

**Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalties Regarding Beneficiary Inducements
(RIN 0936-AA10)
Summary of Final Rule**

On December, 2, 2020, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published in the *Federal Register* a final rule (85 FR 77684-77895) to revise safe harbors under the federal anti-kickback statute (AKS) and the civil monetary penalty (CMP) law that prohibits inducements offered to patients (beneficiary inducement CMP).

The final rule:

- Adds safe harbor protections under the AKS for certain coordinated care and associated value-based arrangements;
- Adds protections under the beneficiary inducement CMP law for certain patient engagement and support arrangements to improve quality of care, health outcomes, and efficiency of care delivery;
- Adds a new safe harbor for donations of cybersecurity technology;
- Revises the existing safe harbors for electronic health records (EHR) arrangements, warranties, local transportation, and personal services and management contracts; and
- Adds new safe harbors to codify protections for beneficiary incentives under the Medicare Shared Savings Program, and for certain telehealth technologies offered to patients receiving in-home dialysis, enacted by the Bipartisan Budget Act of 2018 (BBA 2018).

The regulations are effective January 19, 2021.

Also on December 2, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a final rule (85 FR 77492-77682) to update regulations implementing section 1877 of the Social Security Act (the physician self-referral law). Health Policy Alternatives has prepared a separate summary of that final rule.

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I. EXECUTIVE SUMMARY

OIG describes the purpose of this final regulation as removing potential barriers to more effective coordination and management of patient care and delivery of value-based care designed to improve quality of care, health outcomes and efficiency. HHS has identified the AKS and the Beneficiary Inducement CMP law, among other laws, as potentially inhibiting beneficial arrangements that may improve patient care coordination among providers and across settings. Providers, suppliers and other stakeholders are potentially discouraged from entering into innovative arrangements to improve quality, health outcomes and efficiencies as well as lower costs.

On October 19, 2019, OIG published a proposed rule to add or amend various regulatory protections under the AKS and the beneficiary inducement CMP to protect certain value-based arrangements that improve quality, outcomes, and efficiency. The proposals focused on arrangements to advance the coordination and management of patient care, with an aim to support innovative methods and novel arrangements, including the use of digital health technology such as remote patient monitoring and telehealth. OIG sought to strike the correct balance between flexibility for beneficial innovation and safeguards to protect patients and federal health care programs. Further, the agency cautions that these types of arrangements are still subject to case-by-case review, including with respect to the requisite intent of the parties.

In the final rule, OIG finalizes the proposed new and modified AKS safe harbors and the exception to the beneficiary inducements CMP with modifications and clarifications. The agency says it tried to strike the correct balance between flexibility for beneficial innovation and safeguards to protect patients and federal health care programs. The new and modified safe harbors were designed to further the goals of access, quality, patient choice, appropriate utilization, and competition, while protecting against increased costs, inappropriate steering of patients, and harms associated with inappropriate incentives tied to referrals.

OIG notes that many beneficial arrangements do not implicate the AKS statute. Other beneficial arrangements may implicate the AKS statute and may not fit into a safe harbor; OIG notes that these other arrangements may not necessarily be unlawful and will be analyzed based on the totality of the facts and circumstances, including the intent of the parties.

II. BACKGROUND

A. Anti-Kickback Statute

OIG describes the anti-kickback statute, including the penalties and fines applicable to whomever 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. As the legislation was intentionally broad, Congress later directed HHS to promulgate regulations providing safe-harbors for those innocuous commercial arrangements and business practices not subject to sanctions under the anti-kickback statute.¹ Subsequent legislation provided criteria for those safe-harbors² and a series of regulations have established a number of them in various areas. OIG lists several factors the agency considers when establishing or modifying safe harbors. Notwithstanding the beneficial impacts of arrangements potentially protected by the new and revised safe harbors, OIG remains concerned about reduced patient freedom of choice, potential decreases in provider competition, and potential benefits to providers or health care professionals that may vary inappropriately based on their ordering decisions.

Providers, health care professionals and others may seek to comply with safe harbors to assure that the business practices would not be subject to AKS enforcement actions. OIG notes that compliance with a safe harbor insulates the individual or entity from liability only under the AKS and the beneficiary inducement CMP; compliance with requirements imposed by other federal or state laws or regulations is still necessary.

B. Beneficiary Inducement CMP

OIG also describes the CMP law generally and in particular the beneficiary inducement CMP which imposes CMPs on persons who offer or transfer remuneration to a Medicare or state health care program (e.g., Medicaid) beneficiary that the person knows, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service payable in whole or in part by Medicare or the state health care program. Remuneration includes transfers of items or services for free or for other than fair market value.

Any practice that is permissible under the AKS is excepted from the definition of remuneration for the beneficiary inducement CMP; however, exceptions to the definition of remuneration for the beneficiary inducement CMP do not apply under the AKS. The BBA 2018 created a new exception to the beneficiary inducement CMP definition of remuneration for telehealth technologies furnished on or after January 1, 2019 by a provider of services or renal dialysis

¹ Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (P.L. 100-93).

² Section 205 of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191).

facility to a Medicare beneficiary with end-stage renal disease (ESRD) who is receiving home dialysis covered under Part B.

III. SUMMARY OF FINAL PROVISIONS, PUBLIC COMMENTS, AND OIG RESPONSES

A. General

OIG reports that while many comments supported its proposals, some were concerned that additional flexibility could increase risks of fraud and abuse; for example, some opposed the safe harbors for value-based arrangements citing the potential for harm due to fraud and abuse. These concerns were taken into consideration in finalizing the safe harbors.

With respect to aligning the safe harbors with exceptions to the physician self-referral law finalized in the CMS physician self-referral final rule, OIG states that it has tried to align value-based terminology and safe harbor conditions with those adopted by CMS wherever possible. However, because there are fundamental differences in the statutory structures and sanctions under the different laws, complete alignment is not possible. The AKS is an intent-based, criminal statute that covers all referrals of federal health care programs; by contrast, the physician self-referral law is a strict liability, civil law prohibiting payment by CMS for a limited set of services referred by physicians who have certain financial arrangements with the entity furnishing the service.

The safe harbors were designed to ensure protected arrangements are not disguised kickback schemes, and OIG acknowledges that for those value-based arrangements that implicate both the AKS and the physician self-referral law, the value-based safe harbors may protect a narrower universe of those arrangements than the exceptions under the physician self-referral law.

OIG states that many requirements of the final safe harbors are consistent, noting in particular the areas of cybersecurity and electronic health records. The value-based terminology is aligned in all but one respect; the definition of value-based activities has what OIG calls a slight difference in language to integrate the new rules into existing structures. However, compliance with a value-based safe harbor may require meeting conditions that are different from or in addition to those under a physician self-referral exception.

OIG rejects a suggestion to treat compliance with the physician self-referral law as a rebuttal of any implication of intent under the AKS, noting that the fact that a party complies with the physician self-referral law is not evidence that the party has or does not have the intent to induce or reward referrals under the AKS.

B. Federal Anti-Kickback Statute Safe Harbors

1. Value-Based Framework for Value-Based Arrangements

OIG provides background and a high-level description of its framework for value-based arrangements protected under the proposed new and revised safe harbors. This is designed to

remove what it refers to as real or perceived barriers to industry-led innovation to deliver more efficient and better coordinated health care and to help speed up the transition from volume-based to value-based reimbursement. Key components of this transition are better care coordination across the continuum of care, reduced duplication of services, and open sharing of health data (consistent with privacy and security rules).

OIG finalizes its value-based framework under which greater flexibilities are provided to the parties when they assume more downside financial risk for the cost and quality of care. This is referred to as the tiered value-based framework under which the requirements of the three safe harbors vary based on the degree of risk assumed by the parties. Modifications to the specific terminology developed for the framework are described below.

Generally, the term “value-based” is used in a non-technical way to indicate value achieved through improved care coordination, improved health outcomes, lower costs (or reduced cost growth), and improved efficiencies. The final rule does not include a definition of the term “value” itself; OIG believes that stakeholders and parties to value-based arrangements are best positioned to determine value. However, the agency believes the concept of value is adequately expressed in some of the definitions of pertinent terminology, such as “value-based purpose” or “value-based activity.”

Responding to concerns that the safe harbors may lead to increased fraud and abuse, OIG notes that it has included safeguards in each of the value-based safe harbors to prevent against medically unnecessary care, cherry-picking, stinting on care, coercive marketing, or limitations on clinical decision-making. For example, certain entities that pose heightened program integrity risks and that are less likely to be at the front lines of health care are either ineligible to rely on the safe harbor or subject to additional safeguards. Similarly, the absence of traditional safeguards of fair market value or broad prohibitions on taking into account volume or value or referrals caused concern among some commenters; OIG believes it has included sufficient additional requirements to the safe harbors to address potential fraud and abuse risks.

The safe harbors included in the final rule address a variety of scenarios, covering value-based arrangements for publicly and privately insured patients. Noting that the AKS does not generally apply to arrangements limited solely to patients who are not federal health care program beneficiaries, if an offer of remuneration is intended to pull through referrals of federal health care program beneficiaries or business, the AKS could be implicated.

OIG cautions that all safe harbor conditions must be met precisely for the protection to apply. If a particular arrangement does not fit into one of the three value-based safe harbors, parties may look to other safe harbors, seek an OIG Advisory Opinion, or look to the language of the statute itself. Additionally, the federal safe harbors do not preempt any applicable state law unless that state law incorporates the federal law by reference.

The value-based safe harbors are effective January 19, 2021 and are prospective in nature; they may not be applied retrospectively.

2. Value-Based Terminology (§1001.952(ee)(14))

OIG finalizes its proposal to define terms that are used consistently in value-based safe harbors and that are intended to work with one another to describe the universe of value-based arrangements potentially eligible for safe harbor protection and of individuals and entities that can engage in protected arrangements. In response to comments, some of the definitions are modified in the final rule or provide additional clarity.

Value-based arrangements are conducted under the auspices of a value-based enterprise (VBE) which essentially is a network of participants that agree to collaborate, for example, to improve care coordination, increase efficiency, or improve quality and outcomes.

a. Value-Based Enterprise (VBE)

As finalized, the term VBE means two or more VBE participants:

- Who collaborate to achieve at least one value-based purpose;
- Each of which is a party to a value-based arrangement with the other or with at least one other VBE participant in the VBE;
- That have an accountable body (e.g., Board of Directors) or person (or entity) responsible for financial and operational oversight of the VBE; and
- That have a governing document that describes the VBE and how the VBE participants intend to achieve the VBE's value-based purpose(s).

The definition is aligned with the definition finalized by CMS for purposes of the physician self-referral law. It is intended to encompass a wide range of VBEs, including larger entities that function as ACOs; it also encompasses Indian health programs. OIG confirms that VBE participants may join and leave a VBE at any time as long as the VBE has at least two participants. It also clarifies that the terms and definitions it finalizes for use for the value-based safe harbors do not apply outside the context of those safe harbors; for example, these definitions would not apply to state Medicaid programs and their administration of existing value-based arrangements. In response to a comment, OIG notes that the final rule does not specify how VBE participants must prove they are collaborating to achieve a value-based purpose.

(1) Accountable Body or Responsible Person

OIG views the accountable body or responsible person as serving as a gatekeeper to ensure VBE participants are playing a legitimate role in the VBE and its arrangements. Further, the accountable body or person would identify and address program integrity issues. The OIG believes the accountable body or responsible person criterion is especially important to ensure that the arrangements operate for value-based purposes because there is no similar program for oversight of VBEs to the oversight that applies under CMS-sponsored models. Oversight may include monitoring whether VBE participants are furthering care coordination and management for the target patient population.

However, in the final rule, the OIG declines to assign a number of specific requirements or duties to the accountable body, preferring instead to afford flexibility to accommodate a broad range

and scope of VBEs. Thus, it does not prescribe requirements for (i) the manner in which accountable bodies are formed; (ii) specific oversight duties of the accountable body; or (iii) requirements for VBE participants to affirmatively recognize the accountable body's oversight role, agree in writing to cooperate with the accountable body's oversight efforts, or report data to the accountable body. Additionally, OIG does not require the VBE (or its accountable body) to establish compliance programs, to designate a compliance officer, or to periodically review patient medical records; however, it does believe these are best practices. The accountable body itself serves as the oversight body that performs a compliance function.

The agency also intends for the accountable body or responsible person criterion to be tailored to the size and complexity of the VBE; for example, a larger VBE may wish to create a separate governing body to serve as the accountable body.

The definition does not require the accountable body or person to be independent of the interests of individual VBE participants or to have a distinct duty of loyalty to the VBE. A distinct duty of loyalty could pose conflicts of interests for accountable body members that are, or are employed by, a VBE participant. However, OIG believes the accountable body or responsible person must act to further the VBE's value-based purpose, and parties may include this duty in the contractual arrangements.

The accountable body or responsible person is not required to submit data to HHS for safe harbor compliance though OIG clarifies that it has the authority to request that data for oversight purposes. Finally, citing administrative burden concerns, OIG does not require the accountable body to implement a process for patients to express concerns or to ensure that VBE participants secure informed consent for each patient treated within the VBE.

(2) Governing Document

This criterion is intended to provide transparency on the structure of the VBE, the value-based purpose(s) of the VBE, and the VBE participants' roadmap for achieving the purpose(s). It does not have to be formal bylaws, and written documentation of the terms of a value-based arrangement may suffice if it describes the enterprise and how the parties intend to achieve the value-based purpose(s).

OIG clarifies that the governing document must be a single document; a collection of writings will not satisfy this criterion. Noting that the definition does not prescribe a particular format and affords flexibility to accommodate varying sizes and natures of VBEs, the agency believes that a single governing document ensures there is a clearly identifiable governance structure for the VBE which may be more easily amended over time as the value-based activities or participants evolve.

b. Value-Based Arrangement

In the final rule, CMS modifies the text of its proposed definition to clarify that only the VBE and one or more of its VBE participants, or VBE participants in the same VBE, may be parties to a value-based arrangement. OIG further clarifies that it does not preclude protection for

arrangements between entities that have common ownership either under this definition or under the conditions of the value-based safe harbors. The definition of value-based arrangement (which covers commercial and private insurer arrangements) is an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:

- The value-based enterprise and one or more of its VBE participants; or
- VBE participants in the same value-based enterprise.

The modification is intended to clarify that the term value-based arrangement captures arrangements for care coordination and certain other value-based activities among VBE participants within the same VBE.

The definition is intended to ensure that each value-based arrangement is aligned with the value-based purpose(s) of the VBE as well as subject to the VBE's financial and operational oversight. Further, the value-based arrangement (and its value-based activities) must be tailored to meet the needs of a defined patient population.

OIG cautions that qualification as a value-based arrangement is necessary to protect remuneration exchanged under the arrangements; however, that is only the first part of the analysis. The value-based arrangement must then satisfy all the conditions of an applicable safe harbor. In response to a comment, OIG notes that neither the definition of value-based arrangement nor any of the safe harbor conditions preclude the use of nondisclosure agreements. Another commenter requested a 90-day grace period for VBE participants to execute value-based arrangements; OIG declines to do so believing it to be unnecessary.

The definition of value-based arrangement is aligned with the definition finalized by CMS for purposes of the physician self-referral law.

c. Target Patient Population

A defined patient population is referred to as the target patient population and is defined as follows:

An identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:

- Are set out in writing in advance of the commencement of the value-based arrangement; and
- Further the VBE's value-based purpose(s).

OIG finalizes the definition without any modifications. The requirement for legitimate and verifiable criteria set out in writing in advance is intended to ensure that the selection process is transparent and that VBE participants choose the patient population in an objective manner that furthers the value-based purpose(s) of the arrangement.

The target patient population definition is not limited to federal health care program beneficiaries. OIG had considered whether to limit the definition to patients with a chronic condition or shared disease state, but it declines to do so in the final rule because it prefers to

afford greater flexibility to VBEs. Additionally, the definition aligns with CMS' definition of the same term.

Use of the adjective legitimate is intended to convey that the target patient population selection process is based on *bone fide* criteria that further a value-based purpose; OIG confirms that this criterion is sufficiently flexible to be based on social determinants of health. The agency also clarifies that targeting lucrative patients (cherry-picking) or avoiding high-cost or unprofitable patients (lemon-dropping) are not legitimate criteria.

OIG had sought comment on whether to require payor involvement in the target patient population selection process; citing issues raised by commenters relating to operational infeasibility, the agency does not include such a requirement.

Parties may amend their selection criteria to modify them over time. Those modifications may only be made prospectively; however, OIG states that no amendment is required to attribute patients retroactively to the target patient population, provided such patients meet the selection criteria established prior to the commencement of the value-based arrangement.

In response to a comment, OIG states that nothing in the definition precludes parties to a value-based arrangement from identifying the target patient population as the entire patient population that a particular VBE participant services. However, it notes that selecting the parties' entire patient population would need to be closely scrutinized to ensure that board selection criteria is legitimate and necessary to achieve the value-based purpose of the arrangement.

d. Value-Based Activity

OIG finalizes its definition of value-based activity without modification. The term is defined as follows:

- (A) Any of the following activities, provided the activity is reasonably designed to achieve at least one value-based purpose of the VBE:
 - 1) The provision of an item or service;
 - 2) The taking of an action; or
 - 3) The refraining from taking an action; and
- (B) Does not include the making of a referral

This definition differs from CMS' definition of value-based activity because CMS does not specify that the making of a referral is not a value-based activity. This is because the physician self-referral law has a separate definition of referral. OIG clarifies that making referrals, or documenting reasons for referrals, without also engaging in a value-based activity is not sufficient to meet the requirements of the definition because making referrals is not a value-based activity. However, the agency clarifies that the exclusion of referrals from the definition is not intended to interfere with preferred provider networks; OIG intends to require parties to engage in activities other than making referrals to be protected under the safe harbor.

OIG emphasizes that its definition is intended to be broad and to include actions parties take or refrain from taking under a value-based arrangement to further a value-based purpose; this is

designed to encourage parties to innovate when developing these activities. The definition does not require that an activity achieve a value-based purpose; rather, it requires that the activity be reasonably designed to achieve that purpose. Reasonably designed means that parties should fully expect the value-based activities they develop to further one or more value-based purposes.

While the agency had considered several modifications to its proposed definition, as noted earlier, it does not finalize any changes. For example, OIG declines to expressly exclude any activity that results in information blocking in the definition because parties subject to the information blocking regulations must comply with them. Nothing in the safe harbor changes that obligation.

e. VBE Participant

OIG adopts a different approach to addressing concerns about the risk of fraud and abuse posed by certain entities under the value-based safe harbors and the patient engagement and supports safe harbor. In the proposed rule, the definition of VBE participant would have specifically excluded several entities from the definition of VBE participant to make them ineligible for protection under those safe harbors. The definition of VBE participant in final rule permits any individual or entity (other than a patient) that engages in at least one value-based activity as part of a value-based enterprise to be included in the definition, including those entities that the agency believes pose a higher risk of fraud and abuse. However, within each value-based safe harbor and the patient engagement and supports safe harbor, the applicable safe harbor regulation identifies entities that may not rely on the particular safe harbor to protect remuneration exchanged with a VBE or VBE participant. The final definition reads as follows:

VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient.

The final definition mostly aligns with CMS' definition with two exceptions: 1) OIG uses the term individual instead of person (as the latter is used in the CMS rule), and 2) CMS does not exclude patients. With respect to patients, OIG clarifies that patient means an individual acting in their capacity as a patient and includes the patient's family members or others acting on the patient's behalf.

In response to a comment, OIG clarifies that nothing in the definition of VBE participant precludes an integrated health delivery system from creating a value-based arrangement within its own system.

In the proposed rule, OIG contemplated how to provide safe harbor protection for technology companies under the definition of VBE participant. In the final rule, under the care coordination arrangements safe harbor only, OIG protects remuneration in the form of digital health or other technology exchanged by a limited technology participant with a VBE participant or the VBE itself. (This limited pathway for safe harbor protection is described in paragraph (2) below.)

The revised approach to addressing OIG's concerns about the risks of fraud and abuse posed by certain entities divides the universe of VBE participants into three categories:

- VBE participants that may rely on the value-based safe harbors for all types of arrangements that meet safe harbor conditions.
- Limited technology participants that may only rely on the care coordination arrangements safe harbor for arrangements involving digital health technology.
- VBE participants that are ineligible to rely on any of the value-based safe harbors for any type of arrangement.

OIG states it adopted a risk-based approach to determine the scope of the applicability of the value-based safe harbors; it identified ineligible entities based on several attributes, including products and services they offer, their business structures, and the extent to which they are on the front lines of care coordination and treatment decisions.

(1) Entities Ineligible for Safe Harbor Protection

Generally, the following entities are deemed ineligible for safe harbor protection under the final rule: pharmaceutical companies; pharmacy benefit managers (PBMs); laboratory companies; compounding pharmacies; manufacturers of devices or medical supplies; DMEPOS companies; and medical device distributors and wholesalers. However, with respect only to the care coordination arrangements safe harbor, manufacturers of devices and medical supplies and DMEPOS companies may, as limited technology participants, protect certain digital health technology arrangements to allow them to participate in such arrangements. Throughout the preamble, OIG reiterates that while these entities may still be VBE participants and participate in care coordination or value-based care, any remuneration exchanged by these entities under those arrangements is not protected by the value-based safe harbors.

Pharmaceutical companies. OIG's decision to exclude pharmaceutical companies is based in part on a concern about the potential for pharmaceutical manufacturers to use the value-based safe harbors to protect arrangements intended to market their products or inappropriately tether clinicians to the use of a particular product rather than as a means to create value by improving the coordination and management of patient care.

Pharmacy benefit managers. OIG believes PBMs are less likely to be on the front line of care coordination and treatment decisions notwithstanding their indirect role in supporting value-based care and coordinating care through medication adherence programs or formulary design. It also finds that PBM arrangements (e.g., establishing benefit networks and associated management services with payors, pharmaceutical companies and pharmacies) raise different program integrity concerns which would require different safeguards. However, OIG clarifies that payors that own, are affiliated with, or under common ownership with a PBM are eligible for safe harbor protection. Similarly, a payor that carries out its own pharmacy benefit management services in administering the plan is eligible for safe harbor protection; the PBM functions would be considered ancillary to the payor's core business of administering the plan.

Laboratory companies. The term used in the final rule to describe this category of ineligible entity is laboratory companies in lieu of clinical laboratory. It is intended to describe companies

that operate clinical laboratories and that bill for their laboratory services through their own billing numbers. The term does not extend to clinical laboratories that are owned and operated through other types of entities, such as hospitals and physician practices, where the operation of the clinical laboratory is not the entity's predominant or core line of business. For example, a hospital will not be considered a laboratory company if the laboratory services it furnishes through a laboratory that is a "department of the hospital" under Medicare are billed through the hospital's provider number.

Medical Device Manufacturers, Distributors, and Wholesalers

OIG does not believe that medical device manufacturers, distributors, or wholesalers are as directly engaged in care coordination activities as providers and clinicians; it also has concerns based on past law enforcement experience about the potential use of the value-based safe harbors to protect arrangements intended to inappropriately tether clinicians to the use of a particular product which may not be in the patient's best clinical interest. However, OIG does provide for a limited exception to protect the exchange of digital health technologies by manufacturers of devices and medical supplies (and DMEPOS companies) under the care coordination arrangements safe harbor (described below); this is because OIG foresees that digital health technologies hold promise for improving care coordination and management.

The final rule adds a definition of the term "manufacturer of a device or medical supply" at §1001.952(ee)(14)(iv) as follows:

(iv) Manufacturer of a device or medical supply means an entity that meets the definition of applicable manufacturer in 42 CFR 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or medical supply in 42 CFR 403.902, but not including entities under common ownership with such entity.

In citing 42 CFR 403.902, OIG relies on CMS's definition of "applicable manufacturer" that is used for purposes of the Open Payments provisions of the Patient Protection and Affordable Care Act because the agency believes it effectively captures the universe of entities it seeks to designate as limited technology participants and those that will otherwise be carved out of safe harbor protection.

OIG clarifies that to capture distributors and wholesalers that do not hold title to the device or medical supply on the ineligible entity list, the ineligible entity list in each value-based safe harbor includes a separate category for "a medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies."

The agency adopts its policy that physician-owned distributorships are not eligible for safe harbor protection. They are captured by one of two categories on the ineligible entity lists in each of the value-based safe harbors: 1) manufacturers of devices or medical supplies or 2) medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies.

DMEPOS companies

While OIG believes that DMEPOS companies may play a role in value-based arrangements, especially in the post-acute care arena, and that they provide health technology services that facilitate care coordination and management, past law enforcement experience leads the agency to generally add these companies to the ineligible entity list. The one limited exception is protection under the care coordination arrangements safe harbor for the exchange of digital health technologies by DMEPOS companies; OIG refers to this as the limited technology participant pathway.

The final rule speaks in terms of entities or individuals that sell or rent DMEPOS; this is intended to focus on the nature of the business (i.e., the sale or rental of DMEPOS) to more accurately capture the entities that the agency considers higher risk. OIG clarifies that the carve out for DMEPOS companies does not apply to a pharmacy or to a physician, provider, or other entity that primarily furnishes services. Thus, these parties may rely on the three value-based safe harbors to the same extent as other eligible VBE participants.

