October 23, 2019

Protecting Payment for Value – OIG and CMS Propose New AKS Safe Harbors and Stark Exceptions

On October 9, 2019, the U.S. Department of Health and Human Services Office of the Inspector General ("**OIG**") and Centers for Medicaid & Medicare Services ("**CMS**") released their long-awaited proposed rules describing potential changes to regulations implementing the federal anti-kickback statute (the "**AKS**"), beneficiary inducement provisions of the civil monetary penalty law (the "**CMPL**"), and the physician self-referral law (the "**Stark Law**"). OIG and CMS have described the changes as efforts to reduce barriers to the coordination and delivery of value-based care.

OIG's proposed rulemaking (the "**OIG Proposed Rule**") and the proposed rulemaking from CMS (the "**CMS Proposed Rule**") each include three new provisions for value-based care arrangements presenting different financial risk profiles. The OIG Proposed Rule includes additional revisions related to electronic health records, designed to facilitate access to the most current technology, as well as updates to existing safe harbors and a few discreet safe harbors designed to support value-based initiatives and care coordination.

Click here for the OIG Proposed Rule and here for the CMS Proposed Rule.

I. Proposals to Protect Certain Value-Based Care Arrangements

a. Scope

Each of the proposed safe harbors and exceptions protects remuneration exchanged between a "value-based entity" and its "value-based participants" pursuant to a "value-based arrangement." OIG and CMS have proposed to define "value-based entity," "value-based participant," and "value-based arrangement" similarly, and both agencies have solicited comment on the definitions.

i. "VBE Participant"

The Proposed Rules define a "value-based participant" ("**VBE participant**") as an individual or entity that engages in at least one value-based activity as part of a value-based entity (the phrase used in the OIG Proposed Rule) or "value-based enterprise" (the phrase used in the CMS Proposed Rule) (collectively, "**VBE**").[1] Entities not meeting the definition of a VBE cannot avail themselves of this safe harbor, even if all other elements of the safe harbor are satisfied.

Notably, OIG would *exclude* from this VBE definition pharmaceutical manufacturers; manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics, or supplies ("**DMEPOS**"); and laboratories.[2] In taking this position, OIG noted its view that many pharmaceutical manufacturers have been participating in value-based arrangements through outcomes-based and value-based contracts for their products, patient medication adherence programs, and data analytics, and that these arrangements would require different safeguards than those in the OIG Proposed Rule. In a marketplace that is converging in many ways, these categorical exclusions may prove unduly and

[1] Dep't of Health & Human Servs, Ctrs. for Medicare & Medicaid Servs., CMS-1720-P, *Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations* 33 (proposed Oct. 9, 2019) (to be codified at 42 C.F.R. part 411) (hereinafter referred to as "CMS Proposed Rule"); Dep't of Health & Human Servs., Office of Inspector General, RIN 0936-AA10, *Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbor Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements* 52 (proposed Oct. 9, 2019) (to be codified at 42 C.F.R. parts 1001 and 1003) (hereinafter referred to as "OIG Proposed Rule").

[2] OIG Proposed Rule at 53–54.

unnecessarily limiting. OIG is also considering exclusion of entities such as pharmacies (or some subset of pharmacies), pharmacy benefit managers, pharmaceutical wholesalers/distributors, and medical device companies (with a potential carve-out for manufacturers of beneficial digital technologies).[3] In contrast, CMS's proposal does not currently exclude these entities from being VBE participants, but CMS is inviting comment as to whether some or all should be excluded.[4]

ii. "Value-Based Entity" or "Value-Based Enterprise"

Under the proposals, a VBE is a group of at least two VBE participants that:

- collaborate to achieve at least one value-based purpose (more on "value-based purposes" below);
- are each a party to a value-based arrangement (more on "value-based arrangements" below) with at least one other VBE participant in the VBE (*e.g.*, if the network is comprised of only two VBE participants, they must have at least one value-based arrangement with each other in order for the network to qualify as a VBE);
- establish an accountable body (*e.g.*, board of directors, if the VBE is a corporation; presumably a committee if the VBE is not a distinct entity) or person responsible for financial and operational performance of the common value-based activities; and
- have a governing document describing the VBE and how the VBE participants intend to satisfy the VBE's value-based purpose(s).[5]

OIG is also considering further requirements, including:

- requiring the VBE to implement and maintain a compliance program governing its value-based arrangements;
- delineating the VBE's specific oversight responsibilities (*e.g.*, verification of participant performance, utilization, cost, patient experience, quality of care); and
- requiring the accountable body or responsible person to be independent or have a duty of loyalty to the VBE.[6]

CMS is generally not considering similar requirements, but it intends to review the comments to the OIG Proposed Rule in finalizing its rule.

iii. "Value-Based Arrangement"

OIG and CMS propose to define a "value-based arrangement" broadly, as an arrangement that (i) is between or among the VBE and one or more of its VBE participants, or VBE participants in the same VBE, and (ii) provides for at least one value-based activity for a target patient population.[7]

Under the Proposed Rules, a "value-based activity" must include an activity that is reasonably designed to achieve at least one value-based purpose of the VBE.[8] Wellness screenings could be an example.

