

What a Difference a Year Makes— Key Anti-Kickback Statute and Stark Law Developments

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Over the last year, we have seen two significant, and in some ways unprecedented, actions by the Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) in addressing the regulatory regime surrounding the “fraud and abuse laws”—the Physician Self-Referral Law¹ (known as the “Stark law”), the federal anti-kickback statute² (AKS), and the beneficiary inducement civil monetary penalty statute³ (BIS). First, CMS and OIG proposed the most substantial revisions to the regulations for these laws in the last decade.⁴ These proposals would create an entirely new construct—the value-based enterprise—to attempt to accommodate the Medicare payment system’s transition from fee-for-service to a value-based system. CMS and OIG did not stop there, also proposing numerous changes (and some clarifications to existing CMS positions) to the existing definitions, exceptions, and safe harbors, aimed at reducing compliance burden. Second, in response to the novel coronavirus (COVID-19) pandemic, CMS issued a nationwide blanket waiver of certain Stark law requirements for the duration of the declared emergency. OIG followed up with its own Policy Statement that corresponds to CMS’ Stark law waiver and created a new pathway for posing questions regarding AKS and BIS compliance issues.

Both are important actions by CMS and OIG to increase flexibility and reduce regulatory burden, and consequent False Claims Act exposure risk. Organizations, however, also should understand that these movements do not lessen the importance of compliance efforts. If anything, the importance has increased, and the focus has shifted to new areas. Compliance and legal departments should evaluate how to adjust their policies and auditing and monitoring efforts to address these current and proposed changes. Although this article does not cover every significant proposed change to the Stark law, AKS, and BIS, we endeavor to note those we

believe of most interest for compliance professionals.

THE OIG AND CMS PROPOSED RULE

Value-Based Arrangements

For value-based arrangements, OIG proposed three new safe harbors (full financial risk, substantial downside financial risk, and care coordination), and CMS proposed a new Stark law exception with different prongs (full financial risk, meaningful downside financial risk, and other value-based arrangements).⁵ In brief, the proposed new safe harbors and exception protect remuneration under a qualified value-based arrangement (VBA). A VBA is an arrangement for the provision of at least one value-based activity for a target patient population between a value-based enterprise (VBE) and one or more of its participants, or among participants in the VBE. A value-based activity means providing an item or service, taking an action or refraining from taking an action, so long as the activity is reasonably designed to achieve at least one value-based purpose and is not simply making a referral.

In theory, the exception and safe harbors should permit VBE participants to share value-based payments and other remuneration to coordinate the care of the target population. Compliance with the exception and safe harbors will require compliance resources and attention given the numerous requirements. The proposed Stark law value-based exception excludes many requirements common to other compensation exceptions such as that the remuneration be fair market value, commercially reasonable, and not take into account the volume or value of a physician's designated health services (DHS) referrals. CMS noted that including such requirements in the exception for VBAs would conflict with CMS's goal of addressing regulatory barriers to value-based care transformation. In contrast, OIG drafted the proposed AKS safe harbors in a more restrictive manner.

These differences between the Stark law exception and AKS safe harbors will, in practice, result in arrangements satisfying the Stark law exception but still require a facts and circumstances risk assessment under the AKS because the arrangement may not fully satisfy the corresponding AKS safe harbor.

The following explains key tenants of the value-based proposals and important compliance considerations.

Operating the VBE

A VBE is a collaboration between two or more VBE participants to achieve at least one value-based purpose. The VBE must have an accountable body or person responsible for financial and operational oversight of the VBE and a governing document that describes the VBE and how its participants intend to achieve the VBE's value-based purposes. One of the VBE participant's compliance programs will likely need to assume responsibility for operating the VBE including monitoring the other VBE participants' activities. This creates a new compliance structure for both the accountable body and other VBE participants to coordinate activities and monitor compliance. Creating a VBE raises other issues, from structuring counsel engagements to maintain attorney-client privilege among independent VBE participants to sharing data and other information on the VBE participant's activities.

