FOLEY HOAG LLP

Summary of Final Rule: Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

NOVEMBER 24, 2020

Haider David Andazola
handazola@foleyhoag.com
202.261.7391

FOLEY HOAG LLP

OVERVIEW

On November 20, 2020, the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) published a Final Rule making modifications to the safe harbors applicable to the anti-kickback statute (AKS) and beneficiary inducement civil monetary penalties (CMP) law. The Final Rule represents an expansive and comprehensive overhaul of the AKS and beneficiary CMP law regulatory framework that seeks to accommodate the emerging area of value-based contracting in the health care industry.

The Final Rule sets forth foundational terminology for identifying and classifying different aspects of value-based payment arrangements ("VBAs") and contracting for the purposes of the AKS and the beneficiary inducement CMP law. Based on this common foundation, the Final Rule creates several VBA-related safe harbors, the primary three of which reflect a tiered approach that divides protection for certain VBAs based on the level of risk shared by the contracting parties in the arrangement. More specifically, the Final Rule creates a safe harbor for in-kind remuneration exchanged as part of VBAs that do not involve the sharing of risk between contracting parties at all, and then builds on that framework to establish two additional safe harbors that protect broader types of remuneration (including monetary remuneration) but involve a greater degree of risk-sharing. Notably, the OIG finalized the general exclusion of pharmaceutical manufacturers, labs, and other types of entities, from eligibility under any of these three VBA-related safe harbors, and many of the other new safe harbors. The Final Rule, however, finalizes a "Limited Technology Participant" definition through which certain medical device/supply manufacturers and durable medical equipment (DMEPOS) suppliers can participate in some of the VBA-related safe harbors.

In addition, the Final Rule finalizes modifications to many existing safe harbors, some of which are value-based in nature. For example, the Final Rule finalizes modifications to the personal services and management contracts safe harbors that extends protection to certain "outcomes-based payments." The Final Rule also modifies the existing warranty safe harbor to extend protection to warranties involving bundled items and services, albeit with key clarifications that the safe harbor is intended to protect only the warranty remedies and not any other remuneration that may be related to the bundled warranty, such as the provision of free or price-reduced items and services that facilitate the implementation of the bundled warranty.

The provisions of the Final Rule are effective January 19, 2021. Should the incoming Biden-Harris Administration wish to revise provisions finalized by the Final Rule, another round of notice-and-comment rulemaking would be necessary.

Below we provide a high-level summary of the Final Rule's key provisions.

Table 1: Summary of additions/modifications made to AKS and beneficiary inducement CMP in the Final Rule.

New Safe Harbors	Modified Safe Harbors	"Remuneration" Definition Exceptions
• Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (no risk) • Value-Based Arrangements with Substantial Downside Financial Risk • Value-Based Arrangements with Full Financial Risk • Patient Engagement and Support Safe Harbor • CMS-Sponsored Models Safe Harbor • Cybersecurity Technology and Services Safe Harbor • ACO Beneficiary Incentives Exception	• Electronic Health Records Safe Harbor • Personal Services and Management Contracts and Outcomes-Based Payments Safe Harbor • Warranties Safe Harbor • Local Transportation Safe Harbor	• Telehealth Technologies for In-Home Dialysis Patients Exception

I. VALUE-BASED TERMINOLOGY

The Final Rule finalizes foundational VBA-related terminology that serves to inform the application of the AKS and beneficiary inducement CMP law to an evolving value-based healthcare landscape. The key definitions included below apply across multiple safe harbors, particularly if they involve some value-based component.

- **Value-Based Enterprise (VBE)**
  - Defined as two or more VBE participants (i) collaborating to achieve at least one value-based purpose; (ii) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (iii) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (iv) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).1
  - A VBE need not be a formal separate legal entity.
  - A VBE should have an accountable body or responsible person that is appropriate for its size and resources and is capable of carrying out the associated responsibilities.

[1] VBE participants may join and leave the VBE throughout its existence.

