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HHS tackles barriers to value-based care: Part 1 – New protections for value-based arrangements under Stark and the AKS and other key AKS changes

October 28, 2019

Nearly a decade after the Affordable Care Act signaled a transition of the U.S. health care system to value-based care, the Department of Health and Human Services (HHS) published on October 9 two long-awaited proposed rules intended to "modernize and clarify" the physician self-referral law (Stark Law) and federal anti-kickback statute (AKS) to reduce regulatory burdens and accelerate the transition. These proposals – an AKS Proposed Rule issued by the HHS Office of Inspector General (OIG)[1] and a Stark Proposed Rule issued by the Centers for Medicare & Medicaid Services (CMS)[2] – follow and incorporate feedback from corresponding Requests for Information issued in summer 2018[3] as part of HHS's "Regulatory Sprint to Coordinated Care."

Part 1 of this client alert focuses on HHS's proposals to allow and encourage the shift toward **value-based payment** under both the AKS and Stark Law, as well as other **key AKS proposals**, including important changes to the warranty and personal services safe harbors. Part 2 will follow and will focus on important proposals to further update and amend the Stark Law regulations.

Overview

Both the AKS Proposed Rule and the Stark Proposed Rule include significant proposals related to value-based arrangements, including new AKS safe harbors and corresponding Stark exceptions for arrangements involving substantial or full downside financial risk, and a separate AKS care coordination arrangements safe harbor and Stark value-based arrangements exception that do

[1] HHS OIG, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (to be published Oct. 17, 2019), available at https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

[2] CMS, Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations (to be published Oct. 17, 2019), available at https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations

[3] *See* HL Client Alert, HHS watchdog eyes anti-kickback safe harbors for care coordination, beneficiary incentives, and cost-sharing (August 29, 2018), available at https://www.hoganlovells.com/~/media/hogan-lovells/pdf/2018/2018_aug_29_health_alert_hhs_watchdog_eyes_anti-kickback_safe_harbors.pdf

not require downside risk, but impose other more rigorous requirements as a result. Among the key takeaways from the lengthy and detailed proposals are –

- While HHS's rules would respond to the call for greater certainty that legitimate value-based arrangements would not risk running afoul of the health care fraud and abuse laws, that **certainty would come at the cost of substantially reduced flexibility**. Indeed, due to concerns about the need for safeguards against abusive arrangements, the proposed rules include numerous detailed requirements and call for a level of oversight and monitoring that many providers may find difficult to implement as a practical matter. The need for greater balance between flexibility and safeguards is likely to be a major theme of industry comments on the proposed rules.

- As has been widely reported, **HHS decided not to include safe harbor protection for value-based or outcomes-based contracting for the purchase of drugs**, which the administration indicated it was "working on" as a potential subject for future rulemaking. It's unclear whether that delay relates to the current politics around drug pricing or just to the difficulty of including everything in one rulemaking. But in the meantime, drug manufacturers, along with durable medical equipment (DME) manufacturers and clinical laboratories, would be explicitly excluded from participation in the proposed AKS safe harbors for value-based arrangements. Although non-DME device manufacturers would not be categorically excluded from the safe harbors, the proposed rules set up hurdles that often may be too high to qualify for protection, and OIG indicates that it is actively considering whether to exclude them as well.

Other key proposals in the AKS Proposed Rule apply beyond the context of value-based arrangements and would offer new flexibility to manufacturers and others, including a proposed expansion of the warranty safe harbor to cover a broader range of product and product-related guarantees, and proposed changes to the personal services safe harbor that would allow new flexibility in setting compensation for services.

Based on the expected dates of publication in the Federal Register, comments on both rules will be due by December 31, 2019.

