

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 Proposed Rule

On October 17, 2019, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published in the *Federal Register* a proposed rule (84 FR 55694–55765) 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 proposed rule would:

- Add safe harbor protections under the AKS for certain coordinated care and associated value-based arrangements;
- Add 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;
- Add a new safe harbor for donations of cybersecurity technology;
- Revise the existing safe harbors for electronic health records (EHR) arrangements, warranties, local transportation, and personal services and management contracts;
- Add 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 which were enacted by the Bipartisan Budget Act of 2018 (BBA 2018).

The proposed changes would become effective prospectively only after a final rule is issued.

Also on October 17, 2019, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule (84 FR 55765–55847) 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 proposed rule.

Comments on both proposed rules must be submitted by close of business on December 31, 2019.

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I. EXECUTIVE SUMMARY

OIG describes the purpose of this proposed regulation as modifying existing and proposing new safe harbors to the AKS, and a new beneficiary inducement CMP exception, to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves 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 August 27, 2018, OIG issued a request for information (OIG RFI) that sought feedback on how the AKS and beneficiary inducement CMP law may be modified to foster arrangements that promote care coordination and advance the delivery of value-based care while also protecting against fraud and abuse against patients and federal health care programs. While most commenters argued for reforms to the safe harbors and exceptions to the definition of remuneration, other commenters noted that risks associated with greater flexibility require adequate safeguards. In response, OIG proposes a number of new safe harbors as well as changes to existing safe harbors under the AKS as well as new exceptions for the beneficiary inducement CMP.

The proposals are guided by several principles:

- Design safe harbors to permit beneficial innovation to health care delivery.

- Promulgate safe harbors and exceptions that do not drive innovation to limited channels which do not reflect up-to-date understandings of medicine, science and technology.
- Design safe harbors that are useful for a broad range of individuals and entities engaged in the coordination and management of patient care.

OIG says it tried to strike the correct balance between flexibility for beneficial innovation and safeguards to protect patients and federal health care programs; it seeks comment throughout the proposed rule on whether it has achieved the proper balance. 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. Any final safe harbors provide only prospective protection.

Noting that value-based payment (VBP) models may curb some fraud and abuse risks, OIG lists a number of other risks that they could pose, including stinting on care, cherry picking, dropping costly or noncompliant patients (lemon dropping), and manipulating or falsifying data used to verify performance and outcomes for payment. It notes there may be other risks attendant to new, emerging VBP models, and it seeks comment on how best to address existing and emerging risks for its proposals.

The proposals were developed with a focus to ensure protected arrangements (i) promote coordinated patient care and foster improved quality, better outcomes, and improved efficiency and (ii) are not used to perpetrate fraud or abuse against patients or programs. They were also designed to ensure that such safe harbors only protect arrangements that present a low risk of harm to the federal government and to beneficiaries of federal health programs. OIG notes that the proposals in this rule are in many cases more restrictive than those in the CMS physician self-referral law proposed rule; it says the proposals are a backstop protection for arrangements that may be protected under the CMS rule. The agencies intend to examine their final rules to create a regulatory landscape that is well-coordinated and allows for beneficial innovation; is as streamlined as possible, consistent with program integrity; and provides strong protections for patients and programs.

II. BACKGROUND

1. 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. The proposed rule lists a number of 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

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).

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. Throughout the proposed rule, it seeks comment on whether the proposals adequately address these concerns, and if not, the degree to which the concerns may occur and ways to address them.

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; compliance insulates the individual or entity from AKS liability but not necessarily from liability under other federal or state laws or regulations.

2. 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 purposes of the beneficiary inducement CMP do not apply under the AKS. As noted above, BBA 2018 created a new exception to the beneficiary inducement CMP definition of remuneration for telehealth technologies furnished by a provider of services or renal dialysis facility to a Medicare beneficiary with end-stage renal disease (ESRD) who is receiving home dialysis.

III. PROVISIONS OF THE PROPOSED RULE: ANTI-KICKBACK STATUTE SAFE HARBORS

A. Value-Based Framework

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).

The challenges faced by the agency in designing appropriate safe harbors is complicated by the extensive variation in care coordination and value-based arrangements envisioned by the health care industry, variation among patient populations and provider characteristics, emerging health care technologies and data capabilities, and measurement of quality and performance. Additionally, OIG does not want to chill beneficial innovation but must still be wary of fraud and abuse against patients and programs.

OIG notes that the safe harbors it proposes provide greater flexibilities to the parties when they assume more downside financial risk for the cost and quality of care (what it refers to as a tiered structure). While the proposals focus on downside risk, **comments are sought on whether other types of risks (clinical risk, upside risk, operational risk, contractual risk, etc.) would have a comparable effect to shift incentives for those making referring and ordering decisions.**

Remuneration has two relevant dimensions for the proposed safe harbor policies: payments by payors and remuneration exchanged between clinicians, providers, suppliers and others. Examples of the latter include sharing staff (e.g., care coordinators) or technology (e.g., data analytics tools) to improve quality or efficiency or to achieve outcomes or performance targets. The suite of safe harbors in the proposed rule would address a variety of scenarios, covering value-based arrangements for publicly and privately insured patients. OIG cautions that all safe harbor conditions must be met precisely for the protection to apply.

B. Proposed Value-Based Terminology (§1001.952(ee)(12))

OIG proposes to define terms that are used consistently in several proposed safe harbors and 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.

These arrangements would be 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. Where possible, the proposed rule seeks to align its terminology with that used in the CMS physician self-referral proposed rule. Generally, the term “value-based” is used in a non-technical way to indicate value achieved through improved care coordination, improved health outcomes, lowers costs (or reduced cost growth), and improved efficiencies. **OIG seeks comment on whether it should define value in the context of care coordination or VBP, including whether it should be defined for financial arrangements under advanced alternative payment models (APMs).**

1. Value-Based Enterprise (VBE)

The term VBE would describe a network of individuals and entities that agree to collaborate to achieve one or more value-based purposes participating in arrangements eligible for safe harbor protection.

- The VBE must have at least two VBE participants.
- Each VBE participant must be a party to a value-based arrangement (or arrangements) with at least one other VBE participant in the VBE.
- The VBE must have an accountable body (e.g., Board of Directors) or person (or entity) responsible for financial and operational oversight of the VBE.
- The VBE must have a governing document that describes the VBE and how the VBE participants intend to achieve the VBE’s value-based purpose(s).

a. Accountable Body or Person

The accountable body or person would serve 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. **OIG seeks comment on whether it should require compliance programs for the value-based arrangements seeking safe harbor protection, and if so, whether the accountable body or person should be responsible for that program.** The OIG believes the accountable body or 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 as applies under CMS-sponsored models. Oversight may include monitoring whether VBE participants are furthering care coordination and management for the target patient population.

OIG is considering several additions for the accountable body or person criterion in the final rule:

- Requiring all VBE participants to acknowledge the role of the accountable body or person and agree (in writing) to cooperate with its oversight efforts.
- Adding specific oversight responsibilities, such as oversight of utilization of items and services, cost, quality of care, patient experience, technology adoption, and data issues.
- Adding reporting requirements for VBE participants or a mechanism to access and verify VBE participant data on performance under any value-based arrangement.

OIG welcomes comment on these potential additions or other suggestions to ensure effective oversight.

The agency also intends for the accountable body or person criterion to be implemented in a way that is 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 would 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. **However, OIG is considering and seeks comment on imposing a condition requiring that independence or duty of loyalty as another criterion.**

b. 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).

c. Assumption of Downside Financial Risk

Two of the proposed safe harbors require that a VBE assume downside risk from a payor. Depending on the arrangements (for example where one VBE participant contracts with payors on behalf of other VBE participants), the VBE could still be at risk albeit through one of the VBE participants.

2. Value-Based Arrangement

The proposed definition of value-based arrangement (which would cover commercial and private insurer arrangements) is as follows:

An arrangement for the provision of at least one value-based activity for a target patient population between or among:

- The VBE and one or more of its VBE participants; or
- VBE participants in 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.

3. Target Patient Population

A defined patient population is referred to as the target patient population and would be 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).

The requirement for legitimate and verifiable criteria 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 is considering whether to limit the definition to patients with a chronic condition, or alternatively to limit any or all of the proposed safe harbors to patients with chronic conditions, since this population would benefit most from care coordination the proposed rule seeks to encourage. It is also considering whether to limit the definition to patients with a shared disease state that would benefit from care coordination.

The agency is also considering whether to define chronic condition, and, if it does, whether to reference the list of the chronic conditions used for Medicare Advantage Special Needs Plans for patients with chronic conditions.

OIG seeks comment on a number of issues:

- How best to address the need for flexibility if it limits the final safe harbor to patients with a chronic condition or shared disease state, including feedback on how these

limitations might impact the ability of VBE participants to provide better coordinated care for other categories of patients.

- Whether to substitute “evidence-based criteria” for the proposed requirement for “legitimate and verifiable criteria” with the goal being to have more parameters and structure to the selection of the patient population.
- Whether parties other than VBE participants (such as payors) should or could be involved in selecting the target population, and if so, how. Additionally, whether including or requiring payors to select either the target patient population or the relevant outcomes measures and targets (or both) would benefit value-based arrangements.
- Whether the alignment of a value-based arrangement’s target patient population or its outcomes measures and with payor-driven incentives should be treated as a favorable factor by OIG.

4. Value-Based Activity

OIG proposes to define value-based activity as follows:

Any of the following activities (other than making a referral), provided the activity is reasonably designed to achieve at least one value-based purpose of the VBE:

- The provision of an item or service.
- The taking of an action (e.g., providing a care coordinator).
- The refraining from taking an action (e.g., not ordering certain items and services pursuant to a medically appropriate care protocol).

The agency is considering a number of modifications for the final rule as follows:

- a. Whether to interpret “reasonably designed” to mean the value-based activities set forth in the value-based arrangement are expected to further the value-based purpose(s) of the arrangement.
- b. Whether VBE participants entering into a value-based arrangement must engage in an evidence-based process to design value-based activities they believe will further the value-based purpose(s).
- c. Whether to exclude from the definition of value-based activity any activity that results in information blocking.

OIG is intent on excluding information blocking from protection under any of its proposed safe harbors; an arrangement that would meet the definition of value-based activity but that could be used for information blocking purposes should not qualify for protection under the safe harbors. Information blocking practices cited in the proposed rule include locking electronic health information into the VBE, keeping electronic health information only between VBE participants, or preventing referrals or other electronic health information from leaving the VBE or being transmitted from a VBE participant to another provider. The exclusion would be based on the definition of information blocking (and its exceptions) established under the 21st Century Cures Act (Cures Act) as well as on definitions and exceptions established by the Office of the National Coordinator (ONC) for Health Information Technology through rulemaking.

5. VBE Participant

The proposed definition of VBE participant is an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. Because potential VBE participants could encompass a wide variety of entities, including non-traditional health care entities (e.g., health technology companies), **OIG seeks comment on any fraud and abuse risks posed by financial arrangements with these entities as well as suggestions for additional safeguards.**

a. Exclusion of Manufacturers and Laboratories

The definition would specifically exclude a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); or (iii) a laboratory. Citing past oversight experience with these entities, OIG is concerned that because they are heavily dependent on practitioner prescriptions and referrals, they might misuse the proposed safe harbors as a way to remunerate practitioners and patients to market their products. OIG assumes these companies are less likely to be on the front line of care coordination and treatment decisions than practitioners, hospitals and other health care entities that provide direct patient care; **it seeks comment on this assumption.**

The agency is considering whether to include these entities in the definition of VBE participant (as well as for outcomes-based compensation under the personal services and management contracts safe harbor described in section III.J below) in the final rule and **seeks examples of how and the extent to which they participate in care coordination and management and how they may be involved in providing beneficial technology to coordinate and manage care.**

OIG seeks comment on additional safeguards in the safe harbors to prevent abusive marketing practices, protect clinical decisionmaking about products, and reduce the risk of cost-shifting to federal health care programs. It is considering a safeguard that would preclude protection for value-based arrangements and outcomes-based payments that impose exclusivity requirements. It is also considering whether to impose heightened standards and conditions (such as enhanced monitoring, reporting, and data submission) on certain entities.

The agency notes that the proposed rule includes some opportunities for protection for manufacturers and other entities excluded from the definition of VBE participant, including modifications to the personal services and management contracts safe harbor, for cybersecurity items and services, and for CMS-sponsored models. Further, these entities may use the OIG advisory opinion process for arrangements they seek to undertake. In response to the OIG RFI, pharmaceutical manufacturers sought safe harbor protection for emerging outcomes-based and value-based contracting practices and related patient medication adherence programs. Noting that these arrangements raise different program integrity issues, OIG may consider them in future rulemaking.

OIG seeks comment on whether it should exclude other entities from the definition of VBE participant, such as pharmacies and compounding pharmacies. It is interested in examples of beneficial arrangements pharmacies may undertake in the value-based framework and on appropriate safeguards. OIG is especially concerned that compounding pharmacies pose a heightened risk of fraud and abuse. It may also exclude pharmacy benefit managers (PBMs),

wholesalers, and distributors from the VBE participant definition for similar reasons that it proposes to exclude manufacturers and laboratories. **OIG seeks examples that demonstrate how PBMs engage in care coordination and management with providers and suppliers as well as on the risks and benefits of including PBMs within the definition.**

b. Health Technology Companies

Companies that provide mobile health and digital technologies to physicians, hospitals and patients to coordinate and manage patient care are VBE participants under the proposed definition. OIG notes the companies also provide many devices, technologies, software, and applications to support a wide range of services for providers and patients (e.g., diabetes management services).

However, because of past experience involving kickbacks paid to physicians, hospitals, and ambulatory surgical centers (ASCs) to market medical devices as well as concerns about physician-owned distributorships, OIG is considering excluding some or all device manufacturers from the definition of VBE participant and from protection under the proposed safe harbors. For example, device manufacturers would be excluded from participating in the outcomes-based payment arrangements. The agency is not convinced that device manufacturers play a comparable role in patient care coordination and management as those entities OIG proposes to include in the VBE participant definition. **OIG seeks comment on its assumption.** It may undertake future rulemaking for specifically tailored safe harbor protection for value-based and outcomes-based contracting for device manufacturers, which may include the issue of purchase and sale arrangements.