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[3] *Id.* at 59.
[4] CMS Proposed Rule at 43.
[5] CMS Proposed Rule at 32; OIG Proposed Rule at 39.
[6] OIG Proposed Rule at 40–43.
[7] CMS Proposed Rule at 32; OIG Proposed Rule at 44.
[8] CMS Proposed Rule at 32; OIG Proposed Rule at 50. Making a referral cannot be the value-based activity.

Proposed value-based purposes are not particularly specific. They include coordinating and managing care, improving quality of care, reducing costs or expenditures of payors without reducing quality of care, and transitioning to healthcare and payment mechanisms based on quality of care and cost control.[9] Although the definition suggests flexibility among the four value-based purposes, OIG would require value-based arrangements to further directly at least the first of these four purposes—coordination and management of patient care.[10] Given the open-ended nature of these definitions, one would expect that most value-based arrangements would be covered.

The Proposed Rules define a "target patient population" as an identified patient population selected by the VBE or its VBE participants using "legitimate and verifiable criteria" that are set out in writing in advance and further the VBE's value-based purpose.[11] The target patient population may include individuals who are not Federal health care program beneficiaries. OIG and CMS explain that "legitimate and verifiable criteria" may include medical or health characteristics, geographic characteristics (*e.g.*, a county or zip code), payor status (*e.g.*, all patients with a particular insurance plan or payor), or other defining characteristics.[12] Of note, OIG is considering limiting the target patient population to individuals with a chronic condition or a shared disease state who would benefit from care coordination, which would significantly limit the scope of value-based arrangement safe harbors.[13]

iv. Directly Connected

Of note, OIG has proposed limiting safe-harbor protection to remuneration that is:

- *primarily used* to engage in value-based activities that are *directly connected* to the coordination and management of care of the target patient population (for the care coordination arrangements safe harbor), or

- *directly connected* to one or more of the VBE's purposes, at least one of which must be the coordination and management of care for the target patient population (for the safe harbors for substantial downside risk arrangements and full financial risk arrangements).[14]

The OIG's use of different standards creates some ambiguity with respect to their meaning. In particular, the absence of "*primarily used*" from the second standard raises a question of whether the primary use of remuneration under those safe harbors can be something else. The OIG Proposed Rule lacks clarity in this regard, and simply states that, to have a direct connection, remuneration must have a "close nexus" to the coordination and management of care for the target patient population, rather than the VBE participants' referral patterns and business generated.[15] OIG does not give any examples of arrangements that it would consider to have a direct connection to the coordination and management of care, and makes only the obvious point that "pay-to-play" arrangements where a VBE participant offers, or must provide, remuneration to receive referrals or to be included in a "preferred provider network" would not meet this requirement.[16]

By way of contrast, the CMS Proposed Rule does not include a similar requirement.

[9] CMS Proposed Rule at 33.
[10] OIG Proposed Rule at 45, 71.
[11] CMS Proposed Rule at 33; OIG Proposed Rule at 45.
[12] CMS Proposed Rule at 44.
[13] OIG Proposed Rule at 47.
[14] *Id.* at 70.
[15] *Id.* at 78.
[16] *Id.* at 98.

v. General Requirements

The safe harbors and exceptions have various requirements. Some apply to each safe harbor or exception. Others apply depending on the level of risk assumed by the VBE and applicable VBE participant. Others are unique to one or the other of the OIG and CMS Proposed Rules.

The two most notable are requirements for (i) documentation, recordkeeping, and monitoring requirements to ensure that the value-based arrangement is achieving its value-based purpose(s) and (ii) exclusion of arrangements that include marketing items or services to patients or patient recruitment activities.