  - A VBE should have a governing document to clearly identify the governance structure for the VBE and it should be updated as the VBE evolves.

- **Value-Based Arrangement (VBA)**
  - Defined to mean an arrangement for the provision of at least one "value-based activity" for a "target patient population" to which the only parties are the VBE and one or more of its VBE participants, or VBE participants in the same VBE.
  - VBAs are not *de facto* safe harbor protected—rather, an arrangement that meets the definition of a VBA is eligible to seek protection in one of the three primary VBA-related safe harbors.
  - The VBA definition does not limit protection for entities under common ownership, but a particular safe harbor itself may contain requirements rendering such entities ineligible for protection.

- **Target Patient Population**
  - Defined to mean an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that (i) are set out in writing in advance of the commencement of the VBA; and (ii) further the VBE's value-based purpose(s).
  - Does not need to be limited to federal health care program beneficiaries and could encompass all patients with a particular disease state, for example.

- **Value-Based Activity**
  - Defined as an activity that is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (i) the provision of an item or service; (ii) the taking of an action; or (iii) the refraining from taking an action.
  - Making a referral is not a value-based activity.
  - By "reasonably designed," the OIG means that parties should fully expect the value-based activities they develop to further one or more value-based purposes, which would be a fact-specific inquiry.
  - The value-based activity is intended to be broad and to include the actions parties take or refrain from taking pursuant to a VBA and in furtherance of a value-based purpose.

- **VBE Participant**
  - Defined as an individual or entity that engages in at least one value-based activity as part of a VBE, other than a patient acting in their capacity as a patient.
  - VBE participants are no longer limited to specific entities (except that patients can never be VBE participants), although the VBA-related safe harbors themselves limit the type of entities eligible for protection.

- **Value-Based Purpose**
  - Defined as (i) coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (iv) transitioning from health care delivery and payment mechanisms based on the volume of items and services

provided to mechanism based on the quality of care and control of costs of care for a target patient population.

- Coordination and Management of Care is defined as the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

II. CARE COORDINATION ARRANGEMENTS TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY SAFE HARBOR ("CARE COORDINATION SAFE HARBOR")

Overview. The Final Rule finalizes the creation of a care coordination safe harbor to protect in-kind remuneration exchanged between qualifying VBE participants with VBAs that assume no or less than substantial downside financial risk. The protected remuneration must be used "predominantly" to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. The offeror of the remuneration must also not take into account the volume or value of, or condition an offer of remuneration on (i) referrals of patients that are not part of the VBA's target patient population; or (ii) business not covered under the VBA. The recipient, on the other hand, must make a contribution in advance of receiving the in-kind remuneration equal to at least 15 percent of either the offeror's cost or the fair market value of the remuneration to ensure adequate "engagement" and "accountability" by the recipient. An exchange of remuneration will not be protected if the offeror knows or should know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

Excluded Entities and "Limited Technology Participants." Consistent with the other VBA-related safe harbors, certain entities are ineligible for protection under the care coordination safe harbor, including:

- pharmaceutical manufacturers, wholesalers, and distributors;
- PBMs;
- laboratory companies;
- pharmacies that primarily compound drugs or primarily dispense compounded drugs
- manufacturers of devices or medical supplies (except with respect to digital health technology, as described below)
- entities or individuals that sell or rent DMEPOS (other than a pharmacy, a medical device or supply manufacturer that also sells or rents DMEPOS, or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible);
- medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies; and
- medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians.

Notwithstanding the exclusion above, some entities are eligible to for protection under the care coordination safe harbor as "limited technology participants." A "limited technology participant" means a VBE participant that exchanges digital health technology with another VBE participant or a VBE, and that is a manufacturer of a device or medical supply (with ownership interest limitations) or an entity that sells or rents DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services—this entity can participate as a normal VBE participant). "Digital technology" is defined to mean hardware, software, or devices that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care. Digital technology includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

Remuneration Limited to VBE Participants. Remuneration exchanged with patients, including any cost-sharing waivers, are not protected by the care coordination safe harbor—only remuneration between VBE participants is protected. The safe harbor is strictly limited to in-kind remuneration, which could include, for example, data analytics technology and services provided by one practice to another (even if one practice receives referrals from the other) that identifies practice patterns that deviate from evidence-based protocols or confirm whether follow up care recommended is being sought by patients. If there are multiple streams of remuneration flowing under a single VBA, the parties would need to evaluate each stream separately for compliance with the safe harbor.