The agency discusses difficulties defining a universe of device manufacturers that would be excluded from the definition of VBE participant. **It seeks comment on the following issues:**

- Whether to use the definition of applicable manufacturer in 42 CFR 403.902 (the Sunshine Act provisions of the Affordable Care Act (ACA)).
- Whether to include in the definition an entity that manufactures any item that requires Food and Drug Administration (FDA) premarket approval, FDA premarket notice, or is classified as a medical device by the FDA.
- Whether to define a device manufacturer, in whole or in part, with respect to whether the item it manufactures is eligible for separate or bundled payment from a federal health care program or other payor, or is used in a test eligible for separate or bundled payment.
- Whether to include wholesalers or distributors when they sell or distribute medical devices.
- Whether the proposals are too broad or too narrow.
- Other potential definitions or considerations that would exclude medical device manufacturers without limiting beneficial digital technologies.

c. Alternatives to VBE Participant Exclusion List

In lieu of excluding broad categories of entities from the definition, OIG is considering whether to distinguish among entities included or excluded based on product type, company structure, heightened fraud risk, or other factors. It believes making distinctions based on product type or

arrangement type might lessen the challenges posed by increasing integration of health care company business lines and the movement toward digital technologies.

It is also considering whether to regulate the type of items, goods, or services that may be included in an arrangement protected under a safe harbor instead of regulating the types of entities included or excluded. OIG would take into account any heightened risk of fraud based on enforcement experience, claims analysis, provider enrollment and other data. **It seeks feedback on the kinds of products or arrangements that should not be protected under safe harbors based on heightened fraud risk.**

Another alternative the agency is considering is to exclude entities from the new proposed safe harbor protections for care coordination arrangements, value-based arrangements with substantial downside financial risk, value-based arrangements with full financial risk, and arrangements for patient engagement and support. Each safe harbor could include a requirement to exclude certain entities, such as drug and device manufacturers, DMEPOS suppliers, laboratories, pharmacies, PBMs, etc. Excluded entities could vary by safe harbor.

OIG also seeks comment on how to treat hospitals, health systems, and other entities when they own or operate an entity the agency proposes to exclude, such as a laboratory or DMEPOS supplier, or when a health system or other entity develops devices or technology.

6. Value-Based Purpose

a. Definition

As proposed, a value-based purpose means any of the following:

- Coordinating and managing the care of a target patient population (which may include taking significant steps to prepare or position oneself to effectively coordinate and manage patient care).
- 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 is considering whether to limit the purpose relating to appropriately reducing costs (or expenditure growth) to situations where there is improvement in patient quality of care or the parties are maintaining an improved level of care.

It seeks comment on whether it should include other objectives in its list of purposes in the definition as well as whether it should specifically include other purposes in the various proposed safe harbors. In lieu of requiring some value-based activities to directly further care

coordination and management, OIG is instead considering requiring only that the activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes.

b. Care Coordination and Management

OIG also proposes to define coordinating and managing care (and coordination and management of care) to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants or between VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for that population.

The agency distinguishes between referral arrangements (which are not protected) and legitimate care coordination arrangements which involve referrals across settings but also include other beneficial activities. OIG wants to protect against abusive practices that are characterized as care coordination and management, such as churning patients across care settings to maximize reimbursement. **It seeks comment on how to revise the definition to prevent these activities.**

One approach is to preclude some or all safe harbor protection for arrangements between entities that have common ownership. OIG acknowledges that while this policy might protect against abusive cycling of patients for financial gain among commonly owned entities, it may also prevent protection for coordination arrangements among entities in integrated health systems.

For this potential exclusion, the agency seeks comment on how to define common ownership and how to distinguish between beneficial and problematic financial arrangements among commonly owned entities.

Billing or administrative services would not be considered management of patient care; however, sharing or using health information technology (IT) and data to identify target patient populations, coordinate care, or measure outcomes would fit the definition.

OIG seeks comment on the following cybersecurity concerns:

- Whether remuneration in the form of cybersecurity items or services should meet the definition of care coordination and management.
- If so, whether it should be limited to donated items and services used in conjunction with health IT.
- Whether parties should instead seek protection from the proposed cybersecurity safe harbor.

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

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

The new proposed safe harbor would be for care coordination arrangements and is 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 would 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.

1. Outcome Measures

VBE participants would establish one or more specific evidence-based, valid outcome measures against which the recipient will be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population.

The measures must have a close nexus to the value-based activities and to the needs of the target patient population. An evidence-based measure would have to be grounded in legitimate, verifiable data or other information, whether the information is internal to one of the VBE participants or from credible external sources (e.g., a medical journal). Measures related to patient satisfaction or convenience could not serve this purpose in part because they may not reflect actual improvement in care quality, outcomes, or efficiency. **However, OIG seeks feedback on whether categories of evidence-based patient satisfaction or convenience outcomes measures exist.**

OIG is considering a requirement that outcome measures be designed to drive meaningful improvement in care quality, outcomes and efficiency. It intends to be flexible to accommodate the range of value-based arrangements covered by the safe harbor. **The agency seeks comment on this as well as on whether the outcome measures requirement should be more broad or narrow.**

In the final rule, the agency may require measures to be rebased where feasible; this could be periodic, annually or otherwise. Rebasing under this proposal would likely be aligned with rebasing under the proposed modifications to the personal services and management contracts safe harbor related to outcomes-based payments (discussed in section III. J. below). **OIG seeks feedback on the following:**

- Whether the appropriate time frame for rebasing should depend on the type of outcome measure or nature of the arrangement (and if so why).
- What rebasing time periods are best for different types of measures or arrangements.
- Whether rebasing should be tied to any relevant requirements set by payors.
- Whether to require a particular party to be responsible for implementing the rebasing and which party is best positioned to do so.

For the final rule, OIG may also incorporate the CMS Quality Payment Program measures into this requirement; it is also considering a different standard for IT.

For IT, the agency may require an adoption and use standard, a performance standard, or a similar standard to serve as a benchmark for assessing a recipient's use of in-kind remuneration without requiring the parties to establish outcome measures to measure performance. Parties giving IT may be required to put in writing the specific reasons for which the IT is being

provided, which must be directly related to care quality, efficiency or outcomes, and may also be required to specify specific, meaningful measures against which the recipient will be measured.

Again for the final rule, OIG is considering whether to add safeguards for the exchange of IT as follows:

- Requirements that apply under the current EHR items and services safe harbor (at §1001.952(y)(4)).
- A limit on the timeframe during which a recipient may receive IT (such as 1, 3 or 5 years) after which the recipient would pay fair market value for continued use of the IT.
- Remedies for failure to achieve the applicable standard.

2. Commercial Reasonableness

The value-based arrangement would have to be commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE. For the final rule, OIG may define a commercially reasonable arrangement as one that would make commercial sense if entered into by reasonable entities of similar type and size, even without the potential for referrals. **Comment is sought on whether the definition is required and if so what it should be.**

3. Writing

The value-based arrangement would have 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). Minimum requirements for the writing include the following:

- The value-based activities to be undertaken by the parties;
- The term of the arrangement;
- The target patient population;
- A description of the remuneration;
- The offeror's cost for the remuneration;
- The percentage of the offeror's cost contributed by the recipient;
- If applicable, the frequency of the recipient's contribution payments for ongoing costs; and
- The specific evidence-based, valid outcome measure(s) against which the recipient will be measured.

OIG says that the writing is a key safeguard to ensure VBE participants are not using the value-based arrangement to incentivize business referrals. **The agency seeks comment on whether a single writing signed by all parties is burdensome and whether a collection of writings would suffice provided that all parties sign a writing acknowledging consent to the arrangement.**

4. Limitations on Remuneration

OIG proposes several restrictions for the remuneration; the remuneration must:

- Be in-kind;

- Be used primarily to engage in value-based activities directly connected to care coordination and management for the target patient population;
- Not induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and
- Not be funded by, and not otherwise result from the contributions of, any individual or entity outside of the applicable VBE.

a. In-Kind

Only in-kind, nonmonetary remuneration would be protected. A care coordinator may be shared by one VBE participant with another VBE participant; however, the safe harbor would not protect cash given to a VBE participant to hire a care coordinator. The safe harbor would not protect ownership or investment interest in the VBE or any distributions related to ownership or investment interest. Finally, gift cards would not be protected under the safe harbor.

b. Primarily Engaged in Value-Based Activities

In-kind remuneration may indirectly benefit patients outside the scope of the value-based arrangement (spillover effects); under the proposal this would not jeopardize the safe harbor protection as long as the parties primarily use the remuneration for its intended purpose(s). For the final rule, OIG may limit the remuneration exchanged to value-based activities that only benefit the target patient population; **it seeks comments on this approach.**

c. No Medically Unnecessary Services or Reduction of Medically Necessary 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.

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

This condition is 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 decisionmaking of VBE participants. **OIG seeks comment on this policy and whether there may be defined, limited circumstances under which non-VBE participants may contribute to the value-based arrangement.** The agency may require that the remuneration be provided directly from the offeror to the recipient, thereby prohibiting the involvement of third-party vendors and contractors (and other non-VBE participants) in the VBE. **It seeks comment on the practical impediments of such an approach.**

5. Volume or Value; Other Business

This requirement would prohibit the offeror of the remuneration from taking into account the volume or value of, or condition the remuneration either:

- 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. Safe harbor protection would not apply for any remuneration explicitly or implicitly offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside the arrangement.

As an alternative requirement for this provision in the final rule, OIG may require that the aggregate compensation paid by the offeror is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties for which payment may be made by a federal health care program. The agency thinks this may better protect against bad actors that would use care coordination arrangements as an affirmative defense for an unlawful referral arrangement. **It seeks comment on whether this would either add to or maintain barriers to beneficial care coordination and value-based arrangements.**

6. Contribution Requirement

Safe harbor protection would be conditioned on the recipient's payment of at least 15 percent of the offeror's costs for the in-kind contribution to ensure that the remuneration would actually be used for the care coordination and management of the target patient population. Payment would be made in advance for one-time costs and at regular intervals for ongoing costs.

OIG is considering a specific requirement for the valuation of the remuneration, such as fair market value or reasonable value. If it opted for fair market value, the agency would not require parties to get independent fair market valuations.

OIG is considering several alternative policies for the final rule **and seeks comment on them:**

- Whether certain recipients (e.g., rural providers, small providers, Tribal providers, providers serving underserved populations, and critical access hospitals) should either pay a lower contribution percentage or pay no contribution at all.
- What level of contribution percentages (e.g., from 5 to 35 percent) would invest recipients in using the remuneration to advance care coordination and management of the target patient population but still allow flexibility for parties with fewer resources.
- Whether to set contribution amounts by type of remuneration (e.g., higher contributions for health IT; lower contributions for care coordinators).
- For ongoing costs and add-ons (e.g., software upgrades), whether to require a contribution for the initial provision of remuneration but not for any upgrades, updates or patch.

7. Requirements of a Value-Based Arrangement

Under the proposal, a value-based arrangement:

- Must be directly connected to the care coordination and management of the target patient population;

- Must not place any limitation on VBE participants’ ability to make decisions in the best interest of their patients;
- Must not 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 regulations; and
- Must not include marketing to patients of items or services or engage in patient recruitment activities.

a. Direct Connection to Care Coordination and Management

OIG interprets this condition as requiring a close nexus to the care coordination and management of the target patient population as opposed to VBE participants’ referral patterns and other business generated. In the final rule, the agency may substitute alternative language for “direct connection” such as reasonably related and directly tied to better convey this close nexus.

b. No Limitations on Decisionmaking; Restrictions on Directing or Restricting Referrals

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. It also seeks to preserve patient freedom of choice. However, OIG does not intend for this criterion to prevent VBEs or VBE participants from discussing benefits of getting care from other VBE participants.

c. No Marketing or Patient Recruitment Activities

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. It would restrict any party to a value-based arrangement, or the party’s agent, from marketing or engaging in patient recruitment activities for items and services offered or furnished to the target patient population of the arrangement.

This condition should not be construed to prevent VBE participants from educating patients on permissible value-based activities. However, this would not include, for example, a situation where a post-acute care provider placed a staff member at a hospital to market its services to hospital patients. **OIG seeks comments on its approach.**

8. Monitoring and Assessment; Termination

a. Monitoring and Assessment

OIG seeks 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 should occur at least annually (or once during an arrangement of less than one year) and would 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 evidence-based, valid outcome measure(s) in the arrangement.

The monitoring and assessment would 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 would be provided to the VBE's accountable body or responsible person.

The proposal does not mandate any particular manner in which monitoring and assessment should be done. OIG believes it should be tailored based on the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources. For the final rule, it may require both the offeror and the recipient of the remuneration to jointly conduct the monitoring and assessment. **Comment is sought on this policy and also sought on how monitoring of utilization, referral patterns, and expenditure data could reduce the potential for gaming of abuse.**

b. Termination

Under the proposal, a value-based arrangement must be terminated within 60 days of a determination, through monitoring and assessment reports, that the arrangement:

- Is unlikely to further care coordination and management for the target patient population;
- Has resulted in material deficiencies in quality of care; or
- Is unlikely to achieve the evidence-based, valid outcome measure(s).

If the value-based arrangement is not terminated within 60 days of such a determination, the parties would lose safe harbor protection for the arrangement. **OIG seeks comment on whether to adopt a longer or shorter termination period. It also seeks comment on whether to provide for a period for remediation before requiring termination.**

The agency does not propose to define material deficiency in quality of care since it may vary based on the nature of the VBE and the value-based arrangements.

OIG is considering for the final rule whether to require VBEs to submit certain data to HHS that identifies the VBE, its participants, and value-based arrangements, as a requirement for safe harbor protection. This is because there would be no governmental programmatic requirements, oversight, or monitoring of the kind that occurs with CMS-sponsored models. If such a requirement were finalized, types of required data may include National Provider Identifier (NPI) numbers or other identifying information of VBE participants and other parties participating in the arrangement. Information would be submitted to HHS in a form and manner, and at times, specified by the Secretary. **OIG seeks comment on this policy as well as on the types of data that should be submitted, potential reporting burdens for VBEs, and different or additional activities to ensure appropriate oversight.**

9. No Diversion, Resell, or Use for Unlawful Purposes

Remuneration would not be 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.

10. Materials and Records

This condition would 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 proposal does not specify parameters for the creation or maintenance of documentation.

OIG seeks comment on whether it should propose parameters for the creation or maintenance of documents as well as whether it should require parties to maintain the materials for a specified period of time (e.g., 6 or 10 years).

11. Possible Additional Safeguards

OIG is considering some additional conditions under this safe harbor for the final rule; **it seeks comment on these approaches.**

a. Bona Fide Determination

This condition would require the VBE's accountable body or responsible person to make two *bona fide* determinations for 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.

The *bona fide* determinations would have to be made in advance of, or contemporaneous with, the commencement of the value-based arrangement.

b. Cost-Shifting Prohibition

This condition would prohibit VBEs or its participants from shifting costs to federal health care programs. Specifically, it would prohibit 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.

