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Analysis of OIG's New and Revised Regulatory Safe Harbors to the Federal Health Care Program Anti-Kickback Statute and Beneficiary Inducement Prohibition

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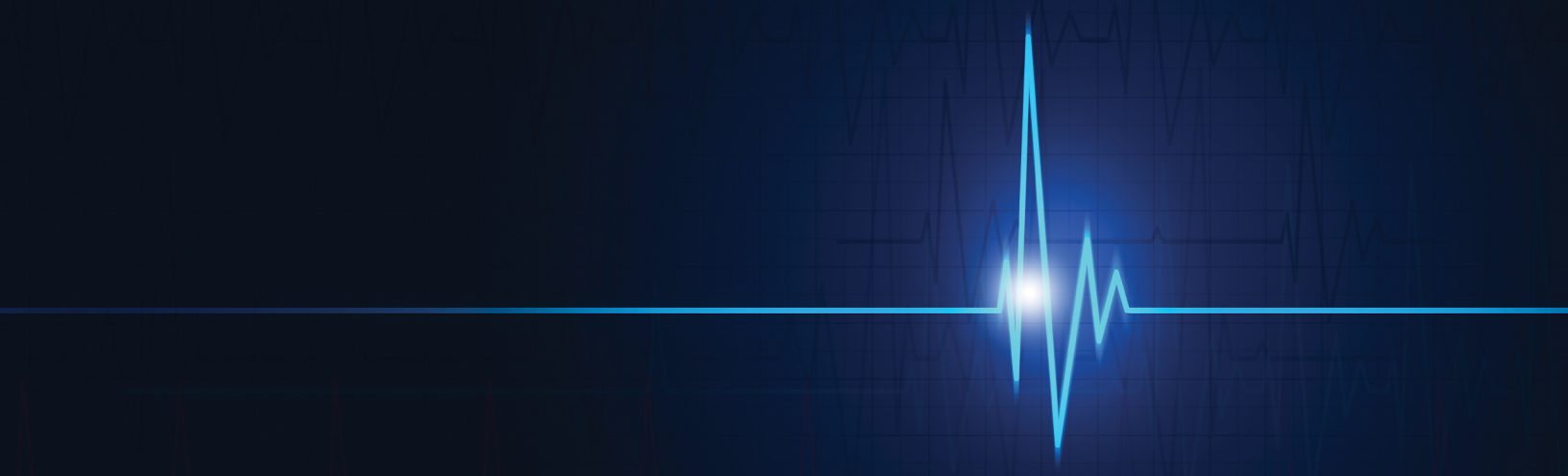

On November 20, 2020, the Office of Inspector General for the U.S. Department of Health and Human Services (the "OIG") published a final rule (the "Final Rule"), 85 Fed. Reg. 77684 (Dec. 2, 2020), implementing new and revised flexibilities under the federal health care program Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) (the "AKS") and the Beneficiary Inducement Prohibition, 42 U.S.C. 1320a-7a(a)(5) (the "BIP"). Many of the new flexibilities were explicitly designed to adapt the AKS and the BIP to the health care industry's accelerating shift away from fee-for-service-based reimbursement and toward value-based reimbursement of health care items and services. Substantially adopting proposed rules published over a year ago, the Final Rule includes:

- Four new safe harbors potentially applicable to "value-based arrangements"
- Significant revisions to the safe harbor for personal services and management contracts
- A new safe harbor for donations of cybersecurity items and services, and revisions to the safe harbor for donations of EHR items and services
- Revisions to the warranty and local transportation safe harbors
- A new exception to the BIP, for telehealth items and services provided to patients with end-stage renal disease

Many of these changes offer substantial new flexibility for health care industry participants, particularly those who are or may become involved in value-based care. Although many managed care organizations have previously engaged in various value-based remuneration arrangements under the managed care safe harbor, 42 C.F.R. 1001.952(t), the new and revised safe harbors allow flexibility for new types of value-based remuneration, as well as value-based remuneration exchanged by entities and individuals not covered by the managed care safe harbor.

For instance, OIG focuses – both in regulatory text and rulemaking commentary – on protecting the involvement of health technology companies in value-based care. This focus recognizes the increasing and critical contributions arising from the health technology sector in improving care value, quality, and coordination, and the manner in which these contributions have brought these companies within the ambit of the AKS. The new safe harbors may carve out a space for health technology companies to make meaningful contributions to the transition to value-based care without incurring undue regulatory risk.

In a long overdue change, the new rules also open safe harbor protection for personal services arrangements where aggregate compensation is not fixed in advance. This change recognizes both the reality that such arrangements are common to the industry and pose no meaningful risk to the Federal Health Care Programs ("FHCPs"), as well as the need for additional flexibility in paying for personal services in a value-based reimbursement environment. This need is further recognized by a safe harbor provision for certain outcomes-based compensation, a common and necessary feature of many value-based arrangements.

Overall, the Final Rule offers significant new opportunities for health care industry collaboration aimed at improving the quality and coordination of care. Industry participants should carefully consider the scope of the new safe harbors in strategizing about value-based initiatives going forward. Nevertheless, the Final Rule leaves substantial restrictions in place. For instance, many types of health care industry participants are ineligible to rely on the new value-based safe harbors. Additionally, the safe harbors for value-based arrangements do not protect monetary remuneration unless either full financial risk or substantial downside financial risk (for the cost of all items and services provided to patients) has been assumed, fail to protect returns on investment and distributions in value-based entities, and impose potentially significant hurdles before full compliance can be achieved. In many ways, the flexibilities afforded by the Final Rule fall well short of the flexibilities that the Centers for Medicare and Medicaid Services ("CMS") simultaneously extended to value-based arrangements implicating the Federal physician self-referral prohibition (the "Stark Law"), 85 Fed. Reg. 77492 (Dec. 2, 2020). As a result, many important value-based initiatives will necessarily continue to rely on the same case-by-case risk analysis under the AKS that industry participants have employed to date.

The Final Rule takes effect on February 1, 2021 and will have exclusively prospective effect.

New and Revised Federal Health Care Program Anti-Kickback Statute Safe Harbors

I. New Safe Harbors for Remuneration Exchanged Under Value-Based Arrangements

In the Final Rule, OIG provides new flexibility for organizations engaged or considering involvement in value-based arrangements by promulgating four new safe harbors to entities that participate in a "value-based enterprise" ("VBE"). A VBE can be large or small in scope, as long as it is constructed by formalizing relationships between individuals and/or entities focused on developing value-based care, for instance between health systems and the physician practices with which they work, or between physicians and the group practice with which they are affiliated, or between technology companies and their provider partners. Entities that enter into these structures as a means of pursuing their efforts toward value-based care may protect certain exchanges of remuneration that would not have been protected by any previously existing safe harbors. Two of these new safe harbors (if fully satisfied) protect *any* type of remuneration, including monetary remuneration, while the other two new safe harbors can protect only in-kind remuneration. Each of these new safe harbors relies on a set of new interrelated regulatory definitions.

A. Value-Based Enterprises and Associated Definitions

To avail themselves of any of the new value-based safe harbors, individuals and entities will need to establish a VBE, which must:

- Have at least two **VBE participants** that are collaborating to achieve a **value-based purpose**;
- Consist of participants each of which is party to a **value-based arrangement** with at least one other VBE participant in the VBE;
- Have an accountable body or person responsible for financial and operational oversight; and
- Have a governing document that describes the VBE and how VBE participants intend to achieve its value-based purpose(s).