Compounding pharmacies

Because of profound concerns about fraud and abuse in the compounding pharmacy industry, compounding pharmacies are not eligible for protection under the value-based safe harbors or under the safe harbors for patient engagement tools and supports (at §1001.952(hh)) and outcomes-based payments (at §1001.952(d)).

The agency distinguishes between compounding pharmacies and other pharmacies that may compound drugs during the course of business. A compounding pharmacy includes entities that primarily compound drugs or primarily dispense compounded drugs, such as topical pain creams, with or without licensure or valid prescriptions. OIG believes that most retail pharmacies and community pharmacies do not primarily compound drugs or primarily dispense compounded drugs and thus may avail themselves of protections under the various safe harbors. The agency does not establish a standard for what constitutes primarily compounding drugs or primarily dispensing compounded drugs. Where an entity has multiple lines of business, one of which is a compounding pharmacy, it should use the multiple lines of business test (described in paragraph (3) below) to determine eligibility for protection under the safe harbors.

(2) Digital Health Technologies and Limited Technology Participants

OIG sought to afford protection for companies that provide mobile health and digital technologies to physicians, hospitals and patients to coordinate and manage patient care. In the final rule, it offers a narrow pathway for certain medical device manufacturers and DMEPOS companies to exchange digital health technologies. Specifically, limited technology participants may exchange digital health technologies with a VBE or VBE participant under the care coordination arrangements safe harbor only.

The term limited technology participant means a VBE participant that is a manufacturer of a medical device or supply or a DMEPOS company; however, the definition includes language to specifically exclude physician-owned distributorships.

The term digital health technology is defined in broad terms 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. The definition specifically includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose. OIG intends to protect a wide range of mobile and digital technologies for care coordination and management, such as remote monitoring, predictive analytics, care consultations, and telehealth as well as other technologies that may not yet be developed.

The agency adds safeguards for these limited technology participant arrangements. The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant. OIG feels this condition addresses program integrity concerns raised by manufacturers and companies that rely heavily on practitioner referrals. This condition only applies to limited technology participant arrangements under the care coordination arrangements safe harbor.

OIG clarifies that VBE participants that are not on the ineligible entity list may exchange digital health and other technologies under the care coordination arrangement, and they are not subject to the additional safeguard described above that applies only to limited technology participants. It also clarifies that, by definition, limited technology participants may not rely on the safe harbor to exchange other forms of remuneration.

(3) Entities with Multiple Business Lines

Commenters sought guidance on how entities with multiple business lines or with multiple regulatory classifications would be viewed for purposes of safe harbor eligibility, including for example an entity or health system that operates both eligible and ineligible business lines. Others requested clarification on how the eligibility standards would be impacted by corporate affiliations or shared ownership. OIG responds that eligibility of a particular entity for protection under the safe harbor is assessed at the corporate level by considering the entity's predominant or core lines of business. The preamble includes several examples.

- A pharmacy operated within the same corporate entity as a pharmaceutical manufacturer would not be eligible to rely on the value-based safe harbors if the entity's core function is pharmaceutical manufacturing.
- A corporation that manufactures devices as its predominant function and also manufactures pharmaceutical products incorporated into or integral to a medical device is treated as a device manufacturer and may be eligible for protection as a limited technology participant.

The agency notes that large corporations with multiple business lines within a single corporate entity must assess whether they have a predominant or core business; the OIG does not provide

or suggest standards for making those determinations but expects parties to use reasonable methods in doing so.

OIG also provides the following examples for other corporate circumstances:

- A pharmacy (other than a compounding pharmacy) under common ownership with a PBM would be eligible to rely on the value-based safe harbors.
- A health system comprised of multiple corporate entities is assessed by considering each line of business, and the fact that some lines of business are ineligible does not disqualify others eligible lines of business from protection under the value-based safe harbors.

The agency cautions that, apart from any value-based arrangement, transfers of remuneration from one entity to another may implicate the AKS if those transfers are intended to induce or reward referrals for items and services covered by a Federal health care program. This potential liability arises even where the recipient subsequently uses the remuneration in a manner that is protected by a safe harbor.

f. Value-Based Purpose

CMS finalizes its proposed definition of value-based purpose without modification. The term means any of the following:

- Coordinating and managing the care of a target patient population.
- Improving the quality of care for a target patient population.
- Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population.
- 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.

The definition is intended to include infrastructure investment and operations needed to redesign care delivery to better coordinate care for patients across settings.

OIG clarifies several points. First, nothing in the definition is designed to tell parties how to define or measure quality though certain conditions under one or more value-based safe harbors may do so. Second, neither this definition nor the value-based safe harbors require achievement of the value-based purpose; value-based purpose when read in conjunction with value-based activity requires activities reasonably designed to achieve the value-based purpose. Third, the definition itself does not foreclose internal cost-savings arrangements; however, parties should analyze whether those arrangements further at least one purpose in the definition and whether those arrangements are permitted under the conditions of a value-based safe harbor.

g. Coordination and Management of Care

The definition of care coordination and management (or coordinating and managing care) in the final rule is modified from what OIG had proposed. It means the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or

more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

The definition is revised to clarify that the VBE itself may engage in the care coordination and management and that efforts to improve efficiency can be part of care coordination and management. The regulation text changes also clarify that achievement of the goal(s) is not a requirement; rather, the efforts must be designed to achieve those goals.

OIG notes that many activities (such as patient monitoring, patient diagnostic activities, patient treatment, communication related to patient activities, or predictive analytics) may constitute care coordination and management; its intention is to require beneficial activities beyond a mere referral of a patient or ordering of an item or service. Coordination and management of care requires some additional, deliberate effort and sharing of information, across two or more parties, that is designed to augment care delivery.

OIG clarifies the statement it made in the proposed rule that the provision of billing or administrative services would not be considered management of patient care; instead, it considers “any billing or financial management services arrangement that is characterized as facilitating the coordination and management of patient care to be outside the scope of this definition for purposes of this rule.” It defines financial services for purposes of this clarification as bookkeeping operations, contract management, revenue cycle management, or other similar activities. It addresses this issue by adding new conditions in the care coordination arrangements safe harbor (§1001.952(ee)(1)(iii)(A)) as opposed to modifying the definition that applies more broadly.

With respect to whether remuneration in the form of cybersecurity items or services should meet the definition of care coordination and management, the final rule clarifies that sharing of cybersecurity items and services alone does not meet the definition of care coordination and management. However, when provided in conjunction with, for example, health information technology that incorporates cybersecurity technology, it may qualify.

OIG notes that the definition applies only in the context of the safe harbor regulations; it does not affect CMS’ interpretation or definition of the term or concept under the physician self-referral law or otherwise.

3. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor (§1001.952(ee))

CMS finalizes a new safe harbor for care coordination arrangements designed to protect in-kind remuneration exchanged among qualifying VBE participants with value-based arrangements. (Monetary remuneration associated with care coordination may be protected under other proposed safe harbors.) The safe harbor does not require parties to bear or assume downside financial risk. There are numerous listed conditions parties must satisfy to qualify for safe harbor protection, and each offer of remuneration must be analyzed separately for compliance. The final rule includes a few modifications to the safe harbor.

The safe harbor includes conditions related to commercial reasonableness, outcomes measures, written documentation, record retention, monitoring, termination, marketing and patient recruitment, and diversion and reselling of remuneration. Protected remuneration must be used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Recipients must pay 15 percent of the offeror's cost or 15 percent of the fair market value of the remuneration. OIG carves out patients and ineligible entities described above from the safe harbor; however, it finalizes a limited pathway for safe harbor protection for digital health technology arrangements for manufacturers of devices and medical supplies and DMEPOS companies (described above). This safe harbor protects only in-kind remuneration exchanged between a VBE and VBE participant or between VBE participants; it does not protect remuneration provided to patients. Unlike the two risk-based value-based safe harbors, there is no pre-participation (or phase-in) period under the care coordination safe harbor. The preamble includes several examples of arrangements that could qualify for protection under the safe harbor.

a. Outcome Measures (§1001.952(ee)(4))

As finalized, VBE participants must establish one or more legitimate outcome or process measures against which the recipient will be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population based on clinical evidence or credible medical or health sciences support.

The measures must include one or more benchmarks related to improving (or maintaining improvement in) the coordination and management of care for the target patient population, and they must relate to the remuneration exchanged under the value-based arrangement. However, the measures may not be based solely on patient satisfaction or patient convenience though measures of patient experience may, under certain circumstances, be used on their own.

The outcome or process measure and its benchmark must be monitored, periodically assessed, and prospectively revised, as necessary, so that working towards the measure continues to advance the coordination and management of care of the target patient population. This condition is intended to ensure that the measures have a close nexus to the value-based activities and to the needs of the target patient population.

The condition as finalized includes several modifications from OIG's proposal. In response to comments, OIG adds process measures; substitutes "legitimate" for "specific evidence-based" and "valid" as a standard for the measures; and requires that the outcome or process measures be based on clinical evidence or credible medical health sciences support. OIG agrees with stakeholders who found the term evidence-based to be too restrictive and the term valid to be too subjective. The agency proposed the language to prevent the use of sham measures; it believes that using the standard legitimate (and its common sense meaning) in combination with a requirement that the measures be based on clinical evidence or credible medical or health sciences support provides a more flexible standard yet still protects program integrity. In using the term "health sciences," OIG intends to include public health, health informatics, research and development, and sciences that look at the treatment and prevention of diseases.

The measures condition permits parties to select both clinical and non-clinical measures, whether generated internally or externally, and will allow participants to select up-to-date outcome or process measures over time. The measures do not have to be independently validated by a third-party source, such as a medical journal, though OIG believes that it would be a best practice to do so. Parties must document the measures selected and the clinical evidence, credible medical support, or credible health science support upon which they relied in making the selection by providing a description of the measures in a signed writing. The parties must also make available to HHS, upon request, all materials and records sufficient to establish compliance with the safe harbor conditions; however, OIG confirms that the measures themselves do not have to be made available to the public.

Parties may select a measure applicable to the entire target patient population or select different measures for different segments of that population. However, the parties must reasonably anticipate that all the measures collectively will advance the care coordination and management of the entire population. OIG also clarifies that the parties need not successfully achieve the measure(s) they select to qualify for protection; however, they must monitor and periodically assess them and potentially revise the measures and benchmarks. This contrasts with the personal services and management contracts safe harbor (§1001.952(d)(2)) that requires agents to achieve the selected outcome measure to qualify for payment.

In the proposed rule, the agency considered requiring measures to be rebased where feasible; for the final rule, it substitutes the term *revise* which is a broader term to achieve the policy goal of ensuring that measures are updated or changed to advance improvements in care coordination. OIG notes that the term *revise* can include rebasing. It does not establish a specific time period for revising measures, but it clarifies that revising must be done prospectively. OIG believes the safe harbor requirements for measures is sufficiently flexible to address information technology (IT) arrangements; thus, separate outcome measure requirements for these arrangements are not required. The agency does not place a time limit on the use of IT-related remuneration under this safe harbor.

b. Commercial Reasonableness (§1001.952(ee)(2))

The value-based arrangement must be commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE. In the final rule, OIG does not define a commercially reasonable arrangement. The requirement focuses on ensuring parties structure the terms of their value-based arrangement (including the amount of the remuneration) in a manner that is calibrated to achieve the parties' legitimate business purposes. The agency emphasizes that the value-based arrangement must be commercially reasonable when considering all value-based arrangements in the VBE.

For those commenters that objected to the commercial reasonableness condition, the agency notes that there is no requirement for the remuneration to be consistent with fair market value and that the remuneration may take into account the volume of patients in the target patient population or the value of referrals or other business generated between the parties resulting from referrals of the target patient population. Thus, OIG finds that the commercial reasonableness condition is an appropriate safeguard.

Because there are multiple dimensions to commercial reasonableness, including financial and nonfinancial terms of an arrangement, OIG notes that an arrangement may be commercially reasonable even where it does not result in profit for one of the parties.

c. Writing (§1001.952(ee)(3))

OIG finalizes a requirement for the value-based arrangement to be set forth in a writing and signed by all the parties before, or contemporaneous with, the beginning of the arrangement (or a material change to an arrangement) with several modifications. Minimum requirements for the writing include the following (modifications are shown in italic font):

- *The value-based purposes of the value-based activities to be undertaken by the parties;*
- The value-based activities to be undertaken by the parties;
- The term of the arrangement;
- The target patient population;
- A description of the remuneration;
- *Either (i) the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or (ii) the fair market value of the remuneration;*
- The percentage *and amount* contributed by the recipient;
- If applicable, the frequency of the recipient's contribution payments for ongoing costs; and
- The outcome *or process* measure(s) against which the recipient will be measured.

The writing requirement may be satisfied by a collection of documents; however, that collection must be in place in advance of or contemporaneous with the beginning of the value-based arrangement. If any material term (e.g., an outcome or process measure) changes during the course of the arrangement, parties must set forth those changes in a signed writing or collection of documents before beginning the modified arrangement. OIG clarifies that each value-based arrangement must be signed by all parties to the arrangement; the VBE's signature alone does not satisfy the writing requirement.

Though OIG had not proposed documentation of the value-based purpose of the value-based activities under the arrangement, it includes this condition in the final rule. It believes it is a logical outgrowth from the requirements for this safe harbor. Because of the requirement for recipients to contribute 15 percent of the cost of the remuneration, parties must document either the fair market value of the remuneration or the offeror's cost of the remuneration (including the reasonable accounting methodology used to determine the cost), depending on the methodology used by the parties to determine the contribution amount.

d. Limitations on Remuneration (§1001.952(ee)(1))

OIG finalizes, in some cases with modifications, several restrictions for the remuneration. Remuneration under this safe harbor must:

- Be in-kind;

- Be 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; and
- Not be exchanged or used—
 - More than incidentally for the recipient’s billing or financial management 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.

(1) In-Kind

Only in-kind, nonmonetary remuneration is protected. The safe harbor does not protect ownership or investment interest in the VBE or any distributions related to ownership or investment interest. Those seeking protection for investment interests may seek protection under other safe harbors (e.g., safe harbor for investment interests at §1001.952(a)). OIG acknowledges that this requirement under this safe harbor differs from the approach taken by CMS though it notes that both risk-based valued-based safe harbors protect both monetary and non-monetary remuneration. Other safe harbors, such as the one for personal services and management contracts and outcomes-based payments protect certain monetary remuneration.

(2) Remuneration used to engage in value-based activities

Noting that in-kind remuneration may indirectly benefit patients outside the scope of the value-based arrangement (i.e., spillover benefits), OIG finalizes its proposals, with modification, that this indirect benefit does not jeopardize the safe harbor protection as long as the parties primarily use the remuneration for its intended purpose(s). OIG agrees that prohibiting spillover benefits is unworkable; instead, the final rule adds a condition that the remuneration exchanged result in no more than incidental benefits to persons outside of the target patient population.

OIG provides a detailed response to a query about how a multi-function device could meet the “predominately used” test under the safe harbor. Assuming the device is furnished by one VBE participant to another and meets the other requirements of the safe harbor, OIG believes that protection would be based on the particular facts and circumstances. The threshold query is whether the functionalities predominantly further value-based activities directly connected to care coordination and management of the target patient population. The fact that some functionalities do not further those activities is not the end of the analysis; for example, if those functionalities could be disabled, then the exchange of the device could be protected. If the device is provided directly by a VBE participant to a patient, it could be protected under the patient engagement and supports safe harbor.

OIG had proposed a condition at §1001.952(ee)(7) requiring that the value-based arrangement be directly connected to the coordination and management care of the target patient population. The agency does not adopt that requirement because it believes it would duplicate the requirements finalized in the rule.

(3) No furnishing of medically unnecessary items or services or reduction of medically necessary items or services

OIG believes that remuneration that induces a provider to order or furnish unnecessary services is inherently suspect. It further states that reductions in medically necessary services are contrary to the purpose of this rulemaking and may be a violation of the CMP law gainsharing provision. It proposed a requirement that the remuneration not be used to induce medically unnecessary services or to reduce medically necessary services. In the final rule, OIG expands this requirement to apply to the value-based arrangement rather than merely the remuneration and clarifies it applies to items as well as services.

(4) No remuneration from individuals or entities outside the applicable VBE

This condition in the proposed rule is not finalized. It was intended to ensure that protected value-based arrangements are closely related to the VBE, that VBE participants are committed to the VBE and working to achieve the goals of the arrangement, and that non-VBE participants do not indirectly use the safe harbor to protect arrangements designed to influence referrals or decision-making of VBE participants. On balance, OIG does not believe the condition would appreciably add to program integrity and it may create unnecessary practical impediments.

e. Taking into Account the Volume or Value of, or Conditioning Remuneration on, Business or Patients Not Covered under the Value-Based Arrangement (§1001.952(ee)(5))

OIG finalizes without modification its proposal to prohibit the offeror of the remuneration from taking into account the volume or value of, or from conditioning remuneration on either of the following:

- Referrals of patients who are not part of the target patient population; or
- Business not covered under the value-based arrangement.

The intent is to prevent remuneration offered under the guise of a value-based arrangement when it is actually intended to induce patient referrals or business not covered under the arrangement. OIG clarifies that value-based care (including coordinated care) may take into account the volume of patients in the target patient population or value of referrals or other business generated between the parties resulting from referrals of the target patient population.

f. Contribution Requirement

In the final rule, safe harbor protection is conditioned on the recipient's payment of at least 15 percent of the offeror's costs of the in-kind remuneration (determined using any reasonable accounting methodology) or the fair market value of the remuneration. The rationales for this requirement are (i) to increase the likelihood that the remuneration is actually used for the care coordination and management of the target patient population; (ii) to ensure the remuneration is tailored to the recipient; and (iii) to promote the recipient's vested interest in achieving the intended purpose of the arrangement. Payment must be made in advance for one-time costs and at reasonable, regular intervals for ongoing costs; for the latter, the frequency of the payment intervals must be documented in writing.

OIG modified its proposal by adding the option to calculate the recipient's contribution based on the fair market value of the remuneration to provide additional flexibility. It clarifies that there is no requirement for an independent valuation of fair market value, and it specifies that the test is fair market value under generally accepted valuation methodologies and not fair market value to the recipient as proposed.

OIG declines to eliminate, lower or provide exceptions for the 15 percent contribution amount. It notes that the same level of recipient contribution is required under the EHR safe harbor. Where the contributions flow in both directions within a care coordination arrangement (from the offeror to the recipient and the recipient to the offeror), both streams must be assessed for protection under the safe harbor, and, if protected, each stream must satisfy the contribution requirement (which could in some circumstances be done through offsets). The agency also notes that it would be reasonable for VBE participants that are sharing in-kind remuneration provided by the VBE or another VBE participant to reasonably and in good faith allocate the "offeror's cost for the in-kind remuneration" or the "fair market value" of the shared resources between the various VBE participants sharing in the resources.

g. Direct connection to the coordination and management of care

OIG does not finalize its proposal to include at §1001.952(ee)(7) a requirement that the arrangement have a direct connection to the care coordination and management of the target patient population. As noted above, OIG requires that remuneration must be used predominately to engage in value-based activities. Thus, the proposed direct nexus requirement would have been duplicative.

h. Preserving clinical decision-making (§1001.952(ee)(7))

OIG seeks to ensure that VBE participants maintain their independent medical or professional judgment to make clinical decisions in the best interests of their patients and to preserve patient freedom of choice. Under the final rule, a value-based arrangement may not limit a VBE participant's ability to do any of the following:

- Make decisions in the best interests of its patients;
- Direct or restrict referrals to a particular provider, practitioner, or supplier if:
 - A patient expresses a preference for a different practitioner, provider, or supplier;
 - The patient's payor determines the provider, practitioner, or supplier; or
 - Such direction or restriction is contrary to applicable Medicare and Medicaid law;or
- Induce parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient.

OIG does not intend for these requirements to prevent VBEs or VBE participants from discussing benefits of getting care from other VBE participants. However, the safe harbor does not give providers the general authority to direct referrals. The agency intends for patients to be able to express a preference for a different practitioner, provider, or supplier, and the value-based arrangement cannot restrict or limit that patient choice. Providers may override care protocols,

guidelines or policies under the safe harbor. OIG notes that it did not propose, nor does it adopt a patient notification requirement.

i. No marketing or patient recruitment activities (§1001.952(ee)(1)(iii))

OIG notes that fraud schemes often involve the purchase of beneficiaries' medical identity or other inducements to lure beneficiaries to get unnecessary care. This condition clarifies that such coercive arrangements are not protected under the safe harbor. OIG proposed a broad restriction prohibiting all marketing and patient recruitment activities under a value-based arrangement. In response to concerns, it finalizes a narrower requirement that protected remuneration may not be *exchanged or used* for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities. This condition should not be construed to prevent VBE participants from educating patients on permissible value-based activities.

Commenters requested definitions for terms like marketing, education, and recruitment. OIG does not want to impose overly prescriptive definitions and states those terms are used in accordance with their commonsense meanings. The agency believes that remuneration exchanged between parties to a value-based arrangement that provide objective patient educational materials or provide objective patient informational activities would not constitute marketing or patient recruitment activities and thus would be protected under the safe harbor. However, these require fact-specific analysis. OIG provides illustrative examples in the preamble of the final rule.

OIG states that nothing in the safe harbor prevents VBEs or VBE participants from marketing their services; however, the exchange or use of remuneration exchanged among the parties to market to or recruit patients is not protected. It clarifies that the marketing of items and services furnished by the VBE or a VBE participant to patients is prohibited. OIG believes that compliance by a payor (e.g., a Medicare Advantage plan) to regulatory marketing requirements under other laws may not be sufficient for compliance with the marketing and patient recruitment condition under this safe harbor. The agency does not believe that the publication of quality and cost data constitutes marketing or patient recruitment activities.

j. Monitoring and Assessment (§1001.952(ee)(9))

OIG finalizes a requirement to ensure there is monitoring and assessment of the performance of the parties to a value-based arrangement of certain key metrics. This monitoring and assessment must occur at least annually (or once during an arrangement of less than one year) and must address the following:

- The coordination and management of care for the target population in the arrangement;
- Any deficiencies in the delivery of quality care under the arrangement; and
- Progress toward achieving the legitimate outcome or process measure(s) in the arrangement.

The monitoring and assessment must be done by the VBE itself, a VBE participant acting on behalf of the VBE, or the VBE's accountable body or responsible person. Monitoring and assessment reports are provided to the VBE's accountable body or responsible person.

The safe harbor does not require a particular manner in which monitoring and assessment must be done, but OIG believes it should be tailored (or reasonable) based on the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources. That is why the regulation text uses the terminology “*reasonably* monitors and assesses” the arrangement [*emphasis added*]. It believes the monitoring and assessment should evaluate how the value-based arrangement is or is not achieving the value-based purpose of the arrangement.

k. Termination (§1001.952(ee)(10))

OIG proposed to require termination of a value-based arrangement within 60 days of a determination, through monitoring and assessment reports, that the arrangement:

- Has resulted in material deficiencies in quality of care; or
- Is unlikely to further care coordination and management for the target patient population.

In response to concerns, OIG modifies this requirement to provide an opportunity to design and implement a corrective action plan to remedy the deficiencies within 120 days. If the corrective action plan fails to remedy the deficiencies within the 120-day period, the value-based arrangement must terminate.

The agency does not define material deficiency in quality of care since it may vary based on the nature of the VBE and the value-based arrangements; however, it clarifies that it views patient harm as a material deficiency in quality of care.

OIG had proposed requiring termination of the value-based arrangement if the VBE's accountable body or responsible person determines that the arrangement is unlikely to achieve the outcome measure(s). It does not finalize this condition.

l. No Diversion, Resell, or Use for Unlawful Purposes (§1001.952(ee)(11))

Under the final rule, remuneration is not protected under the safe harbor if the offeror knows, or should know, that it is likely to be diverted, resold, or used by the recipient for an unlawful purpose, including for purposes other than care coordination and management of a target patient population. OIG believes the standards are clear notwithstanding commenters' opinions to the contrary. It provides examples in the preamble to the final rule, for example, where remuneration is provided far in excess of reasonable need (e.g., 100 tablets where 10 would objectively suffice).

m. Materials and Records (§1001.952(ee)(12))

OIG finalizes its proposal to require the VBE, or its participants, to make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the safe harbor.

The final rule specifies that the VBE or its participants must maintain records and materials sufficient to document compliance for at least 6 years. OIG notes this aligns with the requirement in CMS' final rule, and it applies to all three value-based safe harbors.

With respect to materials and records that may contain proprietary or other confidential information, OIG notes that parties submitting records may designate in writing that all or part of the information in such records is exempt from disclosure under the fourth exemption of the Freedom of Information Act (covering trade secrets and confidential commercial or financial information).

n. Possible Additional Safeguards

OIG considered but did not finalize the following additional conditions under the safe harbor in the final rule:

Bona Fide Determination. This condition would have required the VBE's accountable body or responsible person to make two *bona fide* determinations for the value-based arrangement in advance of, or contemporaneous with, the commencement of the value-based arrangement:

- The arrangement is directly connected to care coordination and management for the target patient population.
- The arrangement is commercially reasonable, considering both the arrangement and all value-based arrangements within the VBE.

