EPSTEIN BECKER GREEN | Health Care & Life Sciences

CLIENT ALERT

HHS's Regulatory Sprint to Coordinated Care

Part 2: OIG Issues Long-Awaited Proposed Rules

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This Client Alert serves as the second in a three-part series in which we describe and analyze the rules proposed by the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") as part of its "Regulatory Sprint to Coordinated Care."

On October 17, 2019, OIG and the Centers for Medicare & Medicaid Services ("CMS") published in the *Federal Register* companion proposed rules that present significant changes to the regulatory framework of the federal health care program's Anti-Kickback Statute ("AKS"), the civil monetary penalties ("CMP") law, and the federal physician self-referral law (commonly referred to as the "Stark Law"). Unless an extension is granted, public comments must be delivered to the agencies by 5 p.m. (EST) on December 31, 2019.

Part 1 of this three-part series provided background on the proposed rules.[1] This Part 2 focuses on OIG's proposed new and modified safe harbors to the AKS and exceptions to the CMP law.[2] In addition to providing summaries of the important aspects of these

[1] The full text of Part 1 of this series is available at https://www.ebglaw.com/news/hhss-regulatory-sprint-to-coordinated-care-part-1-cms-and-oig-issue-long-awaited-proposed-rules/.

[2] *See* 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," 84 FR 55694 (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.

proposed regulations, we suggest areas and topics on which we believe the public should consider submitting comments. In fact, OIG introduced the proposed safe harbors by acknowledging the challenges it faces in designing safe harbor protections for emerging health care arrangements of unknown design and unproven efficacy. OIG's struggle to provide the flexibility necessary to allow for beneficial innovation while including adequate safeguards to protect patients and federal health care programs is evident through the number of alternative proposals set forth in the *Federal Register* and the more than 200 solicitations for comment, feedback, and examples included throughout the preamble.

Although we have identified many positive aspects of OIG's proposed rule, considerable segments of the industry may be unsatisfied with positions taken by OIG. For example, OIG proposes to exclude various members of the health care and life sciences industry from many of these proposed safe harbors. OIG has proposed to exclude (or is considering excluding) the following: pharmaceutical manufacturers; medical device manufacturers; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, or supplies ("DMEPOS"); clinical and anatomical laboratories; and pharmacies and pharmacy benefit managers. OIG solicits comments on these proposed and potential exclusions.

One issue we believe the proposed rule does not include is a stand-alone safe harbor for what have been traditionally referred to as "gainsharing" arrangements, in which a health care entity and a group of physicians might collaborate to achieve internal cost savings while ensuring that such savings do not result in patient harm. Although OIG proposes to protect certain gainsharing arrangements, arrangements that relate solely to the achievement of internal cost savings for a particular entity would not be protected as part of these proposed rules.

An overarching issue addressed in both OIG's proposed rule and CMS's proposed rule under the Stark Law (which will be addressed in Part 3 of this three-part series) is the interrelationship between the AKS safe harbors and Stark Law exceptions. Both HHS agencies have developed their own respective rules in connection with the Regulatory Sprint, and both agencies acknowledge that, where appropriate, they try to propose consistent definitions and requirements. On this issue, OIG states in its preamble how the two agencies are attempting to work in concert to create some level of consistency while also acknowledging the differences between the laws:

> In many respects, OIG's proposed rules for value-based arrangements are different or more restrictive than CMS's comparable proposals, in recognition of the difference in statutory structures and penalties. For some arrangements, we believe it is appropriate for the [AKS], which is a criminal, intent-based statute, to serve as a "backstop" protection for arrangements that might be protective by a less restrictive exception to the civil, strict liability [Stark Law]. For any final rule, we would examine our rules in combination with any rules CMS may choose to finalize with the goal of creating an overall regulatory landscape that is well coordinated and serves the intended purpose to allow for beneficial innovation; that is as

> streamlined as possible, consistent with program integrity considerations; and that provides strong protections for patients and programs, both in terms of promoting value and ensuring that the Government can take action to protect patients and address fraud and abuse.

