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CLIENT ALERT

Stark Law Updates Aimed at Advancing the Transition to Value-Based Care: CMS Issues a Final Rule Creating New Exceptions for Value-Based Arrangements

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On December 2, 2020, the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") published in the *Federal Register* companion final rules that present significant changes to the regulatory framework of the federal physician self-referral law (commonly referred to as the "Stark Law"), the federal health care program's Anti-Kickback Statute ("AKS") and the federal civil monetary penalties ("CMP") law.[1] The final rules are the culmination of the agencies' efforts in connection with the Regulatory Sprint to Coordinated Care, an HHS-led effort to remove potential regulatory barriers to care coordination and value-based care that are inherent in the historical framework of the AKS and Stark Law that kicked off with the publication of proposed rules by CMS and OIG in October 2019.[2]

In the final rules, CMS acknowledges comments that the current physician self-referral law prohibitions are antithetical to the stated goals of policy-makers and explains that the agency is "finalizing an interwoven set of definitions and exceptions that depart from the historic exceptions to the physician self-referral law in order to facilitate the transition to a value-based health care delivery and payment system." The new rules go into effect

[1] *See* CMS, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 85 FR 77492 (Dec. 2, 2020), *available at* https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations. *See also* 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* https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

[2] *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. *See also*, OIG, "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 84 FR 55694 (Oct. 17, 2019), *available at* https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

January 19, 2021, except for certain changes that may impact the calculation of compensation and distributions provided within a "group practice," which do not become effective until January 1, 2022.

The CMS final rule adopts several new exceptions to the Stark Law, including three exceptions that interrelate with new safe harbors and corresponding modifications addressed by OIG in its final rule. These new exceptions and safe harbors aim to address the need for the health care fraud and abuse regulations to facilitate the transition to value-based care and foster care coordination instead of serving as an impediment. The new regulatory exceptions for value-based arrangements would apply to remuneration paid: (1) within a value-based enterprise that assumes "full financial risk"; (2) to a physician who assumes "meaningful downside financial risk"; and (3) when participants to a value-based arrangement do not assume financial risk, but the arrangement nonetheless encourages the delivery of coordinated patient care and promotes the goals of transitioning to a value-based payment model.

In addition to the new value-based arrangement exceptions, CMS adopted a new exception to the Stark Law concerning the provision of non-monetary remuneration to physicians in the form of cybersecurity technology and related services, as well as a number of modifications to the existing exception for electronic health records. Finally, CMS adopted a new exception for limited remuneration provided to a physician in a calendar year, which does not include some of the "technical" requirements found in other Stark Law exceptions, such as the writing and signature requirements.

The remainder of CMS's final rule focuses on modifications to, and clarifications of, a variety of concepts and issues impacting the overall application and interpretation of the Stark Law, which even though not specifically related to the implementation of value-based payment models may be relevant to accomplishing value-based objectives. Most significantly, CMS formally clarified several key terms and concepts that apply in many (if not most) of the Stark Law exceptions, such as the definitions of "fair market value" ("FMV"), "commercial reasonableness," and the "volume or value of referrals."

This Client Alert is the second in a series of Client Alerts that are intended to provide an overview of the OIG and CMS final rules and will specifically focus on the new Stark Law exceptions for value-based arrangements. This Client Alert will be followed by our final Client Alert in the series, which will address the new exceptions for cybersecurity technology and services and limited remuneration to physicians, as well as the modifications to other definitions, exceptions, and key concepts. For an overview of the OIG final rules that modify the AKS and CMP law, please refer to our previously published Client Alert.

An overarching issue addressed in both the OIG and CMS final rules is the interrelationship between the AKS safe harbors and Stark Law exceptions. Despite their mutual goal of preventing fraud, waste, and abuse in federal health care programs, OIG and CMS acknowledge that, where appropriate, they try to develop consistency in the definitions and requirements that are fundamental to the AKS safe harbors and Stark Law

exceptions. On a positive note, CMS eliminated an element found in several Stark Law exceptions that required the financial relationship to comply with the AKS and other federal and state laws and regulations governing billing or claims submission. At the same time, the rules established by CMS and OIG diverge in certain key respects that result in more expansive application of the Stark exceptions than the AKS safe harbors. For example, CMS and OIG took different approaches in defining the types of health care stakeholders that can participate in a "protected" value-based arrangement—CMS imposed no limitations on the types of persons or entities that can participate in a value-based arrangement, while the OIG excluded a number of participants from safe harbor protection, including clinical labs, durable medical equipment suppliers, compounding pharmacies, and others.[3] In allowing the Stark Law exceptions to apply to a broader range of value-based arrangements, CMS noted that it relies on the AKS to serve as a "backstop" that will protect against abusive relationships entered into with improper intent.

