

Health Care Law Update

November 2019

New Stark Law Rules Proposed

Key Notes:

- New proposed rules offer greater certainty in interpreting Stark Law regulations and allow for new opportunities for care coordination among health care providers participating in value-based arrangements.
- Proposed changes permit greater flexibility in financial arrangements between physicians and DHS entities.

On October 9, 2019, the Centers for Medicare & Medicaid Services (CMS) issued long-awaited proposed changes to the Stark Law regulations as part of the Department of Health & Human Services' Regulatory Sprint to Coordinated Care initiative. This initiative seeks to promote value-based care by examining federal regulations that impede providers' efforts to deliver better coordinated care to patients. Accordingly, the proposed rules offer greater certainty for health care providers participating in value-based arrangements and providing coordinated care for patients. They also modernize and clarify the existing Stark Law regulations. The changes were largely based on feedback CMS received to its Request for Information issued in June 2019, as well as observations gleaned from submissions under the CMS Self-Disclosure Protocol. The changes are extensive and impact a variety of financial arrangements between physicians and entities that provide designated health services (DHS). CMS solicited feedback on many of the proposed rules, so the final rules likely will differ from the proposed rules in many respects. Notwithstanding this likelihood, CMS's guidance regarding its interpretation of the existing Stark Law regulations will be immediately helpful for providers participating in federal health care programs.

The Office of Inspector General (OIG) concurrently issued new proposed safe harbors to the Anti-Kickback Statute and Civil Monetary Penalties Law that align in many respects with CMS's proposals. This alert summarizes the highlights of CMS's proposed changes to the Stark Law regulations.

Value-Based Arrangements Exceptions

Three new exceptions are intended to accommodate the health care industry's shift from a volume-based payment and delivery model to a value-based payment and delivery model by allowing two or more health care providers to coordinate to achieve a value-based purpose. Value-based purposes include:

- coordinating and managing the care of a target patient population,
- improving the quality of care for a target patient population,
- appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population, and
- transitioning from health care 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 a target patient population.

The new exceptions protect:

- Value-based arrangements where a value-based enterprise has assumed full financial risk from a payor for patient care services for a target patient population, such as capitation or global budget payments.

- Value-based arrangements where a physician has meaningful downside financial risk, meaning that the physician is at risk to repay the entity at least 25% of the value of the remuneration that the physician receives under the value-based arrangement.
- Other value-based arrangements, provided they satisfy specified requirements.

Due to the disincentives for overutilization and stinting on patient care inherent in volume-based payment models, CMS is not proposing to include the standard Stark Law requirements that the compensation be fair market value and not take into account the volume or value of a physician's referrals or other business generated by the physician for DHS entities.

Other New Exceptions

The proposed rules also include:

- A new exception for limited remuneration from an entity to a physician for items or services the physician provides, without requiring a written agreement, if the standard compensation-related requirements are met and the remuneration does not exceed \$3,500 per year. A hospital could utilize this exception, for example, to pay a physician who provides services on an infrequent or short-term basis.
- A new exception that permits the donation of qualifying cybersecurity technology and related services under certain conditions, which CMS created because it recognizes that the risks associated with a cyberattack on a single provider or supplier in an interconnected system are ultimately borne by every entity in the system.

Revisions to Existing Regulations

The new rules proposed by CMS would also:

- Create two alternative definitions to the term "commercially reasonable," including (i) that the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements even if no referrals are made, and (ii) that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and

specialty even if no referrals are made. Recognizing that some arrangements are necessary even though they don't result in profit (such as services that support community need and essential lines of services, and services that improve quality and health outcomes), CMS confirmed that the determination of commercial reasonableness is not based on whether an arrangement is profitable.

- Create new rules to clarify when compensation is deemed not to take into account the volume or value of referrals and other business generated by the physician. In response to the *Tuomey* decision, CMS reaffirmed its position that, with respect to employed physicians, a productivity bonus does not take into account the volume or value of the physician's referrals solely because corresponding hospital services are billed each time the employed physician personally performs a service (i.e., there are no "shadow" referrals).
- Revise the definition of "designated health services" to clarify that a service provided by a hospital to an inpatient does not constitute a DHS if furnishing the service does not affect the amount of Medicare payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System. Accordingly, physician referrals for hospital services for patients already admitted to the hospital and assigned a Diagnosis-Related Group would not be considered DHS.
- Establish a definition of "isolated financial transaction" and clarify that the exception cannot be used to retroactively cure noncompliance with the Stark Law, such as making one payment for multiple services provided over an extended period.
- Establish a rule providing that the writing and signature requirements are deemed satisfied if (i) the compensation arrangement satisfies all of the requirements of an applicable exception other than the writing or signature requirements, and (ii) the parties obtain the writing or signature within 90 days after the date the compensation arrangement begins.
- Clarify that the "exclusive use" requirement under the rental of office space or equipment exceptions means that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment. Thus, multiple lessees may use the rented space or equipment at the same time.

- Modify the physician recruitment exception to require the physician practice to sign the recruitment agreement only if the practice retains a portion of the funds passed through the practice to the recruited physician.
- Make the fair market value exception available for the rental or lease of office space, thus allowing for lease arrangements of less than one year.
- Amend the electronic health record (EHR) exception to clarify that donations of cybersecurity software and services associated with the EHR are protected under the EHR exception. CMS also requested comments on the existing 15% physician contribution requirement.

A Move in the Right Direction

Comments on the proposed rules are due on December 31, 2019. The proposed rules are not effective, and may not be relied on, until finalized by CMS.

While the Stark Law regulations will continue to be technical, the proposed rules offer some relief from uncertainty, as well as new opportunities for collaboration among health care providers to deliver better, more cost-effective care to patients.

FOR MORE INFORMATION

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