OIG seeks to clarify that legitimate shifting of some costs resulting from achieving care coordination goals or other value-based purposes is permissible, such as increased primary care costs as reductions in unnecessary hospitalizations are achieved or increased costs for remote monitoring or care management services.

c. Fair Market Value Requirement and Restriction on Remuneration Tied to Volume or Value of Referrals

The proposed safe harbor does not include fair market value requirements or restrictions on remuneration based on the volume or value of business; however, OIG is concerned about the lack of these conditions. Its proposed safe harbor tries to distinguish between beneficial care coordination arrangements and payment-for-referral schemes; **it seeks comments for potential additional safeguards.**

It is considering several alternative policies for which it seeks feedback:

- Whether to include a fair market value requirement on any remuneration exchanged pursuant to a value-based arrangement.
- Whether to include a further, or alternate requirement, prohibiting VBE participants from determining the amount or nature of the remuneration they offer, or the VBE participants to whom they offer such remuneration, in a manner that takes into account the volume or value of referrals or other business generated, including both business or patients that are part of the arrangement and those that are not.
- Whether to require value-based arrangements to be fair market value but not prohibit determining the amount or nature of the remuneration on the volume or value of referrals or other business generated.
- Whether to prohibit remuneration based directly on the volume or value of business generated between the parties (thereby permitting remuneration based indirectly on the volume or value of referrals or other business generated between the parties).

d. Additional Requirements for Dialysis Providers

OIG notes that the dialysis market is dominated by a few dialysis providers which it believes increases the risk of fraud and abuse. It is also concerned that current market consolidation could impact access to dialysis care, care quality and health outcomes, and that its proposed safe harbor could lead to a decrease in competition in the market. **The agency seeks comment on these concerns.**

OIG may include 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. The conditions may include enhanced monitoring, reporting, or data submission requirements; they could also be fair market value requirements, restrictions on paying remuneration based on volume or value of referrals, *bone fide* determinations described above, and cost-shifting prohibitions.

12. Example

The proposed rule includes an example of a value-based arrangement protected under the proposed safe harbor and provides a condition-by-condition process for parties to use in analyzing whether an arrangement meets the requirements of the safe harbor.

13. Alternative Regulatory Structure

In lieu of the proposed rule's approach of modifying the personal services and management contracts safe harbor and adding new safe harbor protections for care coordination arrangements, value-based arrangements with substantial downside financial risk, and value-based arrangements with full financial risk, OIG is considering for the final rule a different regulatory structure. It would rely solely 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.

Generally, instead of requiring aggregate compensation to be set in advance, it would require that the methodology for determining the compensation be set in advance.

For value-based arrangements that satisfy applicable requirements of the VBE framework described above, it would remove the requirement that aggregate compensation not be determined in a manner that takes into account the volume or value or referrals (though it may add accountability and transparency requirements).

For value-based arrangements that satisfy applicable requirements of the VBE framework described above and assume substantial downside financial risk, it would also remove the requirement that aggregate compensation be consistent with fair market value in an arm's-length transaction.

OIG is considering different ways to remove the volume or value requirement—either entirely or in part—and still require that the compensation not relate directly to the volume or value of referrals or other business generated between the parties.

OIG is also considering whether to remove the fair market value requirement entirely, or remove it only for in-kind remuneration or only for monetary remuneration. It is also considering removing the fair market value requirement where a non-fair market value arrangement primarily benefits the offeror without regard to any increase in the volume or value of referrals with such benefit independent of any increase in the volume or value of referrals (e.g., a hospital offering care managers to a post-acute care facility to better coordinate care and prevent avoidable readmissions for which the hospital might be penalized). It may also permit a broader set of free or below fair market value arrangements for providers in rural or underserved areas, or providers serving underserved populations.

OIG solicits comment on this alternative structure, and in particular on the following:

- How to protect the exchange of IT and infrastructure that might not be part of a personal services or management contract.
- How parties would determine that a payment for quality outcomes is consistent with fair market value.
- Any special problems a fair market value requirement would pose for providers in rural and underserved areas, providers serving underserved populations, and others.

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

This proposed new safe harbor would 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 would protect 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 would not extend to ownership or investment interest in the VBE or to distributions related to such an interest; **OIG seeks comment on whether this would pose operational challenges in creating a VBE as a separate legal entity.** Nor would it protect remuneration funded by an individual or entity outside the VBE. 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.

1. Substantial Downside Financial Risk

The proposed definition specifies four methodologies that qualify as substantial downside financial risk as follows:

- a. Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses. (Loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures.)
- b. A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss. (Loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures.)
- c. A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population. (The payment must be determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures.)
- d. A partial capitated payment from the payor for a set of items and services for the target patient population. (The capitated payment must reflect a discount equal to at least 60 percent of the total expected fee-for-service payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangement.)

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. OIG notes that it does not consider Medicare prospective payment systems or other like payment methodologies to be substantial downside financial risk.

The agency seeks comment on a number of issues as follows:

- Whether the benchmarks should be changed to ensure appropriate incentives.
- Whether other methodologies should be added to the list.
- Whether the benchmarks (or some of them) should be eliminated or modified.
- Whether new or small VBEs should be afforded other means to establish a benchmark under methodologies 1. through 3. against which to measure losses of payments.
- Whether assumption of substantial downside financial risk, in combination with other proposed safeguards, provides meaningful protections.
- Whether APMs and other payor advanced APMs should be included in the definition;
 - If so, whether advanced APM participants would rely on this safe harbor in lieu of the CMS-sponsored model arrangements safe harbor; what barriers would the definitions of “substantial downside financial risk” and “meaningfully share” pose; and
 - Whether the current definition of substantial financial risk is too narrow.

2. Meaningfully Share

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.

The VBE participant would meaningfully share in the risk if the value-based arrangement has one of the following:

- A risk-sharing payment under which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor.
- A partial or full capitation payment, or similar payment methodology (other than the Medicare inpatient prospective payment system or other like payment methodology).
- In the case of a physician VBE participant, a payment that meets the requirements for the regulatory exception under the physician self-referral regulations for value-based arrangements with meaningful downside financial risk (42 CFR 411.357(aa)(2)).

OIG seeks comment on the 8 percent threshold and on additional or alternative specific thresholds that could be included in the final rule to ensure meaningful engagement in delivery of value through clinical decisionmaking.

3. Additional Conditions

a. Prohibition on Stinting on Care

The remuneration could not induce limitations on or reductions of medically necessary items and services furnished to any patient. OIG is considering whether to add conditions to protect against risk of cherry picking or dropping costly or noncompliant patients (lemon dropping) as well as to require a period of time for the VBE to be at substantial downside financial risk to avoid gaming.

b. Writing

The arrangement must be in writing that describes the nature and extent of the substantial financial downside risk and how VBE participants share in that risk.

c. Volume or Value

Neither the VBE nor any VBE participant offering the remuneration could 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.

d. Clinical Judgment; Patient Choice

The arrangement may not limit any VBE participant's ability to make decisions in the best interest of the patient. The arrangement may not direct or restrict referrals to a particular provider, practitioner or supplier if the patient expresses a preference for (or the patient's payor determines) a particular practitioner, provider or supplier or if the direction or restriction violates Medicare or Medicaid law or regulation.

e. Marketing

The arrangement could not market items and services to patients or engage in patient recruitment activities.

f. Records

The VBE or its participants would have to maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions, and make those records available to the Secretary upon request. **OIG seeks comment on whether it should require maintenance of these records for a minimum period of time, such as 6 or 10 years.**

g. Use of Remuneration

The remuneration must be used primarily for the value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk. Further, the remuneration exchanged must be directly connected to one or more of the VBE's value-based purposes, and one of those purposes must be care coordination and management for the target patient population.

4. Additional Considerations for the Final Rule

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

- A commercial reasonableness requirement.

- A monitoring standard.
- A *bona fide* determination that the arrangement is directly connected to a value-based purpose, at least one of which is care coordination and management for the target patient population. This would be made by the VBE’s accountable body (or responsible person) before or contemporaneous with the beginning of the arrangement.
- 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.

The proposed safe harbor would provide protection in exchange for assuming risk for only a subset of items and services furnished to a target patient population, and OIG is aware of the potential for parties to assume financial risk for such a narrow subset of items and services that the risk is not substantial downside financial risk. **It seeks comments on how to address this issue as well as on other policies and approaches it is contemplating for this safe harbor.**

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

This proposed new safe harbor would 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 would protect both monetary and in-kind remuneration.

The safe harbor would require 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.

Protection under this safe harbor would not extend to ownership or investment interest in the VBE or to distributions related to such an interest; **OIG seeks comment on whether this would pose operational challenges in creating a VBE as a separate legal entity.** It is also considering for the final rule whether to protect ownership or investment interests with respect to VBEs that must contract with a payor on behalf of VBE participants for purposes of value-based arrangements with full financial risk. The safe harbor would not protect remuneration funded by, or otherwise resulting from contributions by, an individual or entity outside the VBE.

1. Full Financial Risk

Full financial risk would be defined to mean that the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor. Prospective in this context would mean that the anticipated cost of all items and services covered by the applicable payor for the target patient population has been determined and paid in advance (e.g., a capitated payment for all covered items and services). An arrangement providing for partial capitated payments would not qualify.

The proposed definition would not prevent a VBE from using global risk adjustments, risk corridors, reinsurance, or stop loss agreements to protect against catastrophic costs; however, the use of these arrangements for non-catastrophic costs would not meet the definition of full financial risk. The definition would not preclude VBEs from conducting back-end reconciliation with payment adjustments for quality and financial performance as long as it is not used to shift material financial risk back to the payor.

OIG is considering other ways of defining full financial risk for the final rule, such as using an actuarial equivalence standard similar to the one used under Medicare Part D. **It seeks comment on using an actuarial standard as well as on other situations that should qualify a VBE as assuming full financial risk.**

Full financial risk could be assumed by the VBE directly or through a VBE participant with legal authority to obligate the VBE.

2. Items and Services

OIG would define items and services using the existing definition at §1001.952(t)(2)(iv) which provides as follows:

(iv) Items and services means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not “items or services” for purposes of this section.

3. Writing

The purpose of this condition is to promote transparency and accountability. A VBE would be required to have a signed writing with a payor that does the following:

- Specify the target patient population.
- Contain sufficient terms to show the VBE is at full financial risk for the target population for at least one year.
- Set forth the material terms of the value-based arrangement (which also must be for at least one year), including the value-based activities the parties will undertake.

OIG believes the minimum one-year requirement would ensure a commitment from the VBE participant to coordinate care for the target patient population of the VBE that has taken on full financial risk.

4. Remuneration

Remuneration exchanged would have to meet all the following conditions:

- It must be used primarily to engage in the value-based activities set forth in writing.

- It must be directly connected to one or more of the VBE’s value-based purposes, at least one of which must be care coordination and management for the target patient population.
- It may not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient.
- It may not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest.
- It may not be funded by, and may not otherwise result from the contributions of, any individual or entity outside of the VBE.

OIG notes that the safe harbor would only protect remuneration exchanged between a VBE and a VBE participant. The safe harbor would not protect remuneration exchanged between or among VBE participants, remuneration between a VBE participant and a downstream contractor, or remuneration between two downstream contractors; however there may be other safe harbors to protect these forms of remuneration.

VBE participants may not claim additional or separate payment (directly or indirectly) from a payor for items and services covered under the value-based arrangement. For example, safe harbor protection would not extend to payment made by the VBE to a VBE participant for telehealth services furnished to a target patient population if the VBE participant could also claim payment for those services from the payor. However, VBE participants would be permitted to submit no-pay claims if a payor required it.

5. Additional Conditions

a. Volume or Value

Neither the VBE nor any VBE participant could 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. **It seeks comment on this condition and additional safeguards it should include to prevent the safe harbor from being used to protect payments for referrals that are not part of the value-based arrangement.**

b. Utilization Review and Quality Assurance Programs

OIG proposes to require the VBE to provide (or arrange for) an operational utilization review program and a quality assurance program. The quality assurance program would protect against underutilization and specify patient goals; this would include measurable outcomes, where appropriate. The agency notes these requirements mirror those under the existing safe harbor for price reductions offered by contractors with substantial financial risk to managed care organizations at §1001.952(u).

OIG is considering for the final rule ways to update this requirement to reflect utilization review and quality assurance mechanisms in effect today.

c. Marketing

The arrangement could not market items and services to patients or engage in patient recruitment activities.

d. Records

The VBE or its participants would have to maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions, and make those records available to the Secretary upon request. **OIG seeks comment on whether it should require maintenance of these records for a minimum period of time, such as 6 or 10 years.**

4. Additional Considerations for the Final Rule

a. Downstream Contractors

As noted above, the safe harbor would only protect remuneration exchanged between a VBE and a VBE participant; it would not protect remuneration exchanged between or among VBE participants, remuneration between a VBE participant and a downstream contractor, or remuneration between two downstream contractors.

OIG seeks comment on whether it should for the final rule protect remuneration from a VBE participant to a downstream contractor (which could also be a VBE participant). It is concerned that downstream arrangements pose higher risks of fraud and abuse. **The agency specifically seeks comment on the following issues:**

- Whether additional safeguards could be implemented under the full financial risk safe harbor (or a different proposed safe harbor) to protect legitimate arrangements between VBE participants and downstream contractors that advance the value-based purpose(s) of the VBE.
- Whether OIG should incorporate some of the safeguards proposed in the safe harbor for care coordination arrangements or the safe harbor for parties at substantial downside financial risk. If so, whether certain safeguards would best capture the need to protect against fraud and abuse risks without imposing undue burden on parties to the arrangements.
- Whether OIG should limit protection to arrangements between VBE participants that are part of the same VBE, or whether to extend protection to arrangements between (i) a VBE participant and a downstream contractor, (ii) arrangements between two downstream contractors, or (iii) both.

Comments should include specific examples of downstream arrangements that may not be protected under existing safe harbors or any of the safe harbors proposed under the proposed rule but warrant protection under this proposed safe harbor because of the level of risk assumed by the VBE.

b. Data and Prohibition on Cost-Shifting

To further protect against the use of value-based arrangement payments for referrals unrelated to coordinating care and improving health outcomes and value, the agency may include the following additional 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.

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

The OIG proposes to establish a new safe harbor (the “patient engagement and support safe harbor”) at proposed paragraph 1001.952(hh) for patient engagement tools and supports furnished to improve quality, health outcomes, and efficiency provided by VBE participants (as defined in proposed paragraph 1001.952(ee)) to a specified target patient population. This safe harbor is intended to remove barriers from the anti-kickback statute and the beneficiary inducements CMP³ that impact provider’s abilities to provide patients tools and supports.

