



EDUCATIONAL RESOURCES

Relaxation of Requirements Under Stark and The Anti-Kickback Statute

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Introduction



Introduction

- 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.

Introduction

- 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.”

Introduction

- 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”).

Introduction

- Stark is a civil statute. It states that if a physician (or an immediate family member) has a financial interest (ownership or compensation) in a health care provider, the physician cannot refer a Medicare/Medicaid patient to the provider for “designated health services” (“DHS”) unless a Stark exception is met. DHS includes durable medical equipment (“DME”).

Introduction

- 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
 - referring or arranging for the referral of a patient covered by a federal health care program (“FHCP”) or
 - recommending the purchase of a service/product covered by an FHCP.

Introduction

- The Office of Inspector General (“OIG”) has published a number of “safe harbors.”
- If an arrangement complies with a safe harbor, 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 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.

Introduction

- Recognizing the challenge imposed by Stark and the AKS on providers moving into the VBC space
 - CMS updated Stark and
 - the OIG updated the AKS

Background



Background

- In the summer of 2018, CMS and the OIG sought input from interested parties by issuing Requests for Information.
- AAHomecare submitted a letter containing the association's comments.
- One comment was that it would be ill-advised for physicians to be allowed to self-refer for DME.
- The Final Rules do not change the Stark prohibition against physicians self-referring for DME.

Background

- 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.
- Finally, on November 20, 2020, CMS and the OIG issued the Final Rules.
- 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.

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 DME suppliers.

Value-Based Enterprise (“VBE”) Exceptions

- 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.

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 \$5,000 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.

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.

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, 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 was 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.

Anti-Kickback Statute



New VBE Safe Harbors

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

New VBE Safe Harbors

- The following entities may not utilize the new value-based safe harbors:
 - pharmaceutical manufacturers
 - distributors
 - wholesalers
 - PBMs
 - labs
 - compounding pharmacies
 - DME suppliers
- Notwithstanding the foregoing, under certain conditions, the OIG permits DME manufacturers and DME suppliers to use the new Care Coordination Arrangements safe harbor.

New VBE Safe Harbors

- 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.
 - 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.

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:
 - Health-related technology
 - Patient health-related monitoring tools
 - 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.

New Patient Engagement and Support Safe Harbor

- 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
 - wholesalers
 - PBMs
 - labs
 - compounding pharmacies
 - certain DME manufacturers
 - 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.

Modifications of Existing Safe Harbors

- *Personal Services and Management Contracts and Outcomes-Based Payments* safe harbor. This safe harbor now includes the protection of certain outcome-based payment arrangements. 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
 - wholesalers
 - PBMs
 - labs
 - compounding pharmacies
 - certain DME manufacturers
 - DME suppliers

Modifications of Existing Safe Harbors

- 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.

Modifications of Existing Safe Harbors

- *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.



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Stark and the Anti-Kickback Statute



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:
 - Remove the sunset provision
 - Allow the recipient to pay its portion of the EHR at reasonable intervals
 - Delete the prohibition on donating replacement technology
 - 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.”



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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-stage renal disease (“ESRD”) receiving home dialysis treatment to be provided monthly clinical assessments through telehealth.

Applicability to DME Suppliers



Applicability to DME Suppliers

- Certain components of the final rules do not directly apply to DME suppliers.
- There are two reasons for this
 - At present, most DME suppliers are not integrated into the VBC arena; most suppliers are paid on an FFS basis.
 - Several of the changes specifically exclude DME suppliers.

Applicability to DME Suppliers

- On the other hand, other components of the final rules do directly apply to DME suppliers. These include:
 - 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).
 - 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.

Applicability to DME Suppliers

- Modification to the Stark definition of “commercial reasonableness” clarifying that
 - the key question is whether the arrangement makes sense as a means to accomplish the parties’ goals and
 - commercial reasonableness is not one of valuation -- it is expressly not based on whether the arrangement is profitable or not.

Applicability to DME Suppliers

- 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).

Applicability to DME Suppliers

- 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.
- 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.

Applicability to DME Suppliers

- These modifications and clarifications bring Stark and the AKS into line with each other.
- 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 DME suppliers to enter into collaborative arrangements with physicians, hospitals, and other providers when the arrangements are designed to improve patient outcomes.



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Limit to Safe Harbor: Court Order in Medtronic Case



Limit to Safe Harbor: Court Order in Medtronic Case

- A court order in a whistleblower lawsuit against Medtronic suggests that even if an arrangement technically complies with Personal Services and Management Contracts (“PSMC”) safe harbor to the AKS, the safe harbor may not afford protection when the compensation is intended to function as an inducement for additional business.
- United States of America, et al., ex rel. Dr. Kuo Chao v. Medtronic PLC, et al., is a whistleblower (qui tam) lawsuit by Dr. Chao against Medtronic and others.
- Medtronic is the manufacturer of a medical device called the “Pipeline,” a flexible cylinder-shaped medical device that is surgically inserted at the site of a brain aneurysm to help treat the aneurysm and its associated symptoms.

Limit to Safe Harbor: Court Order in Medtronic Case

- Physicians order Pipeline devices for their patients.
- Medtronic provides the devices to the hospitals where the physicians work, and the hospitals seek reimbursement for the Pipeline device from Medicare, Medicaid, and other government health care programs.
- Dr. Chao alleges that these reimbursements are tainted with fraud because they are the result of a multifaceted kickback scheme in which Medtronic compensates physicians to induce them to order a greater number of Pipeline devices for their patients.

