SPECIAL REPORT

WAS 2023 THE RETURN OF THE STARK LAW?

What hospitals, health systems and other stakeholders can take away from increased Stark Law enforcement activity in 2023, and what it means for the future.

McDermott Will & Emery

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INTRODUCTION

The year 2023 was historic from a Stark Law enforcement perspective, as we witnessed a resurgence of False Claims Act (FCA) enforcement actions predicated on Stark Law violations. This increase was capped off in December 2023 by the largest-ever settlement predicated on alleged Stark Law violations in history. The 2023 enforcement actions primarily implicated physician compensation arrangements implemented by health systems and hospitals.

What lessons can be garnered for stakeholders in 2024 and beyond? This *Special Report* surveys several of the 2023 Stark Law enforcement actions and explains why, in light of recent regulatory developments, future complaints predicated on similar alleged conduct may be less likely or potentially, at least, more defensible. This *Special Report* then discusses key takeaways and compliance considerations gleaned from 2023 enforcement activity that may be useful to hospitals, health systems and other entities in tailoring their compliance plans. Finally, this *Special Report* offers several "best practice" recommendations for stakeholders to consider when developing physician compensation plans designed to expand their physician networks.

STARK LAW: OVERVIEW

The Physician Self-Referral Law (the Stark Law) prohibits a physician from making a referral to an entity for the furnishing of designated health services (DHS)[1] payable by Medicare if that physician (or immediate family member of the physician) has a financial relationship – including a direct or indirect ownership or investment interest or compensation arrangement – with the entity (a DHS Entity).[2] Further, a DHS Entity may not submit a claim or bill any payor for DHS furnished pursuant to the prohibited referral.[3] A person or entity that collects any amount from an individual billed in violation of the Stark Law is liable to the individual for an overpayment in the amount so collected, and failure to timely refund such overpayment may expose the person or entity to civil monetary penalties and potential exclusion from federal healthcare programs.[4] Further, violations of the Stark Law may also form the basis for liability under the federal FCA, for which violators may be liable for up to three times the value of the claims submitted plus additional fines per claim submitted.[5]

The Stark Law and its interpretive regulations contain numerous exceptions under which a physician is permitted to make referrals for Medicare-reimbursable DHS – and the DHS Entity receiving the referral is permitted to bill for such services – even if a financial relationship exists between the physician and the DHS Entity.[6] All elements of an applicable Stark Law exception must be squarely satisfied for the arrangement to be protected; otherwise, the referral is prohibited, and the DHS Entity may not submit a claim or bill for such service. For purposes of this *Special Report*, the Stark Law compensation exceptions – particularly those related to bona fide employment relationships (the Bona Fide Employment Exception)[7] and value-based arrangements (the Value-Based Exceptions)[8] – are especially relevant.

2023 STARK SETTLEMENTS: A SURVEY

Following several years of decreased activity, 2023 saw the resurgence of FCA settlements based on allegations of Stark Law violations, many of which focused on physician compensation arrangements that did not fit within any Stark Law exception. The settlements ranged from a few million dollars to $345 million,

[1] DHS includes all of the following services: (i) clinical laboratory services; (ii) physical therapy, occupational therapy, and outpatient speech-language pathology services; (iii) radiology and certain other imaging services; (iv) radiation therapy services and supplies; (v) durable medical equipment and supplies; (vi) parenteral and enteral nutrients, equipment, and supplies; (vii) prosthetics, orthotics, and prosthetic devices and supplies; (viii) home health services; (ix) outpatient prescription drugs; and (x) inpatient and outpatient hospital services. 42 C.F.R. § 411.351.

[2] 42 U.S.C. § 1395nn(a).

[3] 42 U.S.C. § 1395nn(a)(1)(B).

[4] 42 U.S.C. § 1395nn(g).

[5] *See* 31 U.S.C. § 3729(a)(1).

[6] 42 U.S.C. § 1395nn(b); *see* 42 C.F.R. §§ 411.355–411.357.

[7] The Bona Fide Employment Exception protects any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of DHS if the following conditions are strictly satisfied:

> (1) The employment is for identifiable services.
> (2) The amount of the remuneration under the employment is—
> (i) Consistent with the fair market value of the services; and
> (ii) Except as provided in paragraph (4), below, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.
> (3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.
> (4) Paragraph (2)(ii), above, does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).
> (5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of 42 C.F.R. § 411.354(d)(4).