Cost-Shifting Prohibition. This condition would have prohibited VBEs or their participants from shifting costs to federal health care programs by prohibiting the following:

- Billing federal health care programs, other payors, or individuals for the remuneration;
- Claiming the value of the remuneration as bad debt for purposes of payment under federal health care programs, or
- Otherwise shifting costs to a federal health care program.

Fair Market Value Requirement and Restriction on Remuneration Tied to Volume or Value of Referrals. OIG does not adopt a blanket prohibition on determining the amount or nature of remuneration in a manner that takes into account the volume or value of referrals or other business generated. Instead, it finalizes a narrower prohibition that the offeror of the remuneration cannot take into account the volume or value of, or condition an offer of remuneration on referrals of patients that are not part of the value-based arrangement's target patient population; or business not covered under the value-based arrangement.

Additional Requirements for Dialysis Providers. Noting that the dialysis market is dominated by a few dialysis providers which OIG believes increases the risk of fraud and abuse, it considered

but does not finalize including certain specific conditions on dialysis providers to ensure their care coordination arrangements operate to improve care coordination and management and are not pay-for-referral schemes.

Submission of Information to HHS. OIG considered but does not finalize a condition for the care coordination safe harbor to require submission of data to HHS on the VBE, VBE participants, and value-based arrangements. As noted above, it finalizes a narrower requirement for materials and records to be submitted upon request of HHS.

Alternative Regulatory Structure. It does not finalize its proposal for a different regulatory structure based on modifying the personal services and management contracts safe harbor to create tiered protection for value-based arrangements, removing existing requirements under the personal services and management contracts safe harbor as parties assume more downside financial risk.

4. Value-Based Arrangements with Substantial Downside Financial Risk (§1001.952(ff))

OIG finalizes a new safe harbor to protect certain value-based arrangements of VBEs that assume (or that are contractually obligated to assume in the next 6 months) “substantial downside financial risk” from a payor for providing items and services for a target patient population. It protects both monetary and in-kind remuneration.

The protection is limited to those VBEs that assume substantial downside financial risk and VBE participants that “meaningfully share” in the VBE’s downside financial risk. It does not extend to ownership or investment interests in the VBE or to distributions related to those interests. Protection is not available for arrangements downstream of a VBE participant, such as arrangements between two VBE participants. The agency is concerned that under many downstream arrangements, VBE participants receiving remuneration may assume little or no financial risk and still bill for services on a fee-for-service basis, thereby retaining the incentives to bill based on volume as opposed to value.

The safe harbor in the final rule is modified from what OIG had proposed in several respects, including the level of risk that must be assumed, the omission of one methodology to assume that risk (described below), the addition of a condition precluding ineligible entities from protection under the safe harbor, and allowing certain outside funding. OIG notes that while the safe harbor may be used by participants in CMS-sponsored models, it is intended for other kinds of value-based arrangements, including arrangements in the commercial market.

The safe harbor does not align precisely with the exception for meaningful downside financial risk under the CMS physician self-referral law final rule, especially with respect to risk thresholds. OIG explains that this is due in part to the different statutory structures as well as to the broader focus of the AKS as compared to the more limited focus on physician risk arrangements and remuneration under the CMS final rule.

a. Substantial Downside Financial Risk (§1001.952(ff)(9))

(1) Risk methodologies

OIG specifies three methodologies that may qualify as substantial downside financial risk under its definition in the final rule; they are substantially modified from the proposed rule. It does not finalize the proposed population-based payment methodology.

Shared Savings and Losses Methodology

- The VBE must assume financial risk equal to at least 30 percent of any loss.
- Losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care.

OIG reduces the risk threshold from 40 to 30 percent. Risk may be assumed prospectively or retrospectively.

Episodic Payment Methodology

- The VBE must assume financial risk equal to at least 20 percent of any loss.
- Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a *bona fide* benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care.
- The parties must design the clinical episode of care to cover items and services collectively furnished in more than one care setting.

OIG does not change the risk threshold from the proposed rule. Risk may be assumed prospectively or retrospectively. It notes that while parties must design the clinical episode of care to cover items and services collectively furnished in more than one care setting even if a particular patient ultimately receives items and services in only one setting. OIG clarifies that the final rule does not require the payor to discount the cost of items and services in the clinical episode of care by 20 percent; rather, the VBE must assume risk equal to at least 20 percent of any loss where savings and losses are compared to a *bona fide* benchmark designed to approximate the expected total cost of care for that defined clinical episode.

VBE Partial Capitation Methodology

- The VBE receives from a payor a prospective, per-patient payment that is designed to produce material savings.

- Payment is made 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.

OIG does not include a risk threshold for this methodology. Further, it eliminates the proposed discount percentage requirement. Instead it requires that the partial capitation methodology result in material savings. The agency does not define material savings though it provides some examples, including utilization targets intended to lower costs versus historical utilization. The absence of a specific definition is intended to provide flexibility. OIG believes payors have ample experience in designing actuarial models to assess and project costs and establish rates to consider several variables, including risk adjustment.

Payments under the partial capitation methodology must be in the form of prospective, per-patient amounts for a predefined set of items and services for the target patient population; they may not, for example, include fee-for-service payments under Medicare.

(2) Clarifications

The safe harbor does not preclude a VBE from assuming other types of risk from a payor, such as investment risk, contractual risk, and clinical risk for complex patients, as long as it also assumes substantial downside risk from the payor. OIG notes that the other types of risk must be analyzed for compliance with the AKS.

The final rule does not require that parties rely on historical expenditures or evidence-based, comparable expenditures when setting benchmarks to calculate losses or savings. The Shared Savings and Losses Methodology and the Episodic Payment Methodology both require the use of a *bona fide* benchmark, which OIG explains is any legitimate benchmark that is designed to approximate the cost of care. This is intended to establish a baseline tailored to the contract or value-based arrangement between the VBE and the payor, and it permits adjustments (such as prospective or retrospective risk adjustment) as long as the methodology for those adjustments is established in advance. OIG notes that benchmarks that are validated or designed with generally accepted actuarial principles will likely be *bona fide*; parties may look to Innovation Center models, the Medicare Shared Savings Program, Medicaid programs, and private payors for models of validated benchmarks.

OIG also clarifies that reinsurance arrangements to protect against catastrophic losses are permissible if the arrangements are not used to materially shift the substantial downside risk the VBE is required to assume.

The definition is intended to permit parties to design two-sided risk methodologies which would permit upside as well as downside financial risk.

Substantial downside financial risk for the specified items and services and target patient population must be assumed for the entire period of the value-based arrangement; that period must be at least one year in length. OIG notes that it does not consider Medicare prospective payment systems or other like payment methodologies to be substantial downside financial risk.

b. Meaningful Share (§1001.952(ff)(9))

The purpose of this criterion is to ensure that VBE participants ordering or arranging items and services for patients closely share the VBE's goals and share in the accountability if those goals are not met.

In the final rule, there are two ways for a VBE participant to meaningfully share in the substantial downside financial risk of the VBE:

Risk-Sharing Payment Methodology

- The VBE participant assumes two-sided risk for at least 5 percent of the losses and savings (as applicable) realized by the VBE pursuant to its assumption of substantial downside financial risk.

The modifications made from the proposed rule are intended to clarify that risk assumed must be two-sided risk. OIG lowers the risk threshold from 8 to 5 percent. VBE participants may not satisfy this criterion by assuming other types of risk (e.g., operational or contractual risk).

If a VBE has catastrophic losses that trigger reinsurance, the VBE participant would calculate the amount owed to the VBE based on the VBE's losses as adjusted by any applicable reinsurance.

Meaningful Share Partial Capitation Methodology

- The VBE participant receives 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 the predefined set of items and services.
- The VBE participant must not claim payment in any form from the payor for the predefined items and services.

The final rule more fully describes the permissible capitation methodology which the agency believes ensures VBE participants assume a meaningful share of the risk. The methodology does not specify a particular percentage of items and services that must be covered. OIG clarifies that this methodology precludes Medicare fee-for-service payments.

The OIG does not finalize the proposed *CMS Exception Methodology* where payments that met the physician self-referral law's regulatory exception for meaningful downside financial risk at 42 CFR 411.257(aa)(2) would meet the criterion for meaningful share under this AKS safe harbor. This is because CMS' exception does not fit within the framework of the OIG's safe harbor; under the CMS exception methodology, risk is tied to the percentage of the total value of remuneration a physician receives whereas under the safe harbor, risk is tied to the percentage of risk assumed by the VBE.

As discussed further below, a payor who is a VBE participant of a VBE that assumes substantial downside financial risk is not required to meaningfully share in the downside risk. In this situation, the VBE is assuming risk from a payor that elects to be a VBE participant and enter into a value-based arrangement with a VBE. The final rule does not define the term payor, but OIG confirms it includes managed care organizations that contract with Medicare, Medicaid and other federal health care programs.

OIG believes it is appropriate for the VBE to have higher risk thresholds than the VBE participant in part because the VBE participant is likely to have a narrower focus that is specific to the items and services it furnishes.

The VBE participant must be at risk for a meaningful share of the VBE's risk throughout its participation in the value-based arrangement (other than during the 6-month phase-in period).

c. Ineligible Entities (§1001.952(ff)(1))

OIG adds a condition to exclude from protection under this safe harbor the categories of ineligible entities described above in section III.2.e.(1), such as manufacturers, distributors or wholesalers of drugs or medical devices; PBMs; laboratory companies; compounding pharmacies; or DMEPOS companies.

d. VBE's Assumption of Risk from a Payor (§1001.952(ff)(2))

The final rule provides two options for a VBE to assume financial risk from a payor, of which only one will be protected under the safe harbor. The VBE, acting directly or through a VBE participant (other than a payor), assumes substantial downside financial risk through a value-based arrangement or through a written contract with the payor. The assumption of risk must be for a period of at least one year.

Assumption through Value-Based Arrangement

Where a payor is a VBE participant in the value-based arrangement, and the VBE assumes risk from the payor through the value-based arrangement, remuneration exchanged between the payor and the VBE is protected under the safe harbor, including remuneration to implement a substantial downside financial risk methodology (e.g., shared savings and losses).

Assumption through Written Contract

If the payor does not wish to be part of a VBE, the VBE may assume the risk from the payor through a written contract. However, that written contract is not a value-based arrangement and thus remuneration exchanged pursuant to the contracted is not protected under the safe harbor. The only condition that applies to these contracts is that there be evidence of the VBE's assumption of risk from the payor. In these circumstances, the VBE and the payor would have to assess whether any remuneration exchanged complies with the AKS in the absence of the safe harbor.

OIG modifies the risk assumption requirement to clarify that the payor cannot act on behalf of the VBE; the VBE must be a distinct legal entity or be represented by a VBE participant (other than a payor) that acts on the VBE's behalf.

The agency emphasizes that the safe harbor applies to arrangements where the target patient population is comprised of patients insured by the payor with which the VBE can enter into the risk arrangement. Thus, patients enrolled in fee-for-service Medicare generally could not be part of that target patient population though participation of beneficiaries in a CMMI model or the Medicare Shared Savings Program may change the analysis. It is also possible that Indian health care providers might not be risk-bearing entities under the safe harbor.

In response to comment, OIG states that there is no requirement that the items and services be provided directly to the target patient population, and there is nothing in the safe harbor that prevents the VBE's risk from encompassing items and services for, but not provided directly to, the target patient population, such as ancillary products and services.

e. Phase-In Period (§1001.952(ff)(2))

OIG finalizes its proposal to protect remuneration exchanged between the VBE and a VBE participant during the 6-month period before the date by which the VBE must assume substantial downside financial risk (referred to as the phase-in period). This applies only insofar as the VBE is contractually obligated to assume that risk from a payor.

Assuming all the safe harbor conditions are met, including the contractual obligation of the VBE to assume substantial downside financial risk from a payor, remuneration exchanged between a VBE and a VBE participant during the phase-in period would be protected even if the VBE ultimately does not assume substantial downside financial risk at the conclusion of the phase-in period. OIG clarifies that parties may not exchange remuneration during the 6-month phase-in period to establish the VBE; this is because the VBE must already be in existence to contract with the payor.

Generally, OIG does not believe that income guarantee payments made during the phase-in period would qualify for protection under the safe harbor, in part because they do not satisfy any of the methodologies in the definitions of substantial downside financial risk or meaningfully share. Further, it is not clear how those payments would satisfy one of the three value-based purposes.

f. Remuneration Used to Engage in Value-Based Activities (§1001.952(ff)(4))

Under the final rule, remuneration must be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE assumes substantial downside financial risk.

OIG clarifies that remuneration exchanged between either a VBE and a payor (as a VBE participant) pursuant to a methodology that meets the definition of "substantial downside

financial risk,” or between a VBE and a VBE participant (other than a payor) pursuant to a methodology that meets the definition of “meaningful share,” need not be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk. This is because remuneration exchanged under the methodologies protected under the safe harbor effectuates the assumption of risk required by the safe harbor; thus, there is no need to require that remuneration under these circumstances be used predominantly to engage in value-based activities. However, all other remuneration must be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed the risk.

OIG also clarifies that the items and services to which the value-based activities must be directly connected are those for which the VBE assumes (or will assume) substantial downside financial risk; this is intended to protect remuneration exchanged during the phase-in period before the VBE has actually assumed any risk.

g. Direct Connection to Value-Based Purposes (§1001.952(ff)(4))

The final rule requires protected remuneration to be directly connected to at least one of three value-based purposes. These purposes are (i) the coordination and management of care for the target patient population; (ii) improving the quality of care for the target patient population; and (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for the target patient population.

h. Reductions in Medically Necessary Items and Services (§1001.952(ff)(7))

OIG had proposed to require that the remuneration exchanged under the value-based arrangement not induce VBE participants to reduce or limit medically necessary items or services furnished to any patient. In the final rule, OIG expands this to apply more broadly to all the terms and conditions of the value-based arrangement and not merely to remuneration exchanged.

i. Ownership or Investment Interests (§1001.952(ff)(4))

This safe harbor does not protect an ownership or investment interest in the VBE, or any distributions related to ownership or investment interests.

j. Remuneration from Individuals or Entities Outside the Applicable VBE

OIG had proposed a condition that the safe harbor would not protect remuneration funded, or otherwise resulting from contributions, by an individual or entity outside of the applicable VBE. It does not finalize this condition. However, the agency notes that the exchange of remuneration between parties other than the VBE and a VBE participant (e.g., remuneration exchanged between a third-party donor and a VBE participant or a VBE) would not be protected by this or any value-based safe harbor. In response to a question about the application of the policy to affiliates, OIG does not believe contributions or funding from an affiliate of the VBE (that is not a VBE participant) would be protected under the safe harbor.

k. Writing (§1001.952(ff)(5))

OIG finalizes its writing requirement as follows:

The value-based arrangement is set forth in writing, is signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement, and specifies all material terms including:

- Terms evidencing that the VBE is at substantial downside financial risk or will assume such risk in the next 6 months for the target patient population;
- A description of the manner in which the VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) has 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.

As modified from the proposed rule, parties must document the manner in which (i) the VBE assumes risk from a payor and (ii) the VBE participant assumes a meaningful share of such risk. OIG also permits the writing requirement to be satisfied by a collection of documents. It does not require documentation of the offeror's costs. Finally, the writing must be established before (or contemporaneous with) the beginning of the value-based arrangement as well as before (or contemporaneous with) the beginning of any material change to the value-based arrangement.

The agency notes that this writing requirement does not apply to contracts between a payor and a VBE where the payor is not a VBE participant. Nonetheless, those contracts must be in writing.

l. Does Not Take into Account the Volume or Value of, or Condition Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement (§1001.952(ff)(6))

As it does for the care coordination arrangements safe harbor, OIG finalizes a requirement that VBE or VBE participant offering the remuneration may not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

m. Preserving Clinical Decision-Making (§1001.952(ff)(7))

As it does for the care coordination arrangements safe harbor, OIG finalizes its conditions for protection under the safe harbor that the value-based arrangement must not limit the VBE participant's ability to make decisions in the best interests of its patients and the condition related to directing or restricting referrals (both described in more detail in section III.3.h. above).

n. Materials and Records (§1001.952(ff)(8))

OIG finalizes the same materials and records requirements under this safe harbor as it does for the care coordination arrangements safe harbor. Thus, records and materials sufficient to

document compliance with the safe harbor must be maintained for at least 6 years and must be made available to HHS upon request.

o. Marketing of Items and Services (§1001.952(ff)(4))

As it does with respect to the care coordination arrangements safe harbor, rather than prohibiting all marketing and patient recruitment activities, this provision prohibits the exchange of remuneration for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for patient recruitment activities.

p. Downstream Arrangements (§1001.952(ff))

The substantial downside financial risk safe harbor only protects remuneration exchanged between a VBE and a VBE participant. Remuneration exchanged between VBE participants or from a VBE participant to a downstream contractor is not protected. VBE participants seeking to exchange remuneration in this manner must look to another safe harbor, such as the safe harbors for care coordination arrangements, for personal services and management contracts, or for outcomes-based payments.

However, where a VBE participant is acting on behalf of a VBE to contract or enter into a value-based arrangement with a payor, that VBE participant may exchange remuneration with other VBE participants.

q. Possible Other Safeguards

To further protect against the use of value-based arrangement payments for referrals unrelated to coordinating care and improving health outcomes and value, OIG considered whether to including the following additional conditions for the final rule:

- A commercial reasonableness requirement.
- A monitoring standard.
- A requirement to submit data and other information to HHS about the VBE, its participants and the value-based arrangement.
- A prohibition on cost-shifting to federal health care programs, and other payors and individuals.

OIG does not finalize any of these additional conditions.

5. Value-Based Arrangements with Full Financial Risk (§1001.952(gg))

OIG finalizes a new safe harbor to protect certain value-based arrangements of VBEs that assume (or that are contractually obligated to assume in the next 6 months) “full financial risk” from a payor for a target patient population. It protects both monetary and in-kind remuneration between a VBE and its VBE participants.

The safe harbor requires a signed writing with the payor that specifies the target patient population and contains terms evidencing that the VBE is at full financial risk for that population for a minimum of one year. There are fewer conditions under this safe harbor to reflect the level

of financial risk assumed by the parties. OIG acknowledges that there are few providers currently assuming this level of risk.

Protection under this safe harbor does not extend to ownership or investment interests in the VBE or to distributions related to such an interest. The safe harbor does not protect remuneration funded by, or otherwise resulting from contributions by, an individual or entity outside the VBE.

As is the case with the other value-based safe harbors described above, this safe harbor does not provide protection for remuneration exchanged by ineligible entities (e.g., manufacturers, distributors or wholesalers of drugs or medical devices or supplies; PBMs; laboratory companies; compounding pharmacies; or DMEPOS companies).

The safe harbor does not require a VBE to take on other payor functions, such as enrollment, grievance and appeals, solvency standards or other administrative functions. Noting that some state laws may limit or condition the ability of providers to take on full financial risk, OIG believes there is enough flexibility under the safe harbor for payors, VBEs and VBE participants to structure full financial risk arrangements. For example, VBE participants could combine their risk as long as the collective risk amounts to risk for all items and services covered by the payor. The agency notes that the safe harbor does not preempt state law unless that state law incorporates the federal law.

While the safe harbor does not include a specific provision relating to Medicare Advantage plans, OIG believes the safe harbor may be available to protect remuneration exchanged under certain Medicare Advantage plan arrangements.

OIG believes this safe harbor closely aligns with CMS' full risk exception; however, the safe harbor includes different conditions such as the writing requirement and that the VBE provide for a quality assurance program.

a. Full Financial Risk (§1001.952(gg)(10))

In the final rule, OIG modifies its definition of full financial risk to respond to concerns from comments. The definition requires that the VBE be 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 1 year.

OIG defines prospective basis to mean the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor before the provision of items and services to patients in the target patient population. An arrangement providing for partial capitated payments does not qualify.

The proposed rule would have required prospective payment. Under the final rule, the VBE must assume risk on a prospective basis which is intended to eliminate a requirement for the payor to pay the VBE prospectively before the provision of services to each patient in the target patient population.

The definition does not prevent a VBE from using global risk adjustments, risk corridors, reinsurance, or stop loss agreements to protect against catastrophic costs; this could be appropriate to address challenges of assuming risk for high-cost or specialty items and services or new technologies. However, the use of these arrangements for non-catastrophic costs is not protected under the safe harbor. VBEs are not precluded from conducting back-end reconciliation with payment adjustments for quality and financial performance as long as that reconciliation is not used to shift material financial risk back to the payor.

OIG emphasizes that a VBE participant may not claim payment in any form from the payor for items and services covered under the arrangement because the VBE has assumed full financial risk from the payor; this would include payments to offset losses the VBE participant incurred.

OIG notes that while it is not possible under the definition for the VBE to be at full financial risk for less than all of the items and services covered by the payor, a VBE and payor could agree to limit a target patient population by disease or condition.

Full financial risk may be assumed by the VBE directly or through a VBE participant with legal authority to obligate the VBE. In response to a comment, OIG notes that it does not dictate how the VBE exchanges remuneration with VBE participants, so a VBE could impose front-end withholds or dues assessments on VBE participants.

b. Items and Services (§1001.952(gg)(10))

OIG proposed to define items and services using the existing definition of that term at §1001.952(t)(2)(iv). A commenter noted that use of that existing definition would require the VBE to assume risk for services reasonably related to the provision of health care items, devices, supplies or services, including non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. The agency agrees; in the final rule, the term is defined to mean “health care items, devices, supplies or services” without cross-reference to any definition of the term elsewhere in the regulations. Thus, if a VBE is willing to assume the risk for items and services reasonably related to the provision of health care items, devices, supplies or services, it may do so; however, that is no longer a requirement for protection under the safe harbor.

c. Ineligible Entities (§1001.952(gg)(1))

As it does for the substantial downside financial risk safe harbor, OIG adds a condition to exclude from protection under this safe harbor the same categories of ineligible entities described above in section III.2.e.(1), such as manufacturers, distributors or wholesalers of drugs or medical devices; PBMs; laboratory companies; compounding pharmacies; or DMEPOS companies.

d. VBE’s Assumption of Risk from a Payor (§1001.952(gg)(2))

As it does for the substantial downside financial risk safe harbor, the final rule provides two options for a VBE to assume financial risk from a payor, of which only one will be protected

under the safe harbor. The VBE, acting directly or through a VBE participant (other than a payor), assumes full financial risk through a value-based arrangement or through a written contract with the payor. The assumption of risk must be for a period of at least one year.

Assumption through Value-Based Arrangement

Where a payor is a VBE participant in the value-based arrangement, and the VBE assumes risk from the payor through the value-based arrangement, remuneration exchanged between the payor and the VBE is protected under the safe harbor, including remuneration to implement the full financial risk methodology. OIG clarifies that the payor may not act on behalf of the VBE; the VBE must be a distinct legal entity or be a VBE participant (other than a payor) acting on the VBE's behalf.

To enable the payor and VBE to use the safe harbor to protect remuneration exchanged pursuant to their value-based arrangement, OIG clarifies at §1001.952(gg)(4) that the payor is exempt from the prohibition on a VBE participant from claiming payment in any form from the payor for items and services covered under the value-based arrangement.

Assumption through Written Contract

If the payor does not wish to be part of a VBE, the VBE may assume the risk from the payor through a written contract. However, that written contract is not a value-based arrangement and thus remuneration exchanged pursuant to the contract is not protected under the safe harbor. The only condition that applies to these contracts is that there be evidence of the VBE's assumption of risk from the payor. In these circumstances, the VBE and the payor must assess whether any remuneration exchanged complies with the AKS in the absence of the safe harbor.

In response to a comment, OIG states that a VBE may assume full financial risk for all of the items and services provided to all a VBE participant's patients, provided the VBE and VBE participant have defined the target patient population to include all the VBE participant's patients. If the VBE participant's patients are insured by multiple payors, the VBE must assume full financial risk from each payor that insures a patient who is part of the target patient population. It also clarifies that the VBE's risk encompasses all items and services covered by the applicable payor, regardless of whether a VBE participant or another provider provides the items and services to a patient in the target patient population.

e. Phase-in Period (§1001.952(gg)(1))

As it does for the substantial downside financial risk safe harbor, OIG finalizes its proposal to protect remuneration exchanged between the VBE and a VBE participant before the date by which the VBE must assume full financial risk (referred to as the phase-in period). However, for the full financial risk safe harbor, the phase-in period is 12 months as opposed to the 6-month period finalized for the substantial downside financial risk safe harbor. The OIG believes a full 12-month period is warranted for value-based arrangements that assume full financial risk.