The OIG discusses various tools and supports that can improve care coordination but it also raises concerns about the potential for improper patient engagement tools and support causing inappropriate utilization, steering of patients to particular providers or products, increased costs to the health care system, and anti-competitive effects. The OIG also notes that depending on the facts, providing patient engagement tools and supports may implicate the Federal anti-kickback statute and beneficiary inducements CMP or they may be protected under existing safe harbors or may be exceptions to the definition of remuneration under the beneficiary inducements CMP⁴. In addition, some tools and supports may qualify for protection under the Medicare Shared Savings Program’s waiver for patient incentives⁵ or a waiver for beneficiary incentives provided under an Innovation Center model.

1. Limitations on Offerors

The OIG proposes that only patient engagement tools and supports furnished by a VBE participant would receive protection. The OIG notes its intent to limit safe harbor protection to VBE participants is to align the safe harbor with the value-based framework.

The OIG solicits comments, including illustrative fact patterns, about the following:

³ A practice permissible under the anti-kickback statute, based on a statutory exemption or regulations, is also exempted from the beneficiary inducements CMP (Section 1128A(i)(6)(B) of the Act).

⁴ Examples of exceptions to the definition of “remuneration” under the beneficiary inducement CMP include the local transportation safe harbor (42 CFR 1001.952(bb)), and the exception for incentives given to individuals to promote the delivery of preventive care (42 CFR 1000.3110).

⁵ Medicare Program; Final Waivers in connection with the Shared Savings Program, 80 FR 66726, 66743 (Oct 29, 2015).

- Potential patient engagement tools and supports that would improve care coordination and health outcomes where the offeror does not meet the proposed definition of a VBE participant because the offeror is not part of a VBE.⁶
 - For example, should the final rule safe harbor protection also include a hospital or physician group practice that provides tools and supports and is not part of a VBE but would otherwise satisfy all the conditions in the proposed safe harbor.
- The fraud and abuse risks associated with removing the requirement that the offeror is a VBE participant and additional safeguards that would offset those risks.
 - The OIG discusses concerns that offers of remuneration by pharmaceutical manufacturers could improperly influence the patient and the clinician’s decision to prescribe one drug over another.
 - The OIG is also concerned that manufacturers, distributors, and suppliers of DMEPOS and laboratories may inappropriately use tools and supports to market their products or divert patients from a more clinically appropriate item or induce medically unnecessary demand for an item.
- The impact of any exclusion in the VBE requirements that have potentially negative impact on providing beneficial tools and supports. Specifically,
 - Whether the proposed exclusion of certain entities from the definition of “VBE participant” might negatively impact patient’s ability to receive beneficial items and services, including new technologies; and
 - Whether the proposed conditions at (hh)(2), limiting funding by and other contributions from non-VBE participants might negatively impact the patient’s ability to receive beneficial items and services.
 - The potential impact of excluding pharmacies, PMBs, wholesalers, and distributors from the definition of “VBE participant”.⁷
- Whether the proposed safe harbor should protect only in-kind tools and supports furnished by VBE participants that assume at least some financial risk. The OIG states this would better align protected remuneration with the value-based framework.
 - If financial risk is required of VBE participants what would be the appropriate level of financial risk?

2. Limitations on Recipients

This proposed safe harbor would protect patient engagement tools and supports furnished to patients in a target patient population (as defined in proposed 1001.952(ee)). The OIG notes that the VBE or VBE participants may define the target patient population without regard to payor type and thus, this proposed safe harbor would not be limited to Federal health care program beneficiaries.

⁶ The proposed definition of a VBE participant in 1001.952(ee) does not include pharmaceutical manufacturers, distributors, and suppliers of DMEPOS, and laboratories,

⁷ The OIG note that if it finalizes excluding applicable manufacturer as a VBE participant and does not include an exclusion in the patient engagement and support safe harbor it would adopt the definition of “applicable manufacturer” in 42 CFR 403.92 which includes distributors and wholesalers (which includes re-packagers, re-labelers, and kit assemblers) that hold title to a covered drug, device, biological or medical supply.

The OIG acknowledges that some VBEs may not be able to prospectively identify the individual patients in the target patient population and includes examples of 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 solicits comments on the following:

- Whether it should provide safe harbor protection for tools and supports VBE participants provided to a broader universe of patients instead of the target patient population as long as the tools and support predominately meet the needs of the target population and have a direct connection to the coordination and management of care for the patient.
- Challenges, if any, limiting the safe harbor protection to only patients in the target patient population when the VBE’s assigned beneficiaries are identified retrospectively or on a preliminary prospective basis.

3. Limitations on Type of Remuneration

The OIG proposes at 1001.952(hh)(3)(i), (ii) and (iii) to limit a patient engagement “tool or support” to:

- in-kind, preventive items, goods, or services; or
- items, goods, or services 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 that have a direct connection to the coordination and management of care of the target patient population.

This limitation would exclude gift cards, cash, and any cash equivalent (e.g. a check or pre-paid debit card).

The in-kind requirement means the patient must receive the actual tool or support and not funds to purchase the tool or support. The OIG notes that cash reimbursement would not satisfy the in-kind requirement, but a voucher for a particular tool or support (e.g. a meal voucher) would satisfy the in-kind requirement.

The OIG does not propose a specific definition of “preventive care item or service” to allow flexibility for providing preventive care items and services as a means to improve patient outcomes and better overall patient health.⁸ This safe harbor would protect tools and supports that a VBE participant reasonably determines, within the medical judgement of the applicable provider treating the patient, to be preventive care.

The OIG solicits comments on the following:

- Whether the proposed categories for patient engagement tools and supports are sufficiently flexible to incorporate appropriate items and also sufficiently targeted to protect against the risks of fraud and abuse due to inappropriate remuneration to patients.

⁸ The OIG does not intend to incorporate the definition of preventive care found in the regulations interpreting the beneficiary inducements CMP, 42 CFR 1003.110.

- The OIG believes that health related technology and patient health related monitoring tools and services might include wearable monitoring devices that collect information and transmit data to a patient’s physician for treatment or disease monitoring.
- Whether it should require the VBE participant to confirm that the tools and services provided are not duplicative of or substantially the same as tools and services the patient already has.
 - Whether the safe harbor should protect the provision of a new cell phone or a wireless service to a patient who needs an application for remote monitoring if the patient only needs the application for their existing cell phone.

In response to the OIG RIF, many commenters urged the OIG to consider social determinants of health in designing safe harbors; social determinants are described as health related nonmedical items, goods, and services that address basic needs essential to patient’s health, such as food, shelter, safety, clothing, income, and transportation. The OIG is considering whether to explicitly include protection for tools and supports that address some social determinants of health and meet all the other safe harbor conditions. Although all social determinants have the potential to meet health outcomes, the OIG notes that some social determinants (such as transportation to medical appointment, nutrition, and safe housing) may be more aligned with preventive care and coordination and management of care for patients.

The OIG seeks inputs on the following related issues, including illustrative examples and data supporting the efficacy of a particular tool or support:

- Which social determinants are most crucial to improving care and transitioning to value-based care and payment and how the final safe harbor should make distinctions among the categories of social determinants by protecting some tools and supports but not others?
- Whether to specify specific tools and supports that would be permissible and whether to base such a list on CMS guidance.
- Whether instead of using the proposed categories, the final rule should list specific tools and supports. The OIG is interested in which tools and supports should be listed and how it should account for emerging tools and supports.

a. Cash and Cash Equivalent Incentives

In response to the OIG RFI, commenters requested protection of cash incentives to patients as a reward for engaging in certain healthcare-related activities such as attending a primary care visit and completing milestones in a behavior modification program. The OIG notes it has significant concerns about allowing providers to offer cash or cash equivalent to patients due to enforcement experience suggesting cash incentive can result in medical theft and misuse of patients’ Medicare numbers; lead to inappropriate utilization of medically unnecessary items and services; and cause improper patient steering.

After consideration of these comments, the OIG is considering whether to protect patient incentives and supports in the form of cash and cash equivalent (e.g. check or debit card) in certain circumstances. To prevent the misuse of case incentives, the OIG is considering

safeguards such as a momentary limit on the aggregate amount of remuneration provided, such as \$75 per year⁹, and limiting the use of cash remuneration to patients attending medically necessary primary care or other prescribed treatment visits, or for successful participation in a behavior modification or substance use disorder treatment program. The OIG is also considering requiring offerors to have evidence-based reasons for using a cash incentive and it **seeks comments on potential criteria to ensure that the arrangement is evidence based**, such as ensuring the arrangement is supported by the Joint Commission, the Agency for Healthcare Research and Quality, or other independent organization that develops quality standards or measures.

b. Waiver or Reduction of Cost-Sharing Obligations

In response to the OIG RFI, commenters requested protection for routinely waived or reduced cost-sharing obligations. The OIG states that cost sharing is a programmatic requirement. It notes that several safe harbors and beneficiary inducements CMP exceptions already exist for certain reductions, waivers, and differentials in cost-sharing.¹⁰ In addition, the OIG is proposing protection at 1001.952(ii) for certain cost-sharing waivers or reductions under the CMS-sponsored model patient incentives safe harbor.

The OIG seeks comments on the following:

- Information on the potential benefits of permitting the waiver or offset of cost-sharing obligations as part of a value-based arrangement.
- Safeguards that would mitigate fraud and abuse concerns such as marketing schemes targeting patients for unnecessary or poor-quality items.
- What conditions should be included to permit cost-sharing waivers that would protect only cost-sharing waivers associated with certain specified services, such as care management and remote monitoring. This would address concerns raised about the collection of small cost-sharing amounts where the costs of collection exceed the amount to be collected. The OIG notes this waiver would likely include conditions similar to those proposed in 1001.952(hh).
- The need to offer a patient a share of the savings generated by the patient for a payor, such as savings when a patient selects a clinically appropriate but less costly setting to obtain services. The OIG believes this is part of a plan's benefit design and a safe harbor protection is not necessary.

c. Gift Cards

Gift cards are not considered to be in-kind items, goods or services. The OIG considers gift cards similar to cash and cash equivalents and is concerned that gift cards could induce patients to seek medically unnecessary items and services. Because gift cards may be effective at

⁹ The OIG's 2016 "Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries Policy Statement" sets the retail value of permissible inexpensive or nominal value gifts at \$15 per item and \$75 in the aggregate per patient on an annual basis. This statement is available at <https://OIG.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

¹⁰ 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.

promoting behavioral change, the OIG is considering including protection for a limited circumstance using gift cards, such as gift cards provided to patients with certain behavioral health conditions to effect behavioral change.

The OIG seeks comment on the following:

- Recent studies assessing the positive or negative effects of gift card incentives on promoting behavioral changes.
- The risk of fraud and abuse associated with gift cards, including any anti-competitive effects for small providers and suppliers.
- Any additional safeguards, such as excluding pre-paid debit cards from any protection for gift cards.

4. Additional Proposed Conditions

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

a. Furnished Directly to the Patient

The OIG proposes at 1001.952(hh)(i) that the tool or support must be furnished directly to the patient by a VBE participant. The OIG believes this would prevent entities excluded from participating in a VBE from directly or indirectly furnishing tools or supplies to patients and help patients understand who is furnishing the tool or support.

The OIG seeks comments on the following:

- Whether it should require the VBE participant to provide written notice to any patient receiving a patient engagement tool or support that includes what the remuneration is and the purpose for the remuneration.
- Whether the tool or support could be provided through someone acting on the VBE participant's behalf and under the VBE participant's direction such as a physician practice providing the tool through an employee of the practice.
- The applicability of how a VBE participant orders or arranges for the delivery of a tool or a support from an independent third party.

b. Funding Limitations

The OIG proposes at 1001.952(hh)(2) to limit funding or contributing to patient engagement tools and supports furnished by a VBE participant to a VBE participant. The VBE participant would be prohibited from accepting or using funds or free in-kind items or services furnished by any individual or entity outside of the VBE to finance or facilitate patient engagement tools or supports. For example, staff time dedicated to ordering or distributing blood pressure cuffs or technology expenses or help desk services could not be provided from an entity outside of the VBE. The OIG believes this requirement is necessary to reduce inappropriate patient steering and would ensure that the entities proposed to be excluded as VBE participants would not indirectly furnish tools and supports under the safe harbor. This proposed safe harbor does not

prohibit arrangement between VBE participants and others (including vendors and manufacturers) for the purchase and sale of tools and supports furnished under the safe harbor. Such arrangements, however, must be assessed on a case-by-case basis for compliance with the Federal anti-kickback statute and any other applicable laws.

The OIG seeks comments on whether there may be defined, limited circumstances in which non-VBE participants could contribute or otherwise participate in the provision of tools and supports eligible for safe harbor protection.

c. Prohibition on Marketing and Patient Recruitment

The OIG proposes at 1001.952(h)(3)(iii) that remuneration must not include any in-kind item, good or service used for patient recruitment or marketing of items or services including items or services offered to patients where the party knows or should know that the patient would not use the item as intended and would instead resell the item.

The OIG seeks comments on the following:

- Any benefits of allowing some targeted marketing or similar outreach to the target patient population for the purpose of engaging them in evidence-based prevention or wellness activities, or in improving population health outcome.
- How best to preclude marketing of reimbursable items and services and patient recruitment while still permitting beneficial educational efforts and activities that promote patient awareness of care coordination activities and tools and supports.

d. Direct Connection

The OIG proposes at 1001.952(hh)(3)(i) 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 proposed conditions at 1001.952(ee) (discussed above in this summary). 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 communication.

The OIG seeks comments on the following:

- Whether it should require a “reasonable connection” rather than a “direct communication”.
- Whether it should require the VBE to make a *bona fide* determination that the VBE’s participant’s arrangement to provide tools and supports to patients is directly connected to the coordination and management of care for the patient (as proposed in 1001.952(ee)).
- Whether to require the patient engagement tools and supports be directly connected to any of the four value-based purposes instead of requiring a direction connection specifically to care coordination and management.

e. Medical Necessity

The OIG proposes at 1001.052(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.

f. Nature of the Remuneration

The OIG proposes at 1001.052(hh)(3)(is) that the tool or support must be recommended by the patient’s licensed healthcare provider. **The OIG seeks comments about whether it should require the healthcare provider to certify in writing¹¹** that the particular item or service is recommended solely to treat a documented chronic condition of a patient in a target patient population. The OIG also requests comments on how providers would meet this requirement and how this certification should be made available.

