NEW STARK LAW AND ANTI-KICKBACK REFORMS AIMED AT VALUE-BASED CARE

Overview. OIG and CMS, through a coordinated effort, issued sweeping and much-anticipated final changes to the Anti-kickback and Stark rules. These changes are generally physician and industry-friendly.

Background. On November 20, 2020, the Department of Health and Human Services (HHS), through a coordinated effort between the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG), publicly released final rules that overhaul the regulations governing the federal Physician Self-Referral Law (Stark Law) and Anti-Kickback Status (AKS), as well as the Civil Monetary Penalty (CMP) Law. These rules were formally published in the Federal Register on December 2, 2020.

While the rules provide broad updates and revisions to both the Stark and AKS regulatory schemes, a central focus is to facilitate value-based arrangements in health care delivery. This is reflected in new exceptions and safe harbors that are specific to value-based activities and arrangements. As part of HHS' "Regulatory Sprint to Coordinated Care," the rules were developed by CMS and OIG in an effort to "advance the transition to a value-based healthcare delivery and payment system…" As stated by OIG, the rules are intended "to reduce the regulatory barriers to care coordination and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination."

Although CMS and OIG coordinated their rulemaking efforts, it is important to recognize that the rules contain meaningful differences. The exceptions to the Stark Law are somewhat broader, but also are governing by a strict liability civil statute that requires strict adherence to the elements of each exception. In contrast, the safe harbors set forth in the OIG rules reflect the intent-based criminal AKS. The OIG rules are somewhat narrower than the CMS rules. However, OIG points out that failure to adhere to every element in an OIG safe harbor does not necessarily mean that the AKS has been violated; rather, each arrangement will be evaluated in totality on a case-by-case basis to evaluate intent.

The Value-Based Regulatory Framework. In broad terms, both CMS and OIG have adopted value-based exceptions and safe harbors that are tiered based on the degree of risk assumed by the value-based enterprise (VBE): (1) full financial risk; (2) "substantial" or "meaningful" downside financial risk; or (3) other value-based arrangements not rising to the level of full, substantial or meaningful risk. Generally, the greater the risk assumed by the VBE, the broader the exception or safe harbor latitude.

CMS Rules: Stark Exceptions. In the Final Rule, CMS created three regulatory value-based exceptions combined into one new subsection of the Stark Law compensation exceptions. These exceptions were created in response to industry concerns that common and beneficial arrangements, such as gainsharing, pay-for-quality arrangements, and clinically integrated networks, triggered Stark Law

scrutiny, but were not protected by existing exceptions. To qualify as a value-based arrangement, the arrangement must be reasonably designed to achieve at least one value-based purpose. For more additional information on what qualifies as a value-based arrangement, please reference the Stark/AKS FAQ on ACP Online under Regulatory Resources.

Full Financial Risk. This exception applies to value-based arrangements among VBE participants in a VBE that has assumed full financial risk for the cost of all covered items and services for each patient in the target patient population for the entire term of the value-based arrangement. Assuming that the VBE can satisfy this requirement, the VBE Participants can enter into value-based arrangements with each other without significant restrictions. Importantly, there is no requirement that the physicians who are VBE Participants take on any downside financial risk themselves; instead, the financial risk must be taken by the VBE. There are also no additional restrictions such as a fair market value or volume and value of referrals limitations.

PRACTICE NOTE: If a clinically integrated network agrees to manage the delivery of care to a payor's enrollees for a set capitated amount of money, that would satisfy the "full financial risk" requirement. In contrast, being at full financial risk for only a portion of patient care does not satisfy this requirement. Notably, this type of true full financial risk, with no carve out for specific items or services, is rare and presents other regulatory challenges (e.g., state regulation of insurance).

PRACTICE NOTE: While CMS did not create specific set in advance and writing requirements, parties that take advantage of the full risk exception must nonetheless create a written record of the value-based arrangement.

Meaningful Financial Risk to the Physician. As noted, the main difference between the full financial risk exception and the meaningful downside risk exception is the level of risk that the physician needs to take. This exception applies to value-based arrangements in which a physician is at "meaningful downside financial risk" for the entire term of the value-based arrangement, which is defined to mean the physician is at risk for at least 10 percent of his or her total remuneration. While the full risk exception applies to risk that is accepted by the VBE, the meaningful downside risk exception applies to risk accepted by the physician.

CMS has also set some additional regulatory requirements commensurate with the lower level of financial risk (i.e., from 25 percent to 10 percent). Specifically, the description of the nature and extent of the downside risk must be set forth in writing, and the methodology used to determine the amount of remuneration must be set in advance of the undertaking of the value-based activity for which the remuneration is paid. In contrast, the full financial risk exception does not have the writing and set in advance requirements.

PRACTICE NOTE: Like the full financial risk exception, there is a requirement that records must be made and retained for six years documenting the methodology for determining, and the actual amount of, remuneration paid.

Indirect Value-Based Arrangements Regardless of Level of Risk Undertaken by VBE or VBE Participants. In its Final Rule, CMS recognized that value-based arrangements will often create indirect compensation arrangements between a physician and another VBE Participant that is a designated health services (DHS) entity. Therefore, CMS finalized its proposal to make exceptions to the referral prohibition applicable to indirect financial arrangements where the relationship closest to the physician is a value-based arrangement. This, along with the revisions to the definition of an "indirect compensation arrangement" will help provide more flexibility for physician compensation in connection with value-based arrangements that would not otherwise be protected under existing exceptions.