Ensuring the VBE Follows Its Stated Purpose

As proposed, a "value-based purpose" is 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 the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or 4) transitioning from health care 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. For the AKS safe harbors, OIG created a “mandatory purpose” of coordinating and managing the care of the target population. A VBE will satisfy the Stark law VBA exception if any one of the purposes is present.

The VBE accountable body will be responsible for ensuring the value-based purpose is met and monitoring for improved outcomes. If the purposes are not able to be met, or outcomes plateau, a determination surrounding adjusting the purpose or activities or potentially winding down the VBE should be contemplated.

VBE Structure and Payments

The proposed Stark law exception and AKS safe harbors vary by the types of remuneration protected (in-kind or in-kind and monetary) and the level of financial risk assumed by the parties. The regulatory regimes follow a tiered structure and offer greater flexibility when parties assume more downside risk for the cost and quality of care. Monitoring compliance with the particular prong of the Stark law exception and AKS safe harbor will be another task for the compliance program. While the full-risk and substantial/meaningful risk safe harbors and prong of the exception have more flexibility, it is not clear that these options will be popular among organizations, at least in the short term. For example, the AKS substantial risk safe harbor would require a repayment obligation of remuneration received by the VBE, rather than simply forfeiting future payments. Even the care coordination (*i.e.*, “no-risk”) safe harbor has potentially limited practical use since it restricts remuneration to only in-kind payments. Also, no-risk participants must contribute at least 15 percent of the value of the in-kind remuneration received. While the Stark law exception would permit monetary payments, the result would be a financial arrangement among referral sources for the purpose of coordinating the care of a

shared target population (likely involving cross-referrals) that would not have clear AKS protection.

Target Patient Population Incentives

The OIG proposed a new AKS safe harbor permitting remuneration to patients in the form of tools and supports to achieve patient engagement, including addressing social determinants impacting outcomes. This safe harbor, however, is limited to in-kind remuneration that is furnished directly by a VBE participant to a patient in a target patient population, is directly connected to the coordination and management of care, and satisfies a number of other conditions. These conditions include a prohibition on providing cash, cash equivalents, or gift cards (although the OIG requested comments on this position) and an annual \$500 retail value limit. The tool or support must be an in-kind “preventive care item or service” or one that is “designed to identify and address a patient’s social determinants of health,” including non-medical items impacting health, such as food, shelter, safety, clothing, income, and transportation.

Many organizations carefully limit providing remuneration to federal health care program beneficiaries due to the AKS and BIS. Existing OIG guidance limits “nominal value” remuneration to \$15 per instance and \$75 aggregated annually. Other BIS exceptions, like the “promotes access to care” exception, protect other remuneration within certain parameters. The OIG’s proposed safe harbor would expand the AKS and BIS protection, but only in the context of a VBE. Again, this would be another item on the compliance program agenda for the VBE accountable body and the VBE participants.

Stark Law Burden Reduction Proposals

CMS addressed head-on the challenge of creating bright, if not at least brighter, line rules for three key terms in Stark law compliance—“fair market value,” “volume

or value,” and “commercially reasonable.” Additionally, CMS undertook other burden reduction measures including the creation of a new exception for *de minimis* physician compensation, expanding the applicability of grace periods, and highlighting a pathway for “curing” Stark non-compliance. These proposals, if finalized, would simplify aspects of Stark law compliance efforts. The proposals, however, do not eliminate the need for strong compliance program systems to ensure Stark law compliance.