See 42 C.F.R. 1001.952(ee)(14)(viii). This definition itself includes several critical defined terms. A **VBE participant** is an individual or entity that engages in at least one **value-based activity** as part of a VBE. *See* 42 C.F.R. 1001.952(ee)(14)(ix). A **value-based arrangement** is an arrangement for the provision of at least one **value-based activity** for a **target patient population**, to which the only parties are either the VBE and its participant(s) or a set of VBE participants. *See* 42 C.F.R. 1001.952(ee)(14)(vii).

A **value-based activity** ("VBA") involves providing something, doing something, or refraining from doing something, provided that the activity is reasonably designed to achieve at least one **value-based purpose**. *See* 42 C.F.R. 1001.952(ee)(14)(vi). Making a referral alone does not constitute a value-based activity for purposes of this definition[1]; although "[p]arties to a value-based arrangement may make referrals and document the reasons for the referrals as part of a value-based arrangement without losing safe harbor protection under an applicable safe harbor…the parties also must be performing one or more value-based activities." 85 Fed. Reg. at 77705. In other words, VBE participants must engage in value-based work beyond simply referring patients to one another.

A **value-based purpose** may be one of four specified 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, or (4) transitioning from health care 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. *See* 42 C.F.R. 1001.952(ee)(14)(x).

A **target patient population** is an identified patient population selected by the VBE or its participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the **value-based arrangement**, and that further the value-based arrangement's **value-based purposes**. *See* 42 C.F.R. 1001.952(ee)(14)(v). OIG explains in rulemaking

[1] CMS has stated that the making of a referral, as that term is defined by the Stark Law, can constitute a "value-based activity" for purposes of the Stark Law. See 85 Fed. Reg. 77492, 77500-501 (Dec. 2, 2020).

commentary that its use of the phrase "legitimate and verifiable criteria" is intended to provide flexibility in identifying a target patient population, and could include a variety of factors, including social determinants of health such as safe housing or transportation needs. Criteria used to target "particularly lucrative patients ("cherry-picking") or avoid high-cost or unprofitable patients ("lemon-dropping")" would not be considered legitimate.

Thus, for collaborators that are already working together to develop value-based care strategies, it may be relatively (and intentionally) easy to construct a VBE. OIG provides a deliberately flexible understanding of the various relationships and structures that may constitute a VBE. In fact, OIG "emphasize[s] that [it] perceive[s] the administrative steps required to establish a VBE as relatively minimal, and they should not pose a significant burden on providers..." 85 Fed. Reg. at 77783. For instance:

- OIG illustrates multiple ways in which a VBE could show that its participants were collaborating to achieve a value-based purpose, including records of time spent on value-based activities, collaboration between parties, and participation in applicable meetings.
- OIG confirmed that "VBE participants may join and leave a VBE throughout the existence of the VBE." 85 Fed. Reg. at 77695. For instance, a health system and a large physician practice could form a VBE, with physicians and other physician practices entering and leaving the VBE as appropriate to their current role in treating a set of overlapping patients. A technology company could construct a VBE with multiple provider partners and not risk safe harbor protection for qualifying arrangements if some provider partners terminated their arrangements and de-participated from the VBE.
- The form of the accountable body may be appropriate to each VBE; "[f]or instance, a representative from each VBE participant in a VBE could, but is not required to, be part of the VBE's accountable body. Where parties already have a governing body that constitutes an accountable body or responsible person, such parties are not required to form a new accountable body or designate a responsible person for purposes of creating a VBE." 85 Fed. Reg. at 77697-98.
- OIG offers flexibility with respect to the governing document and writing documenting the value-based arrangement, explaining that "[a] single document could constitute both the VBE's governing document and the writing required for a value-based arrangement so long as it includes all of the requisite requirements for each writing. In addition, an existing payor contract could qualify as a governing document so long as it describes the value-based enterprise and how the VBE participants intend to achieve the VBE's value-based purpose(s)." 85 Fed. Reg. at 77699. Nevertheless, OIG will *not* permit the governing document for a VBE to be set out in multiple writings (although it will allow multiple writings for the documentation of the value-based arrangement).

For an entity or individual to rely on any of the new value-based safe harbors, its first step must be to establish a VBE consistent with these definitions. Once a VBE is formed, an arrangement between a VBE and a VBE participant (or between VBE participants) will qualify as a VBA (such that remuneration offered or paid under it will potentially be eligible for any of the new value-based safe harbors' protections) as long as it:

> With respect to the care of a patient population identified on the basis of legitimate and verifiable criteria determined in advance of the arrangement, is reasonably designed for the parties to collaborate (directly and perhaps with others) to either (1) coordinate and manage that care, (2) improve the quality of that care, (3) appropriately reduce the costs to, or growth in expenditures of, payors without reducing the quality of that care, or (4) transition from a volume-based care delivery and payment system to a quality-based system for that care (*e.g.*, through team-based coordinated care models, infrastructure to provide patient-centered coordinated care, and accepting (or preparing to accept) financial risk).

B. New Value-Based Safe Harbors Applicable to *Any* Remuneration, Including Monetary Remuneration

While VBEs and VBAs may be easily formed, compliance with the new value-based safe harbors may be unattainable for a variety of reasons. A VBE and its participants may rely on one of the new value-based safe harbors to protect remuneration exchanged to promote the VBE's value-based purposes only if they comply with all of the criteria of an applicable safe harbor. However, only two of the new safe harbors protect exchanges of monetary remuneration, and they require the VBE to accept from a payor either full financial risk or substantial downside financial risk for *all* items and services provided to patients in

the target patient population. If such financial risk is accepted, these safe harbors could, for instance, be available to protect certain bonuses or other transfers from the VBE to a VBE participant to fund or reward value-based activities. However, neither of these safe harbors protects any exchange of remuneration between entities downstream of the VBE, including exchanges of remuneration between VBE participants. For instance, these safe harbors would *not* protect any shared savings or losses (or other remuneration) between a hospital VBE participant and its employed or contracted physicians (even if the physicians are VBE participants themselves); however, the VBE could enter into VBAs directly with physicians who are VBE participants themselves in order to share savings or losses with the physicians, assuming all requirements of the applicable safe harbor are met. Essentially, to satisfy either of these two safe harbors, the VBE itself must either offer, pay, solicit, or receive the remuneration to or from a VBE participant.

1. New Safe Harbor for VBAs with Full Financial Risk

The most flexible of these two new safe harbors applies only in narrow circumstances, *i.e.*, when the VBE accepts **full financial risk**, meaning that the VBE – or a VBE participant on behalf of the VBE – is financially responsible on a prospective basis for the costs of *all* items and services covered by the applicable payor for each patient in the target patient population for a term of at least one year. If and when such risk is accepted – which may not be often – this safe harbor could protect a variety of types of remuneration exchanged between a VBE and a VBE participant, as long as the remuneration is directly connected to a value-based purpose. For instance, the safe harbor could potentially protect an arrangement by which an integrated delivery system (that is a VBE that accepts capitation payments for all services provided to a target patient population) shares savings achieved for that population through use of a new care coordination software with a software developer (if a VBE participant), or an arrangement by which the system pays bonuses to VBE-participating physician practices based on their achievement of value-based performance targets for the care of patients, or by which the system makes fee-for-service payments to facilities and professionals who provide services to patients with rare disease states.