Outcome Measures or Benchmarks. The Final Rule requires that the parties to a VBA under the Care Coordination safe harbor establish one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support. The measure(s) must: (i) include one or more benchmarks related to improving, or maintaining improvement, in the coordination and management of care for the target patient population; (ii) relate to the remuneration exchanged under the VBA; and (iii) not be based solely on patient satisfaction or patient convenience. The outcome measure can be applied to the entire target population, or to different segments of the target population. The outcome or process measure and its benchmark must be monitored, periodically assessed, and prospectively revised, as necessary, so that working towards the measure continues to advance the coordination and management of care of the target patient population and to ensure that there is a close nexus between the value-based activity and what the parties are measuring.

Writing and Documentation. The care coordination safe harbor will consist of a writing requirement set forth in a single document or a collection of documents. The writing must, at a minimum, state (i) the value-based activities to be undertaken by the parties to the value-based arrangement; (ii) the term of the value-based arrangement; (iii) the target patient population; (iv) a description of the remuneration; (v) either the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration; (vi) the percentage of the offeror's cost contributed by the recipient; (vii) if applicable, the frequency

of the recipient's contribution payments for the offeror's ongoing costs; and (viii) the outcome or process measure(s) against which the recipient would be measured.

Similar writing and documentation requirements apply to the other VBA-related safe harbors.

Monitoring and Assessment. The VBE, a VBE participant, or the VBE's accountable body or responsible person must reasonably monitor and asses the following, no less frequently than annually, or once during the term of the value-based arrangement for arrangements with terms less than 1 year: (i) the coordination and management of care for the target patient population in the value-based arrangement; (ii) any deficiencies in the delivery of quality care under the value-based arrangement; and (iii) progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement. The OIG will not require monitoring and assessment of utilization, referral patterns, and expenditure data, although the OIG states that monitoring and assessment of such data may be a best compliance practice for many arrangements. If material deficiencies in the quality of care are found, or if it is unlikely that further advancement in the coordination and management of care for the target patient population will be made, the parties must terminate the arrangement within 60 days or institute a corrective action plan within 120 days.

Marketing of Items or Services for Patient Recruitment Activities. The care coordination safe harbor, along with the other VBA-related safe harbors, share a general prohibition that remuneration may not be exchanged or used for the purpose of marketing items or services furnished by the VBE or VBE participant to patients or for recruitment activities. Whether remuneration is being exchanged or used for the purposes of marketing items or services for patient recruitment activities or for an educational activity requires a fact-specific analysis.

Table 2: OIG illustrative examples of prohibited marketing/patient recruitment activity.

Allowed Educational Activity	Prohibited Marketing Activity
If a SNF or home health agency placed a staff member at a hospital to assist patients in the discharge planning process, and in doing so, the staff member educated patients regarding care management processes used by the SNF or home health agency, this would not constitute marketing of items and services (provided the staff member only worked with patients that had already selected the SNF or home health agency and SNF or home-health agency care was medically appropriate for such patient).	If the SNF or home health agency placed a staff member at a hospital to perform care coordination services and to market the SNF's or home health agency's services to hospital patients, the arrangement would not comply with this requirement because the remuneration being exchanged pursuant to the arrangement — the services offered by the staff member — would be exchanged for the purpose of engaging in marketing.

Non-finalized Safeguards. Many safeguards OIG considered in the Proposed Rule were not included in the Final Rule, including but not limited to:

- A proposed prohibition on cost-shifting through claiming remuneration exchanged as a bad debt for payment under a federal healthcare program, or through other means that shift costs to the federal government.
- A proposed requirement on dialysis providers specifically to ensure their care coordination arrangements operate to improve the management and care of patients that are not pay-for-referral schemes.
- Proposed additional reporting requirements submitted to OIG that would identify the VBE, VBE participants, and value-based arrangements.