New Exceptions for Value-Based Arrangements

The Stark Law prohibits physicians who have a financial relationship with an entity from referring patients to that entity for certain "designated health services" unless an exception is met. Many of the existing Stark Law exceptions have historically required that payments be set in advance, at FMV, and not determined in a manner based on the volume or value of referrals—limitations that may be interpreted to restrict value-based payments made to referring physicians for pursuing and achieving high-quality, cost-effective, and coordinated care. Accordingly, CMS finalizes three new exceptions for 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 throughout all three of the Stark Law exceptions (and align with corresponding terms used by OIG in its finalized corollary safe harbors):

- "**Value-based enterprise**" 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 (1) the VBE and one or more VBE participants or (2) 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

[3] CMS was swayed by commenter's concerns that excluding certain types of entities (in particular, laboratories and durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") suppliers) from participating in VBEs could inhibit the movement toward value-based care and limit the utility of the value-based exceptions. CMS stated, "We find the commenters' assertions that laboratories and DMEPOS suppliers may play a beneficial role in the delivery of value-based health care persuasive."

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.

A key factor in each of the new value-based exceptions is that the value-based arrangement furthers one of the four enumerated "value-based purposes." Despite assertions by CMS in both the proposed and final rules that it believes that stakeholders are familiar with the plain language and meaning of these purposes, none of the four finalized concepts has a universally accepted definition and all are continuing to evolve. One entity's concept of "improving the quality of care" or "coordinating and managing care" may be vastly different from another's. Interestingly, while it is expected that most value-based arrangements will involve activities that coordinate and manage care of a target patient population, the final rule neither defines "coordinating and managing care" nor requires that care coordination and management be included in order to qualify as a value-based arrangement. Notably, this is different than OIG's approach, which created a safe harbor that specifically relates to care coordination. And while it is beneficial that the rule protects a broad range of quality and care coordination activities and is not constrained by today's notions of quality and care coordination, it also leaves open the possibility of being second-guessed by future enforcers and highlights the need to document carefully that arrangements meet the criteria of the value-based exception.

The three exceptions, which provide greater flexibility, and impose fewer requirements, as the parties to the value-based arrangement take on more financial risk, apply to the following categories of arrangements: (1) value-based arrangements where certain requirements are met, (2) value-based arrangements where the physician assumes meaningful downside financial risk, and (3) value-based arrangements where the VBE assumes full financial risk from the payor. In finalizing these exceptions, CMS made it quite clear that the value-based arrangement exceptions are designed to facilitate creativity and innovation. In this way, although the regulations do not replace the waivers included in CMS-sponsored value-based programs, it is CMS's expectation that the new exceptions will eliminate the need for any new Stark waivers for value-based arrangements.

The exceptions apply irrespective of whether the arrangement relates to Medicare or non-Medicare patients or a combination of both. Importantly, CMS states that the exceptions are not intended to suggest that current value-based arrangements do not satisfy the requirements of existing exceptions to the physician self-referral law. The new exceptions apply only to "compensation arrangements" and not other types of financial relationships to which the physician self-referral law applies. In addition, in furtherance of the flexibility that may be required for these arrangements to be successful, CMS has not included in any of the value-based exceptions the typical requirements that the remuneration paid to the physician be consistent with FMV or not determined in a manner that takes into account the volume or value of referrals made by, or other business generated by, the physician.