More specifically, remuneration between a VBE and a VBE participant would be protected by this new safe harbor only if:

- The VBE has assumed full financial risk prospectively, for all items and services covered by the payor for each patient in the target population;
- The VBE's assumption of full financial risk is set forth in a written agreement (or the VBE has entered into a written contract or arrangement to assume such risk within the next year, which allows parties to exchange remuneration related to preparing to accept risk);
- The VBA is set forth in a signed writing specifying all material terms;
- The VBE participant does not claim payment in any form from a payor for the items or services covered under the VBE's risk arrangement;
- The remuneration provided by or shared among the VBE and the VBE participant is directly connected to one or more of the VBE's value-based purposes, does not include the offer or receipt of ownership or investment interests or distributions, and is not exchanged or used for the purpose of marketing items or services furnished by the VBE or the VBE participant to patients or for patient recruitment activities;
- The VBA does not induce the parties to reduce or limit medically necessary items or services;
- The offeror of the remuneration does not take into account the volume or value of, or condition remuneration on, referrals of patients who are not part of the target patient population or business not covered under the VBA;
- The VBE provides or arranges for a quality assurance program for services furnished to the target patient population that protects against underutilization and assesses the quality of care furnished to the target patient population; and
- For a period of six years, the VBE makes records available to HHS.

See 42 C.F.R. 1001.952(gg). This safe harbor opens tremendous opportunity for organizations that are or are considering accepting capitation (or other payment structures placing them, prospectively, at full financial risk for the cost of care provided to a patient population) to collaborate with other organizations and individuals to achieve high value care for these patients. While VBEs (or their collective participants) must remain at full financial risk for *all* items and services provided to a patient in the targeted patient population, VBEs may still calibrate the scope of their value-based efforts by targeting larger or smaller patient populations (*e.g.*, all covered patients in a geographic area, or only covered patients in a geographic area that have a particular disease state).

For organizations able to offer novel technologies and strategies to a fully at-risk VBE for improving care coordination, management, and value, the safe harbor may protect creative compensation arrangements with the VBE to reap a portion of the benefits of their innovation. While compensation arrangements incorporating shared profits or business volume have historically been severely inhibited by the AKS, such arrangements may fit within this new safe harbor, as protected remuneration *may* take into account the volume or value of business covered under the VBA.

2. New Safe Harbor for VBAs with Substantial Downside Financial Risk

A somewhat narrower safe harbor is available to a potentially broader scope of arrangements, *i.e.*, for remuneration exchanged between a VBE participant and a VBE that does not accept full financial risk, but rather accepts **substantial downside financial risk**, meaning that the VBE either:

- Accepts financial risk equal to at least
  - Thirty percent (30%) of any loss, where savings and losses are calculated by comparing (A) current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population, to (B) a bona fide benchmark designed to approximate the expected total cost of such care (the "Shared Savings and Losses Methodology"), or
  - Twenty percent (20%) of any loss where losses and savings are calculated by comparing (A) current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that is covered by the applicable payor, to (B) a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care, and the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting (the "Episodic Payment Methodology"); **or**
- Receives a prospective, per-patient payment that is designed to produce material savings, and is paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services (the "Partial Capitation Payment Methodology"). *See* 42 C.F.R. 1001.952(ff)(9)(i).

Under both the Shared Savings and Losses and Episodic Payment risk sharing methodologies, the assumption of risk must take into account *all* items and services covered by the applicable payor and furnished to the targeted population; should a VBE limit its risk under either of these methodologies to only certain items and services (*e.g.*, certain outpatient items and services), the remuneration between the VBE and the VBE participant would not be eligible for this safe harbor. On the other hand, the Partial Capitation Payment Methodology by definition allows the assumption of risk with respect to only certain – and sometimes narrow – subsets of items and services, *e.g.*, the subset of services furnished by the VBE participant. The Episodic Payment Methodology, which is inherently service-specific, requires the episode of care to cover at least two care settings, *e.g.*, a hospital stay and a post-acute setting such as a physician clinic or skilled nursing facility.

Not only must the VBE accept substantial downside financial risk in one of the fashions prescribed above, but the VBE participant must "**meaningfully share**" in the VBE's downside financial risk. To "meaningfully share" in such risk, the VBE participant must either (A) assume two-sided risk for at least five percent (5%) of the losses and savings realized by the VBE pursuant to its assumption of risk (*e.g.*, through a withhold or repayment structure); or (B) receive from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for that predefined set of items and services, and not claim payment in any form from the payor for any of the predefined items and services.[2] *See* 42 C.F.R. 1001.952(ff)(9)(ii).

Assuming the VBE accepts sufficient downside financial risk and the VBE participant meaningfully shares in it, this new safe harbor could apply to not only (A) the exchange of remuneration by which the VBE participant meaningfully shares in the VBE's financial risk, but also (B) other remuneration exchanged between the VBE and the VBE participant, to the extent that the remuneration is used predominantly to engage in value-based activities and has a direct connection to the VBE's value-

[2] If the VBE participant is the payor from which the VBE accepts significant downside financial risk, the "meaningful share" requirement does not apply. See 42 C.F.R. 1001.952(ff)(3).

based purposes. *See* 42 C.F.R. 1001.952(ff)(4). Thus, in the latter case, the safe harbor requires an examination of both the *use* of the remuneration and the *purpose* in providing it. For instance, a bonus payment from a VBE to a VBE participant, with no restrictions on its use, would not be protected under this safe harbor (unless the bonus was the result of the VBE participant's meaningful sharing in the VBE's financial risk). However, the safe harbor could potentially protect a grant of funds made from a VBE to a VBE participant to be used (exclusively or predominantly) to develop or enhance the participant's value-based capabilities and activities. For instance, a VBE could provide funds to VBE-participating physician practices to use to add care coordination technology and staff to their practices. In rulemaking commentary, OIG stated that safe harbor protection would not be available to either the VBE or the VBE participant if the recipient used the remuneration for other purposes, even if in a manner unknown to the offeror and in violation of a contractual obligation.[3]

Other safe harbor requirements include:

- The VBE's assumption of substantial downside financial risk is set forth in a written agreement with at least a one year term (or the VBE has entered into a written contract or arrangement to assume substantial downside financial risk in the next six months, which – as with the full financial risk safe harbor – would allow parties to exchange remuneration related to *preparing* to accept risk);
- The VBA is set forth in a signed writing specifying all material terms, including evidencing that the VBE is or will be at substantial downside financial risk, a description of the manner in which the VBE participant has a meaningful share of such risk, and the value-based activities, the target patient population, and the type of remuneration exchanged;
- The remuneration provided by or shared among the VBE and the VBE participant is directly connected to one or more of the VBE's value-based purposes (other than the purpose of preparing to accept financial risk), is used predominantly to engage in value-based activities directly connected to the items and services for which the VBE has assumed substantial downside financial risk, does not include the offer or receipt of ownership or investment interests or distributions, and is not exchanged or used for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for patient recruitment activities;
- The VBA does not induce the parties to reduce or limit medically necessary items or services;
- The offeror of the remuneration does not take into account the volume or value of, or condition remuneration on, referrals of patients who are not part of the target patient population or business not covered under the VBA;
- The VBA does not: (1) limit the VBE participant's ability to make decisions in the best interests of its patients, (2) direct or restrict referrals to a particular provider if a patient expresses a different preference, the patient's payor determines the provider, or such direction or restriction is contrary to applicable law; or (3) induce parties to reduce or limit medically necessary items or services furnished to any patient; and
- For a period of six years, the VBE makes records available to HHS. *See* 42 C.F.R. 1001.952(ff).

