 (which we wrote about [here](#)). OIG received 337 [comments](#) from stakeholders on the proposed rules, which it addressed in the Final Regulations and corresponding preamble text. Between the time of the publication of the proposed and Final Regulations, the world experienced a global pandemic from a coronavirus disease caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), which is a virus known as COVID-19. As a result of the COVID-19 pandemic, the United States and state governments declared a public health emergency, and agencies such as the OIG issued guidance to assist health care providers during the pandemic. We mention the COVID-19 pandemic to provide context for this significant rulemaking and the influence that the global COVID-19 pandemic had on it, including delaying the issuance of the final rules, as well as the fact that OIG includes references to the COVID-19 pandemic throughout its preamble text. The Final Regulations state that their effective date is January 19, 2021.

The AKS provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs. The law also prohibits paying remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program. The AKS contains numerous safe harbors, the compliance with which, protects parties from violation of the AKS. However, because the AKS is an intent-based statute, an arrangement that falls outside of a safe harbor is not necessarily illegal, but instead, would be analyzed on a case-by-case basis to determine if one purpose of the arrangement was the prohibited conduct under the AKS.

The CMP was enacted in 1981 as a means to combat fraud and abuse in the Medicare and Medicaid programs. Under the CMP, the OIG can impose civil penalties and assessments against those who offer or transfer remuneration to a Medicare or Medicaid beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service that is reimbursed by the Medicare or Medicaid programs. There are a number of exceptions to the definition of remuneration under the CMP. Since the activities that implicate the AKS and CMP are similar, one of the exceptions to the CMP's definition of remuneration is any practice that is permissible under the AKS. Notably, there is no similar exception under the AKS for an arrangement that does not meet a safe harbor but does meet the definition of excepted remuneration under the CMP. However, in practice, the OIG analyzes arrangements that implicate both the AKS and the CMP in tandem, and if an arrangement meets an exception to the CMP, the OIG is likely to conclude that it does not violate the AKS.

OIG explains in the preamble that, since the AKS was enacted in 1972, there have been significant changes to the delivery of, and payment for, health care items and service, both within and outside of Federal health care programs. Health care delivery and payment has shifted from being primarily a volume-based, fee-for-service payment system, to a system that is focused on quality and value of care as well as improved care coordination across health care settings.

The OIG is undertaking this significant revision to the AKS and the CMP due to concerns that the AKS and CMP are having a "chilling effect on innovation and value-based care because arrangements in which providers and others coordinate the care of patients with other providers, share resources among themselves to facilitate better care coordination, share in the benefits of more efficient care delivery, and engage and support patients can implicate these statutes."

The OIG's changes in the Final Rule are intended to address these concerns by adding seven new safe harbors and modifications to four existing safe harbors under the AKS, as well as adding an exception to the definition of remuneration under the CMP. The OIG's final changes are intended to protect low-risk arrangements that further the agency's goals of access, quality, patient choice, appropriate utilization, and competition. At the same time, the Final Regulations maintain protection against the fraudulent and abusive practices that the AKS and CMP are intended to prevent because such practices could increase costs to Federal health care programs or compromise quality or patient choice. While a value-based payment system does not present the same fraud

and abuse risks that are present in a volume-based payment system (such as overutilization), a value-based payment system poses other potential risks (such as underutilization, cherry-picking or lemon-dropping) that OIG seeks to protect against in the Final Regulations.

According to the OIG, these Final Regulations are anticipated to: "(1) Remove barriers to robust participation in beneficial value-based health care delivery and payment systems, including those administered by CMS and non-Federal payors; (2) facilitate arrangements for beneficial patient care coordination among affiliated and unaffiliated health care providers, practitioners, suppliers, and others; (3) remove barriers to providing tools and supports to patients to better engage them in their care and improve health outcomes; (4) provide certainty for participants in the Medicare Shared Savings Program and Innovation Center models; (5) facilitate the continued adoption and use of electronic health records by making permanent the safe harbor for the donation of such items and services; and (6) promote more robust cybersecurity throughout the health care system."

The OIG's expected benefits from these anticipated outcomes are significant, including: "(1) Improved care coordination for patients, including Federal health care program beneficiaries; (2) improved quality of care and outcomes for patients, including Federal health care program beneficiaries; (3) potential reduction in compliance costs to individuals and entities to which the Federal anti-kickback statute's and Beneficiary Inducements CMP's prohibitions apply; (4) reduction in administrative complexity and related waste from continued progress toward interoperability of data and electronic health records; (5) protection against the corruption of or access to health records and other information essential to the safe and effective delivery of health care; and (6) reduction in impacts of cybersecurity attacks, including the improper disclosure of protected health information (PHI), and reduction in costs associated with cybersecurity attacks, including ransom payments, costs to patients whose PHI is improperly disclosed, and costs to providers, suppliers, and others to reestablish cybersecurity."

The OIG provided some illustrations of the types of arrangements that may now be protected under the new safe harbors, which were not previously protected, such as:

- "A hospital—in recognition that new reimbursement models may extend hospital accountability for a patient's health beyond inpatient or outpatient care—may wish to provide recently discharged patients with free health coaching, technology that facilitates remote monitoring, a non-reimbursable home visit, or nutritional supplements to promote the best health outcomes after discharge.
- A hospital, recognizing that clinical collaboration and care coordination may improve patient transitions from one care delivery point to the next, may wish to provide care coordinators that furnish individually tailored case management services for patients requiring post-acute care.
- A medical device manufacturer may wish to offer a physician practice or hospital a data analysis service to track clinical practices, clinical outcomes, and patient impact as they relate to hospital- or health-care-acquired pressure injuries.
- A hospital may wish to provide support and to reward institutional post-acute providers for achieving outcome measures that effectively and efficiently coordinate care across care settings and reduce hospital readmissions. Such measures would be aligned with a patient's successful recovery and return to living in the community.
- A physician may wish to offer—for free—a prescription pickup service to retrieve filled prescriptions from the pharmacy and get them to the patient to expedite the patient's adherence to the physician's ordered treatment.
- A primary care physician, dialysis facility, or other provider could furnish a smart tablet that is capable of two-way, real-time interactive communication between the patient and his or her physician. In turn, the Federal health care program beneficiary's access to a smart tablet could facilitate communication through telehealth and the provision of in-home dialysis services."

