Key Takeaways from OIG's AKS Sprint Proposed Rule

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In what some have called the most noteworthy regulatory development in a generation, the Department of Health and Human Services (HHS) issued proposed rules to amend the regulations for the federal physician self-referral statute (Stark law),[1] the federal Anti-Kickback Statute (AKS),[2] and the civil monetary penalty (CMP) statute[3] as part of the "Regulatory Sprint to Coordinated Care" (Sprint) initiative. HHS specifically identified the broad reach of these laws as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the federal health care programs and the commercial sector.[4] The Sprint's stated purpose is to reduce regulatory barriers and accelerate the transformation of the health care system into one that achieves the "Triple Aim" under the theory that paying for value will improve outcomes, lower costs or reduce growth in costs, and improve efficiencies in care delivery by promoting care coordination.[5]

The HHS Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS) have worked closely in developing proposals to advance the Sprint's purpose. This article focuses on the OIG's Proposed Rule. In summary, OIG proposes to establish new safe harbors or to modify existing safe harbors addressing the following:

- *Value-Based Arrangements*. Three proposed new safe harbors would protect certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordinated and managed patient care:
  - –Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (§ 1001.952(ee) ("No-Risk" Safe Harbor));
  - –Value-Based Arrangements With Substantial Downside Financial Risk (§ 1001.952(ff)); and
  - –Value-Based Arrangements With Full Financial Risk (§ 1001.952(gg)).
- *Patient Engagement*. A proposed new safe harbor (§ 1001.952(hh)) would protect certain tools and supports furnished by a value-based enterprise to patients to improve quality, health outcomes, and efficiency.
- *CMS-Sponsored Models*. A proposed new safe harbor (§ 1001.952(ii)) would protect certain remuneration provided in connection with a CMS-sponsored model (as defined in the Proposed Rule), which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.

- *Cybersecurity Technology and Services*. A proposed new safe harbor (§ 1001.952(jj)) would protect donations of cybersecurity technology and services.
- *Electronic Health Records Items and Services*. Proposed modifications to the existing safe harbor for electronic health records items and services (§ 1001.952(y)) would add protections for certain related cybersecurity technology, update provisions regarding interoperability, and remove the sunset date.
- *Outcomes-Based Payments and Part-Time Arrangements*. Proposed modifications to the existing safe harbor for personal services and management contracts (§ 1001.952(d)) would add flexibility for outcomes-based payments and part-time arrangements.
- *Warranties*. Proposed modifications to the existing safe harbor for warranties (§ 1001.952(g)) would revise the definition of "warranty" and provide protection for bundled warranties for one or more items and related services.
- *Local Transportation*. Proposed modifications to the existing safe harbor for local transportation (§ 1001.952(bb)) would expand the mileage limits for rural areas and eliminate mileage limits for transportation for patients discharged from inpatient facilities.
- *Accountable Care Organization (ACO) Beneficiary Incentive Programs*. A new safe harbor would codify the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).
- *Telehealth for In-Home Dialysis*. A proposed amendment to the definition of "remuneration" in the CMP rules at 42 C.F.R. § 1003.110 would interpret and incorporate a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients.

In examining the proposals, it becomes apparent that there is a genuine effort to attempt to balance the Sprint's ambitious goals with the existing statutory landscape and the government's traditional program integrity concerns. At times, there is considerable flexibility in the proposals, and at other times, the proposed requirements may create, in practice, new barriers to achieving the value-based goal. This article focuses on the most significant proposals.

New Value-Based Safe Harbors

OIG, similar to CMS, proposed three new safe harbors based on whether the "value-based enterprise" (VBE) assumed full, substantial downside, or no risk. In its Proposed Rule, OIG explained its proposed safe harbor requirements for value-based arrangements are intended to be more restrictive than CMS' comparable proposals, as OIG views the criminal, intent-based AKS to serve as a "backstop" protection for arrangements that might be protected by a less restrictive exception to the civil, strict liability Stark law.[6]

In its Proposed Rule, OIG explained its proposed safe harbor requirements for value-based arrangements are intended to be more restrictive than CMS' comparable proposals, as OIG views the criminal, intent-based AKS to serve as a "backstop" protection for arrangements that might be protected by a less restrictive exception to the civil, strict liability Stark law.

