Are We There Yet? OIG and CMS Issue Long-Awaited Final Rules Aimed at Promoting Innovative Value-Based Care Models and Arrangements

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Traditionally, the U.S. health care system has relied on a fee-for-service (FFS) payment methodology, pursuant to which reimbursement is made for each item or service provided, regardless of cost or the resulting patient outcomes. Due to the unsustainable ongoing increase in health care costs, however, the paradigm is shifting to a value-driven system whereby payors pay for the ***value*** of the health care items and services providers deliver—as measured by improving health outcomes and quality, reducing costs, or both—rather than the ***volume*** of services they provide. Value-based care models and arrangements include a wide variety of performance-based payment strategies that link financial incentives to health care providers' performance on a set of defined measures that are designed to achieve better value.

Both public and private payors are using various value-based care strategies in an effort to drive improvements in quality and to slow the growth in health care spending. Value-based care strategies range from paying incentives to providers for achieving quality and/or reducing costs to requiring providers to assume a degree of financial risk in providing services to a particular patient population. However, as stakeholders seek to shift from traditional FFS reimbursement to value-based care models and arrangements, they face significant regulatory and operational barriers, including obstacles posed by the traditional fraud and abuse laws that generally prohibit the exchange of remuneration relating to items or services covered by federal health care programs.

Recognizing the need to address the impediments the fraud and abuse laws pose to the adoption of

coordinated care and value-based care arrangements, on December 2, 2020, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) published long-awaited companion final rules to revise the anti-kickback statute (AKS) safe harbors and the civil monetary penalties (CMP) rules, and the federal physician self-referral law (commonly referred to as the "Stark law") exceptions, respectively.[1] While the final rules address a variety of arrangements and modify various existing regulations, they focus heavily on care coordination and value-based care.

This article focuses on the new value-based safe harbors and exceptions under the AKS and Stark law, and compares and contrasts the agencies' rules. The new value-based safe harbors and exceptions offer entities new ways to provide remuneration that is tied to measures taken to achieve desired outcomes, rather than the performance of a service. Questions remain, however, regarding whether these safe harbors and exceptions ultimately will promote innovative value-based care arrangements and how OIG and CMS will interpret and enforce these arrangements going forward.

Despite these lingering questions, the value-based safe harbors and exceptions appear to be a step in the right direction for certain segments of the health care industry. By way of example, the following types of value-based arrangements could now be structured to satisfy the requirements of one or more of the new safe harbors and exceptions:

- providers that receive care coordination, shared savings, or similar value-based payments from commercial payors and that desire to pass a portion of those payments to downstream referring physicians;
- hospitals that desire to pay physicians for assisting the hospitals in achieving certain quality and cost-saving benchmarks;
- hospitals and skilled nursing facilities engaging in efforts to reduce readmissions;
- accountable care organizations that do not participate in the Medicare Shared Savings Program and wish to provide remuneration among the accountable care organization and its participants; and
- integrated health care delivery systems that provide remuneration among their members.

Both the AKS safe harbors and the Stark law exceptions are designed to protect remuneration provided pursuant to value-based arrangements between a value-based enterprise (VBE) and one or more VBE participants that are intended to achieve one or more value-based purposes. The following key terms are used consistently between both the AKS safe harbors and the Stark law exceptions.

- **"Value-based enterprise" (VBE)** means two or more VBE participants that are collaborating to achieve at least one value-based purpose, each of which is a party to a value-based arrangement with the other or at least one other VBE participant. The VBE is required to have an accountable body and a governing document.
- **"Value-based arrangement"** means an arrangement to provide at least one "value-based activity" for a target patient population to which the only parties are (i) the VBE and one or more VBE participants or (ii) two or more VBE participants in the same VBE.
- **"Target patient population"** means 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 of the commencement of the value-based arrangement and further the VBE's value-based purpose.
- **"Value-based activity"** is defined as providing an item or service, or taking or refraining from taking an action, that is

reasonably designed to achieve at least one of the VBE's value-based purposes. A value-based activity does not include the making of a referral.