Another overarching issue in OIG's proposed rule is language in the preamble in which OIG stresses that it is publishing only proposed rules and that "**no final determination has been made that the arrangements described in the proposals are, or should be, exempt from liability under the [AKS]**" (emphasis in the original). OIG also states in the preamble that any final safe harbors would provide only prospective protection, as opposed to retrospective protection. Even though OIG's position is understandable, given past experience with the amount of time between a regulation being proposed and when it is finalized, entities are still left questioning whether certain arrangements can be entered into while awaiting the issuance of these final regulations. Moreover, although these new safe harbors would be in addition to currently existing safe harbors that entities could continue to look to for protection, this position could impede current development of value-based care arrangements while the health care community awaits final rules—which is exactly the opposite of the objective of the Regulatory Sprint.

Proposed Value-Based Safe Harbors

OIG's proposed suite of value-based safe harbors are intended to support a more rapid transition from volume to value-based care and to provide greater flexibility to parties as they assume greater downside financial risk. In developing these new safe harbors, OIG proposes definitions for the following key terms:

- **"Value-based enterprise"** ("VBE") would mean two or more participants of a value-based arrangement that are collaborating to achieve at least one value-based purpose. The VBE would also be required to have an accountable body and a governing document.

- **"Value-based arrangement"** would mean an arrangement to provide at least one "value-based activity" for a target patient population.

- **"Target patient population"** would be defined as a patient population selected by the VBE or VBE participants using legitimate and verifiable criteria. Significantly, as currently defined, this term is not limited to federal health care program beneficiaries. OIG also specifically requested public comment on whether the definition should be limited to applying only to patients with chronic conditions or a shared disease state.

- **"Value-based activity"** would be defined as those activities of providing an item or service, or taking or refraining from taking an action, that is reasonably designed to achieve one of the VBE's value-based purposes. OIG notes in the preamble that under no circumstance would simply making a referral constitute a value-based activity. OIG proposes excluding from the definition any activity that results in

"information blocking," which OIG describes, by way of example, as the donation of health information technology that prevents or unreasonably interferes with the exchange of electronic health information with other providers in order to "lock in referrals." The issue of "information blocking" is discussed in more detail below under the new cybersecurity and proposed updated electronic health records ("EHR") safe harbors.

- **"VBE participant"** is defined as an individual or entity that engages in at least one value-based activity as part of a VBE. At present, this term expressly excludes pharmaceutical manufacturers; DMEPOS manufacturers, distributors, and suppliers; and laboratories. OIG seeks comments on whether it should exclude these entities as well as pharmacies and pharmacy benefit managers. OIG also expresses concern that some medical device manufacturers might misuse value-based arrangements to disguise improper payments and states that it is considering excluding some or all device manufacturers from what constitutes an eligible VBE participant.

- **"Value-based purpose"** would mean coordinating and managing the care of a target patient population, improving the quality of care for a target patient population, reducing costs without compromising quality, or transitioning from health care delivery mechanisms based on volume to mechanisms based on value.

Care Coordination Safe Harbor

The first new safe harbor OIG proposes is the "care coordination arrangements to improve quality, health outcomes, and efficiency" safe harbor (the "Care Coordination" safe harbor). Any person or entity could use this safe harbor to promote value-based care and facilitate care coordination, even when assuming no downside financial risk.

Under the proposed Care Coordination safe harbor, VBE participants could exchange in-kind remuneration pursuant to a value-based arrangement. Among the safe harbor's other requirements, the participants to the arrangement must establish 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. This safe harbor would protect only in-kind, non-monetary remuneration, such as the provision of a care coordinator, and the party receiving the remuneration must reimburse the offeror for at least 15 percent of its costs. (But see the below description of proposed modifications to the personal services and management contracts safe harbor that would add protection for certain outcomes-based payment arrangements offering protection beyond in-kind remuneration.) The remuneration could not be funded by any individual or entity outside of the VBE, and the value-based arrangement must be commercially reasonable and not take into account the volume or value of referrals outside of the arrangement. The proposed safe harbor includes monitoring and assessment requirements, and the parties must terminate the arrangement if it is determined that it resulted in material deficiencies

in the quality of care or is unlikely to further the coordination and management of care for the target patient population.