Fair Market Value

CMS proposed⁶ to revise the definition of “fair market value” to “the value in an arm’s-length transaction, *with like parties and under like circumstances, of like assets or services*, (or rental properly for general commercial purposes) *consistent with the general market value* of the subject transaction.” CMS also proposed to redefine “general market value” to “[t]he price that assets or services (or property) would bring as the result of bona fide bargaining *between the buyer and seller in the subject transaction* on the date of acquisition of the assets or at the time the parties enter into the service (or rental) arrangement.” In other words, “fair market value” is the value of the goods, services, or rental property in a *hypothetical* arm’s-length transaction between a *hypothetical* buyer and seller, and “general market value” is the value the goods, services, or rental property would bring as the result of bona fide bargaining between the *actual* buyer and seller *in the subject transaction* on the date of the arrangement.

CMS explained this change should more clearly permit consideration of the particular characteristics of the buyer, seller, and the local market and better reflect valuation practices. The proposal discredits the compensation “survey says” approach that is sometimes overly relied upon when assessing fair market value compensation. That said, this

redefinition does not remove the need to conduct, in some way, a fair market value and general market value analysis in assessing physician compensation or rental payments.

Volume or Value

One of the most significant proposed changes is the redefinition of the “volume or value” standard⁷ to nullify the *Tuomey*⁸ and *UPMC*⁹ decisions’ variations on the “correlation” theory—that a surgeon’s or proceduralist’s work relative value unit (wRVU) compensation can vary with or take into account the volume or value of the inpatient or outpatient hospital referrals because of the correlation between the compensation and the referral.

CMS proposed several changes to achieve a “bright line” rule, including:

- 1) striking “varies with” from the second element of the “indirect compensation arrangement” definition;
- 2) clarifying that compensation that is not fair market value does not necessarily take into account the volume or value of referrals, and compensation that takes into account the volume or value of referrals is not necessarily inconsistent with fair market value; and
- 3) creating a definition expressly stating the only two ways compensation “takes into account” the volume or value of the physician’s referrals or other business generated—*either* when the physician’s compensation formula includes referrals as a variable and there is a “positive correlation” between the resulting compensation and the volume or value of the physician’s referrals or other business generated for the DHS entity *or* when there is a “predetermined, direct correlation” between the physician’s *prior* referrals to the DHS entity and the physician’s “prospective rate of compensation” for a specified duration. While CMS uses the term “correlation” in these proposed definitions, the examples in the preamble show that it

intends for there to be a *causal* connection between referrals and the amount of compensation.

This proposal brings welcome relief to any lingering concerns that productivity-based compensation for physicians who generate facility fees will create a volume/value issue. CMS' proposal to limit the DHS definition for inpatient hospital services effectively limits the relevant physician compensation arrangement to the admitting physician, further reducing the potential scope of any noncompliance.¹⁰ These proposed changes should pose some of the least burdens on compliance programs; however, compliance programs will still need to ensure compensation terms are structured to meet this definition.

Commercially Reasonable

For the first time, CMS proposed¹¹ to define “commercially reasonable,” providing two definitions for comment; either “the particular arrangement furthers a legitimate purpose of the parties and is on similar terms and conditions as like arrangements” or “the arrangement makes commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.” Either definition would include the statement “an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.”

CMS' clear intent was to obstruct further advancement of the “practice loss” theory in FCA litigation. This argument posits that if an employer does not profit from the professional collections of the physician when compared to the physician's compensation, the arrangement must be commercially unreasonable. Particularly in the hospital context, there are many legitimate reasons to employ physicians where the hospital does not profit from the physician's professional collections, such as accreditation

requirements, community need, payor mix, type of practice, and mission fulfillment. It is so common that the Medical Group Management Association (MGMA) publishes surveys measuring practice losses across specialties along with its salary surveys. CMS, however, did not completely close down the argument by using the word “may.” It will still be important for organizations to document the commercial reasonableness for employing physicians to stave off government inquiries and to explain the economic realities of employing physicians.