Exception for Value-Based Arrangements That Meet Certain Requirements

In a move to further expand participation in value-based arrangements, CMS elected to finalize an exception of broad applicability to "value-based arrangements" that do not require physicians to bear financial or downside risk. CMS cited comments from the industry and took what it believes to be a bold move in finalizing this exception, stating:

> [I]t is not possible to transform health care without a strong, aligned partnership between entities furnishing designated health services and physicians. Those commenters noted that this alignment of financial interests is key to the behavior shaping necessary to succeed in a value-based payment system. They also asserted that permitting physicians and physician groups (especially smaller practices that are not used to risk-sharing or are too small to absorb downside financial risk) to assume only upside risk—or, for that matter, no financial risk—would encourage more physicians to participate in care coordination activities now while they continue to build toward entering into two-sided risk-sharing arrangements. In consideration of these and similar comments, as well as our belief that bold reforms to the physician self-referral regulations are necessary to foster the delivery of coordinated patient care and achieve the Secretary's vision of transitioning to a truly value-based health care delivery and payment system, we proposed an exception.

This exception is designed to be available to the largest number of entities regardless of risk, size, and sophistication. However, as we explain below, because this exception contains other extensive and complex safeguards, more akin to traditional Stark requirements, it may well deter participation of precisely those entities CMS desires to include.

The "value-based arrangements exception" to the Stark Law 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

(6) 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 (1) be for, or result from, value-based activities undertaken by the physician for patients in the target patient population, and (2) 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 (1) the patient expresses a preference for a different provider, practitioner, or supplier; (2) the patient's insurer determines the provider, practitioner, or supplier; or (3) the referral is not in the patient's best medical interests in the physician's judgment.

Further, and unique to this value-based exception, there are numerous administrative, tracking, measurement, and documentation requirements that serve to both evidence the value-based purpose of the parties as well as monitor its success. Specifically, the proactive and continuous monitoring element of this exception requires the parties to monitor, in real time, whether the value-based activities required under the arrangement have actually been furnished, the progress toward attainment of the outcome measurements, and whether and how continuation of the value-based activities is expected to further the purposes. Based upon this analysis, the parties must, if warranted, take appropriate measures to modify or terminate the ineffective activity, or risk compensating a physician during a period of noncompliance in violation of Stark. Monitoring must occur by the enterprise, or one or more of the parties to the arrangement, no less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than one year.

CMS expects that the activities that trigger payment be tied rationally to some measure of success and the movement towards achievement of a value-based goal, and that "they are operating *as intended* and serving *their intended purposes* . . . and have in place mechanisms to address identified deficiencies, as appropriate." Accordingly, each of these "value-based arrangements" must be evaluated and monitored continuously,

carefully, and in real time. These arrangements are thus not "set it and forget it" arrangements that can evergreen or renew with few modifications. They require active compliance monitoring and documentation that they are meeting their stated value-based purposes and goals.

Absent persistent and meaningful oversight, this is an area of not insignificant risk, in our estimation. Failure to appropriately monitor these value-based arrangements could lead to activities of parties no longer supporting the value-based goal, resulting in a conclusion that the remuneration under the arrangement is no longer protected by the exception. Unless another exception exists, these payments could violate Stark. Even the quality of the monitoring could be brought into question. Was the entity's monitoring and oversight reasonable and adequate? Did the entity know or should it have known that the value-based activity was not achieving its intended purpose? When did the VBE participants become aware, or should have become aware, of such failure? The totality of these requirements and the possibility of a value-based arrangement being deemed "ineffective" and therefore falling out of compliance with the exception may very well limit its adoption and use. This is a far cry from the bright line expected of an exception to the strict-liability Stark Law.

Exception for Value-Based Arrangements When There Is Meaningful Downside Financial Risk to the Physician

The second new exception is 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. This exception recognizes that not all providers are prepared to accept full financial risk but will consider participating in alternative payment models that provide for undertaking some downside financial risk. Although CMS believes that downside financial risk curbs the influence of traditional fee-for-service payments, contains inherent protections against program and patient abuse, and has great potential to shape behavior to improve outcomes, eliminate waste, and reduce cost, CMS nonetheless includes additional guardrails beyond those set forth in the full financial risk exception.

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 10 percent risk of repayment would apply to in-kind remuneration as well, such as infrastructure or care coordination services. This is a significant expansion from the proposed exception, which required physicians to be responsible for 25 percent of the total value of the remuneration received. 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, the following:

(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 (a) the patient expresses a preference for a different provider, practitioner, or supplier; (b) the patient's insurer determines the provider, practitioner, or supplier; or (c) the referral is not in the patient's best medical interests in the physician's judgment.

