CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

FEBRUARY 16, 2021

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Historically, health care in the United States has been based on fee-for-service ("FFS"). That is, third party payors ("TPPs") pay a physician, hospital or other provider for the service rendered...regardless of the outcome. A by-product of FFS has been very little coordination among providers regarding a particular patient. The FFS approach has proven to be inefficient and expensive.

With 78 million Baby Boomers retiring at the rate of 10,000 per day, and with many Boomers living well into their 80s, the financial strain on the nation's health care delivery system is markedly increasing. TPPs have concluded that the FFS system is no longer financially viable and that a new approach is necessary.

This new approach is "value-based care," also known as "coordination of care" and "patient outcome management." Value-based care ("VBC") is premised on providers collaborating to provide health care for a patient and for remuneration to the providers to be based, at least in part, on whether certain metrics are achieved. VBC may result in providers referring patients to each other, providing services to each other, and sharing in the remuneration paid for the care of the patient.

The challenge is that VBC has run up against the prohibitions and restrictions of the federal physician self-referral law ("Stark") and the federal anti-kickback statute ("AKS"). Stark and the AKS came into existence when health care was almost entirely based on FFS. And while there have been modifications/updates over the years to Stark and the AKS, such updates have not addressed how these two statutes fit within the VBC framework.

- **Stark** is a civil statute. It states that if a physician[2] (or an immediate family member) has a financial interest (ownership or compensation) in a health care provider, then the physician cannot refer a Medicare/Medicaid patient to the provider for "designated health services" ("DHS") ...unless a Stark exception is met.

- The **AKS** is a criminal statute. It states that a person/entity cannot pay or receive (or offer to pay or agree to receive) anything of value in exchange for (i) referring or arranging for the referral of a patient covered by a federal health care program ("FHCP") or (ii) recommending the purchase of a service/product covered by an FHCP. The Office of Inspector General ("OIG") has published a number of "safe harbors." If an arrangement complies with a safe harbor then the remuneration exchanged between the parties does not constitute illegal remuneration under the AKS. If an arrangement does not meet the terms of a safe harbor, it does not mean that the arrangement violates the AKS; rather, it

[1] This White Paper is a broad summary of changes to Stark and the Anti-Kickback Statute. Many details, contained in the changes, are not addressed. This White Paper does not constitute legal advice. The reader should obtain advice from his/her attorney regarding changes to Stark and the Anti-Kickback Statute.

[2] The Stark definition of "physician" is a "doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor."

means that the parties will need to conduct an in-depth analysis in light of the language of the AKS, court decisions and other published guidance.

Recognizing the challenge imposed by Stark and the AKS on providers moving into the VBC space, (i) CMS updated Stark and (ii) the OIG updated the AKS. In a broad fashion, this White Paper discusses (i) the updates to Stark and the AKS and (ii) how the updates apply to pharmacies.

Background

In the summer of 2018, CMS and the OIG sought input from interested parties by issuing Requests for Information. In early October 2019, CMS and the OIG simultaneously issued proposed rules modifying Stark and the AKS. Providers and other interested parties submitted many comments. And then finally on November 20, 2020, CMS and the OIG issued the Final Rules that are the subject of this white paper.

The goal of the Final Rules is to encourage health care providers to collaborate in the provision of health care...without being unduly restricted by Stark and the AKS. Nevertheless, the AKS will remain as a "back stop" designed to prevent arrangements that while being technically correct on their face, are in reality designed to funnel remuneration to referral sources.

Stark

Value-Based Enterprise ("VBE") Exceptions

The goal of the VBE exceptions is to facilitate the transition of health care to the VBE model. The final definition of a "VBE participant" does not exclude any specific providers/suppliers.

- The *Full Financial Risk exception* applies to value-based arrangements among VBE participants that have assumed full financial risk for the cost of patient care in the target patient population for a defined period of time.

- *Meaningful Downside Financial Risk to the Physician exception* protects remuneration paid under a value-based arrangement where the physician assumes a meaningful level of financial risk for failure to meet the value-based purpose of the VBE.

- The *Value-Based Arrangements exception* pertains to value-based arrangements ... even if no risk is assumed by the VBE participants. Because the parties are assuming little to no risk, they have to meet certain requirements not mandated by the other two value-based exceptions.

Execution of Documents

Documents can be prepared and executed within 90 days of the beginning of the arrangement. The arrangement must satisfy all requirements of an applicable exception except for the

documentation/execution. Further, electronic signatures (that comply with applicable law) are accepted.