The protection during the phase-in period applies only insofar as the VBE is contractually obligated to assume that risk from a payor.

f. Writing (§1001.952(gg)(3))

OIG finalizes a writing requirement to promote transparency and accountability. A VBE must have a writing signed by the parties that specifies all material terms, including the value-based activities and the term of the arrangement.

As it does for the substantial downside financial risk safe harbor, the agency clarifies that the writing may be satisfied by a collection of documents. The requirement does not dictate how parties document their value-based arrangements. It notes that this writing requirement does not apply to contracts between a VBE and a payor that are not value-based arrangements.

g. 1-Year Minimum Term of Value-Based Arrangement

As noted above, OIG had proposed to require a minimum one-year term for the value-based arrangement. It does not finalize this condition because it believes that the requirement for a VBE participant to assume full financial risk for at least one year is a sufficient safeguard.

h. Remuneration Used to Engage in Value-Based Activities

OIG had proposed to require that the remuneration exchanged be used primarily to engage in the value-based activities set forth in the parties' signed writing. It does not finalize this condition because it does not believe the condition is necessary to protect against inappropriate inducements for referrals given the other safeguards (e.g., assumption of full financial risk and limitations on exchanges between the VBE and VBE participants).

This policy for the full financial risk safe harbor differs from the approach taken in the substantial downside financial risk safe harbor where only monetary remuneration exchanged pursuant to a risk methodology that meets the definition of "substantial downside financial risk" or "meaningful share" is excluded from the requirement that remuneration exchanged be used predominantly to engage in value-based activities.

i. Direct Connection to Value-Based Purposes (§1001.952(gg)(3))

The final rule includes a condition that the remuneration provided by, or shared among, the VBE and VBE participant must be directly connected to one or more of the VBE's value-based purposes. This final policy is modified to remove the proposed requirement that all remuneration be directly connected to the purpose of coordinating and managing care for the target patient population. Unlike other value-based safe harbors, OIG is not requiring that the direct connection be tied to any specific value-based purpose.

In response to comments, OIG confirms that the safe harbor may be used to protect arrangements for bonus payments based on quality outcomes or shared savings and losses arrangements (among others) as long as the arrangements meet all the conditions of the safe harbor, including

that the remuneration exchanged must be directly connected to one or more value-based purposes. It also explains that the full financial risk safe harbor does not dictate how payment is made between the VBE and the VBE participant for items and services furnished to the target patient population; as long as the VBE assumes full financial risk from a payor and the VBE participant does not claim payment from the payor for the items and services furnished to the target patient population, the VBE could pay the VBE participant on a fee-for-service basis.

j. No Reduction in Medically Necessary Items or Services (§1001.952(gg)(6))

As finalized, the value-based arrangement may not induce parties to reduce or limit medically necessary items or services furnished to any patient. This was broadened to apply to the value-based arrangement as opposed to the proposal which applied the limitation only to remuneration.

k. Taking into Account the Volume or Value of, or Conditioning Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement (§1001.952(gg)(7))

Neither the VBE nor any VBE participant may take into account the volume or value of, or condition remuneration on, referrals of patients outside the target patient population or business not covered under the arrangement. This is intended to prevent what OIG refers to as swapping arrangements to steer patients outside the target patient population to the party offering remuneration.

l. Offer or Receipt of Ownership or Investment Interests (§1001.952(gg)(5))

As it does for the substantial downside financial risk safe harbor, OIG does not protect an ownership or investment interest in the VBE, or any distributions related to ownership or investment interests under the full financial risk safe harbor.

m. No Remuneration from Individuals or Entities Outside the Applicable VBE

OIG had proposed not to protect any remuneration funded by, or otherwise resulting from contributions by, any individual or entity outside of the applicable VBE, under the full financial risk safe harbor. It does not finalize this condition because commenters convinced the agency that this condition could restrict the exchange of beneficial remuneration.

n. Utilization Review and Quality Assurance Programs (§1001.952(gg)(8))

OIG had proposed to require the VBE to provide (or arrange for) an operational utilization review program and a quality assurance program. It finalizes only part of its proposal. While a quality assurance program is required under the final rule, OIG drops the additional requirement for an operational utilization review program. It notes that some quality assurance programs include operational utilization review programs and specify patient goals.

The quality assurance program must protect against underutilization and assesses the quality of care furnished to the target patient population. Parties may select activities and mechanisms they determine are most suitable to assess the quality and appropriateness of care furnished to the

target patient population, subject to requirements under state law. Additionally, OIG clarifies that a VBE does not have to establish a quality assurance program itself; it may contract for such a program or rely on the payor to carry out the program.

o. No Marketing of Items and Services or Patient Recruitment Activities (§1001.952(gg)(5))

As it does with respect to the other value-based safe harbors, rather than prohibiting all marketing and patient recruitment activities, OIG finalizes a condition under this safe harbor that prohibits the exchange of remuneration for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for patient recruitment activities.

p. Materials and Records (§1001.952(gg)(9))

OIG finalizes the same materials and records requirements under this safe harbor as it does for the other value-based safe harbors. Thus, records and materials sufficient to document compliance with the safe harbor must be maintained for at least 6 years and must be made available to HHS upon request.

q. Downstream Arrangements (§1001.952(gg))

Consistent with the conditions of the substantial downside financial risk safe harbor, the full financial risk safe harbor only protects remuneration exchanged between a VBE and a VBE participant. Remuneration exchanged between VBE participants or from a VBE participant to a downstream contractor is not protected. VBE participants seeking to exchange remuneration in this manner must look to another safe harbor, such as the safe harbors for care coordination arrangements, for personal services and management contracts, or for outcomes-based payments.

However, where a VBE participant is acting on behalf of a VBE to contract or enter into a value-based arrangement with a payor, that VBE participant may exchange remuneration with other VBE participants.

r. Additional Considerations for the Final Rule

OIG had proposed, but does not finalize, the following two conditions:

- A requirement to submit data and other information to HHS about the VBE, its participants and value-based arrangement.
- A prohibition on cost-shifting to federal health care programs, and other payors and individuals.

6. Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency (1001.952(hh))

The OIG finalizes, with modifications, the “patient engagement and support safe harbor” at §1001.952(hh) for patient engagement tools and supports furnished to improve quality, health outcomes, and efficiency provided by VBE participants as defined in paragraph

§1001.952(ee)(14) and discussed above in section III.B.2) to a specified target patient population. The OIG states at §1001.952(hh)(3)(i) and (ii) that patient engagement tools or supports consist of in-kind items, goods, or services that have a direct connection to the coordination and management of care of the target patient population. While other items are services listed in the proposed rule (such as health-related technology, patient health-related monitoring tools or services; or supports and services designed to identify and address a patient's social determinants of health) are omitted from the specific language, OIG does not exclude them from covered tools and supports. They will be included insofar as they advance the goals specified at §1001.952(hh)(3)(vi).

a. Entities Ineligible for Protection

The OIG proposed that only patient engagement tools and supports furnished by a VBE participant would receive protection. The OIG's final definition of a VBE participant has been expanded to allow all entity types to be eligible VBE participants, and within each safe harbor OIG specifies those entities that are ineligible to use a particular safe harbor.

For the patient engagement and support safe harbor, the OIG finalizes (at §1001.952(hh)(1)(i) through (viii)) that the following entities are ineligible to use the safe harbor to provide protected remuneration to patients:

- Pharmaceutical manufacturers, wholesalers, and distributors;
- PBMs;
- Laboratory companies;
- Pharmacies that primarily compound drugs or primarily dispense compounded drugs;
- Manufacturers of devices or medical supplies (except for digital health technology as discussed below)
- Entities or individuals that sell or rent DEMPOS (other than a pharmacy, a medical device or supply manufacturer that also sells or rents DEMPOS, or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible);
- Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies; and
- Medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians.

This expanded list of excluded entities addresses the OIG's concern that certain types of entities present a higher risk of misusing the safe harbor to market their products and services instead of using them to improve the coordination and management of patient care.³

The OIG acknowledges the role that digital health technology has in improving the coordination and management of patient care. Similar to the policy finalized for the care coordination arrangements safe harbor (§1001.952(ee)), a tool or support furnished or funded by a manufacturer of a device or medical supply is eligible for safe harbor protection only if the tool

³ Section III.B.2.e of the final rule discusses the OIG rationale for the various types of ineligible entities and entities with multiple lines of business.

or support is digital health technology (as defined in §1001.952(ee)(14)(ii)).⁴ The OIG notes that eligible VBE participants, other than a manufacturer of a device or medical supply, are not limited to digital health as defined for these specific manufacturers.

The OIG disagrees with comments requesting expansion of the safe harbor to entities that are not VBE participants. The OIG believes that limiting safe harbor protection to VBE participants requires entities to adhere to certain principles that promote value-based objectives. It thinks the required administrative steps are relatively minimal and should not provide a significant burden on providers, including solo practitioners, and providers in rural or underserved areas. The OIG notes that a solo practitioner, small practice or a provider in a rural or underserved area could partner with another entity or individual to form a VBE without changing the membership of the practitioner's practice.

The OIG discusses the risks, based on longstanding enforcement and oversight experience, that the ineligible entities present for misuse of providing remuneration to beneficiaries as a means to market their products and services. Although under the final care coordination arrangements safe harbor, DMEPOS companies are also eligible for the limited digital technology participant pathway, this exception is not included in the patient engagement and support safe harbor. The OIG states this difference is based on the risks associated with entities and individuals that sell or rent DMEPOS when they directly interact with patients, including evidence of inducements paid to beneficiaries to order medically unnecessary products.⁵ This restriction doesn't mean that patients cannot receive digital tools and supports related to DMEPOS under the safe harbor, but they cannot be provided by entities and individuals that sell or rent DMEPOS.

In response to comments, the OIG states that health technology companies are eligible to be VBE Participants and furnish protected tools and supports. If the health technology company is a manufacturer of a device or medical supply, then it may only furnish protected tools and supports that correspond to the definition of digital health technology. If the health technology company is an entity or individual that sells or rents DMEPOS covered by a Federal health care program (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services) or any other type of ineligible entity, it may not use the safe harbor.

The OIG agrees with commenters that a downside financial risk should not be required for the safe harbor protection and does not finalize this condition for safe harbor protection.

b. Limitations on Recipients

The OIG finalizes, with modification, its proposal to limit safe harbor protection to patient engagement tools and supports furnished to patients in a target patient population (as defined in

⁴ "Digital health technology" is defined as hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

⁵ The OIG defines DMEPOS companies for the patient engagement and support safe harbor companies at §1001.952(hh)(1)(vi).

§1001.952(ee)(14)). The OIG clarifies that to qualify for safe harbor protection, a tool or support must be furnished by a VBE participant to a patient in the target patient population of a value-based arrangement in which the VBE participant is a party. The OIG notes this language ensures that the remuneration is linked to the target patient population relevant to the VBE and has a direct connection to the coordination and management of care of the relevant population. The OIG finalizes that the VBE or VBE participants may define the target patient population without regard to payor type and thus, the safe harbor is not limited to Federal health care program beneficiaries.

Commenters suggested the safe harbor should include a broad category of protected recipients. Some commenters highlighted problems with retrospectively or prospectively assigning patients to the target patient population in CMS-sponsored models which could be a VBE, where beneficiaries are assigned retrospectively or on a preliminary prospective basis (e.g. ACOs participating in the Medicare Shared Savings Program). The OIG believes that requiring a VBE participant to specify a target patient population prior to offering patient engagement tools and supports will link the tools and supports to the underlying value-based purposes of the VBE and decreases the risk that remuneration will be offered to patients as an inducement to seek care.

The OIG notes that VBE participants have flexibility in determining how to define a target patient population; the population must be selected using legitimate and verifiable criteria that are documented and further the VBE's value-based purpose. In addition, a VBE participant could establish multiple target patient populations and target patient population selection criteria can be modified prospectively by amending existing value-based arrangements. In addition, the OIG states that VBE participants can retroactively attribute patients to the target population without amending the value-based arrangement if patients meet the selection criteria established prior to the beginning of the value-based arrangement.

c. Furnished Directly to the Patient

The OIG proposed at §1001.952(hh)(2) that the tool or support must be furnished directly to the patient by a VBE participant. After consideration of comments, the OIG finalizes this proposal, with a modification, to extend safe harbor protection to a VBE participant that provides patient engagement tools or supports through a third party that qualifies as an "eligible agent". "Eligible agent", as defined in §1001.952(hh)(9), is any person or entity that is not identified as ineligible to furnish protected tools and supports under §§1001.952(hh)(1)(i) through (viii)). The eligible agent must be an individual or entity that could furnish protected tools and supports even though the eligible agent does not need to be a VBE participant. Eligible agents could be employees and contractors of a practice when the VBE participant is the practice or other third parties such as technology vendors or retailers. The OIG notes the safe harbor does not protect any remuneration that is furnished by a third party that is not an eligible agent.

The OIG agrees with commenters that a tool or support should be eligible for safe harbor protection if it is furnished to a caregiver or family member of a patient in the target population. The OIG believes that the "furnished directly" condition is applicable to caregivers and family members and states that intervening caregivers and family members or others acting on behalf of the patient may facilitate the provision of the tool or support without the remuneration running

afoul of the “furnished directly” requirement as long as the item satisfies all conditions of the safe harbor conditions.

The OIG disagrees with comments that the patient should be notified in writing about the tool or support. The OIG believes beneficiaries are unlikely to receive tools or supports without an awareness of the source and purpose of these items. The OIG notes that VBE participants have an incentive to communicate about the tools and supports provided without a formal patient notification requirement.

d. Funding Limitations

The OIG finalizes, with modifications, its proposal to limit funding or contributing to patient engagement tools and supports furnished by a VBE participant to a VBE participant. Patient engagement tool or support must not 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 identified as ineligible to furnish protected tools and supports. The OIG believes these modifications ensure that entities ineligible for protection under the safe harbor are not able to circumvent that restriction by indirectly funding or contributing to tools and supports protected under the safe harbor. It also clarifies that the patient receiving the tool or support must be a member of the target patient population of a VBA to which the VBE participant is a party.

Several commenters found this condition unduly restrictive. The OIG responds that this condition is an important safeguard that prevents entities ineligible for safe harbor protection from circumventing the conditions of the safe harbor. The OIG notes that nothing in this condition prevents a charity or foundation from providing tools and supports directly to patients (assuming the arrangement complies with the Federal anti-kickback statute or Beneficiary Inducements CMP). In response to a specific comment about construction companies, the OIG states that nothing in the safe harbor prevents construction companies from modifying homes or providing other construction services free to patients, provided the arrangements comply with the statute.

e. Nature of the Remuneration

The OIG finalizes, with modifications, its proposal at §1001.952(hh)(3)(i) to limit a patient engagement “tool or support” to in-kind items, goods, or services. Under §1001.952(hh)(3)(ii), those tools and supports must have a direct connection to the coordination and management of care of the target patient population. This limitation excludes cash, and any cash equivalent (e.g. a check or pre-paid debit card). As discussed below, commenters provided numerous suggestions regarding specific types of remuneration potentially protected under the safe harbor. In the final rule, the OIG provides examples of potentially protected types of remuneration but notes that these are just examples and not an all-inclusive list.

i. In-Kind Remuneration. The OIG finalizes, with modifications, that protected patient engagement tools and supports include in-kind items, goods and services provided they meet all applicable safe harbor conditions. The final regulatory text (§1000.952(hh)(3)(i)) does not specify specific examples of protected in-kind items, goods or services because it believes the

safe harbor should protect a broad range of tools and supports. Although, the OIG states that preventive care can be protected under the safe harbor, it does not include preventive items in the final regulatory text. Instead, to make clear that preventive items, goods, or services can be covered under the safe harbor, it amends the goal of “management of a disease or condition” to read “prevention or management of a disease or condition” at §1001.952(hh)(3)(vi) (discussed below in this section).

Comments about examples of in-kind remuneration ranged from commenters recommending identification of categories to commenters recommending a comprehensive list. In response, the OIG notes that rather than listing specific examples the safe harbor provides protection for a broad range of in-kind items, goods or services which includes health-related technology, patient health-related monitoring tools or services, or supports and services designed to identify and address a patient’s social determinants of health, the final safe harbor contains a list of goals at §1001.952(hh)(3)(vi), at least one of which a tool or support must advance in order to qualify for safe harbor protection.

The OIG disagrees with a comment that the safe harbor lacks sufficient flexibility for the provision of tools and supports that promote patient engagement. The OIG notes that nothing in the safe harbor limits the ability of VBE participants to educate patients about available tools and supports as long as the VBE participant does not use the patient engagement tools to market other reimbursable items or services or for patient recruitment.

In response to comments requesting clarification about “preventive care item or service,” the OIG responds that the final safe harbor regulation does not identify a specific category of remuneration for preventive care items, goods, or services. Instead these items and services could be protected under the safe harbor’s general protection of in-kind items, goods, or services that satisfy the conditions of the safe harbor, including advancing one of the safe harbor’s enumerated goals.

ii. Cash, Cash Equivalents, and Cards. The OIG finalizes, with modifications, its proposal to exclude protection for remuneration in the form of cash and cash equivalents at §1001.952(hh)(3)(iii). The OIG does not finalize its proposal to exclude protection for gift cards because some gift cards could be considered in-kind remuneration eligible for safe harbor protection.

In response to comments urging protection for gift cards under the safe harbor, the OIG states that limited use gift cards, gift cards that can be redeemed only for certain categories of items (such as fuel-only gift cards redeemable at gas stations) could meet the in-kind requirement under the safe harbor and is consistent with OIG’s existing guidance regarding limited-use gift cards.⁶ Gift cards offered by large retailers or online vendors selling a wide variety of items could be easily diverted from their intended purpose or converted to cash, and the OIG would consider these gift cards to be cash equivalents and not eligible for protection under the safe harbor. In the final rule, the OIG discusses its longstanding program integrity concerns about cash, cash equivalents, and gift cards.

⁶ 81 FR 88393 n.19 (Dec.7, 2016).

The OIG agrees with comments that cash and cash equivalents may be a useful way to address social determinants of health, but because it remains concerned about the high risk of fraud and abuse, it finalizes protection only of in-kind remuneration. The OIG discusses alternatives, such as vouchers or limited-use gift cards to provide transportation to access medical services. The OIG notes that arrangements involving cash or cash equivalents used to address social determinants of health are not necessarily illegal, but they would need to be evaluated under the anti-kickback statute on a case-by-case basis.

In the proposed rule, the OIG solicited comments on including gift cards when they are provided to patients with certain conditions, such as substance abuse disorders, as part of an evidence-based treatment program for the purpose of effecting behavioral change. The OIG discusses the comments received and acknowledges that contingency management interventions that include payments to the patient are effective treatments for certain conditions, including substance abuse disorders. After weighing the potential benefits of contingency management interventions with the potential risks to program integrity, the OIG does not expand the patient engagement and support safe harbor to include cash and cash-equivalent payments offered as part of contingency management interventions or other programs to motivate behavior changes. The OIG notes that in-kind remuneration and certain limited-use gift cards offered as part of contingency management interventions or other programs could receive protection under the safe harbor if all safe harbor conditions are met.

The OIG states that contingency management incentive arrangements that do not comply with a safe harbor can be analyzed on a case-by-case basis for compliance with the Federal anti-kickback statute and Beneficiary Inducements CMP. However, incentives that are included in a service covered by a Federal health care program would not implicate the Federal anti-kickback statute or the Beneficiary Inducements CMP, provided that the applicable billing and coverage rules are followed. In addition, a CMS-sponsored model may qualify for protection under the safe harbor at §1001.952(ii).

In response to comments about nominal amounts of cash or cash equivalent, the OIG reiterates its guidance that it considers inexpensive gifts of nominal value to mean in-kind items and services with a retail value of no more than \$15 per item or \$75 in the aggregate per beneficiary on an annual basis.⁷ The OIG states that cash and cash-equivalent payments under \$75 would not be covered by this guidance. In response to comments about payments to patients participating in the Medicare Shared Savings Program, the OIG recognizes that the Accountable Care Organization (ACO) Beneficiary Incentive Program, administered by CMS as part of the Medicare Shared Savings Program, allows an ACO to make incentive payments to beneficiaries of up to \$20 per qualifying service as an incentive to encourage utilization of medically necessary primary care services if certain requirements are met. The OIG states that nothing in the safe harbor would prevent ACOs from continuing to participate in the ACO Beneficiary Incentive Program. The OIG notes it is not protecting similar incentives in this safe harbor.

⁷ OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), available at <https://OIG.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

iii. Waiver or Reduction of Cost-Sharing Obligations. The OIG does not finalize a condition to protect cost-sharing waivers or reductions under the safe harbor.

Many commenters supported protecting waivers of beneficiary cost-sharing obligations for a wide range of services. The OIG does not believe that a safe harbor promulgated through an OIG regulation is the appropriate way to waive beneficiary cost-sharing because beneficiary cost-sharing is a programmatic requirement created by statute. It notes that several safe harbors and beneficiary inducements CMP exceptions already exist for certain reductions, waivers, and differentials in cost-sharing.⁸ In addition, the OIG does not think it would be appropriate to make distinctions regarding cost-sharing waivers based on particular categories of services. In response to comments, the OIG declines to amend its interpretation of “reasonable collection efforts”.⁹

iv. Social Determinants of Health. The final rule protects in-kind tools and supports that identify and address a patient’s social determinants of health, provided the tools and supports otherwise meet all applicable safe harbor conditions including the \$500 annual cap, the requirement for a direct connection to the coordination and management of the care of the target patient population, the requirement that the tool or support is recommended by the patient’s licensed health care professional, and the requirement that the tool or support advances at least one of the enumerated goals set forth at §1001.952(hh)(3)(vi). The OIG believes the goals ensure that protected tools and supports have a close nexus to care coordination, quality of care, and health outcomes. The OIG does not finalize including specific examples of tools and supports that identify and address social determinants of health. The OIG does not want to inappropriately limit the type or range of in-kind tools and supports and wants to allow the licensed health care professional to determine what works best for the patient, as long as all conditions of the safe harbor are met.

Numerous commenters urged the OIG to extend explicit safe harbor protection to a wide range of tools and support to address food insecurity, housing instability, and transportation needs. The OIG responds that its decision not to finalize specific examples might allow tools and supports to address the categories cited by the commenters if they meet all the safe harbor conditions. In response to comments suggesting definitions for social determinants of health, the OIG does not believe a definition is needed and does not provide a specific definition in this final rule.

The OIG provides an illustrative list of examples of tools and supports related to social determinants of health that may qualify under the safe harbor if all safe harbor conditions are met. The OIG stresses this is not an exhaustive list. Illustrative examples include provision of in-kind transportation such as transit vouchers or rideshares organized the VBE participant; providing broadband access to a patient to enable remote patient monitoring or virtual care; and grocery or meal delivery services.

The OIG also states the safe harbor is specifically focused on the coordination and management of patient care, and other important aspects of addressing social determinants of health are not

⁸ An example of a safe harbor is the waiver of cost-sharing amounts at section 128a(i)(6)(A) of the Act and 42 CFR 103.110.

⁹ Reasonable collection efforts are defined under section 1128A(i)(6)(A)(iii)(II) of the Act.

covered in this rule because they do not relate to coordination and management of patient care. Examples provided by the OIG of items that would unlikely fit in the safe harbor include tools and supports related to finding employment.

In response to comments about activities of daily living, the OIG does not believe a specific goal related to activities of daily living is necessary. It believes that in-kind tools and supports for the management of daily living could meet several of the enumerated goals for the safe harbor. The OIG notes that nothing in this rule alters any existing program rules or benefits to support activities of daily living.

v. Health-Related Technology and Patient Monitoring. The OIG does not finalize its proposal to include examples of health-related technology and patient monitoring tools and services in regulatory text. The OIG states that health-related technology and patient health-related monitoring tools and supports can be protected remuneration if all safe harbor conditions are met.

In response to concerns that the safe harbor would stifle innovative health care provider arrangements for care coordination implemented via remote patient monitoring, the OIG states that it believes the safe harbor, including the final broadened language, will expand opportunities for innovation. The OIG believes that tools such as connected scales or blood pressure monitors that track and transmit data to a patient's licensed health care professional could be protected, if all other conditions of the safe harbor are met. In response to comments requesting clarification about how telehealth tools and supports fit within the category of health-related technology, the OIG responds that in-kind telehealth supports can be protected under the safe harbor if all the conditions of the safe harbor are met. For example, a smartphone that facilitates telehealth services with a patient's licensed health care professional, or a platform or software that facilitates telehealth services, may be a protected form of remuneration. The OIG agrees with a comment that patient communication and counseling services may also qualify as protected in-kind remuneration.

vi. Not Duplicative. The OIG does not finalize a requirement that the VBE participant confirm that the tool or support is not duplicative of, or substantially the same as, tools and services the patient already has. In the proposed rule, the OIG solicited comments on whether or not it should make this a requirement and discusses the concerns raised by commenters regarding the challenges in implementing this requirement.