- **"VBE participant"** means an individual or entity that engages in at least one value-based activity as part of a VBE.
- **"Value-based purpose"** means (1) coordinating and managing the care of a target patient population, (2) improving the quality of care for a target patient population, (3) appropriately reducing costs without compromising quality, or (4) transitioning from health care delivery mechanisms based on volume to mechanisms based on value.

Perhaps one of the most significant discrepancies between the two final rules is OIG's decision to exclude key segments of the health care and life sciences industry from protection under the value-based safe harbors. CMS, in contrast, did not exclude any entities from the scope of the Stark law's exceptions. Specifically, OIG excluded the following entities from the value-based safe harbors' and the outcomes-based payment provisions of the personal services and management contracts safe harbor's protections: pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers (PBMs); laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices or medical supplies; entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and medical device distributors and wholesalers (collectively, "ineligible entities").

OIG Value-Based Safe Harbors

OIG finalized three new safe harbors for remuneration exchanged between or among participants in value-based arrangements and developed new terminology to define the scope of value-based arrangements that may qualify for safe harbor protection. The value-based safe harbors, as finalized, are similar to the safe harbors OIG proposed in 2019,[2] with some modifications. The three safe harbors provide greater flexibility, and impose fewer requirements, as the parties to the value-based arrangements take on more financial risk. The three safe harbors are: (i) care coordination arrangements to improve quality, health outcomes, and efficiency; (ii) value-based arrangements with substantial downside financial risk; and, (iii) value-based arrangements with full financial risk.

Care Coordination Safe Harbor

The care coordination safe harbor protects arrangements involving in-kind remuneration exchanged between a VBE and VBE participant, or between VBE participants, when such remuneration is used predominately to engage in value-based activities that are directly connected to the coordination and management of care of the target patient population. The entities do not have to assume any financial risk to avail themselves of this safe harbor's protections; however, the parties must document the value-based arrangement's material terms in writing in advance of, or contemporaneous with, the commencement of the value-based arrangement.

Among the safe harbor's 13 requirements, the remuneration may not be used or exchanged for marketing or patient recruitment activities, or more than incidentally for billing or financial management services. The arrangement must be commercially reasonable, and the terms must be set forth in a writing that is signed in advance of, or contemporaneous with, the commencement of the value-based arrangement. Protected arrangements cannot: induce VBE participants to furnish medically unnecessary care or reduce or limit medically necessary care; limit medical decisionmaking or patient freedom of choice; or take into

account the volume or value of referrals of patients who are not part of the target patient population or business outside the value-based arrangement.

While this safe harbor does not generally protect remuneration exchanged by ineligible entities, the Care Coordination safe harbor permits digital health technology to be provided by certain device manufacturers and DMEPOS suppliers to a VBE or VBE participant. "Digital health technology" is defined by OIG as hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care.

One of the key requirements of the Care Coordination safe harbor is that the parties must establish one or more outcome or process measures (not based solely on patient satisfaction or convenience) that are reasonably anticipated to advance the coordination and care management of the target patient population. The outcome or process measures must include at least one benchmark against which the parties can periodically evaluate the arrangement to establish whether it has advanced the care coordination and management of the target patient population. If, based on the benchmark, it is determined that the value-based arrangement resulted in material deficiencies in care or is unlikely to further the coordination and management of care for the target patient population, the parties must, within 60 days, either terminate the arrangement or develop and implement a corrective action plan. Unlike the modifications to the personal services and management contracts safe harbor,[3] which require the agents of a principal to actually achieve the outcome measure to receive payment, the Care Coordination safe harbor requires only that the parties to the value-based arrangement *reasonably anticipate* that the outcome or process measures will advance the coordination and management of the target patient population's care.

Finally, the safe harbor requires the VBE or VBE participant to retain documentation sufficient to establish compliance with the safe harbor's conditions for at least six years. A key distinction between the Care Coordination safe harbor and the corollary Stark law exception is that OIG's safe harbor is limited to in-kind remuneration, whereas the Stark law exception permits cash payments. Furthermore, the recipient of remuneration under the safe harbor is required to contribute at least 15 percent of the cost or value of the remuneration.