The majority of the changes made in the Final Regulations will likely be welcomed by the regulated industry because they provide new opportunities for safe harbor protection which reduces uncertainty. However, the Final Regulations also introduce new complications in needing to understand a fresh overlay of agency interpretations

and new and revised regulations. Further, it will take time for stakeholders to consider whether and how to enter into and structure new value-based arrangements, or restructure existing value-based arrangements, in reliance on the new value-based safe harbors.

This white paper summarizes each of OIG's final rules, in eleven sections numbered as follows (which follows the order from the Final Regulations):

- I. Value-Based Terminology
- II. Three New Safe Harbors for Value-Based Arrangements
  1. New Safe Harbor for Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency
  2. New Safe Harbor for Value-Based Arrangements with Substantial Downside Financial Risk
  3. New Safe Harbor for Value-Based Arrangements with Full Financial Risk
- III. New Safe Harbor for Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency
- IV. New Safe Harbor for CMS-sponsored Model Arrangements and CMS-sponsored Model Patient Incentives
- V. New Safe Harbor for Donation of Cybersecurity Technology and Related Services
- VI. Changes to the Safe Harbor for Donation of Electronic Health Records Items and Services
- VII. Changes to the Personal Services and Management Contracts Safe Harbor, Including Protection for Outcomes-Based Payment Arrangements
  1. Flexibilities Added to the Existing Safe Harbor
  2. New Provision for Outcomes-Based Payments
- VIII. Changes to the Warranties Safe Harbor
- IX. Changes to the Local Transportation Safe Harbor
- X. Regulatory Codification of a Statutory Exception under the MSSP. The ACO Beneficiary Incentive Program Safe Harbor
- XI. New Exception to the CMP for Telehealth Technologies Donated to Existing ESRD Patients for In-Home Dialysis

As with the OIG proposed regulations in October 2019, the Final Regulations were published contemporaneously with final regulations from the HHS Centers for Medicare and Medicaid Services ("CMS") that make numerous significant changes to the regulations under the federal physician self-referral law ("Stark Law or "Stark").<sup>3</sup> Our white paper summarizing the final changes to the Stark Law is posted [here](#). As we noted in that summary, although the Stark Law is a civil, strict liability payment law with regulatory provisions that are promulgated by CMS, and the AKS is an intent-based, criminal law with regulatory provisions that are promulgated by OIG, the agencies worked together in the process of developing these sweeping regulatory changes—particularly with respect to the new value-based exceptions/safe harbors and related definitions (as noted in Sections I and II, below). Both agencies recognize the need to modernize and clarify the Stark Law and AKS, which are often analyzed in tandem because financial arrangements may implicate both laws.

The following is a summary of OIG's Final Regulations:

## **I. Value-Based Terminology**

The OIG has finalized 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 new safe harbors for value-based arrangements, it is critical to carefully review the new defined terms that form the basis for safe harbor protection, certain of which are described below.

<sup>3</sup> As used herein, the term "Stark Law" or "Stark" may refer to the Stark statute at Section 1877 of the Social Security Act and/or the Stark regulations at 42 C.F.R. § 411.350 *et seq.*

There are three safe harbors specific to value-based arrangements that are similar in many respects to the new exceptions for value-based arrangements under the Final Stark Rules. Each of these safe harbors utilize a common, core set of definitions, which are similar to definitions used by CMS in the Final Stark Rules. The Final OIG Rules also contain a new safe harbor for arrangements for patient engagement and support, which uses much of the value-based terminology for the value-based safe harbors described below.

First, each of the value-based safe harbors requires activity that is reasonably designed to achieve at least one value-based purpose. There are four **value-based purposes**: (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 costs to or growth in expenditures of payors 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. Note that this definition does not include merely controlling health care costs; if no other value-based purposes is involved, then controlling costs must be paired with the maintenance of care quality. The OIG addressed comments opposed to the idea that the cost reduction must reduce costs only **for payors**, and pointed out that while this definition requires addressing cost reduction or slower growth in expenditures of payors, the definition of value-based purpose that OIG is finalizing does not foreclose internal cost-savings arrangements for **providers (such as gainsharing)**. However, parties to such internal cost-savings arrangements must consider whether such arrangements would further at least one other part of the value-based purpose definition and specified safe harbor conditions in order to receive safe harbor protection.

The three value-based safe harbors protect the exchange of certain payments or value between a **value-based enterprise** and its **value-based enterprise participants** pursuant to a **value-based arrangement** reasonably designed to achieve at least one of these value-based purposes.

This means that in order to use any of the three value-based safe harbors, participants must maintain a **value-based enterprise**, or "**VBE**". A value-based enterprise is two or more of a wide range of potential individual or entity **value-based enterprise participants**, or "**VBE participants**," collaborating to achieve at least one value-based purpose. Value-based enterprise participants can include clinicians, hospitals, suppliers, payors, post-acute providers, disease management companies, and social service organizations. The value-based safe harbors are not intended to apply to equipment or other value provided to a patient. Accordingly, patients (including family members and those acting on behalf of patients) are not considered value-based enterprise participants.