Because of risks associated with fraud and abuse, the OIG is considering limitations on the nature of remuneration and **requests comments on the following:**

- A requirement that the VBE participant furnishing patient engagement tools and supports demonstrate and document the desired adherence to a treatment plan, adherence to a drug regimen, adherence to a follow-up care plan, management of a disease, improvement in measurable health outcomes, or patient safety and a monitoring requirement to ensure that the tools and supports do not result in reduced quality of care or patient harm.
- Specific examples of other types of remuneration that should not be covered by this proposed safe harbor and input on how the categories of remuneration should be better defined, including any limitations or safeguards necessary to protect against fraud and abuse risks.

g. Advancement of Specific Goals

The OIG proposes at 1001.952(hh)(3)(vii) that the incentives and supports must advance the following specific goals:

- adherence to a treatment regimen as determined by patient’s health care provider;
- adherence to a drug regimen as determined by patient’s healthcare provider;
- adherence to a follow-up care plan established by the patient’s healthcare provider;
- management of a disease condition as directed by the patient’s healthcare provider;
- improvement in evidence-based measurable health outcomes for a patient or the target patient population;
- ensuring patient safety; or
- some combination of the above.¹²

The OIG intends for this proposed condition to protect a range of tools and supports. It does not propose to specify which tools and supports would be included but it does provide some examples in the proposed rule.

h. No Diversion or Resell

¹¹ The certification in writing would be required under 18 U.S.C, symbol 1001 and 1519.

¹² 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 proposes at 1001.952(hh)(4) that this safe harbor would not protect a tool or support if the offeror knows or should know 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 notes that it would not consider a tool or support to be diverted if furnished indirectly to a patient through caregivers, family members, or others acting on the patients' behalf.

i. Monetary Cap

The OIG proposes at 1001.952(hh)(5) that the aggregate retail value of patient engagement tools and supports furnished by a VBE participant to a patient could not exceed \$500 on an annual basis. The OIG proposes that the cap could be exceeded for certain patients who lack financial resources. Specifically, the cap could be exceeded if the patient engagement tools and supports are provided to a patient based on a good faith, individualized determination of the patient's financial need. The OIG is not specifying any particular method of determining financial need; it believes VBE participants need to make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income and resource guidelines uniformly applied. **The OIG requests comments on this approach and whether it should include a cap without any exceptions.**

The OIG proposes that the retail value is determined when the patient engagement tool or support is provided and proposes to interpret retail value to mean the fair market value to the recipient or commercial value to the recipient.

The OIG is concerned that beneficiary incentives can cause beneficiaries to receive unnecessary or harmful care but it does not want a monetary cap to present a barrier to achieving the intended benefits for patients by this proposed safe harbor. **The OIG requests comments on the following:**

- Whether other safeguards proposed in this rule would offer meaningful protection against fraud and abuse and eliminate the proposed requirement of a monetary cap.
- The appropriate level of a monetary cap that would be sufficient to allow the beneficial arrangements and protect against fraud and abuse.
- Whether the cap should apply to individual VBE participants or the VBE as an entire entity. The OIG is also interested in associated recordkeeping burdens associated for an individual VBE participant and the entire VBE entity.
- Alternatives to a monetary limit, such as a limitation on the frequency of remuneration to once a year or a per-occurrence limitation.
- Suggestion for treating ongoing costs associated with tools and supports such as batteries, maintenance costs, or upgrades.

j. Materials and Records

The OIG proposes, at 1001.952(hh)(6), to require the VBE or a VBE participant to make available to the Secretary, upon request, all information sufficient to establish compliance with this proposed safe harbor. **The OIG requests comments if it should include a requirement**

that VBE participants retain materials and records for a set period of time, e.g. at least 6 years or 10 years.

5. Potential Safeguards

As discussed below, the OIG is concerned that many VBE participants would not be subject to the governmental programmatic requirements, oversight, or monitoring applied to CMS-sponsored models and is considering additional safeguards.

a. Prohibition on Cost-Shifting

The OIG is considering prohibiting VBE participants from billing Federal health care programs, other payors, or individuals for the tool or support; claiming the value of 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 seeks comments on the following:

- Directly billing any third party, including patients, for the patient engagement tool or support of any operational costs attendant to the provision of the patient engagement tools and supports; and
- Claiming the cost of the patient engagement tool or support and any operational costs attendant to the provision of engagement tools and supports as bad debt for payment purposes under Medicare or a State healthcare program.

b. Consistent Provision of Patient Incentives

The OIG is considering whether to require VBE participants to provide the same patient engagement tools or supports to an entire target patient population or consistently offer these items to all patients satisfying specified, uniformed criteria. The OIG believes this is necessary to protect a VBE participant from targeting certain patients based on certain characteristics, such as insurance status.

The OIG seeks comments on the following:

- Whether this safeguard would limit certain VBE participants' ability to offer tools and supports due to the potential cost of furnishing the item to an entire target patient population instead of a smaller subset.
- Reasons why offering remuneration to a smaller subset of the target population would be appropriate and not increase the risk of fraud and abuse, such as targeting particularly lucrative patients to receive items (cherry picking) or failing to provide items to high-cost patients (lemon dropping).

c. Monitoring Effectiveness

The OIG is considering 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 require VBE participants to have policies and procedures to address any identified material deficiencies. The OIG would apply an objective standard of reasonableness. **The OIG seeks comments on this safeguard and any anticipated burdens and way to mitigate any associated burden.**

d. Retrieval of Items and Good

The OIG is considering 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 population, the VBE no longer exists, or the offeror is no longer a VBE participant. The OIG is considering setting a minimum value for the items or good above which reasonable retrieval efforts would need to be made. **The OIG seeks comments about whether any retrieval requirement should be limited to tools and supports that are practicable to recover and where harm to the patient or disproportional expense to the VBE participant would not occur.**

e. Advertising

The OIG is considering requiring VBE participants not to publicly advertise the patient engagement tool or support and would prohibit their use as marketing tools. This would be similar to the local transportation safe harbor, 42 CFR 1001.952(bb). **The OIG seeks comments on whether this restriction would impose a barrier to the success of care coordination and value-based arrangements.**

G. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

1. Overview

OIG defines the term “CMS-sponsored models” as 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). For prior and current tests of CMS-sponsored models, OIG and CMS have collaborated on waivers of certain provisions of the Federal anti-kickback statute and certain CMP law authorities. These waivers have been developed and issued on a model-by-model basis, creating what OIG refers to as a “patchwork” fraud and abuse waiver framework. Commenters to the OIG RFI asked that the patchwork framework be replaced by a simplified, standardized approach to protecting CMS-sponsored model arrangements under the anti-kickback statute and the beneficiary inducements CMP, thereby providing uniformity and predictability for parties participating in CMS-sponsored models.

OIG proposes to standardize protection of CMS-sponsored model arrangements by creating a new safe harbor (1001.952(ii)) that would permit 1) remuneration between and among parties to arrangements under CMS-sponsored models and 2) remuneration in the form of incentives and supports provided by model participants to patients covered by the model. The new safe harbor would provide model parties an additional pathway to protection from sanctions under the anti-kickback statute and beneficiary inducements CMP. OIG notes that to ensure immunity from

criminal and civil prosecution, an arrangement needs to meet the requirements of only one safe harbor, but cautions that all conditions of the chosen safe harbor or waiver must be met. Parties to existing arrangements for which model-specific fraud and abuse waivers already have been issued, would be able to continue using those waivers. Alternatively, those parties could choose to comply with the proposed CMS-sponsored models safe harbor; other safe harbors as proposed or modified elsewhere in this rule (e.g., value-based arrangements safe harbor); or any other applicable, existing safe harbor or CMP exception. **OIG seeks comment on broadening the scope of the proposed CMS-sponsored models safe harbor to protect remuneration between and among parties to arrangements under CMS initiatives beyond those authorized under sections 1115A and 1899 of the Act.**

OIG notes that the compliance flexibility being offered to CMS-sponsored model participants relies on the oversight and monitoring undertaken by CMS for their sponsored models. Similar flexibility would not be applicable to commercial and private insurance arrangements, as these are not subject to oversight and monitoring by CMS. OIG notes that commercial and private insurers could choose to structure their arrangements covering both public and private patients to satisfy other safe harbors being proposed in this rule that do not distinguish between public and private patient populations.

2. Definitions and Related Expectations

To implement the new safe harbor for CMS-sponsored models, OIG proposes the following interrelated definitions, as described in the table below.

Term	Proposed Definition
CMS-sponsored model party	CMS-sponsored model participant or another individual or entity that the CMS-sponsored model’s participation documentation specifies may enter into a CMS-sponsored model arrangement.
Participation documentation	Participation agreement, cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that is currently in effect and specifies 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 and that is consistent with, and is not a type of arrangement prohibited by, the participation documentation.
CMS-sponsored model patient incentive	Remuneration that is not of a type prohibited by the participation documentation and is furnished consistent with the CMS-sponsored model by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant’s direction and control) directly to a patient under the CMS-sponsored model.

Regarding patient incentives, OIG notes that a CMS-sponsored model participant may not always know whether a particular patient is in a CMS-sponsored model at any given point in time. Therefore, OIG is considering two alternatives: 1) extending the patient incentive definition above to include patients beyond those under a CMS-sponsored model; or 2) defining a term CMS-sponsored model patient such that a CMS-sponsored model participant could provide incentives to any patient (or any beneficiary) that meets the other conditions of the safe

harbor. **OIG solicits comment on the scope of the definition of CMS-sponsored model patient incentive and on the alternatives under consideration.**

Additionally, OIG proposes the following expectations for the use of the new safe harbor:

- CMS would notify model participants, through participation documentation or other public means as determined by CMS, when participants may use this safe harbor under a CMS-sponsored model (e.g., specify allowable types of patient incentives).
- CMS may impose, and CMS-sponsored model participants would be expected to satisfy, certain programmatic requirements imposed by CMS when using this safe harbor.
- If CMS makes this safe harbor available for a model, the safe harbor would not be available to protect any remuneration that fails to satisfy any program requirements imposed by CMS on the model participants.
- As a condition of participation in the CMS-sponsored model, CMS may require participants to disclose to CMS when they use this safe harbor.

3. Proposed Conditions for CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

a. General Considerations for Arrangements and Incentives

OIG proposes conditions to ensure that arrangements and patient incentives protected under the CMS-sponsored model safe harbor 1) do not lead to stinting on medically necessary care or induce inappropriate utilization; 2) are consistent with the quality, care coordination, and cost-reduction goals of a CMS-sponsored model; and 3) can be readily overseen by CMS and OIG. CMS would determine whether the safe harbor would be available for financial arrangements or patient incentives or both under any specific model.

OIG notes that when testing models, CMS has discretion to limit model participation by provider type or entity characteristics. The scope of entities, arrangements, or incentives protected under the CMS-sponsored models safe harbor would be determined by CMS and could be set on a model-specific basis. Unlike other safe harbors proposed elsewhere in this rule (e.g., exclusion of DMEPOS suppliers from the safe harbor for patient engagement and support), no entities would be summarily excluded from potential protection under the CMS-sponsored models safe harbor. OIG links the wide discretion proposed for CMS to implement the CMS-sponsored models safe harbor to the inherent structural features of such models that may mitigate fraud and abuse risk (e.g., CMS monitoring and oversight).

OIG also proposes that, in general, to qualify for protection under the CMS-sponsored models safe harbor, model incentives must be offered by a model participant (or a participant's agent) directly to a patient covered by the model. Protection could cover a broad range of incentives; CMS would have discretion to identify permissible incentives and would describe them in model participation documentation or other public resource. Incentives typically would be offered for free or below-fair-market value and would advance the model's goals. OIG states that CMS-sponsored models might permit waivers of cost-sharing amounts or provide cash incentives to promote certain clinical goals.

b. Conditions for CMS-Sponsored Model Arrangements

Remuneration between or among CMS-sponsored model parties, under a CMS-sponsored model arrangement in a model for which CMS has determined that this safe harbor is available, would be protected from sanctions if all of the following conditions are met:

- The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;
- Model parties (or other providers or suppliers) are not induced to provide unnecessary items or services or to limit medically necessary items or services;
- 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;
- Model parties, before or contemporaneous with the commencement of, the CMS-sponsored model arrangement, set forth the terms of the arrangement in a signed writing.
 - At a minimum, the writing must specify the activities to be undertaken by the model parties and the nature of the remuneration to be exchanged under the model arrangement;
- Model parties 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; and
- Model parties satisfy programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

c. Conditions for CMS-Sponsored Model Patient Incentives

A CMS-sponsored model patient incentive under a CMS-sponsored model arrangement in a model for which CMS has determined that this safe harbor is available, would be protected from sanctions if all of the following conditions are met:

- The model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the model;
- The model patient incentive has a direct connection to the patient's healthcare, and the connection must be considered from both healthcare and financial perspectives;
- The model participant makes available to the Secretary, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was distributed in a manner that meets the conditions of this paragraph;
- The model participant satisfies such programmatic requirements (e.g., model-specific) as may be imposed by CMS in connection with the use of this safe harbor; and
- A patient may retain any incentives received prior to the termination or expiration of the participation documentation of the model participant.

d. Duration of Protection

OIG notes that the definitions related to CMS-sponsored models are crafted to align the duration of safe harbor protection for arrangements and incentives with each model's duration as provided for in its participation documentation. The arrangement or incentive must begin and end while the model parties are operating under an existing CMS-sponsored model. One or more activities of a model may extend beyond the last performance period under which services are provided under the model (e.g., final reconciliation and shared savings distribution). The CMS-sponsored models safe harbor would protect the last payment or exchange of value.

OIG presents alternatives for determining the duration of safe harbor protection as follows: 1) terminating protection after the end of the performance period or within a set period thereafter; 2) terminating protection upon termination of the model participation documentation or within a set period thereafter; or 3) until the last payment or exchange of anything of value made by a model party occurs, even if the model has otherwise terminated. **OIG seeks comment about the alternatives presented, including implementation of one or any combination of these options. OIG also seeks comment as to whether a model participant should be able to continue to provide the outstanding portion of any service to a patient if the service was initiated before its participation documentation terminated or expired, and about any gaming opportunities thereby created.**

H. Cybersecurity Technology and Related Services

OIG proposes a new safe harbor to protect donations of certain cybersecurity technology and related services at a new §1001.952(jj). The proposed safe harbor is based on comments and suggestions offered by stakeholders, and OIG believes it could help improve cybersecurity in the health care industry, where an attack on the weakest link of an interconnected health information technology (IT) system poses risks to the protection of patient records and the transmission capabilities within the entire system. It notes that the Health Care Industry Cybersecurity Task Force report issued in June 2017¹³ recommended that the Congress consider a cybersecurity exception to the physician-self referral law and the anti-kickback statute.

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, it believes that the proposed safe harbor would promote increased security for health IT systems without protecting arrangements that serve as marketing platforms or inappropriately influence clinical decision-making.