New Exception for De Minimis Compensation Arrangements

CMS also proposed a new exception for the provision of limited physician compensation, which, if finalized, should provide compliance programs an additional tool to avoid instances of “technical” Stark noncompliance.¹² The proposed exception allows entities to provide remuneration of up to \$3,500 per calendar year in exchange for the physician's provision of items and services, provided the arrangement meets certain requirements. Importantly, the exception would permit short-term compensation arrangements that involve payments of \$3,500 or less, *even if the arrangement is not set forth in writing and the remuneration is not set in advance of providing the items or services.*

The exception would also cover multiple arrangements within the same year, so long as the collective payments did not exceed \$3,500. Once an entity reaches the \$3,500 limit, the parties can document the arrangement on a go-forward basis to qualify for another exception (*e.g.*, the personal services exception). Moreover, under the proposed grace period for temporary noncompliance with the writing requirement (discussed below), parties would have 90 days from the date payments exceed \$3,500 to document the arrangement in writing.

Grace Period for Temporary Noncompliance with the Stark Law Writing Requirement

CMS proposed to amend the special rule on compensation arrangements and extend the 90-day grace period for temporary noncompliance to the requirement that an arrangement be set forth in a “writing.”¹³ Previously, the grace period was only available for missing signatures. Effectively, this would allow parties 90 days to obtain a written document or missing signatures to ensure an otherwise compliant arrangement is adequately documented. Moreover, the grace period for both the writing and signature requirements is not mutually exclusive, meaning parties can rely on it for arrangements that are neither in writing nor signed at the outset.

CMS noted that the expanded grace period’s scope would not impact the requirement that compensation be “set in advance,” which is found in many Stark law exceptions and a special rule deeming compensation “set in advance” when a specific formula is set out in writing before the furnishing of items or services. CMS importantly noted that if a compensation methodology is set forth in a writing at the outset of the parties’ arrangement, then the parties will necessarily meet the “set in advance” requirement of an applicable exception. If, however, the compensation arrangement was not reduced to writing, the parties are not precluded from meeting the “set in advance” requirement. In such circumstances, the parties would need to rely on other evidence supporting that the “set in advance” requirement was satisfied.

Modifications to the Period of Disallowance and a Proposed Noncompliance “Cure”

CMS’ proposed rule would also eliminate large portions of the Stark regulations “period of disallowance” definition, which provides definitive endpoints regarding the period of disallowance (the period of noncompliance).¹⁴ CMS acknowledged

that the endpoints enumerated were unwieldy and not particularly helpful for providers and thus deleted much of the text, noting that the inquiry for a particular party was fact-specific. The most significant commentary, however, surrounded CMS’ clarification that parties to a financial arrangement can “cure” potential noncompliance due to administrative or operational errors or discrepancies when the error or discrepancy is discovered and rectified during the course of the financial relationship.

Notably, CMS stated parties can only “cure” “live” arrangements. In other words, parties cannot retroactively cure noncompliance where there is not a current financial relationship. CMS noted it views parties who correct errors or issues during the course of an arrangement as not “turning back the clock” to address past compliance; rather, they are actively monitoring and ensuring compliance with the Stark law. To illustrate, suppose a hospital maintained a compliant lease arrangement with a physician for the rental of office space for \$2,000 a month, but an accounting error caused the hospital to collect only \$1,800 for two months. Assuming the arrangement was still active, the hospital could collect the outstanding \$400 and avoid a Stark law violation.

COVID-19 RESPONSE

Within a few weeks of the COVID-19 emergency unfolding, the OIG and CMS issued several important guidance documents on AKS and Stark law issues. First, on March 17, 2020, the OIG issued a policy statement permitting a routine waiver of copays for telehealth services.¹⁵ The OIG has also begun a “frequently asked questions” portal where organizations can pose COVID-19 related questions and obtain published OIG responses in short order.¹⁶ Many of the FAQs asked thus far have been relatively non-controversial in the context of responding to a pandemic, such as physicians

supplying personal protective equipment (PPE) to a nursing home in which the physicians treat patients where the nursing home was experiencing a shortage of PPE. Nonetheless, the OIG FAQ portal is a welcome additional instrument for industry guidance.