The value-based enterprise must have a person or other governing body responsible for the financial and operational oversight of the enterprise. The value-based enterprise need not be a separate legal entity. A value-based participant could act as the responsible person or entity. In addition, the value-based enterprise must have a governing document that describes the enterprise and how the participants intend to achieve their value-based purposes. The governing document could 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.

A value-based arrangement is simply an arrangement to provide at least one value-based activity for a target patient population, where the only parties are the value-based enterprise and its value-based enterprise participants, or value-based enterprise participants in the same value-based enterprise. A value-based activity means the provision of an item or service, or the taking, or refraining from taking, an action that is reasonably designed to achieve at least one value-based purpose.

Embedded throughout these definitions and the value-based safe harbors is the concept of a **target patient population**. A target patient population is an identified patient population selected by the value-based enterprise or its participants that is set out in writing in advance of the commencement of the value-based arrangement and that furthers the value-based enterprise's value-based purposes. The participants must use legitimate and verifiable criteria to choose their target patient population. While the selection criteria need to be identified in advance, the individual patients do not need to be identified in advance.

The following types of entities are ineligible to rely on any of value-based safe harbors (with a few exceptions described below):

- (i) pharmaceutical manufacturers, distributors, and wholesalers;
- (ii) PBMs;
- (iii) Laboratory companies;
- (iv) Pharmacies that primarily compound drugs or primarily dispense compounded drugs;
- (v) Medical device or supply manufacturers;
- (vi) Medical device distributors or wholesalers that are not otherwise a manufacturer of a device/supply; and
- (vii) Suppliers of durable medical equipment, prosthetics, orthotics, or supplies ("DMEPOS") (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

These entities may participate in a value-based enterprise, but any value these entities provide to other participants will not receive safe harbor protection. The OIG specifies that, where a single corporate entity operates multiple business lines, eligibility for the value-based safe harbors (*i.e.*, whether the entity is the type of entity listed above that is not eligible for the safe harbors) turns on the entity's predominant or core business. Large corporations with multiple business lines within a single corporate entity need to assess whether they have a predominant or core business; the OIG did not prescribe a specific standard or test for conducting such an assessment.

The final rules align the OIG and CMS definitions related to value-based arrangements in nearly all respects. Although differences in the nature and scope of the Stark and Anti-kickback laws necessitate some differences between CMS' value-based Stark exceptions and OIG's value-based anti-kickback safe harbors, the definitions creating the compliance framework for organizations to meet the exceptions and safe harbors are nearly identical.

## **II. Three New Safe Harbors for Value-Based Arrangements**

The below sets forth key requirements to qualify for protection under the three new safe harbors for value-based arrangements. In addition to the requirements noted below, each of these safe harbors, as well as the safe harbor for patient engagement tools/supports (which uses value-based terminology), has a requirement to maintain records relating to the arrangement sufficient to establish compliance with the conditions of the safe harbor for a period of six years.

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

The first value-based safe harbor applies to participants who collaborate to coordinate and manage care for a target patient population, without assuming financial risk. The safe harbor has a variety of conditions, which can be categorized as sets of financial conditions, process conditions, and fraud protection conditions.

The first financial condition of the safe harbor is that it solely protects in-kind remuneration exchanged between a VBE and the participants, or among the VBE participants. Unlike the two other value-based safe harbors that involve the participants' assumption of financial risk, the care coordination safe harbor does not protect any exchange of monetary value. All of the in-kind remuneration must be used predominantly to engage in value-based activities directly connected to coordination and management of care for the target patient population, and must not result in more than incidental benefit to persons outside of the target patient population. The remuneration must not be exchanged or used more than incidentally for the recipient's billing or financial management services or for marketing items or services to patients or for patient recruitment.

The recipient of the in-kind remuneration must contribute at least 15% of either the offeror's cost of the remuneration (using any reasonable accounting methodology), or the fair market value of the in-kind remuneration. This 15% contribution must be paid in advance of the contribution if the remuneration is a one-time cost, or at reasonable, regular intervals if the remuneration is ongoing. This percentage contribution highlights the principal benefit of the care coordination safe harbor: participants are permitted to exchange

equipment, software, personnel, services, or other in-kind value without the recipient paying full fair market value, yet still receive safe harbor protection against anti-kickback claims so long as all conditions of the safe harbor are met.

The last financial condition is that 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.

A key process condition is that the participants set out one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health sciences support. These measures must include one or more benchmarks related to improving or maintaining improvements in the coordination and management of care for the target patient population, and must be monitored, assessed, and revised as necessary to ensure that the measures and benchmarks continue to advance the coordination and management of the target patient population. The measures must relate to the in-kind remuneration exchanges, and must not be patient satisfaction or patient convenience measures.

Beyond setting these measures, at least annually the value-based enterprise must monitor and assess the coordination and management of care for the target patient population, any deficiencies in the delivery of quality care, and progress toward achieving the legitimate outcome or process measure(s). If this monitoring and assessment finds that the arrangement has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the target patient population, then within 60 days the parties must either terminate the arrangement or develop and implement a corrective action plan designed to remedy the deficiencies within 120 days.

The value-based arrangement must be set out in writing (which can be a collection of documents) and signed, at or prior to the beginning of the arrangement or any material change in the arrangement. The contract must state: (1) the value-based purposes of the activities to be undertaken; (2) term; (3) the target patient population; (4) a description of the remuneration; (5) the offeror's cost, or fair market value, of the remuneration or the fair market value; (6) the percentage of that cost to be contributed by the recipient(s) and (if ongoing) the schedule of contribution payments; and (7) the outcome or process measure(s) against which the recipient will be assessed.