The definition of "set in advance" is amended to allow the modification of compensation during the term of an agreement where the modified compensation is not based on the volume or value of referrals. The modification can occur at any time, including the first year, as long as (i) all of the requirements of an applicable exception are met; (ii) the modified compensation is established prior to the furnishing of the services/products; and (iii) the modified compensation is set out in writing in sufficient details that allow it to be verified. The new rule allowing 90 days to prepare and execute documentation is not applicable to the modification of compensation.

Disallowance

CMS deleted the rules on the period of disallowance. However, parties to an arrangement can correct errors for up to 90 days after a compensation arrangement ends.

Indirect Compensation

Exceptions are available to protect a physician's referrals to an entity when the indirect compensation includes a value-based arrangement to which the physician is a direct party. The link closest to the physician may not be an ownership interest - rather - it must be a compensation arrangement that meets the definition of a value-based arrangement.

Limited Remuneration to a Physician

Limited remuneration may be paid to a physician, for substantive services rendered, without a written agreement or compensation set in advance. The remuneration cannot exceed $5000 per calendar year.

Patient Choice

An entity may direct a physician to refer to a specific provider, practitioner, or supplier. The compensation must meet specified conditions designed to preserve patient choice, comply with the TPP's guidelines, and protect the physician's medical judgment. The compensation cannot be contingent on the volume or value of referrals.

Fair Market Value ("FMV")

FMV is the value in an arm's-length transaction consistent with the general market value of the transaction. For example, FMV of equipment is determined without taking into account its intended use. FMV of an office space lease considers the space as used for general commercial purposes (not taking into account potential referrals from the lessor).

Volume or Value of Referrals/Business Generated

The new rule discusses when arrangements will be construed as taking into account the volume or value of referrals or other business generated. The focus will be when the formula used to calculate compensation to or from a physician includes the volume or value of referrals or other business generated as a variable (i.e., when the compensations varies based on referrals or other business generated). This special rule also applies to the group practice definition to ensure that a physician member's compensation does not take into account the volume or value of referrals for DHS unless permitted for productivity bonuses and profit shares.

Commercial Reasonableness

The key question to consider when determining if an arrangement is commercially reasonable is whether the arrangement makes sense as a means to accomplish the parties' goals. Commercial reasonableness determination is *not* one of valuation; it is expressly *not* based on whether the arrangement is profitable or not.

Rental of Office Space and Equipment

CMS clarifies that these exceptions do not prohibit multiple lessees from using the space or equipment, or prevent a lessee from inviting another party (other than the lessor) to use the rented office space/equipment.

Group Practice

If a physician group practice establishes a valid value-based model, then distribution of profits to physician members will be construed as not taking into account the volume or value of the physicians' referrals. The effective date of this change is January 1, 2022.

Consistency of Stark and the AKS

The requirement that an arrangement must comply with the AKS as a precondition to meeting a Stark exception is removed.

<u>Anti-Kickback Statute</u>

New VBE Safe Harbors

The three new value-based safe harbors contain protection against potential fraud, including: (i) a prohibition against taking into account the volume or value of referrals outside the target patient population and (ii) limits on directed referrals.

The following entities may not utilize the new value-based safe harbors: pharmaceutical manufacturers; distributors; wholesalers; PBMs; labs; compounding pharmacies and DME suppliers.

The following are the new VBE safe harbors:

- The *Value-Based Arrangements with Full Financial Risk safe harbor* provides the greatest flexibility, because it requires the assumption of the most risk. "Full Financial Risk" is defined as responsibility for the costs of all items and services covered by a payor for each patient in the target populations for the term of one year.

- The *Value-Based Arrangements with Substantial Downside Risk safe harbor* protects both in-kind and monetary remuneration if the VBE participants assume a certain amount of risk.

- The *Care Coordination Arrangements safe harbor* does not require the participants to take on risk. It does, however, require that the arrangement be measured based on at least one evidence-based outcome measure. The exchange of in-kind remuneration, but not monetary payments, is permitted under this safe harbor on condition that outcome measures are achieved and certain other requirements are met.

New Patient Engagement and Support Safe Harbor

This new safe harbor provides protection for certain patient engagement tools. Its protection is limited to in-kind remuneration provided by VBE participants to patients.