On March 30, 2020, CMS issued nationwide Section 1135 waivers applicable to the Stark law in response to the pandemic.¹⁷ With a retroactive effect to March 1, 2020, the waivers exempt health care entities from sanctions under the Stark law for noncompliance, provided certain conditions are met, and absent the government's determination of fraud or abuse. Importantly, and discussed further below, CMS has structured the waivers to apply only to arrangements that meet one of several required COVID-related purposes. On April 21, 2020, CMS issued explanatory guidance on the scope and application of these waivers.¹⁸

Finally, on April 3, 2020, the OIG issued a Policy Statement stating OIG's intention not to impose administrative sanctions under the AKS for remuneration covered by the first 11 (of 18) Stark law waivers.¹⁹ While the OIG's Policy Statement does not extend to *all* of the Stark law blanket waivers, it covers the situations that are most likely to implicate the AKS, including payments made either by a DHS entity or by a physician for space or equipment rental, or for the purchase of items or services, and direct remuneration to physicians in the form of non-monetary compensation or medical staff incidental benefits, or loans at below fair market value (FMV) or with terms that are not commercially available. All of the conditions and definitions that apply to the Stark law blanket waivers apply to the OIG's Policy Statement. This extends to the requirement that the blanket waivers apply only to financial relationships that solely relate to at least one of the CMS "COVID-19 Purposes," discussed below. The OIG's Policy Statement by its terms only applies

to conduct occurring on or after April 3, 2020, and will terminate concurrently with the Stark law blanket waivers. While the Policy Statement is not retroactive to March 1, 2020, it seems reasonable to conclude that the OIG would also not impose sanctions on arrangements that met a Stark law blanket waiver prior to April 3, 2020.

The Stark law waivers and AKS Policy Statements are important actions by CMS and the OIG to reduce regulatory burden during this time of emergency. These actions, however, do not remove AKS and Stark law compliance risks or address all situations. Rather, compliance with the Stark law waivers and AKS Policy Statement presents their own compliance issues during and after the COVID-19 emergency.

The Arrangement Must Be Related to COVID-19 Purposes

CMS specified that the Stark law waivers apply only to financial relationships related to the COVID-19 national emergency and the remuneration or referrals described in the waivers "must be solely related to COVID-19 Purposes." A "COVID-19 Purpose" means any one of the following:

- diagnosing or providing medically necessary treatment of COVID-19 for any patient or individual, regardless of whether the patient or individual is diagnosed with a confirmed case of COVID-19;
- securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19;
- ensuring the ability of health care providers to address patient and community needs due to COVID-19;
- expanding the capacity of health care providers to address patient and community needs due to COVID-19;

- shifting the diagnosis and care of patients to appropriate alternative settings due to COVID-19;
- addressing medical practice or business interruption caused by COVID-19 to maintain the availability of medical care and related services for patients and the community.

This last COVID-19 Purpose (addressing medical practice or business interruptions caused by COVID-19) raises some questions of what degree of financial assistance may be provided to physicians simply to address interruption of their business, similar to the business interruption suffered by virtually all businesses. This COVID-19 Purpose also requires that the activity or arrangement maintain the availability of services for patients in the community. The actions that meet this purpose may change over time, but currently, simply giving financial assistance to physicians to soften the financial blow of business interruption may not meet this Purpose. In contrast, financial assistance contingent on the physician providing a reciprocal benefit to the hospital or community likely would be deemed related to a COVID-19 Purpose. For example, permitting delays in or (perhaps) abatement of rent, or furnishing space, equipment, or personnel, when *necessary* for the practice to continue to safely and affordably furnish services to COVID-19 and/or non-COVID patients, is arguably protected.