Value-Based Arrangements with Substantial Downside Financial Risk

The second safe harbor is for value-based arrangements with substantial downside financial risk and protects both cash and in-kind remuneration exchanged between a VBE and a VBE participant in cases where the VBE has assumed "substantial downside financial risk" from a payor for a period of at least one year and the VBE participant "meaningfully shares" in the VBE's substantial downside financial risk. OIG defined "substantial downside financial risk" as financial risk the VBE assumes via certain shared savings and losses methodologies, episodic payment methodologies, and partial capitation methodologies.[4] A VBE participant "meaningfully shares" in the VBE's substantial downside financial risk if the VBE participant (1) assumes two-sided risk for at least 5 percent of the losses and savings; or (2) receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, for which payment is designed to approximate the expected total cost of those expenditures for the predefined items or services. VBE participants cannot separately claim payment in any form from the payor for the predefined items or services covered by the partial capitated payment.

The remuneration between the VBE and the VBE participant must be directly connected to one or more of the following value-based purposes: the coordination and management of care; improving the quality of care; and appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care. The value-based arrangement may not induce the reduction or limitation of medically necessary items or services furnished to any patient.

The Substantial Downside Financial Risk safe harbor is not available to ineligible entities and does not protect downstream arrangements among VBE participants or ownership and investment interests in the VBE or any distributions thereof.

Similar to the Care Coordination safe harbor, the Substantial Downside Financial Risk safe harbor also includes documentation requirements and prohibits the use of the remuneration for marketing or patient recruitment activities.

Value-Based Arrangements with Full Financial Risk

The third value-based safe harbor protects both cash payments and in-kind remuneration exchanged between a VBE and a VBE participant in cases where the VBE, or a VBE participant, other than the payor, acting on behalf of the VBE, has assumed, through a written contract or a value-based arrangement, "full financial risk" on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in a target population.[5] The Full Financial Risk safe harbor contains fewer requirements than the Care Coordination and Substantial Downside Financial Risk safe harbors but, like the other safe harbors, does not protect downstream arrangements or ownership or investment interests in the VBE or any distributions related to an ownership or investment interest. Because protection under this safe harbor requires the VBE or VBE participant to assume full financial risk for the cost of all of the items and services provided to a target patient population, it is likely unattainable for most entities.

CMS Value-Based Arrangement Exceptions

Similar to OIG, CMS finalized three new exceptions to protect compensation arrangements with physicians that are implemented within a VBE. The value-based exceptions are similar to the exceptions CMS proposed in 2019,[6] with some modifications. Like the OIG safe harbors, the three exceptions provide greater flexibility, and impose fewer requirements, as the parties to the value-based arrangement take on more financial risk. The three exceptions are: (i) value-based arrangements where certain requirements are met; (ii) value-based arrangements where the physician assumes meaningful downside financial risk; and (iii) value-based arrangements where the VBE assumes full financial risk from the payor.

Value-Based Arrangement Exception

The most broadly applicable value-based exception to the Stark law promulgated by CMS protects value-based arrangements that are set forth in a writing (signed by the parties) that details the following: (1) the value-based activities to be undertaken under the arrangement; (2) how the value-based activities are expected to further the value-based purpose(s) of the VBE; (3) the target population for the arrangement; (4) the type or nature of the remuneration; (5) the methodology used to determine the remuneration; and (5) the outcome measures against which the recipient of the remuneration is assessed, if any (which outcome measures must be objective, measureable, and selected based on clinical evidence or credible medical support).