Although the safe harbor contains many requirements (whether as to eligibility or to compliance), this stringency is by design, *i.e.*, satisfaction of the applicable requirements allows VBEs and VBE participants to exchange remuneration (including monetary remuneration) that either is inconsistent with fair market value, is commercially unreasonable, and/or takes into account the volume or value of referrals (of patients within the target patient population) or other business generated (under the VBA). For instance, an IPA (that is a VBE) might accept substantial downside financial risk from a payor for losses associated with care provided to its patient population, *e.g.*, through the Partial Capitation Payment Methodology; if the IPA enters into a VBA with its VBE-participating member physician practices who meaningfully share in the IPA's risk, this safe harbor could protect monetary transfers from the IPA to those practices to enable the practices to purchase technological upgrades designed to facilitate improved patient care.

C. New Safe Harbors Available Only for In-Kind Remuneration

The other two new value-based safe harbors are available exclusively to protect exchanges of in-kind remuneration, *e.g.*, the provision of personnel or technology aimed at care improvement. One of these safe harbors, for care coordination

[3] This differs from OIG guidance on other safe harbors, e.g., the discount safe harbor, wherein OIG has stated that the offeror of a discount can achieve safe harbor protection by complying with the safe harbor requirements applicable to it, even if the recipient of the discount fails to comply with the safe harbor requirements applicable to the recipient. See 64 Fed. Reg. 63518, 63526-27 (Nov. 19, 1999).

arrangements, is available not only for remuneration exchanged between a VBE and its participants, but also for remuneration exchanged between VBE participants. *See* 42 C.F.R. 1001.952(ee). The other is available for remuneration provided by a VBE or a VBE participant to FHCP beneficiaries in the target patient population. *See* 42 C.F.R. 1001.952(hh).

1. New Safe Harbor for Care Coordination Arrangements

The new safe harbor for care coordination arrangements protects in-kind remuneration between a VBE and a VBE participant, or between VBE participants, pursuant to a VBA, if the remuneration is used predominantly to engage in value-based activities that are "directly connected to the coordination and management of care for the target patient population" and "does not result in more than incidental benefits to persons outside of the target patient population." *See* 42 C.F.R. 1001.952(ee)(1). The Final Rule defines "coordination and management of care" to mean the deliberate organization of patient care activities and sharing of information between VBE participants, between VBE participants and the VBE, or between VBE participants and patients, and that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population. *See* 42 C.F.R. 1001.952(ee)(14)(i). Accordingly, this safe harbor may facilitate the development and expansion of a variety of in-kind transfers between health industry participants that are either VBEs or VBE participants, *e.g.*, the provision of case managers by health systems to independent physician practices, the provision of discharge planners by skilled nursing facilities to hospitals, or the provision of certain upgrades or new services by a technology company to a health care provider partner.

However, in-kind remuneration for the coordination and management of care is protected by the new safe harbor only if:

- The recipient pays at least fifteen percent (15%) of the offeror's cost for, or the fair market value of, the remuneration, either in advance (for one-time costs) or at regular intervals (for ongoing costs);

- The VBA is commercially reasonable, which criterion "focuses on ensuring that parties structure the terms of their [VBA]…in a manner that is calibrated to achieve the parties' legitimate business purposes." 85 Fed. Reg. at 77732. OIG states in rulemaking commentary that it "recognize[s] that a [VBA] may, and often will, result in referrals", but that "[t]he commercial reasonableness requirement is intended to ensure that the terms of the [VBA], considering both the arrangement itself and all [VBAs] within the VBE, are calibrated to achieve the value-based purpose(s) of the arrangement, not the generation of referrals." 85 Fed. Reg. at 77733. OIG declined to define "commercially reasonable", stating opaquely that "[t]here are multiple dimensions to commercial reasonableness, including both the financial and nonfinancial terms of an arrangement", such that an "arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." *Id.* Accordingly, if a health system and physician practices are part of a VBE, the health system could suffer financial loss from a care coordination program offered to the physician practices, if the program was calibrated to improve coordination of care (but had the ancillary effect of increasing referrals);

- The parties establish "legitimate" outcome or process measures that (i) they 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, (ii) include benchmarks related to improving coordination and management of care for the target patient population, (iii) are monitored, periodically assessed, and prospectively revised to ensure that the coordination and management of care continues to be advanced, (iv) relate to the remuneration exchanged, and (v) are not based solely on patient satisfaction (whether a patient's expectations for a health care encounter were met) or patient convenience (for instance, assessing access or accessibility to care). The measures "do not need to be independently validated by a medical or other journal or another third-party source" and "can be process-based, such as, for example, a measurement of the number of patients with diabetes that had their blood pressure tested…" 85 Fed. Reg. at 77728. Further, OIG clarifies in rulemaking commentary that it is the *design* of the outcome measures that is important, and that *actual* achievement of safer, more effective, or more efficient care is not required[4];

[4] Actual achievement of outcome measures is required in order to satisfy the revised safe harbor for personal services and management contracts, discussed infra.

- The VBE monitors and assesses, no less frequently than annually, the coordination and management of care for the target patient population, any deficiencies in the delivery of quality of care, and progress toward achieving the legitimate outcome or process measures. Further, if it is determined that the VBA 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, the parties must – within sixty (60) days – terminate the arrangement or develop and implement a corrective action plan to remedy the deficiencies within one hundred and twenty (120) days (and then terminate the arrangement if the deficiencies are not remedied);

- The remuneration is not exchanged or used more than incidentally for the recipient's billing or financial services, or for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities, although "[r]emuneration exchanged between parties to a [VBA] may be used to inform patients in the target patient population that the VBE participant participates in the [VBA] without such information being considered a marketing or recruitment activity." *Id.* at 77746.

- The terms of the VBA are memorialized in a signed writing, which states the value-based purpose of the value-based activities, the value-based activities to be undertaken, the term of the VBA, the target patient population, a description of the remuneration, the offeror's cost (or the fair market value of) the remuneration, the percentage and amount contributed by the recipient, the frequency of the recipient's contribution payments, and the outcome or process measures against which the recipient will be measured (including documentation of the credible support for the measures). OIG states that the writing requirement can be satisfied by a collection of documents;

- The offeror of the remuneration does not take into account the volume or value of, or condition remuneration on, referrals of patients who are not part of the target patient population or business not covered under the VBA;

- The VBA does not limit the VBE participant's ability to make decisions in the best interests of its patients, induce parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient, or direct or restrict referrals to a particular provider, practitioner, or supplier if a patient expresses a preference for a different one, the practitioner, provider, or supplier is determined by the patient's payor, or such direction or restriction is contrary to applicable law;

- The offeror does not and should not know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose; and

- For a period of at least six years, materials and records are made available to HHS upon request. *See* 42 C.F.R. 1001.952(ee).