The safe harbor proposal is similar to an exception to the physician self-referral law proposed in the CMS proposed rule. OIG worked closely with CMS to ensure as much consistency as possible within the differences in the underlying statutes. Because of the similarities, OIG may consider comments submitted to the CMS on the proposed cybersecurity exception to the self-referral prohibition in addition to the comments received on this proposed rule, and may "take additional actions" when crafting the final rule, if warranted.

¹³ The report is available at <https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf>

Under the proposal, nonmonetary remuneration in the form of certain types of cybersecurity technology and services would be protected if certain conditions are met. The proposed conditions for the safe harbor are:

- The technology and services are necessary and used predominantly to implement and maintain effective cybersecurity.
- The donor does not:
 - directly take into account the volume or value of referrals or other business generated between the parties when determining eligibility for the donation or the amount or nature of the technology or services to be donated; or
 - condition 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.
- The arrangement is set forth in a written agreement that is signed by the parties and describes the technology and services provided and the recipient's contribution, if any.
- The donor does not shift the costs of the technology or services to any federal health care program.

Details of the proposed safe harbor follow.

1. Definitions

Under the proposal, “cybersecurity” would be defined as 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 (NIST) Framework for Improving Critical Information, which is not specific to the health care industry. OIG seeks to avoid a narrow definition that might become obsolete over time. **Comments are sought on whether a definition tailored to the health care industry would be more appropriate.**

“Technology” would be defined as any software or other type of information technology other than hardware. The proposed definition would be 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. While it recognizes that cybersecurity may require certain hardware, OIG is concerned that donations of valuable, multifunctional hardware may pose a higher risk of constituting a disguised payment for referrals. Hardware is generally multifunctional and therefore would not meet the proposed requirements that donations be used predominantly for cybersecurity. OIG offers the example that the proposed safe harbor would not protect a laptop computer or tablet used by a physician to enter information into an electronic health record (EHR), but it would protect encryption software for the laptop or tablet. A similar exclusion of hardware applies in the current EHR donation safe harbor at §1001.952(y). **OIG solicits comments on excluding donations of hardware and any specific cybersecurity risks or limitations that would result.**

For the final rule, OIG is considering adding a limited protection for specific hardware that is necessary for cybersecurity if the hardware stands alone (i.e., is not integrated within multifunctional equipment) and serves only cybersecurity purposes. A two-factor authentication

dongle is offered as an example. **Comments are solicited on what types of hardware might qualify and whether they should be protected under the cybersecurity safe harbor.** A broader alternative for hardware donations is discussed below in section III.H.6.

OIG notes that the proposed safe harbor does not extend to donation of cybersecurity measures that are outside of technology or services, such as installation, improvement or repair of infrastructure related to physical safeguards that could improve cybersecurity. For example, upgraded wiring or high security doors would not be protected donations. OIG considers these as extremely valuable and having multiple benefits in addition to cybersecurity and therefore pose a risk that the purpose of the donation is to pay for or influence referrals.

2. Conditions on Donation and Protected Donors

As shown above, five conditions would be required for a donation of cybersecurity technology and services to be protected non-monetary remuneration. Two of these relate to the purpose of the donation and prohibit donors from taking into account the volume or value or referrals or other business generated.

First, the safe harbor is limited to technology and services that are necessary and used predominantly to implement and maintain effective cybersecurity. OIG does not intend to protect donations of technology or services that are otherwise used in the normal course of the recipient's business. **OIG seeks comment on whether this proposed condition would unintentionally limit the donation of cybersecurity technology and services that are vital to improving the cybersecurity of the health care industry.**

OIG intends that a wide range of cybersecurity technology and services be protected if they meet the requirements. It does not distinguish between cloud-based software and software installed locally. Examples offered of software considered necessary and predominantly used for cybersecurity include 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. **Comments are solicited on the proposed breadth of protected technology and services and whether OIG should include or exclude certain technology, categories of technology, services or categories of services in the proposed exception.** OIG emphasizes that in all cases, the donation of services must be nonmonetary. For example, if an entity experienced a cyberattack that involved ransomware, payment of the ransom amount for a recipient would not be protected.

For the final rule OIG is considering 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 allow 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 does not propose to condition the protection on compliance with a specific framework or standards, but **seeks comments on how donors and recipients could practically demonstrate that the deeming provision is met, such as through documentation, certification or other methods “not prescribed by regulation”**.

The second condition would prohibit donors from directly taking 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 or conditioning the donation (or its amount and nature) on future referrals. OIG acknowledges that a donor would provide cybersecurity technology and services only to entities that connect to its systems, but the proposed condition would prohibit the donor from conditioning the donation on referrals or other business generated.

OIG states that nothing would require a donor to donate cybersecurity technology and services to every individual or entity connected to its system. Recipients could be selected in a variety of ways as long as selection is not based on the volume or value of referrals or other business generated. A donor could, for example, base eligibility or the nature of the donation on a risk assessment, or it could provide a higher level of cybersecurity technology to entities with which it has bi-directional connections than those with a read-only connection. Other examples are offered.

In once difference from the current EHR safe harbor, OIG does not propose to include a list of selection criteria which would be deemed to meet this requirement 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. Therefore, OIG does not believe a list of selection criteria like those included in the EHR safe harbor is needed. **However, it is considering adding such a list in the final rule, and comments are sought on whether it should include a list and whether it should be based on the permitted conduct at §1001.952(y)(5)(i)-(vii),¹⁴ and any other conditions or permitted conduct that OIG should enumerate.**

OIG does not propose to restrict the types of individuals and entities that may make cybersecurity donations, but is concerned that referral sources may be beholden to donors and is considering narrowing the scope of entities that may provide remuneration under the cybersecurity safe harbor, as it has for other safe harbors. **Comments are solicited on whether**

¹⁴ §1001.952(y)(5) provides that for purposes of the EHR safe harbor, the determination of a donation is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if the determination is based on any of the following: (i) the total number of prescriptions written by the beneficiary (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a federal health care program); (ii) the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units); (iii) the total number of hours that the recipient practices medicine; (iv) the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor); (v) whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff; (vi) the level of uncompensated care provided by the recipient; or (vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

particular types of entities should be excluded from donating cybersecurity technology and related services, and if so, why. OIG has previously distinguished between individuals and entities with direct and primary patient care relationships that have a central role in the health care delivery infrastructure (such as hospitals and physician practices) and suppliers of ancillary services and manufacturers or vendors that indirectly furnish items and services used in the care of patients. (Readers are referred to 71 FR 45110, 45128.) OIG asks whether its historical enforcement concerns and other considerations regarding direct and indirect patient care are present for purposes of cybersecurity donations.

3. Conditions for Recipients

The proposed safe harbor would prohibit a potential recipient or the potential recipient's practice from making receipt of the technology or services or the amount and nature of the technology or services a condition of doing business with the donor.

OIG is not proposing to require a recipient contribution under the cybersecurity safe harbor because it seeks to remove a barrier to donations that improve cybersecurity in the health care industry. It does not believe that a minimum contribution requirement is necessary or practical. Because the level of services might vary by recipient and over time, some physician practices, particularly those in rural areas, might not be able to make the required contribution which would threaten cybersecurity of the systems in which they participate. Similarly, if donors were to aggregate costs of cybersecurity updates across recipients, determining pro-rata contributions may become unworkable. Despite not proposing a federal minimum contribution, OIG states that donors would be free to require recipients to contribute to the cost so long as the determination of the contribution requirement does not take into account the volume and value of referrals between the parties. **OIG solicits comments on the omission of a contribution requirement and any specific cybersecurity risks or limitations that would result from this omission.**

OIG notes that the proposed safe harbor is not intended to require that donations must be between two parties. For example, two hospitals and a large multi-specialty physician practice might agree to jointly subsidize cybersecurity technology and services for smaller physician practices in their area.

No restrictions are proposed for the type of recipients of cybersecurity technology or services. As a result, OIG believes that patients would be included as protected recipients if the donation meets all the conditions of the safe harbor. It expects that donations to patients would be more limited, such as anti-malware tools. **Comments are sought on what types of cybersecurity technology a donor might consider giving to a patient, whether additional or different safeguards would be needed, and whether patients should be protected at all under the safe harbor.** Specifically, OIG asks whether it should include conditions similar to the beneficiary inducements CMP exceptions under §1003.110, such as whether cybersecurity technology or service donations to patients should not be offered as part of any advertisement or solicitation or not be tied to the provision of other items or services covered by Medicare, Medicaid, or other state health programs.

4. Written Agreement

Under the proposed cybersecurity safe harbor, the arrangement would be set forth in a written agreement that is signed by the parties and describes the technology and services provided and the recipient's financial contribution, if any. OIG does not interpret this to mean that every item and every service must be specified in the agreement. **Comments are specifically sought on whether additional or different terms be required in a written agreement.**

5. Prohibition on Cost-Shifting

OIG proposes that the donor may not shift the costs of the technology or services to any federal health care program as a condition of protection under the cybersecurity safe harbor. An example offered 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 could not be included as an administrative expense.

6. Alternative Proposed Condition for Protection of Cybersecurity Hardware

OIG proposes and solicits 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. Under the alternative, a protected donation could include cybersecurity hardware that the donor has determined is reasonably necessary based on cybersecurity assessments of its own organization and the recipient that are based on industry standards. The donor would be required to have a risk assessment that identifies the recipient as a risk to the donor's cybersecurity, and the recipient would have to have a cybersecurity risk assessment to provide a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat.

OIG believes the proposal is built on existing legal requirements and best practices for information security, and these are discussed. For example, the HHS Office of Civil Rights named conducting a risk analysis the first step in carrying out standards and implementation specifications for the Health Insurance Portability and Accountability Act (HIPAA) Security Rule.¹⁵ More broadly, NIST Special Publication 800-30¹⁶ provides standards for information security practices and describes the role of risk assessment.

Recognizing that many organizations cannot afford in-house personnel focused on cybersecurity, OIG believes that a goal of the safe harbor is to increase the ability of all health care organizations to improve cybersecurity practices, regardless of resources. It sees protecting hardware based on a risk assessment as furthering that goal. Under the safe harbor as proposed, donors could donate a risk assessment of the recipient and under this alternative proposal the donor could then make hardware donations reasonably based on the risk assessment of the donor and recipient.

¹⁵ HHS Guidance on Risk Analysis at <https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html>.

¹⁶ NIST Special Publication 800-30 Revision 1, *Guide for Conducting Risk Assessments* (Sept. 2012), available at <https://nvlpubs.nist.gov/nistpubs/legacy/sp/nistspecialpublication800-30r1.pdf>.

Regarding this alternative proposal, comments are specifically sought on:

- Descriptions of existing practices of potential donors and recipients with respect to risk assessments that would provide a basis to determine whether a donation of cybersecurity hardware is reasonable and necessary.
- Whether a definition of risk assessment based on NIST Special Publication 800-30 would be sufficient for the proposed exception and alternative proposal to allow donations of hardware.
- Whether OIG should include specific standards for cybersecurity risk assessment such as NIST Special Publication 800-30.
- Explanations of the types of hardware necessary for effective cybersecurity, particularly from the provider perspective. OIG is considering additional safeguards if this alternative proposal is finalized, such as limits on the type of cybersecurity hardware permitted. It notes that even if it finalizes this proposal, multifunctional hardware would still be prohibited because it would not meet the requirement to be necessary and predominantly used to implement and maintain cybersecurity.
- Whether a 15 percent financial contribution should be required from a recipient of cybersecurity hardware, similar to that in the EHR exception, and whether a different financial contribution amount would be appropriate, such as 5, 20, or 30 percent.
 - OIG may exempt small and rural providers if this alternative is finalized with a financial contribution requirement, and seeks comments on the exemption, including (1) how small or rural practices should be defined, (2) whether other potential recipients should be exempted, such as critical access hospitals, because of the burden imposed by the financial contribution and (3) whether upgrades, updates and patches of previously donated remuneration should be exempt from any financial contribution.

7. Solicitation of Comments

OIG describes the challenges of striking a balance between the risk of cybersecurity attacks and the risk associated with permitting parties to donate valuable technology and services.

Comments are sought on whether the proposal establishes the right balance and if not, what changes are recommended to do so. Commenters are asked to consider the proposal in its entirety, including the proposed conditions, optional deeming provision, alternative condition, and definitions. OIG is especially interested in comments from health care providers because they bear the cybersecurity risk are experienced in compliance with other safe harbors.

Specifically, OIG asks the following questions:

- Does the proposed condition that the technology and services be necessary and used predominantly to implement and maintain effective cybersecurity (proposed §1001.952(jj)(1)) permit the donation of the right types of cybersecurity technology and services that could meaningfully improve the cybersecurity posture of the health care industry while also ensuring that the donated technology and services do not pose undue risk of improperly influencing referrals?
 - If not, what other standard or limitation would be appropriate to strike the right balance between cybersecurity risks and program integrity risks?

- Does excluding hardware from the definition of “technology” further OIG’s aim of balancing cybersecurity risks with the program integrity risks?
 - If not, what other conditions should be imposed to limit the value of remuneration protected by the proposed safe harbor so it does not improperly influence referrals? For example, should the safe harbor impose a monetary value limit on the total amount of donations that a donor can make to a recipient, or should the safe harbor require the recipient to contribute to the costs of a donation once the value has exceeded certain monetary thresholds?

I. Electronic Health Records

Current 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 expires on December 31, 2021.

In this rule, OIG proposes changes to the EHR safe harbor and notes that CMS is proposing parallel changes to the EHR exception under the physician self-referral regulations. OIG has aimed to be as consistent as possible with the CMS proposed rule, and will consider comments submitted to CMS on these issues and may also “take additional actions” when crafting the final rule.

1. Interoperability

Current conditions of the EHR safe harbor require donated items and services to be interoperable and prohibit the donor from taking actions to limit the interoperability of the donated item or service. ONC has previously issued a proposed rule to implement provisions of Title IV of the Cures Act (84 FR 7424), which includes proposed changes to the ONC Health IT Certification Program and provisions regarding information blocking. These provisions, if finalized, would affect provisions of §1001.952(y) regarding interoperability and the “data lock-in”.

2. Deeming

Under section §1001.952(y)(2), software donated under the EHR safe harbor must be interoperable, and software certified under the ONC certification program is deemed to be interoperable. OIG proposes what it refers to as two 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 EHR certification criteria identified in the then-applicable version of 45 CFR part 170. Under the proposal, OIG would require 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 would not meet the proposed condition.
- To be consistent with ONC proposed changes to the certification program, the regulatory text would be changed to remove the reference to “editions” of the certification criteria.