OIG Rules: AKS Safe Harbors. As is the case with the CMS Stark exceptions, OIG issued three new safe harbors for value-based arrangements, each tied to the level of risk assumed by the VBE and, potentially, a VBE participant.

VBE Assumes Full Financial Risk. Generally protects monetary or in-kind remuneration between VBE and VBE participants, provided the VBE is at full risk for all health care items, supplies, devices, and services, on a prospective basis for at least a year with a payer for each patient in the target patient population, through a written value-based arrangement that specifies all material terms.

Substantial Downside Financial Risk. Generally protects monetary or in-kind remuneration between VBE and VBE participants, provided the VBE assumes "substantial downside risk" from a payer, and each VBE participant assumes a "meaningful share" of the VBE's total risk, as those terms are described in the rules, on a prospective basis for at least a year, through a written value-based arrangement that specifies all material terms. The assumption of risk provisions require that the VBE assume either 20 percent or 30 percent of any downside loss, depending on how that loss is calculated, and that the VBE participant assumes the 2-sided risk for at least 5 percent of the losses and savings, as applicable.

Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency. Generally protects in-kind remuneration only, exchanged between a VBE and VBE participants, or among VBE participants, if it used predominately to engage in value-based activities directly connected to coordination and management of care for the target patient population and does not result in more than incidental benefits for persons outside that target population. The arrangement must be set forth in writing and contain enumerated terms, and must be commercially reasonable, taking into account the arrangement itself and all value-based arrangements within

the VBE. The recipient must pay at least 15 percent of the offeror's cost or fair market value for the in-kind remuneration.

Notably, the protections of these new safe harbors and the other OIG-issued safe harbors are generally not available to certain entities. Additional information on this topic can be found in the FAQ which is located on ACP Online under Regulatory Resources.

Impact of New AKS Safe Harbors. The three Stark Law value-based exceptions cannot be reviewed in silo. For many value-based arrangements, parties will need to comply with both the Stark Law and the AKS. While the two risk-based exceptions are similar to their AKS counterparts, the no risk value-based exception and safe harbor have some important differences. These differences are summarized below.

> **PRACTICE NOTE:** It is often the case that meeting a Stark Law exception also means there is little AKS risk, yet an arrangement that meets a Stark Law value-based arrangement exception still must also be analyzed for AKS purposes. For a number of reasons, arrangements that meet a Stark Law exception might not need an AKS safe harbor.

1. Under the value-based arrangement exception, CMS will allow for monetary and in-kind remuneration to be protected. In contrast, OIG will only protect in-kind remuneration under its safe harbor that protects care coordination arrangements to improve quality, health outcomes, and efficiency. While OIG has created other potential safe harbors for monetary value-based arrangements, it does not appear that the new safe harbors align with the CMS value-based exception.
2. Under the value-based arrangement AKS safe harbor, OIG requires that the recipient of the in-kind remuneration contribute at least 15% of the value of the item or service. The value-based Stark Law exception has no contribution requirement. Therefore, if a referral source receives in-kind remuneration and does not contribute to the cost, the compensation arrangement should include safeguards or other evidence that the remuneration does not induce referrals of federal healthcare program patients.
3. OIG requires that arrangements seeking protection under its no-risk value-based safe harbor be designed to coordinate the care and management of a patient population. CMS ultimately declined to adopt that standard in its Final Rule definition of value-based arrangement. Therefore, if a value-based arrangement does not coordinate care and manage a patient population, the compensation arrangement should include safeguards or other evidence that the remuneration does not include referrals of federal healthcare program patients.
4. As discussed, CMS declined to add the "referrals" restriction in the definition of value-based activities. In its Final Rule, CMS explicitly notes that sometimes making a referral is, in fact, a value-based activity. Yet, OIG declined to align its definition of value-based activity, precluding referrals from being considered value-based activities. The problem with this disparity is that value-based arrangements will, by their very nature, involve compensation that is contingent on

retaining patients within the VBE and, when protocols warrant, referring patients for certain items or services.

PRACTICAL TAKEAWAYS. For those involved in or considering value-based arrangements, the following points should be considered:

- As a general proposition, these rule changes are significant and are industry-friendly. As it relates to value-based arrangements, they provide new guidance that can help drive risk decisions and structuring details or modifications.
- While the rules were developed in coordination between CMS and OIG, there are significant differences in content and impact. As a result, many arrangements will need to be evaluated under both sets of rules and potential inconsistencies will need to be resolved.
- Remember that the OIG rules are generally more restrictive than the CMS rules. Failure to meet an OIG safe harbor, however, does not end the AKS analysis; a case-by-case assessment should be undertaken.
- Neither CMS nor OIG rules pertaining to value-based arrangements protect ownership relationships.
- In general, a value-based arrangement not only must meet regulatory requirements at the outset, but will need to be monitored and assessed on an ongoing basis to show continuing performance with corrective action if deficiencies are identified.