42 C.F.R. § 411.357(c).

[8] *See* 42 C.F.R. § 411.357(aa).

which is the largest-ever FCA settlement predicated on violations of the Stark Law. Taken together, the settlements particularly underscore potential fraud and abuse risks faced by health systems that are seeking to increase revenue by implementing financial alignment strategies with referring physicians. Several of these 2023 Stark Law settlements are surveyed below.

In March 2023, a health system in Michigan paid more than $69 million to resolve allegations arising under a *qui tam* action that alleged violations of the FCA predicated on improper financial relationships with certain referring physicians and a physician-owned investment group that resulted in the submission of false claims to federal healthcare programs.[9] The alleged improper relationships involved financial arrangements spanning from 2006 to 2016, which did not satisfy any exception to the Stark Law, including medical director arrangements, employment relationships, and office space and equipment rental arrangements.

In April 2023, a health system in Maryland agreed to pay $5 million to resolve allegations the system submitted false claims to the Medicare program resulting from compensation arrangements that violated the Stark Law. The allegations arose from conduct that the health system self-disclosed to the government related to actual or potential Stark Law violations occurring from 2008 through 2011 related to the health system's compensation paid to certain cardiologists for interpretations of cardiovascular and peripheral imaging studies that allegedly exceeded fair market value (FMV).

In May 2023, a Massachusetts hospital, physician group (the Group) and the latter two entities' parent corporation agreed to pay more than $5.7 million to resolve allegations arising from a *qui tam* action alleging that several of their physician compensation plans, each entered into at some point prior to 2018, created direct or indirect financial relationships that violated the Stark Law. The government alleged that (i) at the end of each fiscal year, the hospital transferred a portion of its operating margin from certain hospital outpatient departments where the Group's physicians referred Medicare beneficiaries for outpatient hospital services to the Group, which used the amounts to cover employment expenses and distributed the excess to its employed physicians as a bonus based on either personally performed services or time-based units for hours worked (although, at least in one instance, in equal shares); (ii) the hospital similarly transferred a percentage of its operating margin to the Group with respect to two individual physicians who practiced at the hospital's main campus, and the Group compensated the physicians in a manner consistent with that described above; and (iii) the hospital transferred all of its profit for certain injectable drugs administered at the hospital's outpatient department to the Group, which then allocated the proceeds to physicians based on personally performed injections or time-based units of work. As the operating margin was calculated by the hospital by subtracting the hospital outpatient departments' expenses from its fiscal-year revenue, the operating margin thus included revenue derived from DHS. As such, the government alleged that these payment mechanisms ultimately served to incentivize the Group's physicians to order outpatient services at the hospital's outpatient departments by paying the Group's physicians bonuses, at least in part, out of the facility fees the hospital received from Medicare, creating a financial relationship between the hospital and the Group's physicians for which no Stark Law exception applied.

[9] The settlement did not include any determination of guilt.

In October 2023, an Illinois-based imaging company and its owner agreed to pay more than $85 million to resolve FCA allegations that, between 2014 and 2023, they had paid cardiologists compensation in excess of FMV to supervise positron emission tomography (PET) scans in violation of the Stark Law.[10] Additionally, the government alleged that the imaging company purportedly relied upon a consultant's FMV analysis that the company knew was premised on fundamental inaccuracies about the services being provided by the cardiologists and was ultimately withdrawn by the consultant.

In December 2023, a health system operating three hospitals and numerous other healthcare facilities paid $42.5 million to resolve a *qui tam* action. The action was brought in 2017 alleging FCA violations based upon the health system's financial relationships with certain physicians. The system allegedly provided non-employee neonatologists and surgeons with free services in the form of hospital-employed nurse practitioners, hospitalists and physician assistants, purportedly in exchange for referrals by the physicians to the system. It was further alleged that the system employees provided most of the professional care services at the system's neonatology intensive care unit, while the private neonatology physicians billed for and were reimbursed for that care.

Also in December 2023, a large, Indiana-based health system agreed to pay $345 million to resolve allegations that it violated the FCA by knowingly submitting claims to Medicare for services referred in violation of the Stark Law.[11] The complaint alleged that the system entered into compensation arrangements with physicians that exceeded FMV and/or took into account the volume or value of referrals made by such physicians for the purpose of capturing the physicians' "downstream referrals." The complaint also alleged the system sought out favorable FMV opinions by identifying valuation firms that employed more liberal valuation methodologies and, in at least one instance, provided a valuation firm with misleading and/or inaccurate data to obtain a favorable opinion upon which it relied when proceeding with implementing its proposed compensation plan.