The fraud protection conditions of the care coordination safe harbor include that the arrangement must be commercially reasonable, and not take into account the volume or value of, or condition the remuneration on, referrals of patients that are not part of the target patient population or any business not covered under the value-based arrangement. The value based arrangement 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) induce the furnishing of medically unnecessary items or services, or reduce or limit medically necessary items or services to any patient.

Lastly, contrary to the general ineligibility rule for medical device/supply manufacturers and DMEPOS suppliers (described above), these entities are generally eligible for protection under the care coordination safe harbor, but only for the exchange of **digital health technology** with the value-based enterprise or its participants. Digital health technology means hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care. However, manufacturers of medical devices/supplies that have physician ownership (as reported under the CMS Open Payments program) are **not** eligible for safe harbor protection for providing digital health technology to value-based enterprises and their participants.

The corresponding Stark exception protecting value-based arrangements that focuses on care coordination is found at 42 C.F.R. § 411.357(aa)(3), and it includes some variations from the AKS safe harbor described above. Two key differences are that the care coordination Stark exception is not limited to in-kind remuneration and does not require a contribution amount from the recipient.

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

For a value-based arrangement to be protected under this safe harbor, a VBE must assume **substantial downside financial risk** from a payor, and a VBE participant must assume a meaningful share of the VBE's substantial downside risk. The safe harbor, as finalized, protects both monetary and in-kind remuneration exchanged pursuant to value-based arrangements between VBEs and VBE participants if the safe harbor conditions are met.

The final safe harbor does not offer protection for arrangements downstream of a VBE participant, such as arrangements among VBE participants.

The final safe harbor may be used by participants in CMS-sponsored models, if safe harbor conditions are met, but it is primarily intended for other kinds of value-based arrangements, including arrangements in the commercial market.

Two of the key financial-related conditions of this safe harbor are the definition of substantial downside financial risk and meaningful share.

**Substantial Downside Financial Risk** To use this safe harbor, the VBE must have assumed (or have entered into a contract to assume within the next 6 months), substantial downside financial risk from a payor for a period of at least a year. There are 3 ways a VBE can assume substantial downside financial risk from a payor.

The first methodology under which a VBE can assume substantial downside financial risk from a payor is where the VBE and the payor compare: (1) a baseline of current expenditures for all items and services covered by the payor and furnished to the target patient population, with (2) a *bona fide* benchmark that approximates the expected total cost of such care. The VBE must assume financial risk for at least 30% of any loss.

The second methodology is similar to the first but focused on a narrower clinical episode of care rather than total cost of care. This methodology requires comparing: (1) current expenditures for all items and services covered by the payor and furnished to the target patient population for a defined clinical episode of care; with (2) a *bona fide* benchmark approximating the expected total cost of care for the defined clinical episode. The VBE must assume financial risk for at least 20% of any loss.

The last substantial downside financial risk methodology is a partial capitation methodology pursuant to which the VBE receives from the payor a prospective, per-patient payment that is (1) designed to produce material savings; and (2) paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the patient target population.

**Meaningful Share** To receive safe harbor protection for value paid from the VBE to a VBE participant, the participant must be at risk for a meaningful share of the VBE's substantial downside financial risk. There are two ways a participant can take a meaningful share of this risk. First, the VBE participant can assume two-sided risk of at least 5% of the substantial downside risk that the VBE accepts.

Alternatively, the VBE participant can receive from the VBE prospective, per patient payments for a predefined set of items and services furnished to the target patient population that are designed to approximate the expected total cost for the predefined set of items and services, so long as the participant does not claim payment in any form from the payor for the predefined items and services.

The other financial conditions of the safe harbor include a requirement that the remuneration paid to the VBE participants be directly connected to one or more of the VBE's value-based purposes (excluding the value-based purpose of transitioning from volume-based to value-based care). If the parties wish to use the per patient methodology for substantial downside financial risk, then the remuneration must be used predominantly to engage in value-based activities directly connected to the items and services for which the VBE assumes substantial downside financial risk. The remuneration may not include the offer or receipt of any ownership

interest in an entity or any ownership distributions. Lastly, the remuneration may not be used for marketing or patient recruitment.

There are 3 other fraud protection conditions of this safe harbor. First, the VBE may not condition payment on, or take into account the volume or value of, patient referrals who are not part of the target patient population, or business not covered under the value-based arrangement.

The value-based arrangement must not induce parties to reduce or limit medically necessary items or services. The value-based arrangement must not limit a participant's ability to make decisions in the best interests of patients. Lastly, the value-based arrangement must not direct or restrict referrals to a particular provider, practitioner or supplier if: (1) a patient expresses a different preference; (2) the payor determines the provider, practitioner, or supplier; or (3) the referral restriction is contrary to applicable Medicare or Medicaid law.

For process requirements, the safe harbor requires that the value-based arrangement be in a writing (which can be a **collection of documents**) signed by the parties in advance of or contemporaneous with the commencement of the value based arrangement and any material change. The contract or other writing must include all material terms, including the substantial downside financial risk of the VBE, the way that participant(s) are assuming a meaningful share of the VBE's substantial downside financial risk, and the value-based activities, the target patient population, and the type of remuneration exchanged.

Finally, the safe harbor does not apply to remuneration exchanged by (i) pharmaceutical manufacturers, wholesalers, and distributors; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers, distributors, or wholesalers of devices or medical supplies; or (vi) entities or individuals that manufacture, sell, or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible).