It is helpful that OIG and CMS adopted the same proposed terminology for the exceptions and safe harbors. As a threshold matter, arrangements are protected only if done under the auspices of a VBE, which is a collaboration among two or more VBE participants to achieve at least one "value-based purpose." The VBE must have an "accountable body or person" responsible for financial and operational oversight of the VBE, and a "governing document" that describes the VBE and how VBE participants intend to achieve the VBE's value-based purposes. While OIG enumerates four potential "value-based purposes," "coordinating and managing the care of a target patient population" acts as a "super purpose" that must be present to meet any of the safe harbors. OIG further defines "coordinating and managing care" to be "the deliberate organization of patient care activities and sharing of information between two or more VBE participants or 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 the target patient population."

The safe harbors vary by the types of remuneration protected (in-kind versus in-kind and monetary) and the types of safeguards included as safe harbor conditions. The safe harbors also follow a tiered structure; the safe harbors offer greater flexibility for value-based care arrangements where the parties assume more downside risk for the cost of care. The most flexible safe harbor is where the VBE is fully at risk for the cost of care for the target patient population. Less flexibility is available for VBEs that are at substantial downside financial risk (which is defined in four alternative ways[7]), with less flexibility still for VBEs that take on no risk. Chiefly among

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the no-risk restrictions is the requirement that the remuneration only be in-kind where monetary or in-kind remuneration is possible for the substantial or full risk safe harbors. Also, "no-risk" recipients must contribute at least 15% of the cost of the in-kind remuneration received.

Common requirements among all the safe harbors include that the remuneration is used primarily to engage in the value-based activities and is directly connected to one or more of the value-based purposes (at minimum the "super purpose"). Remuneration cannot induce the reduction or limitation of medically necessary services; take into account the volume or value of, or condition the remuneration on, referrals of patients not part of the target patient population or business not covered by the value-based arrangement; and cannot be funded by non-VBE participants. OIG expects the VBE to monitor the achievement of the value-based purposes and terminate the VBE if it is "unlikely" to achieve the desired outcomes or further coordination and management of care or has resulted in material quality deficiencies.

In an interesting twist, OIG also indicated it is considering abandoning this new safe harbor construct and instead making further changes to the personal services and management contracts safe harbor to cover value-based payments and arrangements among VBEs with varying levels of risk.[8] As OIG did not include proposed regulatory text for this concept, it is somewhat difficult to understand. The main problem that this approach would pose, which OIG acknowledges and seeks comments on, is that this safe harbor has a fair market value and volume/value requirements that would appear to conflict with certain VBE activities.

New Patient Engagement Safe Harbor

This proposed safe harbor may have the most potential to address longstanding problems with achieving the Triple Aim—enabling patient engagement by providing tools and support to achieve that engagement, including addressing the social determinants that impact outcomes. However, this safe harbor is limited to in-kind remuneration that (1) is furnished directly by a VBE participant to a patient in a target patient population, (2) is directly connected to the coordination and management of care, and (3) satisfies certain additional enumerated conditions. These conditions include a prohibition on providing cash, cash equivalents, or gift cards (although OIG is open to reconsidering this position based on comments) and an annual $500 retail value limit. The tool or support must be an in-kind "preventive care item or service" or one that is "designed to identify and address a patient's social determinants of health," including non-medical items that impact health, such as food, shelter, safety, clothing, income, and transportation. OIG specifically notes that it did not propose a specific definition of "preventive care item or service" to provide flexibility for VBE participants that seek to furnish preventive care items and services as a means to improve patient outcomes and better overall patient health.

We note that there is a curious discussion of who can provide the tool or support. The proposed regulatory text says that the tool or support must be provided "directly by the VBE participant" and, in the preamble, OIG solicits comments on whether it should expressly permit the VBE participant to furnish the tool through someone acting on its behalf and direction.[9] The example provided is of a physician practice VBE participant furnishing the tool through a physician practice member or employed nurse. Now, it is unclear how else a physician practice would provide a tool to a patient other than through a practice employee or physician, which is especially curious because the safe harbor also requires that the patient's treating health care provider recommend the tool. Also, it seems reasonable to assume that practices would likely need to hire outside assistance in managing these patient engagement programs, except the safe harbor does not appear to contemplate that need. We expect OIG will clarify this issue in the final rule.