The raft of familiar requirements includes restrictions on remuneration that induces parties to furnish medically unnecessary items or services or reduces or limits medically necessary items or services; restrictions on limiting professional decision-making and directing or restricting referrals; and restrictions on taking into account the volume or value of referrals and conditioning receipt of remuneration on patient referrals other than for the target patient population or for business covered by the value-based arrangement.

b. The Three Proposals

Moving beyond the general scope, there are three proposed safe harbors and three proposed exceptions:

- *One* for **value-based arrangements** that do not involve downside financial risk.
- *One* for arrangements with **substantial downside risk**.
- *One* for arrangements with **full financial risk**.

At a high level, OIG and CMS offer greater regulatory flexibility to parties that have assumed greater financial risk.

Significantly, none of the proposals requires remuneration to be fair market value or to be set in advance (the CMS Proposed Rule, however, requires the *methodology* for calculating the remuneration to be set in advance). Interestingly, the CMS Proposed Rule does not prohibit the methodology for calculating remuneration from taking into account the volume or value of referrals (though it does prohibit *conditioning* receipt of remuneration on patient referrals other than for the target patient population or for business covered by the value-based arrangement). Still, given the requirements that have been proposed, there are some clear limitations to their utility, and it is quite possible that organizations might find in a number of instances that they can more readily find protection under the existing managed care safe harbors or risk-sharing arrangements exception, which, if it holds, would be a surprising outcome after so much fanfare for the new rules.

i. Care Coordination Arrangements and Value-Based Arrangements

Unlike the "care coordination" arrangements safe harbor proposed under AKS, which protects only in-kind remuneration, the corresponding "value-based arrangements" exception proposed under the Stark Law reaches both in-kind and monetary remuneration.[17] The OIG and CMS proposals both come with a variety of technical requirements, and the OIG Proposed Rule includes requirements that CMS did not include, most notably a 15% contribution requirement for recipients, described below:

[17] CMS Proposed Rule at 71–72.

- *Contribution.* The recipient must pay at least 15% of the offeror's initial cost, and for any ongoing costs, must make such contributions on reasonable, regular intervals, with the frequency of such payments documented in writing (again, this is just OIG now, but CMS is considering a similar proposal).[18]

- *Commercially Reasonable.* The value-based arrangement must be commercially reasonable, considering both the arrangement itself and all other value-based arrangements within the VBE.[19]

- *No Diversion.* The arrangement is not protected if the offeror knows or should know that the remuneration is likely to be diverted, resold or used by the recipient for an unlawful purpose.[20]

OIG is considering additional requirements, including:

- A limitation requiring that remuneration may benefit *only* the target patient population (*i.e.*, the safe harbor would not protect arrangements with "spillover" benefits to other individuals).[21] So, for example, a care coordinator provided to a practice by a VBE couldn't also consult on any non-VBE patient.

- For remuneration in the form of health information technology ("**IT**"), a prohibition on making the receipt of items or services a condition of doing business with the offeror, and limiting the time during which a recipient can receive IT, after which time the recipient must pay fair market value for continued use of the IT.[22]

If OIG adopts the IT requirements, VBE participants that do not share in meaningful downside risk may more easily satisfy the EHR safe harbor or proposed cybersecurity technology safe harbor.

ii. Substantial Downside Risk Arrangements and Meaningful Downside Risk Arrangements

This proposed safe harbor and exception would protect *in-kind and monetary* remuneration between VBEs and VBE participants that *meaningfully share* in the VBE's *downside financial risk*.

What does it mean to share "meaningfully" in downside risk? OIG and CMS provide different definitions. Under the OIG Proposed Rule, a VBE participant meaningfully shares in the VBE's financial risk if the payment it receives:

- puts the VBE participant at risk for 8% of the VBE's total risk under the payor agreement (*e.g.*, an 8% withhold, recoupment payment, or shared losses payment);

- is a partial or fully capitated payment (excluding the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, etc.); or

- is protected by the corresponding Stark Law exception (discussed below), if the VBE participant is a physician.[23]

Under the CMS Proposed Rule, a physician is at meaningful financial risk if he or she is responsible for at least 25% of the value of the remuneration available under the value-based arrangement, or is financially responsible on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for the target

[18] CMS Proposed Rule at 82; OIG Proposed Rule at 84.
[19] OIG Proposed Rule at 94.
[20] *Id.* at 105.
[21] *Id.* at 89.
[22] *Id.* at 83.
[23] *Id.* at 128–29.

patient population for a specified period of time.[24] To satisfy the proposed Stark Law exception, the physician would be required to assume meaningful financial risk for the duration of the arrangement.