The corresponding Stark exception protecting value-based arrangements that take on meaningful downside financial risk is found at 42 C.F.R. § 411.357(aa)(2), and it includes some differences from the AKS safe harbor described above, including differences in what meaningful risk means, and how the remuneration must connect to the value-based purposes of the VBE.

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

A third value-based safe harbor applies to remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement when a VBE has assumed (or enters into a written contract to assume in the next year) full financial risk from a payor. A VBE is at full financial risk if the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least a year. "Prospective basis" means the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to providing the items and services to the target patient population.

The other financial conditions to the full financial risk safe harbor are similar to the substantial downside financial risk safe harbor. The remuneration paid to the VBE participants must be directly connected to one or more of the VBE's value-based purposes. The VBE participant must not claim payment in any form from the payor for items or services covered under the contract between the payor and the VBE. The remuneration may not include the offer or receipt of any ownership interest in an entity or any ownership distributions. Lastly, the remuneration may not be used for marketing or patient recruitment.

Also similar to the substantial downside financial risk safe harbor, the full financial risk safe harbor prohibits the value-based arrangement from inducing the VBE or the VBE participants to reduce or otherwise limit medically necessary items or services. However, this safe harbor adds a requirement that the VBE provide a quality assurance program to protect against underutilization and assess the quality of care to the target patient population.

The VBE or VBE participant offering the remuneration must not take into account the volume or value or condition the remuneration on, referrals of patients outside the target patient population or business not covered under the value based arrangement.

For process requirements, the value-based arrangement must be set forth in a signed writing (which can be a **collection of documents**) that specifies all material terms, including the value-based activities and the target patient population.

The full financial risk safe harbor excludes protection for remuneration exchanged by the following entities: (i) pharmaceutical manufacturers, wholesalers, and distributors; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers, distributors, or suppliers of devices or medical supplies; or (vi) entities or individuals that manufacture, sell, or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible).

The corresponding Stark exception protecting value-based arrangements that take on full financial risk is found at 42 C.F.R. § 411.357(aa)(1), and is similar to the AKS safe harbor described above.

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

Utilizing the same value-based terminology and concepts, the OIG finalized a new safe harbor which protects remuneration provided to patients in the form of patient engagement tools/supports meeting specified conditions. The new safe harbor sets forth conditions with respect to who may provide the tools/supports, who may receive the tools/supports, and the nature of the tools/supports that can be provided.

First, the tool/support must be provided by a VBE participant or by the eligible agent of the VBE participant, but, for both the VBE participant and the eligible agent, this safe harbor contains the same general ineligibility rules for specified entities that the value-based safe harbors (described above) contain. However, contrary to the general ineligibility rule for medical device/supply manufacturers, such entities are eligible to use the patient engagement tool/support safe harbor if the patient engagement tool or support provided by the manufacturer is "digital health technology" (as defined above). Manufacturers that have physician ownership (as reported under the CMS Open Payments program), however, are not eligible for this safe harbor even if the tool/support is digital health technology. In addition, the tool/support cannot be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or by an entity that is not eligible to furnish the tool/support per the criteria above.

Second, the tool/support must be provided to a patient in the target patient population of a value-based arrangement to which the eligible VBE participant is a party, and it must be furnished directly to the patient or the patient's caregiver, family member or other individual acting on the patient's behalf. The availability of a tool/support cannot be determined in a manner that takes into account the type of insurance coverage of the patient. The OIG explained in preamble text that this requirement is meant to ensure that actual needs are used to determine the appropriate target patient population, instead of the potential value of items provided to such patients that may be reimbursable by Federal health care programs in the future. If the tools/supports are offered to a population that happens to be disproportionately comprised of Medicare or Medicaid beneficiaries, as long as the decision to offer tools/supports is not based on the patient's insurance status, this would not run afoul of this requirement.

Third, there are a number of conditions with respect to the nature of the tools/supports that can be provided, including:

- The aggregate retail value of the tools/supports furnished by to the patient cannot exceed \$500 on an annual basis (as adjusted annually for inflation). The OIG explained in preamble text that the cap applies per VBE participant and per patient, not at the VBE level or value-based arrangement level, which means a patient may receive tools/supports from multiple VBE participants (in one or more

VBEs) in a given year, provided no single VBE participant furnishes the patient with more than \$500 in aggregate retail value.

- The tool/support needs to be an “in-kind” item, good or service with a direct connection to coordination and management of care a defined term of the target patient population, and cannot be cash or cash equivalent. The OIG explained in preamble text that, provided all safe harbor requirements are met, tools and supports could include, among others, “health-related technology, patient health-related monitoring tools and services, and supports and services designed to address a patient’s social determinants of health.” The OIG did not list any examples in regulatory text (as it had done in the proposed rule) to ensure that “the final rule does not inappropriately limit the type or range of in-kind tools and supports that could be protected by this safe harbor,” but rather “will allow the licensed health care professional to determine the specific type of tool or support that works best for the patient, as long as all conditions of the safe harbor are met.”
  - o 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 or a **limited-use** gift card for a particular tool/support (such as a voucher for a meal or a taxi or a gift card that can be redeemed only for fuel or a healthy meal delivery service) to satisfy the “in-kind” requirement. Debit cards, rebate checks, and most gift cards (such as those offered by large retailers or online vendors) are considered cash equivalents and would not be protected under the safe harbor.
  - o The OIG pointed out that to the extent the tool/support is an item or service that is covered under a Federal health care program (and appropriately billed), then there is not a transfer of remuneration to a beneficiary and the arrangement would not implicate the AKS, so it would not require safe harbor protection. But the AKS would be implicated by waiving or reducing cost-sharing obligations for the covered item or service or providing extra items or services (that are not part of the covered item/service) for free. Further, the OIG does not intend for this safe harbor to protect waivers or reductions of patient cost-sharing obligations, and discounts would need to comply with the separate safe harbor for discounts in order to receive safe harbor protection.
- Importantly, the tool/support needs to be recommended by the patient’s licensed health care professional and needs to advance one or more of the following goals: adherence to a treatment regimen, drug regimen or follow-up care plan determined or established by the patient’s licensed health care professional; prevention or management of a disease or condition as directed by the patient’s licensed health care professional; and ensure patient safety.
- The tool/support cannot result in medically unnecessary or inappropriate items or services reimbursable by a Federal health care program and neither the VBE participant, nor the eligible agent of the VBE participant, may use the tool/support to market other items or services reimbursable by Federal health care programs or for patient recruitment purposes. The OIG explained that this condition does not necessarily preclude the provision of objective education and reminders to patients or otherwise providing information about available tools/supports to established patients, or notification to an entire target patient population about available tools/supports (provided the notification is not accompanied by prohibited marketing or patient recruitment).