Examples of in-kind patient engagement tools are: (i) health-related technology; (ii) patient health-related monitoring tools and (iii) support services designed to address a patient's social determinants of health. The safe harbor does not protect the giving of cash, cash equivalents, and certain types of gift cards. The aggregate value of the patient engagement tools and supports cannot exceed $500 per year.

The safe harbor does not apply to certain VBE participants, including pharmaceutical manufacturers, distributors, and wholesalers; PBMs; labs; compounding pharmacies; certain DME manufacturers; and DME suppliers.

Modifications of Existing Safe Harbors

Local Transportation safe harbor. The OIG expanded the mileage limits up to 75 miles for residents in rural areas. There is no distance requirement for transporting inpatients to their residence upon discharge.

Warranty safe harbor. Protection is afforded to a bundle of one or more items and related services, provided that they are paid for by the same TPP and under the same payment.

Personal Services and Management Contracts and Outcomes-Based Payments safe harbor. This safe harbor now includes the protection of certain outcome-based payment arrangements. To be protected, the payments must be based on the achievement of certain measures. Outcomes

measures related solely to patient satisfaction and/or internal cost savings are excluded from safe harbor protection. Safe harbor protection under this *new provision* is not available to pharmaceutical manufacturers, distributors and wholesalers; PBMs; labs; compounding pharmacies; certain DME manufacturers, and DME suppliers.

In addition, the OIG removed the current safe harbor requirement that the aggregate payment for a management or services arrangement be set out in advance. Going forward, only the *methodology* needs to be set in advance. This makes the safe harbor consistent with the parallel Stark exception. The OIG also removed the requirement that a part-time arrangement have a schedule of services specifically set out in the written agreement.

ACO Beneficiary Incentive Program safe harbor. The Balanced Budget Act of 2018 included a statutory provision excluding incentive payments, made to a beneficiary who receives the payments as part of the ACO Beneficiary Incentive Program, from the definition of remuneration.

Stark and the Anti-Kickback Statue

Electronic Health Records ("EHR")

CMS and the OIG finalized changes to the EHR exception to Stark and the EHR safe harbor to the AKS. The final rules (i) remove the sunset provision, (ii) allow the recipient to pay its portion of the EHR at reasonable intervals; (iii) delete the prohibition on donating replacement technology; and (iv) delete the prohibition on the donor taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other e-prescribing or electronic health record systems.

Cybersecurity Technology

The goal of the new safe harbor and Stark exception is to facilitate the donation of cybersecurity technology to recipients that may not be able to afford adequate protection against cyberattacks. The technology/services must be "necessary and used predominantly to implement, maintain, or reestablish cybersecurity." The parties have the discretion to decide what technology/services qualify for protection. Donors cannot take into account the volume or value of referrals or other business generated between the parties, Under the safe harbor, the arrangement must be set forth in writing and signed by the parties. On the other hand, CMS requires that the arrangement be documented in writing (e.g., exchange of emails).

Beneficiary Inducement

Telehealth for In-Home Dialysis

The Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2018 included a provision to permit individuals with end-state renal disease ("ESRD"), receiving home dialysis treatment, to be provided monthly clinical assessments through telehealth. The Act

included a beneficiary inducement exception for telehealth services provided to those patients. The OIG finalized certain safeguards for such telehealth services.

Applicability to Pharmacies

Value-Based Arrangements

Pharmacies can enter into value-based arrangements to take care of patients. For example:

- Pharmacies can enter into coordination of care arrangements with treating physicians in accordance with (i) the new Stark VBE exceptions: (a) Full Financial Risk exception; (b) Meaningful Downside Financial Risk to the Physician exception; and (c) Value-Based Arrangements exception; and (ii) the new AKS VBE safe harbors: (a) Value-Based Arrangements with Full Financial Risk safe harbor; (b) Value-Based Arrangements with Substantial Downside Risk safe harbor; and (c) Care Coordination Arrangements safe harbor.

- If pharmacies enter into value-based arrangement with individual/entities not falling within the Stark definition of "physician," then while the arrangements do not have to comply with the Stark VBE exceptions, the arrangements should be structured to comply with the AKS VBE safe harbors.

- Coordination of care arrangements can be (i) part of an Accountable Care Organization ("ACO") model or (ii) directly between the pharmacy and the physician/non-physician provider.