OIG includes a detailed discussion of each of the Care Coordination safe harbor's requirements in the preamble. In particular, OIG discusses at great length the outcome measures requirement (which it notes should not simply reflect the status quo); the recipient contribution requirement (which it acknowledges could impose a significant financial burden on certain recipients); and the monitoring and assessment requirement (through which it seeks to ensure that the VBE's accountable body will periodically assess the parties' performance of key metrics under each value-based arrangement). OIG also discusses additional safeguards it is considering for the Care Coordination safe harbor, such as imposing a fair market value requirement on any remuneration exchanged and prohibiting VBE participants from determining the amount or nature of remuneration, or to whom they offer it, in a manner that takes into account the volume or value of other business generated. OIG also is considering possible additional requirements specific to dialysis providers.

This proposed safe harbor is worthy of public comment, with respect to the 15 percent requirement (which derives from the EHR safe harbor, is currently a significant impediment to the adoption of EHR by small physician organizations and organizations serving the underserved, and, as described below, is under consideration for modification) as well as OIG's considering the adoption of additional limitations regarding fair market value and that the remuneration not take into account volume or value of business generated, which would seriously constrain care coordination efforts.

Of particular note is OIG's proposed alternative regulatory structure under which it would rely solely on the personal services and management contracts safe harbor at 42 C.F.R. § 1001.952(d) as a platform to create tiered protection for value-based arrangements. This proposal would be in lieu of finalizing the safe harbors that would protect entities not at full financial risk. This proposal is deserving of public comment, taking into consideration OIG's proposed modifications to the personal services and management contracts safe harbor (described below) that would (1) eliminate some of the very exacting requirements that have long made that safe harbor extraordinarily difficult to achieve and largely out of reach for most arrangements, and (2) protect certain outcomes-based payment arrangements.

Value-Based Arrangements with Substantial Downside Financial Risk

The second of the proposed value-based safe harbors is the "value-based arrangements with substantial downside financial risk" safe harbor (the "Substantial Financial Risk" safe harbor). This safe harbor would protect both cash payments and in-kind remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement in cases where the VBE has assumed "substantial downside financial risk," and the VBE participant "meaningfully shares" in the VBE's substantial downside financial risk.

OIG proposes to define the term "substantial downside financial risk" by reference to four specific methodologies:

i. Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures or to the extent such that is unavailable, evidence-based comparable expenditures;

ii. A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures or to the extent such that is unavailable, evidence-based comparable expenditures;

iii. A prospectively paid population based payment for a defined subset of the total cost of care of a target patient population where such payment is determined based upon a review of historical expenditures or to the extent such that is unavailable, evidence-based comparable expenditures; or

iv. A partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments based on historical expenditures or to the extent that is unavailable, evidence-based comparable expenditures of the VBE participants to the value-based arrangements.

OIG requests public comments on the above definition of "substantial downside financial risk" and whether the benchmarks should be higher or lower, whether there are other methodologies that should be considered, and the appropriateness of the proposed benchmarks. We note that this OIG definition of "substantial downside financial risk" is very different from, and far more stringent than, CMS's physician self-referral definition of the same term, which we will address in Part 3 of this three-part series.

As proposed, this safe harbor would apply only to the exchange of remuneration between VBEs that have assumed substantial downside financial risk and VBE participants that meaningfully share in that risk. Downstream arrangements among VBE participants would not be protected; VBE participants would then need to look to the Care Coordination safe harbor for protection, which, as described above, is limited to in-kind remuneration.

We believe that the OIG's substantial limitations with respect to these defined terms and its failure to propose protection for downstream arrangements will result in the vast majority of individuals and entities wishing to engage in value-based arrangements likely finding this proposed safe harbor to be of limited utility. Therefore, we suggest that the public consider submitting comments on the potential limited benefits of OIG's proposal for this safe harbor.

Value-Based Arrangements with Full Downside Financial Risk

The third proposed value-based safe harbor is the "value-based arrangements with full financial risk" safe harbor (the "Full Financial Risk" safe harbor). This safe harbor would protect both cash payments and in-kind remuneration exchanged between a VBE and a VBE participant in cases in which the VBE has assumed "full financial risk," which OIG proposes to mean that the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the payor. OIG notes that a VBE would be at full financial risk if it received a prospective, capitated payment for all Medicare Part A and B services for a target patient population. A contract with a Medicaid managed care organization to receive a fixed per-patient-per-month amount also would qualify as full financial risk if the fixed amount covered the cost of all Medicaid-covered items and services furnished to the target patient population. Significantly, partial capitation arrangements, including bundled payment programs, would not qualify as full financial risk.

