GW GARFUNKEL WILD, P.C. ATTORNEYS AT LAW Alert

October 2019

DHHS PROPOSES STARK LAW AND ANTI-KICKBACK STATUTE REFORMS TO SUPPORT VALUE-BASED AND COORDINATED CARE

On October 17, 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule to update and clarify certain aspects of the federal physician self-referral law ("Stark Law"). On the same date, the Office of Inspector General ("OIG") also issued a proposed rule to update the federal anti-kickback statute and civil monetary penalties law, as part of the Department of Health and Human Services' "Regulatory Sprint to Coordinated Care," which aims to reduce regulatory barriers, facilitate the transition to value based care and promote care coordination. This Client Alert provides a brief summary of both proposed rules.

1. Stark Law Proposed Rule. Generally, the Stark Law prohibits a physician from making referrals for certain "designated health services" ("DHS") payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service, unless a Stark Law exception is satisfied. The Stark Law also prohibits persons/entities from submitting claims to Medicare for services provided pursuant to a prohibited referral. The Stark Law is a "strict liability" law, such that no intent to violate the Stark Law is necessary for the government to prove a violation.

If adopted, the proposed rule would create new exceptions to the Stark Law for value-based arrangements, as well as for donations of certain cybersecurity technology. There are three separate value-based care exceptions, each of which has unique requirements. Of note, the new value-based exceptions would not prohibit remuneration that takes into account the volume or value of a physician's referrals, but they would prohibit remuneration conditioned on referrals of patients who are not included in the target population, or business that is not covered by the value-based arrangement.

The proposed rule also, among other updates and clarifications, proposes to revise certain standards and concepts that are common to many Stark law exceptions, including: (i) the "set in advance" standard; (ii) the "fair market value" standard; (iii) the "commercially reasonable" standard; and (iv) the "volume or value of referrals" and "other business generated" standards. Each of these standards is critically important to providers seeking to comply with a Stark Law exception, and if adopted, the revisions should ease the burden of compliance.

CMS also proposed to revise (i) the "group practice" regulations by, among other changes, revising the definition of overall profits and restructuring certain aspects of the special rule for productivity bonuses and profit sharing; and (ii) the special rules on compensation arrangements, by extending the current 90 day period to document and sign a compensation arrangement, provided all other requirements of an exception are satisfied.

This summary is not intended to capture all of the proposed revisions to the Stark Law, which are nuanced and complex. We strongly encourage anyone who would like additional information to contact the GW attorney with whom you normally work. Comments to the proposed rule are due by December 31, 2019.

2. Anti-Kickback/CMPL Proposed Rule. The OIG's proposed rule would revise safe harbors to (i) the federal anti-kickback statute, which makes it a crime to knowingly and willfully offer, pay, solicit, or receive remuneration (i.e., virtually anything of value) to induce or reward the referral of business reimbursable by a Federal health care program; and (ii) the beneficiary inducement provision of the civil monetary penalties law, which provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State healthcare program beneficiary that the person knows, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program. If adopted, the proposed rule would create a number of new safe harbors, and modify existing safe harbors, in an attempt to promote coordinated patient care and foster improved quality, efficiency and outcomes.

In the proposed rule, the OIG created new anti-kickback safe harbors for: (i) remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordinated and managed patient care; (ii) certain tools and support furnished to patients to improve quality, health outcomes and efficiency; (iii) remuneration provided in connection with a CMS-sponsored model, which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models; and (iv) donations of cybersecurity technology and services. These new safe harbors, if implemented, should provide greater flexibility to providers.

In addition, the rule proposes to modify existing safe harbors in order to: (i) add protections to the existing safe harbor for electronic health records items and services for certain cybersecurity technology, update provisions regarding interoperability, and remove the sunset date; (ii) modify the existing safe harbor for personal services and management contracts by adding flexibility with regard to outcomes-based payments and part-time arrangements; (iii) revise the definition of "warranty" and provide protection for bundled warranties for one or more items and related services; (iv) modify the local transportation safe harbor to expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities; and (v) codify the statutory exception to the definition of "remuneration" related to Accountable Care Organization Beneficiary Incentive Programs for the Medicare Shared Savings Program.

Finally, the proposed rule would amend the definition of "remuneration" in the civil monetary penalties law interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients. The modifications are intended to facilitate arrangements that do not pose a significant risk of fraud and abuse, while improving efficiency and outcomes.

Comments to the OIG's proposed rule are due 75 days from the date of publication of the Notice of Proposed Rulemaking in the Federal Register, or by December 31, 2019.

* * * * *

The proposed changes, once finalized, may create opportunities for providers to enter into new arrangements or require revisions to existing arrangements. If you have any questions about this alert, please contact the Garfunkel Wild attorney with whom you regularly work.

Contact Information:

111 Great Neck Road Great Neck, NY 11021 516.393.2200	411 Hackensack Avenue Hackensack, NJ 07601 201.883.1030	350 Bedford Street Stamford, CT 06901 203.316.0483	677 Broadway Albany, NY 12207 518.242.7582