The OIG did not finalize a number of requirements it had proposed as part of this safe harbor. For example, the OIG did not finalize a requirement to retrieve the tool/support in certain circumstances, but the OIG pointed out that VBE participants should cease providing tools/supports they find to be ineffective given the requirement to advance one or more of the listed goals, and ongoing services (such as recurring monthly fitness center fees) should be terminated if the individual is no longer part of the patient population or the entity is no longer a VBE participant since those are requirements of the safe harbor.

#### **IV. New Safe Harbor for CMS-sponsored Model Arrangements and CMS-sponsored Model Patient Incentives (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 created 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 Medicare Shared Savings Program; 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 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. Although the promulgation of this safe harbor does not preclude OIG from issuing model-specific waivers in the future, CMS noted that it expected OIG's issuance of model specific waivers in the future to be infrequent.

The final rule is largely the same as the proposed rule except for some reformatting of the safe harbor to move some language in the definitions to the body of the safe harbor and the addition of a new paragraph to address the time frames for when safe harbor protection begins and ends. In addition, the safe harbor now has several provisions which expand the application of the safe harbor to that which CMS has specified in the participation documentation. Specifically, the safe harbor now protects (i) financial arrangements and incentives set forth by CMS in the participation documentation, (ii) arrangements where CMS has articulated a different standard in the participation documentation to the requirement in the safe harbor that the patient incentive have a direct connection to the patient's health care, and (iii) arrangements where an individual other than the CMS sponsored model participant or its agent furnish an incentive to a patient under a CMS-sponsored model as set forth in the participation documentation.

OIG noted 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.

CMS did not propose a parallel Stark exception to the AKS safe harbor for CMS-sponsored model arrangements because the 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.

#### **V. New Safe Harbor for Donation of Cybersecurity Technology and Related Services (42 C.F.R. § 1001.952(jj))**

The OIG finalized, with some slight modifications and clarifications, the previously proposed creation of a safe harbor to protect donations of certain cybersecurity technology and related services. Most modifications to the proposed rule are limited to regulatory organization changes as opposed to changes in the scope of the safe harbor. As stated in the preamble to the Final Regulations, "[t]his safe harbor will protect arrangements intended to address the growing threat of cyberattacks impacting the health care ecosystem. In addition to software and other types of information technology, the final safe harbor will protect certain cybersecurity hardware donations that meet conditions in the safe harbor." The final safe harbor is intended to protect from regulatory scrutiny health care organizations that assist providers and suppliers in the acquisition of cybersecurity technology either through donation or subsidy.

Overall, only a small number of commentators expressed concern about the proposed safe harbor, stating that such a safe harbor may be abused or could be used to further anticompetitive behavior. The OIG responded by stating their belief that "the safeguards appropriately balances the risks against the potential benefits of properly structured donations to help address the critical cybersecurity needs of the health care industry."

As finalized with some slight regulatory organizational modifications, 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, maintain, or reestablish 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 (this does not have to be a single document, as clarified in the Final Regulations), and there may not be cost shifting to any Federal health care program.

Notably, the OIG is not finalizing its proposed requirement that parties be required to conduct a risk assessment prior to donating cybersecurity-related hardware. Cybersecurity-related hardware, under the final rule, may be donated as long as the donation satisfies the other conditions of the safe harbor, in particular, that the donation be necessary and used predominately for effective cybersecurity. The Final Regulations note that "[i]n most cases, multifunctional hardware would not be used predominantly for effective cybersecurity and thus would fall outside the scope of protection of this safe harbor."

The corresponding new Stark exception protecting the donation of cybersecurity technology and related services is found at 42 C.F.R. § 411.357(bb), and is generally aligned with the AKS safe harbor.

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

The OIG finalized, with some slight modifications and clarifications, the previously proposed modifications to 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.

Proposed revisions to the deeming provision have been finalized. "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 finalized modification of 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 proposed revisions to the "information blocking" condition have not been finalized; instead, this condition has been removed from the safe harbor. The specific condition being removed prohibited the donor or any person on the donor's behalf from taking any action to limit or restrict the use, compatibility, or interoperability of the donated EHR items or services. The OIG initially proposed changes that would better align this condition with the 21st Century Cures Act by, for example, updating definitions for consistency. While commenters were supportive of updating the safe harbor, they also raised questions and concerns regarding how such a provision would work in a safe harbor, particularly when such revisions would rely on other regulations that have not yet been finalized. The OIG concluded that there are now other enforcement authorities that are better suited than a safe harbor condition to deter information blocking and penalize individuals and entities that engage in information blocking.