The difference between the two is striking: the numbers themselves are different—8% for OIG but a full 25% for CMS—and the direction of the difference is remarkable. It's physicians who must sign up for 25% downside risk in order to be eligible for protection. This is all the more striking when one notes that the longstanding Stark exception for risk-sharing arrangements has no threshold at all.

iii. Full Financial Risk Arrangements

Moving further along the risk spectrum, from "meaningful" to full financial risk, participants would remain eligible for protection for both *in-kind and monetary* remuneration.

Here, too, there are differences between OIG's and CMS's view of the world. OIG would protect *only* remuneration between (i) a VBE that has financial responsibility and (ii) a VBE participant. OIG would *not* protect remuneration among VBE participants, or between a VBE participant and a downstream contractor.[25] CMS is not as strict. The proposed Stark Law exception would protect payments to physicians not only from the VBE, but also from other VBE participants.[26]

Under the Proposed Rules, the applicable VBE participant cannot claim additional or separate payment in any form directly or indirectly from a payor for items or services covered under the value-based arrangement, except for catastrophic loss and other reconciliations that do not shift material financial risk back to the payor. The full scope of this provision isn't clear. For example, what if a VBE accepts a capitated rate for medical expenses and receives a separate fee for administrative services, such as credentialing? The OIG Proposed Rule does not protect an entity that receives a partial capitated payment (*i.e.*, covers a limited set of items/services or is in combination with a fee-for-service payment for a defined set of items/services).[27] The CMS Proposed Rule likewise does not propose to protect such payments, though CMS indicates that it is considering doing so and is also considering alternative definitions for "full financial risk."[28]

c. CMS-Sponsored Initiatives

The OIG Proposed Rule includes a safe harbor for arrangements between parties in a CMS-sponsored model, program, or other initiative.[29] The CMS Proposed Rule does not create a separate exception for such arrangements, because CMS expects that such arrangements could be structured to meet one of the other proposed exceptions.[30]

Although a new safe harbor would alleviate the need for OIG to issue future waivers for new CMS payment models, the majority of participants in CMS-sponsored initiatives may be expected to continue to rely on broader waivers of certain provisions of the AKS, the Stark Law, and the CMPL previously issued by OIG and CMS for numerous CMS payment models.[31]

[24] CMS Proposed Rule at 328–29.
[25] OIG Proposed Rule at 145.
[26] CMS Proposed Rule at 64.
[27] OIG Proposed Rule at 137.
[28] CMS Proposed Rule at 57.
[29] OIG Proposed Rule at 193–94.
[30] CMS Proposed Rule at 62.
[31] OIG Proposed Rule at 199–200

II. Proposals Related to Sharing of Health IT

EHR and cybersecurity technology continue to be of utmost importance to providers, regardless of whether they are part of a VBE. Responsive to comments in this area, OIG and CMS proposed modifications to the existing EHR safe harbor and exception, respectively, and proposed adding a new cybersecurity technology safe harbor and exception.

a. Modifications to EHR Safe Harbor/Exception

OIG and CMS proposed nearly identical modifications to the EHR safe harbor and exception. These would:

- eliminate the sunset provision, which otherwise is set to close the safe harbor and exception on December 31, 2021;
- eliminate the prohibition on replacement technology if the recipient already possesses equivalent items or services;[32]
- *potentially* expand the scope of protected EHR donors by either removing the limitation that donors bill Federal health care programs, or adding entities with indirect responsibility for patient care (*e.g.*, health systems and ACOs) to the list of protected donors (OIG is considering this);[33] and
- *potentially* eliminate or reduce the contribution requirement either (i) overall, or for either all recipients or rural physician organizations only, or (ii) just for updates to previously donated EHR (both OIG and CMS are considering this).[34]

b. Cybersecurity Technology Safe Harbor/Exception

In addition to the proposals described above for EHR generally, OIG and CMS propose a new safe harbor and exception for donations of cybersecurity technology. These proposals carry fewer restrictions than the current EHR safe harbor and exception. In particular, neither would require the recipient to pay 15% of the cost. However, OIG and CMS are considering requiring the offeror to conduct a risk assessment of potential recipients to determine whether the donation is necessary, which is not required under the EHR safe harbor/exception.[35] It is unclear whether offerors of cybersecurity technology would be able to rely on a *recipient's* annual risk assessment conducted as part of its Health Insurance Portability and Accountability Act of 1996 ("HIPAA") compliance program, for purposes of satisfying such a requirement.