The OIG notes, however, that tools or supports that are duplicative of items or services that a patient already owns or has access to may not advance one of the goals listed at §1001.952(hh)(3)(vi) and may not be eligible for safe harbor protection. For example, providing a patient with a new smartphone would not necessarily advance any of the enumerated goals if the patient already has a cell phone with sufficient functionality. If a new smartphone adds functionality needed for remote monitoring that is not available on the patient's existing cell phone, the new smartphone may be eligible for safe harbor protection. The OIG notes that protection under the safe harbor is not conditional on achieving one or more of the enumerated goals; the VBE participant must reasonably expect the tool or support to be effective in advancing a goal.

f. Prohibition on Marketing and Patient Recruitment

The OIG finalizes, with modifications at §1001.952(hh)(6), that neither the VBE participant nor an eligible agent of the VBE participant may use patient engagement tools or supports to market other reimbursable items or supplies for patient engagement purposes. The OIG clarifies its intent to preclude protection of tools and supports used solely for patient recruitment purposes or used to market other reimbursable items and services to the patient. The marketing prohibition only applies with respect to the marketing of items and services reimbursable by Federal health care programs. The OIG notes this condition does not preclude a VBE participant from educating patients, such as providing objective educational materials.

Commenters generally supported the proposed prohibitions on marketing and patient recruitment but requested clarification that certain activities, such as providing information to established patients or members of the target patient population about available tools and supports, would not be prohibited. In response, the OIG provides the following example: A physician VBE participant informs a patient with asthma that clean air in the home will help control asthma symptoms and informs the patient that the VBE has a program to provide air filters and the patient may be eligible to receive free air filters provided by the physician. The OIG stresses that any protected tool or support must satisfy the other conditions of the safe harbor, including that the tool or support is recommended by the patient's licensed health care professional and advances one or more of the goals for the safe harbor.

In response to comments, the OIG states that the terms marketing, recruitment, and education are used in accordance with their commonsense meanings. It considers "advertising" to be a subset of "marketing," and the prohibition on using tools or supports to market other reimbursable items or services also prohibits advertising. The OIG provides several examples in the final rule, including providing a tablet to manage diabetes. In this example, the VBE participant may counsel a patient with diabetes about the benefits of the non-billable remote monitoring program that includes a free tablet to facilitate the program. The tablet is used to convey information about nutritional information, wellness tips, and appointment reminders; the tablet is not used to market other reimbursable items or services or for patient recruitment. If the VBE participant uses the tablet to send patient notifications to induce them to obtain test, equipment, supplies or other reimbursable items and services, the VBE participant is using the tablet to market other reimbursable items and services and would not be protected under the safe harbor. Similarly, if the VBE participant advertises that patients will receive a free tablet if they register for the program, this would not be protected under the safe harbor. The OIG also clarifies that notification to an entire target patient population about the availability of tools and supports does not necessarily raise concerns, but whether or not a notification satisfies the conditions of the safe harbor requires a fact-specific analysis. For example, if a physician uses an announcement to an entire target population that they could get free air filters if the patient comes in for an office visit, that would constitute prohibited marketing, even if the announcement also had an educational purpose.

The OIG notes the safe harbor does not prohibit a hospital posting general information such as the hours of operation of its food pantry. Providing free marketing items such as refrigerator magnets and notepads would not be protected if provided for the purpose of marketing; these items may be excluded from the definition of remuneration under the Beneficiary Inducements CMP if they are of nominal value.¹⁰

The OIG discusses that neither the VBE participant, nor an eligible agent of the VBE participant, may use the patient engagement tools or supports to market other reimbursable items or supplies for patient recruitment purposes. The OIG notes this would preclude safe harbor protection for tools and supports used by a patient recruiter to induce or recruit beneficiaries to receive items or services reimbursed by a Federal health care program. In response to comments, the OIG notes that the patient engagement tool or support may be furnished directly to the patient or the patient's caregiver, family member, or other individual acting on the patient's behalf by a VBE participant.

g. Additional Finalized Conditions

As discussed below, the finalized patient engagement and support safe harbor includes safeguards to balance the benefits of the tools and supports and to minimize the risks of harm to patients and payors.

i. Direct Connection. The OIG finalizes its proposal at §1001.952(hh)(3)(ii) that the tool or support furnished to the patient must have a “direct connection” to the coordination and management of care for the patient. The OIG interprets “direct connection” to mean that the VBE has a good faith expectation that the tool or support will further the coordination and management of care for the patients (as described in the conditions at §1001.952(ee)). The OIG does not believe it would be difficult for the participant to clearly articulate the connection between the tool or support and a care coordination and management purpose. In order to provide for flexibility and innovation, the OIG is not describing specific patient engagement tools and supports considered to provide direct connection.

In response to comments about requiring the VBE to make a *bona fide* determination that tools or supports have a direct connection to the coordination and management for care for the patient, the OIG discusses its decision not to finalize this requirement considered in the proposed rule. The OIG notes the VBE and VBE participants may satisfy the requirement to have a direct connection in a variety of ways without establishing a *bona fide* determination.

Several commenters suggested the OIG broaden the safe harbor to include additional value-based purposes: improving the quality of care; appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care; and transitioning the health care delivery and payment systems to value-based care. The OIG disagrees with this suggestion because it believes that these purposes are applicable to VBE participants and not to patients. In contrast, coordination and management of care more directly relates to the patient engagement

¹⁰ OIG Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

goals of the safe harbor.¹¹ The OIG believes there is flexibility in designing arrangements for patient engagement tools protected by the safe harbor and notes that a program to provide grab bars to patients recovering from knee surgery to prevent falls could be tailored to improve health outcomes for the patient and designed to achieve safe, more effective care.

ii. Medical Necessity. The OIG finalizes its proposal at §1001.952(hh)(3)(iv) that the tool or support furnished to the patient must not create medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program.

In response to a concern about protection under the safe harbor for community-based services, the OIG notes that to qualify for protection any incentive for participation in community-based services needs to meet all the safe harbor conditions, including that the remuneration cannot result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program. In addition, community-based services would need to be recommended by the patient's licensed health care professional and have a direct connection to the coordination and management of care of the target population.

iii. Licensed Health Care Professional Recommendation. The OIG proposed a safe harbor condition that would limit safe harbor protection to tools or supports recommended by the patient's health care provider. The OIG finalizes this proposal at §1001.952(hh)(3)(v) with modification; it clarifies that the tool or support must be recommended by the patient's licensed health care "professional" instead of "provider". The OIG notes that the term "provider" is often used to mean a hospital or other entity that furnishes institutional health care services and that "professional" emphasizes the importance of a health care professional's medical judgement, as well as the patient's relationship with a health care professional. The OIG is not finalizing a written certification requirement.

The OIG recognizes that social workers, case workers, and others who may not be licensed clinicians play an important role in patient care, but, for purposes of the safe harbor, it is requiring a recommendation by a licensed health care professional. The OIG does not define the term "licensed health care professional" but does provides examples. The OIG notes the following could recommended tools or supplies, assuming they are appropriately licensed by the appropriate State licensing body for each respective profession: physicians¹²; osteopathic practitioners; chiropractors; physician assistants; nurse practitioners; clinical nurse specialists; certified registered nurse anesthetists; physical therapists; occupational therapists; clinical psychologists; qualified speech-language pathologists; qualified audiologists; and registered dietitians or nutrition professionals.

iv. Advances Specific Goals. The OIG finalizes, with modifications, at §1001.952(hh)(3)(vi) that the incentives and supports must advance the following specific goals:

- adherence to a treatment regimen as determined by patient's health care professional;

¹¹ At 1001.952(ee)(14)(i), the final rule defines "coordination and management of care" to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

¹² Physicians includes Doctor of Medicine, osteopathy, dental surgery, dental medicine, and optometry.

- adherence to a drug regimen as determined by patient’s healthcare professional;
- adherence to a follow-up care plan established by the patient’s healthcare professional;
- prevention or management of a disease condition as directed by the patient’s healthcare professional;
- ensuring patient safety; or
- some combination of the above.¹³

The OIG does not finalize the proposed goal relating to improvement in measurable evidence-based health outcomes for the patient or for the target patient population because it believes this goal is captured by the other goals. The final rule also revises the goal of “management of a disease or condition” to “prevention or management of a disease or condition” and, as noted earlier, replaces references to “licensed health care providers” to “licensed health care professionals”. The OIG intends for this condition to protect a range of tools and supports and does not specify which tools and supports would be included.

v. Prohibition on Cost-Shifting. In the proposed rule, the OIG considered prohibiting VBE participants from billing Federal health care programs, other payors, or individuals for the tool or support; claiming the value of the tool or support as a bad debt for payment purposes under a Federal health care program; or otherwise shifting the burden of the value of the tool or support onto a Federal health care program, other payors, or individuals. The OIG does not finalize this condition; it does not believe including a cost-sharing prohibition would add appreciable increased protection for programs or patients.

The OIG notes that if a provider or supplier furnishes items or services that are covered items or services under a Federal health care program, the provision of those items or services alone would not implicate the Federal anti-kickback statute. The Federal anti-kickback statute would be implicated by a provider waiving or reducing any required cost-sharing obligations for the covered item or service incurred by a Federal health care program beneficiary or providing extra items or services for free. The OIG notes that nothing in this rule exempts parties from the responsibility for compliance with all applicable coverage and billing rules.

vi. No Selection Based on Payor. In the proposed rule, the OIG solicited comments on whether to include a provision which would require VBE participants to provide the same patient engagement tools or supports to an entire target patient population or otherwise consistently offer these to all patients who satisfy specified, uniformed criteria. The OIG noted that this would protect against a VBE participant targeting certain populations based on the patient’s insurance or health status, which could result in targeting particularly lucrative patients to receive tools and supports (cherry-picking) or avoiding high-cost patients (lemon-dropping).

The OIG finalizes at §1001.952(hh)(8) that the availability of patient engagement tools and supports cannot be determined in a manner that takes into account the type of insurance coverage of the patient.

¹³ The OIG notes that the word “drug” is synonymous with and inclusive of “medication” and “follow-up care plan would include “discharge plans”.

The OIG acknowledges commenters' concerns regarding the practical challenges of including a consistent provision requirement under the safe harbor, especially an overly broad consistent provision requirement. The OIG believes that offering protected tools or supports without regard to the patient's payor types addresses its concerns about the possibility of discriminatory provision of tools and supplies based on the payor type without providing additional burdens. Offering tools and supports to patients based on clinical characteristics, such as a specified chronic condition or geographic consideration based on a ZIP code, would not be precluded even if the patient population disproportionately has the same insurance. The OIG notes that providing tools and supports to patients above a certain age or with a particular illness could result in all or virtually all patients being Medicare beneficiaries; however, as long as the patients are not selected based on their Medicare insurance status, the condition would not be violated. The OIG also notes that a VBE could define its target patient population based on income (which might overlap with Medicaid or dual-eligible populations) but could not base selection on enrollment in Medicaid or as dual eligible for both Medicare and Medicaid.

vii. Monitoring Effectiveness. In the proposed rule, the OIG solicited comments about requiring VBE participants to use "reasonable efforts" to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient and requiring VBE participants to have policies and procedures to address any identified material deficiencies. The OIG is not finalizing these conditions. After consideration of the comments, it does not believe these are necessary in light of the totality of the other conditions finalized.

viii. Retrieval of Items and Goods. In the proposed rule, the OIG solicited comments about requiring offerors to engage in reasonable efforts to retrieve an item or good furnished as a tool or support under certain circumstances such as the patient is no longer in the target patient population, the VBE no longer exists, or the offeror is no longer a VBE participant. The OIG is not including a retrieval requirement in the final safe harbor. The OIG agrees with comments about the administrative burden and other challenges with any retrieval requirement. The OIG notes that offerors are free to make retrieval efforts as long as this decision is applied in a consistent manner. In addition, the safe harbor requires termination of ongoing services such as recurring monthly fees associated with a fitness center, if the individual is no longer part of the target patient population or the entity is no longer a VBE participant.

ix. Monetary Cap. The OIG finalizes, with modifications, its proposal at §1001.952(hh)(5) that the aggregate retail value of patient engagement tools and supports furnished by a VBE participant to a patient may not exceed \$500 on an annual basis. The OIG does not finalize its proposal that the cap could be exceeded for certain patients who lack financial resources. After consideration of comments, the OIG includes an inflation adjuster. Specifically, the monetary cap will be adjusted for inflation to the nearest whole dollar effective January 1 of each calendar year using the Consumer Price Index-Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. This information will be published on the OIG website.

In response to comments supporting an exception to the proposed cap based on financial need, the OIG notes that nothing in this final rule makes it necessarily unlawful for a provider or other party to furnish for free or below fair market value tools and supports that exceed \$500 per year

to an individual. These arrangements can be evaluated on a case-by-case basis; the OIG has issued favorable advisory opinions to health care stakeholders seeking to furnish free or below fair market value tools and supports to patients.¹⁴

The OIG clarifies that the retail value of patient engagement tools 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 and determined when provided to the patient. The OIG notes that the cap applies per VBE participant and per patient and is not at the VBE level or the value-based arrangement level. Thus, a patient may receive a number of tools and supports from a number of VBE participants (in one or more VBEs) through the course of a year, as long as no single VBE participant individually provides more than \$500 in aggregate value to the patient per year. The VBE participant providing the tool or support is responsible only for tracking the aggregate value of tools and supports it provides to the patient. 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.

Several commenters recommended the OIG increase the cap over time to account for changes in technology or care innovation. The OIG believes that the \$500 cap strikes an appropriate balance between giving flexibility to VBE participants to provide a beneficial tool and support to a patient and protect patients from the improper influence of valuable remuneration. The OIG is concerned that tools and supports of higher value could improperly influence patients' selection of treatments or providers that are not in their best interest.

x. Diversion of Resale. The OIG does not finalize its proposal that would have excluded from safe harbor protection tools or supports if the offeror knew, or should have known, that the item is likely to be diverted, sold, or utilized by the patient for other reasons than as a patient engagement tool or support. The OIG agrees with a commenter who questioned the feasibility of a VBE participant determining the likelihood of diversion, and the OIG believes that other safeguards adequately address the concern that a tool or support may be inappropriately provided to a patient.

xi. Materials and Records. The OIG finalizes, with modifications, its proposal at §1001.952(hh)(7), to require the VBE or a VBE participant to make available to the Secretary, upon request, all information sufficient to establish compliance with the safe harbor. In the proposed rule, the OIG considered a time period such as six or ten years; the final rule requires that records must be kept for a period of at least six years.

xii. Notice to Patients. In the proposed rule, the OIG solicited comments about requiring the VBE to provide a patient receiving a tool or support written notification identifying the VBE participant and the nature and purpose of the tool or support. The OIG is not finalizing any

¹⁴ As an example, see OIG, OIG Adv. Op. No. 19-03 (March 6, 2019) available at https://oig.hhs.gov/fraud/docs/advisory_opinions/2019/AdvOpn19-03.pdf. This advisory opinion is about a program offered by a medical center that provides free, in-home follow-up care to eligible individuals with congestive heart failure and the proposed expansion of this program to include certain individuals with chronic obstructive pulmonary disease.

requirement for a formal notice to the patient; it expects the health care professional will communicate the purpose of the tool or support to the patient.

7. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (§1001.952(ii))

OIG uses the term “CMS-sponsored models” in this section to mean, collectively, those payment models and initiatives being tested by CMS through the Innovation Center and the Medicare Shared Savings Program (under sections 1115A and 1899 of the Act, respectively).

OIG proposed the addition of a safe harbor at paragraph 1001.952(ii) that would protect remuneration under a CMS-sponsored model:

- Between and among parties to arrangements under the model; or
- In the form of incentives provided by model participants (and their agents) to patients covered by the model; and
- When certain additional considerations are satisfied (e.g., the patient incentive has a direct connection to the health care of the patient).

After considering stakeholder input, OIG finalizes the safe harbor for CMS-sponsored models with a few and mostly non-substantive changes, as discussed further below.

a. Safe Harbor for CMS-sponsored Models: General Comments

OIG’s stated goal for creating this safe harbor is to bring uniformity and predictability for participants in CMS-sponsored models. OIG offers the following clarifications:

- The new safe harbor does not supersede the existing fraud and abuse waivers previously issued by OIG for CMS-sponsored models.
- Existing waivers will remain in effect according to the respective terms of each waiver.
- Model parties may choose to utilize an existing waiver or the new safe harbor (or any other applicable safe harbor) when framing their arrangements, but all conditions of the waiver or safe harbor, respectively, must be satisfied.
- OIG retains the option of issuing new model-specific waivers in the future, although expects they seldom will be needed.

OIG modifies the introductory text (paragraph 1001.952(ii)(1) and (2)) to emphasize that CMS determines the specific types of financial arrangements and model patient incentives, if any, to which protection under this safe harbor will apply.

b. Safe Harbor for CMS-sponsored Models: Scope and Definitions (§1001.952(ii)(3))

To delimit the scope of the new safe harbor, OIG proposed definitions for the following terms: *CMS-sponsored model*, *CMS-sponsored model arrangement*, *CMS-sponsored model participant*, *CMS-sponsored model party*, *CMS-sponsored model patient incentive*, and *participation documentation*. The proposed definitions would clearly confine the availability of the safe harbor to the financial arrangements and model patient incentives of the Innovation Center’s models and the Medicare Shared Savings Program (MSSP).

OIG considered requests seeking expansion of the proposed scope of the safe harbor to a variety of arrangements (e.g., commercial payor models, models under State Innovation Waivers). OIG does not revise the definition of a *CMS-sponsored model* to extend the flexibility of the new safe harbor beyond the MSSP and Innovation Center models. OIG cites the inherent program integrity safeguards, ongoing CMS oversight, and participant screening by CMS that are built into those two programs and that are much less likely to be duplicated in the design of other financial arrangements.

OIG also considered explicitly expanding the scope of the safe harbor to a variety of other specified patient incentives outside of the MSSP or Innovation Center models (e.g., tools and supports under a Medicaid section 1115 waiver), but does not do so. OIG, however, notes the breadth and flexibility of incentives potentially available through CMS-sponsored models (e.g., transportation, nutrition support, home monitoring technology, gift cards), given the following:

- The definition of a *CMS-sponsored model patient incentive* is broadly constructed as *remuneration not of a type prohibited by the participation documentation* of the model.
- The definition of incentives permitted under a particular CMS-sponsored model is established by CMS in that model's participation documentation.
- The definition of which entities may provide an incentive under the terms of a model or program rests with CMS.

OIG notes that a CMS-sponsored model participant may not be certain of a beneficiary's alignment to a model at the time when that beneficiary could benefit from a specific model patient incentive. OIG states that the incentive potentially could qualify under the safe harbor, if the model's terms are structured to allow the incentive to be furnished before the beneficiary's alignment is completed.

OIG also notes that model patient incentives and financial arrangements would continue to be protected when changes are made to an Innovation Center model during the model's test period, as long as the incentives and arrangements continue to fall within the parameters set by CMS for the updated model design and continue to meet the terms of the safe harbor.

OIG also makes a number of refinements to the definitions as proposed, including:

- Modifying the definitions to better distinguish them from the conditions for safe harbor protections (e.g., rewording, relocating);
- Clarifying that *CMS-sponsored model arrangement* refers to a financial arrangement; and
- Modifying the definition of *participation documentation* by replacing *cooperative agreement* with *legal instrument setting forth the terms and conditions of a grant or cooperative agreement* to allow for future models that might be implemented by a type of grant that is not a cooperative agreement.

CMS finalizes the proposed definitions for *CMS-sponsored model*, *CMS-sponsored model arrangement*, *CMS-sponsored model participant*, *CMS-sponsored model party*, *CMS-sponsored model patient incentive*, and *participation documentation* with the clarifications, modifications, and refinements as described above. The final definitions are excerpted in the table below.

Term	Final Definition
CMS-sponsored model party	CMS-sponsored model participant or another individual or entity whom the CMS-sponsored model's participation documentation specifies may enter into a CMS-sponsored model arrangement
Participation documentation	Participation agreement, legal instrument setting forth the terms and conditions of a grant or cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS, specifying the terms of a CMS-sponsored model
CMS-sponsored model participant	An individual or entity that is subject to, and is operating under, participation documentation with CMS to participate in a CMS-sponsored model
CMS-sponsored model arrangement	A financial arrangement, between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model, that is consistent with, and is not a type of arrangement prohibited by, the participation documentation
CMS-sponsored model patient incentive	Remuneration not of a type prohibited by the participation documentation that is furnished to a patient under the terms of a CMS-sponsored model

Created by HPA from the preamble and regulation text of the final rule

c. Safe Harbor for CMS-sponsored Models: Conditions for Safe Harbor Protection (§1001.952(ii)(1) and (2))

OIG proposed conditions that must be met for CMS-sponsored model arrangements and CMS-sponsored model patient incentives to qualify for protection under this new safe harbor. OIG finalizes the two sets of conditions largely as proposed, while providing modifications and clarifications that include the following:

- For clarity, OIG moves to this section language from some of the proposed definitions to consolidate the conditions in a single location distinct from the definitions themselves.
- OIG emphasizes that the types of financial arrangements and incentives that could qualify for safe harbor protections are specified by CMS.
 - CMS will determine if the new safe harbor is applicable to any new CMS-sponsored model, specify availability (or not) of the safe harbor for that model, and notify participants about safe harbor availability through the model's participation documentation and/or other public means chosen by CMS.
 - For existing CMS-sponsored models, CMS may determine whether the new safe harbor is applicable to their arrangements and incentives, and issue for each a public notice or otherwise notify model participants of that determination. The model's parties may then choose to rely on any previously issued, model-specific, fraud and abuse waivers or the safe harbor. All requirements of the waiver or the safe harbor, respectively, must be met.
- OIG affirms that CMS-sponsored model parties may determine the documentation type that would best memorialize their model arrangement to demonstrate safe harbor compliance, including through a collection of documents as opposed to one agreement.
- Regarding the requirement for model arrangements to satisfy "such programmatic requirements as may be imposed by CMS in conjunction with the use of this safe harbor", OIG clarifies that those requirements would be included in the model's participation documentation or otherwise be made publicly available.

- The requirement for a model patient incentive to have a direct connection to the patient's health care is modified by adding "unless the participation documentation expressly specifies a different standard". The specified different standard would take precedence.

CMS-sponsored Model Arrangements (§1001.952(ii)(1)(i) through (vi))

OIG finalizes the conditions that must all be met for a CMS-sponsored model arrangement to qualify for the CMS-sponsored models safe harbor as excerpted below.

- (i) The CMS-sponsored model parties reasonably determine that their arrangement will advance one or more goals of the model.
- (ii) Remuneration under the arrangement does not induce model parties or other providers or suppliers to furnish medically unnecessary items or services, or to reduce or limit medically necessary items or services furnished to any patient.
- (iii) The model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model.
- (iv) The model parties, prior to or contemporaneous with the commencement of the model arrangement, set forth the terms of the arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the parties and the nature of the remuneration to be exchanged under the arrangement.
- (v) The parties to the model arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor.
- (vi) The model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

CMS-sponsored Model Patient Incentives (§1001.952(ii)(1)(i) through (v))

- (i) The CMS-sponsored model participant reasonably determines that the model patient incentive will advance one or more goals of the model.
- (ii) The model patient incentive has a direct connection to the patient's health care, unless the model's participation documentation expressly specifies a different standard. (The different, expressly-specified standard takes precedence.)
- (iii) The model patient incentive is furnished by a model participant (or by an agent of the participant), unless otherwise specified by the model's participation documentation (i.e., an individual other than a participant or its agent can furnish the incentive).
- (iv) The model participant makes available to the Secretary, upon request, all materials and records sufficient to establish whether the model patient incentive was distributed in a manner that meets the conditions of this safe harbor.
- (v) The model patient incentive is furnished consistent with the CMS-sponsored model and satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

d. Safe Harbor for CMS-sponsored Models: Duration of Protection (§1001.952(ii)(4))

OIG considered several alternatives for determining the duration of safe harbor protection of a CMS-sponsored model's arrangements and incentives, and finalizes the following in new paragraph 1001.952(ii)(4):

- Safe harbor protection begins on or after the first day of performance for models governed by a grant or cooperative agreement as set forth in a legal instrument (e.g., as specified in a Notice of Award);
 - Safe harbor protection ends no later than 6 months after model closeout occurs.
- Safe harbor protection begins on or after the first day on which services under the model begin for models governed by other than a grant or cooperative agreement;
 - Safe harbor protection ends no later than 6 months after the final payment determination made by CMS under the model.

OIG believes that the finalized language is applicable to a variety of model types (e.g., episode-based, pay-for-performance) and extends sufficiently long to accommodate financial reconciliations that occur after clinical activity under a model has ceased. OIG clarifies that for models having an “implementation period” before all of the model's provisions become effective, and if that period is described in the participation documentation, services furnished during the implementation period are also protected under the safe harbor. Otherwise, protection does not extend to remuneration exchanged for activities (e.g., care coordination, patient care) that occur before the model begins or after the model expires or is terminated.

Finally, OIG finalizes as proposed that a patient receiving a model patient incentive may retain that incentive if the incentive was given on or after the first day, and no later than the last day, on which patient care services may be furnished under the model. Model participation documentation that specifies a different timeframe for incentive retention would take precedence.

