

Stark and Anti-Kickback Law Regulatory Revision Proposed by CMS

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On Oct. 17, 2019, the Centers for Medicare and Medicaid Services (**CMS**) released substantive proposed regulatory changes to Stark regulations.¹ The goal is to provide relief for value-based arrangements so as not to run afoul of the Physician Self-Referral law (Stark) and the Federal Anti-Kickback law. These laws are intended to prevent doctors from referring patients for services that would financially benefit them, or taking financial kickbacks to generate new business. The impetus for the proposal is that these laws and implementing regulations can sometimes hinder efforts to improve patient care, especially in an era where health care institutions and providers (more predominate in hospital systems versus dental clinics at this time) are increasingly being paid for quality of care and how well they coordinate a patient's care with other providers.

These laws were described in an earlier Litch's Law Log² that included the following still very sound advice:

"Because of the complexity of these laws, any question about receiving or providing benefits for patient referrals, or your financial interest in another health care facility where your patients might be referred, should be reviewed by an attorney experienced in health law."

With that caveat in mind, below is a general overview of the main CMS proposed regulatory changes.³

CMS attempts to clarify the terms "fair market value", "volume or value" and "commercially reasonable" as these are critical to determining whether there is Stark law violation. CMS proposes that general market value means the same as fair market value, revising the definition of fair market value (FMV) to read:

"The value in an arm's length transaction, with like parties and under like circumstances, or the assets or services, consistent with the general market value of the subject transaction."

General market value will mean:

"[t]he price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service agreement."

Essentially this will permit consideration of the particular characteristics of the buyer, seller, and local market.

Regarding volume or value, this was problematic because previously CMS had considered that Stark law was violated where a flat or fixed amount compensation was augmented to reflect the volume or value of the physician's services and not subject to a FMV defense. CMS proposes to eliminate language that compensation cannot vary in a manner that takes into account volume or referrals to a designated health service (DHS). Note that group practices will need to continue to satisfy the "group practice" definition special rules (or safe harbor) for productivity bonuses and profit shares.

CMS proposes that employed or contracted physicians could make direct referrals to the DHS entity without violating the volume or value standard, nor would a productivity bonus to an employed physician or unit-

based compensation to a non-employed physician. The following examples were provided:

- Physician office space rented from a hospital that is \$5000 monthly, but reduced by \$5 for each diagnostic test referred to the hospital.
- Physician office space rented from a hospital that is \$2000 a month if the physician is in the hospital's top 25% of admitting physicians in the prior month, \$2500 if in the second quartile, and \$3500 if in the bottom half of admitting physicians.

CMS also defines "commercially reasonable" as meaning: "the particular arrangement furthers a legitimate purpose of the parties and is on similar terms and conditions as like arrangements;" and "the arrangement makes commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty." The effect here is that a proposed "loss" in written arrangements is not necessarily commercial unreasonable.

CMS proposes three value-based exceptions for a core entity called a "value-based enterprise" or VBE. A VBE needs to have a body or person that is accountable for the financial and operational oversight of the VBE, and a governing document describing how VBE and participants intend to achieve a value-based purpose. This would appear to protect value-based entities such as accountable care organizations (ACOs) or clinically integrated networks where a group of providers collaborate to coordinate care. To qualify, the arrangement must be reasonably designed to achieve at least one value-based purpose:

1. Coordinating and managing care of a target patient population;
2. Improving the quality of care of a target patient population;
3. Appropriately reducing the costs to, or growth in expenditure, to payers without reducing quality of care for a target patient population;
4. Transition from health care delivery and payment mechanism based on the volume of items and services provided to mechanism based on quality of care and control of costs of care for target patient population.

This column presents a general informational overview of legal issues. It is intended as general guidance rather than legal advice. It is not a substitute for consultation with your own attorney concerning specific circumstances in your dental practice. Mr. Litch does not provide legal representation to individual AAPD members.

¹<https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>

²<https://www.aapd.org/assets/1/7/4398.pdf>

³This column relies heavily on the following articles: Barsky TA (Crowell & Moring LLP) and Melvin DH (McDermott Will & Emery LLP). *The Sprint to Modernize and Clarify the Stark Law- Part 1 and Part 2*. AHLA Connections, December 2019 (1- 16) and January 2020 (26-32). AHLA stands for the American Health Law Association.

CMS would exclude from value-based activity the making of a referral. This is confusing because while clearly the Stark law was designed to prevent self-referrals (and the resulting financial benefit), one of the central tenants of value-based care is coordination and management of care. It is hard to see how that goal can be obtained without financial incentives for physicians to refer patients to a particular provider, supplier, or practitioner.

There are proposed exceptions/protections for remuneration between VBE participants or between VBE participants and a VBE:

- Full financial risk- For example, if a clinically integrated network agrees to manage the delivery of care to a payer's enrollees for a set capitated amount of money;
- Meaningful downside financial risk to physician—This is likely to see limited use because either a physician is on the hook for 25 % of the value of remuneration or for ALL costs of a defined set of items and services for a specific period of time;
- Value-based arrangements- The physicians and VBE will not be at financial risk, but arrangements must be in writing to describe activities such as identifying the target population and the methodology to determine remuneration and performance or quality standards.

For all of this to work as intended, HHS Office of Inspector General (OIG) interpretations of the Anti-kickback law must be consistent with Stark regulations, because for many value-based arrangements parties will need to comply with both the Stark and Anti-Kickback laws.

These proposals make the Stark law clearer, but there is still much complexity and perhaps no better example in health law that illustrates how health care is a heavily regulated sector. Whether it is appropriately regulated is an issue for another column.

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