Modified Personal Services and Management Contracts Safe Harbor

OIG proposes to modify the personal services and management contracts safe harbor to eliminate two requirements that have bedeviled health lawyers for many years—that aggregate compensation be set in advance and that part-time arrangements specify the exact schedule of services. Instead, the safe harbor would require that the methodology for an arrangement's compensation be set in advance of the initial payment. This modification would more closely align this safe harbor with the personal service arrangements exception to the physician self-referral law and enable many non-risky independent contractor arrangements to qualify for safe harbor protection.

In addition, OIG proposes creating an Outcomes-Based Payment Arrangements safe harbor within the personal services and management safe harbor for outcomes-based payment arrangements that meet certain conditions. Under this proposal, qualifying outcomes-based payments could be

made between parties that were collaborating to measurably improve quality of patient care, appropriately or materially reduce costs while maintaining quality, or both. OIG proposes to define "outcomes-based payment" as payments from a principal to an agent that: (1) reward 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 (2) achieve one or more outcome measures that appropriately reduce payer costs while improving, or maintaining the improved, quality of care for patients. Internal cost savings alone would not qualify for protection. OIG maintains a requirement that the methodology for the payment is set in advance, commercially reasonable, consistent with fair market value, and not determined in a manner that directly takes into account the volume or value of referrals or other business generated for which payment may be made by a federal health care program. OIG also requires the parties regularly monitor and assess the agent's performance, including the impact of the arrangement on quality of care and periodically rebase the measures during the term.

New Cybersecurity Safe Harbor and Revised EHR Safe Harbor

OIG also proposes to create a new safe harbor to allow for the donation of certain cybersecurity technology and related services and to modify the existing safe harbor protecting certain EHR donations. In proposing to protect cybersecurity donations, OIG appears to be responding to both the concerns raised by HHS' Health Care Industry Cybersecurity Task Force and the practical reality that in an interconnected system, a weakness at one point can pose a risk for the system as a whole. In truth, this proposed safe harbor seems to reflect an appreciation for the reality that our current health care system increasingly relies on technology and data exchange and that cybersecurity threats pose a significant risk.

Proposed modification to the existing EHR safe harbor would remove the threat of a sunset date, and potentially remove the current 15% cost contribution requirement. Among other things, OIG is also considering protecting donations of replacement technology, which does not fit within the EHR safe harbor as currently constructed. Like other OIG proposals, a number of alternatives appear to be under consideration. While the multitude of alternatives make it challenging to glean what it is, exactly, that OIG is contemplating for a final rule, if OIG finalizes the most lenient proposals, it could make the EHR safe harbor significantly less burdensome for those seeking to make protected donations.

Key Takeaways

Becoming a VBE May Not Be for Everyone

The good news for existing ACOs and clinically integrated networks (CINs) is that they likely qualify as a VBE without additional action. For everyone else, deciding to enter into a VBE with other, independent providers may pose some practical challenges. Someone will need to be the accountable person who is responsible for oversight of the VBE's participants' activities and compliance. That responsibility may create some fiduciary duty conflicts since the "accountable person or entity" will need to switch between their VBE hat and their employer's hat, including monitoring their employer's compliance as a VBE participant. Combined with the governing document requirement, as a practical matter, it may be difficult to qualify and function as a VBE without creating a new organizational structure, which would appear to increase burden, rather than achieve the Sprint's stated goal of reducing it.

The provider community also should comment on OIG's consideration of precluding or limiting VBE safe harbor protection for arrangements between entities under common ownership. Coordination of care is one of the very reasons for establishing health systems (wholly owned entities) and joint ventures (affiliated entities). Precluding participation in VBEs would appear counterproductive to the purpose of the Sprint rulemaking.

Are Better Outcomes Forever Achievable?