8. Cybersecurity Technology and Related Services

OIG finalizes a new safe harbor to protect donations of certain cybersecurity technology and related services at a new §1001.952(jj). Changes are made from the proposed rule. Like the donation of any valuable technology or services to physicians and other sources of referrals, OIG states that the donation of cybersecurity technology or services can pose risks of fraud and abuse. However, OIG believes that the safe harbor appropriately balances the risks against the potential benefits of helping the healthcare industry address the increasing threats to the security of health information technology (IT) systems.

The safe harbor is similar to an exception to the physician self-referral law adopted in the CMS final rule. OIG worked closely with CMS to ensure as much consistency as possible within the differences in the underlying statutes.

Under the final rule, nonmonetary remuneration consisting of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity is protected under the AKS and Beneficiary Inducements CMP if certain conditions are met. The conditions for the cybersecurity safe harbor are:

- The donor does not:

- directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential donation recipient, or the amount or nature of the technology or services to be donated; or
- condition the donation, or the amount of the donation, on future referrals.
- The recipient does not make receipt of the donation or the amount or nature of the technology or services donated, a condition of doing business with the donor.
- A general description of the technology and services provided and the amount of the recipient's contribution is set forth in writing and signed by the parties.
- The donor does not shift the costs of the technology or services to any federal health care program.

OIG notes that the structure of the regulatory text is changed from the proposed rule, with the limitation to cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity placed in the introductory paragraph, instead of as a condition. This mirrors the structure of the electronic health record (EHR) safe harbor at §1001.952(y).

Details of the cybersecurity safe harbor follow.

a. Purpose of Donation

The safe harbor protection is limited to donated technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. In the final regulatory text, OIG removes a proposed reference to “certain types of” cybersecurity technology to avoid creating ambiguity about the scope of the safe harbor. The addition of a reference to *reestablishing* effective cybersecurity is a change from the proposed rule. OIG considers this a clarification as it had proposed that the safe harbor protect donations that include business continuity software that mitigates the effects of a cyberattack and data recovery services to allow a recipient's operations to continue during and after a cyberattack.

b. Protected Donors

The safe harbor applies to all donors, without any limitation as to the type of individual or entity donating cybersecurity technology and services, as long as the other conditions of the safe harbor are satisfied. OIG had sought comments on whether any limitation on donor types would be appropriate under the safe harbor. In the end, it believes that the types of donor limitations that apply to the EHR safe harbor at §1001.952(y) are not needed in this case. OIG concludes that the other conditions in the cybersecurity safe harbor are sufficient, whereas donations of EHR involve the exchange of patient clinical information and represent a greater risk that the donation is for the donor to secure additional referrals from the recipient.

To address concerns that potential recipients might condition referrals on a cybersecurity donation, OIG finalizes a condition that prohibits recipients from conditioning referrals and future business on a cybersecurity donation. OIG notes that donations or solicitations of

cybersecurity technology and services conditioned on business or in exchange for federal health care program referrals would not be protected by this new safe harbor and would be highly suspect under the AKS.

c. Permitted Recipients

The safe harbor protects donations of cybersecurity technology and related services to any individual or entity, without limitation and without any additional or different safeguards for any recipient. OIG had sought comment on this issue, and in particular on whether donations to patients should be treated differently. It concludes that additional conditions are not necessary, citing in particular the final rule requirements that the donation be necessary and predominantly used for cybersecurity. That is, donations to patients must be necessary; in determining necessity, OIG expects potential donors of cybersecurity to patients to consider existing cybersecurity measures and the nature of the patient's interaction to systems. Further, OIG notes that donations to patients may be subject to other laws to safeguard patient data. It rejects the suggestion by some commenters that the safe harbor be limited to situations in which there is an established relationship between the donor and recipient because it believes that this might work against the goal of encouraging improvements to the cybersecurity of the health care system through appropriate donations.

d. Definitions

Under the final rule, "cybersecurity" means the process of protecting information by preventing, detecting, and responding to cyberattacks. This broad definition is derived from the National Institute for Standards and Technology Framework for Improving Critical Infrastructure Cybersecurity (NIST CSF), is not specific to the health care industry, and is widely accepted across all types of industries, the public and private sectors, and internationally. OIG sought to avoid a narrow definition that might become obsolete over time. It notes that the safe harbor does not protect payments of ransom to or on behalf of a recipient in response to a cyberattack; this is not viewed as reestablishing effective cybersecurity and does not qualify as nonmonetary remuneration. Potential donors and recipients are encouraged to ensure a comprehensive, systematic approach to identifying and managing cybersecurity risks. OIG declines to adopt various specific recommendations to modify the definition; it believes that the NIST CSF is broad enough to capture many commenter concerns.

"Technology" means any software or other type of information technology. This definition is broad enough to capture Application Programming Interface technology (which is neither software nor a service) and other technology and services that may become available in the future. OIG notes that the safe harbor protection of services includes installation and configuration of donated software on the recipient's system.

In a change from the proposed rule, the final rule does not exclude hardware from the definition of technology. OIG had been concerned about donations of valuable multifunctional hardware being disguised as payment for referrals and sought comment on this issue. Many commenters had suggested that the exception apply only to certain types of hardware, and OIG concludes that its program integrity concerns are adequately addressed by limiting the exception to donated

services and technology that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. It emphasizes that it does not expect most donations of multifunctional hardware to meet the predominant use condition.

After consideration of comments, OIG declines to require that a risk assessment be conducted prior to the donation of hardware, although it notes that parties are free to donate risk assessments if the conditions of the safe harbor are met. It had solicited comments on an alternative approach that would protect a donation of cybersecurity hardware that the donor has determined is reasonably necessary based on a risk assessment of its own organization and that of the potential recipient.

Examples of hardware that could be permitted under the exception (if all requirements are met) include computer privacy screens, two-factor authentication dongles and security tokens, facial recognition cameras for secure access, biometric authentication, secure identification card and device readers, intrusion detection systems, data backup systems, and data recovery systems.

Examples of hardware that does not meet the conditions for protection include servers, drives, upgraded wiring, physical security systems, fire retardant or warning technology, and high security doors, which have functions that extend well beyond cybersecurity. OIG notes that although donation of an encrypted server might improve the recipient's cybersecurity, it likely would not be used predominantly for cybersecurity.

e. Scope of Protected Technology and Services

The safe harbor protects a broad range of cybersecurity technology and services, including certain hardware, as discussed above with respect to the definition of "technology." The safe harbor does not distinguish between cloud-based software and software installed locally. OIG emphasizes that all donations must be necessary and predominantly used for cybersecurity. Therefore, most technology and services that include cybersecurity as one of multiple functions would not be protected by this safe harbor. Other safe harbors, such as the EHR safe harbor, may apply. Where parties seek to donate technology, separate functions of the technology need not be protected under different safe harbors if the donation meets the terms of one safe harbor. OIG reminds readers that the advisory opinion process is available to parties seeking a legal opinion regarding the scope of the safe harbor as applied to specific facts and circumstances.

The proposed rule offered examples of technology protected under the cybersecurity safe harbor if all the conditions are met, including malware prevention software; software security measures to protect endpoints that allow for network access control; business continuity software; data protection and encryption; and email traffic filtering. Examples offered of protected services include services associated with developing, installing, and updating cybersecurity software; cybersecurity training services; cybersecurity services for business continuity and data recovery services; models that rely on third-party service providers to manage, monitor, or operate cybersecurity of a recipient and services associated with performing cybersecurity risk assessment or analysis.

f. Monetary Cap

The safe harbor does not impose any monetary limit on donations of cybersecurity technology and services. OIG had sought comments on whether there should be a limit on the total amount of donations made by a donor to a recipient. It concludes that no cap is needed because donations of cybersecurity technology and services would naturally be limited to what is needed for effective cybersecurity, with no incentive for excessive donations.

g. Deeming Provision

The final rule does not include a deeming provision. In the proposed rule OIG had sought comment on whether to deem certain arrangements to satisfy the requirement that the technology or services be necessary and predominantly used to implement and maintain effective cybersecurity. The possible deeming provision would have allowed donors and recipients to demonstrate that the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to widely-recognized cybersecurity framework or set of standards, such as those developed or endorsed by NIST, or other national or international standards bodies.

OIG is concerned that a deeming provision could inadvertently protect donations that are not necessary or used predominantly to implement, maintain, or reestablish cybersecurity. Further, it concludes that without selection of one or more specific frameworks, a deeming provision could be subject to manipulation. However, parties are encouraged to implement cybersecurity programs that follow widely recognized industry frameworks.

h. Volume and Value Condition

Donations are not protected under the safe harbor if donors directly take into account the volume or value of services or other business between the parties when determining the eligibility of the recipient for the donation or the amount or nature of the technology or services to be donated. Further, donations are not protected if donors condition the donation or its amount and nature on future referrals. Similarly, the donation is not protected if the recipient, the recipient's practice, or any affiliated individual or entity makes receipt of the technology or services, or their amount, a condition of doing business with the donor.

OIG does not include a list of selection criteria which would be deemed to meet this requirement (similar to the one required under the EHR safe harbor at §1001.952(y)(5)) because it does not believe that donations of cybersecurity pose the same risks. It believes legitimate cybersecurity donations are self-protective and likely to be based on security risks rather than the volume and value of referrals.

i. Recipient Contribution

The safe harbor does not require that recipients contribute to the cost of the donated cybersecurity technology and services. OIG sought comments on this issue and concluded that such a requirement is not necessary to guard against fraud and abuse, and that it might be burdensome in the context of cybersecurity donations because the necessity of donated services

might vary unpredictably in response to cybersecurity threats. Overall, OIG believes that a contribution requirement would pose a barrier to donations that is outweighed by the need for widespread improvement in the cybersecurity status of the health care industry.

OIG notes that donors are free to require recipients to contribute to the cost of the donated technology and services as long as the contribution is unrelated to the volume or value of referrals or other business between the parties. For example, a donor is free to structure donations that require a contribution for the initial cybersecurity donation but not for subsequent patches and upgrades as long as the donor does so consistently and according to the terms of the written agreement with the recipient.

j. Patching and Updates

OIG views donations of cybersecurity software patching and updates as protected under the safe harbor as long as all conditions of the safe harbor are satisfied.

k. Writing Requirement

Under the safe harbor, the arrangement must be set forth in a written agreement that is signed by the parties and that includes a general description of the technology and services provided and the recipient's financial contribution, if any. OIG does not intend that every item and every service must be specified in the agreement, and the regulatory text (§1001.952(jj)(4)) is changed from the proposed rule to reference to a "general description" to clarify this intention. OIG notes that the terms do not need to be set forth in a single signed writing; a "collection of documents" approach is permitted.

Further, OIG states that it does not intend this requirement to introduce any fair market value requirement, force parties to determine the fair market value of the donation, or compel the parties to hire a valuation consultant. By the amount of the recipient's contribution, if any, OIG means either the sum certain a donor will collect as contribution or, if the donor will collect a percentage of the total value of the donation, the percentage that will be applied. OIG expects that the parties would document in writing any material changes in the donation over time.

l. Cost Shifting

As a condition of protection under the cybersecurity safe harbor, the donor may not shift the costs of the technology or services to any federal health care program. An example that was offered in the proposed rule is that while a hospital's own cybersecurity costs are considered an administrative expense for purposes of its cost report, donations of cybersecurity technology and services to other individuals and entities may not be included as an administrative expense.

9. Electronic Health Records

Regulations at §1001.952(y) provide a safe harbor for certain arrangements involving donation of interoperable EHR software or information technology and training services. The EHR safe harbor was set to expire on December 31, 2021.

In this rule, OIG eliminates the sunset and makes other changes to the EHR safe harbor. It notes that CMS has made parallel changes to the EHR exception under the physician self-referral regulations. The changes involve adding a reference to donations of cybersecurity software and services, clarifying the deeming provision, eliminating the safe harbor condition related to information blocking, modifying the contribution requirement, allowing donations of replacement technology, expanding the scope of protected donors, and updating the definition of interoperable. OIG does not finalize proposed changes to the definition of electronic health record.

a. Cybersecurity

OIG adds a specific reference to cybersecurity in the introductory text to §1001.952(y) to clarify that the safe harbor is available to protect the donation of cybersecurity software and services and software that “protects” EHRs. Specifically, the language clarifies that the safe harbor applies to software or IT and training services, *including cybersecurity software and services*, necessary and used predominantly to create, maintain, transmit, receive, *or protect* electronic health records if the identified conditions are met. The final rule eliminates the proposed reference to “certain” cybersecurity software and services, which OIG notes makes no substantive difference, as any software and services that meets all the conditions is protected under the EHR safe harbor.

Elsewhere in this final rule (see section III.B.8. above), OIG finalizes a new separate safe harbor to protect arrangements involving the donation of cybersecurity technology and related services. The new cybersecurity safe harbor is broader and includes fewer requirements than the EHR safe harbor. The expansion of the EHR safe harbor is intended to make clear that an entity donating EHR software and providing training and other related services may also donate cybersecurity software to protect the EHR. The definition of cybersecurity mirrors the one finalized for the cybersecurity safe harbor. To be protected, the donation of cybersecurity software and services must comply with only one of the two safe harbors. OIG acknowledges overlap between the safe harbors but notes that the purposes differ. The EHR safe harbor clarification is aimed at cybersecurity donations with a predominant purpose of protecting EHRs, whereas the cybersecurity safe harbor protects donations of cybersecurity technology and services used predominantly to implement, maintain, or reestablish effective cybersecurity.

b. Deeming

Under section §1001.952(y)(2), software donated under the EHR safe harbor must be interoperable, and software certified under the Office of the National Coordinator for Health Information Technology (ONC) certification program is deemed to be interoperable. OIG makes what it refers to as clarifying changes to the regulatory text.

- The current requirement deems that software is interoperable if at the time it is provided to the recipient it *has been certified* to an edition of the certification criteria identified in

the then-applicable version of 45 CFR part 170. Under the final rule, OIG requires that the software *is certified* at the time it is provided to the recipient, meaning that the certification must be current. Software that has been certified in the past but on the date of donation is no longer maintaining certification does not meet the condition.

- The regulatory text is modified to refer to certification criteria instead of “EHR certification criteria” to be consistent with terminology in the ONC regulations.
- To be consistent with ONC changes to the certification program, the regulatory text is changed to remove the reference to “editions” of the certification criteria.

OIG notes that the deeming provision is optional. If an EHR item or service loses certification, it would no longer qualify under the deeming provision. It could still qualify under the safe harbor if it meets the definition of interoperable and all the other conditions of the safe harbor.

c. Information Blocking

One condition of the EHR safe harbor (§1001.952(y)(3)) prohibits the donor from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems (including, but not limited to, health IT applications, products, or services).

OIG does not finalize its proposal to incorporate a reference to information blocking, and instead deletes the entire condition proposed at (§1001.952(y)(3)). It had proposed to modify the text to require that the donor does not engage in a practice constituting information blocking, as defined in 45 CFR part 171 in connection with the donated items or services. However, after considering comments, OIG believes this condition, which dates to the 2006 origins of the safe harbor, is no longer needed. Newer enforcement authorities provided to OIG and ONC allow them to directly address information blocking under the Cures Act and CMS has separate related authority to require provider attestations; these authorities make the safe harbor condition unnecessary. Moreover, OIG notes that ONC provides for eight exceptions to the prohibition on information blocking while as written the safe harbor condition did not take into account actions that may be reasonable and necessary, such as implementing privacy and security measures.

OIG emphasizes that the safe harbor condition requiring interoperability remains, and along with the optional deeming provision, it will ensure that donations of EHR items and services will further the goal of an interoperable health system and prevent the lock-in of referrals by limiting the flow of electronic health information. OIG is committed to taking action against individuals and entities that engage in information blocking. Readers are referred to OIG’s April 2020 proposed rule on information blocking (85 FR 22979).

d. Sunset Provision

The EHR safe harbor was originally adopted in the 2006 Final EHR Safe Harbor Rule (71 FR 45110) and was scheduled to expire on December 31, 2013. The sunset was included because OIG believed that the need for the exception would diminish over time as the use of EHR technology became a standard and expected part of medical practice. In subsequent rulemaking

the sunset date was extended to December 31, 2021, as OIG continued to believe that the need for the exception would diminish over time.

In this rule, the sunset is eliminated, and the safe harbor is made permanent. OIG now believes that continued availability of the EHR exception promotes EHR technology adoption by providing certainty with respect to the cost of EHR items and services for recipients and in other ways.

e. Contribution Requirement

As a condition to the EHR safe harbor, the recipient must pay 15 percent of the donor's cost of the technology. OIG sought comment on alternatives that would reduce or eliminate the requirement for all recipients or for small or rural physician organizations. This condition is set forth in §1001.952(y)(11).

OIG retains the 15 percent contribution requirement but removes the requirement that the payment be made in advance for updates to existing EHR systems. The final regulatory text specifies that if the donation is the initial donation of EHR items and services or the replacement of part or all of an existing system, the recipient must pay 15 percent of the donor's cost before receiving the items and services. The contribution for updates to previously donated items and services need not be paid in advance of receiving the update.

After reviewing comments OIG continues to believe that the contribution requirement is an important safeguard against fraud and abuse due to the specific risks of inappropriate generation of referrals that are presented by donation of EHR items and services. However, in recognition that EHR system updates sometimes need to be made quickly to remedy security issues or other problems, OIG believes it is reasonable and would not create additional risk to remove the requirement that contributions for updates be made in advance of their receipt. By contrast, OIG believes that parties can reasonably plan for making contributions associated with initial and replacement donations in advance. OIG rejects suggestions for limiting contributions to certain types of donations because it could lead parties to structure donations to game the difference in required contributions.

f. Equivalent Technology and Scope of Protected Donations

OIG finalizes its proposal to allow donations of replacement EHR technology. This change is codified by removing paragraph §1001.952(y)(7) which prohibits the donation of equivalent items and services. OIG finds that with the rapid pace of advancement in EHR technology there may be valid business or clinical reasons for a recipient to replace an entire system rather than to update an existing technology. Under the final rule, replacement technology is treated the same as a new donation and must meet all the conditions of the safe harbor to receive protection.

g. Protected Donors

The final rule expands the scope of protected donors under the EHR safe harbor, as identified in §1001.952(y)(1). In the proposed rule OIG did not formally propose a change but had stated that

it was considering doing so and sought comments on the issue. The changes are made to support greater use of EHR technology.

The expansion permits donations of EHR technology under the safe harbor by parent companies of hospitals, health systems, accountable care organizations and potentially others. Specifically, the existing requirement that protected donors be limited to those who submit claims or payment requests directly or through reassignment to a federal health care program is expanded to include an entity that is *comprised of* these types of individuals or entities. The existing language that excludes laboratory companies as donors and permits health plans as donors is retained.

OIG sees little added risk to protecting donations of interoperable electronic health records software or information technology and training services by entities such as health systems or accountable care organizations because these entities may have financial risk for patient outcomes and generally do not directly receive referrals. OIG continues to have concerns about protecting EHR donations made by laboratories or manufacturers or suppliers of items, however.

h. Definitions

After reviewing comments, OIG does not finalize changes it had proposed¹⁵ to the definition of “electronic health record.” The proposed changes to the definition were not intended to substantively change the scope of protection under the safe harbor, and commenters raised issues that led OIG to conclude that the proposed changes might inadvertently introduce complexities.

The existing definition, moved to a new paragraph §1001.952(y)(14)(iv), is as follows:

Electronic health record shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

Changes to the definition of “interoperable” are finalized, with modification from the proposed rule, to align with the definition in the Cures Act.¹⁶ The final text appears at a new §1001.952(y)(14)(iii) and is shown below. Although the Cures Act definition includes the phrase, the proposed reference to data exchange “without special effort on the part of the user” is not adopted because that language also refers to a certification requirement for EHR under the Cures Act. OIG does not want to imply that it is incorporating a certification requirement into the definition of interoperable for purposes of the EHR safe harbor. In addition, the proposed inclusion of a reference to the information blocking regulations is not finalized. (See the discussion of eliminating information blocking as a condition of the EHR safe harbor in paragraph c. above.)

Interoperable shall mean able to:

¹⁵ The proposed definition of *Electronic health record* was a repository of electronic health information that: (A) Is transmitted by or maintained in electronic media; and (B) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.

¹⁶ The definition appears in section 3000(9) of the Public Health Service Act.

- (A) Securely exchange data with and use data from other health information technology; and
- (B) Allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

10. Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (§1001.952(d))

a. Personal Services and Management Contracts

OIG proposed to update the personal services and management contracts safe harbor to remove barriers to care coordination and value-based arrangements. It finalizes the following policy changes without modification:

- Instead of requiring the aggregate compensation be set in advance, the safe harbor requires that the methodology for determining compensation be set in advance; and
- The requirement to specify the schedule, length and exact charge for services of an agent on a periodic, sporadic or part-time basis is eliminated.

(1) Elimination of Requirement To Set Aggregate Compensation in Advance (§1001.952(d)(1))

In lieu of the condition under the safe harbor that the aggregate amount of compensation to be paid over the course of the agreement must be set out in advance, the final rule substitutes a requirement that the parties to the arrangement determine the compensation methodology before the initial payment is made under the arrangement. The safe harbor retains existing conditions that the compensation reflect fair market value, be commercially reasonable, and not take into account the volume or value of referrals or business otherwise generated between the parties. OIG believes the change closely aligns this safe harbor with the physician self-referral law exception for personal services arrangements (42 CFR 411.357(d)).

OIG clarifies for commenters that several compensation methodologies could be used under the safe harbor if they meet other conditions of the safe harbor, such as the fair market value and commercial reasonableness conditions. It explains that the intent behind the change is to enhance flexibility while mitigating the risk of parties adjusting the agent's compensation to reward referrals or promote unnecessary utilization of services.

The agency declines to define terms like fair market value or commercially reasonable; it notes that those terms have been used throughout the safe harbors over the years and that parties have ample experience with their meaning under the AKS. It declines to adjust its longstanding interpretation of these terms to align them with the definitions finalized in the CMS physician self-referral final rule.

OIG did not propose to change the signed writing requirement. However, it notes that the writing requirement may be met either through a single document or a collection of documents as long as they are signed. For a collection of documents, the signatures could be applied to each document or to a single document that incorporates the separate documents by reference.

(2) Elimination of Requirement To Specify Schedule of Part-Time Arrangements (§1001.952(d)(1))

OIG finalizes its proposal to eliminate the condition that required contracts for services provided on a periodic, sporadic, or part-time basis to specify “exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.” While the condition was added to address concerns that these types of arrangements are especially vulnerable to abuse (e.g., part-time arrangements could easily be modified based on changing referral patterns), the agency believes it can be removed to provide parties more flexibility in designing *bona fide* business arrangements if the other safeguards are met. Those safeguards include that the arrangement must be for a year or more and that the compensation must reflect fair market value, be commercially reasonable, and not take into account the volume or value of referrals or business otherwise generated between the parties. The change more closely aligns this safe harbor with the physician self-referral law exception for personal services arrangements.

b. Protection for Outcomes-Based Payment Arrangements (§1001.952(d)(2) and (3))

OIG finalizes with modifications its proposal to protect outcomes-based payment arrangements such as shared savings and losses, episodic payments, gainsharing, and pay-for-performance. To exchange remuneration pursuant to the outcomes-based payment arrangements safe harbor, parties must determine legitimate outcome measures, establish the types of services to be performed to achieve an outcome measure, set benchmarks, monitor and assess achievement, and ultimately achieve outcome measures. Additionally, the term of the agreement must be for a minimum of one year. The safe harbor is intended to support outcomes-based payments that facilitate care coordination, encourage provider engagement across care settings, and advance the transition to value.

(1) Outcomes-Based Payment

Outcomes-based payments are limited to payments between or among a principal and an agent that (i) reward the agent for successfully achieving one or more legitimate outcome measures (described in (2) below) or (ii) recoup from or reduce payment to an agent for failure to achieve the legitimate outcome measure(s).

An outcomes-based payment is expanded in the final rule to include payment of shared losses from an agent to the principal for failure to achieve an outcome measure. Additionally, OIG struck language from its proposed definition that required effective and efficient care coordination and instead ties the payment to achievement of legitimate outcomes measures which is a substantially more flexible standard.

The final rule specifically excludes the following types of payments from protection under the safe harbor:

- Payments that relate solely to achievement of internal cost savings for the principal.
- Payments based solely on patient satisfaction or patient convenience measures.
- Payments made directly or indirectly by ineligible entities described above in section III.2.e.(1) (e.g., manufacturers, distributors or wholesalers of drugs or medical devices; PBMs; laboratory companies; compounding pharmacies; or DMEPOS companies).

OIG believes that ineligible entities depend heavily on practitioner prescriptions and referrals and might use outcomes-based payments primarily to market their products to providers and patients.

The agency had considered whether to limit protections for outcomes-based payment arrangements to VBE participants; in the final rule, it declines to limit the safe harbor to a particular list of arrangements or particular types of arrangement structures or measures.