However, unlike the more generally applicable exception for value-based arrangements described above, there is no explicit requirement that the arrangement be commercially reasonable, and there are no specific monitoring requirements or time frames.

Exception for Value-Based Arrangement When There Is Full Financial Risk

The third exception is aimed at protecting remuneration paid within a VBE that has assumed full financial risk with a payor and contains the fewest requirements. The exception focuses on two key elements: (1) the degree of financial risk, and (2) how the remuneration is structured.

The first essential element is that 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. 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.

According to CMS, full financial risk may take the form of capitation payments or a global budget payment from a payor and would not prohibit other approaches to full financial risk. CMS states that, for Medicare patients, full financial risk is financial responsibility for all items and services covered under Medicare Parts A and B.

In a change from the proposed rule, CMS relaxed the time frame for becoming fully financially responsible, extending the time from six to 12 months after commencement of the value-based arrangement.

The second essential element is that 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; and

(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 (a) the patient expresses a preference for a different provider, practitioner, or supplier; (b) the patient's insurer determines the provider, practitioner, or supplier; or (c) the referral is not in the patient's best medical interests in the physician's judgment.

Helpfully, 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.

Indirect Compensation Arrangements to Which the Value-Based Exceptions Are Applicable

The Stark Law has long applied to not just direct, but also indirect remuneration between a physician and a designated health services ("DHS") entity, even when multiple entities or financial arrangements separate the two. The final rule addresses the application of the three value-based exceptions to indirect compensation arrangements and extends the value-based exceptions' protection to indirect compensation arrangements that qualify as value-based arrangements. The exceptions for value-based arrangements are available to protect the physician's referrals to an entity when an indirect compensation arrangement includes a value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party.

CMS believed that this clarification was necessary because compensation to a physician under a value-based arrangement could take into account the volume or value of referrals or other business generated by the physician for the entity, or may not be FMV for specific items or services provided by the physician—therefore, the indirect compensation arrangement may not be able to satisfy the current exception for indirect compensation arrangements.

To determine whether CMS's value-based exceptions could apply to an indirect arrangement, entities will need to determine if an indirect compensation arrangement exists and, if so, determine whether the compensation arrangement to which the physician (or practice) is a *direct party* would qualify as a value-based arrangement and

satisfy an applicable value-based arrangement exception. The link closest to the physician cannot be an ownership interest—it must be a compensation arrangement that meets the definition of a "value-based arrangement." This application of the indirect compensation analysis is applicable to indirect compensation arrangements that cannot avail themselves of the full financial risk exception, but seek to compensate physicians for enhancing value-based health care delivery and payment (not just providing items or services).

Price Transparency

In the proposed rule, CMS solicited comments on whether to include price transparency requirements as a condition to meet exceptions under the Stark Law, most notably the new value-based proposals. Specifically, CMS sought comments on whether requiring a referring physician to provide information to beneficiaries about the physician's financial relationships, price transparency, or other data that potentially impacts consumer purchasing would reduce harm to the Medicare program. However, CMS did not at that time have a specific proposal, though it did discuss briefly the use of posters, websites, and other notices designed to alert patients that cost sharing and pricing may differ with regard to referred DHS. Ultimately, in the final rule, CMS declined to finalize any changes to the Stark regulations specific to transparency-related required activities. In declining to directly address the issue of transparency, CMS agreed with commenters that requiring price transparency as an element of compliance with the physician self-referral law might not be the best mechanism to achieve the agency's objectives. The agency has already taken action outside of the physician self-referral law to address hospital and health insurer price transparency.

Looking Forward

While the adoption of exceptions specific to value-based arrangements appear to be a positive development in granting regulatory flexibility that is necessary to further the transition to value-based payment, these exceptions also come with a high degree of uncertainty. If past is prologue, interpretation and enforcement of these new rules by CMS will continue to be a work in progress, and it remains uncertain how much latitude CMS will provide to parties engaging in value-based arrangements, as well as how the intended "backstop" of the OIG's more narrow value-based AKS safe harbor protection will play out in the development of value-based arrangements and in future government enforcement actions.

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