OIG notes that it is proposing to update the definition of “interoperable,” as discussed further in section III.I.6 below. It emphasizes that any changes to the definition would be prospective only; donated software that met the definition of interoperable and met the deeming requirements at the time of the donation would continue to be protected if the proposed changes are finalized.

3. 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 discusses the various federal activities that have evolved related to information blocking, and the ONC NPRM proposals at 45 CFR part 171 for implementing the information blocking provision of the Cures Act, which enacted section 3022 of the Public Health Service Act (PHSA).

Under the proposal, the text of §1001.952(y)(3) would be modified to reflect the ONC proposed rule regarding information blocking. Specifically, the text would 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. OIG notes that the EHR safe harbor applies primarily to health care providers, but that health plans are also protected donors. Providers are subject to the information blocking provisions of the Cures Act while health plans may not be. Rather than having different conditions for providers and health plans, OIG believes that it is reasonable to have one condition that applies the same information blocking knowledge standard to all parties who voluntarily seek the safe harbor to protect donations of EHR items and services. **OIG specifically solicits comments on aligning the condition at §1001.952(y)(3) with the ONC proposed information blocking definition for both providers and health plans.** It states that the current requirements already include concepts similar to the Cures Act prohibitions on information blocking and that the proposed modifications would not place any additional burden on health plans that voluntarily seek to protect donations.

4. Cybersecurity

OIG proposes to add 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 would clarify that the safe harbor applies to software or IT and training services, *including certain cybersecurity software and services*, necessary and used predominantly to create, maintain, transmit, receive *or protect* electronic health records if the identified conditions are met. Elsewhere in this proposed rule (see section III.H above), OIG proposes a new separate safe harbor to protect arrangements involving the donation of cybersecurity technology and related services.

The proposed cybersecurity safe harbor is broader and includes fewer requirements than the EHR safe harbor. The proposed 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. OIG proposes to use a definition of

cybersecurity that mirrors the one proposed for the cybersecurity safe harbor. The donation of cybersecurity software and services would need to comply with only one of the two safe harbors. **OIG seeks comments on its proposal and in particular whether modification of the EHR safe harbor is necessary.**

5. The 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.

Responding to subsequent comments requesting that the EHR safe harbor be made permanent, OIG reverses its view and now proposes to eliminate the sunset date. It 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. **OIG seeks comment on whether it should select a later sunset date instead of making the exception permanent and if so, what that date should be.**

6. Definitions

OIG proposes to update the existing definitions in §1001.952(y) of “electronic health record” and “interoperable” to reflect terms and provisions of the Cures Act. The proposed updated definitions would appear in a new paragraph §1001.952(y)(14) and follow:

Electronic health record shall mean 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.

Interoperable shall mean able to:

- (1) Securely exchange data with, and use data from other health information technology without special effort on the part of the user;
- (2) Allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
- (3) Does not constitute information blocking as defined in 45 CFR part 171.

The new definitions are not intended to substantively change the scope of protection. The proposed definition of interoperable is consistent with the definition of “interoperability” that appears in section 3000(9) of the PHSA (as added by the Cures Act), with the addition of a reference to the regulatory definition of information blocking. OIG intends to work with ONC to ensure that definitions align across the final EHR safe harbor and information blocking regulations.

OIG is also considering an approach that would link the definition of “interoperable” with the proposed definition of “interoperability” at 45 CFR 171.102, if the ONC finalizes that definition. This would allow for additional future updates to be adopted in the EHR safe harbor by reference.

Alternatively, OIG is considering revising the regulations to eliminate the term “interoperable” and instead incorporate the term “interoperability” as defined in section 3000(9) of the Cures Act. Under that alternative approach the regulations would require donations of software to meet interoperability standards established in title XXX of the PHSA and its implementing regulations. Software would be deemed to meet the interoperability standards if at the time of donation, it is certified by a certifying body authorized by ONC to health IT certification criteria identified in 45 CFR part 170. **OIG seeks comment on whether using terminology identical to the PHSA and ONC regulations would facilitate compliance with the requirements of the EHR exception and reduce regulatory burden resulting from the differences in the agencies’ terminology.**

7. Additional Proposals and Considerations

a. 15 Percent Recipient Contribution

Currently, §1001.952(y) requires that as a condition to the EHR safe harbor, the recipient must pay 15 percent of the donor’s cost of the technology. OIG is aware of the burden on recipients associated with the 15 percent contribution, particularly on small and rural practices, and that application of the contribution to upgrades and updates is restrictive and cumbersome and may act as a barrier to adoption.

No formal proposals regarding the 15 percent contribution are made in this rule, and OIG is considering retaining the requirement without change in the final rule. **However, OIG is also considering for the final rule, and solicits comments on, three separate alternatives to the existing requirement:**

- Eliminating or reducing the 15 percent contribution requirement for small or rural physician organizations. Comments are specifically solicited on how “small or rural practices” should be defined and whether “rural practices” should be defined as those located defined in the safe harbor for local transportation at §1001.952(bb); defined as those in medically underserved areas under section 330(b)(3) of the PHSA; or defined similarly to a “small provider of services or small supplier” as in 42 CFR 424.32. Comments are also solicited on other subsets of potential physician recipients for which the 15 percent contribution is a particular burden.
- Reducing or eliminating the 15 percent contribution requirement in the EHR exception for all recipients. Comments are sought on the potential impact of this approach on adoption of EHR technology, and any attendant risks of fraud and abuse. Specific examples are sought of any prohibitive costs associated with the 15 percent contribution requirement, both for the initial donation of EHR technology, and subsequent updates and upgrades.

- Modifying or eliminating the 15 percent contribution for updates to previously donated EHR software or technology. For example, OIG is considering requiring a contribution for the initial investment and any new modules but not for any software updates. Comments are sought on this alternative and others that would still involve some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update.

b. Replacement Technology

OIG proposes to allow donations of replacement EHR technology, and **seeks comments on whether this change is necessary and the types of situations in which the donation of replacement technology would be appropriate.** OIG is interested in how it might safeguard against situations where donors inappropriately offer, or recipients inappropriately solicit, unnecessary technology instead of an upgrade to existing technology.

CMS notes the rapid pace of advancement in EHR technology, and this proposal is made in response to previous comments stating that in some situations, replacement technology is appropriate but prohibitively expensive.

c. Protected Donors

For the final rule, OIG is considering expanding the group of entities that may be protected donors under the EHR safe harbor, which are described in §1001.952(y)(1). In its initial 2006 rulemaking, OIG applied the protection to a donor that is an individual or entity that provides patients with health care items or services covered by a federal health care program and submits claims to Medicare, Medicaid or other federal health care programs, and otherwise meets the safe harbor conditions. In 2013 rulemaking, laboratories were removed from the scope of potential donors to address potential abuse. While OIG remains concerned about the potential for abuse, it is considering expanding the scope of donors in order to advance the Department's objective to advance the adoption of EHR technology.

Specifically, OIG might eliminate the requirement that protected donors be limited to those who submit claims or payment requests directly or through reassignment to a federal health care program. Alternatively, it may modify that requirement to protect as donors health systems or accountable care organizations that neither are health plans or submit claims for payment. Some previous commenters suggested protecting any risk-bearing entity that participates as an Advanced APM in the Medicare Quality Payment Program. **OIG is interested in comments on other types of entities and potential donors who would avail themselves of a broadening of the protected donors. Comments are also solicited on whether removal of this restriction would impact the widespread adoption of EHR technology, and on any attendant risks of fraud and abuse.**

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

Commenters to the OIG RFI complained that the personal services and management contracts safe harbor posed barriers to care coordination and value-based arrangements. OIG proposes to update the safe harbor through a number of changes and additions as follows:

- Instead of requiring the aggregate compensation be set in advance, require that the methodology for determining compensation be set in advance;
- Strike the requirement to specify the schedule, length and exact charge for services of an agent on a periodic, sporadic or part-time basis; and
- Protect certain outcomes-based payments.

1. Elimination of Requirement To Set Aggregate Compensation in Advance (§1001.952(d)(5))

The agency proposes to remove the current 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. To prevent parties from adjusting compensation to reward referrals or unnecessary utilization, OIG proposes to instead require that the parties to the arrangement determine the compensation methodology before the initial payment is made under the arrangement.

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 would continue to apply. OIG believes the change would more closely align this safe harbor with the physician self-referral law exception for personal services arrangements (42 CFR 411.357(d)).

2. Elimination of Requirement To Specify Schedule of Part-Time Arrangements (§1001.952(d)(3))

This condition currently requires that contracts for services provided on a periodic, sporadic, or part-time basis specify “exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.” This condition was added to address OIG concerns that these types of arrangements are especially vulnerable to abuse; for example, part-time arrangements could easily be modified based on changing referral patterns.

OIG proposes to eliminate it to provide parties flexibility in designing *bona fide* business arrangements when parties provide legitimate services as needed. The agency believes that existing safeguards (e.g., the arrangement must be for a year or more; and 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) are sufficient. OIG believes the change would more closely align this safe harbor with the physician self-referral law exception for personal services arrangements.

3. Proposal to Protect Outcomes-Based Payments (§1001.952(d)(2) and (3))

OIG proposes to protect outcomes-based payment arrangements (such as shared savings, shared losses, episodic payments, gainsharing, and pay-for-performance) recognizing that these arrangements may facilitate care coordination, encourage provider engagement across care settings, and promote the shift to value.

a. Outcomes-Based Payment

Outcomes-based payment would be defined to be a payment from a principal to an agent that:

- Rewards the agent for improving (or maintaining the improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across settings; or
- Achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients.

Payments that relate solely to achievement of internal cost savings for the principal would be excluded. For example, sharing financial risk or gain only as it relates to a Medicare prospective payment system for a single provider (e.g., the hospital inpatient prospective payment system) would not qualify for protection; however, arrangements where financial risk or gain is shared across care settings could be protected.

OIG is considering whether to define the term by specifically referencing types of outcomes-based payments (i.e., shared savings and losses, gainsharing etc.). **If it does so, OIG seeks comment on whether it should further define those types of outcomes-based payments in the final rule using definitions applicable under the Medicare Shared Savings Program or from Innovation Center models.** The agency provides examples of the types of arrangements it envisions in the preamble.

b. Excluded Entities

Outcomes-based payments would exclude any payments made, directly or indirectly, by any of the following:

- A pharmaceutical manufacturer.
- A DMEPOS manufacturer, distributor, or supplier.
- A laboratory.

OIG believes that these types of entities depend heavily on practitioner prescriptions and referrals and might use outcomes-based payments primarily to market their products to providers and patients. OIG is also considering excluding pharmacies, compound pharmacies, PBMs, wholesalers, and distributors. **It seeks comments on this approach.**

The agency is also considering for the final rule whether to limit protections for outcomes-based payment arrangements to VBE participants.

c. Goal of Outcomes-Based Payment Arrangement

All outcomes-based payments would have to be made between parties that collaborate to measurably improve care quality, materially reduce costs while maintaining quality, or both. Protection is limited to those arrangements that foster these goals.

d. Collaboration

All outcomes-based payments would have to be made between parties that are collaborating to achieve the goals of outcomes-based payment arrangements. The agreement would have to specify any services to be performed (or refrain from being performed) to qualify for outcomes-based payment.

e. Outcome Measures

The parties to an outcomes-based payment arrangement would have to establish one (or more) specific evidence-based, valid outcome measure that the agent must satisfy to receive the outcomes-based monetary remuneration from the principal. This differs from the proposed care coordination and management safe harbor in that satisfaction of the outcomes measure is required to receive an outcomes-based payment.

The measures must relate to the goals of outcomes-based payment arrangements (i.e., measurably improve care quality, materially reduce costs while maintaining quality, or both). Parties must select outcomes measures based on clinical evidence or credible medical support.

Measures that simply reward the status quo would not meet this condition. OIG acknowledges that payment for maintenance of high quality may pose a low risk of fraud or abuse; **it seeks comment on whether, and if so how, to protect maintenance of high quality without protecting arrangements disguised as payments for referrals.** For the final rule, the agency is considering whether to impose stricter standards for outcome measures in this safe harbor than those that apply for the proposed care coordination and maintenance safe harbor.

The parties would be required to regularly monitor and assess the agent's performance on each outcome measure. Further, they must periodically rebase the benchmark or outcome measure. The intent behind rebasing is to take into account improvements already achieved. The agency believes rebasing will prevent parties from inappropriately carrying over savings from previous performance periods or from receiving payments that do not reflect legitimate outcomes achievement. **OIG seeks comment on whether to establish a specific timeframe with a performance period to rebase, such as 1, 3 or 5 years.**

f. Methodology

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 acknowledges this may be difficult due to the lack of industry standards to determine fair market value for outcomes-based arrangements and also because some of these arrangements do not necessarily correlate payments with actual services. It is considering a different approach for the final rule, such as valuing outcomes-based payments separately from other compensation or substituting a different safeguard to ensure payments are for legitimate participation in value-based care arrangements.

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.

g. Writing and Monitoring

The outcomes-based payment arrangement would have to be set forth in writing and signed by the parties before or contemporaneous with the beginning of the terms of the arrangement. The writing would also be required to include:

- Specification of all the services to be performed for the term of the agreement.
- The outcomes measures involved.
- The evidence-based data or information relied on to select the outcomes measure(s).
- The schedule for regular monitoring and assessment of the outcomes measure(s).

OIG suggests that the parties consider appropriate documentation and records to show compliance with the safe harbor.

h. Additional Safeguards

Under the proposal, the agreement may not either limit any party's ability to make decisions in their patients' best interest or induce any party to reduce or limit medically necessary items or services.

The term of the agreement would have to be for at least one year. Services under the agreement could not counseling or promotion of a business arrangement or other activity that violates state or federal law.

i. Technical Change

OIG would restructure §1001.952(d) by moving the existing personal services and management contracts provisions to paragraph (1).

K. Warranties (1001.952(g))

1. Bundled Warranties

The OIG proposes 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 modification would 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. The OIG believes this proposal could promote the use of warranted items by protecting warranties that encompass services, such as support and educational services. For example, this proposal would protect a warranty covering wound care products and certain related support services, such as access to a wound specialist.¹⁷

a. Inclusion of Services in Bundled Warranties

The OIG is proposing to protect warranty arrangements that apply to one or more items and services, provided the warranty covers at least one item. The OIG clarifies this proposed change 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.¹⁸

The OIG discusses 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. The OIG is considering a safeguard that would prohibit direct patient outreach by a seller offering a warranty but would allow the seller to pay an independent intermediary to perform services that require direct patient outreach, as long as compensation for the service is not tied to the volume or the value of any warranted item used by the patient.