This safe harbor could potentially apply to a variety of in-kind remuneration exchanged by and within a VBE to promote care coordination and management (although remuneration seeking to further only one of the other three defined value-based purposes is *ineligible* for this safe harbor). For instance, many hospitals and health systems currently employ various types of care managers to assist in planning and coordinating follow-up care for hospital patients. Under the new safe harbor for care coordination arrangements, a hospital that enters into a VBA with a physician group might extend its care coordination program to "provide a physician group with care managers (who identify the physician group's high-risk patients and help manage patients' care transitions, medications, and home-based care) to ensure patients receive appropriate follow-up care post-discharge; data analytics systems to help the group's physicians ensure that their patients are achieving better health outcomes; and remote monitoring technology to alert the group's physicians when a patient needs a health care intervention to prevent unnecessary emergency room visits and readmissions." 85 Fed. Reg. at 77726. Similarly, a skilled nursing facility could provide a discharge planner to a hospital under a VBA. Provided each of the safe harbor criteria are met – including that the physician group (or hospital) contributes 15% of the costs or the fair market value of the care coordinators (or of the discharge planner) – the program would be subject to safe harbor protection.

Many hospitals already operate care coordination programs that provide great value to shared patients of both the hospitals and independent physician groups, recognizing that the independent physician groups may derive some incidental value from

such programs – and that the derivation of incidental value does not implicate the AKS. In the interest of facilitating enhanced care coordination and management, this safe harbor would go further and protect a hospital's provision of certain non-monetary remuneration directly to a physician, *i.e.*, remuneration that carries an independent value, not just an incidental value.

2. New Safe Harbor for Patient Engagement Tools and Supports

OIG promulgated a second value-based safe harbor to protect up to $500 of annual, in-kind remuneration that takes the form of patient engagement tools and supports, but the remuneration must be provided by a VBE or VBE participant to a patient in the target patient population. *See* 42 C.F.R. 1001.952(hh). No assumption of financial risk by the VBE or any VBE participant is necessary for the protection of this safe harbor to be attained. To be protected, such an engagement tool or support must:

- Be furnished directly to the patient, or the patient's caregiver or family member, including through an "eligible agent" on the contributor's behalf (*e.g.*, any individual or entity other than those who OIG identifies as ineligible to rely on this safe harbor);
- Be an in-kind item or service, and not cash or a cash equivalent[5], that:
  - Has a direct connection to the coordination and management of care of the target patient population;
  - Does not result in medically unnecessary or inappropriate items or services reimbursed by a FHCP;
  - Is recommended by the patient's licensed health care professional; and
  - Advances at least one of the following goals: (1) adherence to a treatment regimen, drug regimen, or follow-up care plan determined by the patient's licensed health care professional, (2) prevention or management of a disease or condition as directed by the patient's licensed health care professional; and (3) ensures patient safety;
- Not be funded or contributed by a VBE participant that is not a party to the applicable VBA;
- Have an aggregate retail value to a patient on an annual basis that does not exceed $500, to be adjusted annually based on the Consumer Price Index. The "retail value is the commercial cost the patient would have incurred at the time the VBE participant provides the tool or support if the patient had procured the tool or support on the open market on their own." 85 Fed. Reg. at 77807. OIG notes that "VBE participants are not required to monitor the value of tools and supports provided by other parties — even within the same VBE — to a particular patient." 85 Fed. Reg. at 77807;
- Not be used to support or market other FHCP-reimbursable items or services, or for patient recruitment purposes;
- Be the subject of records made available, on request, to HHS; and
- Not have its availability determined in a manner that takes into account the type of insurance coverage of the patient. *See* 42 C.F.R. 1001.952(hh).

In rulemaking commentary, OIG offers a non-exclusive, illustrative list of engagement tools and supports that could be protected by the safe harbor, including

> "provision of in-kind transportation, such as transit vouchers or rideshares organized by the VBE participant; home modifications such as grab bars, air filters or purifiers, and other physical or structural modifications that allow patients to live safely at home; temporary housing for an individual experiencing homelessness or living far from a hospital following a surgical discharge; providing broadband access to a patient to enable remote patient monitoring or virtual care; grocery or meal delivery services, nutrition supplements, and nutrition education; exercise or fitness programs or equipment; vehicle modifications; incentives as part of addiction recovery programs, including peer-to-peer programs and contingency management programs; incentives as part of mental health programs; and supports related to interpersonal violence." 85 Fed. Reg. at 77795.

The breadth of this list is compelling and offers potentially extensive new opportunities for VBE participants to directly support patient engagement; in rulemaking commentary, OIG repeatedly stated that it is "agnostic" about the type of tools and supports eligible for protection under this safe harbor, as long as all of the elements of the safe harbor are met – including a recommendation from a licensed health professional and a direct connection to the coordination and management of care. *See, e.g.*, 85 Fed. Reg. at 77781, 77788, 77795. For instance, a technology company could enter into an arrangement

[5] Limited-use gift cards are eligible for contribution under this safe harbor.

with a health care provider that includes the technology company's provision of medication tracking tools to patients, which could potentially improve patient care and enhance shared VBE goals with respect to avoiding adverse medication events. In rulemaking commentary, OIG stated that the contribution of multifunctional equipment such as a smartphone could be protected by this safe harbor, as long as the tool or support "advances" one of the safe harbor's identified goals. See 85 Fed. Reg. 77796.[6]

In other rulemaking commentary, OIG states specifically that, in some cases, "in-kind remuneration and certain limited-use gift cards offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes could receive protection under the patient engagement and support safe harbor if all safe harbor conditions are satisfied." 85 Fed. Reg. at 77791. However, "offering incentives to patients as a reward for accessing care may not satisfy the prohibition on marketing and patient recruitment" and "remuneration offered as a reward or incentive is not protected if it results in a beneficiary being furnished medically unnecessary care or inappropriate items or services reimbursed by a Federal health program…" Id. at 77792. Nevertheless, this safe harbor could substantially open opportunities to engage patients with direct incentives to engage in their own care, incentives that have been historically challenging to implement without regulatory risk. Further, to the extent the tool or support is itself an item or service billable to a Federal health care program, the provider may bill for it in compliance with applicable billing rules and requirements.

D. Entities Ineligible to Rely on the Value-Based Safe Harbors

Despite opposition from some commenters, OIG finalized, with modifications, its proposal to exclude certain health care industry participants from relying on *any* of the value-based safe harbors. Remuneration offered, paid, solicited, or received by the following industry participants is ineligible for protection under any of the new value-based safe harbors:

- Pharmaceutical manufacturers, distributors, and wholesalers;
- Pharmacy benefit managers (PBMs);
- Laboratory companies;
- Pharmacies that primarily compound drugs or primarily dispense compounded drugs;
- Manufacturers of devices or medical supplies;
- Entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and
- Medical device distributors and wholesalers. *See* 42 C.F.R. 1001.952(ee)(13), (ff)(1), (gg)(1), (hh)(1).