New AKS and Stark protections for value-based arrangements – But not for everyone

OIG and CMS propose to establish new protections for value-based arrangements in the form of three new AKS safe harbors and three new Stark Law exceptions that would be broadly available to protect arrangements between hospitals, other health care providers or practitioners, and/or payors that qualify as Value-Based Enterprise (VBE) Participants. In contrast, the proposed exclusion of other health care entities from the AKS safe harbors and the rigorous requirements of those safe harbors are likely to limit the proposal's benefits for drug and device manufacturers and clinical laboratories, though the proposed rules do offer the chance for these entities to press for further changes in comments. In addition, the absence of safe harbor protection does not necessarily mean that an arrangement violates the AKS, and entities that may wish to seek an advisory opinion from OIG could find support for a value-based arrangement in various elements of the proposed safe harbors.

Who can participate in a protected "value-based enterprise"?

The AKS and Stark proposals both would define a VBE Participant as an individual or entity that engages in at least one value-based activity as a part of a value-based enterprise, but with significant exclusions under the AKS Proposed Rule.

- Specifically, OIG's VBE Participant definition would exclude pharmaceutical manufacturers, DMEPOS manufacturers, distributors, or suppliers, and laboratories – meaning these entities would not be protected under the value-based safe harbors. OIG expresses concern that these entities might misuse the proposed safe harbors "primarily as a means of offering remuneration to practitioners and patients to market their products."[4]

- For similar reasons, OIG is considering also excluding pharmacies, pharmacy benefit managers (PBMs), and wholesalers and distributors of pharmaceutical products from the definition of VBE Participant.

- OIG does not propose to categorically exclude non-DME device manufacturers from the definition of VBE Participant, but asks for comment on whether it should do so and how it should define which manufacturers would be excluded. OIG acknowledges that certain medical technologies provide services such as remote monitoring, predictive analytics, data analytics, care consultations, patient portals, and telehealth that may be used to coordinate and manage care. However, OIG expresses concern that permitting medical device manufacturers to act as VBE Participants could allow some manufacturers, particularly manufacturers of implantable devices, to disguise improper inducements to purchase the medical devices they manufacture as payments for care coordination.[5]

- OIG also seeks comment on an alternative approach – rather than excluding broad categories of entities, OIG suggests it could distinguish among entities that would be excluded from a safe harbor for value-based arrangements, based on factors like product type, company structure, heightened fraud risk, or other factors.[6]

- Note that any remuneration under protected value-based arrangements may not be funded by, and may not otherwise result from the contributions of, any individual or entity outside of the VBE. OIG explicitly states that this is to prevent entities outside the definition of a VBE – like drug manufacturers and labs – from indirectly gaining protection for arrangements that they cannot enter into directly.

The Stark Proposed Rule imposes none of these exclusions or limitations, although CMS requests comment on whether it should do so in order to align better with the AKS Proposed Rule. In any case, because the AKS poses an independent legal risk for value-based arrangements, the proposed rules will offer limited benefit to entities excluded from the AKS safe harbors if the current definition of VBE Participant is finalized.

Value-based arrangement requirements

The AKS and Stark proposals include a common set of requirements for a protectable value-based arrangement. A VBE would be defined as two or more participants collaborating to achieve at least one "value-based purpose" under a value-based arrangement. The VBE must have a governing document and an accountable body (such as a board of directors) or person responsible for financial and operational oversight of the enterprise.

The AKS Proposed Rule adds further requirements, similar to those in existing safe harbors, to address OIG's concern that protected arrangements are *bona fide*, do not shift costs, and do not result in stinting on care. For example, the value-based arrangement must be documented in a signed writing; must not reduce medically necessary care or unduly limit patient choice; and must not be tied to referrals or business outside the value-based arrangement. OIG requests

[4] AKS Proposed Rule at 54.
[5] *Id.* at 61-62.
[6] *Id.* at 66-67.

comment on whether the VBE should be required to have a compliance program and whether the accountable body should be independent of the VBE and have specific oversight responsibilities, such as oversight related to utilization of items and services, cost, quality of data, and other metrics.[7]

Beyond these base requirements, the proposed rules take a "tiered approach," with growing flexibility available to the parties as they assume more financial risk for the cost of care.