III. Additional Proposals

a. Additional AKS Proposals

i. Modification of Personal Services and Management Contracts Safe Harbor

The most significant proposed modifications would:

[32] CMS Proposed Rule at 233–34, 240; OIG Proposed Rule at 255, 264.
[33] OIG Proposed Rule at 264.
[34] CMS Proposed Rule at 238; OIG Proposed Rule at 240.
[35] CMS Proposed Rule at 273; OIG Proposed Rule at 227.

- require that the *methodology for determining the compensation* under personal services and management contracts be set in advance, rather than the existing requirement that the *aggregate compensation* under these agreements be set in advance;

- protect certain outcomes-based payments (detailed below); and

- 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 exact charge for such intervals.

Eliminating the requirement that *aggregate* compensation must be set in advance is the most notable change as it would dramatically expand the scope of the safe harbor, aligning its requirements more closely with the Stark Law's personal services exception.

The proposal to establish specific protection for outcomes-based payments would protect:

- so-called outcomes-based payments (such as shared savings payments, shared losses payments, gainsharing payments, pay-for-performance payments, or episodic or bundled payments),

- *if* the parties satisfy monitoring obligations like those proposed for the care coordination safe harbor described above,

- *and* the payments do not relate solely to achievement of internal costs savings for the principal,

- *and* the payments are fair market value, and commercially reasonable,

- *and* the arrangement is periodically rebased,

- *and* possibly (OIG has solicited comment) the parties do not include pharmaceutical manufacturers, DMEPOS organizations, or others who also would be excluded from the proposed care coordination safe harbor.

Given the multiple elements of the safe harbor that would need to be satisfied, it may be easier to satisfy the requirements of the "ordinary" version of the existing safe harbor, once that is amended to protect formula-based payments.

ii. Modification of Warranties Safe Harbor

The OIG Proposed Rule contains several modifications to the existing warranties safe harbor. Today, the safe harbor protects only warranties offered on *a single item*. The proposal would expand protection to reach bundled warranties of both *items and related services* (but not warranties covering services only).[36] For example, the safe harbor could protect a warranty covering both wound care products and related support services (*e.g.*, access to a wound specialist and an online wound documentation system—some readers may recognize the fact pattern from Advisory Opinion No. 01-08).[37]

OIG proposes three main limitations:

- First, all federally reimbursable items covered by the warranty must be reimbursed by the same federal health care program, in the same payment. This requirement is a close cousin of the "same methodology" requirement in the discount safe harbor. It would be a real limitation. For example, it would seem to prohibit warranties

[36] OIG Proposed Rule at 287.
[37] *See* Dep't of Health & Human Servs., Office of Inspector General, Adv. Op. No. 01-08 (July 3, 2001).

covering *both* a surgical implant (paid under the IPPS, OPPS, or ASC fee schedule) *and* physical therapy services related to the surgery (paid under the Medicare Physician Fee Schedule). OIG's concerns about retaining the integrity of programmatic financing seem to have prevailed over recognition of increasingly integrated service offerings.

- Second, warranty payments would be limited to the cost of the items and services subject to the warranty. For example, the manufacturer of a surgical closure device couldn't offer a protected warranty that would promise to pay for post-surgical hospitalization costs if an incision wound failed to heal properly.

- Third, a warranty could not be conditioned on exclusivity or minimum-purchase requirements.[38]

OIG is also considering: (i) extending the safe harbor to warranties covering services only, if sufficient safeguards exist; (ii) adding additional safeguards intended to limit potential anti-competitive effects (OIG does not explain what such safeguards might entail, but expresses that its intent is to mitigate likely barriers to entry for manufacturers and suppliers that cannot enter into bundled warranties);[39] and (iii) revising the reporting requirements to provide for more flexibility including whether to allow for delayed reporting (*e.g.*, in situations when the efficacy of a drug therapy is not known for several years after the purchase).

iii. Patient Engagement and Support Safe Harbor; Local Transportation; and Other New Safe Harbors

OIG proposes a new safe harbor to protect certain arrangements for *in-kind* (*not* cash) patient engagement tools and support to improve quality, health outcomes, and efficiency—if *furnished by VBE participants* to patients in a target patient population (the "**Patient Engagement and Support Safe Harbor**").[40] Like the three value-based care proposed safe harbors, the remuneration must have a direct connection to the coordination and management of care of the target patient population. "Patient engagement tools and supports" include preventive items, goods, and services, such as health-related technology, patient health-related monitoring tools and tools designed to identify and address social determinants of health.[41] Depending on the circumstances, arrangements may also be protected under existing safe harbors (*e.g.*, local transportation or incentives for delivery of preventive care).