Non Value-Based Arrangements

Separate and apart from value-based arrangements, pharmacies can enter into collaborative arrangements with physicians and other providers in which such arrangements incorporate the following modifications to Stark and the AKS:

- Modification to the *Personal Services and Management Contracts safe harbor* to the AKS by removing the requirement that the *aggregate* payment for a management or services arrangement be set out in advance (i.e., only the *methodology* needs to be set out in advance). For example, instead of being required to pay a Medical Director (e.g., exactly $18,000 per year), the pharmacy can feel comfortable in paying the Medical Director on an hourly basis.

- Modification to the *Personal Services and Management Contracts safe harbor* to the AKS by removing the requirement that a part-time arrangement have a schedule of services specifically set out in the written agreement. From a practical standpoint, this element of the safe harbor has always been difficult to meet.

- Modification to the Stark definition of "commercial reasonableness" ... clarifying that (i) the key question is whether the arrangement makes sense as a means to accomplish the parties' goals and (ii) commercial reasonableness is *not* one of valuation - it is expressly *not* based on whether the arrangement is profitable or not.

- Clarification to the Stark "volume or value standard and other business generated standard" by stating that the amount of compensation will be considered to take into account the volume or value of referrals or other business generated only when the *formula* used to calculate compensation to or from a physician includes the volume or value of referrals or other business generated.

- Clarification that the Stark definition of "fair market value" means the value in an arm's length transaction consistent with the general market value of the subject transaction (i.e., the intended use of the equipment or facility space is not taken into consideration...and the proximity to a referral source lessor is not taken into consideration).

- The ability of the parties to a transaction (that implicates Stark) to sign documents (memorializing the arrangement) within 90 days of the beginning of the arrangement.

- Under Stark, allowing remuneration (not to exceed $5,000 per calendar year) to be paid to a physician, for substantive services rendered, without a written agreement or compensation set in advance. For example, assume that a pharmacy's medical director unexpectedly resigns and the provider quickly arranges for a new medical director to start performing services before a Medical Director Agreement is signed. This modification to Stark would permit this.

- The modification to the Stark definition of "set in advance" to allow the modification of compensation during the term of an agreement where the modified compensation is not based on the volume or value of referrals.

- Modifications to the Stark EHR exception and AKS EHR safe harbor by (i) removing the sunset provision; (ii) allowing the recipient to pay its portion of the EHR at reasonable intervals; (iii) deleting the prohibition against donating replacement technology; and (iv) deleting the prohibition against the donor taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other e-prescribing or electronic health record systems.

- Enactment of the new Stark Cybersecurity Technology exception and new AKS Cybersecurity Technology safe harbor, the goal of which is to facilitate the donation of cybersecurity technology to recipients that may not be able to afford the protection against cyberattacks. Donating providers have a great deal of discretion in deciding the types of technology and services that qualify for protection.

Conclusion

The November 20, 2020 Final Rules bring Stark and the AKS into line with each other. For example, before the modifications and clarifications (i) the Stark Personal Services exception allowed compensation on a per hour or per unit of service basis, while (ii) the Personal Services and Management Contracts safe harbor to the AKS only allowed fixed annual compensation. And so an arrangement could comply with the Stark exception but violate the AKS safe harbor. The modification solves this dilemma.

Stark comes into play when a party includes a physician (as defined by Stark) and/or his family member. There is no "intent" element in Stark. An arrangement either meets the Stark exception … or it does not. There is no "gray" … just "black and white." On the other hand, the AKS is intent-based, which can often lead the parties into a gray area.

If a pharmacy wishes to enter into an arrangement with a physician (as defined by Stark), then the pharmacy must comply with both Stark and the AKS. On the other hand, if the pharmacy enters into an arrangement with a provider who does not fall under Stark, then the pharmacy only must comply with the AKS (and any other relevant laws). As stated earlier in this White Paper, if an arrangement does not comply with all of the elements of an AKS safe harbor, it does not mean that the arrangement violates the AKS. Rather, it means that the parties need to analyze the arrangement thoroughly under the language of the AKS, court decisions, and OIG guidance.

The modifications to Stark and the AKS show that CMS and the OIG recognize that Stark and the AKS were too limited in today's health care climate. The modifications provide additional freedom to pharmacies to enter into collaborative arrangements with physicians, hospitals and other providers … when the arrangements are designed to improve patient outcomes.

What is of paramount importance is for pharmacies not to attempt to use these modifications to "game the system" by entering into arrangements that are not designed to improve patient outcomes – but rather – are designed to funnel remuneration to a referral source.

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