While the Full Financial Risk safe harbor's requirements are less onerous than the requirements of the Care Coordination and Substantial Financial Risk safe harbors, this safe harbor, like the others, is likely to be of limited utility because it applies only to remuneration exchanged between a VBE at full financial risk and a VBE participant pursuant to a value-based arrangement. In other words, this safe harbor would not protect remuneration exchanged between or among VBE participants that are part of the same VBE, or remuneration exchanged between a VBE participant and a downstream contractor.

Patient Engagement and Support Safe Harbor

In an effort to promote patient engagement tools that encourage adherence to care protocols, OIG proposes a new "patient engagement and support" safe harbor (the "Patient Engagement" safe harbor). Under this proposed safe harbor, a VBE participant could provide an in-kind preventive item or/and service directly to a patient in a target patient population to advance a treatment or drug regimen, promote adherence to a follow-up care plan, manage a disease or condition, improve health outcomes, or ensure patient safety. The safe harbor would impose a $500 annual aggregate cap on the value of items and services provided (except where the engagement tools and supports are furnished to patients based on a good faith, individualized determination of the patient's financial need), and would impose a condition that the offeror of the item or service does not know (and should not know) that it is likely to be diverted, sold, or utilized by the patient for a purpose other than for which it is provided.

As currently proposed, this safe harbor would be available only to VBE participants who, under the proposed rule, would exclude pharmaceutical manufacturers, pharmaceutical distributors, DMEPOS suppliers, and laboratories. In addition, stakeholders that participate in CMS model arrangements, like Innovator or Next-Gen Accountable Care Organizations ("ACOs"), may find that the safe harbor's limitation to VBEs fails to provide

much beyond existing fraud and abuse waivers (although it would extend those protections beyond the scope of those programs, if applicable).

The proposed safe harbor also requires a "direct connection" between the item, good, or service being offered and the coordination and management of patient care. OIG views a "direct connection" to mean "a good-faith expectation that the tool or support will further the VBE's coordination and management of care for the patient." Although the proposal attempts to tie the incentive to a particular health outcome, it also attempts to prohibit "extravagant" tools or supports merely for the purpose of steering patients. Therefore, OIG seeks comments on whether it should increase the safe harbor's threshold by requiring VBEs to make a *bona fide* determination of a direct connection, or whether it should, alternatively, decrease the criteria to require just a "reasonable connection."

OIG seeks comments on all of the requirements, including (1) whether it should expand the proposed safe harbor to entities beyond value-based enterprises, (2) whether it should extend the safe harbor to all patients (rather than to just a "target patient population"), and (3) the proposed monetary cap.

In the proposed rule, OIG does not define the phrase "preventive care item or service" in order to ensure that the definition remains flexible to encompass rapidly advancing technology. At the same time, OIG names smart watches and other "wearable" monitoring devices as examples of what might be protected under the proposed safe harbor. OIG requests public comments on whether the safe harbor should require that the item or service not be duplicative of a tool or service the patient already has. Stakeholders interested in this safe harbor may wish to comment on this point as such a requirement seems unnecessary in light of the proposed requirement pertaining to the sale or diversion of the item or service. Moreover, this type of requirement would prove difficult to operationalize, requiring a level of inquiry that is not practical. Indeed, just because a patient has a similar tool does not mean that the tool has the necessary connectivity to accomplish the parties' care objectives.

Commenters and stakeholders that supported the inclusion of cash incentives when commenting on the initial Request for Information ("RFI") may be disappointed to learn that cash and cash-equivalents are not covered by the proposed Patient Engagement safe harbor. While OIG acknowledged that a number of studies support the position that cash incentives improve patients' adherence to treatment plans and participation in care, OIG reverted to its historical "significant concerns" that cash incentives create risks related to identity theft, promote inappropriate utilization, and may lead to inappropriate patient steering. OIG requests comment on this issue, and explains criteria it would consider implementing should it expand this proposed safe harbor to include cash and cash-equivalent incentives.

