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New Opportunities for Value-Based Care with HHS Finalization of Stark Law, Anti-Kickback Statute, and Civil Monetary Penalties Law Reforms

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The Department of Health and Human Services ("HHS"), in collaboration with the Centers for Medicare & Medicaid Services ("CMS") and the Office of the Inspector General ("OIG"), has issued two final rules clarifying certain regulatory terms and adding and amending exceptions and safe harbors to accommodate "value" transactions under the Anti-Kickback Statute ("AKS"), the federal Physician Self-Referral Law (the "Stark Law"), and the Civil Monetary Penalties Law (the "CMP Law"). These changes, as we noted in our discussion of the proposed regulations, are arguably the most significant changes in the Stark Law, AKS, and the CMP Law in recent history.

The White House announced a regulatory freeze and encouraged the new administrators of the relevant agencies to review and, if appropriate, suspend all regulations that were either not yet published in the Federal Register, or that were published in the Federal Register but had not yet taken effect as of January 20, 2021. The two final rules we address in this alert were published and effective as of January 19, 2021 and are thus not subject to the regulatory freeze. The freeze notice also encouraged regulators to review all recently effective regulations; these two final rules are among those being reviewed. Given the favorable response to these regulations, changes are unlikely. We will post any updates as they become available.

Below is a summary of the new rules, followed by certain examples of potential real-life applications of the changes.

I. Changes to the Stark Law Regulations

CMS's final rule with changes to the Stark Law regulations include three new exceptions and amendments to an existing exception relating to electronic health records ("EHR"). CMS has also issued clarifying guidance on certain previously undefined terms that are fundamental to interpreting key Stark Law regulations.

1. **New Exceptions**

A. Value-Based Compensation Arrangements

CMS implemented three new exceptions at 42 C.F.R. § 411.357(aa) for certain remunerations exchanged between or among eligible participants in a value-based arrangement. These exceptions and their various requirements apply based on the level of risk assumed by the arrangement's participants.

The final rule distinguishes between arrangements where (1) remuneration is paid regardless of whether there is any downside financial risk undertaken by the participants; (2) the participants take on "meaningful downside financial risk" amounting to at least 10% of the total value of the remuneration received under the arrangement; or (3) the participants take on full financial risk for the duration of the arrangement.

Each of these scenarios is accompanied by certain rules that the arrangement participants must comply with, with the full financial risk model requiring the fewest safeguards because of the inherent protections against abuse in that model. CMS also included in its final rule an exception that makes these value-based exceptions available for indirect compensation arrangements as long as a physician or physician organization is a direct party to the arrangement.

Notably, these value-based compensation exceptions do not include typical Stark Law requirements that compensation be set in advance, that compensation be consistent with fair market value, or that compensation not be determined in a manner that takes into account either the volume or value of referrals or any other business generated between the parties. CMS commented that "disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address are built into the value-based definitions and will operate in tandem with the requirements included in the exceptions to protect against program and patient abuse." However, all three exceptions do require that the compensation arrangement be commercially reasonable.

B. Limited Remuneration Arrangements.

CMS added a new exception at 42 C.F.R. § 411.357(z) to protect payment for items or services furnished by a physician that does not exceed an aggregate of $5,000 per calendar year (to be adjusted each year for inflation). A signed written agreement is not required for this exception. The arrangement does, however, need to comply with the typical Stark requirements that compensation be set in advance, that compensation be consistent with fair market value, and that compensation not be determined in a manner that takes into account either the volume or value of referrals or any other business generated between the parties.

C. Donations of Cybersecurity Technology.

CMS also added protection for arrangements involving the donation of certain cybersecurity technology and related services at 42 C.F.R. § 411.357(bb), with the stated goal of "removing a perceived barrier to donations to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records or other information essential to the delivery of health care." Donors may not take into account either the volume or value of a recipient's referrals or any other business generated by the recipient, or require the donation as a condition of doing business with the donor. Additionally, the donation, which may include hardware, must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

2. **Modifications to Existing EHR Exception**

The Stark EHR exception at § 411.357(w) was scheduled to expire. Recognizing that the "continued availability of the EHR exception provides certainty with respect to the contribution costs related to the donations of electronic health records items and services, facilitates adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns . . ., and helps preserve the gains already made in the adoption of interoperable [EHR] technology," CMS permanently deleted the sunset provision.

3. **Guidance on Fundamental Terminology**

Several exceptions to the Stark Law rely on the use and interpretation of fundamental terminology, including such key concepts as: "commercially reasonable;" "fair market value;" and "not determined in a manner that takes into account either the volume or value of referrals or any other business generated between the parties" (the "Volume or Value Standard"). Taking into account that the health care industry has consistently sought further guidance from CMS on these concepts, CMS adopted clearer guidance for interpreting each of these terms:

A. Commercially Reasonable. Commercially reasonable is defined (at 42 C.F.R. § 411.357(l)(4)) to mean that a particular arrangement must further 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. CMS clarified that an arrangement may be commercially reasonable even if it does not result in profit for the parties.

B. Fair Market Value. Fair market value is defined (at 42 C.F.R. § 411.351) as the value in an arm's-length transaction, consistent with the general market value of the subject transaction. There are particular nuances to this definition with regard to the rental of office space. In its discussion, CMS noted certain "extenuating circumstances" that may allow payments to physicians that are higher than compensation surveys would seem to justify. We address this further in our discussion on new opportunities in the industry below.

C. Volume or Value Standard. CMS also explained its understanding that the Volume or Value Standard is violated only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity. CMS notes that, "only when the mathematical formula used to calculate the amount of the compensation includes referrals or other business generated as a variable, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or other business generated." Note that CMS's clarification of the Volume or Value Standard explicitly rejected the problematic standard applied in the *Tuomey* case.

II. Changes to AKS and CMP Law Regulations

OIG's final rule with changes to the AKS regulations includes several new safe harbors as well as amendments to certain existing safe harbors. OIG's final rule also codifies one new exception under the CMP Law.

1. **New AKS Safe Harbors**

In finalizing these new AKS safe harbors, OIG reiterated that failure to satisfy a statutory safe harbor does not indicate that a financial arrangement is in violation of AKS; rather, each arrangement is analyzed according to the totality of the circumstances. Notably, these new safe harbors only offer prospective protection for applicable arrangements.

A. Value-Based Compensation Arrangements

Similar to the Stark Law exceptions for value-based compensation arrangements, OIG finalized its proposal to include three similar value-based safe harbors at 42 C.F.R. § 1001.952. The first protects care coordination arrangements designed to improve quality, health outcomes, and efficiency. There is a contribution requirement, where the recipient of the remuneration must contribute 15% of the offeror's cost or the fair market value of the remuneration. The second protects value-based arrangements where participants undertake "substantial downside financial risk," which can be calculated in three ways (via a shared savings and losses methodology, an episodic payment methodology, or a partial capitation methodology). Finally, the third protects value-based arrangements where the participants take on full financial risk.

Like the Stark Law exceptions, the AKS safe harbors are designed on a sliding scale – fewer safeguards are required where greater downside financial risk is undertaken by the participants. However, the Stark Law exceptions are not exactly the same as the AKS safe harbors. Although OIG and CMS intended to align these value-based compensation arrangements, they acknowledged that several differences exist, stating that "complete alignment is not feasible because of fundamental differences in statutory structures and sanctions across the two laws." One key difference is that unlike for the Stark Law, where both monetary and in-kind remuneration are protected for all three risk levels, monetary remuneration is only protected under the AKS safe harbors where participants take on meaningful downside financial risk or full financial risk. Additionally, unlike CMS, OIG decided to categorically exclude certain types of entities (laboratories; pharmaceutical manufacturers; DMEPOS manufacturers, distributors, and suppliers; pharmacy benefit managers; wholesalers; and distributors), rendering them ineligible for protections under the value-based safe harbors. OIG provided a very limited protection under AKS for certain digital technology arrangements involving device or supplies manufacturers and DMEPOS companies.

B. Patient Engagement

OIG adopted a new safe harbor at 42 C.F.R. § 1001.952(hh) to protect certain in-kind remuneration furnished under patient engagement and support arrangements. There is a $500 value cap on the amount of protected remuneration per patient per year. Several other requirements were finalized, including that the remuneration must have a direct connection to the coordination and management of care.

C. CMS-Sponsored Models

OIG adopted a new safe harbor at 42 C.F.R. § 1001.952(ii) to protect certain remuneration provided in connection with a CMS-sponsored model. This would eliminate the need for OIG to issue model-specific waivers for each new CMS-sponsored model.

D. Cybersecurity Technology and Services

OIG adopted a new safe harbor at 42 C.F.R. § 1001.952(jj) to protect certain donations of cybersecurity technology and related services, with the stated goal of helping to improve the cybersecurity posture of the health care industry. As in the similar Stark exception, the rule encompasses hardware donations that meet certain conditions.

E. ACO Beneficiary Incentive Programs

OIG finalized a new safe harbor at 42 C.F.R. § 1001.952(kk) to codify the statutory exemption for ACOs operating a CMS-approved beneficiary incentive program under the Medicare Shared Savings Program.

2. **Amendments to Existing AKS Safe Harbors**

In addition to adding new safe harbors, OIG also finalized various amendments to existing AKS safe harbors in its final rule.

- OIG modified the existing safe harbor for EHR items and services (at 42 C.F.R. § 1001.952(y)) to add protections for certain cybersecurity technology, to update provisions regarding interoperability, and to remove the sunset provision.
- OIG modified the existing safe harbor for warranties (at 42 C.F.R. § 1001.952(g)) to protect warranties for a bundle of one or more items and related services rather than just a single item. The modification also excludes beneficiaries from the

reporting requirements applicable to buyers. Additionally, the modification directly codifies the definition of “warranty” rather than defining it by reference to the Federal Food, Drug, and Cosmetic Act to clarify that FDA-regulated drugs and services are not excluded from this safe harbor.

- OIG modified the existing safe harbor for local transportation (at 42 C.F.R. § 1001.952(bb)) to expand mileage limits for rural areas and remove any mileage limitations for transporting patients discharged from an inpatient facility after spending 24 hours in observation status.
- In a highly significant change, OIG modified the existing safe harbor for personal services and management contracts (at 42 C.F.R. § 1001.952(d)) to increase flexibility for part-time or sporadic arrangements, including arrangements for which aggregate compensation is not known in advance. OIG aimed to bring this safe harbor into alignment with the Stark Law personal services exception (which requires that the payment methodology, but not the full payment amount and specific schedule of payments, be set in advance), thereby simplifying compliance. The modification also introduces new provisions for outcome-based payments to reward improvements in patient or population health.

3. **New CMP Law Exception**

OIG amended the definition of “remuneration” in the CMP Law regulations at 42 C.F.R. § 1003.110 to add an exception for the provision of certain telehealth technologies related to in-home dialysis services.

III. New Opportunities for Value-Based Care

The Stark Law and AKS have been considered extremely burdensome for participants of value-based care and care coordination efforts in the health care industry. With the finalization of these two landmark rules, HHS, OIG, and CMS hoped to align financial incentives with care quality. The goal was to continue to protect patients from abuse while providing more flexibility for providers to engage in innovative opportunities by removing or diminishing some regulatory barriers to these efforts. We aim to highlight some examples of opportunities presented by the changes implemented by the final rules.

OIG referred to an imagined case study in its proposed rule involving a hospital that discharges patients to a particular skilled nursing facility (SNF). Numerous health outcomes studies have indicated that hospital patients discharged to post-acute care settings such as SNFs have high rates of readmission to acute care. The cost of hospital readmissions is significant by itself, but studies also indicate that hospitals incur sizable reputation costs that provide incentives for hospitals to do a better job of taking steps to reduce their readmission rates. Imagine an arrangement between the SNF and the hospital whereby the hospital provides a nurse to follow patients discharged from the hospital to the SNF, and the SNF in turn provides staff to assist the hospital in coordinating the transition of care from the hospital to the SNF. This arrangement would facilitate greater monitoring services and care coordination for patients recently discharged from the hospital and, in the long term, potentially reduce readmission rates and associated costs while simultaneously providing better health outcomes for patients. This arrangement could likely be structured to fall into the new Stark Law value-based care exception and the associated AKS safe harbor protecting arrangements where participants take on no downside financial risk.

As another example, consider an arrangement between a Managed Care Organization (MCO), intermediary physician association (IPA), and their patients. The MCO might choose to enter into an arrangement to provide the patient with a device to monitor metrics such as the patient’s heart rate or blood oxygen levels. The MCO might then provide bonuses for physicians of the IPA who monitor this information in real time and intervene as necessary to improve the patient’s outcomes. Under the new rules, the MCO and IPA would be able to enter into this arrangement with less regulatory hassle than before, even if they would still have to follow certain safeguards to comply with the Stark Law and AKS.

In its commentary, CMS also provided an example of how to determine compliance with the Stark Law requirement that compensation be consistent with fair market value where there are "extenuating circumstances." CMS presented a potential scenario relating to orthopedic surgeons, stating that although independent salary surveys may indicate that $450,000 per year may generally be an appropriate salary for an orthopedic surgeon in a particular area, "extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject [] transaction." Thus, for instance, it may be appropriate to pay an orthopedic surgeon significantly more than $450,000 if the physician is a top, highly sought-after orthopedic surgeon who uses particular techniques to achieve a high success rate. Here again, we see how the changes implemented by these rules and the commentary supporting their adoption provide opportunities for greater flexibility for the industry.

Ultimately, the final rules provide a "range of arrangements to improve the coordination and management of patient care and the engagement of patients in their treatment," all while reducing the regulatory cost of entering into these arrangements for program participants.

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