OIG proposes changes to existing Anti-Kickback Statute safe harbors

November 19, 2019

On October 9, 2019, the Office of Inspector General (OIG) released proposed changes interpreting the federal Anti-Kickback Statute (AKS) and its regulatory safe harbors, including changes to several existing safe harbors.

Personal services and management contracts safe harbor

The proposed rule would revise the safe harbor in several key ways:

- Remove the requirement that arrangements intended to be on a periodic, sporadic or part-time basis must specify the exact schedule of services to be provided under the arrangement;
- Revise the requirement related to compensation to require only the methodology for determining compensation (not the aggregate compensation) be set in advance (including for outcomes-based payment arrangements);
- Expand the existing safe harbor for personal services and management contracts to protect arrangements in which the agent's compensation is dependent on the achievement of particular outcomes. The proposed safe harbor for "Personal Services and Management Contracts and Outcomes-Based Payment Arrangements" would exclude from the definition of remuneration any **outcomes-based payments** when certain requirements are met, including the following:
    - The payments are:
        - made between or among parties collaborating to:
            - measurably improve (or maintain improvement in) the quality of patient care; or
            - appropriately and materially reduce costs to, or growth in expenditures of, payors while improving

or maintaining quality of care for patients.

- limited to payments from a principal to an agent to:
  - reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or
  - achieve one or more outcome measures that appropriately reduce payor costs while improving or maintaining improved quality of care for patients.

- Eligibility for outcomes-based payments must be conditioned on the agent satisfying one or more specific evidence-based, valid outcome measures that are:
  - related to:
    - measurably improving (or maintaining improvement in) the quality of patient care;
    - appropriately and materially reducing costs to, or growth in expenditures of, *payors* while improving or maintaining quality of care for patients; or
    - both; and
  - selected based on clinical evidence or credible medical support.
- The arrangement is set forth in a signed writing, in advance of or contemporaneously with the start of the term. The term of the arrangement must be at least one year in length. The signed writing must include (i) the services to be performed, (ii) the outcome measures that the agent must satisfy to receive payment, (iii) the clinical evidence or credible medical support relied on to select each outcome measure, and (iv) the schedule for monitoring and assessing the outcome measures. The arrangement may not limit any party's ability to make decisions in their patients' best interest or induce any party to reduce or limit medically necessary items or services, nor may the arrangement involve the counseling or promotion of a business arrangement or other activity that violates state or federal law.
- The parties must do the following for each outcome measure under the agreement:
  - regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care; and
  - periodically rebase each measure during the term of the agreement to the extent applicable.
- Additional conditions and limitations of the new outcomes-based payment provision include:
  - The principal must have policies and procedures to promptly address and correct identified material performance failures or material deficiencies in the quality of care resulting from the outcome-based payment arrangement;
  - The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the arrangement is:
    - set in advance
    - commercially reasonable
    - consistent with fair market value
    - not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made, in whole or in part, by a federal health care program;
  - It only applies to cost savings that accrue to payors, not that solely relate to internal cost savings for a principal. This limitation, if finalized, would prohibit the use of this safe harbor to protect typical gainsharing arrangements; and
  - It does not apply to any payments made, directly or indirectly, by a pharmaceutical manufacturer; a manufacturer, distributor or supplier of durable medical equipment, prosthetics, orthotics or supplies; or a laboratory.

Warranty safe harbor

The proposed rule would revise the warranty safe harbor to:

- modify the definition of "warranty;"
- expand the safe harbor to cover bundled warranties when certain conditions are met;
- exclude beneficiaries from the reporting requirements applicable to buyers of items and services with warranties; and
- prohibit manufacturers and suppliers from conditioning a warranty on a buyer's exclusive use of, or minimum purchase of, any of the manufacturer's or supplier's items or services.

Local transportation safe harbor

The proposed rule would also revise the local transportation safe harbor to:

- increase the mileage limit from 50 miles to 75 miles from the healthcare provider if the patient resides in a rural area;
- eliminate the mileage limit if a patient is being discharged from an inpatient facility to the patient's residence or another residence of the patient's choosing;
- increase the mileage limit from 50 miles to 75 miles from any stop on the route to any stop at a location where health care items or services are provided for shuttle service in rural areas.

These proposed changes to the AKS regulatory safe harbors will likely generate many public comments regarding how these proposals will impact real-life arrangements. Public comments on the proposed changes to the regulations interpreting the AKS are due December 31, 2019. As a result, the OIG will not finalize the proposed changes until 2020.

This publication is part of a series of updates regarding CMS and OIG's proposed fraud and abuse law changes. Bricker & Eckler's health care attorneys will continue to publish analyses of the proposed rule.

Authors