III. VALUE-BASED ARRANGEMENTS WITH SUBSTANTIAL DOWNSIDE FINANCIAL RISK ("SUBSTANTIAL DOWNSIDE RISK SAFE HARBOR")

Overview. The Final Rule finalizes the creation of the substantial downside risk safe harbor that protects remuneration more broadly than the care coordination safe harbor, but requires that the VBE assume "substantial downside financial risk" (determined under one of three methodologies) from a payor. Thus, the substantial downside risk safe harbor will only be available for contracts or value-based arrangements where the target patient population is comprised of patients insured by a payor with which a VBE can enter into a risk arrangement. Furthermore, the safe harbor requires that the VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) must assume a "meaningful share" of the VBE's total risk equal to at least 5 percent. The substantial downside risk safe harbor protects remuneration exchanged between VBE and VBE participants, and it does not protect remuneration exchanged downstream of a VBE participant, such as arrangements between two VBE participants. Moreover, unlike the care coordination safe harbor, the substantial downside financial risk safe harbor does not include the "limited technology participant."

Substantial Downside Financial Risk. The "substantial downside financial risk" requirements that the VBE must agree to assume with a payor can be satisfied by one of three methodologies:

- Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the total cost of such care
- Risk equal to at least 20 percent of any loss where losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care
- A prospective per-patient payment that is designed to produce material savings and is paid monthly, quarterly, or annually for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services

Meaningful Share. The "meaningful share" requirement that VBE participants must assume is satisfied where the VBE participant assumes *two-sided* risk for at least 5 percent of the losses and savings (as applicable) realized by the VBE pursuant to its assumption of substantial downside financial risk. Alternatively, "meaningful share" can be satisfied where the VBE participant receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, and the VBE participant does not claim payment in any form from the payor for the predefined items and services.

VBE's Assumption of Risk from Payor. For the purposes of the substantial downside risk safe harbor (and full risk safe harbor described below), the OIG distinguishes between two different ways that a VBE can assume risk from the payor. The first involves entering into a VBA that meets the definition of a VBA under the regulations. The second involves entering into a contract with the payor that places the VBE at substantial downside risk. The OIG clarifies that the remuneration exchanged pursuant to the first method is eligible for protection under the substantial downside risk safe harbor provided that all safe harbor requirements are met. But remuneration exchanged pursuant to a separate contract with the payor is not because eligible for protection under the safe harbor because the written contract that places the VBE at risk is not a VBA. The VBE and the payor would need to assess any potential remuneration exchanged pursuant to the risk arrangement contract and its compliance with the AKS.

Moreover, the OIG clarifies that this safe harbor is unlikely to be available for Medicare Parts A and B because outside of CMMI models, there is no mechanism for a VBE to contract with the Medicare program as a payor to assume substantial downside financial risk.

Phase-In Protection. The safe harbor protects remuneration exchanged between the VBE and a VBE participant during the 6 months prior to the date by which the VBE must assume substantial downside financial risk. The VBE must have a contract or VBA with the payor to assume risk within the next 6 months for this protection to apply. The safe harbor would still apply to the remuneration exchanged during the phase-in period if the parties ultimately determine that they cannot assume the financial risk at the conclusion of the phase-in period as long as all of the requirements for the safe harbor continue to apply.

Writing and Documentation. The safe harbor requires that the VBE and VBE participants must document the manner in which the VBE assumes risk from a payor and the VBE participant assumes a meaningful share of such risk. The writing requirement can be satisfied by a collection of documents, and the writing must be established in advance of, or contemporaneous with, the commencement of the value-based arrangement "and any material change." The VBE or its VBE participants must maintain records and materials sufficient to establish compliance with the conditions of the safe harbor for at least 6 years.

