CMS and OIG finalize major changes to Stark and Anti-Kickback regulations: What health care entities need to know

November 23, 2020

On November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) issued long-awaited final rules to "modernize and clarify" the regulations that interpret the Medicare Physician Self-Referral Law (Stark Law), which has not been significantly updated since it was enacted in 1989. The Stark Law final rule is intended to address "undue regulatory impact and burden of the physician self-referral law" and provide "critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations."

On the same day, the Department of Health and Human Services Office of Inspector General (HHS-OIG) issued its final rule modifying existing safe harbors to the Federal Anti-Kickback Statute (AKS) and finalizing a new exception to the civil monetary penalty (CMP) law prohibiting inducements to beneficiaries. The OIG's final rule "aims to reduce regulatory barriers to care coordination and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination."

This publication outlines key features of both CMS' and OIG's final changes to the fraud and abuse laws.

Stark Law final rule – Highlights

Important changes contained in the Stark Law final rule include:

Group practice: Changes to the rules governing how group practices compensate their physicians (effective January 1, 2022).

- When determining whether the physician's compensation, share of overall profits, or productivity bonus is based on, is directly or indirectly related to, or takes into account the volume or value of the physician's referral to the group practice, CMS stated that the new special rule for determining whether compensation to a physician takes into account the volume or value of referrals applies.
- CMS finalized, with modifications, its policy that profits from designated health services (DHS) that are directly attributable to a physician's participation in a value-based enterprise may be distributed to the participating physician.
- The most notable and significant change to the group practice structure in the final rule is a new definition of "overall profits" of a group that can be distributed to physicians in the group. CMS noted that stakeholders have expressed confusion about the definition. With respect to the "five physician" concept, CMS clarified that if there are *fewer* than five physicians in a group, "overall profits" means the profits derived from all the DHS of the group. CMS also clarified that that overall profits means the profits derived from *all* the DHS of any component of the group that consists of at least five physicians (which may include all physicians in the group) and thus, the distribution of profits from DHS on a service-by-service basis is prohibited. The final rule also removes "Medicaid" from the definition of overall profits.

Other significant changes (effective January 19, 2021)

- Three new exceptions for arrangements that facilitate value-based health care delivery and payment.
    - Full financial risk
    - Value-based arrangements with meaningful downside financial risk to the physician
    - Value-based arrangements
- Extension of the value-based exceptions to indirect compensation arrangements that include a value-based arrangement to which the physician or physician organization is a direct party.
- A new exception for donations of cybersecurity technology that includes hardware in addition to software and services.
- A new exception for limited remuneration to physicians capped at $5,000 per physician per year.
- A new definition of commercial reasonableness:
    - Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. The new definition also explicitly states that "[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."
- A revised definition of designated health services (DHS) that clarifies that for services furnished to hospital inpatients, a service is not considered DHS if the furnishing of the service does not increase the amount of Medicare's payment to the hospital (such as by pushing the claim into outlier status) under the inpatient, inpatient rehabilitation facility, inpatient psychiatric facility, or long term care hospital prospective payment systems.
- New definitions for fair market value and general market value.
- Codification of the concept that a single instance of forgiveness of an amount owed in settlement of a bona fide dispute can be an isolated financial transaction.
- Alignment of the definition of "physician" with the meaning set forth in section 1861(r) of the Social Security Act, which has the effect of limiting when doctors of podiatric medicine, doctors of optometry and chiropractors are considered physicians for purposes of the Stark Law.
- A new special rule for reconciling compensation following the expiration or termination of a compensation arrangement to allow parties up to 90 consecutive calendar days to reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement.
- A revised definition of indirect compensation arrangement that CMS acknowledges will "reduce the number of unbroken chains of financial relationships that fall within the ambit of the physician self-referral law as indirect compensation arrangements (although they may still implicate the anti-kickback statute, depending on the facts and circumstances)" and

that as a result, "many unbroken chains of financial relationships will no longer be required to satisfy the writing requirement."

- Modification of the special rules on compensation, including the directed referral rule which will now require, among other things, that if a physician's compensation is conditioned on referrals to a particular provider, practitioner or supplier, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner or supplier. However, the requirement to make referrals to a particular provider, practitioner or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner or supplier.
- A revised definition of when compensation takes into account the volume or value of referrals or other business generated and eliminates the proposed definition that would have applied to fixed compensation.
- Clarification that the signature requirement contained in many exception "may be satisfied by an electronic or other signature that is valid under applicable Federal or State law".