While OIG anticipates that most outcomes-based arrangements would include certain services to meet the safe harbor requirements, it does not add a specific requirement to perform services in the safe harbor (though the term services is used in several places in the regulation text).

No specific timeline is set for the parties to achieve outcomes, and no particular mechanism is specified to track progress toward meeting outcomes measures. However, parties must regularly monitor and assess the agent's performance for each measure, and no payment may be made to the agent until the outcome measure is achieved.

(2) Legitimate Outcome Measure

A legitimate outcome measure is an outcome measure that is (i) selected based on clinical evidence or credible medical support, and (ii) has a benchmark that is used to quantify either or both of the following:

- Improvements in, or the maintenance of improvements in, the quality of patient care.
- A material reduction in payor costs or to growth in payor expenditures while maintaining or improving quality of care for patients.

This is a modification from the proposed rule which would have required parties to collaborate to measurably improve quality of patient care, materially reduce payor costs while maintaining quality, or both.

The agency changes the standards “evidence-based” and “valid” in the proposed rule to “clinical evidence” and “legitimate” in the final rule in order to provide some flexibility while also establishing an expectation that the measures be credible and appropriate.

While the term outcome measure under this safe harbor has the same meaning as it does under other safe harbors, the outcome measures selected for this safe harbor must have benchmarks that relate to improving or maintaining the quality of patient care, reducing payor costs or growth

in expenditures, or both. Those benchmarks, and the remuneration for achieving outcomes measures, must be periodically assessed and revised. For example, if an outcome measure is based on cost savings over the course of a year, then annual reassessments of the benchmark and remuneration is appropriate to ensure that the remuneration is fair market value. The OIG had proposed to require rebasing of benchmarks during the term of the agreement, but under the final rule parties must assess whether the continued use of the benchmark or measure (and the associated remuneration) is appropriate, and, if it is not, then they must revise them.

Unlike the care coordination arrangements safe harbor, OIG declines to permit use of process measures on their own to qualify for protection under the outcomes-based payment safe harbor; however, parties may use outcome measures that include a process measure.

(3) Writing and Monitoring

The outcomes-based payment arrangement must be set forth in writing and signed by the parties before or contemporaneous with the beginning of the terms of the arrangement. The writing must include (at a minimum) the following:

- A general description of the services to be performed for the term of the agreement.
- The outcomes measures involved.
- The clinical evidence or credible medical support that parties relied on to select the outcomes measure(s).
- The schedule for regular monitoring and assessment of the outcomes measure(s).

Instead of requiring the writing to specify the services that must be performed under the arrangement, the final rule only requires a description of the types of services that will be performed. However, OIG notes that other conditions of the safe harbor will require documentation of services furnished or activities performed to achieve the outcome.

(4) Methodology for Compensation

The methodology for determining aggregate compensation paid between the parties over the term of the agreement must:

- Be set in advance;
- Be commercially reasonable;
- Be consistent with fair market value; and
- Not be determined in a manner that directly takes into account volume or value of referrals or business otherwise generated for which payment may be made (directly or indirectly) by a Federal health care program.

With respect to the fair market value criterion, OIG declines to adopt the fair market value standard applied by CMS under the physician self-referral law. The agency does not adopt any particular standard for determining whether aggregate compensation methodology is consistent with fair market value. It acknowledges that evaluating whether an outcomes-based arrangement is consistent with fair market value may be difficult due to the lack of industry standards and that it may evolve over time and adapt as the industry shifts to value-based care.

With respect to the volume or value criterion, the agency recognizes that incentivizing care coordination and behavioral changes through outcomes-based payments may require the parties to indirectly take into account the volume or value of referrals or business otherwise generated between the parties. It believes it should be possible to structure these arrangements without directly taking these considerations into account.

(5) Other Safeguards

Other conditions of the final rule that must be met for protection under the outcomes-based payment arrangement safe harbor include the following:

- The agreement may neither limit any party's ability to make decisions in their patients' best interest nor induce any party to reduce or limit medically necessary items or services.
- The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

11. Warranties (§1001.952(g))

The OIG finalizes, with modifications, its proposals to revise the current safe harbor protection to include bundled warranties for one or more items and related services, when certain conditions are met. This safe harbor will allow manufacturers and suppliers to warrant that a bundle of items or one or more items in combinations with related services, such as product support services, will meet a specified level of performance under a warranty agreement.

a. Inclusion of Services in Bundled Warranties

The OIG finalizes its proposal to protect warranty arrangements that apply to one or more items and services, provided the warranty covers at least one item. The safe harbor does not provide protection to service only warranties. The OIG is concerned that warranties for services that are not tied to one or more related items could present increased fraud and abuse risks.

The OIG agrees with comments that the revised safe harbor will offer greater flexibility to buyers and sellers to use innovative arrangements that warranty the value of an entire bundle of items or that include bundled items and services. The OIG notes that this revision in the safe harbor would not protect free or reduced-price items or services that sellers provide either as part of a bundled warranty agreement or ancillary to a warranty agreement.¹⁷ The safe harbor protects the offer and exchange of warranty remedies under a warranty arrangement, provided all of the safe harbor's conditions are satisfied.

¹⁷ The OIG notes that a seller's provision of laboratory testing for free or at a reduced charge as part of a warranty would implicate the anti-kickback statute. Similarly, provision of medication adherence services for free or at a reduced cost would implicate the anti-kickback statute.

A commenter recommended the OIG protect warranties that cover services only such as those provided by medical device manufacturers offering data analytics via software solutions that can improve health care outcomes and costs. The OIG reiterates its concern that service-only warranty arrangements present an increased risk of fraud and abuse. The OIG notes that the determination of whether services meet a clinical outcome goal established by a warranty arrangement can be more subjective than warranties involving items and could induce patients to select a particular provider, especially if the clinical results are not easily achievable. The OIG suggests that outcomes-based arrangements for only services may be protected under the personal services and management contracts and outcomes-based payment arrangement safe harbors at §1001.952(d).

The OIG confirms that under the safe harbor a warranted bundle of items and services could incorporate services offered by the manufacturer that are not federally reimbursable and are offered free of charge. The OIG emphasizes, however, that the safe harbor only protects remuneration provided as a warranty remedy and services offered free by the manufacturer are not themselves protected under this safe harbor. Using an example provided by a commenter, the OIG states that a manufacturer could offer a bundled warranty that warrants the clinical effectiveness of a self-injected drug contingent on the patient receiving post-prescribing product administration and education by a nurse offered by the manufacturer. The OIG notes that if non-reimbursable items or services offered for free as part of a bundled warranty have independent value to a buyer, the parties to the warranty arrangement may look to other safe harbors (the personal and management contracts and outcomes-based payments safe harbors) to protect the exchange of those items and services.

The OIG acknowledges comments recommending other additional safeguards within the safe harbor, but it believes additional safeguards are not necessary.

In the proposed rule, the OIG discussed concerns with medication adherence services offered by drug manufacturers because manufacturers may promote adherence to prescribed medications, even when the patient may have harmful side effects or the medication is not effective for the patient. Some commenters did not support restrictions on the way sellers could provide warranted medication adherence services. The OIG agrees with comments that medication adherence services can have a beneficial impact on patient health and health care cost but remains concerned that medication adherence programs have increased fraud and abuse risks. However, the OIG does not impose any restrictions in this final rule on the manner in which warranted medication adherence services may be provided when offered as part of a bundled warranty. The OIG also declines to impose a requirement that warranted medication adherence services must either be provided by an independent intermediary or subject to the approval of a licensed medical professional.

The OIG disagrees with comments asserting that medication adherence services never constitute remuneration and thus never implicate the anti-kickback statute. The OIG states that the provision of free or below fair market value medication adherence services could implicate the anti-kickback statute but might not in all circumstances; implication of the anti-kickback statute would be dependent upon the facts and circumstances of a specific offering. In response to a comment about pharmacies providing adherence and medication therapy management services,

the OIG states that nothing in the safe harbor changes pharmacies' ability to provide these services, but any financial arrangement could implicate the anti-kickback statute and should be analyzed.

In response to a concern about the provision of free or reduced-price laboratory testing as part of a warranty arrangement, the OIG clarifies it did not intend to suggest in the proposed rule that in all instances, confirmatory laboratory testing for determining if a warranted outcome was achieved would implicate the anti-kickback statute. The OIG states that in the case of confirmatory laboratory testing related to a warranty arrangement the testing could have independent value to the buyer and reiterates that arrangement could implicate the anti-kickback statute and should be analyzed.

b. Requirements for Federally Reimbursable Items and Services Subject to Bundled Warranty Arrangements To Be Reimbursed by the Same Federal Health Care Program and in the Same Program

The OIG finalizes its proposal to require that all federally reimbursable items and supplies subject to the warranty arrangement be reimbursed by the same Federal health care program and in the same Federal health care program payment.

Commenters objected to this condition in order to qualify for protection under the safe harbor. Commenters noted that care coordination arrangements often require payment from different reimbursement methodologies and included an example in which a joint replacement can occur in a hospital or ASC and the patient is discharged to a skilled nursing facility or to home health care. Other commenters stated the condition was outdated and unworkable in value-based arrangements.

The OIG responds that the warranties safe harbor is not designed to protect warranties involving items purchased by multiple buyers across different care settings or reimbursed by different payment systems. It believes that such an arrangement poses an increased risk of inappropriate utilization and overutilization. The OIG notes that such arrangements may qualify for protection under other safe harbors discussed in this final rule, including the safe harbor for care coordination arrangements (§1001.952(ee)), value-based arrangements with substantial downside financial risk (§1001.952(ff)), and value-based arrangements with full financial risk (§1001.952(gg)).

The OIG acknowledges that some Medicaid programs reimburse items and services with a variety of payment methodologies, including separate, unbundled reimbursement for some items, but it remains concerned that providing a safe harbor protection to warranties containing separately reimbursable items would introduce a higher risk of fraud and abuse. Responding to a comment about the arrangement described in Advisory Opinion No. 18-10 which approved a bundled warranty arrangement in which some of the items in the bundle were separately reimbursable under certain States' Medicaid programs, the OIG acknowledges that this arrangement would not be covered by the warranties safe harbor. The OIG notes that the advisory opinion process remains available for a legal opinion regarding facts and circumstances that may not be protected by the safe harbor.

The OIG acknowledges comments it received in response to its solicitation about necessary exceptions to the safe harbor, but it concludes that exceptions are not necessary. The OIG recognizes that a seller may not know under which reimbursement methodology a particular item will be reimbursed, but it believes a bundled warranty arrangement could specify that only items and services reimbursed by the same Federal health care program are included in the warranty. For example, a warranty could explicitly state that warranty remedies are available only for patients or procedures in which the bundled items and services are reimbursed by the same program and same payment even where alternative reimbursement methodologies for those items and services exist.

The OIG agrees with a comment that the safe harbor would not protect a warranty bundle consisting of a particular federally reimbursed drug product and a companion diagnostic test. The OIG states that the safe harbor could protect a warranty covering the drug product, and if the seller wants to provide a companion diagnostic test to determine if a warranted outcome has been achieved, other safe harbors might protect the provision of the companion diagnostic test to the extent the provision of the companion diagnostic test implicates the anti-kickback statute.

The OIG appreciates the comments it received in response to its questions related to population-based warranties. The OIG may consider specifically tailored safe harbor protection for value-based contracting and outcomes-based contracting in future rulemaking.

c. Capped Amount of Warranty Remedies

The OIG finalizes its proposal to modify paragraph (4) of §1001.952(g) to limit the remuneration a manufacturer or supplier may pay to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary to the cost of the item and service covered by the warranty.

In response to a comment, the OIG clarifies the safe harbor could be used to protect reimbursement for hospital expenses incurred as a result of a bundle of items that failed to meet the clinical outcomes guaranteed by a warranty arrangement. The total warranty remuneration provided, including the cost of any replacement items, would be limited to the original cost of the items and services incurred by the buyer.

d. Prohibition on Exclusivity and Minimum-Purchase Requirements

The OIG finalizes its proposal to prohibit manufacturers and suppliers from conditioning warranties on the exclusive use of one or more items or services and from imposing minimum-purchase requirements of any item or service.

Some commenters were supportive of this requirement; others argued that these safeguards are unnecessary. The OIG acknowledges that exclusivity and minimum purchase requirements may provide certain efficiencies, but it considers exclusivity and minimum-purchase requirements for a warranty as potentially abusive steering practices that could interfere with clinical decision making and result in inappropriate utilization. In response to commenters urging the OIG to omit

these requirements from population-based warranties that typically require some minimum level of use of the product, the OIG reiterates its concerns about warranty protection linked to exclusivity and minimum purchase requirements and does not extend protection under the warranties safe harbor for items used across a patient population.

In response to a commenter requesting clarification of an “exclusive” product as compared to a “preferred product,” the OIG states this safe harbor is not intended to impact arrangements to purchase a “preferred product” which is independent of any potential unrelated bundle warranty offered by the product’s manufacturer. The OIG states that the exclusive-use and minimum-purchase provisions in the safe harbor prevent a manufacturer or supplier from receiving safe harbor protection for a warranty that is conditioned on the buyer’s exclusive use or minimum purchase of items or services. The OIG interprets the “conditioned on” standard to mean that a causal connection exists between receiving a warranty and maintaining exclusivity or minimum-purchase requirements. The safe harbor does not prohibit exclusive-use or minimum-purchase requirements that are conditioned upon commercial terms unrelated to the offer of a warranty.

e. Reporting Requirements

In the proposed rule, the OIG discussed stakeholders’ concerns that the safe harbor’s existing reporting requirements could limit the ability to offer innovative warranty arrangements. The OIG recognized that outcomes-based warranty arrangements could provide payments from manufacturers over several years if a therapy does not meet clinical outcomes at designated time points. The OIG stated it was considering ways to modify the reporting requirements to accommodate outcomes-based warranty arrangements and still protect the Government’s interest in having an accurate and timely report of any price reductions a seller offers a buyer under a warranty arrangement protected by the safe harbor.

In the final rule, the OIG addresses these concerns by (i) clarifying that the safe harbor can be used to protect warranty arrangements that span multiple years; (ii) changing references in the safe harbor from “the price reduction” to “any price reduction” to make clear that more than one price reduction may occur during a warranty arrangement; and (iii) clarifying that buyers are obligated to report price reductions in a manner compatible with the reimbursement methodology for the warranted items of services, including circumstances in which a provider does not submit cost responses or a formal “claim for payment” unless the payor does provide a reporting mechanism.

A commenter noted that many items and services are reimbursed by Medicare Advantage plans or Medicaid managed care organizations, and buyers have no obligation to report reduction in a “cost reporting mechanism” or “claim for payment” as referenced in the warranties safe harbor. The OIG clarifies that buyers, other than beneficiaries, are obligated under the safe harbor to report price reductions in a manner compatible with the reimbursement methodology for the item(s) or services(s) even if not reported in a “cost reporting mechanism” or a “claim for payment”. It states this requirement applies to buyers even when they do not have an expressed obligation to report a price reduction or replacement product under applicable requirements of the Federal health care program for the warranted item or service to which the price reduction applies. In the event that a payor does not provide any mechanism for reporting of costs, such reporting is not required for a buyer to obtain safe harbor protection.

The OIG agrees with commenters that under the warranties safe harbor, buyers can report multiple warranty payments related to the same item or bundle of items and services at various times in a warranty arrangement. To clarify that more than one price reduction may occur during a warranty arrangement, the OIG finalizes corresponding revisions to the warranties safe harbor to change all references to “the price reduction” to “any price reduction”. The OIG also does not believe the safe harbor needs expansion to accommodate the sellers’ requirement to report price reductions. The OIG states sellers must report price reductions on the initial invoice or statement sent to the buyer or, when the amount of any price reduction is not known at the time of sale, report the existence of a warranty on the invoice and later provide the buyer with documentation of the calculation of any price reduction resulting from the warranty. The OIG notes that the warranties safe harbor does not include a time requirement for the seller to provide the documentation of the price reduction. The OIG expects buyers and sellers to fulfill their reporting obligations in a timely fashion but does not prescribe a timeline.¹⁸ The OIG agrees with a commenter that the reporting requirement is not triggered until remuneration is received under the warranty arrangement.

In response to a comment about the methodology for allocating a rebate for a bundle of items, the OIG states the safe harbor does not set forth a specific methodology to allocate reporting across multiple or a combination of items and services. The OIG believes that in most cases a warranty remedy paid to a bundled warranty should be reported proportionately to the cost of each bundled item or service, but buyers have the flexibility to adopt different but reasonable allocation methodologies.

f. Definition of “Warranty”

The OIG finalizes its proposal to define “warranty” directly and not by reference to 15 U.S.C. §2301(6)¹⁹ in order to clarify that the definition of warranties safe harbor applies to FDA-regulated drugs and devices. The OIG defines “warranty” based on the definition in 15 U.S.C. §2301(6) with modifications to replace references to a “product” with references to “items” or “bundle of items” and to substitute references to the “material” of a product with “quality”. The definition continues to include a “written affirmation of fact or written promise [that] affirms or promises that [items and services] ... will meet a specified level of performance over a specified period of time.” The OIG believes this will provide protection for warranty arrangement conditioned on clinical outcome guarantees.

Commenters urged the OIG to confirm that a partial refund or retrospective rebate resulting in a price adjustment would constitute a “refund” or “other remedial action” as those terms are used in the warranties safe harbor (§1001.952(g)(7)(ii)). The OIG reiterates that its definition is based on the definition codified at 15 U.S.C. §2301(6) which defines “refund” as refunding the actual purchase price (less reasonable depreciation based on actual use where permitted by rules of the Commission). Although the OIG has not explicitly adopted this definition, it believes the definition provides guidance for interpreting the term “refund”.

¹⁸ Reporting obligations are defined in §1001.952(g)(1) and §1001.952(g)(3).

¹⁹ The Magnuson-Moss Act enacted 15 U.S.C. §2301 which in paragraph (6) defines “written warranty” in conjunction with the sale of a consumer product.

The OIG states that regardless of how “refund” is defined, the safe harbor contemplates that manufacturers or suppliers may “take other remedial action” if an item fails to meet the specifications in the written arrangement. The OIG believes that a partial refund or retrospective rebate resulting in a price adjustment could constitute “other remedial action” as long as all the other conditions of the safe harbor were met.

In response to comments, the OIG states the expanded warranties safe harbor could be used to protect a wide range of warranty arrangements, including warranty arrangements conditioned on clinical outcomes guarantees, which could include warranties conditioned upon “value-based” outcomes. The OIG declines to provide specific examples of clinical outcome guarantees that might be protected because it does not want to narrow innovative arrangements that might seek coverage under the safe harbor. The OIG also notes that the warranties safe harbor is silent on whether a warranty arrangement protected under the safe harbor can have a single triggering condition or multiple triggering conditions in order to qualify for safe harbor protection.

12. Local Transportation (§1001.952(bb))

The OIG proposed to modify the existing safe harbor for local transportation to (i) expand the distance limitations applicable to residents of rural areas from 50 to 75 miles and (ii) remove any mileage limitation for a patient transported from an inpatient facility from which the patient has been discharged after admission as an inpatient to the patient’s residence or another residence of the patient’s choice.

The OIG finalizes, with modifications, its proposed revisions to the safe harbor for local transportation. The OIG clarifies the mileage limits do not apply when the patient is discharged from an inpatient facility following an inpatient admission or released from a hospital after being in observation status for at least 24 hours.

a. Expansion of Mileage Limit for Patients Residing in Rural Areas

The OIG finalizes its proposal to increase the limit on transportation of residents in rural communities from 50 to 75 miles of the health care provider.

Many commenters supported the increase in the mileage limit for safe harbor protection for residents of rural areas to 75 miles. Several commenters disagreed and recommended various options including increasing the limitation to 150 miles and eliminating any mile restrictions. Commenters discussed the challenges rural communities have accessing health care as the number of local health care providers decreases and close. The OIG discusses the reasons it finalizes an increase to 75 miles, including its belief this limit is not likely to be subject to abuse. It notes the safe harbor is intended for local transportation and that in enacting the CMP provision prohibiting inducements to Federal and state health care program beneficiaries, Congress intended that the statute not preclude the provision of complimentary local

transportation of nominal value.²⁰ The OIG is concerned that 150 miles is not local and could serve as an inducement for beneficiaries to travel long distance for care they might be able to obtain locally. The OIG notes that programs offering transportation for rural area patients at greater distances are not necessarily unlawful, but the facts and circumstances of each program must be evaluated on a case-by-case basis.

Many commenters recommended the OIG expand the mileage limit further for certain categories of patients, such as those who live in areas without public transportation, those who lack access to specialty health care services due to closures, those living in frontier areas and homeless individuals. Comments also suggested various options for providing protection from fraud and abuse for transportation beyond 75 miles to a patient's medical provider including provider certification in writing. Other comments requested wholesale exemption from the mileage limitation for specific providers including Indian health care providers and community health centers. The OIG believes maintaining the design of the current safe harbor provides a single, uniform mileage limit for rural areas that offers bright-line guidance and reduces administrative burden.²¹ The OIG notes that VBE participants may meet the conditions for providing certain transportation services under the patient engagement and support safe harbor (§1001.952(hh)).

In response to commenters requesting removal of any restrictions regarding the use of federal funds for the cost of transportation furnished to patients, the OIG states it did not propose to modify the existing prohibitions on shifting the cost of protected transportation to any federal health care program, other payors or individuals. The OIG notes where parties are required by federal or state law to provide transportation services those arrangements might not implicate the AKS. In these circumstances, the parties should assess whether there is any remuneration passing to the patient by providing a covered item or service paid for by a federal health care program.

The OIG notes that this safe harbor does not modify existing federal law regarding IHS appropriations for transportation services furnished to its beneficiaries. The OIG also excluded protection for free or discounted air transportation under the existing local transportation safe harbor, and it did not propose changes to this provision. The OIG also notes that it did not propose to expand the 25-mile limit for urban areas.

b. Elimination of Distance Limitations on Transportation of Discharged Patients to Their Residence

The OIG finalizes its proposal to eliminate any distance limit on transportation of a patient discharged after an inpatient stay, for both patients residing in an urban or rural area, if the transportation is to the patient's residence or another residence the patient chooses.

²⁰ H.R. Conf. Rep. No. 104-736 at 255. See also 79 FR 59717, 59722-23 (Oct. 3, 2014) and 81 Fed Reg 88368, 88379 (Dec. 7, 2016).

²¹ In the 2016 rule finalizing the local transportation safe harbor, the OIG stated that while it understood that a set mileage limit is not a one-size-fits-all solution, it believes that a bright-line rule is easier for all parties to apply (81 FR 88388 (Dec. 7, 2016)).

The OIG confirms that the term “residence” in this safe harbor²² includes custodial care facilities that serve as a patient’s permanent or long-term residence provided that the patient established the custodial care facility as a residence before receiving treatment. The term also includes a homeless shelter when a patient is homeless or established the homeless shelter as a residence prior to the hospital admission. The OIG also affirms that a residence of the patient’s choice can include the residence of a friend or relative who is caring for the patient post-discharge.

The OIG notes this safe harbor does not require an entity to offer transportation. The offer of transportation must be made consistently and available without regard to the volume or value of the Federal health care program business. The entity sponsoring the transportation cannot offer it only to affiliated facilities.

c. Transportation to Locations Other Than a Patient’s Residence or a Residence of the Patient’s Choice

Many commenters recommended modification of the safe harbor to protect transportation to any location of the patient’s choice, including to another health care facility when there is a medical need for the transfer. Commenters provided various examples of why this is beneficial to the patient, including transportation from an emergency room to another health care facility.

The OIG agrees that the patients could benefit by extending safe harbor protections, but it believes that protecting transportation between health care providers in a position to refer to each other is not sufficiently low risk to warrant safe harbor protection and that transportation arrangements could be used to steer patients to health care facilities that may not be in their best interests. The OIG notes that patients discharged from inpatient facilities may be offered transportation to a nursing facility if it is their residence. In addition, the safe harbor for patient engagement and support offered by VBE participants (§1001.952(hh)) could protect transportation of patients from an inpatient hospital to another health care facility for post-acute care treatment.

d. Elimination of Distance Limitations for Patients Other Than Those Discharged After an Inpatient Admission

Numerous commenters requested expansion of the exemption from distance limitations for discharged hospital inpatients to include patients in a hospital outpatient department, ambulatory surgery center (ASC), hospital emergency room, and patients in a hospital observation status for a substantial period.

The OIG responds that the safe harbor mileage limitation does not apply in two circumstances. First, the mileage limits does not apply when the patient is discharged from an inpatient facility following an inpatient admission. Second, based on comments, the OIG is expanding the safe harbor and removes the mileage limitation when a patient is discharged after spending 24 hours in observation status. The OIG believes that an extended stay in observation status at a hospital is similar to an inpatient stay.

²² As used in paragraph 1001.952(bb)(1)(iv)(B).