Non-finalized Safeguards. Many safeguards OIG considered in the Proposed Rule were not included in the Final Rule, including but not limited to:

- A proposed commercial reasonableness requirement
- A proposed monitoring standard
- A proposed cost-shifting prohibition
- A proposed requirement to submit certain information to the Department regarding the VBE, VBE participants, and the VBA

IV. VALUE-BASED ARRANGEMENTS WITH FULL FINANCIAL RISK ("FULL RISK SAFE HARBOR")

Overview. Similar to the substantial downside financial risk safe harbor, the full risk safe harbor applies only where the VBE assumes "full financial risk" from a payor, defined as risk on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least one year. The requirement that the VBE be at full financial risk on a prospective basis does *not* mean that the VBE must be prospectively *paid* by the payor prior to the provision of items and services to each patient. Instead, it means that the VBE must assume financial responsibility prior to the provision of items and services, and the payor could pay the VBR at any point in the coverage period and engage in retrospective reconciliations, as long as the VBE assumed full financial risk for a term of at least 1 year. The OIG clarifies that it is not dictating the manner in which the VBE exchanges remuneration with VBE participants, so a VBE could impose front-end withholds or dues assessments on VBE participants.

Full Financial Risk. "Full financial risk" is defined to mean that the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the payor for each patient in the target patient population for a term of at least 1 year. The VBE must assume risk for all items and services covered by the applicable payor for each patient in the target patient population, including drugs (but pharmaceutical manufacturers are unable to give or receive remuneration that is protected under the safe harbor). A VBA that involves anything less than full risk is not covered by this safe harbor, although the VBE may limit the target patient population for which it bears full financial risk, provided that it does so using legitimate and verifiable criteria as defined by regulations.

Re-Insurance. The VBE may enter into reinsurance or other risk-adjustments arrangements that could address losses incurred by VBE participants by using reinsurance payments to reimburse VBE participants. The OIG does not specify a limit on the amount of loss coverage a VBE may have, but it expects any stop-loss or other risk adjustment arrangements to act as protection for the VBE against catastrophic losses and not as a means to shift material financial risk back to the payor.

Phase-In Period. Like with the substantial downside financial risk safe harbor, the Final Rule finalizes a slightly higher 1-year phase-in period that would protect remuneration exchanged pursuant

to a VBA between a VBE and a VBE participant where the VBE is contractually obligated to a payor to assume full financial risk in the next year.

Quality Assurance Program. VBEs seeking protection under this safe harbor must provide or arrange for a quality assurance program for services furnished to the target patient population that: (i) protects against underutilization of items and services furnished to the target patient population; and (ii) assess the quality of care furnished to the target patient population. Such a quality assurance program may include an operational utilization review program and specify patient goals, but an operational utilization review program is no longer a requirement, as initially proposed.

Non-finalized Safeguards. Many safeguards OIG it considered in the Proposed Rule were not included in the Final Rule, including but not limited to:

- A proposed cost-shifting prohibition
- A proposed requirement to submit certain information to the Department regarding the VBE, VBE participants, and the VBA

V. ARRANGEMENTS FOR PATIENT ENGAGEMENT AND SUPPORT TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY ("PATIENT ENGAGEMENT AND SUPPORT SAFE HARBOR")

Overview. The patient engagement safe harbor protects remuneration in the form of in-kind patient engagement tools and supports furnished directly by VBE participants to patients in a target patient population that are directly connected to the coordination and management of care of the target patient population, and of which is recommended by the patient's licensed health care professional. Cash, cash equivalents, and other tools and supports designed to effectuate a waiver of beneficiary cost-sharing are not protected under the patient engagement and support safe harbor. The value of any tools and supports provided to patients may not exceed $500 annually, and the tools or supports cannot be used solely for patient recruitment purposes or used to market other federally-reimbursable items and services to patients. The patient's insurance coverage may also not be taken into account.