OIG notes that it is still considering a number of adjustments to the proposed safe harbor under which OIG may:

- extend safe harbor protection to patient engagement tools and supports offered by hospitals or physician groups that are *not* part of a VBE;

- require that tools and services not be duplicative of existing tools and services (*e.g.*, if adopted, the safe harbor would not protect providing a new cell phone or wireless service plan to a patient who needs an application for remote monitoring but already has a cell phone);[42]

- protect gift cards, cash, or cash equivalents (capped at $75/year) where the offeror has an evidence-based reason for cash as a mechanism to influence patients' adherence to treatment; and

[38] OIG Proposed Rule at 293.
[39] *Id.* at 295.
[40] *Id.* at 147–48.
[41] *Id.* at 156.
[42] *Id.* at 158.

- protect waivers of small beneficiary cost-sharing amounts associated with certain care coordination services, such as care management and remote monitoring, where costs of collection exceed amount to be collected.[43]

OIG also proposes modifications to the existing local transportation safe harbor, which would: (i) expand the distance that rural residents may travel and (ii) remove mileage limits on transportation from a healthcare facility to the patient's residence.[44] Although this did not seem to be in doubt, OIG did clarify that the safe harbor does cover ride-sharing services.[45]

Lastly, OIG proposes codifying existing statutory exceptions for monetary payments or in-kind services in targeted, limited areas. One is an AKS exception, and would be mirrored in a safe harbor, permitting incentive payments paid from accountable care organizations ("**ACOs**") to assigned beneficiaries under the ACO Beneficiary Incentives Program.[46] The other is a CMPL exception to the definition of "remuneration" that allows individuals with end-stage renal disease ("**ESRD**") receiving home dialysis to receive monthly ESRD-related clinical assessments via telehealth, if certain conditions are met.[47]

b. Unrelated Changes to the Stark Law

CMS proposes a variety of other changes to the Stark Law regulations. Most of these are responsive to issues and arguments that CMS has encountered through the self-disclosure protocol. The changes come in two groups: a number are to definitions in the regulations, and others to exceptions, or the interpretation of exceptions, as summarized below.

i. Revised Definitions

1. "Designated Health Services"

CMS proposes to revise the definition of "designated health services" ("**DHS**") in an important way for hospitals.

The change would define DHS to include *inpatient services only if* the services affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System ("**IPPS**"). The example that CMS provides is this: if, after an inpatient has been admitted under an established diagnosis-related group ("**DRG**"), the patient's attending physician requests a consultation with a specialist not responsible for admission who then orders an x-ray, the x-ray would not be considered a DHS, since it would not affect the IPPS payment.

This raises a few questions in application. First, what if a service results in an outlier payment? CMS acknowledges that could happen, but doesn't clearly state whether it would cause a service to become a DHS. If it would, it would mean that parties wouldn't know whether a service is a DHS until post-discharge—which of course might affect post-hoc liability analyses, but would not be a basis of planning. Second, what if a physician certifies or recertifies the need for a service based on confirmatory diagnosis of the patient, but was not the admitting physician? Further focus on this will be warranted.

CMS is also considering whether to extend the proposal to outpatient healthcare services or other categories of designated health services.[48]

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[43] *See id.* at 151–92.
[44] *Id.* at 300.
[45] *Id.* at 308.
[46] *See id.* at 313.
[47] *See id.* at 316.
[48] CMS Proposed Rule at 154–60.

2. "Commercially Reasonable"

Many of the Stark Law regulations have long required that arrangements must be commercially reasonable in the absence of referrals. CMS has proposed to define "commercially reasonable" to mean that a particular arrangement furthers a legitimate business purpose of the parties, and is on similar terms and conditions as like arrangements. Alternatively, CMS is considering defining the term to mean that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. Both approaches complement the fair market value standard, suggesting that organizations will continue on sensitive transactions to seek a valuation expert's opinion on both fair market value and commercial reasonableness.

Most usefully, CMS acknowledges in the commentary that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. That is welcome validation for organizations that employ or engage physicians or groups at a loss when considering just professional fees, but that serve appropriate business or mission purposes.