The proposed safe harbor does not include protection of warranties covering only services. The OIG discusses the reasons it believes that warranties covering only services could present increased risk for fraud and abuse. **The OIG seeks comments on the potential fraud and abuse risks if the safe harbor protection for warranties is expanded to include service-only warranties and potential safeguards to mitigate these risks.**

b. Conditions on Bundled Warranties

The OIG proposes to include the following conditions on bundled warranty arrangements: (1) all federally reimbursable items and services must be reimbursed by the same Federal health care program and in the same payment; (ii) a manufacturer or supplier must not pay any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than the cost of the items and services subject to the warranty; and (iii)

¹⁷ For more details about this example, see Advisory Opinion No.01-08 available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-08.pdf>.

¹⁸ 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. In addition, provision of medication adherence services for free or at a warranty reduced charge would implicate the anti-kickback statute.

manufacturers and suppliers cannot condition bundled warranties on the exclusive use of one or more items or services or impose minimum purchase requirements.

c. Requirements for Federally Reimbursable Items and Services Subject to Bundled Warranty Arrangements

The OIG proposes a new paragraph (5) to require all federally reimbursable items and supplies subject to the bundled warranty are reimbursed by the same Federal health care program and in the same payment. The OIG states this would be satisfied when the federally reimbursable items and services subject to the bundled warranty are reimbursed by the same MS-DRG payment, the same APC payment, or the same Medicaid managed care program. The OIG believes that allowing sellers to bundle items and services reimbursed by different Federal health care programs could create incentives for overutilization or inappropriate utilization. The OIG is also concerned that bundled warranties could create barriers to entry for certain manufacturers and suppliers that cannot offer a bundled warranty and it seeks comments on additional safeguards to limit the potential anti-competitive effects that bundled warranties may have in the drug and device markets.

The OIG recognizes that the proposed requirement might inhibit warranties that are conditioned on the collective performance across a patient population because these items would not be reimbursed in the same payment. To permit population-based warranties, **the OIG requests comments about an option to require all items and services be reimbursed according to the same payment methodology, but not necessarily in the same payment.** The OIG notes that retrospective reconciliation payments, such as those used in the Innovation Center payment models, would not be considered one payment, as required under this proposal, when the reconciliation payments are paid to one entity but are not direct payments for items and services provided by that entity.

The OIG also requests comments about whether it should include any exemptions to the requirement that all items and services subject to a bundled warranty be paid by the same payment, such as when bundled items are reimbursed according to the same payment under Medicare but reimbursed separately under Medicaid.¹⁹

2. Capped Amount of Warranty Remedies; Prohibition on Exclusivity and Minimum-Purchase Requirements

The OIG proposes to modify paragraph (4) 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. The OIG also proposes a new paragraph (6) 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.

The OIG seeks comments on the effectiveness of these proposals in preventing or mitigating fraud and abuse risks, as well as additional safeguards it should consider.

¹⁹ The OIG provides examples in Advisory Opinion No. 18-10.

3. Reporting Requirements

The OIG recognizes 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. It is considering ways to modify the reporting requirements to accommodate outcomes-based warranty arrangements and still protect the Government's interest to have an accurate and timely report of any price reductions a seller offers a buyer under a warranty arrangement protected by the safe harbor. The OIG proposes to exclude beneficiaries from the reporting requirements to other buyers.

The OIG seeks comments on any burden the current reporting requirements impose and the need for more flexible reporting requirements to facilitate warranties tied to clinical outcomes.

4. Definition of "Warranty"

The OIG proposes to define "warranty" directly and not by reference to 15 U.S.C. §2306(6)²⁰ in order to clarify that the definition of warranties safe harbor applies to FDA-regulated drugs and devices. The OIG proposes to define "warranty" based on the definition in 15 U.S.C. §2306(6) with modifications to replace references to a "product" with references to items or bundle of items, substitution of references to the "material" of a product with "quality". The proposed 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.

L. Local Transportation (1001.952(bb))

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

The OIG is proposing to increase the limit on transportation of residents in rural communities from 25 to 75 miles of the health care provider.

The OIG seeks comments on comments on the following:

- Whether 75 miles is a sufficient limit and requests commenters provide data or other evidence to support the appropriate distance.
- How an entity would provide transportation for a distance in excess of 50 miles.
- Should the increase to 75 miles be limited to patients demonstrating financial, medical or transportation needs.
- Safeguards to prevent abuse of this proposed expansion.

2. Elimination of Distance Limit on Transportation of Discharged Patients

²⁰ The Magnuson-Moss Act enacted 15 U.S.C. §2306 which in paragraph (6) defines "written warranty in conjunction with the sale of a consumer product.

The OIG proposes 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. The OIG is also considering protecting transportation to another healthcare facility. In addition, the OIG is considering when transportation home or to another facility should be protected when a patient has not been admitted to an inpatient facility, such as an emergency room or after a procedure at an ASC.

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.

The OIG seeks comments on the following:

- Fraud and abuse risks associated with permitting transportation to another healthcare facility.
- Under what circumstances should transportation be protected when a patient has not been admitted to an inpatient facility.
- Whether transportation of discharged patients in excess of safe harbor mileage limits should be limited to patients with demonstrated need and what standards should apply.

3. Local Transportation for Health-Related, Non-Medical Purposes

In response to comments to the RFI about the importance of local transportation for non-medical purposes that may improve or maintain health, the OIG is considering non-medical purposes in this safe harbor. The OIG notes that in the proposed safe harbor for patient engagement and support offered by VBE participants (proposed 1001.952(hh), discussed above in this summary) includes transportation for health-related, non-medical purposes but this protection is limited to VBE participants.

The OIG seeks comments on the following:

- How the safe harbor could be expanded to improve health outcomes and address non-medical needs without creating an unacceptable risk of fraud and abuse.
- Should this expansion be limited to certain beneficiary populations, such as chronically ill patients.
- Given the proposed safe harbor for patient engagement tools and supports offered by VBE participants, is an additional extension of the local transportation safe harbor for non-medical needs necessary.

4. Use of Ride-Sharing Services

The final rule establishing the local transportation safe harbor (81 FR 88387), included patient transportation provided via a taxi in the safe harbor as long as all other requirements were met. The OIG notes 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 seeks comments from any commenter who disagrees and can provide comments explaining the difference between ride-sharing services and taxis and the need for expansion of the safe harbor.**

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).

M. ACO Beneficiary Incentive Program

The OIG discusses the provisions of the BBA 2018 which added section 1899(m) of the Act to permit ACOs under certain two-sided models to operate CMS-approved beneficiary incentive programs. The OIG notes that in the final rule establishing the ACO Beneficiary Incentive Program, CMS determined that the ACO Beneficiary Incentive Program required additional program integrity safeguards at 42 CFR 425.304(c) to help mitigate program integrity risks.

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 proposes to codify this statutory exception to the definition of remuneration at section 1128B(b)(3)(K) of the Act in its regulations at proposed paragraph 1001.952(kk). It proposes two changes to the statutory language. First, it will clarify the language to state that an ACO may furnish incentive payments only to assigned beneficiaries. Second, it would modify the statutory language “if the payment is made in accordance with the requirements of such subsection” to “if the incentive payment is made in accordance with the requirements found in such subsection”.

The OIG does not propose to establish any additional safe harbor conditions for incentive payments made by under an ACO Beneficiary Incentive Program.

IV. Provisions of the Proposed Rule: Beneficiary Inducements CMP Exception

A. Statutory Exception for Telehealth Technologies for In-Home Dialysis

Section 50302 of 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 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)(g)(J)(i));
- The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual’s ESRD (1128A(i)(g)(J)(ii)); and
- The provision of the telehealth technologies meets any other requirements in regulations promulgated by the Secretary (1128A(i)(g)(J)(iii)).

This exception would be available only for telehealth technologies (defined in the next section) 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 proposes to amend 42 CFR 1003.110. In its proposed condition (i) the OIG would require that the telehealth technologies be furnished to the individual by the provider of services or the renal dialysis facility (defined in title XVIII of the Act) that is currently providing the in-home dialysis, telehealth visits, or other ESRD care to the patient. This would prevent arrangements with providers and suppliers offering telehealth to patients they do not have a prior clinical relationship. The OIG notes that this provision might qualify for protection under other existing or proposed exceptions or safe harbors, including the proposed safe harbor for patient engagement and support (1001.952(hh)).

The OIG seeks comments on the following:

- Any challenges this condition would create.
- 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 suppliers (as defined in title XVIII of the Act).

The OIG proposes at condition (ii) the requirement that the telehealth technologies may not be offered as part of any advertisement or solicitation consistent.²¹ At proposed condition (iii), the OIG proposes 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 would consider technology to be of excessive value if the retail value of the technology is substantially more than is required for telehealth and provides an example that the safe harbor would not protect a donation of a \$600 smartphone when a \$300 smartphone would be sufficient. The OIG also proposes to interpret “telehealth services related to the individual’s ESRD” to mean only those telehealth service paid by Medicare Part B.

The OIG seeks comments on the following:

- Requiring the provider or facility to retain ownership of any hardware and make reasonable efforts to retrieve the hardware when it is no longer needed by the beneficiary for telehealth.
- Whether the OIG should interpret “related to the individual’s ESRD in a more restrictive fashion and protect telehealth technologies that provide the beneficiary with no more than

²¹ 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).

a *de minimis* benefit for any purpose other than furnishing telehealth services related to ESRD.

- Whether the OIG should limit telehealth technologies to telehealth services paid for by Medicare Part B.

B. Additional Proposed Conditions for the Telehealth Technologies Exception

The OIG proposes to amend 42 CFR 1003.110 at condition (iv) that a person must not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the item or service as a bad debt for payment purposes under a Federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a Federal health care program, other payors, or individuals. The OIG also proposes to prohibit claiming the cost of the telehealth technologies and any operational costs related to providing the technologies as bad debt for payment under Medicare or a State healthcare program or shifting the burden of the cost of the technologies and any operational costs to the provision of patient incentives to Medicare, a State healthcare program, other payors, or individuals.

C. Defining Telehealth Technologies

The OIG proposes to define “telehealth technologies” for both for the purpose of the term “remuneration” (42 CFR 1003.110) and the telehealth technologies exception in section 50302(c) of BBA 2018. The OIG proposes to adopt, as part of its definition of “telehealth technologies” the definition of “interactive telecommunications systems” found at 42 CFR 410.87.

The OIG proposes to define “telehealth technologies” as “multimedia communication equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention or ongoing care management – paid for by Medicare Part B – between a patient and the remote health care provider. Telephones, facsimile machines, and electronic mail systems do not meet the definition of ‘telehealth technologies.’” The OIG would not consider smart phones that allow for two-way, real-time interactive communication through secure, video conferencing applications as “telephones”.

The OIG seeks comments on the following:

- Whether the definition is too narrow or too broad and any risks of fraud and abuse associated with this definition.
- Whether telephones, facsimile machines, and electronic mails systems, as used in 42 CFR 410.78(a)(3) should be excluded from the definition.
- Whether to include in the definition technologies such as software, a webcam, data plan, or broadband internet access that facilitates the telehealth encounter and how this would impact access to medically necessary care.
- Whether broadening the definition to include additional technologies would create an undue risk of remuneration.
- Whether there should be limitations or conditions on the provision of telehealth technologies to curb potential abuse, such as limitations of the remuneration (e.g. a cap

on the value of telehealth technologies, such as \$100, \$500, or another amount) to protect the most beneficial arrangements while also preventing the most abusive ones.

D. Other Potential Safeguards

1. Consistent Provision of Telehealth Technologies

The OIG is considering whether as a condition of a safe harbor protection, parties should be prohibited from discriminating in the offering of telehealth technologies. The OIG notes this would require 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 seeks comments on the following:

- Whether this proposed safeguard would limit providers of services' or renal dialysis facilities' ability to offer incentives to the potential cost of furnishing the incentive to all qualifying patients rather than a smaller subset.
- Whether offering remuneration to a smaller subset of qualifying patients is appropriate and whether it would reduce the risk of fraud and abuse.

2. Necessary Technology

The OIG seeks comments on the following:

- Requiring a good faith determination that the individual to whom the technology is furnished does not already have the necessary telehealth technology for the telehealth services provided.
- Requiring the person who furnishes the telehealth technologies to take reasonable steps to limit the use of the telehealth technologies by the individual to the telehealth services described on the Medicare telehealth list.

3. Notice to Patients

The OIG is considering 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 seeks comments on the following:

- Whether there are perceived risks to the patients from hidden costs.
- Whether to include a written notice requirement and what should the notice specify.

4. Patient Freedom of Choice

The OIG is considering 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 seeks comments on whether this requirement would ensure patients understand they have freedom of choice.**

5. Materials and Records Requirement

The proposed exception would not include any requirements for documentation, materials and records. **The OIG seeks comments on this approach and any fraud and abuse risks presented.**

V. Regulatory Impact Statement

The OIG examined the impact of the proposed rule 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 (i.e., \$100 million or more in any year). Because the new CMP exception proposed in this rule 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. **OIG is, nonetheless, interested in comments on whether stakeholders expect there to be increases or decreases in utilization or costs as a result of the proposed changes.**

The Regulatory Flexibility Act requires agencies to analyze whether the proposed 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 for the proposed changes.

The rule does not impose any mandates on state, local or tribal governments, or on the private sector in excess of \$154 million in a year, so no analysis is provided under the Unfunded Mandates Reform Act. In addition, the proposed rule would 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.

OIG anticipates that many providers could potentially be affected by the rule, but that each year only about 5 percent (or roughly 25,000) of those potentially affected would explore value-based arrangements because of the rule. As a result, 25,000 providers would incur an hour of time to review the final rule, resulting in total regulatory review costs of \$5.2 million in each of the first 10 years after the rule is finalized. OIG discusses other anticipated impacts:

- While the proposed changes 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.
- 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 proposed changes would reduce the documentation burden for providers implementing CMS-sponsored model arrangements.
- A proposed CMP exemption 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.

Alternatives Considered. OIG considered not making the proposed changes, but concluded that regulatory reform is necessary to enable stakeholders to pursue innovative care delivery and payment redesign. OIG considered other alternative approaches to proposals to distinguish between beneficial care coordination arrangements and payment-for-referral schemes. It seeks comment on the benefits of its proposals and on ways to best distinguish between payment to reward or induce referrals and payment to promote or support care coordination.

OIG also considered not using value-based terms, definitions, and framework for the proposed safe harbors (as described in proposed sections §1001.951(ee), (ff), (gg), and (hh)), but concluded that these features would act as guardrails that would help to reduce risk of fraud and abuse.

VI. Paperwork Reduction Act

The proposed rule does 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.