The definition of coordinating and managing care as drafted could be read to require continuous improvements to the health outcomes of the target patient population. The cost requirement is phrased as both reducing costs or growth in costs, acknowledging either is beneficial. The amendments to the personal services and management contracts safe harbor to capture outcomes-based payments include both improved quality or maintaining such improved quality, so it is unclear whether omitting maintaining improved outcomes was deliberate or an oversight. Eventually, assuming the VBE does its job and improves outcomes for the target population, there may be a plateau on further improvement. Said another way, achieving a further incremental "improved outcome" may either be prohibitively expensive or may be clinically infeasible with the current state of medicine.

Also, OIG should consider providing more flexible guidance on the measurement of metrics and outcomes to encourage VBE participation. Despite hard work and best intentions, it is possible some metrics may be met in some years and not in others. There would seem to be a need for OIG to acknowledge this situation and permit revision of the outcomes goals in light of experiential clinical data.

Independent Providers Assuming Full or Substantial Risk Seems Unlikely

It is unclear how many providers will use the VBE vehicle to take on full or substantial risk. Often, physicians look for some safeguards against unlimited downside risk in existing arrangements, and one would expect that viewpoint to continue. An alternative approach could be to have the physicians forfeit any payment if the VBE does not meet certain outcomes; but requiring physicians to pay into the VBE seems unlikely to be

widely adopted. Also, state insurance laws generally prohibit entities from accepting full risk unless they are licensed as an insurer or are in a downstream arrangement with a plan (such as an ACO or CIN). Therefore, a plan would be involved in the arrangement and the parties could avail themselves of the existing risk-sharing safe harbor for those payments, so one would not need to rely on the VBE safe harbors.

The Facts and Circumstances Analysis Will Continue to Dominate

The value-based and patient engagement safe harbors are complex and contain several subjective terms that require interpretation. For example, the value-based safe harbor requires specific, evidence-based, valid outcome measures that the parties "reasonably anticipate" will "advance" the coordination and management of care of the target patient population, and the value-based arrangement must have a "direct connection" to such care. The outcomes-based safe harbor requires payments be associated with a collaboration to "measurably improve" quality, "appropriately and materially" reduce costs or growth, and be fair market value (anticipating that the valuation industry will "evolve" to develop currently non-existent models for valuing these payments). It seems likely we will be in the situation of making judgments about whether these subjective elements have been satisfied and, as a practical matter, in many instances resorting to the traditional facts and circumstances analysis. The amount of subjectivity also may dampen providers' willingness to assume the potential liability risk and engage in a VBE.

Exclusion of Some Industries from the Value-Based Safe Harbors Could Inhibit Achievement of the Triple Aim

OIG proposed excluding pharmaceutical manufacturers; manufacturers, distributors, and suppliers of Durable Medical Equipment, Prosthetics, Orthotics, & Supplies; and laboratories from all the proposed additions and changes discussed above related to the value-based and patient engagement safe harbors. Because these types of entities are largely dependent upon practitioner prescriptions, and based on its enforcement experience, OIG expressed a concern that these entities might use outcomes-based payments primarily to market their products to providers and patients. OIG is also considering excluding pharmacies (including compounding pharmacies), device manufacturers, certain health technology companies, pharmacy benefit managers (PBMs), wholesalers, and distributors from the value-based safe harbors.

While OIG may be skeptical of these industries' participation, a wholesale prohibition on participation may be go farther than necessary to mitigate the risk of fraud and abuse. At the outset, we should acknowledge the extraordinary nature of these proposed safe harbors. They provide immunity for arrangements and models that may not even exist today. That said, it is also true that manufacturers and technology companies are well-positioned to legitimately assist in achieving the Tripe Aim. These companies have the resources and expertise

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to develop tools that engage patients and structure programs providers can use to coordinate and manage care, improve outcomes or maintain outcome achievement, and reduce costs or growth in costs. With sufficient, reasonable safeguards built into the safe harbors, it would seem these organizations could safely participate in value-based arrangements or patient engagement programs that are under the direction of a VBE.

Gainsharing Arrangements Could Proliferate

OIG's proposals would protect shared savings payments, gainsharing, and other pay-for-performance arrangements. The most important restriction is that the payments cannot be based solely on internal cost savings, similar to the VBE safe harbors. However, it should be relatively easy for health systems to identify outcome or quality improvements or payer cost savings measurements that also would have an internal cost reduction result. With some adjustments to current practices, this type of payment could become a regular feature of physician compensation in the future. The challenge will be determining fair market value for the outcomes-based arrangements that do not involve services but only involve "collaboration" of the parties.[10] Relatedly, if the arrangement is actually a services arrangement, then it would seem that one could use the first prong of the existing safe harbor and not use the more complicated and burdensome outcomes-based prong.