Excluded Entities and Limited Technology Participants. Consistent with the other VBA-related safe harbors, certain entities are ineligible to use the patient engagement and support safe harbor to furnish protected remuneration to patients, including:

- pharmaceutical manufacturers, wholesalers, and distributors;
- PBMs;
- laboratory companies;
- pharmacies that primarily compound drugs or primarily dispense compounded drugs
- manufacturers of devices or medical supplies (except with respect to digital health technology, as described below)

- entities or individuals that sell or rent DMEPOS (other than a pharmacy, a medical device or supply manufacturer that also sells or rents DMEPOS, or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible);
- medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies; and
- medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians.

Notwithstanding the exclusion above, some entities are eligible to for protection under the patient engagement and supports safe harbor as "limited technology participants." Like with the care coordination safe harbor, a limited technology participant means a VBE participant that exchanges digital health technology with another VBE participant or a VBE. Unlike the care coordination safe harbor, however, a "limited technology participant" under the patient engagement and supports safe harbor cannot be an entity that sells or rents DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services).

Limitation on Recipient. The safe harbor requires that the tools and supports provided by the VBE participant must be provided to a patient in the target patient population of a VBA to which the VBE participant is a party. Moreover, the VBE participant must provide the tools and supports directly to the patient (or caregiver/family member) or through a third party that qualifies as an "eligible agent," defined to mean any person or entity that is not an excluded entity as defined above.

Funding Limitations. The patient engagement tool or support must not be funded or contributed by a VBE participant that is not a party to the applicable VBA or is among the excluded entities. This requirement is meant to protect against circumvention schemes, including potential arrangements involving foundations or charities, where by such entities indirectly fund the patient tools or supports. A foundation or charity could still provide the same patient tools or supports directly to the patient, but would have to comply with any applicable AKS regulations.

VI. CMS SPONSORED SAFE HARBOR

Summary. The CMS sponsored safe harbor protects remuneration between or among CMS-sponsored model parties, or patient incentives, under a CMS-sponsored model arrangement (i.e. CMMI models) for which CMS has determined that this safe harbor is available. The parties must reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model. The focus of this safe harbor is to protect remuneration and patient incentives by an individual *other* than the CMS-sponsored model participant or their agent, and it does not modify existing CMMI model waivers of fraud and abuse laws, although the OIG notes that it expects to issue fewer waivers in the future given the creation of the CMS-sponsored safe harbor.

VII. CYBERSECURITY TECHNOLOGY AND RELATED SERVICES ("CYBERSECURITY SAFE HARBOR")

Summary. The cybersecurity safe harbor protects certain software, hardware, and other types of donated information technology *by any* entity *to any* entity, within certain conditions. The safe harbor is limited to technology and services (no monetary remuneration, including reimbursement for any ransomware attacks) that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. Software that has multiple functions, one of which is cybersecurity, would not meet the "necessary" and "predominant" use standard under the cybersecurity safe harbor. The definition of "cybersecurity" is derived from the NIST Cybersecurity Framework. Notably, there is no monetary value limit for the donated software, hardware, or other cybersecurity technology, although donations cannot be conditioned or take into account the volume or value of referrals.

VIII. ELECTRONIC HEALTH RECORDS ITEMS AND SERVICES SAFE HARBOR ("EHR SAFE HARBOR")

Summary. The Final Rule finalizes changes to the EHR safe harbor, including making the EHR safe harbor permanent through elimination of its sunset provision (Dec. 31, 2021). The EHR will also now expressly include cybersecurity, potentially covering multi-function technology that would not otherwise be covered by the cybersecurity safe harbor established under the Final Rule. "Interoperable" software is defined as software able to "securely exchange data with, and use data from other health information technology," and "allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law." Software can now be deemed "interoperable" by a certification from the ONC, but it will not be a requirement of the safe harbor. The EHR safe harbor will continue to require a 15 percent contribution requirement, but the safe harbor will no longer require that the contribution be made in advance for *updates* to existing EHR systems. Moreover, the EHR safe harbor will now allow replacement EHR technology by removing the condition that prohibits the donation of equivalent items or services. Parent companies of hospitals, health systems, and accountable care organizations will also be added to the list of protected donors.