3. "Fair Market Value"

CMS also proposes to revise the definitions of "fair market value" and "general market value," to remove the current language that limits them not just to the result of bona fide bargaining between the parties, but between parties "who are not otherwise in a position to generate business for the other party." Standing on its own, this could be extremely impactful. However, the commentary explains that the applicable exceptions require both the compensation to be fair market value and, separately, not to reflect the volume or value of referrals or other business generated, so the definition of fair market value would not also incorporate the volume or value or other business generated standards.[49] Although this change would appear to loosen the standard, the commentary suggests that there will still be scrutiny of the payment's relationship to referrals via the volume or value standard.[50]

4. "Volume or Value of Referrals" Standard

In an opinion published in September, the U.S. Court of Appeals for the Third Circuit recently considered the "take into account" and "varies with" prongs of the volume or value standard, holding that (i) compensation "varies with" referrals if the compensation is correlated with referrals (*i.e.*, if compensation tends to increase or decrease as the volume or values tend to increase or decrease) and (ii) "takes into account" referrals if a causal relationship exists between the two (*i.e.*, if the physician's compensation is based on or designed to reflect volume or value of referrals).[51]

Treading on the same ground, but taking a somewhat different approach, CMS wrote that it believes an arrangement to "take into account" the volume or value of referrals only when (i) the mathematical formula used to calculate the amount of compensation includes as a variable referrals or other business generated; and (ii) the amount of compensation *correlates* with the number or value of referrals generated by the physician or the generation of other business for the entity.[52] This proposed definition of "takes into account" would thus seem to conflate the elements articulated by the Third Circuit into the "takes into account" standard.

[49] *See id.* at 127-28.
[50] *See id.* at 292.
[51] *United States ex rel. Bookwalter v. UPMC*, No. 18-1693, 18 (3d Cir. Sept. 17, 2019).
[52] CMS Proposed Rule at 110.

5. Modifications to Group Practice Definition

Currently, the regulations define "overall profits" to mean both (i) the group's *entire* profits derived from DHS and (ii) profits derived from DHS of any *component* of the group practice that consists of at least five physicians. CMS proposes to revise the definition to mean profits derived from all DHS of any component of a group (including all physicians in the group) that consists of at least five physicians. If the group has fewer than five physicians, "overall profits" would mean the profits from all DHS of the group.[53]

CMS presents the change itself as a clarification of how to treat profits of small groups. But most significant is commentary that CMS included, stating that it would *not* consider "overall profits" to mean profits derived from *just some* DHS that a group furnishes. Instead, "overall profits" means profits from *all* DHS. This is particularly relevant for groups establishing bonuses targeted for just certain lab services or DME that a group furnishes.

In response to commenters' concern that downstream compensation made to a physician in a VBE that derives from payments made to a group practice, might violate the requirement that the compensation not directly take into account volume or value of referrals (which is currently prohibited outside of CMS-sponsored programs), CMS proposes to add a deeming provision related to distribution of profits. Under CMS's proposal, when a group distributes to its physicians profits directly attributable to participation in a VBE (*e.g.*, profit shares and productivity bonuses stemming from participation in value-based arrangements), CMS would deem the compensation to not directly take into account volume or value of the physician's referrals.[54]

Additionally, CMS proposes to deem payment of a productivity bonus not *directly* to take into account the volume or value of a physician's referrals if the services on which the productivity bonus is based are not revenues derived from DHS (and, if not Medicare-payable, would not be DHS if Medicare-payable).[55] CMS also makes certain clarifying changes for "incident to" services, explaining that groups may continue to pay a productivity bonus based on services that the physician has personally performed, services "incident to" such personally performed services, or both, provided that the bonus only *indirectly* takes into account the volume or value of the physician's referrals if the referrals are not for services "incident to" the physician's personally performed services.[56] Further, CMS proposes revising the existing deeming provision so that a productivity bonus will not be deemed to take into account the volume or value of referrals if it is based on a physician's total patient encounters or the relative value units personally performed by the physician. CMS is seeking input on whether the provision should limit the methodology to physician work relative value units ("**wRVUs**") or whether wRVUs should merely be one acceptable basis for calculating a productivity bonus deemed not to directly take into account volume or value of referrals.

ii. Other Changes

Finally, CMS proposes a number of other changes, as well as articulations of current agency policy and interpretation. The latter are of particular relevance because, unlike the proposed amendments, they essentially are of immediate effect. We list the key changes below.

- *Interpretation:* Stating that CMS does *not* consider a "transaction" (for purposes of the isolated transactions exception) to include a single payment made for multiple services provided over an extended period of time. This closes the door to arguments that parties can avoid noncompliance when they've not had a services contract

[53] *Id.* at 142–43.
[54] *Id.* at 140–41.
[55] *Id.* at 147.
[56] *Id.* at 147–48.

in place over a long period by simply saying that the arrangement was just an isolated transaction if there was only one payment.[57]

- *Interpretation:* Clarifying in commentary that parties who detect and correct administrative or operational errors or discrepancies can cure the errors in the arrangement if it is still active but cannot do so after the relationship has ended.[58] This is welcome confirmation to the analysis by attentive practitioners that the regulatory requirement has been for compensation paid over the term of an arrangement to be set in advance, and that corrections made during the term therefore are permitted.