OIG solicits comments on the following additional criteria in the proposed Patient Engagement safe harbor:

- prohibiting the VBE participant from billing federal health care programs, other payors, or individuals for the tool or support, writing off the tool/support as bad debt, or otherwise shifting the cost of the tool/support;

- requiring that the tool/support be offered to either the entire target patient population, or having a uniform criteria for offering it to a specific subset;

- requiring that the VBE participant use reasonable efforts to monitor the effectiveness of the tool/support in achieving its intended purpose;

- requiring that the VBE participant use reasonable efforts to retrieve the item or good furnished in certain circumstances, such as the recipient leaving the target patient population; and

- prohibiting publicly advertising the tool/support.

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

Recognizing the need for uniformity and predictability for parties participating in a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Social Security Act ("the Act") and the Medicare Shared Savings Program under section 1899 of the Act (collectively, "CMS-sponsored models"), OIG proposes a new safe harbor to permit remuneration (1) between and among parties to the arrangements and (2) in the form of incentive and supports provided by a CMS model participant and their agents to covered patients. OIG states that the objective of this proposed safe harbor is to "standardize and simplify" AKS compliance for CMS-sponsored model participants by applying uniform conditions across all models and initiatives sponsored by CMS. As such, OIG seeks comments on whether the proposed safe harbor should be expanded to include remuneration between and among parties to arrangements under CMS initiatives that are not authorized by 1115A and 1899 of the Act.

Under the proposed rule, if CMS has determined that the safe harbor is available to the particular model, "remuneration" will not include any exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement if, among other criteria, the arrangement will advance the goals of the CMS-sponsored model and the remuneration is not made to induce medically unnecessary items or services or reduce or limit medically necessary items or services or to induce or reward federal health care program referrals. In addition, OIG is proposing protection for patient incentives, if among other things, the incentive will advance one or more goals of the CMS-sponsored model and the incentive has a direct connection, from both a financial and health care perspective, to the patient's health care. As opposed to the value-based safe harbors that exclude particular entities, under this proposed safe harbor, CMS will have the flexibility to limit participation in a CMS-sponsored model, in effect excluding certain entities (e.g., pharmaceutical manufacturers).

For purposes of the safe harbor, OIG has proposed (and is seeking comments on) specific definitions for various terms such as:

- CMS-sponsored model
- CMS-sponsored model arrangement
- CMS-sponsored model participant
- CMS-sponsored model party
- CMS-sponsored model patient incentive
- Participation documentation

If finalized, this safe harbor would provide another pathway of protection, beyond waivers, for CMS-sponsored model parties.

Cybersecurity

In an effort to remove real or potential barriers that prevent parties from improving security through the use of cybersecurity technologies, OIG proposes to protect donations of cybersecurity software and technology and services deemed necessary and used "predominantly to implement and maintain effective cybersecurity." Permitted cybersecurity software and technology donations under the proposed rule would include business continuity and data recovery services, cybersecurity training services, cybersecurity-as-a-service offerings, services associated with security risk assessments, and threat sharing services.

Under the existing EHR safe harbor, recipients are required to pay at least 15 percent of the donor's costs. However, the proposed rule for cybersecurity technology would not require recipients to pay any portion of the donor's costs. Furthermore, OIG would not require donors to provide cybersecurity technology and services to each entity or individual that connects to the donor's systems. Instead, the donor may use selective criteria for choosing recipients as long as neither the recipient's eligibility nor donated services are determined based on the value or volume of referrals or other business dealings between the two parties.