The 2023 Stark Law settlements summarized above share many similar attributes. First, most of the settlements involved conduct by large health systems or hospitals, which are under increasing pressure to expand clinical integration of physician networks in the face of mounting financial pressures that negatively impact operating margins and financial sustainability. Second, most of the alleged Stark Law violations involved, at least in part, compensation arrangements that exceeded FMV, varied based on the volume or value of a physician's referrals or other business generated, and/or contained impermissible non-monetary remuneration. Finally, the settlements also illustrate the potential pitfalls of relying on FMV analyses that are based upon inaccurate or incomplete inputs.

STARK LAW ENFORCEMENT: NEW TREND OR FLASH IN THE PAN? LIMITATIONS OF THE 2023 STARK LAW SETTLEMENTS

While 2023 saw an uptick in FCA settlements predicated on violations of the Stark Law, it does not necessarily indicate that we will see similar or increased levels of enforcement activity in the future. While the 2023 settlements summarized above are

[10] https://www.justice.gov/opa/pr/mobile-cardiac-pet-scan-provider-and-founder-pay-85-million-resolve-allegedly-unlawful.

[11] As with similar settlements, there was no determination of guilt on behalf of the health system.

illustrative of enduring compliance risks facing health systems and other entities – particularly those risks related to compliance with Stark Law requirements surrounding FMV, volume/value, and potentially commercial reasonableness (often referred to as "the big three")[12] – there are notable limitations to the collective reach of these settlements. Specifically, many of the compensation arrangements that are the subject of the underlying settlements predated the final rule promulgated by the Centers for Medicare & Medicaid Services (CMS) in December 2020 that modernized and clarified the Stark Law regulations (the Modernization Rule).[13] Indeed, the changes introduced by the Modernization Rule call into question whether the underlying arrangements that formed the basis of the above-referenced 2023 Stark Law settlements would have been subject to the same or similar enforcement actions and resulting settlements to the extent they were entered into after the effective date of the Modernization Rule.[14]

Importantly, the Modernization Rule updated the definitions of "fair market value" and "general market value" and added a new definition of "commercially reasonable."[15] Additionally, the Modernization Rule provided a special rule for determining whether compensation "takes into account" the volume or value of a physician's referrals or other business generated, and revised the Stark Law's directed referral requirements, providing commentary that expressly permits a productivity bonus to be conditioned upon an established percentage or ratio of a physician's referrals to a particular provider, practitioner or supplier, as long as certain conditions are satisfied.[16]

In addition to the definitional changes to the Stark Law regulations introduced by the Modernization Rule, the Modernization Rule also created the new Value-Based Exceptions to the Stark Law, which provide significant regulatory flexibilities to support health systems moving toward operational models focusing on coordinated care. In particular, these flexibilities include, depending on the specific Value-Based Exception, no FMV requirements for compensation arrangements with physician referral sources, no prohibition on compensation paid to physician referral sources that varies with the volume or value of the physician's referrals or other business generated, and no requirement that compensation be set in advance. Additionally, the Value-Based Exceptions expressly permit directed referral relationships, provided certain conditions are satisfied. Taken together, strategic and appropriate use of the new Value-Based Exceptions may provide health systems with an additional tool to avoid allegations similar to those underlying some of the allegations that were subject to settlements outlined above. As discussed below, the regulatory flexibilities introduced by the Modernization Rule provide several avenues for achieving clinical integration within the confines of the Stark Law.

Modernization Rule – Definitional Updates and New Special Rules

a. Updates to the Definition of "Fair Market Value"

As previewed above, the Modernization Rule modified several important definitions of terms used throughout many Stark Law exceptions. First, the Modernization Rule amended the definition of "fair market value" to mean, in relevant part, the "value in an arm's-length

[12] Importantly, all of these elements are necessary to satisfy many of the most applicable Stark Law compensation exceptions for hospitals and health systems, including the Bona Fide Employment Exception.
[13] *See* 85 Fed. Reg. 77,492 (Dec. 2, 2020).
[14] We note that some of the Stark Law updates discussed in the Modernization Rule were clarifications of existing CMS policy.
[15] *See* 42 C.F.R. § 411.351.
[16] *See* 42 C.F.R. § 411.354(d)(4).