In addition, the value-based arrangement must be commercially reasonable

and the remuneration paid to the physician must: (i) be for, or result from, value-based activities undertaken by the physician for patients in the target patient population, and (ii) be calculated based on a methodology that is set in advance of the physician undertaking the value-based activities for which he/she is receiving remuneration. Furthermore, the remuneration cannot be an inducement to reduce or limit items or services that are medically necessary and cannot be conditioned on the referral of patients who are not part of the target patient population or business not covered by the value-based arrangement. The payment of remuneration to the physician under a value-based arrangement can be conditioned on the physician's referrals to a particular provider, practitioner, or supplier but must be set out in writing and cannot be required if: the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

Finally, the parties must frequently monitor the value-based arrangement to assess: (i) whether the parties have furnished the value-based activities required under the arrangement; (ii) whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the VBE; and (iii) progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. If the monitoring shows that a value-based activity is not expected to further the value-based purpose(s) of the VBE, or that an outcome measure is unattainable, the parties must either terminate the arrangement or modify the arrangement on a prospective basis to remove and replace the value-based activity or outcome measure against which achievement of the value-based purpose is being assessed.

Exception for Meaningful Downside Financial Risk to the Physician

CMS also created an exception specific to value-based arrangements under which the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE over the duration of the value-based arrangement. A physician is considered to have assumed "meaningful downside financial risk" if the physician must repay or forgo at least 10 percent of the total value of the remuneration that the physician is eligible to receive under the terms of the arrangement. The methodology for implementing the physician's assumption of risk could be structured, for example, as a withholding of compensation, a required repayment of compensation, or the ability to receive incentive payments.

In addition to being subject to the downside risk threshold, the remuneration paid under the value-based arrangement must satisfy several other elements that are in line with the more general value-based arrangement exception. Specifically:

1. the remuneration paid to the physician under the value-based arrangement must: (a) be for, or result from, value-based activities undertaken by the physician for patients in the target patient population, and (b) be calculated based on a methodology that is set in advance of the physician undertaking the value-based activities for which he/she is receiving remuneration.
2. The remuneration cannot be an inducement to reduce or limit items or services that are medically necessary and cannot be conditioned on the referral of patients who are not part of the target patient population or business not covered by the value-based arrangement.
3. The payment of remuneration to the physician under a value-based arrangement can be conditioned on the physician's referrals to a particular provider, practitioner, or supplier but must be set

out in writing and cannot be required if: the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

Unlike the more general exception, however, there is no explicit requirement that the arrangement be commercially reasonable, and there are no specific monitoring requirements or timeframes. It should be noted that this exception does not parallel the OIG safe harbor for value-based arrangements with substantial downside financial risk, as the OIG safe harbor focuses on the level of risk assumed by the VBE, whereas the CMS exception is focused on risk assumed by the physician.

Full Financial Risk Exception

The final exception created by CMS is aimed at protecting remuneration paid within a VBE that has assumed full financial risk. Because CMS believes that meaningful assumption of downside financial risk is likely to curtail, to some extent, the patient and program abuses that arise from incentives inherent under fee-for-service payment models to order medically unnecessary or overly costly items and services, it is the exception with the fewest requirements, and the elements that a value-based arrangement must include to comply with this exception are limited. A VBE will be considered to be at "full financial risk" if it is financially responsible on a prospective basis for the cost of all patient care items and services covered by a payor for patients in the target patient population over a specified period of time. For Medicare patients, this would mean that the VBE is responsible for all items and services covered under Medicare Parts A and B for a target patient population.

First, the VBE within which the remuneration is being paid must be at full financial risk (or contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the arrangement.

Second, the remuneration paid to the physician under the arrangement:

1. Must be for, or result from, value-based activities undertaken by the physician for patients in the target patient population.
2. Cannot be an inducement to reduce or limit items or services that are medically necessary and cannot be conditioned on the referral of patients who are not part of the target patient population or business not covered by the value-based arrangement.
3. Can be conditioned on the physician's referrals to a particular provider, practitioner, or supplier but must be set out in writing and cannot be required if: the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

Although the VBE must be at full financial risk, a value-based arrangement that may take advantage of this exception is not prohibited from paying downstream contractors, including physicians, on something other than a full-risk basis.

