CMS and OIG propose three new value-based care exceptions to remove value-based payment barriers

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Part of the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the regulations interpreting the Physician Self-Referral Law (Stark Law), released on October 9, 2019, includes three new exceptions for value-based arrangements. CMS believes that these changes will facilitate value-based health care delivery and payments and will not pose a risk of program or patient abuse. CMS' goals are to remove regulatory barriers that may inhibit the transition to value-based care and to encourage value-based payment models.

On the same day, the Office of Inspector General (OIG) also released proposed changes interpreting the federal Anti-Kickback Statute (AKS) and its regulatory safe harbors, including proposals for three new value-based arrangement safe harbors. While the CMS and OIG proposals for value-based arrangements are similar in many respects, they contain several important differences.

Specifically, CMS is proposing the following three new compensation exceptions for direct and indirect value-based arrangements:

- The **full financial risk** exception protects remuneration paid under a value-based arrangement in which a value-based enterprise (VBE)[1] has assumed full financial risk (or is contractually obligated to be at full financial risk within the first six months) on a prospective basis from a payor for all patient care items and services for a target patient population during the term of the arrangement. "Full financial risk" can include capitation payments or global budget payments from a payor or other similar types of payments.
- The **meaningful downside financial risk** exception protects value-based arrangements in which the physician has

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meaningful downside financial risk for failure to achieve the value-based purposes of the VBE during the entire term of the arrangement. In this exception "meaningful downside risk" means that the physician is responsible to pay at least 25 percent of the value of the remuneration received on a prospective basis or the physician assumes full financial risk, such as a capitation payment or global budget payment.

- The value-based arrangements exception protects remuneration paid under any value-based arrangement, regardless of the level of risk undertaken by the VBE or any of its VBE participants, if (i) the arrangement is in writing, signed by the parties and includes (a) the value-based activities, (b) how they further the value-based purposes of the VBE, (c) the target population, (d) the type or nature of remuneration, (e) the method used to determine the remuneration and (f) the performance or quality standards against which the recipient of the remuneration will be measured, if any; and (ii) the performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.

Likewise, the OIG is proposing the following value-based safe harbors:

- The full financial risk safe harbor protects arrangements in which a VBE accepts full financial risk, which has generally similar requirements to the proposed Stark full financial risk exception.
- The substantial downside financial risk protects arrangements in which a VBE assumes substantial downside financial risk and differs in several respects from the proposed Stark exception for meaningful downside risk. For example, in the AKS safe harbor, “substantial financial risk” means for the entire term of the arrangement the VBE either (i) shares savings with a repayment obligation of 40 percent of shared losses; (ii) has a repayment obligation of at least 20 percent of any loss under an episode or bundled arrangement; (iii) has a prospectively paid population payment meeting specified requirements; or (iv) has a partial capitation payment. In addition, the VBE participant must meaningfully share in the VBE’s substantial downside financial risk.
- The care coordination safe harbor protects arrangements in which remuneration is exchanged "in-kind" among VBE participants primarily to encourage care coordination and is generally aligned with the proposed Stark value-based arrangements exception. Unlike the Stark value-based arrangements exception, however, the OIG’s care coordination safe harbor requires that the arrangement is “commercially reasonable” and does not permit arrangements involving marketing to patients for items, services or patient recruitment activities.

Overall, the proposed Stark exceptions and OIG safe harbors include fewer requirements if the VBE assumes full financial risk (*i.e.*, they receive no fee-for-service payments in addition to value-based payments). The proposed Stark definitions for "meaningful downside financial risk" and "value-based arrangements" also require that the method to determine the remuneration for the value-based exceptions (but not the actual amount) be “set in advance” of the value-based activities.

In addition to the above requirements, all three value-based Stark Law exceptions must satisfy the same five basic safeguards targeting risks associated with value-based arrangements, namely: (i) the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; (ii) the remuneration is not an inducement to reduce or limit medically necessary items or services to any patient; (iii) the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement; (iv) if the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner or supplier, the value-based arrangement satisfies the requirements applicable to directed referral arrangements; and (v) records of the method for determining and the actual amount of the remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the Secretary of Health and Human Services upon request.

Notably, the proposed Stark Law exceptions do not include the potentially problematic requirement that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician for the entity. CMS is seeking comments regarding whether the proposed exceptions are adequate to protect against fraud and abuse without this requirement and also whether it should add a requirement that the

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arrangement must be "commercially reasonable."

Although these proposed Stark Law exceptions do not prohibit remuneration that takes into account the volume or value of a physician's referrals, they do prohibit remuneration conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement.

These proposed Stark Law exceptions would also be applicable to compensation arrangements between the parties in CMS-sponsored models, programs or initiatives, so long as the compensation arrangement qualifies as a value-based arrangement, and would eliminate the need for new waivers of the Stark Law for value-based arrangements. However, parties can still elect to rely on the program-specific waivers.

CMS acknowledged that VBEs may involve risks, other than financial risk, such as operational, contractual and investment risk. However, it does not believe that these other types of risks would operate similarly to counter volume-based payment incentives. CMS is also proposing to keep in place the existing exceptions for services to enrollees and risk-sharing arrangements.

In this part of the proposed rules, CMS and the OIG are proposing new value-based exceptions that will help the industry move from volume-based to value-based payment models. These three new proposed Stark Law exceptions and AKS safe harbors will likely generate many public comments regarding how these proposals will impact real-life arrangements. Public comments on the proposed changes to the regulations interpreting the AKS and Stark Law are due December 31, 2019. As a result, the OIG and CMS will not finalize the proposed changes until 2020.

This publication is part of a series of updates regarding CMS and OIG's proposed fraud and abuse law changes. Bricker & Eckler's health care attorneys will continue to publish analyses of the proposed rule.

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[1]For purposes of the proposed new Stark Law exceptions, "value-based enterprise" (VBE) means two or more participants (1) collaborating to achieve at least one value-based purpose (such as coordinating care, improving quality of care of a target population, appropriately reducing payor costs or growth in expenditures without reducing quality, and transitioning from volume-based to value-based payment); (2) each of which is a party to a value-based arrangement with VBE participants; (3) that have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) that have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purposes.

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