transaction, consistent with the general market value of the subject transaction."[17] Regarding compensation for services (versus, for example, rental of equipment or office space), the term "general market value" means "the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other."[18]

Parties to a financial arrangement are not required to obtain a formal, independent FMV opinion to demonstrate that an arrangement is in fact FMV, and to that end, stakeholders may establish their own internal methods for determining whether a particular financial arrangement reflects FMV. However, whether or not an independent FMV opinion or other salary survey is sought or relied upon, CMS, in its comments to the Modernization Rule, directly questioned stakeholders' reliance on a specific market benchmark or percentile, noting that "[w]e are uncertain why the commentators believe that it is CMS policy that compensation set at or below the 75th percentile is suspect, if not presumed appropriate," and clarifying that "[t]he commenters are incorrect that this is CMS policy."[19] Instead, CMS clarified that it does not view FMV as a "bright line" test regarding whether physician compensation exceeds FMV but rather that such determinations are unique to the particular parties and the particular arrangement. This clarification benefits health systems and other entities, which may have internal policies requiring elevated review, including by external, independent valuators, to the extent a proposed compensation arrangement exceeds a certain, specified percentile. Instead, health systems may consider relying upon legitimate "business judgment" factors as support for providing physician compensation in excess of a specified percentile, such as the importance of the physician (*e.g.*, name recognition, specialized skill set) and/or related service line, the community need for the physician's services, recruitment or retention difficulties, and leadership and business development considerations, among others. Indeed, given the more individualized approach CMS has intimated must occur related to FMV considerations, enforcement entities are now tasked with a higher burden than simply pointing to a "survey says" thesis as to why a compensation methodology failed to reflect FMV.

Notwithstanding this increased burden, a health system may still find it beneficial to retain the services of an independent valuation firm to opine on FMV, particularly where an arrangement is complex, unique, and/or otherwise purports to highly compensate an individual physician or group of physicians relative to other physicians providing services for that same health system. However, even where an independent FMV is obtained, the health system or hospital should be sure to communicate any legitimate business judgment factors (and the underlying data that support those factors) to their retained valuation firms to ensure that these are taken into account and incorporated into the final valuation report.

b. Defining "Commercial Reasonableness"

In the Modernization Rule, CMS explicitly defined what constitutes a "commercially reasonable" arrangement, clarifying that the phrase means "that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the

[17] 42 C.F.R. § 411.351.
[18] 42 C.F.R. § 411.351.
[19] 85 Fed. Reg. 77,492, 77,558 (Dec. 2, 2020).

parties."[20] In its commentary to the Modernization Rule, CMS explicitly noted that "[t]he determination of commercial reasonableness is not one of valuation,"[21] and clarified that when evaluating whether an arrangement is commercially reasonable, "[t]he test is not whether the compensation terms alone make sense as a means to accomplish the parties' goals; however, the compensation terms of an arrangement are an integral part of the arrangement and its ability to accomplish the parties' goals."[22] CMS provided several examples of why a party may enter into a particular business arrangement notwithstanding the fact that the arrangement may not ultimately be profitable, including, for example, that the arrangement furthers community need and timely access to healthcare services and improves quality and health outcomes – interestingly, and as explained above, these are factors that may potentially affect the FMV analysis. Given the definition promulgated, CMS is requiring a fact-specific inquiry to ascertain whether an arrangement is commercially reasonable, similar to the updated FMV definition. Such fact-intensive inquiries should similarly serve to allow entities better ground to defend against generalized allegations that an arrangement was not profitable, and therefore could not be commercially reasonable.

c. Updates to the "Volume and Value" Requirements

As part of the Modernization Rule, CMS also clarified the analysis that must be undertaken when evaluating whether compensation to or from a physician takes into account the volume or value of DHS referrals or other business generated, implementing two new special rules, respectively.[23] In pertinent part, with respect to a physician who *receives* compensation from an entity, CMS indicated that compensation will only take into account the volume or value of referrals if the formula used to calculate the physician's compensation includes the physician's referrals to or other business generated for the entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlates with the number or value of the physician's referrals to the entity.[24] These regulatory changes cast doubt as to whether the government or a relator would be successful in making similar arguments based on "volume and value" as they may have made in the past, particularly to the extent any such arguments conflict with the new rule.[25]