Conclusion

OIG and CMS both emphasized their goal of removing regulatory obstacles and impediments to the implementation of value-based payment programs. To that end, both agencies finalized value-based "protections" that are seemingly broad and stray from the proscriptive nature of historical safe harbors and exceptions.

Here are some key takeaways from the final rules and considerations for entities contemplating entering into value-based care models and arrangements:

- Although the full financial risk safe harbor and exception are less onerous than the other value-based exceptions, they likely currently are available only to a small number of entities. In general, for example, a VBE that receives a capitated payment (a fixed per-member-per-month amount) or a global budget payment may be able to rely on the safe harbor and exception. Questions remain regarding how VBEs may take on such high levels of risk, including whether the VBEs would be required to comply with state licensure laws that apply to risk-bearing entities.
- Historically, fair market value has been a key determinant of the legitimacy of remuneration. The value-based safe harbors and exceptions do not require remuneration to be fair market value; however, without a fair market value requirement, it is unclear how OIG and CMS will evaluate the legitimacy of remuneration exchanged in value-based compensation arrangements. In addition, value-based arrangements may be coupled with arrangements for the provision of items or services. As a result, as a risk mitigation strategy, entities availing themselves of the value-based exceptions and safe harbors may wish to consider if and how fair market value may serve a purpose in supporting the remuneration paid or given under the value-based arrangement. This may be particularly useful to support the aggregate remuneration paid to the referral source if multiple arrangements are involved.
- The sheer number and extent of the value-based safe harbors' requirements, along with the categorical exclusion of key segments of the health care and life sciences industry, raise questions as to the extent to which the AKS value-based safe harbors actually will promote innovative value-based and care coordination arrangements.
- The new Stark law exceptions contain fewer requirements and restrictions than the new safe harbors. The agencies noted that the differences between the two regulatory schemes are intentional. CMS sought to create exceptions that would allow parties to implement and develop arrangements that avoid the Stark law's strict liability and will look to the OIG regulations as "backstop" protection to capture actors with bad intent.
- Parties contemplating entering into a value-based arrangement should be aware of the resources and infrastructure that may be required to carry out the arrangement in a manner that complies with a safe harbor and/or exceptions. Required elements of each safe harbor and exception include the establishment of metrics, collecting and analyzing data, and monitoring outcomes.

While the final rules may appear to be a welcome change, only time will tell how the new safe harbors and exceptions are interpreted and enforced and how much latitude CMS and OIG will provide to parties engaging in value-based arrangements, particularly if those arrangements ultimately do not achieve a value-based purpose.

Endnotes

1. *See* OIG, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 85 FR 77684 (Dec. 2, 2020), *available at www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the*. *See also* CMS, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 85 FR 77492 (Dec. 2, 2020), *available at www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations*.
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 www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the*.

3. OIG finalized, with modifications, its proposal to revise the personal services and management contracts safe harbor to protect certain outcomes-based payment arrangements that facilitate care coordination, encourage provider engagement across care settings, and advance the transition to value. Although the personal services and management contracts safe harbor is not a "value-based safe harbor," the revisions made to this safe harbor are intended to promote innovation and value-based care.
4. More specifically, a VBE is at substantial downside financial risk if it were subject to risk pursuant to one of three methodologies: (1) financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care; (2) financial risk equal to at least 20 percent of any total loss, where savings and loss is calculated by comparing current expenditures for all items and services furnished collectively in more than one setting to the target patient population pursuant to a defined clinical episode of care that is covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of care for the defined clinical episode of care; or (3) A prospective partial capitated payment from the payor that is: (i) designed to produce material savings and (ii) paid on a monthly, quarterly, or annual basis, for a predefined set of items or services furnished to a target patient population designed to approximate the expected total cost of expenditures for the predefined set of items and services.
5. The safe harbor provides for a one-year phase-in period, during which time the parties may exchange protected remuneration if all of the safe harbor's other conditions are met.
6. *See* CMS, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 84 FR 55766 (October 17, 2019), available at *https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations*.

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