Limit to Safe Harbor: Court Order in Medtronic Case

- Dr. Chao alleges that kickbacks fall into the following categories:
 - Dr. Chao alleges that Medtronic maintains a proctoring program through which it regularly overpays physicians for professional services. According to Dr. Chao, through the proctoring program, Medtronic hires physicians (with experience inserting Pipeline devices) as proctors to teach other physicians how to perform the Pipeline procedure. The proctoring physicians accomplish this, in part, by being present for and supervising the procedure when performed by the trainee physician. The proctors have their own medical practices, and the crux of Dr. Chao's allegation is that Medtronic systematically and habitually overpays its proctors for their proctoring services, which functions as a disguised kickback meant to incentivize the proctors to order more Pipeline devices for their medical practices.

Limit to Safe Harbor: Court Order in Medtronic Case

- Dr. Chao alleges that Medtronic acquired, at an inflated rate, companies in which physicians with a high volume of Pipeline usage held ownership interests. According to Dr. Chao, the results of these acquisitions was that physicians received a substantially windfall that significantly exceeded the fair market value (“FMV”) of their ownership interests. These windfalls, Dr. Chao argues, constitute a kickback that improperly induced these physicians to perform more Pipeline procedures.

Limit to Safe Harbor: Court Order in Medtronic Case

- Dr. Chao alleges that Medtronic maintained two data collection registries, IntrePED and ASPIRe, that it used to disguise kickback payments to Pipeline-using physicians. According to Dr. Chao, Medtronic asked physicians (who performed Pipeline procedures) to upload a small amount of patient and procedure-related data to these registries in exchange for a substantial payment. Dr. Chao alleges that this data was very easy for physicians to gather, and Medtronic paid the physicians for this data in excess of the (i) FMV of the data and (ii) value of the physicians' collection efforts. This excess, Dr. Chao alleges, constitutes a kickback.
- Dr. Chao alleges that Medtronic distributed illegal kickbacks to physicians and hospitals disguised as fellowships, grants, and research funds. According to Dr. Chao, Medtronic distributed these funds based in part on the physicians' or hospitals' volume of Pipeline usage. Dr. Chao alleges that these fellowships, grants, and research funds functioned as improper direct compensation for using more Pipeline devices ... hence, a kickback.

Limit to Safe Harbor: Court Order in Medtronic Case

- Dr. Chao filed his whistleblower lawsuit on March 9, 2017. The lawsuit remained under seal for several years.
- On May 28, 2020, the United States provided notice that it and the state plaintiffs declined to intervene.
- On May 29, 2020, the Court entered an Order unsealing the case.
- On June 29, 2021, Dr. Chao filed a Third Amended Complaint (“TAC”).
- On August 2, 2021, Medtronic moved to dismiss the TAC, one of the grounds being that in his TAC, Dr. Chao allegedly fails to state a claim.
- The United States filed a Statement of Interest (i) arguing that Dr. Chao states a claim for False Claims Act (“FCA”) violations and (ii) urging the Court to deny Medtronic’s Motion to Dismiss. Subsequently, Medtronic and Dr. Chau filed supplemental pleadings.

Limit to Safe Harbor: Court Order in Medtronic Case

- In determining how to rule on the Motion to Dismiss, the Court first pointed out that the government's decision not to intervene has no relevance to resolution of the Motion. The Court stated that while the government did not intervene, it also did not seek to have the case dismissed, as it had the right to do. The Court further stated:
 - The federal anti-kickback statute ("AKS") imposes liability on those who "knowingly and willfully solicit, receive, offer, or pay any remuneration (including any kickback, bribe, or rebate) ... in return for purchasing...or arranging for or recommending purchasing" a medical device subject to reimbursement under a federal health care program ("FHCP"). A payor violates the AKS whenever "one purpose" of the remuneration was to induce future referrals or orders "even if the payments were also intended to compensate for professional services."

Limit to Safe Harbor: Court Order in Medtronic Case

- When the procurement of medical supplies is tainted by a knowing violation of the AKS and the violator knows that the supplies are subject to reimbursement by an FHCP, the submission to the government of a reimbursement claim for those supplies turns the AKS violator into an FCA violator as well.
- The Court denied Medtronic's Motion to Dismiss. In doing so, the Court reasoned:
 - Dr. Chao states a plausible, particularized claim for an illegal health care reimbursement kickback scheme and a corresponding FCA violation. For example, Dr. Chao alleges that Medtronic routinely paid physicians (who proctored Pipeline procedures) a \$3,200 stipend based on eight hours per day at \$400 per hour for a procedure that is known to take less than two hours.

Limit to Safe Harbor: Court Order in Medtronic Case

- The PSMC safe harbor does not defeat Dr. Chao's claims. The Court states that in order for the safe harbor to be met, "[t]he aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that take into account the volume or value of any referrals or business between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." It is plausible, based on Dr. Chao's allegations, that the payments and benefits Medtronic provided its proctors exceeded the FMV of the services the proctors provided. Thus, it is plausible that the PSMC safe harbor does not apply.

Limit to Safe Harbor: Court Order in Medtronic Case

- Even some FMV payments will qualify as illegal kickbacks, such as when the payor has considered the volume of reimbursable business between the parties in providing compensation and otherwise intends for the compensation to function as an inducement for more business. According to 70 Fed. Reg. 4858, 4864 (January 31, 2005), under the AKS, “neither a legitimate business purpose for the arrangement, nor an FMV payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).” Dr. Chao alleges that Medtronic’s practice of engaging and paying proctors was a “system...designed to reward doctors for using Pipelines,” perpetuated by an aggressive sales team co-opting purported clinical programs in order to pay high-volume physicians as remuneration for their Pipeline usage. This is a plausible assertion that, if true, would take the payments out of the safe harbor, regardless of whether those payments were made at FMV.

Questions?





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Thank you

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