Finally, the Modernization Rule also added a new special rule related to directed referrals, which expressly permits incentive compensation to be conditioned on a physician's referrals to a particular provider, practitioner or supplier, provided that the arrangement satisfies certain conditions.[26] Specifically, physician incentive compensation may include a directed referral requirement if, among other elements, the requirement to make referrals to a particular provider, practitioner or supplier requires that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner or supplier.[27] Thus, CMS has expressly acknowledged that DHS Entities, including health systems, can pay productivity bonuses for meeting

[20] 42 C.F.R. § 411.351.
[21] 85 Fed. Reg. 77,492, 77,531 (Dec. 2, 2020).
[22] 85 Fed. Reg. 77,492, 77,532 (Dec. 2, 2020).
[23] *See* 42 C.F.R. § 411.354(d)(5), (6).
[24] 42 C.F.R. § 411.354(d)(5). A "positive correlation" is defined to exist in a compensation formula when one variable decreases as the other variable decreases, or one variable increases as the other variable increases. 42 C.F.R. § 411.354(d)(5)(iii).
[25] The authors note that as of the writing of this *Special Report*, the United States Supreme Court overturned the longstanding "*Chevron* deference" legal doctrine, which historically required courts to defer to federal agencies' interpretations of ambiguous statutes, so long as that interpretation was reasonable. With the upending of the *Chevron* deference doctrine, it is less clear how courts will handle actions brought before it where the matter rests on an interpretation of the Stark Law, which historically deferred to CMS's interpretation.
[26] 42 C.F.R. §§ 411.357(c)(5), 411.354(d)(4).
[27] 42 C.F.R. § 411.354(d)(4)(iv)(B).

certain in-network referral thresholds, provided that all other conditions of the Bona Fide Employment Exception or another applicable exception are satisfied, including, for example, the "volume or value" standard as set forth in the new, above-referenced special rule. Specifically, entities that elect to tie incentive compensation to a directed referral requirement must still ensure that the composition of the bonus pool from which incentive compensation is ultimately paid to the physician does not include referrals for DHS or other business generated as a variable.[28]

In sum, while the developments stemming from the Modernization Rule provide stakeholders with clearer guidelines and potentially increased flexibility when structuring physician compensation arrangements, the "big three" elements – FMV, commercial reasonableness, and whether compensation takes into account the volume or value of the physician's referrals or other business generated – continue to be crucial elements that must be evaluated for Stark Law compliance.

Modernization Rule – Value-Based Exceptions

In addition to the definitional and special rule updates described above, the Modernization Rule also introduced three new Value-Based Exceptions[29] to protect financial relationships where remuneration is paid to a referring physician pursuant to a "value-based arrangement," which, at a high level, means an arrangement for the provision of at least one "value-based activity" for a target patient population.[30] A core feature of each of the Value-Based Exceptions is the need to create a "value-based enterprise" (VBE), which refers to two or more participants collaborating to achieve at least one "value-based purpose."[31] A "value-based purpose" is defined as any of the following: (i) coordinating and managing the care of a target patient population;[32] (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (iv) transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.[33] A "value-based activity" is defined broadly to include the provision of an item or service or the taking or refraining from taking an action, provided that the activity is reasonably designed to achieve at least one value-based purpose.[34]

Once VBE participants have satisfied the relevant definitions to the Value-Based Exceptions, a tiered framework of three exceptions is available to protect the value-based arrangement, whereby the more downside financial risk that the VBE participants accept, the less stringent the standards of the applicable Value-Based Exception become. Conversely, for

[28] CMS noted that "[c]ompensation conditioned, either expressly or otherwise, on the physician making referrals of DHS to a particular provider, practitioner or supplier should not be evaluated for compliance with the volume or value standard" but clarified that the composition of the bonus pool from which the physician is ultimately paid in furtherance of a directed referral requirement must still adhere to the volume or value standard (among other requirements). 85 Fed. Reg. 77,492, 77,550 (Dec. 2, 2020).

[29] Technically, all three exceptions are covered under a single exception at 42 CFR § 411.357(aa) (Arrangements that facilitate value-based health care delivery and payment).

[30] 42 C.F.R. § 411.351. The value-based arrangement must be between the value-based enterprise and one or more of its VBE participants; or VBE participants in the same value-based enterprise. A "VBE participant" means "a person or entity that engages in at least one value-based activity as part of a value-based enterprise." 42 C.F.R. § 411.351.

[31] 42 C.F.R. § 411.351.