However, "limited technology participants" can (if otherwise ineligible) rely on protection offered by the care coordination arrangements safe harbor. OIG explains that "the question of whether a particular entity is eligible to rely on a safe harbor, or whether an entity fits the definition of a limited technology participant, is assessed at the corporate entity level by considering the corporate entity's predominant or core line of business" and that it was not adopting "standards relating to common ownership or corporate affiliation", such that "[c]orporate affiliation, whether by majority ownership, common ownership, or another structure, has no bearing on eligibility." 85 Fed. Reg. at 77718. Accordingly, a physician group that operates a clinical laboratory may remain eligible to rely on the safe harbors, as may a pharmacy that compounds drugs as a secondary line of business. While a hospital may be eligible to rely on a value-based safe harbor if it operates a clinical laboratory as a department of the hospital, a hospital-owned laboratory with its own supplier number and billing number will not be eligible to rely on a value-based safe harbor.

OIG chose not – as it had proposed – to exclude these industry participants from the definition of VBE participant. Therefore, entities of these types *can* form VBEs and be participants in a VBE. However, remuneration exchanged with or by these entity types is not generally eligible for safe harbor protection, and would be subject to a traditional AKS risk analysis. As part of such a risk analysis, VBEs, VBE participants, and these excluded health care industry participants may find that offering or paying remuneration in a manner that satisfies every element of one of the new value-based safe harbors may reduce AKS risk, even if the remuneration is otherwise ineligible for the safe harbor's protection.

[6] In rulemaking commentary, the OIG states that the provision of an item that is duplicative of an item that the patient already possesses may not "advance" such a goal, and thus may not be eligible for protection under the safe harbor. 85 Fed. Reg. at 77797.

E. Protection of Remuneration Exchanged with 'Limited Technology Participants'

In keeping with its focus on accelerating and protecting the involvement of technology companies in the health care industry, OIG provided a "separate pathway, with specific conditions, that protects digital technology arrangements" with manufacturers of devices and medical supplies and DMEPOS companies (excluding physician-owned distributors (or "PODs")) under the safe harbor for care coordination arrangements. 85 Fed. Reg. at 77685. Under this pathway, OIG defines "limited technology participant" to include entities if they are VBE participants and exchange digital health technology with other VBE participants or a VBE. *See* 42 C.F.R. 1001.952(ee)(14)(iii). Thus, even if otherwise identified as ineligible to rely on the care coordination arrangements safe harbor, these limited technology participants may do so to protect the exchange of "digital health technology", defined to mean hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care, including internet and connectivity services used to enable operation of an item or service. *See* 42 C.F.R. 1001.952(ee)(14)(ii). For instance, a medical device manufacturer that builds a remote monitoring device that requires an internet connection, and which participates in a VBE with a health care provider partner, could potentially enter into an arrangement to provide internet service to members of a target patient population that could benefit from the monitoring device.

To qualify for protection, such an exchange *cannot* be conditioned on any recipient's exclusive use of, or minimum purchase of, any item or service manufactured, distributed, or sold by the limited technology participant, although VBAs are *not* required to be "product-agnostic", nor is "digital technology provided under such arrangement [required to] be fully interchangeable with other products." 85 Fed. Reg. at 77720. In other words, while a limited technology participant could not require exclusive use of its own device or supply in order for a patient to receive a support tool, it could offer a support tool that offers its best utility when used with that participant's device or supply. OIG also recognizes that exclusivity provisions are common to technology arrangements, reiterating that such provisions would not necessarily cause the associated exchange of remuneration to violate the AKS, but rather cause the exchange to be outside the safe harbor and thus subject to a traditional AKS analysis. OIG's treatment of exclusivity provisions and minimum purchase requirements is purportedly designed to prevent the "locking in" of VBEs and VBE participants to the digital health technology offered by the "limited technology participant."

F. Other Limitations of the Value-Based Safe Harbors

A key limitation of the value-based safe harbors is that they do not protect remuneration that results from an ownership interest in the VBE or a VBE participant, *e.g.*, a return on investment or an ownership distribution. Many entities have facilitated the creation of value-based collaboration by granting equity interests in an entity involved in coordinating and improving care, including to health care professionals to stimulate their investment in value-based goals and better align incentives across collaborating parties. These grants can be an important tool for promoting value-based alignment and have helped to enhance collaboration, improve coordination, and promote cost savings. While OIG long ago established a separate safe harbor for certain investment interests, this safe harbor is demanding and excludes a wide swath of legitimate arrangements. Excluding remuneration resulting from an ownership interest from protection under the value-based safe harbors may unnecessarily preserve an obstacle to creating approaches to forwarding value-based care; promulgating an appropriately tailored safe harbor to protect remuneration resulting from ownership may have significantly contributed to the efficacy of the Final Rule in accelerating the transition to value-based care.

II. New Safe Harbor for Remuneration Under a CMS-Sponsored Model

OIG promulgated a new safe harbor to protect remuneration exchanged among parties to a CMS-sponsored model arrangement. *See* 42 C.F.R. 1001.952(ii). Compliance with this safe harbor's requirements is closely tied to CMS' particular requirements for each of its sponsored models. For instance, the safe harbor requires that the arrangement advance one or more goals of the CMS-sponsored model and that the parties satisfy the model's programmatic requirements imposed by CMS. *See* 42 C.F.R. 1001.952(ii)(1)(i). OIG explains that "CMS defines the parameters of the model, which includes the types of financial arrangements and incentives that could receive safe harbor protection." 85 Fed. Reg. at 77812. Potentially greatly limiting the utility of the safe harbor, CMS must "affirmatively state that the safe harbor would be available for specific CMS-sponsored model arrangements and CMS-sponsored model patient incentives within a particular model or initiative" and will "notify CMS-sponsored model participants, through participation documentation, or other public means as determined by CMS, when CMS-

sponsored model participants may use this safe harbor under a CMS-sponsored model." 85 Fed. Reg. at 77813.

The new safe harbor "does not supersede OIG's existing fraud and abuse waivers for CMS-sponsored models", which "will continue in effect in accordance with the waiver terms." 85 Fed. Reg. at 77810. For existing models, "CMS would at its discretion issue a public notice or notice to individual CMS-sponsored model participants that such parties can seek protection for such arrangements under this safe harbor as of the effective date of that notice." 85 Fed. Reg. at 77813.

Nevertheless, the safe harbor offers for the first time potential protection from AKS liability to a model-related arrangement, instead of compliance with the terms of a separately issued CMS waiver. By providing safe harbor protection to CMS-model related arrangements, OIG may help to streamline protection for these arrangements instead of fragmenting it between separate CMS waivers.

III. Revisions to the Personal Services and Management Contracts Safe Harbor

A. Elimination of Requirement to Set Aggregate Compensation in Advance

The application of the personal services and management contracts safe harbor has long been limited by its requirement that *aggregate* compensation be set in advance – a requirement that precludes protection for many common health care industry compensation models, including hourly and per diem payment arrangements. The Final Rule eliminates this requirement and instead requires that the *methodology* for determining compensation be set in advance. *See* 42 C.F.R. 1001.952(d)(1)(iv). The safe harbor continues to require that compensation be consistent with fair market value and not determined in a manner that takes into account the volume or value of referrals or other business generated. While this revision makes this safe harbor significantly more expansive and allows for the protection of compensation formulae incorporating value-based methodologies, most time-based, per diem-based, or fee schedule-based arrangements that satisfied every other element of the safe harbor were typically determined to be at very low risk of violating the AKS.