AKS – Care coordination arrangements safe harbor (42 C.F.R. § 1001.952(ee))

The first value-based AKS safe harbor would permit (i.e., not treat as remuneration) certain **in-kind** benefits that **promote care coordination and management**, such as the provision of care coordination personnel or technology for the exchange of patient data between VBE Participants. To be protected, the value-based arrangement would need to:

- Establish at least one specific, evidence-based outcome measure, which the parties reasonably anticipate will advance the coordination and management of care of a target patient population;
- Be commercially reasonable (which, for now, OIG does not propose to define);
- Involve in-kind benefits used primarily to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population;
- Require the recipient of in-kind benefits to cover at least 15% of the cost thereof, either in advance (for one-time costs) or at reasonable, regular intervals (for ongoing costs); and
- Be monitored and assessed on a regular basis for achieving progress towards its outcomes measures and terminated if the VBE's accountable body determines that the arrangement is failing to promote the value-based purpose or resulting in deficient quality of care.

AKS – Value-based arrangements with substantial downside financial risk (42 C.F.R. § 1001.952(ff))

The second value-based safe harbor would protect payments between a VBE and a VBE Participant where the VBE has assumed substantial downside risk from a payor for providing or arranging for items and services subject to the value-based arrangement.

- To be at "substantial downside financial risk," the VBE would need to agree to one of the following with the payor:
  - To take on at least 40% of shared losses;
  - To take on at least 20% of total losses for episodic or bundled payments;
  - To receive prospective, population-based payments; or
  - To receive a partial capitated payment reflecting a discount of at least 60% from expected fee-for-service payments.
- The safe harbor would protect remuneration between the VBE and a VBE Participant, but only if the VBE Participant **meaningfully shares** the VBE's substantial downside financial risk, meaning that the VBE Participant agrees:
  - To take on at least 8% of the amount for which the VBE as a whole is at risk;

[7] *Id.* at 40-41.

  - To be paid under a partial or full capitated payment methodology; or
  - For VBE Participants who are physicians, to meet the criteria for the new proposed Stark exception for value-based arrangements with meaningful downside financial risk to the physician (discussed below).

- As noted, the safe harbor protects only remuneration between the VBE and a VBE Participant, and not between two VBE Participants or any "downstream" non-participant entity. This means the only entities that can take advantage of this safe harbor are those that meet the definition of VBE Participant and are willing to contract with and accept risk from the VBE. One benefit to such VBE Participants is that they do not have the cost sharing requirements of the care coordination safe harbor.
- The remuneration also must be used primarily to engage in value-based activities and be directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population.

AKS – Value-based arrangements with full financial risk (42 C.F.R. § 1001.952(gg))

The third value-based safe harbor would protect payments between a VBE and a VBE Participant where the VBE has assumed full financial risk from a payor, documented in a signed writing with the payor that specifies the target patient population and contains terms committing the VBE to full financial risk for that population for at least one year. To qualify for protection under this proposed safe harbor, the VBE Participant would be precluded from claiming payment in any form directly or indirectly from a payor for items or services covered under the value-based arrangement, or otherwise shifting the costs of the full financial risk arrangement. The remuneration between the VBE and the VBE Participant is subject to similar limitations as the safe harbor for substantial downside financial risk, including that the remuneration must be used primarily to engage in value-based activities and must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population. Like managed care plans protected under the existing managed care safe harbor at 42 C.F.R. § 1001.952(u), a full-risk VBE must include an "operational utilization review program" and a quality assurance program protecting against underutilization.

Stark Law – Exceptions for value-based arrangements (42 C.F.R. § 411.357(aa))

In the Stark Proposed Rule, CMS also proposes to add three exceptions to protect arrangements between providers that are designed to promote better value and outcomes. Although the proposed Stark exceptions use some common terminology and bear some similarity to the proposed AKS safe harbors, entities that are subject to both the AKS and the Stark Law will need to carefully examine both sets of protections to fully assess and mitigate risk under each law. In some respects, OIG's proposals are more restrictive than CMS's, reflecting the view expressed in both proposed rules that the AKS acts as a "backstop" to protect against arrangements that may meet a Stark Law exception but nonetheless may be considered abusive.