The "No-Risk" Safe Harbor Should Permit Expense Reimbursement and Remove the Contribution Requirement

The No-Risk Safe Harbor should permit reimbursement of specific expenses instead of requiring the actual provision of the in-kind remuneration. The entity that provides remuneration (e.g., provision of software, care coordination services) may prefer that the recipient hold the contract with the entity providing the service for liability and other reasons that do not implicate the AKS. Requiring that the entity actually provide the in-kind remuneration may create unnecessary obstacles and complications that could be avoided. Also, the 15% contribution requirement poses some practical obstacles. For example, if a health system wants to provide VBE participants free access to a proprietary data analytics system that the health system built,

what is the "cost" of this system to calculate the 15% contribution? Arguably, the cost is zero because the health system already incurred the costs and providing access to more users may not result in additional costs. It is unclear how OIG would view this situation in relation to the contribution requirement.

Patient Engagement May Include Technology, with Further Clarification

The patient engagement safe harbor goes a long way towards enabling the provider community (albeit through a VBE) to provide the tools and support to patients that will engage them in their care and drive outcome improvement and cost reduction. What remains unclear is whether OIG's historical concerns persist with any capabilities that technology, such as smartphones or watches, could have outside of the medical purpose for which the device is provided to the patient. Advisory Opinion 19-02 approved an arrangement where the smartphone only could make local calls in addition to monitor the device in the patient.[11] Arguably, this type of restriction does not foster true patient engagement with the technology to reap all the potential benefits. If this historical concern persists, it could limit the effectiveness of these patient engagement programs.

Concerns with Marketing and Patient Recruitment Remain

OIG has longstanding concerns with activities that involve marketing to patients and patient recruitment, so it is not surprising to see these restrictions appear in the value-based and patient engagement proposal.[12] However, there is a tension between these restrictions and the ability to effectively communicate with patients in the "target patient population" about the VBE's activities to manage their care. It is not entirely clear why the VBE participants should not be able to tell patients who are in the target patient population (but may not know it) about the benefits of the approach to coordinated care the VBE participants take so the patient has information that may be relevant for making an informed decision about where to obtain care.

Local Transportation and Warranty Changes Should Alleviate Compliance Concerns Outside of the VBE Context

Not all of OIG's Proposed Rule is focused on VBE arrangements. Two of the more significant proposals include the local transportation and warranties safe harbors. For local transportation, OIG would increase mileage protected for rural patients to 75 miles and would have no distance limit for patients being discharged from an inpatient facility and transported home. This change would enable hospitals to ensure the safe and timely discharge of patients for whom transportation may be difficult to obtain. For warranties, OIG would permit bundled warranties for one or more items and related services, remove the confusing beneficiary reporting requirement, and redefine warranty to cover any written affirmation, promise, or undertaking in connection with the sale of an item or bundles of items and services, to refund, replace, or take other remedial action. These changes update the warranty safe harbor to better reflect current legitimate business practices.

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Endnotes

1 42 U.S.C. § 1395nn; 42 C.F.R. § 411.350 *et seq.*
2 42 U.S.C. § 1320a-7b(b); 42 C.F.R. § 1001.952.
3 42 U.S.C. § 1320a-7a(a)(5); 42 C.F.R. § 1003.110 *et seq.*
4 *See* 84 Fed. Reg. 55694, 55695 (Oct. 17, 2019) (Proposed Rule); 84 Fed. Reg. 55766, 55767 (Oct. 17, 2019).
5 *See id.*
6 *See* 84 Fed. Reg. 55694, 55696.
7 42 C.F.R. § 1001.952(ff)(8)(i).
8 *See* 84 Fed. Reg. at 55715-55716.
9 84 Fed. Reg. at 55726.
10 *See* 84 Fed. Reg. At 55746.
11 *See* https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-02.pdf.
12 *See* 84 Fed. Reg. At 55712, 55730.