The OIG also finalized language to clarify that certain cybersecurity software and services are protected under this safe harbor. Furthermore, the proposal to eliminate the sunset provision created in 2013, which states that this safe harbor would have sunset in 2021, is finalized. The OIG also decided to retain the fifteen percent (15%) recipient contribution requirement but removed the requirement that payment of such contribution be made in advance for updates to existing EHR systems. Lastly, the OIG finalized its proposals to allow replacement technology and expand the scope of donors protected by this safe harbor.

The corresponding Stark exception for EHR items and services is found at 42 C.F.R. § 411.357(w). CMS finalized similar changes to the Stark exception for EHR items and services as those described above for the AKS safe harbor for EHR items and services.

## **VII. Changes 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 made two sets of revisions to the existing safe harbor for personal services and management contracts, which add: (1) flexibilities to the existing safe harbor language; and (2) a new provision to protect remuneration for “outcomes-based payments” that meet specified parameters.

### **1. Flexibilities Added to the Existing Safe Harbor.**

First, the OIG removed the requirement that, in order to qualify for the personal services and management contracts safe harbor, *aggregate* compensation must be set in advance. Instead, now only the *methodology for determining* the compensation paid over the term of the agreement must be set in advance. This change removes a key hurdle for many existing arrangements, such as those that contain an hourly rate of compensation, 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 stated in preamble text that the intention of this change is to provide enhanced flexibility to undertake innovative arrangements, while still mitigating the risk of adjusting compensation to reward referrals or unnecessary utilization. The OIG also removed 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.

Commenters on the proposed rule asked the OIG to define certain of the terminology under this safe harbor—including “does not take into account the volume or value of referrals,” “fair market value,” and “commercially reasonable”—in harmony with how CMS had proposed to define such terms under the proposed Stark rule. The OIG declined to do so, stating: “These terms have long existed throughout our existing safe harbors at section 1001.952 without further definition or interpretation by OIG and are well-established.” Furthermore, the OIG declined to make any changes to the requirement of this safe harbor that an agency agreement be set out in writing, but noted in preamble text that the “written agreement requirement can be met either through a single, formal, signed agreement or through a collection of documents if such collection of documents includes all of the required elements of the safe harbor and is signed by the parties (*e.g.*, by signing each document that makes up the agreement, or by signing a single signed document that incorporates separate documents by reference).” This guidance on the writing requirement aligns in many respects with CMS guidance and regulations on meeting the signed writing requirement under applicable Stark exceptions, such as the personal service arrangements exception.

### **2. New Provision for Outcomes-Based Payments.**

Second, the OIG added a new provision to protect remuneration for “outcomes-based payments” that meet specified parameters. To receive a protected outcomes-based payment, an agent must achieve one or more legitimate outcome measures that: (1) are selected based on clinical evidence or credible medical support; and (2) have benchmarks used to quantify either or both of the following: (a) improvements in, or maintenance of improvements in, the quality of patient care; and/or (b) a material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients. The outcomes-based payment must either *reward the agent for successfully achieving, or recoup from or reduce payment to an agent for failure to achieve*, one of the forgoing outcome measures. This means that both shared gains and shared losses (meeting specified conditions) between or among a principal and an agent are protected.

The OIG explained in preamble text that measures that simply seek to reward the status quo would not meet these standards. The OIG also explained that product standardization (*e.g.*, requiring exclusive or minimum level of use of a particular product) is not necessarily precluded by this safe harbor, as long as the measures for product standardization selected by the parties do not limit the ability to make decisions in the patients' best interest and meet other requirements of the safe harbor. Further, while this safe harbor addresses *outcome*

measures as opposed to **outcome or process** measures (as used in the safe harbor for care coordination arrangements), the OIG acknowledged that process measures (*e.g.*, providing or not providing a specific treatment) may serve as a **component** of outcome measures that an agent must achieve to receive an outcomes-based payment, as long as they are supported by strong evidence of improving an outcome. As an example, the OIG states that an outcomes-based payment arrangement could measure the agent's compliance with certain steps of a care process (*e.g.*, providing mammograms) to improve a specific health outcome.

There are a number of restrictions to the types of outcomes-based payments that are protected under this safe harbor. Namely, the payments cannot be based solely on patient satisfaction or convenience measures. In addition, the payments **cannot relate solely to the achievement of internal cost savings for the principal**, as opposed to a payor. This means that, for example, a gainsharing arrangement between a hospital and a physician that only results in internal cost savings for the hospital would not be eligible for protection under this safe harbor. According to the preamble text, numerous commenters urged the OIG to broaden its proposal to also protect cost savings to providers, since limiting it in this way makes the safe harbor "unworkable in practice." The OIG declined to do so, stating: "We are concerned that such payments, while potentially beneficial in generating efficiencies, pose risks to patient care that outweigh the potential for the arrangements to further the care coordination and efficiency goals of this rulemaking if protected." The OIG did recognize, however, that properly structured arrangements that pay physicians for services and achieve only internal hospital cost savings can serve a legitimate purpose, and depending on the facts and circumstances, could be structured to comply with the safe harbor for personal services and management contracts (as modified per the description above).

Further, protected outcomes-based payments do not include any payments made by the same types of entities that are ineligible to rely on the value-based safe harbors, as described above (pharmaceutical and device manufacturers, PBMs, laboratory companies, certain DMEPOS suppliers, and others). However, unlike the value-based safe harbors and patient engagement tools/supports safe harbor, the payments do **not** have to be made by or between a VBE and/or VBE participant(s). The OIG explained in preamble text that it is taking "a broader approach by providing additional protection to a variety of stakeholders, which should facilitate innovation in designing compensation arrangements that are value-based."