All three proposed Stark exceptions would protect a wide variety of models. Each would apply to payments and in-kind assistance (e.g., infrastructure, administrative, or care coordination assistance). In addition, while a target patient population would need to be defined based on reasonable and legitimate parameters (not solely related to profit potential, for example), key to the proposed Stark exceptions is that they apply across payors. That is significant for providers looking to incorporate fee-for-service Medicare and Medicaid patients into a value-based arrangement, whether or not the provider is participating in the Medicare Shared Savings Program or other government initiatives that come with special fraud and abuse waivers.

Two of the value-based Stark exceptions turn principally on financial risk thresholds, but the third does not.

- The "full financial risk" exception (42 C.F.R. 411.357(aa)(1)) would protect remuneration for value-based activities related to the target patient population if the ***VBE*** is at "full financial risk" for each patient covered by the applicable payor in the population.

- The "meaningful downside financial risk" exception (42 C.F.R. 411.357(aa)(2)) would protect such remuneration if the ***physician*** is obligated to take on downside risk for 25% or more of the remuneration he or she receives, or if he or she is at full financial risk, e.g., is prospectively financially responsible for all items and services defined by the arrangement.

- The "value-based arrangements" exception (42 C.F.R. 411.357(aa)(3), and not to be confused with the same term that runs throughout the other two exceptions) does not require assumption of financial risk. Instead, this exception has additional requirements focused on the design of the value-based activities. In particular, documentation must include a description of how the activities are expected to further the value-based purposes of the VBE (which essentially includes improved quality, coordination/management of care, cost reduction, and transition to systems focused on those goals). In addition to other details, the formula or methodology for determining the remuneration must be specified, including any quality measures to be used – *although quality measures are not required*. Unlike the AKS safe harbor that is not tied to risk, the third Stark exception would not be limited to in-kind benefits, and would not require recipients of remuneration to share a particular percentage of the cost.

Essential to each of these proposed exceptions is the welcome lack of any requirement regarding fair market value, commercial reasonableness, or that remuneration not be determined in a manner that takes into account the volume or value of referrals. These conditions, common throughout most Stark Law exceptions, constitute the main barriers identified by providers as inhibiting a full transition to value-based payment arrangements with physicians.

Broader protection for participants in CMS value-based payment models (42 C.F.R. § 1001.952(ii))

Historically, participants in CMS-sponsored value-based models have had to rely on model-specific waivers of the AKS to protect arrangements that they enter into under the model. The AKS Proposed Rule offers a new overarching safe harbor for these models, which would permit:

- Remuneration between and among parties to arrangements under a model or other initiative being tested or expanded by the CMS Innovation Center or the Medicare Shared Savings Program; and

- Remuneration in the form of incentives and supports offered by participants in a CMS-sponsored model (or their agents) to patients covered by the model.

This safe harbor would not extend to commercial and private insurance arrangements that may operate alongside, but outside, a CMS-sponsored model. The ultimate impact of this new safe harbor may be muted because OIG proposes to give broad deference to CMS in deciding how the safe harbor applies to a particular CMS-sponsored model, including which entities and even which arrangements would be protected. This would seem to continue the status quo, where CMS has significant influence over how the AKS applies (or does not apply) to any given CMS-sponsored model.

Expansion of warranty safe harbor (42 C.F.R. § 1001.952(h))

The AKS Proposed Rule would expand the current warranty safe harbor to cover certain bundled warranties, but would continue to impose significant hurdles to protection for warranties in which manufacturers seek to take on more accountability for clinical outcomes related to their products. OIG's comments in the preamble suggest that the agency remains skeptical of broad manufacturer warranty arrangements, especially where the manufacturer would cover outcome-related costs beyond the specific items or services sold to the buyer.

Bundled warranties. OIG proposes to extend the safe harbor to warranties for a bundle of items and/or related services, as long as the bundled items and services are reimbursed under the same federal health care program and **in the same federal health care program payment**.