[32] A "target patient population" is defined as an identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that (i) are set out in writing in advance of the commencement of the value-based arrangement and (ii) further the VBE's value-based purpose(s). 42 C.F.R. § 411.351.

[33] 42 C.F.R. § 411.351.

[34] 42 C.F.R. § 411.351.

arrangements without meaningful downside financial risk, the applicable Value-Based Exception imposes more safeguards.

The new Value-Based Exceptions may be utilized by hospitals and health systems, among other stakeholders, to promote clinical integration while maintaining legally compliant compensation arrangements with physicians and physician groups. Notably, unlike other Stark Law exceptions, the Value-Based Exceptions do not contain an FMV component and do not otherwise prohibit compensation arrangements that vary with the volume or value of a physician's referrals.[35,36] Moreover, the Value-Based Exceptions may be utilized by as few as two VBE participants. Given that many of the 2023 Stark Law settlements summarized above concerned physician compensation arrangements with FMV and/or volume/value issues, it is possible that similar compensation arrangements – or at least particular elements of those compensation arrangements – could be structured to satisfy a Value-Based Exception, to the extent that such compensation arrangements satisfy the necessary definitional requirements for a value-based arrangement.

COMPLIANCE LESSONS AND TAKEAWAYS FROM THE 2023 STARK LAW SETTLEMENTS

In recent years, many hospitals and health systems have faced mounting financial pressures that negatively impact operating margins and financial sustainability. Several methods of expansion historically relied upon by health systems – such as investing in hospital infrastructure or building out service line offerings – are often not feasible due to the prohibitively large volume of upfront capital required to fund these types of projects. As a result, health systems are looking to alternative expansion methods, such as reviewing the "integrity" of their physician networks and looking at pathways to increase the "loyalty" of physicians within those networks as a means to achieving clinical integration. Hospitals see such efforts as a viable alternative to foster enterprise growth. While reviewing physician referral data to improve physician loyalty and network integrity does not in and of itself present risk from a fraud and abuse perspective, the methods by which the hospital or health system goes about obtaining or increasing such loyalty may pose material fraud and abuse risk. For example, a hospital that evaluates community referral data may determine that physicians are referring to other networks for reasons that include longer-than-average wait times for imaging turnarounds or patient complaints about staff. Generally, using network integrity data to improve safety, quality, access, patient experience, efficiency, delivery and continuity of care are all acceptable rationales for reviewing and acting upon such data. On the other hand, where a health system needs to navigate with tact is with respect to implementing physician alignment strategies involving financial arrangements similar to those at issue in the 2023 Stark Law

[35] *See* 85 Fed. Reg. 77,492, 77,510 (Dec. 2, 2020) ("The exception for *bona fide* employment relationships includes requirements that the arrangement is commercially reasonable, the compensation paid to the physician is fair market value, and the compensation is not determined in any manner that takes into account the volume or value of the physician's referrals. None of these requirements are included in the final exceptions at § 411.357(aa). Thus, depending on the terms and conditions of the value-based arrangement, the arrangement many be unable to satisfy all the requirements of the exception for *bona fide* employment relationships. That determination is, of course, fact-specific.").

[36] The authors note, however, that arrangements satisfying a Stark Law exception do not necessarily insulate an entity from enforcement under the Anti-Kickback Statute (AKS). The Office of Inspector General has promulgated similar value-based safe harbors that may contain volume or value constraints depending on the level of risk accepted by the VBE. Under the AKS, satisfaction of an applicable safe harbor is voluntary, but an arrangement that does not meet an applicable AKS safe harbor will be subject to a "facts and circumstances" review.

settlements, which implicate federal and state fraud and abuse laws, including the Stark Law.

While we have discussed the material limitations that can be gleaned from the 2023 Stark Law settlements based on recent regulatory updates promulgated by CMS via the Modernization Rule, there are additional compliance considerations illuminated by the settlements that benefit almost all hospitals and health systems contemplating contracting with physicians as a means of enhancing their overall physician network.

Proper Use of Valuation Firms

The Bona Fide Employment Exception requires, among other elements, that compensation paid to a physician is consistent with FMV – an element that the government focused on in many of the 2023 Stark Law settlements. As discussed above in this *Special Report*, although obtaining a formal FMV opinion is not required, a health system may consider doing so when preparing a new or complex compensation arrangement, particularly where the health system is contemplating compensating the physician substantially in excess of a certain, specified threshold.

