Kudman · Trachten · Aloe LLP

KTA HEALTHCARE ALERT

Proposed Rules to Update Anti-Kickback Statute Safe Harbors and Stark Law Exceptions

November 14, 2019[1]

In an effort to ease restraints on healthcare providers and improve patient care and outcomes, the Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") and the Center for Medicare & Medicaid Services ("CMS") recently proposed changes to the Anti-Kickback Statute ("AKS") and the Physician Self-Referral Law ("Stark Law"). Individuals and organizations subject to AKS and the Stark Law have an opportunity to review the proposed rules and submit comments on the proposed changes by December 31, 2019. Stakeholders should note that until the Final Rule is released, these proposed changes are only tentative.

The proposed changes to Stark-Law and AKS are designed to allow flexibility for: two or more participants, such as physician groups, hospitals, and other provider entities, each a "value-based enterprise participant," to establish a "value-based enterprise" ("VBE") that has a governing body and focuses on achieving certain "value-based purposes." Value-based purposes include, (i) coordinating or managing care for a target patient population; (ii) improving the quality of care for the population; (iii) reducing the costs to, or growth in expenditures of payors, without reducing the quality of care for the population; or (iv) transitioning from healthcare 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 the population. We believe that pharmacies should be covered as an integral participant in the care coordination paradigm and believe comments to that end are appropriate and necessary to improve patient outcomes in any value-based model.

Notably, the proposed value-based arrangements safe harbors expressly exclude pharmaceutical manufacturers, distributors and suppliers, and laboratories from the definition of "value-based enterprise participant." OIG seeks comments on whether the Department should also exclude pharmacies, pharmacy benefit managers, wholesalers and distributors, and all other device manufacturers from the definition. OIG has expressed concern that entities that are dependent on practitioner prescriptions and referrals could potentially misuse the proposed safe harbors by offering remuneration to practitioners and patients to market their products instead of creating value for patients.

Proposals

CMS and OIG propose changes to provide new protections under the Stark Law and AKS for certain value-based arrangements and changes to existing provisions to facilitate value-based healthcare delivery and payment. The proposed changes are described below:

- <u>Value-based Arrangements</u>: three (3) proposed new safe harbors and exceptions to the Stark Law that would protect payments between qualifying value-based participants within value-based arrangements that promote coordinated care. The safe harbors would be available in connection with:

[1] A special thanks to Isa Clarke, Esq., an associate at Kudman Trachten Aloe LLP, who represents corporate and healthcare clients.

- Care coordination arrangements: arrangements that promote quality, health outcomes and efficiency with no downside financial risk

- Value-based arrangements that assume substantial downside financial risks: arrangements under which VBE participants have a risk-sharing obligation in a VBE that has assumed downside financial risk under its agreement with a payor.

- Value-based arrangements that assume full financial risk: arrangements involving "full" financial risk would make a VBE financially responsible for the cost of items and services covered by the payor for each patient. The anticipated cost of care would be determined and paid in advance by the payor and the VBE would be prohibited from claiming additional payment from the payor for covered items or services.

- <u>Patient Engagement Tools</u>: a proposed new safe harbor to protect arrangements under which in-kind patient engagement support or tools are given to patients by a VBE participant to increase patient engagement. OIG is interested in comments on any negative impacts on the provision of tools and support to increase patients' adherence to treatment protocols and whether to set limits on the amount of remuneration provided to steer patients to services.

- <u>CMS-Sponsored Models</u>: a proposed new safe harbor that would protect remuneration among parties to arrangements under a model being tested or expanded by the Medicare Shared Savings Program ("MSSP") or CMS ("CMS-sponsored models"), reducing the need for CMS to issue separate fraud and abuse waivers for new CMS-sponsored models. With respect to the duration of this protection, OIG is seeking comments on whether CMS-sponsored model participants should be allowed to continue to provide any outstanding service to a patient if the service was initiated before its participation expired.

- <u>Cybersecurity Technology Service</u>: a proposed new safe harbor to protect donations of certain cybersecurity technology and related services to promote increased security for healthcare technology systems. OIG is considering, and is seeking comments on allowing donors or recipients to demonstrate that donations are necessary to implement and maintain effective cybersecurity.

- <u>ACO Beneficiary Incentive Programs</u>: a proposal to codify the statutory exception of "remuneration" to make is clear that an ACO may give incentive payments only to assigned beneficiaries under the MSSP. OIG is seeking comments on whether it should make additional conditions in the safe harbor.

Proposed changes to existing safe harbors include:

- <u>Personal Services and Management Contracts</u>: proposed modifications to protect outcomes-based payments and add flexibility to part-time arrangements. The safe harbor would protect payments made for achieving outcome measures for coordinated care. It would also remove the current requirement that the aggregate compensation be set in advance for the term of a contract and remove the requirement that part-time arrangements specify exact schedules in advance. OIG is considering, and is seeking comments on its approach of valuing outcomes-based payments the same as any other compensation – consistent with fair market value.

- <u>Warranties</u>: proposed modifications to broaden the scope of the warranties safe harbor to allow protection for payments under warranty arrangements that include more than a single item. The proposed modification would protect arrangements that include bundled items and services. OIG is soliciting comments on the potential fraud and abuse risks that may arise if the safe harbor is expanded to include services-only warranties and potential safeguards to mitigate those risks.

- Electronic Health Records: proposed modifications to expand the safe harbor to include "certain cybersecurity software and services" as part of an electronic health records arrangement to make it clear that any entity donating electronic health records may also donate related cybersecurity software and services to protect the security of the electronic health records. The modification would also eliminate the safe harbor's sunset date of December 21, 2021. The safe harbor currently includes a requirement that recipients pay 15-percent of a donor's cost of technology. OIG is seeking comments on removing the sunset date entirely and removing the 15-percent contribution requirement for "small or rural practices" or for all recipients.

- Local Transportation: proposed modifications to expand the distance that residents of rural areas may be transported from 50 miles to 75 miles and to remove the mileage limit on transportation of a patient from a healthcare facility to the patient's residence. OIG is soliciting comments on what safeguards would be necessary to prevent abuse associated with expanding the mileage limits and any basis for the exclusion of ride-sharing programs from protection under the existing safe harbor.

If you have any questions about the issues addressed in this Alert or would like assistance in monitoring the comment process, please do not hesitate to reach out to: Barry A. Posner, at bposner@kudmanlaw.com or (212) 868-0174.

* * *