- As OIG notes, this would be a change from the agency's position in Advisory Opinion 18-10 that the warranty safe harbor does not protect bundled warranties.
- The requirement that bundled items and services be reimbursed under the same federal health care program payment would limit the impact of the proposal by withholding protection from warranties for items that are clinically related but happen to be reimbursed under different methodologies, or under different Diagnosis-Related Groups (DRGs) or Ambulatory Payment Classifications (APCs).
- In addition, the safe harbor would not protect manufacturer warranties of services alone without a related item.
- OIG suggests it may be open to allowing certain "population-based warranties" where the manufacturer's payment is not tied to a specific patient or payment; this may offer an opportunity for comment explaining the benefits of other, broader warranty arrangements, including requiring that the items and services be reimbursed according to the same payment methodology, if not necessarily the same payment.

Explicit protection for warranties of clinical outcomes. The safe harbor also would adopt a-specific definition of a "warranty" applicable to FDA-regulated drugs and devices and to include single-item and bundled warranties.

- The proposed definition is similar to the current referenced definition and would continue to protect (i) written affirmations of the quality or workmanship of a manufacturer's product (or services); (ii) a written "undertaking" to "refund, repair, replace, or take other remedial action" with respect to the manufacturer's product (and services) if it fails to meet the specifications set forth in the undertaking; and (iii) an agreement to replace another manufacturer's defective item.
- Although OIG seemingly had previously acknowledged[8] that the warranty safe harbor could protect guarantees of clinical outcomes in addition to product defects, the AKS Proposed Rule offers the clearest statement yet that the safe harbor protects "warranty arrangements conditioned on clinical outcome guarantees,"[9] if the other safe harbor conditions are met.

Limitations on protected warranties. The safe harbor would continue to impose strict requirements for protectable warranties, including new restrictions that would withhold protection from many warranty arrangements that manufacturers had hoped would be included.

[8] *E.g.*, OIG Advisory Opinions 17-03 and 18-10.
[9] AKS Proposed Rule at 299-300.

- The safe harbor would retain the current restriction that prohibits manufacturers from paying for any "medical, surgical, or hospital expense" outside the warranty (except beneficiary cost-sharing), with a minor change in wording to reflect that the warranty now may cover more than a single item.
    - A significant question has been whether OIG might revise the safe harbor to cover warranties that extend beyond the cost of items or services that are sold by the manufacturer and also guarantee payment of the costs of a related procedure (e.g., the surgery in which a device was implanted). The proposed rule continues to allow protection of warranties that cover only those items and services that are actually part of the manufacturer's sale.
    - While OIG clearly is trying to extend protection to warranties of clinical outcomes, this restriction suggests that OIG is not comfortable giving manufacturers additional flexibility in how to **remedy** unsatisfactory outcomes.
    - Given the importance of this question to many potentially beneficial warranty arrangements, manufacturers may wish to comment in support of a broader rule that also would cover the cost of related procedures.
- OIG also adopts a new restriction that the manufacturer may not condition the warranty on the buyer's exclusive use of the manufacturer's items or services or any minimum purchase requirement. This restriction could make otherwise protectable warranties economically infeasible, statistically invalid, or practically impossible, despite a manufacturer's legitimate intent to take on accountability for the performance or value of the product. Manufacturers may wish to comment to explain the legitimate need for minimum volume requirements to ensure that outcome measures are robust and reliable, much as CMS itself does for its quality measures.
- As noted above, if the warranty covers more than one item or service, the federally reimbursable items and services under the warranty must be reimbursed by the same federal health care program and in the same federal health care program payment.
- As under the current safe harbor, the buyer and seller must satisfy their obligations to report any price reduction offered under the warranty.

In sum, the AKS Proposed Rule takes a step toward updating and modernizing the warranty safe harbor, but the rule also would retain or add significant restrictions that likely will continue to be a barrier to broader manufacturer warranty arrangements.

New flexibility under the personal services safe harbor (42 C.F.R. § 1001.952(d))

OIG proposes changes to the existing safe harbor for personal services and management contracts to modernize the safe harbor and address barriers imposed by existing safe harbor requirements.