Next, there are a number of requirements with respect to permitted compensation methodologies under this safe harbor. Specifically, the compensation methodology must be: (1) set in advance; (2) commercially reasonable; (3) consistent with fair market value; and (4) 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. Parties could pay compensation that **indirectly** takes into account the volume or value of referrals or business otherwise generated. With respect to the fair market value standard, the OIG recognized that the process for evaluating fair market value for outcomes-based payments may evolve over time as the health care industry shifts to value-based care payment models. The OIG declined to adopt the fair market value standard that was proposed by CMS in the proposed Stark rule.

Under this safe harbor, there must be a signed writing between the parties that must state at least the following: (1) a **general** description of the services to be performed; (2) the outcome measure(s) the agent must achieve; (3) the clinical evidence or credible medical support relied upon in selecting the outcome measure(s); and (4) the schedule for the parties to regularly monitor and assess the outcome measure(s) (as described below). Further, the term of the agreement must be not less than one year. Neither party can be limited in making decisions in their patients' best interests nor induced to reduce or limit medically necessary items or services, and the services performed under the agreement cannot involve counseling or promotion of an activity that violates any state or federal law.

Finally, for each of the outcome measures, the parties need to regularly monitor and assess the agent's performance, including the impact of the arrangement on patient quality of care, and periodically assess the benchmarks and payments under the arrangement to ensure that the payments are consistent with fair market

value. If the parties determine through this periodic assessment that continued use of a benchmark or measure, or remuneration related thereto, may not be appropriate for achieving the outcome measure, the parties need to make adjustments in order to make sure all conditions of the safe harbor (including the fair market value condition) continue to be met. In addition to these monitoring and assessing requirements as between the parties, the principal must have policies and procedures in place regarding promptly addressing and correcting any material performance failures or material deficiencies in quality of care that result from the arrangement.

In the preamble, the OIG gave as an example parties having an outcome measure related to reducing fall rates in a skilled nursing facility to a certain level from a starting benchmark point. If the parties successfully achieve that outcome measure, a revised outcome measure could be to maintain that low fall rate. Any payments made for both the original and revised outcome measures need to meet all requirements of the safe harbor, including that compensation is consistent with fair market value. The fair market value of an outcomes-based payment to maintain the desired low fall rate level may be lower than the payments for achieving it under the original outcome measure. The periodic assessment of the benchmarks and measures is required in order to monitor whether these types of changes are needed.

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

The Final Rule expands the safe harbor for warranties to include warranty arrangements for bundled items and services. Prior to the revisions, the safe harbor only protected single-item warranties and thus was not available to manufacturers and suppliers who typically bundle their product and service sales. The warranties safe harbor will now protect warranty arrangements for one or more items and related services, as long as all covered items and services are reimbursed by the same federal health care program and in the same payment (*e.g.*, the same Medicaid managed care payment or the same Medicare Part A DRG payment). Although OIG considered expanding the safe harbor to services-only warranties, it ultimately declined to do so.

Additionally, OIG revised the definition of “warranty” to include agreements promising the covered items and services “will meet a specified level of performance over a specified period of time,” which OIG interprets to encompass arrangements conditioned on clinical outcomes guarantees. In line with the broader goals of the Regulatory Sprint, these revisions are designed to encourage manufacturers to offer (and providers to accept) warranties tied to improved health outcomes and more coordinated care.

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

OIG modified the local transportation safe harbor to expand mileage limits for rural areas and eliminate mileage limits for transportation of patients from a health care facility to their residence after the patient's discharge. Free or discounted transportation may now be offered to patients within a 75-mile radius of the provider – an increase from the previous 50-mile limit, but short of the 150-mile radius supported by some commentators. The revised safe harbor also removed any mileage limitation on free or discounted transportation provided to patients discharged from an inpatient facility or released from a hospital after being placed in observation status for at least 24 hours. OIG declined to extend safe harbor protection to transportation for non-medical purposes, but confirmed the safe harbor is available for transportation provided through rideshare services.

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

The OIG Final Rule codifies the statutory exception to the definition of “remuneration” passed in the Bipartisan Budget Act of 2018 for Accountable Care Organizations (“ACO”) participating in CMS-approved MSSPs, without modifications. OIG confirmed its interpretation of the statutory language explained in the proposed rule: for an incentive payment to satisfy the statutory exception and safe harbor, all of the requirements enumerated at section 1899(m) of the Act – related both to ACO Beneficiary Incentive Programs and incentive payments made pursuant to such programs – must be satisfied. No additional requirements, such as the CMS requirements for implementing an ACO Beneficiary Incentive Program, must be satisfied for the safe harbor to be available.

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

Finally, the OIG finalized a new exception to the definition of prohibited "remuneration" under the CMP, 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, or has been selected or contacted by the patient to schedule an appointment or provide services (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); and
- (3) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

In recognition of the fact that the new CMP exception is narrow (only available to a subset of patients and to certain enumerated providers), and thus the chances of fraud and abuse are lower, the OIG made several modifications to the proposed regulations to reduce the requirements from what was included in the proposed regulation. For example, the OIG finalized a broader definition of "telehealth technologies" by removing references to any specific type of technology that could be donated. Under the Final Regulations, "telehealth technologies" means "hardware, software and services that support distance or remote communication between the patient and provider, physician or renal dialysis facility for diagnosis, intervention or ongoing care management." Further, the OIG removed proposed requirements that the donated telehealth technologies must "contribute substantially to the provision of telehealth services, and not be of excessive value or duplicative of technology already owned by the patient."

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*Please contact the authors or your regular Dorsey attorney if you would like assistance with understanding how the final AKS and CMP rules impact your organization.*