When obtaining an FMV opinion, it is vital to provide the valuation firm with complete, correct and accurate data for purposes of the analysis. In order to ensure that accurate inputs are provided for an FMV analysis, it is a best practice for a health system to proactively discuss the scope and details of the analysis with the valuation firm to ensure all parties are aligned. For example, when preparing an FMV report, a valuation firm may assume that all relevant compensation data has been provided by the requesting health system; however, if the health system did not disclose certain forms of compensation that may be promised to a physician beyond his or her base compensation (*e.g.*, sign-on bonuses, guaranteed compensation and other forms of bonus/incentive compensation, including non-monetary compensation), then those types of compensation will not be factored into the ultimate analysis, which may result in a deficient FMV report. Such deficiencies can be avoided by the health system and valuation firm by having an up-front discussion to set forth the scope of the FMV analysis, including the information to be provided by the health system, what that information means, and the assumptions that the valuation firm will make based on that information. As discussed above in this *Special Report*, to the extent there are any unique business-related factors that may bear on an FMV analysis (and potentially a "commercial reasonableness" analysis), these should be clearly communicated to the valuation firm and documented in the ultimate FMV report. Once an FMV report is completed, the parties should again discuss options to ensure that the health system understands the valuation firm's analysis and recommendations.

Relatedly, health systems should thoughtfully approach obtaining second (or third) FMV opinions. Seeking additional FMV opinions may be valid in certain circumstances, such as where a valuation firm's methodologies used in its analysis are invalid or otherwise questionable or the client believes the valuation firm does not have the right skill set or experience for the engagement. However, the government may scrutinize instances of retaining a subsequent valuation firm where the originally retained firm renders a negative opinion that is supported by a valid analytical methodology. Thus, if retaining multiple valuation firms, it is a best practice to ensure there is a reasonable – and well-documented – basis to do so. Finally, it is also a best practice to engage valuation firms through counsel to be able to assert attorney-client privilege over their work in developing their final report and even over the final report itself.

Don't Lose Sight of Commercial Reasonableness

As discussed above, FMV and commercial reasonableness are distinct requirements. While a party may be confident that a financial arrangement reflects FMV through the receipt of a supportive FMV report, this does not necessarily mean that an arrangement is commercially reasonable or is reasonable and necessary to accomplish the legitimate business purposes of the arrangement. For instance, as cited by CMS in preamble commentary in the Modernization Rule, if a hospital requires only one medical director for a particular service line but engages multiple medical directors to provide the same services, such arrangements may potentially reflect FMV but not necessarily be supportable from a commercially reasonable perspective.[37]

Consider Use of the Value-Based Exceptions

The Value-Based Exceptions discussed in this *Special Report* may provide significant flexibility to a health system when structuring physician compensation arrangements that are designed to promote a value-based purpose. While the Value-Based Exceptions have now been available for several years, they were introduced when the entire healthcare industry was responding to the challenges presented by the COVID-19 pandemic, and thus utilization has been muted in many instances. As discussed above, the Value-Based Exceptions do not require that a financial arrangement be commensurate with FMV or avoid taking into account the volume or value of a physician's referrals or other business generated (although "commercial reasonableness" is still required for the Value-Based Exception without downside financial risk).[38] Thus, the Value-Based Exceptions may provide an attractive alternative for Stark Law protection in circumstances where their use is applicable.

Further, the Value-Based Exceptions may permit hospitals and health systems to provide non-monetary remuneration to physician VBE participants if it relates to the furnishing of a value-based activity that furthers a value-based purpose with respect to the target patient population. Prior to the promulgation of the Modernization Rule, the provision of non-monetary remuneration within a financial arrangement implicated by the Stark Law could only be protected by a small number of exceptions, such as the non-monetary compensation exception or the exception for medical staff incidental benefits.[39] In one settlement discussed above, a central allegation was that a health system furnished private physicians with free services in the form of hospital-employed nurse practitioners, hospitalists and physician assistants. Following the implementation of the Value-Based Exceptions, a value-based arrangement could theoretically be structured that contemplates the provision of support staff to a physician VBE participant in furtherance of achieving a value-based purpose, such as managing a target patient population across a care continuum, provided all other elements of the relevant Value-Based Exception were satisfied.