Relaxed requirements for personal service compensation

OIG proposes to eliminate two barriers that have long prevented health care companies from meeting the strict terms of the safe harbor:

- OIG would eliminate the requirement that the "aggregate compensation" under a personal services agreement be set in advance. Instead, OIG would require that the "methodology for determining the compensation" must be set in advance of the first payment. This change would allow safe harbor protection for many currently unprotected arrangements, such as a

service contract where the agent is paid a defined hourly rate but the number of hours to be worked is not set in advance.

- OIG also would eliminate the requirement that, if an agreement provides for the services of an agent on a periodic, sporadic or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals.

"Outcomes-based" compensation for personal services

OIG also proposes to create a new paragraph in the safe harbor to protect certain "outcomes-based" compensation for services. A protected "outcomes-based payment" would be a payment from a principal to an agent that:

- Rewards the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or

- Achieves one or more outcomes measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients.

OIG is considering whether it should further define specific types of payment arrangements that would qualify for this safe harbor in the final rule.[10] As with the proposed value-based safe harbors, OIG proposes to exclude payments made, directly or indirectly, by a pharmaceutical manufacturer; a DMEPOS manufacturer, distributor, or supplier; or a laboratory. OIG is also considering whether to exclude pharmacies, PBMs, wholesalers and distributors of pharmaceutical products, and whether to more specifically limit the protection of outcomes-based payment arrangements for personal services to VBE Participants.[11]

The proposed safe harbor for outcomes-based compensation includes traditional personal service contract requirements (e.g., compensation is based on a methodology set in advance, commercially reasonable, consistent with fair market value, and does not directly take into account the volume or value of business otherwise generated between the parties) along with additional "outcomes-based" requirements (e.g., the parties regularly monitor the agent's performance against the outcomes measures and periodically rebase the measures during the term of the agreement).

The personal services safe harbor as an alternative vehicle for protection of value-based arrangements

The AKS Proposed Rule also notes that OIG is considering whether to use the personal services safe harbor as an alternative to establishing specific safe harbors for value-based arrangements.[12] Under this alternative approach, OIG would create tiers of protection for value-based compensation under the personal services safe harbor. An entity would have to qualify for each tier, but once qualified, would receive incremental flexibility in structuring compensation arrangements:

- In the first tier, OIG would remove the requirement that aggregate compensation under service arrangements be set forth in advance, substituting a requirement that the methodology for determining the compensation be set in advance.

[10] AKS Proposed Rule at 272-274.
[11] *Id.* at 276.
[12] *Id.* at 117-120.

- In the second tier, for value-based arrangements that meet applicable requirements of the VBE framework discussed above, instead of three specific safe harbors, OIG would remove the requirement that aggregate compensation not be determined in a manner that takes into account the volume or value of referrals. OIG is also considering incorporating certain safeguards for this tier, such as the monitoring requirement and certain accountability and transparency requirements, from the proposed care coordination safe harbor.
- To qualify for the third tier, parties would have to meet the requirements of the VBE framework and assume substantial downside financial risk, and OIG would also remove the requirement that the aggregate compensation be consistent with fair market value in arm's-length transactions.

OIG solicits comments on certain variations to this model, as well as comments on operational challenges with implementation.

Cybersecurity and electronic health records

The AKS Proposed Rule and Stark Proposed Rule include parallel proposals to protect donations of cybersecurity technology and amend the existing AKS safe harbor and Stark exception for electronic health records (EHR) arrangements. The two agencies coordinated to promote consistency between the AKS safe harbors and the proposed Stark Law exceptions.

Cybersecurity technology and related services (42 C.F.R. § 1001.952(jj); 42 C.F.R. §411.357(bb))

OIG proposes a new AKS safe harbor, and CMS proposes a new Stark Law exception, to improve the "cybersecurity hygiene" of the health care industry by removing barriers to donations of cybersecurity technology and services, allowing "parties to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of health care." The safe harbor and exception would protect donations of software and other information technology, but not hardware – based on the rationale that donations of "valuable, multifunctional hardware" pose a higher risk of improper referrals than software. The safe harbor's requirements would include that the donated technology and/or services are "necessary and used predominantly" to promote cybersecurity; is not tied to other business by either the donor or the recipient; and is documented in a signed writing.