Similarly, the Final Rule also removes the safe harbor's requirement that part-time contracts specify the schedule, length, and charge for intervals of work, providing similar flexibility for parties to arrange for part-time services in circumstances where not all this information can be known in advance (*e.g.*, call coverage services).

B. Protection for Outcomes-Based Payments

The Final Rule also expands the safe harbor to protect an "outcomes-based payment" meeting certain criteria. *See* 42 C.F.R. 1001.952(d)(2). In particular, for receipt of an outcomes-based payment to qualify for protection, the recipient must achieve one or more legitimate outcome measures that are selected based on clinical evidence or credible medical support, and have benchmarks used to quantify improvements in, or maintenance of improvements in, quality of patient care, and/or a material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care. *See* 42 C.F.R. 1001.952(d)(2)(i). In rulemaking commentary, OIG states that "[i]n selecting outcome measures, parties have broad latitude under this safe harbor to identify opportunities for improving or maintaining the improvement of patient care and reducing costs to payors in ways that are scientifically valid, measurable, and transparent." 85 Fed. Reg. at 77842. Therefore, entities making outcomes-based payments may choose from a range of potentially relevant outcome measures while retaining safe harbor protection. OIG further states that "process measures supported by strong evidence of improving an outcome may serve as a component of outcome measures that an agent must achieve to receive an outcomes-based payment", such that process measures may be part of determining receipt of an outcomes-based payment. 85 Fed. Reg. at 77843.

To qualify for safe harbor protection, the parties must regularly monitor and assess the agent's performance relative to quality of care measures and periodically assess and, as necessary, revise benchmarks and remuneration. *See* 42 C.F.R. 1001.952(d)(2)(vii). Thus, a once-aspirational outcome measure with which performance has, over time, become the status quo must be revised, either to continue to advance enhanced performance or to ensure that performance does not fall below the outcome measure. The entity making an outcomes-based payment must also have policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the arrangement. *See* 42 C.F.R. 1001.952(d)(2)(viii). Protected payments must reward the agent for successfully achieving one or more qualifying

outcome measures, or recoup from or reduce payment to an agent for failure to achieve such outcome measures. *See* 42 C.F.R. 1001.952(d)(3)(ii). Outcomes-based payments *cannot* be related solely to achievement of internal cost savings for the principal or based solely on patient satisfaction or patient convenience measures. *See* 42 C.F.R. 1001.952(d)(3)(iii)(B), (C). Thus, efficiency-based payment methodologies (*e.g.*, gainsharing) are ineligible for protection under the outcomes-based provisions of the safe harbor if they do not contribute to better care coordination, improvements in quality of care, or reduction in FHCP costs.

Additionally, the outcomes-based methodology for determining the aggregate compensation paid between the parties must be set in advance, commercially reasonable, consistent with fair market value, and not determined in a manner that directly takes into account the volume or value of referrals or other FHCP business generated. *See* 42 C.F.R. 1001.952(d)(2)(ii). Further, the agreement must be set out in writing and signed by the parties in advance of or contemporaneous with the commencement of the terms of the outcomes-based payment arrangement, and the writing must include a general description of the services, the outcome measures, the clinical evidence or credible medical support for the measures, and the schedule on which the parties will monitor and assess the care quality and outcome measures. *See* 42 C.F.R. 1001.952(d)(2)(iii). The agreement must be for at least a year, and must not limit any party's ability to make decision in their patients' best interests, nor induce any reduction or limitation of medically necessary items or services. *See* 42 C.F.R. 1001.952(iv), (v).

As with the value-based safe harbors, certain entities may engage in outcomes-based payments for personal services, but are ineligible for protection under this new safe harbor provision. In particular, outcomes-based payments from pharmaceutical companies, pharmacy benefit managers, laboratory companies, compounding pharmacies, medical device manufacturers, distributors, and wholesalers, medical supply manufacturers, and DMEPOS companies *cannot* be protected under the new safe harbor provision. *See* 42 C.F.R. 1001.952(d)(3)(iii)(A).

IV. New Safe Harbor for Donations of Cybersecurity Technology and Services

OIG finalized a new cybersecurity safe harbor that protects the donation of certain software, hardware, and other types of information technology by any entity to any entity, within certain conditions. As adopted, the final safe harbor reads as follows:

> "(bb) Cybersecurity technology and related services. (1) Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met: (i) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. (ii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor. (iii) The arrangement is documented in writing." 42 C.F.R. 1001.952(bb).

The safe harbor is limited to technology and services (*i.e.*, no monetary remuneration is protected, even if restricted to the purchase or acquisition of such technology and services) that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. Software that has multiple functions, only one of which is cybersecurity, would not meet the "necessary" and "predominant" use standard under the cybersecurity safe harbor. There is no monetary value limit for the donated software, hardware, or other cybersecurity technology, although donations cannot be conditioned on or take into account the volume or value of referrals.

The cybersecurity safe harbor is broader in scope and does not include many of the restrictions contained in the analogous safe harbor for donations of EHR items and services. For example, unlike the EHR safe harbor, the cybersecurity safe harbor permits the donation of hardware in certain circumstances, and there are no contribution requirements for the software, services, and hardware to qualify the donation for protection. This new safe harbor, therefore, offers an important avenue to protect new types of donations by technology companies and others to health care industry participants.

V. Revisions to the Safe Harbor for Warranties

The Final Rule modifies the existing safe harbor for warranties (42 C.F.R. § 1001.952(g)) so as to (i) protect warranties for one or more items and related services if compliant with certain conditions, such as all federally reimbursable items and services subject to bundled warranty arrangements must be reimbursed by the same Federal health care program and in the same payment ("same program/same payment requirement"); (ii) exclude beneficiaries from the reporting requirements applicable to buyers; and (iii) define "warranty". In rulemaking commentary, OIG clarified the scope of buyers' reporting obligations to make clear that the safe harbor is designed to accommodate the various reimbursement systems under which buyers may report price reductions.

A. Services in Bundled Warranties

The Final Rule revises the safe harbor to protect, for the first time, warranties covering services, although the safe harbor does not protect warranties that warranty *only* services. OIG explains that it believes warranties for services that are not tied to one or more related items could present heightened fraud and abuse risk, but is establishing greater flexibilities to buyers and sellers to enter into innovative arrangements that warranty the value of an entire bundle of items, or a bundle that includes both items and services. The revised safe harbor does not protect "exclusive-use or minimum-purchase requirements as a condition of a warranty", to minimize anticompetitive risks and deter against patient steering that could interfere with clinical decision-making. 85 Fed. Reg. at 77849. The revised safe harbor also caps warranty remuneration for any medical, surgical, or hospital expense incurred by a beneficiary at the cost of the items and services subject to the warranty, to safeguard against sellers providing excess remuneration to providers to induce referrals. *See* 42 C.F.R. 1001.952(g)(4). OIG explicitly declined to include a requirement that arrangements relate to evidence-based clinical improvement objectives, or to impose a commercial reasonableness requirement. 85 Fed. Reg. at 77850.