The OIG is not removing the mileage limitation for other patients categorized as outpatients, including patients in the emergency room or ASC. It is concerned that creating an exception for these categories of patients would make the exception too broad and result in potentially abusive arrangement.

e. Local Transportation for Health-Related Non-Medical Purposes

In the proposed rule, the OIG sought comments about extending protection under the safe harbor to transportation provided for nonmedical purposes. Commenters generally supported extending protection to include transportation to obtain services that address social determinants of health including obtaining food and housing services. Some comments suggested potential safeguards for expanded safe harbor protection for transportation for non-medical purposes.

The OIG acknowledges the importance of addressing social determinants of health but is not expanding the local transportation to protect patient transportation for nonmedical purposes. As explained in the 2016 final rule establishing the safe harbor²³, the OIG continues to believe that the risk of beneficiaries being improperly induced to obtain items or services is too high for safe harbor protection when the transportation is for non-medical purposes. The OIG states that the safe harbor for patient engagement and support offered by VBE participants (§1001.952(hh)) could protect nonmedical transportation if the transportation has a direct connection to the coordination and management of care of the target patient population and meets the other conditions of the safe harbor.

f. Use of Ride-Sharing Services

The final rule establishing the local transportation safe harbor (81 FR 88387) included patient transportation provided via a taxi as long as all other requirements were met. The OIG clarifies that although it did not explicitly refer to ride-sharing services, for purposes of the safe harbor, it considers ride-sharing services similar to taxis.

The OIG discusses how the same safe harbor requirements that apply to other forms of transportation also apply to transportation provided by ride-sharing services. Similar to other forms of transportation, to the extent that the ride-sharing service provides services beyond those for obtaining medical care, it would not be protected by the safe harbor. The OIG notes that transportation to obtain a prescription, to a food store, or any other location related to obtaining medically necessary items or services, when provided on a patient-specific basis, would be protected (81 FR 88384). In response to comments, the OIG states that the provider of transportation cannot advertise that it provides free or discounted transportation to a specific health care provider.

13. ACO Beneficiary Incentive Program (42 CFR 1001.952(kk))

²³ 81 FR 88384 (Dec. 7, 2016)

The BBA 2018²⁴ added section 1899(m) of the Act to permit ACOs under certain two-sided models to operate CMS-approved beneficiary incentive programs. Section 50341(b) of the BBA 2018 added section 1128B(b)(3)(K) of the Act which states that “illegal remuneration” under the anti-kickback statute does not include “...an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1899, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.”

The OIG finalizes its proposal to codify this statutory exception to the definition of remuneration in its regulations at 1001.952(kk). The OIG finalizes two proposed interpretations of the statutory language. First, it clarifies its interpretation of the language to state that an ACO may furnish incentive payments only to assigned beneficiaries. Second, it interprets the statutory language “if the payment is made in accordance with the requirements of such subsection” to mean “if the incentive payment is made in accordance with the requirements found in such subsection”. This means that 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 to be protected remuneration. The OIG did not propose to establish any additional safe harbor conditions for incentive payments made by an ACO to an assigned beneficiary under an ACO Beneficiary Incentive Program established under section 1899(m) of the Act.

Several commenters expressed support for the ACO Beneficiary Incentive Program safe harbor; a few requested that the safe harbor be expanded to protect any future beneficiary incentives covered under CMS-sponsored payment models, including protection for ACOs participating in any Innovation Center demonstration. The OIG responds that this safe harbor codifies a statutory safe harbor that is specific to ACO Beneficiary Incentive Programs and that these suggestions are beyond the scope of the statute and its proposal. The OIG notes that if commenters are requesting safe harbor protection for beneficiary incentives provided through existing CMS-sponsored models developed pursuant to section 1115A(d)(1) of the Act, any fraud and abuse waiver applicable to beneficiary incentives under the relevant model would potentially provide protection. The OIG also notes this final rule finalizes a safe harbor for CMS-sponsored models at 1001.952(ii) that protects certain CMS-sponsored model patient incentives under models for which CMS has determined that this safe harbor should apply (discussed above in section B.7).

C. Civil Monetary Penalties (CMP) Authorities: Beneficiary Inducements CMP

1. Exception for Telehealth Technologies for In-Home Dialysis (§1003.110(10))

Section 50302 of the BBA 2018 amends section 1881(b)(3) of the Act to permit an individual with end stage renal disease (ESRD) receiving home dialysis to receive their monthly ESRD-related clinical assessments by telehealth, if certain conditions are met. Section 50302(c) of the law creates a new exception to the definition of “remuneration” in the beneficiary inducements CMP. Specifically, the following exceptions were added at section 1128A(i)(6)(J) of the Act for

²⁴ Pub. L. 115-123, 132 Stat. 64.

the provision of telehealth technologies to an individual who is receiving home dialysis paid under Medicare Part B if:

- The telehealth technologies are not offered as part of any advertisement or solicitation (section 1128A(i)(6)(J)(i));
- The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's ESRD (section 1128A(i)(6)(J)(ii)); and
- The provision of the telehealth technologies meets any other requirements in regulations promulgated by the Secretary (section 1128A(i)(6)(J)(iii)).

This exception is available only for telehealth technologies (defined below) furnished by a provider of services or a renal dialysis facility to patients with ESRD receiving in-home dialysis payable by Medicare Part B.

The OIG finalizes, with modifications, its proposal incorporating this statutory exception for furnishing telehealth technologies to certain in-home dialysis patients to its definition of remuneration at (§1003.110(10)). As discussed below, the OIG finalizes this provision to align with the statutory exception and removes most of the additional proposed conditions that were not in the statutory exception. The OIG also modifies the definition of “telehealth technologies” and includes physicians as a type of practitioner that can donate telehealth technologies to a patient.

a. General Comments

Although commenters overwhelmingly supported the proposed exception, some commenters raised concerns about the proposed conditions that encompassed more than the statutory exception. Commenters were concerned these additional proposals could impede patient access to telehealth services, increase administrative burden, and increase work required by staff.

In response to these comments, the OIG made several modifications to the final exception including alignment with the statutory text. The OIG believes these modifications are consistent with the narrow exception to the CMP beneficiary inducement statute which is limited to a subset of patients receiving in-home dialysis and specific providers. The OIG believes the potential for fraud and abuse is limited because the exception is only available to established patients receiving in-home dialysis reimbursed by Medicare Part B. The OIG explains that the two statutory conditions address common fraud and abuse risks associated with providing free telehealth technologies to certain beneficiaries.

b. Definition of “Telehealth Technologies”

The OIG proposed to adopt, as part of its definition of “telehealth technologies” the definition of “interactive telecommunications systems” found at 42 CFR 410.87(a)(3).²⁵ Specifically, the OIG proposed to define “telehealth technologies” as “multimedia communication equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive

²⁵ The OIG discusses CMS' expansion of the types of technology that can be used to provide telehealth services, the types of services that can be provided by telehealth, certain coverage requirements related to originating and distant sites and other flexibilities to help health care providers respond to the Covid-19 public health emergency (PHE). The OIG notes that most of these flexibilities will remain until the Secretary ends the declaration of the PHE.

communication between the patient and distant site physician or practitioner used in the diagnosis, intervention or ongoing care management – paid for by Medicare Part B – between a patient and the remote health care provider.” Telephones, facsimile machines, and electronic mail systems would not meet the definition of “telehealth technologies.” Smart phones that allow for two-way, real-time interactive communication through secure, video conferencing applications would not be considered “telephones”.

For purposes of the telehealth technologies exception to the definition of “remuneration,” the OIG finalizes, with modifications, its proposal to define “telehealth technologies” as hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management. The OIG states that the final definition is technology agnostic; it includes both the technologies it had proposed to include and exclude from the definition (telephones, facsimile machines and electronic mail systems). The OIG emphasizes that for a donation of technology to be protected, it must meet all the conditions of this exception including being provided for furnishing services related to the recipient’s ESRD.

The OIG agrees with comments that the definition of telehealth technologies should not be restrictive and should focus on the functionality of the technology to provide telehealth rather than specific types of technology. The OIG acknowledges that this broadened definition might inappropriately induce patients to pursue in-home dialysis or select a particular provider or physician, but it believes this risk is mitigated because of the restrictions on marketing and other safeguards.

The OIG states the revised definition is supported by the statutory exception in the Act which gives the Secretary authority to define “telehealth technologies” and does not limit the definition under the exception to any related Medicare definitions. The OIG notes that parties still need to comply with any other applicable government regulations that address the use or functioning of telehealth technology, HIPAA, and other federal and state privacy and security laws.

In response to comments about specific technologies, the OIG explains it is not providing an exhaustive list of eligible technologies because it does want to inadvertently limit telehealth technologies that are determined suitable to facilitate telehealth services to beneficiaries with ESRD and to allow for the evolution of the technology. The OIG notes that the definition covers technology based on its function, and the finalized definition includes equipment used to monitor data and report to physicians and dialysis facilities (e.g., Bluetooth-enabled stethoscope) where appropriate, provided the technologies satisfy all the conditions of the exception. The OIG agrees with comments that a distinction between two-way, real-time technology and asynchronous technology is not necessary and that some audio-only technology, including a virtual check-in, may be appropriate.

The OIG also agrees with comments that the definition should include peripheral devices or applications that the physician determines are necessary to complete a proper assessment of the patient during a telehealth service. The OIG notes that the definition encompasses technologies for remote patient monitoring. The OIG did not propose and is not adopting any geographic limitation. The OIG also notes that policies about what constitutes a physician telehealth service

are outside the scope of this rulemaking; protection of telehealth technologies is not conditioned on being provided for the purpose of furnishing “telehealth services” paid for by Medicare Part B (discussed below in section e).

c. Furnished by Specified Individuals and Entities Currently Providing Care to the Patient

Section 1128A(i)(6)(J) of the Act limits the exception to technologies provided “by a provider of services or the renal dialysis facility (as defined in title XVIII of the Act) to an individual with ESRD who is receiving home dialysis for which payment is being made under part B of such title....” In the proposed rule, the OIG sought comment on whether it should interpret the statutory exception to apply not only to the “provider of services or the renal dialysis facility (as defined in title XVIII of the Act)” but also to suppliers (as defined in title XVIII of the Act).

The OIG finalizes, with modifications, the proposed condition at 1001.110(10)(i) that interprets the statutory language so that the exception is only available to the provider of services or the renal dialysis facility that is currently providing in-home dialysis, telehealth services, or other ESRD care to the patient. The OIG states the exception is limited to telehealth technologies furnished by a provider of services, physicians, or a renal dialysis facility currently providing in-home dialysis, telehealth services, or other ESRD care to the patient or has been selected or contacted by the patient to schedule an appointment or provide services.

Several commenters supported the OIG’s interpretation that the provision of telehealth technologies is limited to patients with whom the donors have a prior clinical relationship. A commenter expressed concern that this interpretation would be operationally difficult to implement and the exception should also include patients that have selected a provider but is not yet receiving in-home dialysis. The OIG agrees with the commenter because the protected telehealth technologies cannot be offered as part of any advertisement or solicitation. The OIG notes that a provider, physician or facility may offer or furnish telehealth technologies to a patient with ESRD who is receiving home dialysis paid for by Medicare Part B after the patient selects and initiates contact with a provider, facility, or physician to schedule an appointment or other services.²⁶

The OIG agrees with commenters that expanding the exception to a broad range of practitioner types by using “suppliers” poses additional fraud and abuse risks. To minimize the risk and consistent with section 1128A(i)(6)(J) of the Act, the OIG finalizes the exception by including “physicians” but not suppliers.²⁷ Under this final exception, a physician must meet the definition

²⁶The OIG notes if a patient is unable to call a provider or physician but has otherwise given consent for a person (e.g., a family member or a case manager, or a provider or supplier when the patient is attending an appointment or receiving services) to schedule appointments or upcoming services for them, then a request for an appointment or upcoming services made on behalf of the patient is sufficient to meet the patient-initiated contact requirement.

²⁷ The definition of “suppliers; in title XVIII includes a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

of physician as set forth in section 1861(r) of the Act²⁸ and be providing in-home dialysis, telehealth services, or other ESRD care to the patient. The OIG believes it is unlikely that all practitioners under 1861(r) (such as dental surgeons, doctors of podiatric medicine or chiropractors) would be eligible for protection under this exception

d. Prohibition on Advertisement or Solicitation

The OIG finalizes its proposal at condition (ii) that telehealth technologies may not be offered as part of any advertisement or solicitation consistent.²⁹ The OIG notes that stakeholders should interpret the terms “advertisement” and “solicitation” consistent with their common usage in the health care industry (81 FR 88368, 88373).

e. Provided for the Purpose of Furnishing Telehealth Services Related to an Individual’s ESRD

The OIG proposed to interpret “for the purpose of furnishing telehealth services related to the individual’s ESRD” to mean the technology contributes substantially to the provision of telehealth services related to the ESRD, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if the technology is adequate for telehealth purposes. The OIG also proposed to interpret “telehealth services related to the individual’s ESRD” to mean only those telehealth service paid for by Medicare Part B.

The OIG finalizes, with modification, its proposal to interpret “for the purpose of furnishing telehealth services related to the individual’s ESRD” to mean the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual’s ESRD; consistent with the statutory language in section 1128A(i)(6)(J)(ii) of the Act.

The OIG does not finalize the proposed requirement that the telehealth technologies not be of excessive value. In response to comments supporting a prohibition of technologies with excessive value, the OIG acknowledges that telehealth technology with substantial independent value might serve to inappropriately induce the beneficiary, but it believes the limited nature of the exception and the other conditions of the exception provide appropriate safeguards.

The OIG does not finalize the proposed requirement that the telehealth technologies not be duplicative technology that the beneficiary already owns.

The OIG does not finalize its proposal to interpret “telehealth services related to the individual’s ESRD” to mean only those telehealth service paid by Medicare Part B. The OIG agrees with comments that section 1128A(i)(J)(6) of the Act does not include this limitation. The OIG acknowledges this means providers, physicians, and renal dialysis facilities have the flexibilities to determine whether telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual’s ESRD. The OIG believes the limited nature of the

²⁸ Section 1861(r) of the Act includes Doctor of Medicine or osteopathy, Doctor of Dental Surgery, Doctors of podiatric medicine, Doctor of Optometry, and chiropractors in the definition of “physician”.

²⁹ The OIG notes that stakeholders should interpret the terms “advertisement” and “solicitation” consistent with their common usage in the health care industry (81 FR 88368, 88373 (December 7, 2016)).

exception and other safeguards appropriately limits the risk of fraud and abuse. The OIG notes that this exception does not change the Medicare coverage or payment requirements related to the provision of these services or submitting claims for reimbursement. This exception may protect a physician, provider, or renal dialysis facility from CMP liability for providing a patient telehealth technology for the purpose of furnishing a telehealth services, but that does not mean they can bill for those services. The OIG states that billing medically unnecessary telehealth services is not protected by this exception and would implicate criminal and civil health care fraud statutes.

The OIG reiterates that it intends for this exception to apply to all types of telehealth technology provided for furnishing distant or remote services through various modalities. It states that at a minimum, such services include the following types covered by Medicare: telehealth services, virtual check-in services, e-visits, remote care management, and remote patient monitoring. The OIG provides specific examples including virtual ESRD management (e.g., nurse assessment, social worker support, dietician care), patient education, and monitoring vital signs. Other services may be considered telehealth services for the purpose of this exception based on the facts and circumstances of the care provided.

The OIG agrees with commenters that the proposed conditions imposed additional requirements not included in the statute. If additional safeguards are needed, the OIG states the Secretary has the authority to implement those under section 1128A(i)(6)(iii) of the Act.

In response to a comment raising concerns about restricting the technology to services only related to the individual's ESRD, the OIG clarifies that it is not requiring a donor to technically limit the telehealth technologies. Under the finalized condition, the OIG states that technologies that are multifunctional and have additional purposes in furnishing telehealth services related to the individual's ESRD are not precluded and may be protected. As long as all the conditions of the exception are met, a tablet that a patient uses to access telehealth services for their ESRD care could be protected even though the tablet has other purposes or functionalities such as the ability to download other applications. Commenters raised concerns about the OIG's suggestion in the proposed rule that would restrict telehealth technologies to those that do not provide no more than a *de minimis* benefit for any purpose other than furnishing telehealth services related to ESRD. The OIG agrees with commenters and does not finalize a *de minimis* benefit standard in this exception.

The OIG also does not finalize a requirement to make a good faith determination that the individual does not already have the necessary telehealth technology. Determining whether the provision of telehealth technology meets this condition requires an analysis of the specific facts and circumstances of the patient, including how the telehealth technologies support furnishing telehealth services related to the patient's condition. The OIG notes that nothing in this exception prevents parties from asking patients about their existing technology needs and capabilities and nothing in this exception requires patients to answer such inquiries. However, if a patient has existing telehealth technology and is already able to receive all necessary telehealth services, providing the patient with additional telehealth technology may not have the purpose of furnishing telehealth services. In response to comments about retrofitting a patient's existing technologies instead of providing fully integrated telehealth technology, the OIG states that in

making a determination about the technology for potential protection under this exception, the donor needs to assess the particular facts and circumstances for that patient and the potential technology. The OIG does not intend for this exception to require that donors attempt to retrofit a patient's existing technology.

The OIG agrees with commenters recommending that telehealth services include both ESRD-related issues and comorbidities. The OIG recognizes that patients with ESRD generally receive care for comorbidities that affect their ESRD. Although not required, the OIG believes it would be a best practice for the donor to document contemporaneously how the telehealth services relate to the individual's ESRD care, such as management of care, monitoring of health or treatment.

f. Ownership and Retrieval of Technology

In the proposed rule, the OIG considered a condition that would require the provider or facility to retain ownership of any hardware and make reasonable efforts to retrieve the hardware once the beneficiary no longer needs it for the permitted health purposes. After consideration of comments, the OIG is not finalizing this condition.

The OIG notes that the condition that telehealth technologies be provided to a beneficiary with ESRD who is receiving home dialysis for which payment is made under Medicare Part B would require termination of technology services (e.g., recurring monthly data plan fee or application that require ongoing subscription fees) if the individual is no longer receiving home dialysis paid by Medicare Part B. The technology services would also need to be terminated if the patient is no longer using them for ESRD-related telehealth services. The exception does not protect sham donations of technology given to individuals to keep indefinitely.

g. Prohibition on Cost-Shifting

The OIG does not finalize its proposal to require as a condition of protection under the exception that the provider of services or renal dialysis facility not separately bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the costs of the telehealth technologies as a bad debt for payment purposes, or otherwise shift the burden of the costs of the telehealth technologies to a Federal health care program, other payors, or individuals.

The OIG believes that the combination of the final conditions and the limited-nature of this statutory exception will adequately protect against fraud and abuse risks and an additional safeguard related to cost-shifting is not necessary. In addition, the OIG does not want to exclude arrangements from this exception that involve furnishing telehealth or other services to the ESRD patient receiving in-home dialysis and are also billable to Medicare. The OIG recognizes that these services, as long as applicable Medicare rules are met, may appropriately result in Medicare paying for costs of certain technologies or an appropriate increase in certain Medicare costs. In addition, this final exception covers a wider range of telehealth technologies used to support providing telehealth services other than the types of technologies used to provide Medicare Part B covered "telehealth services".

h. Other Potential Safeguards

i. *Consistent Provision of Telehealth Technologies.* The OIG does not finalize any condition related to prohibiting parties from discriminating in the offering of telehealth technologies. In the proposed rule, the OIG sought comments about a condition requiring providers and renal dialysis facilities to provide the same technologies to any Medicare Part B eligible patient receiving in-home dialysis, or to consistently offer telehealth technologies to all patients satisfying specific, uniform criteria.

The OIG acknowledges comments explaining why providing the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis may be impractical or impossible. It also agrees with comments highlighting that a patient's need for technology may vary based on numerous factors including location, availability of transportation, financial, diagnosis, and treatment plan. The OIG also agrees with comments that technology should be provided on an as-needed basis and the final decision involves patient choice. The OIG concludes that because the finalized exception is only available to established patients receiving specific services paid for by Medicare Part B, the potential for fraud and abuse is reduced.

ii. *Notice to Patients.* The OIG does not finalize any condition requiring a written explanation of the reason for the technology and any potential hidden costs associated with the telehealth services to any patient who elects to receive telehealth technology. The OIG agrees with commenters that this information should be conveyed through the physician-patient relationship or in the normal facility-patient communications; parties are free to provide this information through written notice.

iii. *Patient Freedom of Choice.* The OIG does not finalize any condition requiring offerors of telehealth technologies to advise patients when they receive the technology that they still retain the freedom to choose any provider or supplier of dialysis services and to receive dialysis in any appropriate setting.

The OIG agrees with comments that existing laws are better suited to protecting patient freedom of choice. It also thinks the condition that limits the offering or furnishing of telehealth technologies to an established patient or a patient that initiates contact with the provider, facility, or physician to schedule an appointment or other services also supports patient autonomy.

iv. *Materials and Records Requirement.* The OIG does not finalize any condition related to the development or retention of materials and records or other documentation requirement. The OIG notes that maintaining documentation that the provision of telehealth technologies satisfies the exception may be a good compliance practice.

v. *Other Offerors.* The OIG discusses commenters' suggestions that telehealth technologies may benefit a broader range of patients, including the uninsured and medically underserved patients. In response to comments about charitable clinics or charitable pharmacies, the OIG states that charitable clinics or charitable pharmacies that meet the conditions in paragraphs (10)(i) and (10)(ii) may be eligible to protect the provision of telehealth technologies under this exception. The OIG notes that several other exceptions and safe harbors may apply to

the provision of telehealth technologies to patients, including the patient engagement and support safe harbor finalized in this rule.

vi. Recipient. A commenter requested that OIG clarify that the dialysis provider can also provide members of the care team who are not employed by the dialysis provider with the technology and software necessary to accommodate telehealth for dialysis patients. The OIG responds that this comment is outside the scope of the statutory exception; the exception does not protect remuneration between a dialysis provider and other members of a patient's care team. The parties may seek protection under a safe harbor such as the care coordination arrangement safe harbor finalized in this rule or request an advisory opinion.

Another commenter requested clarity about situations in which technologies provided to beneficiaries could also result in potential indirect benefits to other providers who may be in a referral source relationship with the donor of the technologies, including an integrated delivery care system. The OIG responds that any indirect benefit to a provider who may be a referral source for a donor would need to be analyzed under the Federal anti-kickback statute. The OIG states that arrangements that fit into an exception to the Beneficiary Inducements CMP are not automatically protected from liability under the Federal anti-kickback statute.

V. Regulatory Impact Statement

The OIG examined the impact of the rules as required by Executive Order 12866 on Regulatory Planning and Review, the Regulatory Flexibility Act (RFA), the Unfunded Mandates Reform Act of 1995, Executive Order 13132, and Executive Order 13771.

Executive Order 12866 requires agencies to provide a regulatory impact analysis for all major rules with economically significant effects (of \$100 million or more in any year.) Because the new CMP exception in these rules and the revised safe harbors impose no requirements on any party, OIG expects the aggregate economic impact of the rule would be minimal – significantly less than \$100 million.

The Regulatory Flexibility Act requires agencies to analyze whether a rule would have a significant impact on a substantial number of small providers or small rural hospitals. Because this rule does not impose any requirements on physicians, suppliers, or small rural hospitals, OIG has concluded that a regulatory flexibility analysis is not required.

These final rules do not impose any mandates on state, local or tribal governments, or private sector in excess of \$154 million in a year so no analysis is provided under the Unfunded Mandates Reform Act. In addition, they do not affect any requirements or costs of state or local governments nor require offsetting of at least two prior regulations under Executive Orders 13132 and 13771.

While being unable to provide quantitative estimates of impact of the rules, OIG expects that the flexibilities permitted under the rules are likely to reduce waste and result in lower costs for patients and payers and may generate other benefits such as improved quality of patient care and lower compliance costs for providers and suppliers. OIG reviews research supporting cost

savings and improved health care outcomes resulting from value-based care and care coordination arrangements and estimating the costs of data breaches and cyberattacks.

OIG discusses other anticipated impacts:

- Participation among providers in value-based, care coordination, patient engagement and support, and other arrangements will likely increase.
- The adoption and use of electronic health records will be facilitated and cybersecurity throughout the health system will be promoted.
- While the changes finalized in the rule are not expected to reduce the costs of complying with existing fraud and abuse laws for providers undertaking value-based arrangements, they are not expected to increase those costs. Some providers may incur legal and administrative costs to ensure their arrangement complies with applicable safe harbors or exceptions.
- Provisions protecting donations of cybersecurity technology, EHR arrangements, warranties, and local transportation could reduce costs for smaller providers and potentially save money overall from fewer cyberattacks, ransomware, and similar threats.
- If new safe harbor protections are finalized, fewer fraud and abuse waivers would need to be prepared saving OIG approximately 1,040 employee hours per year.
- The final changes will reduce the documentation burden for providers implementing CMS-sponsored model arrangements.
- A CMP exception for certain telehealth technologies provided to patients receiving in-home dialysis could reduce barriers to the use of in-home dialysis and potentially improve quality of care for beneficiaries with ESRD.

VI. Paperwork Reduction Act

The final rules do not impose information collection or recordkeeping requirements; therefore, the OIG does not need review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.