- *Interpretation:* Clarifying that an electronic signature that is legally valid under federal or state law is sufficient to satisfy any Stark Law exception signature requirements.[59] This aligns with CMS's recognition that a "heap of papers" can, if the right papers (whether hard-copy or electronic) are in the heap, satisfy the requirement for a writing. Emails within a heap that contain electronic signatures can suffice.

- *Interpretation:* Clarifying that, depending on the circumstances, the obligation to document that the compensation formula was set in advance can be satisfied through "informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules," or documents used by physicians in similar situations.[60] Allowing internal notes to file suggests that this writing requirement could be satisfied without bilateral support.

- *Proposal:* Easing the writing requirements for compensation arrangements by proposing to deem both the writing *and* the signature requirement to be satisfied if: (i) the compensation arrangement satisfies all other requirements of the applicable exception; and (ii) the parties obtain the required writing or signature within 90 days from the date that it failed to satisfy.[61] This deeming provision previously only applied to the signature requirement.

- *Proposal:* Adding a new exception for limited remuneration to a physician, in acknowledgement of non-abusive industry practices, such as short-term medical director services, allowing limited remuneration *without a written arrangement in place* if: (i) the arrangement is for items or services actually provided by the physician; (ii) the amount of remuneration to the physician is limited (not exceeding $3,500/year, adjusted for inflation); (iii) the arrangement furthers a legitimate business purpose and is on similar terms as like arrangements, regardless of whether either party profits; (iv) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (v) the remuneration does not exceed fair market value.[62]

- *Proposal:* Removing the categorical exclusion of surgical items, devices, or supplies (that are not single-use) from the carve-out from the definition of "remuneration."[63]

- *Proposal:* Deleting the rigid period of disallowance rules and instead providing guidance on how to conduct a case-by-case analysis of the period.[64] (While just a proposal, this practically may be viewed to have immediate

[57] *Id.* at 170.
[58] *Id.* at 181.
[59] *Id.* at 197.
[60] *Id.*
[61] *Id.* at 192–93.
[62] *Id.* at 250–51.
[63] *Id.* at 154–65.
[64] *See id.* at 178.

effect, as it effectively underscores language already in the period of disallowance rules and related commentary that they are just deeming provisions, and parties are free to conclude that a period of disallowance ended at another time).

- *Proposal:* Expanding the carve-out of titular ownership or investment interests for compensation arrangements to the Stark Law rules governing ownership and investment interests. "Titular ownership or investment interests" include those interests that exclude the right to receive financial benefits of ownership or investment, including, but not limited to, distribution of profits, dividends, proceeds of sale, or similar returns on investment.[65] This exclusionary principle would apply to all financial relationship between physicians and entities furnishing DHS and could be beneficial in states prohibiting the corporate practice of medicine. CMS explains that because a physician with titular ownership does not have the right to distribution of profits or proceeds of a sale, the physician would not have a financial incentive to make referrals to the entity, reducing risk of abuse.

* * *

The commentary to the Proposed Rules suggests that OIG and CMS seek to protect arrangements that would reduce the cost curve and improve quality. But there are areas in which the agencies' desire to protect against "bad actors" may have impaired the goal of achieving flexibility for beneficial arrangements that are developing in a modern healthcare economy. The burdens for compliance with the Proposed Rules in their current form, particularly the AKS safe harbors, might be prohibitive for certain arrangements that would be beneficial while presenting minimal concern for overutilization or abuse. Commentary from industry may help the agencies to appreciate how real those burdens may play out to be, how the balance might be recalibrated, and how, in some ways, the agencies' articulation of limited safe harbors and exceptions might unduly chill beneficial arrangements that parties otherwise were comfortable developing under facts and circumstances analyses on the AKS side and under other exceptions (*e.g.*, the risk sharing arrangements exception) on the Stark Law side.

Ropes & Gray will continue to monitor developments related to the Proposed Rules, and will discuss some of these issues during a webinar on October 23 (click here for registration or replay information). If you have any questions regarding the Proposed Rules, or if you would like to discuss how the Proposed Rules might affect your organization, please contact any member of Ropes & Gray's Health Care group or your usual Ropes & Gray advisor.

[65] *Id.* at 182–83.