IX. PERSONAL SERVICES AND MANAGEMENT CONTRACTS AND OUTCOMES-BASED PAYMENT AMENDMENTS ("PERSONAL SERVICES AND MANAGEMENT CONTRACTS SAFE HARBOR")

Overview. The Final Rule finalizes changes to the personal services and management contracts safe harbor that substitutes the requirement that aggregate compensation be set in advance with a requirement that the *methodology* for determining compensation be set in advance. The Final Rule also removes the requirement that the contract must specify the schedule, length, and the exact charge for interval-based services. The personal services and management contracts safe harbor will also now

potentially protect outcomes-based payment arrangements between a principal and an agent that reward improving patient or population health by achieving one or more outcomes measures.

Outcomes-Based Payments. The personal services and management contracts safe harbor protects remuneration that consists of outcomes-based payments as long as the outcomes-based payment achieves one or more "legitimate outcome measures" that (i) are based on clinical evidence or credible medical support, and (ii) have benchmarks that are used to quantify improvements in, or maintenance of improvements in the quality of care and/or a material reduction in costs to or growth in expenditures of payors while maintaining or improving the quality for patients. The methodology for determining any outcomes-based payments must be established in advance, be commercially reasonable, consistent with fair market value, and not determined in a manner that takes into account or is conditioned upon referrals, among other requirements. The outcomes-based payments must be limited to payments between or among the principal and an agent, an agent being defined as any person *other* than a *bona fide employee* of the principal who has an agreement to perform services for or on behalf of the principal. Notably, outcomes-based payments cannot include payments made directly or indirectly by the list of entities generally excluded under the substantial downside financial risk and full risk safe harbors, and the payments may not be solely related to achievement of internal cost savings for the principal or based solely on patient satisfaction or patient convenience measures.

X. WARRANTIES ("WARRANTY SAFE HARBOR")

Overview. The Final Rule finalizes changes to the warranty safe harbor that protect a bundle of items or a bundle of items and services (although it does not protect services only) that are federally reimbursable by the same Federal health care program and in the same Federal health care program payment (although not necessarily a single payment amount). The warranty safe harbor, however, will not protect free or reduce-priced items or services that sellers provide either as part of a bundled warranty arrangement or ancillary to a warranty arrangement. In other words, the safe harbor only protects remuneration provided as a warranty *remedy*, and services offered for free or at a reduced price by sellers would not themselves be protected under the safe harbor. The contracting parties would need to seek protection under a different safe harbor if non-reimbursable items or free items offered to the buyer as part of the bundled warranty have independent value to a buyer.

Definition of Warranty. The Final Rule defines "warranty" directly to include drugs and devices regulated under the FDCA, and any services in combination with one or more related items. Moreover, the definition of a "warranty" will expressly apply to warranty arrangements conditioned on clinical outcomes guarantees, provided other safe harbor requirements are met.

Medication Adherence. As described above, to the extent that medication adherence services are provided by a seller for free or at reduced costs as part of a bundled warranty, such as by a pharmaceutical manufacturer in connection with a drug, such services are not covered by the warranty safe harbor. The warranty safe harbor only protects the warranty *remedy* for a bundle of items and

services, and it does not protect ancillary items or services that are offered in connection with the bundled warranty that are less than fair-market value. The OIG also explicitly disagreed with a commenter asserting that medication adherence services can never constitute remuneration and thus never implicate the anti-kickback statute, and indicated that each arrangement involves a fact-dependent analysis. The OIG also dismissed as "outside the scope" of the rulemaking a commenter's suggestion that it establish a separate safe harbor protecting manufacturer-supported patient adherence programs.