However, the safe harbor still does not protect free or reduced-priced items or services that sellers provide either as part of a bundled warranty arrangement or ancillary to a warranty arrangement. Instead, it merely protects the offer and exchange of warranty remedies under a warranty arrangement, provided all of the safe harbor's conditions are satisfied. The safe harbor also protects warranties that apply to one or more items and related services only if the federally reimbursable items and services subject to the warranty arrangement are reimbursed by the same Federal health care program and in the same Federal health care program payment. *See* 42 C.F.R. 1001.952(g)(5). In OIG's view, this same program/same payment requirement protects against potential gamesmanship and cost-shifting; however, it may also create significant obstacles to protecting otherwise innocuous bundled warranty arrangements.

B. Reporting Requirements

To address concerns that the safe harbor's reporting requirement may limit the ability of sellers to offer innovative warranty arrangements, or make protection unavailable for providers that lack specific reporting obligations under FHCPs and do not file cost reports, OIG clarified that (i) the safe harbor may be used to protect warranty arrangements that span multiple years; (ii) changes in the safe harbor, *i.e.*, from "the price reduction" to "any price reduction" mean that more than one price reduction may occur pursuant to a warranty arrangement; and (iii) buyers are obligated to report price reductions in a manner compatible with the reimbursement methodology for the warrantied items or services, including circumstances in which a provider does not submit cost reports or a formal "claim for payment", unless the payor does not provide a reporting mechanism.

C. Definition of Warranty

Previously, "warranty" was defined by reference to another statute. The Final Rule defines "warranty" directly, clarifying that the warranties safe harbor is available for drugs and devices regulated under the Federal Food, Drug, and Cosmetic Act. *See* 42 C.F.R. 1001.952(g)(7). OIG makes clear that the safe harbor protects not only warranties covering a "product", but also warranties covering an item or bundle of items, or services in combination with one or more related items, as well as warranty arrangements conditioned on clinical outcomes guarantees, provided other safe harbor requirements are met. However, the new definition parallels the prior definition's language requiring a written promise that an item, bundle of items, or bundle of items and services is defect-free or will meet a specified level of performance over a specified period of time. The explicit

inclusion of warranties based on clinical outcomes guarantees is an important addition and may open the door for a variety of innovative arrangements between manufacturers and providers that align incentives to achieve desired clinical outcomes for patients.

VI. Revisions to the Safe Harbor for Local Transportation

The Final Rule amends the existing safe harbor for local transportation furnished to beneficiaries (42 C.F.R. § 1001.952(bb)), expanding mileage limits for rural areas (up to 75 miles) and eliminating mileage limits for transportation to convey patients discharged from the hospital to their place of residence, with the goal of increasing access and helping patients facing longer travel distances to obtain health care. In addition, OIG clarifies that the safe harbor is available for transportation provided through rideshare arrangements, but does not protect transportation for non-medical purposes (*e.g.*, to address social determinants of health), nor transportation of patients to any location of their choice or to another provider or facility.

VII. New Safe Harbor for ACO Beneficiary Incentives

The Final Rule codifies the statutory exception to the definition of "remuneration" as related to Accountable Care Organization ("ACO") Beneficiary Incentive Programs for the Medicare Shared Savings Program. *See* 42 C.F.R. 1001.952(kk). The exception (and codified safe harbor) clarify that an ACO may furnish incentive payments only to assigned beneficiaries. *See id.* OIG declined to add any additional conditions for purposes of satisfying the regulatory safe harbor.

VIII. Revisions to the Safe Harbor for EHR Donations

OIG finalized several changes to the EHR safe harbor, including eliminating its sunset provision to make the EHR safe harbor permanent. *See* 42 C.F.R. 1001.952(y). OIG clarified that cybersecurity software and services (with "cybersecurity" defined as "the process of protecting information by preventing, detecting, and responding to cyberattacks", 42 C.F.R. 1001.952(y)(14)(i)) fit within the safe harbor so long as the donated cybersecurity items or services are "necessary and used predominately to … protect health records," and all other requirements of the EHR exception and safe harbor are met.

OIG clarified that "interoperable" software means software that is able to "securely exchange data with, and use data from other health information technology," and "allow[s] for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law." 42 C.F.R. 1001.952(y)(14)(iii). Software can be deemed "interoperable" by a certification from the Office of the National Coordinator for Health Information Technology ("ONC"), but such certification will not be a requirement to satisfy the EHR safe harbor. OIG acknowledged that the ONC's recently published Information Blocking Rule is the more appropriate vehicle to address issues related to information blocking. As such, the Final Rule eliminates the elements of the original EHR safe harbor restricting the donor from taking any action to limit or restrict the use, compatibility, or interoperability of the donated EHR items or services. Such prohibited information blocking conduct will now be regulated only under the Information Blocking Rule.

The EHR safe harbor will continue to require a contribution from the donor of fifteen percent (15%) of costs, but the safe harbor will no longer require that the contribution be made in advance for *updates* to existing EHR systems. *See* 42 C.F.R. 1001.952(y)(11)(i). Further, the EHR safe harbor will now allow replacement of EHR technology by removing the condition that prohibits the donation of equivalent items or services.

Finally, OIG revised the EHR safe harbor to expand the types of entities that can be donors to include those entities comprised of organizations that provide "services covered by a Federal health care program and submit[] claims or requests for payment, either directly or through reassignment, to the Federal health care program." 42 C.F.R. 1001.952(y)(1)(i). Thus, entities such as parent companies of hospitals, health systems, and ACOs can donate such items and services under the protection of the EHR safe harbor.

New Beneficiary Inducement Prohibition Safe Harbor

I. New Safe Harbor for Provision of Telehealth Technologies to ESRD Patients Receiving In-Home Dialysis

The Final Rule amends the BIP's implementing regulations to codify the statutory exception for "telehealth technologies" furnished to certain in-home dialysis patients. *See* 42 C.F.R. 1003.110 (definition of "remuneration"). OIG removed most of the conditions it had included in the proposed rule to finalize an exception available to all "telehealth technologies… furnished to the individual [with end-stage renal disease who is receiving home dialysis for which payment is being made under part B] by the provider of…in-home dialysis, telehealth services, or other end-stage renal disease care to the individual, or [that] has been selected or contacted by the individual to schedule an appointment or provide services", so long as "[t]he telehealth technologies are not offered as part of any advertisement or solicitation; and…are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease." OIG also modified the definition of "telehealth technologies" to include any "hardware, software, and services that support distant or remote communication between the patient and provider…", and included physicians as a type of practitioner that can donate telehealth technologies to a patient. The final definition of "telehealth technologies" removes references to specific types of technology, limits on the type of communication (*i.e.*, now includes telephones, facsimile machines, and electronic mail systems), and the requirement that telehealth services be paid for by Medicare Part B. Further, OIG clarified that the definition means technology used to support communication between providers and patients in instances when the communication is distant or remote, and when the communication is for diagnosis, intervention, or ongoing care management. These modifications reflect OIG's understanding that the new exception is "a narrow exception to the CMP beneficiary inducement statute", by virtue of its application exclusively to telehealth technologies donated to dialysis patients, and therefore does not require substantial regulatory limiting conditions. 85 Fed. Reg. at 77865.

By operation of law, arrangements that fit in the new and modified AKS safe harbors for patient engagement and support and local transportation are also protected under the Beneficiary Inducements CMP, which excepts any remuneration that falls within an AKS safe harbor. *See* 42 C.F.R. 1003.110 (definition of "remuneration").