CMS also requires that any remuneration described in the blanket waivers be a direct financial relationship between a DHS entity and a physician, a physician organization (PO) in whose shoes the physician stands, or a physician's immediate family member; however, parties may request an individual waiver from CMS for specific indirect compensation arrangements.

The 18 Blanket Stark Waivers

CMS provided 18 specific blanket waivers that apply to scenarios where a DHS entity

makes payments to a physician or the physician's immediate family member, or in which a physician provides payments to a DHS entity.

Waivers on FMV Requirements for Leases, Services, Purchases, and Loans

The broadest waivers apply to payments made either by a DHS entity or by a physician, where the payments are for space or equipment rental, or for the purchase of items or services, and the payments or purchases do not represent FMV. The waivers apply to the following scenarios:

- payments by a DHS entity to a physician, or the physician's immediate family member, for services personally performed by the physician, where the remuneration is above or below fair market value for services performed;
- payments made between a DHS entity and a physician, or the physician's immediate family member, for space or equipment rental, where the remuneration is below FMV for the lease;
- payments made between a DHS entity and a physician, or the physician's immediate family member, for items or services purchased, where the remuneration is below FMV for the items or services;
- remuneration resulting from a loan between a DHS entity and a physician, or the physician's immediate family member, where the interest rate is below fair market value or on terms that are unavailable from a bank or other commercial lender.

Notably, these waivers do not relieve compliance with the other elements of Stark law exceptions that were not waived, such as the requirement that the arrangement did not take into account the volume or value of referrals. CMS explained that it has historically interpreted, and currently interprets, the Stark law to permit "multiple bites at the apple" for parties to amend the terms of compensation

arrangements multiple times over the course of the arrangement, even within the first year of the arrangement, provided the elements of a Stark law exception are met. This interpretive statement provides parties flexibility to amend arrangements during this time of uncertainty, both economically and in the duration of the COVID-19 emergency, where the overall arrangement will last at least a year following each amendment, regardless of whether the amendment itself lasts at least a year.

Concerning loans, CMS clarified that a debtor could repay the loan with in-kind services or items or cash, but the waivers do not extend to loan forgiveness. Second, CMS clarified that loan balance and interest payment terms agreed to in reliance of the blanket waivers may continue beyond the termination of the waivers. Loan proceeds, however, may not be dispersed and other remuneration may not be conveyed by parties after the termination of the blanket waivers without satisfying an existing Stark law exception. This clarification is helpful for providers concerned about the scope of protection for arrangements initiated, but arguably not completed, during the waiver period.

Incidental Benefits and Non-Monetary Compensation Waivers

A hospital or other DHS entity may provide non-monetary remuneration to a physician (or the physician's immediate family member) in the following circumstances:

- medical staff incidental benefits exceeding the 2020 limit of \$36 per occurrence;
- non-monetary compensation exceeding the 2020 limit of \$423 per calendar year.

In-Office Ancillary Services Exceptions/Group Practice Waivers

CMS also issued two blanket waivers applicable to physician group practices, effectively waiving the "location test" of the in-office ancillary services exception.

Physician-Owned Hospital and ASC Expansion Waivers

CMS provided two waiver provisions addressing physician-owned hospitals and ASCs intended to expand the capability of physician-owned entities to provide care to patients in light of the COVID-19 pandemic. Specifically, referrals by a physician owner to a hospital temporarily expanding its bed capacity or an ASC converted to a temporary hospital are permitted. Without the waiver, physician-owned hospitals are generally prohibited from expanding their bed capacity, and physician-owned ASCs are generally prohibited from converting an ASC to a hospital. A physician-owned ASC that is considering temporarily converting into a hospital must comply with additional requirements, however, in line with Medicare conditions of participation and other hospital enrollment requirements that are not waived by CMS under Section 1135 waivers.

Physician Home Health Ownership Waiver

CMS will permit physicians to refer patients to a home health agency in which the physician (or the physician's immediate family member) has an ownership or investment interest, regardless of whether the home health agency qualifies as a rural provider.