Reimbursed By The Same Federal Health Care Program And In The Same Federal Health Care Program Payment. The warranty safe harbor is not intended to protect warranties involving more than one item purchased by multiple buyers across different care settings or reimbursed by different payment systems. The OIG states that it remains concerned about providing safe harbor protection to warranties containing separately reimbursable items, such as where a buyer purchases separately reimbursable items to acquire a warranty, and if only one product fails, the buyer could receive the cost of all items in the bundle. The OIG confirms that an arrangement involving a federally reimbursed drug product (e.g., Part D or Part B) in conjunction with a companion diagnostic payable under the clinical laboratory fee schedule would not be specifically protected by the warranty safe harbor because they are paid under different payments.

Capped Amount of Warranty Remedies. The warranty safe harbor will extend to remuneration for any medical, surgical, or hospital expense incurred by the beneficiary, but such remuneration is capped at the cost of the items and services subject to the warranty. The safe harbor could be used to protect reimbursement for hospital expenses incurred as a result of, for example, a bundle of items that failed to meet the clinical outcomes guaranteed by a warranty arrangement. The total warranty remuneration provided, however — including the cost of any replacement items — would be limited to the original cost of the items and services incurred by the buyer.

Reporting Requirements. The Final Rule clarifies that the warranty safe harbor can protect arrangements spanning multiple years and affirms that buyers are obligated to report price reductions in a manner compatible with the reimbursement methodology for the warrantied items or services including circumstances in which a provider does not submit cost reports or a formal "claim for payment," unless the payor does not provide a reporting mechanism. The safe harbor does not prescribe a specific methodology to allocate reporting across multiple items and services that are part of a bundled warranty, but OIG expects that in most cases a warranty remedy paid should be reported proportionately to the cost of each bundled item or service. The OIG recognizes there may be instances, however, where buyers adopt different but reasonable allocation methodologies to account for unique circumstances such as where the failure of a bundle to meet agreed specifications results disproportionately from the failure of a particular item or service.

XI. LOCAL TRANSPORTATION ("LOCAL TRANSPORTATION SAFE HARBOR")

Summary. The Final Rule finalizes an increase of the rural mileage limit for the local transportation safe harbor from 50 to 75 miles, and to remove any mileage limit for a patient transported from an inpatient facility from which the patient was discharged after admission (or was under observation status for at least 24 hours) as an inpatient to the patient's residence (including homeless shelter, nursing facility, etc.) or another residence of the patient's choice (e.g., caregiver's). The Final Rule declines to expand the local transportations safe harbor to protect patient transportation for nonmedical purposes. The Final Rule also confirms that the local transportation can be in the form of ride-sharing arrangements or through other means of local transportation that may "exist in the future (e.g., self-driving cars)."

XII. ACCOUNTABLE CARE ORGANIZATION BENEFICIARY INCENTIVE PROGRAM

Summary. The Final Rule finalizes the statutory exception to the definition of "remuneration" added by section 50341 of the Bipartisan Budget Act of 2018 for ACOs operating a CMS-approved beneficiary incentive program under the Medicare Shared Savings Program. The ACO may only furnish incentive payments to assigned beneficiaries.

XIII. EXCEPTION FOR TELEHEALTH TECHNOLOGIES FOR IN-HOME DIALYSIS

Summary. The Final Rule finalizes the statutory exception to the definition of "remuneration" under the beneficiary CMP as provided by the Bipartisan Budget Act of 2018 to protect the provision of telehealth technologies by a provider of services or renal dialysis facility to an individual for the purpose of furnishing telehealth services related to the individual's end-stage renal disease (ESRD). "Telehealth technologies" is defined to mean hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for the diagnosis, intervention, or ongoing care management. This could include technology ranging from audio/video equipment permitting two-way, real-time interactive communication with the patient to telephones, facsimile machines, and electronic mail systems. In other words, the definition of "telehealth technologies" is intended to be "technology agnostic" and more focused on the functionality of the technology to support telehealth. The Final Rule limits the exception to telehealth technologies furnished by a provider of services, physicians, or a renal dialysis facility currently providing in-home dialysis, telehealth services, or other ESRD care to the patients or has been selected or contacted by the patient to schedule an appointment or provide services. The telehealth technologies must not be offered as part of any advertisement or solicitation.