As currently proposed, OIG would not permit hardware donations as OIG remains concerned that hardware donations pose a higher risk of constituting a disguised payment for referrals. However, OIG proposes an alternative approach for the protection of cybersecurity hardware that would provide an optional safeguard. Under the alternative approach, protected donations would include cybersecurity hardware that is determined by the donor to be reasonably necessary based on its own organizational risk assessment as well as that of the potential recipient. The goal of this approach is to provide donors and recipients more flexibility relative to the types of cybersecurity donations that could be protected while also including an additional safeguard to ensure that such protected donations are "necessary and used predominately to implement and maintain effective cybersecurity." OIG emphasizes the role of risk assessments in providing a reasonable basis for donors to identify risks and threats that need to be mitigated by donating cybersecurity hardware. OIG notes that the proposed alternative would still prohibit multifunctional hardware as it is not deemed necessary, nor is it predominantly used for

purposes of maintaining and implementing effective cybersecurity. Furthermore, OIG provides that if donations do include hardware, then consideration would be given to requiring a 15 percent contribution amount from recipients similar to the EHR safe harbor provision. OIG is soliciting comments on the contribution amount approach and whether other amounts should be considered (e.g., 5 percent, or 20 or 30 percent).

EHR

OIG proposes several amendments to the existing EHR safe harbor that would update the existing safe harbor's interoperability provisions, clarify that particular cybersecurity technology has always been protected under the existing safe harbor, and remove the safe harbor's sunset date.

In regard to interoperability, OIG proposes to define "interoperable" to more closely align with the requirements set out in the 21st Century Cures Act and the rules being developed by the Office of the National Coordinator for Health Information Technology as well as the requirement that the donor not engage in information blocking.

Although OIG has not included any specific amendments to the safe harbor requirement that the recipient pays 15 percent of the donor's cost of technology, OIG notes its awareness that this requirement has proven "burdensome to some recipients and may act as a barrier to adoption of [EHR] technology." As a result, OIG specifically requests that the public submit comments on three alternatives to the existing requirements:

- eliminating or reducing the percentage contribution required for small or rural practices;

- eliminating the percentage contribution requirement for all recipients; and

- modifying or eliminating the contribution requirement for updates to previously donated EHR software or technology.

Personal Services and Management Contracts and Outcome-Based Payment Arrangements

In an attempt to modernize the personal services and management contracts safe harbor, remove barriers for care coordination and value-based arrangements, and more closely align this safe harbor with the Stark Law's personal services exception, OIG is proposing to do the following: (1) change the requirement that aggregate compensation be set in advance to a requirement that the methodology for determining compensation be set in advance; (2) eliminate the requirement that a periodic, sporadic, or part-time basis agreement must specify the schedule, length, and exact charge for intervals; and (3) protect certain outcomes-based payments. We believe that these are all welcome modifications to this safe harbor, and we suggest that the public submit comments to this effect.

Set forth in the preamble, OIG states how in light of the development of new payment models (such as shared savings, shared losses, episodic payments, and gainsharing) and in recognition that such arrangements may promote value-based care, care coordination, and provider engagement, the OIG has proposed expanding this safe harbor to apply to "outcomes-based payments," which are defined as:

> payments from a principal to an agent that: (i) 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 (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care patients.

As part of the outcomes-based payment proposal, OIG is proposing to require parties to establish one or more specific evidence-based, valid outcome measures that the agent must satisfy to be eligible to receive the outcomes-based payment. OIG proposes that outcome measures must relate to improving patient care; appropriately and substantially reducing costs to, or growth in expenditures of, payors while improving or maintaining the improved quality of care; or both. In addition, OIG is considering a requirement that parties rebase (e.g., reset the benchmark to account for improvements already achieved) the benchmark or outcome measure periodically. We encourage stakeholders to submit comments on the definition of "rebase" and the frequency of rebasing.

Participants in outcome-based payment models will want to review this proposed rule and consider commenting because, while OIG seemingly expands the personal services and management contracts safe harbor, the current proposal may not go far enough to protect many types of arrangements, including typical gainsharing arrangements between a hospital and a physician where there are no cost savings to a payor or coordination across settings. Though the intent of the proposed rule to promote the coordination among providers seems clear, even those gainsharing arrangements previously blessed by OIG through the Advisory Opinion process may not receive protection based on OIG's current proposal.

Warranties

In response to comments received through the RFI process, OIG is proposing to modify the warranties safe harbor to (1) protect bundled items for one or more items ***and*** related services, (2) exclude beneficiaries from the reporting requirements, and (3) define "warranty" directly instead of by reference to make clear that the warranties safe harbor applies to FDA-regulated drugs and devices.