Additionally, the Stark Law final rule:

- Finalizes the proposal to allow up to 90 calendar days grace for obtaining writing where an exception requires such and also makes clear that the grace period for writings and signatures can be used in conjunction with the new limited remuneration to physicians exception to potentially extend the time within which the parties can memorialize an arrangement in writing and obtain required signatures and meet the set in advance requirement included in some exceptions.
- Finalizes the proposal to decouple the Stark Law from the Anti-Kickback Statute and removes references to compliance with the Anti-Kickback Statutes from all exceptions except for the fair market value compensation exception.
- Finalizes the proposal to delete the period of disallowance concept from the Stark regulations.
- Does not finalize the price transparency rule included in the proposed rule.

The Stark Law final rule is effective on January 19, 2021, except for the changes to the special rules for profit shares and productivity bonuses in a group practice, which are effective January 1, 2022. CMS stated that it wanted to give group practices until 2022 to modify their compensation methodologies, if needed, based on the final rule changes to the profit share and productivity bonus special rules.

Anti-Kickback Statute final rule – Highlights

The safe harbors resulting from the AKS final rule are summarized below.

- *Value-based arrangements:* Three new safe harbors for certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordinated and managed patient care:
    - Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency
    - Value-Based Arrangements With Substantial Downside Financial Risk
    - Value-Based Arrangements With Full Financial Risk

  These new safe harbors vary by the type of remuneration protected (in-kind or in-kind and monetary), level of financial risk assumed by the parties and safeguards included as safe harbor conditions.

- *Patient engagement and support*: A new safe harbor for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency, capped at $500 per year. The OIG did not finalize its proposal to allow the annual cap to be exceeded for patients based on determinations of financial need.
- *CMS-sponsored models:* A new safe harbor for certain remuneration provided in connection with a CMS-sponsored model (as defined in the final rule), which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.
- *Cybersecurity technology and services:* A new safe harbor for donations of cybersecurity technology and services that also

includes hardware.

- *Electronic health records items and services*: Modifications to the existing safe harbor for electronic health records items and services to add protections for certain related cybersecurity technology, to update provisions regarding interoperability and to remove the sunset date.
- *Outcomes-based payments and part-time arrangements*: Modifications to the existing safe harbor for personal services and management contracts to add flexibility for certain outcomes-based payments and part-time arrangements. Of particular note, OIG finalized its proposal to substitute the requirement in the personal services safe harbor that aggregate compensation be set in advance with a requirement that the methodology for determining compensation be set in advance. Also, the OIG finalized its proposal to eliminate the condition in the safe harbor that required that if an agreement provides for the services of an agent on a periodic, sporadic or part-time basis, the contract must specify the schedule, length and the exact charge for such intervals. Both of these changes will now permit safe harbor protection for arrangements when the total amount to be paid over the course of the term is unknown at the time of execution and for part-time arrangement without a set schedule and more closely aligns this safe harbor with the personal services exception under the Stark Law.
- *Warranties*: Modifications to the existing safe harbor for warranties to revise the definition of "warranty" and provide protection for bundled warranties for one or more items and related services.
- *Local transportation*: Modifications to the existing safe harbor for local transportation to increase mileage limits for rural areas from 50 miles to 75 miles and eliminated distance limitations for transportation of patients discharged from an inpatient facility or released from a hospital after being placed in observation status for at least 24 hours.
- *Accountable Care Organization (ACO) Beneficiary Incentive Programs:* Codification of the statutory exception to the definition of "remuneration" under the anti-kickback statute related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.

With respect to the CMP prohibiting inducements to beneficiaries, the final rule made the following change:

- *Telehealth for in-home dialysis*: An amendment to the definition of "remuneration" in the CMP rules interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients.

The OIG has also published a chart which lists by type of entity (*e.g.* hospitals/physicians, pharmacies) eligibility for the value-based safe harbors, the patient engagement and support safe harbor, and the personal services and management contracts safe harbor for outcome-based payments. For example, the chart highlights that while providers (such as a hospitals) are eligible to use the safe harbor for care coordination arrangements, a pharmacy-benefit manager is not. However, the OIG notes that "*[i]neligible entities may be able to use other new or modified safe harbors if an arrangement satisfies all applicable conditions.*"

The AKS and CMP final rule is effective January 19, 2021.

Authors