Electronic health records (42 C.F.R. § 1001.952(y); 42 C.F.R. § 411.357(w))

OIG and CMS each propose to update existing protections for EHR arrangements, notably by modifying the definitions of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act, updating provisions regarding interoperability, removing the sunset date to make the safe harbor permanent, and adding protections related to cybersecurity.

New safe harbor protections for certain benefits to patients

New safe harbor for in-kind patient tools and support services under a value-based arrangement (42 C.F.R. § 1001.952(hh))

OIG proposes to establish a new safe harbor that would allow VBE Participants to give certain in-kind patient tools and supports, such as preventive care items, health-related technology, patient health monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health. These tools and supports must be furnished directly by a VBE Participant to a patient in a target patient population and must be directly connected to the coordination and management of care.[13] The patient engagement tools and supports may not

[13] *Id.* at 150–51.

include gift cards, cash, or cash equivalents, and could not be used for patient recruitment or marketing. Remuneration would be subject to an annual aggregate limit of $500 in retail value, unless there is an individualized determination of patient financial need.

OIG requests comment on certain additional limitations, such as prohibiting tools that duplicate items the patient already has (e.g., a new cell phone or wireless service when a patient already has one and only needs an app),[14] prohibiting VBE participants from shifting the cost of the tool or support onto a federal health care program or others,[15] requiring VBE Participants to use reasonable efforts to monitor the effectiveness of a tool in achieving the intended care management goals,[16] and prohibiting any public advertisement of the tool or support to patients or to others who are potential referral sources.[17]

Expanded safe harbor for local transportation (42 C.F.R. § 1001.952(bb))

The AKS Proposed Rule would expand the existing safe harbor for local transportation to: (i) allow residents of rural areas to be transported within 75 miles (up from the current 50 mile limit); and (ii) remove any mileage limit on transportation of a patient when the patient is discharged from a facility to the patient's residence.[18] OIG also is considering extending protection to transportation for non-medical purposes (such as to food stores, social services facilities, and exercise facilities, among other things) and providing guidance that the local transportation safe harbor applies equally to ride-share services.

Codified safe harbor for the ACO Beneficiary Incentive Program (42 C.F.R. § 1001.952(kk))

The AKS Proposed Rule would codify the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.[19] The proposed regulatory language would be almost identical to the statutory language, but would clarify that an ACO may furnish incentive payments only to assigned beneficiaries.[20]

Amendment to the Beneficiary Inducement CMP to permit telehealth technologies for In-home dialysis patients

OIG proposes to codify a statutory exception to the Beneficiary Inducements Civil Monetary Penalty (CMP) enacted in the Bipartisan Balanced Budget Act of 2018 to permit an individual with End-Stage Renal Disease (ESRD) receiving home dialysis to elect to receive telehealth technologies. The proposed regulatory language is almost identical to the statutory language, but would (i) clarify that telehealth technologies must be furnished to the individual by the provider of services or the renal dialysis facility that is currently providing the in-home dialysis, telehealth visits, or other ESRD care to the patient, and (ii) add a new condition that a person must not shift the burden of the value of the telehealth technologies onto a federal health care program, other payors, or individuals.

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If you are interested in commenting or have questions about the proposed rules, please do not hesitate to contact the Hogan Lovells lawyer with whom you regularly work or any Hogan Lovells lawyer listed on this alert.

Thanks to Anneke Baran Altieri for assisting in the preparation of this alert.

[14] *Id.* at 158.
[15] *Id.* at 188.
[16] *Id.* at 190.
[17] *Id.* at 191.
[18] *Id.* at 300.
[19] *See* § 1128B(b)(3)(K) of the Social Security Act, as added by § 50341 of the Budget Act of 2018, Pub. L. 115-123, 132 Stat. 64.
[20] AKS Proposed Rule at 313.

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