Notwithstanding the potential usefulness of the Value-Based Exceptions, a few notes of caution are warranted. First, if relying on a Value-Based Exception to protect a physician compensation arrangement, it is important for the entity to ensure that every element of the applicable exception is squarely satisfied. While the

[37] 85 Fed. Reg. 77,492, 77,533 (Dec. 2, 2020).
[38] We note that commercial reasonableness is not required for the Value-Based Exceptions with full financial risk or with meaningful downside financial risk to the physician, although it is required for the Value-Based Exception without financial downside risk. *See* 42 C.F.R. § 411.357(aa).
[39] 42 C.F.R. § 411.357(k), (m).

Value-Based Exceptions provide regulatory flexibility, the exceptions (and definitions) are very detailed and must be structured to achieve legitimate value-based outcomes. For example, if the parties to a value-based arrangement purport that a physician compensation plan furthers a value-based purpose to improve the quality of care for a target patient population, but, in practice, the compensation plan is not designed to further a value-based purpose, it may invite scrutiny from the government and whistleblowers. Finally, since the Value-Based Exceptions are still in their relative infancy, there is limited government interpretation available other than the regulatory text and CMS commentary in the preamble to the Modernization Rule. If relying on Value-Based Exceptions, health systems must be mindful to monitor for further updates and interpretations from the government and should be prepared to operationalize new guidance as it is made available.

Effective Physician Contracting Oversight

Whether relying on the Bona Fide Employment Exception, the Value-Based Exceptions, another Stark Law exception or any combination of the above, it is a best practice for a health system and other stakeholders to establish a compensation committee for the purpose of ensuring physician compensation arrangements squarely satisfy material elements of the exception(s) relied upon. When applicable, the committee should actively review and assess FMV reports that the health system has commissioned. In such instances, meaningful assessment and a critical eye to ensure the valuation firm has been provided accurate information should be top priorities, which may be achieved by proactively meeting with the valuation firm to ensure the parties are aligned regarding the inputs to the valuation as well as the assumptions that will be relied upon by the valuation firm. Moreover, the committee should carefully review any limitations noted in FMV reports to ensure such limitations do not render the report meaningless in relation to the actual or likely physician arrangement. For such functions to be actualized, compensation committees will likely need to take on a proactive role in physician contracting whereby the committee feels empowered to ask difficult questions and make requests of operators who, in some circumstances, may be looking to finalize physician contracts that are time sensitive. Compensation committees should also continue to monitor already-implemented compensation plans and make adjustments over time to reflect any material modifications to the arrangements, which may include incorporating updated financial terms as a result of subsequently obtained FMV analyses. While such reviews may require additional time and money, such actions could end up saving the health system from costly investigations and litigation.

It may also be beneficial for health systems to educate their business development and strategy teams to ensure they have a high-level understanding of the Stark Law and the material elements necessary to satisfy potentially applicable exceptions. This way, the individuals who are tasked with pitching to potential physician employees or contractors do not inadvertently present attractive compensation offers that potentially violate the Stark Law, such as offering incentive compensation that varies with the volume or value of the physician's referrals to the hospital, health system or DHS Entity.

CONCLUSION

The year 2023 saw increased Stark Law enforcement activity, highlighted by the largest-ever FCA settlement predicated on violations of the Stark Law. While the uptick in enforcement activity may be nerve-racking for health systems and other healthcare providers more

generally, the Modernization Rule has provided stakeholders with clearer guidelines and broader flexibilities by which to structure physician compensation arrangements, arguably creating a heightened burden for the Department of Justice or a whistleblower to identify a clear violation of the Stark Law predicated on much of the same conduct that formed the basis of the 2023 settlement agreements. This notwithstanding, health systems and other providers should continue to focus efforts on ensuring physician compensation plans comply with a relevant Stark Law exception. As illustrated by the 2023 enforcement actions, empowering compensation committees to oversee physician contracting, including by engaging with valuation firms and operationalizing advice received in FMV reports, may be an effective method to shield (or at least provide a strong defense) against potential Stark Law liability. Moreover, health systems may consider relying on the Value-Based Exceptions created by the Modernization Rule to provide greater regulatory flexibility when developing physician compensation plans. Finally, engaging with healthcare counsel may be a useful tool for health systems to help navigate the Stark Law compliance landscape in the aftermath of the 2023 enforcement actions and the implementation of the Modernization Rule.

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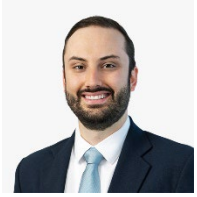

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