With respect to bundled warranties, OIG has proposed the following conditions:

- All federally reimbursable items and services must be reimbursed by the same federal health care program and in the same payment.

- A manufacturer or supplier must not pay any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

- Bundled payment warranties cannot be conditioned on the exclusive use of one or more items or services or minimum purchase requirements of any items or services.

While OIG proposes that the warranty safe harbor exclude warranties for services that are not tied to one or more related items, OIG solicits comments on whether the final rule should extend protection to service-only warranties.

Local Transportation Safe Harbor

To address the importance of transportation in patient access to care, OIG proposes revising the existing "local transportation" safe harbor by (1) expanding the direct transportation and shuttle service distance that rural residents may be transported, from the current limit of 50 miles to 75 miles, and (2) entirely removing mileage limits on transportation between the health care facility of discharge and the patient's residence. OIG seeks comments on whether the rural direct transportation limit should be increased beyond 75 miles. In addition, because the risks for potential abuse upon discharge are lower as compared to transporting patients to the facility, OIG seeks comments on whether discharge transport could be extended to any location of the patient's choosing from the health care facility. Harkening back to when OIG initially created the local transportation safe harbor, OIG is also considering expanding the safe harbor to allow for transportation to locations not directly related to a patient's medical care, such as to food banks, support groups, or exercise facilities.

It is also significant that OIG notes that transportation could also fall under the proposed Patient Engagement safe harbor to the extent it is not covered by the revised local transportation safe harbor, which may prove especially relevant if OIG does not extend the final local transportation safe harbor to cover non-medical transports.

ACO Beneficiary Incentive Program

In the proposed rule, OIG adopts the "ACO Beneficiary Incentive Program" statutory language of the Budget Act of 2018 provision that permits Medicare ACOs in certain two-sided risk models to operate CMS-approved beneficiary incentive programs and allows incentive payments to ACO-assigned beneficiaries who receive certain primary care services. The only substantive change to the current statutory language would be a clarification that the incentive payments could only be made to assigned beneficiaries.

The proposed safe harbor states that "an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Act, as amended by Congress from time to time" will not violate the AKS "if the incentive payment is made in accordance with the requirements found in such subsection." While the new safe harbor could be categorized as regulatory housekeeping, its inclusion introduces an important safeguard for ACOs offering or planning to offer beneficiary incentive programs.

CMP Exception for Telehealth Technologies for In-Home Dialysis

OIG also proposes incorporating an exception to the CMP to include provisions of the Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2018. The legislation allows individuals with end-stage renal disease ("ESRD") that receive home dialysis to also receive their monthly ESRD-related clinical assessments at home via telehealth. While the Budget Act of 2018 incorporated this telehealth technology exception into the "remuneration" definition of the CMP, OIG's proposal incorporates the definition into the regulations with additional interpretation.

The proposed exception would apply to "telehealth technologies" (defined to mean "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication") offered by a provider of services or a qualified renal disease facility to an individual with ESRD who is receiving home dialysis. Medicare may reimburse for the provision of these services if (1) the telehealth technologies are not offered as part of an advertisement; (2) the telehealth technologies contribute substantially to the provision of services related to the recipient's ESRD, are not of excessive value, and are not duplicative of any technology the recipient already owns; and (3) the provider does not bill federal health care programs, other third parties, or otherwise shift the cost of the telehealth technologies. As proposed, the exception also requires that the provider or facility that is currently providing the in-home dialysis or ESRD care to the patient furnish the telehealth technologies to the individual. However, OIG is soliciting comments on whether this interpretation is too narrow and should be expanded to include suppliers.

OIG requests comments as to whether it should expand the definition of "telehealth" to cover software, webcams, broadband internet, data plans, and similar infrastructure-based technologies that facilitate two-way, real-time communication. Presently, OIG defines "telehealth" to encompass "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication," which excludes phones, email, or fax machines but includes smartphones that allow for secure audio/video communication.

Looking Forward and the Importance of Submitting Comments

Given the importance of these issues, Epstein Becker Green and its attorneys are working with clients to organize and submit comments and information in response to this proposed rule. If you are interested in participating in this submission, please contact the

Epstein Becker Green attorney with whom you regularly work, or any of the authors of this Client Alert.

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