Writing and Signature Requirement Waiver

CMS will permit referrals to a DHS entity with whom a physician has a financial relationship where the compensation arrangement does not satisfy the writing or signature requirements of a Stark law exception but satisfies all other requirements of the applicable exception; however, CMS clarified that a provider may rely on another Stark law blanket waiver in addition to relying on the waiver exempting the writing and signature requirements. For example, this permits a health care provider to effectively rely on waivers related to payments that are both (1) above or below fair market value, as

applicable, and (2) not documented in a signed writing.

CMS provided a list of examples of remuneration, referrals, or conduct that may fall within the scope of the waivers. CMS pointed to these as examples only and noted that other scenarios could qualify for the waiver of sanctions.

Waiver Compliance Takeaways

The Stark law waivers and AKS Policy Statement provide the industry regulatory relief at a time when providers are confronting an unprecedented pandemic. Given the waivers and Policy Statement are narrowly tailored and require the relevant entity to satisfy a “COVID-19 Purpose,” arrangements require fact-specific analysis to determine applicability. Moreover, while the waivers provide a reprieve from the FMV requirement of key compensation exceptions and the dollar value limits included in the medical staff incidental benefits and non-monetary compensation exceptions, the waivers will not likely relieve DHS entities from compliance with the other elements of Stark law exceptions.

Even during this time of emergency, it is highly advisable to continue practicing good compliance hygiene by maintaining contemporaneous documentation of a valid COVID-19 Purpose and the particular facts and circumstances for each arrangement where an entity is relying on the Stark law waivers and Policy Statement. Providers should ensure that non-FMV or otherwise commercially unreasonable arrangements are entered into solely for a COVID-19 Purpose.

Finally, it is important for providers to recognize that OIG’s Policy Statement requires compliance with all of the requirements of the applicable Stark law waiver,

including the requirement of a COVID-19 Purpose. Limiting the Policy Statement to the Stark law waivers also means that arrangements between non-DHS entities (such as pharmaceutical or device manufacturers) and physicians are not covered by the Policy Statement; however, these non-DHS entities are also a critical part of addressing the COVID-19 pandemic and may have legitimate reasons to engage with physicians or others in efforts to address the crisis. Thus, arrangements not covered by the Stark law waivers require a careful examination of the facts and circumstances to assess AKS risk.

Endnotes

1. 42 U.S.C. § 1395nn; 42 C.F.R. § 411.350 *et seq.*
2. 42 U.S.C. § 1320a-7b(b); 42 C.F.R. § 1001.952.
3. 42 U.S.C. § 1320a-7a(a)(5); 42 C.F.R. § 1003.110.
4. OIG’s rule is published at 84 Fed. Reg. 55694 (Oct. 17, 2019). CMS’ rule is published at 84 Fed. Reg. 55766 (Oct. 17, 2019).
5. OIG’s proposal is discussed at 84 Fed. Reg. at 55698–55729. CMS’ proposal is discussed at 84 Fed. Reg. at 55772–55789.
6. See 84 Fed. Reg. at 55796–55799.
7. See 84 Fed. Reg. at 55791–55795.
8. See *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015).
9. See *United States ex rel. Bookwalter v. UPMC*, No. 18-1693 (3d Cir. Sept. 17, 2019); *United States ex rel. Bookwalter v. UPMC*, No. 18-1693, slip op. at 24, 33 (3d Cir. Dec. 20, 2019).
10. See 84 Fed. Reg. at 55805.
11. See 84 Fed. Reg. at 55790–55791.
12. See 84 Fed. Reg. at 55828–55830.
13. See 84 Fed. Reg. at 55813–55815.
14. See 84 Fed. Reg. at 55808–55811.
15. See oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf.
16. See oig.hhs.gov/coronavirus/policy.asp.
17. See www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.
18. See www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section-1877g-social-security-act.pdf.
19. See oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf.