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HEALTH CARE ALERT

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With major reforms to Stark and Anti-Kickback regulations, OIG and CMS lead in the Regulatory Sprint Towards Coordinated Care

On Nov. 20, 2020, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) issued two final rules that make sweeping changes to the Physician Self-Referral Law (Stark Law) and Anti-Kickback Statute (AKS). The rules are part of HHS's Regulatory Sprint to Coordinated Care. The final rules advance value-based care by providing greater flexibility for health care providers to participate in value-based arrangements and provide coordinated care for patients. In addition, the rules seek to ease unnecessary compliance burdens for providers and stakeholders, while maintaining strong safeguards against fraud and abuse. Unless otherwise noted the final rules are set to take effect on Jan. 19, 2021.

Physician Self-Referral Law (Stark Law)

CMS issued the highly anticipated final rule to the Stark Law, which is a strict liability civil statute that prohibits physicians from referring patients for certain designated health services payable by a federal health care program to entities with which the physician, or such physician's immediate family member(s), has a financial interest or relationship, unless the arrangement falls squarely within a statutory exception.

In furtherance of HHS's goal to advance value-based care, CMS issued four statutory exceptions to the Stark Law that relate to value-based arrangements:

1. **Value-based arrangements** – A new exception that permits in-kind and monetary remuneration paid under a value-based arrangement. The remuneration must be for, or result from, value-based activities that the recipient undertakes for patients in the target patient population.

2. **Value-based arrangement with meaningful downside risk to the physician** – A new exception that permits in-kind and monetary remuneration paid under a value-based arrangement in which the physician is at meaningful downside financial risk for failing to achieve the value-based purpose(s) of the Value-based Enterprise (VBE). Meaningful downside risk means the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration that the physician receives under the value-based arrangement. The remuneration must be for, or result from, value-based activities that the recipient undertakes for patients in the target patient population.

3. **Full financial risk** – A new exception that permits in-kind and monetary remuneration paid under a value-based arrangement in which a VBE has assumed full financial risk from a payor for patient care services for a target population. Full financial risk means that the VBE is financially responsible, on a prospective basis, for the cost of all patient care items and services covered by the payor for each patient in the target patient population. The remuneration must be for, or result from, value-based activities that the recipient undertakes for patients in the target patient population.

4. **Special rule for indirect compensation arrangements involving value-based arrangements** – A modification to the indirect compensation arrangement regulations that permits the value-based exceptions available under §411.357(aa) to apply when an indirect compensation arrangement includes a value-based arrangement to which the physician or physician organization is a direct party.

Beyond the value-based care exceptions, CMS amended and added two statutory exceptions to the Stark Law:

1. **Limited remuneration to a physician** – New regulations exclude from the definition of remuneration amounts less than or equal to aggregate $5,000 paid from an entity to a physician for the provision of items or services provided by that physician. This is a $1,500 increase from the current regulation.

2. **Cybersecurity technology and related services** – A new exception that permits nonmonetary remuneration in the form of cybertechnology and related services that are necessary and used predominantly to implement, maintain or reestablish cybersecurity. Cybersecurity includes the process of protecting information by preventing, detecting and responding to cyberattacks.

Additionally, the physician's eligibility for, or amount or nature of the technology and services, may not be determined in any manner that takes into account the volume or value of referrals or business generated between the parties. Nor is the receipt of technology and services or amount thereof made a condition of doing business with a donor.

CMS also modified one statutory exception to the Stark Law:

- **Electronic Health Records (EHR) items and services** – A modification to the exception protecting donations of EHR items and services that:
  - clarifies that the protected remuneration may include cybersecurity software and services used predominantly to protect EHRs.
  - eliminates the sunset provision.
  - modifies the timing of physicians' cost sharing payments for items and services received after the initial donation to be at reasonable intervals.
  - eliminated the equivalent technology donation prohibition.

The final rule provides context and color in certain respects, and simplification in other respects, that ultimately provides stakeholders with a much clearer path to compliance with the regulations and an opportunity to explore more flexible business opportunities.

The context, color and simplification, which are crucial to stakeholders' understanding of and compliance with the Stark Law, is provided in several definitions and other fundamental clarifications contained within 42 U.S.C. §§ 411.351 through 411.357:

- **Commercially reasonable** – Formerly undefined, the final rule defines commercially reasonable as "furthering a legitimate business arrangement and is sensible considering the characteristics of the parties, including size, type, scope and specialty." The rule clarifies that an arrangement may be commercially reasonable even if one or more of the parties to the arrangement do not profit.
- **Designated Health Services (DHS)** – The statute formerly defines DHS as several health services, including inpatient and outpatient hospital services, payable by Medicare as designated health services; however, the final rule carves out the provision of inpatient hospital services that do not increase the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient, Inpatient Rehabilitation Facility, Inpatient Psychiatric Facility and Long-Term Care Hospital prospective payment systems.
- **Fair market value** – The final rule clarifies how fair market value is determined based on two common transactions, equipment rental and office space rental.
- **General market value** – In addition to clarifying the definition of general market value with respect to equipment and office space

rental, the final rule provides color with respect to two additional common transaction—the purchase of assets and compensation for services.

- **Physician** – The final rule simplifies the definition of physician by referring to the term as defined in Section 1861(r) of the Social Security Act.
- **Referral** – The final rule adds to the definition of referral to provide that a referral is not considered an item or a service for purposes of the Stark Law.
- **Remuneration** – Surgical devices, items or supplies are currently carved out of the definition of remuneration with respect to such items being furnished in connection with the collection, transportation, processing and storing of specimens. The final rule revises this definition to include surgical devices, items or supplies.
- **Transaction** – Formerly, transaction was defined to flesh out isolated financial transactions—this definition is now simplified as "an instance of two or more persons or entities doing business."
- **Isolated financial transaction** – The final rule creates an independent definition for an isolated financial transaction, which clarifies it as a "one-time transaction involving a single payment between two or more persons, or a one-time transaction that involves integrally related installment payments, provided that the total aggregate payment is fixed prior to the first payment and does not take into account the volume or value of referrals or other business generated by the physician." The payments must be immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note or subject to a similar mechanism to ensure payment even in the event of default. The arrangement includes a one-time sale of property or a practice, a single instance of forgiveness of an amount owed in settlement of a bona fide dispute, or a similar one-time transaction. It does not include single payment for multiple or repeated services.
- **Volume or value-based standard** – The final rule clarifies that a physician's or a physician's immediate family member's compensation is considered to have taken into account the volume or value of referrals if (i) other business or generated by the physician or the physician's immediate family member or (ii) physician referrals to the entity are variables in the physician or the physician's immediate family member's compensation calculation *and* such calculation results in a positive correlation (*i.e.*, the physician's compensation increases and the physician referrals simultaneously increase).
- **Indirect compensation arrangement** – A modification to the definition of indirect compensation arrangement provides that such an arrangement exists if, between the referring physician and the entity, there is an unbroken chain of persons or entities that have a financial relationship between them; within the physician's direct financial relationship, the physician receives aggregate compensation that varies with the volume or value of referral or other business generated

by the referring physician for the entity and the individual unit of compensation received by physician is not fair market value, includes the physician referral to the entity as a variable, or includes other business generated by physician for entity as a variable.

- **Special rule for reconciling compensation** – A new rule that permits an entity and physician who are parties to a compliant compensation arrangement to reconcile all discrepancies and payments under the arrangement within 90 days following expiration or termination. The entire amount of remuneration for items or services must be paid as required under the terms and conditions of the arrangement.
- **Special rule on compensation arrangements** – A new rule for compensation arrangement that governs writing and signature requirements. A writing requirement may be satisfied by a collection of documents. A signature requirement may be satisfied by electronic or other signature valid under applicable federal or state law. A writing and signature requirement may be satisfied if the compensation arrangement otherwise fully complies with an exception and the parties obtain the writing(s) and signature(s) within 90 days immediately following the date on which the arrangement became noncompliant with the applicable exception.
- **Special rule for productivity bonuses and profit shares** – A new rule for determining whether compensation to a physician takes into account the volume or value of referrals that will apply to the productivity bonus, share of overall profits and compensation of physicians who are a part of group practices. This rule will go into effect on Jan. 1, 2022. If there are fewer than five physicians in a group practice, "overall profits" means the profits derived from all the designated health services of the group practice. Overall profits means the profits derived from all the designated health services of any subpart of the group practice that consists of at least five physicians. As a result, profit distributions from designated health services are only permitted on an aggregate basis, as opposed to a service-for-service basis.

Lastly, the final rule further amends the regulations to "de-couple" the Stark Law and the Anti-Kickback Statute. Many of the Stark Law exceptions require compliance with the Anti-Kickback Statute, which is a criminal statute, and thus intent-based. These two regulations have been de-coupled (with the exception of the *fair market value* exception) to avoid introducing intent-based requirements into a strict liability statute.

Anti-Kickback Statute

Alongside CMS and its changes to the Stark Law, the OIG has also promulgated rule changes to the AKS, a criminal statute that prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by a federal health care program. In its new rule, OIG has included seven new AKS safe harbors and modifications to four existing safe harbors.

The OIG has provided the following three safe harbors to protect certain value-based arrangements involving VBEs and network arrangements that focus on value-based outcomes:

1. **Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor** – A new safe harbor that permits in-kind remuneration exchanged between a VBE and VBE participant, or between VBE participants, pursuant to value-based arrangement. The in-kind remuneration must be used predominately for value-based activities directly connected to coordinating and managing care for the target population, among other requirements and limitations.

   A number of entities are ineligible to take advantage of the value-based safe harbors, including pharmaceutical manufacturers, distributors or wholesalers; pharmacy benefit manager; laboratory companies; pharmacies that primarily compound or dispense compound drugs; device and medical supply manufacturers (excluding limited technology participants); entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics or supplies covered by a federal health care program (DMEPOS) (excluding limited technology participants); and medical device distributors and wholesalers that are not device or medical supplies manufacturers.

2. **Value-based Arrangements with Substantial Downside Financial Risk Safe Harbor** – A new safe harbor that permits monetary and in-kind remuneration exchanged between a VBE and VBE participant pursuant to a value-based arrangement, so long as the VBE assumes substantial downside financial risk from a payor and the VBE participant assumes a meaningful share of that risk. Substantial downside risk means:

   a. a financial risk equal to at least 30 percent of any loss of all items and services covered by the payor and furnished to the target patient population.

   b. 20 percent of any loss where either losses and savings are calculated by comparing current expenditures for all items and services to the target patient population for a defined clinical episode of care to a bona fide benchmark designed to approximate the expected total cost, or the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting.

   c. receiving prospective, per-patient payment from a payor designed to produce material savings and paid on a monthly, quarterly or annual basis for a predefined set of items or services furnished to the target patient population and designed to approximate the total expected costs of expenditures.

Meaningful share means that the VBE participant either assumes two-sided risk for at least five percent of the losses and savings realized by the VBE pursuant to its assumption of risk or receives a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predetermined set of items and services furnished to the target patient population. The remuneration must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be one of the following for the target patient population: coordinating and managing care, improving the quality of care, or appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care. Entities ineligible to take advantage of the care coordination safe harbor discussed above are also excluded from using this safe harbor.

3. **Value-based Arrangements with Full Financial Risks Safe Harbor** – A new safe harbor that permits monetary and in-kind remuneration exchanged between a VBE and VBE participant pursuant to a value-based arrangement, so long as the VBE assumes full financial risk from a payor. Full financial risk accounts for the cost of all items and services covered by the applicable payor for each patient in the target patient population on a prospective basis for a term of at least one year. The remuneration must be directly connected to one or more of the VBE's value-based purposes. The same entities that are ineligible from taking advantage of the value-based arrangement safe harbors discussed above are also excluded from using this safe harbor.

In addition to its value-based arrangement safe harbors, the OIG has also promulgated four new AKS safe harbors:

1. **Patient Engagement and Support Safe Harbor** – A new safe harbor protecting the provision of patient engagement tools and support furnished directly by a VBE participant to a patient in a target patient population. Entities ineligible to take advantage of the value-based safe harbors discussed above are also excluded from using this safe harbor, but the safe harbor does include a pathway for manufacturers of devices or medical supplies to provide digital health technology. Specifically, the safe harbor protects in-kind remuneration (*i.e.* not cash or a cash equivalent) that, among other requirements, has a direct connection to the coordination and management of care of the target patient population of the VBE, is recommended by the patient's licensed health care professional, and advances one of five enumerated patient-care goals. The safe harbor caps the amount of in-kind remuneration to an aggregate annual retail value of $500, which is then adjusted each year per the then-current Consumer Price Index.

2. **CMS-Sponsored Models Safe Harbor** – A new safe harbor that permits remunerations between parties to arrangements

under a model or other initiative being tested or expanded by CMS-sponsored model arrangements and CMS-sponsored model patient incentives (*e.g.* Innovation Center models and/or arrangements under the Medicare Shared Savings Program). The safe harbor is intended to provide greater predictability and uniformity across CMS-sponsored models, and reduces the need for separate and distinct OIG fraud and abuse waivers for CMS-sponsored models implemented in the future.

3. **Cybersecurity Technology and Services Safe Harbor** – A new safe harbor for nonmonetary donations of certain cybersecurity technology and related services intended to help facilitate improved cybersecurity in health care. For purposes of the safe harbor, "cybersecurity" is defined as the process of protecting information by preventing, detecting and responding to cyberattacks, while "technology" is defined as any software or other types of information technology. The donor cannot take into account the volume or value of referrals between the parties when providing the donation, condition the donation on future referrals or condition the donation on doing business with the donor. Further, a general description of the donated technology and services, and the amount of the recipient's contribution (if any), must be put in writing that is signed by both the donor and the recipient.

4. **ACO Beneficiary Incentive Safe Harbor** – A new safe harbor that codifies the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.

Alongside the new safe harbors, OIG also finalized modifications to four existing safe harbors:

1. **Electronic Health Records Safe Harbor** – A modification to the safe harbor protecting donations of EHR that:

   a. adds protections for certain cybersecurity technology related to EHR services.

   b. removes the requirement prohibiting donors from taking any action to limit or restrict the use, compatibility, or interoperability of the donated EHR items or services with other electronic prescribing or electronic health records systems.

   c. removes the requirement that previously disallowed donations of EHR if the recipient already possessed items or services similar to those being donated by the donor.

   d. removes the Dec. 31, 2021, sunset provision such that the safe harbor is now in effect indefinitely.

   e. updates provisions relating to requirements surrounding the

"interoperability" of the donated EHR items or services in the safe harbor.

2. **Personal Services and Management Contracts Safe Harbor** – A modification to the safe harbor protecting certain personal services and management contracts that:

   a. eliminates the requirement that "aggregate compensation" be set in advance. Rather, the methodology for determining compensation paid over the term of the agreement must now be set in advance.

   b. eliminates the requirement that a contract must specify the schedule, length and exact charge for such intervals if the arrangement is on a periodic, sporadic, or part-time basis.

   c. adds new protections for outcome-based payment arrangements between parties that reward improving patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across settings, or by achieving one or more outcome measures that appropriately reduce payor costs while improving quality care.

3. **Warranties Safe Harbor** – A modification to the safe harbor protecting certain warranties provided by a manufacturer or supplier of an item to a buyer that:

   a. adds protection for bundled warranties for one or more items and related services upon certain conditions (*e.g.* all federally reimbursable items and services subject to a bundled warranty arrangement must be reimbursed by the same federal health care program and in the same payment).

   b. excludes beneficiaries of a federal health care program from certain reporting requirements applicable to buyers set forth in the safe harbor.

   c. more fully defines the term "warranty" and provides a direct definition of the term separate and apart of the definition given in 15 U.S.C. §2301(6), which was previously referenced in the safe harbor.

4. **Local Transportation Safe Harbor** – Modification to the current safe harbor protecting certain free or discounted transportation that:

   a. expands the safe harbor's distance limitation applicable to residents of rural areas from 50 miles to 75 miles.

   b. provides an exception to certain distance limitations in the safe harbor if the patient is discharged from an inpatient facility following inpatient admission or released from a hospital after

being placed in observation status for at least 24 hours, and the patient is transported to the patient's residence or another residence of the patient's choice.

Conclusion

These final rules will make a significant and lasting change on transactions within the healthcare industry. For more information about the new changes to the Stark Law, Anti-Kickback Statute, contact Kiera Finelli, Kristen Lawrence, Kyle Schrodi or any member of Porter Wright's Health Care Practice Group.