CMS REQUESTS PUBLIC COMMENTS ON THE STARK LAW TO FACILITATE CARE COORDINATION

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U.S. Health Care Alert

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On June 25, 2018, the Centers for Medicare and Medicaid Services ("CMS") published a request for information ("RFI") seeking public input on how to address "undue regulatory impact and burden" of the federal physician self-referral law, also known as the "Stark Law," specifically focusing on the application of the Stark Law in the context of care coordination and alternative payment models and how the Stark Law may hinder such arrangements. [1]

The Stark Law prohibits an entity from submitting claims to Medicare for designated health services ("DHS") referred from a physician if the physician or the physician's immediate family member has a financial relationship with that entity unless an exception applies. [2] A financial relationship under the Stark Law can encompass both ownership and compensation relationships and can be either direct or indirect. Of note, the Stark Law is a strict liability prohibition such that the entity is prohibited from billing Medicare for DHS as a result of prohibited referrals regardless of the parties' intent in entering the arrangement. [3]

CMS explained that the Department of Health and Human Services ("DHHS") has made removing barriers to care coordination a key priority as it looks to transform the current health care reimbursement system into one that pays for value. In several 2017 proposed rulemakings, CMS solicited public comments on suggested improvements to the health care delivery system more generally to reduce burdens on health care providers, patients, and families, inviting ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish the goals of increasing quality of care, lowering costs, improving program integrity, and help make the health care system more effective, simple, and accessible. [4] As a result, CMS received comments on the burden of compliance with the Stark Law in the context of participation in health care delivery and payment reform efforts.

In the RFI, CMS also references President Trump's FY 2019 Budget, which would revise the Stark Law by establishing new protections for health care services furnished through alternative payment models. Specifically, the "Medicare Care Coordination Improvement Act of 2017" (the "Act") was introduced in both the U.S. House of Representatives (H.R. 4206) and the Senate (S. 2051) on November 1, 2017, and remains under consideration by Congress. The Act would provide DHHS authority to grant waivers to fraud and abuse-related statutes that are currently available to participants in the Medicare Shared Savings Program and expand the authority of DHHS to promulgate additional Stark Law exceptions not posing a "significant risk of program or patient abuse, including those that would promote care coordination, quality improvement, or resource conservation by physician practices under [Medicare] part B." The Act would also limit the DHHS Secretary from imposing requirements that could adversely affect physician care coordination in the merit-based incentive payment system or physician participation in alternative payment models and would establish a new statutory exception to the Stark Law for

services furnished pursuant to an arrangement entered into for the purpose of developing or operating an alternative payment model meeting certain enumerated conditions.

CMS is now soliciting the public's input on (i) the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, (ii) whether amendments and/or additions to exceptions to the Stark Law are needed to facilitate such arrangements, and (iii) whether clarification or revisions to current terminology under the Stark Law or new terminology specifically related to health care delivery and payment reform are needed. Specifically, CMS has requested public comments on the following topics:

- Existing or potential arrangements involving DHS entities and referring physicians that participate in alternative payment models or other novel financial arrangements, whether or not sponsored by CMS and specific terms of such arrangements not sponsored by CMS, including a description of the arrangements, concerns regarding the applicability of existing Stark Law exceptions or ability to satisfy such exceptions, the impact of the Stark Law on the arrangements, and how the arrangement would address the program abuses that the Stark Law aims to mitigate.
- Additional Stark Law exceptions necessary to protect DHS entities and referring physicians participating in the same alternative payment model, such as accountable care organizations, bundled payment models, and two-sided risk models under fee-for-service payment systems and in integrated and coordinated care arrangements outside of alternative pay models.
- The utility of the risk-sharing arrangement exception, [5] the special rule for compensation under a physician incentive plan under the personal services exception, [6] and the exception for remuneration unrelated to DHS [7] (and how CMS could broaden the interpretation of arrangements under that particular exception).
- Potential approaches to the application of the Stark Law to financial arrangements among participants in alternative payment models and other novel arrangements, including whether a single exception would suffice or whether amendments to existing exceptions and/or establishing new exceptions is the preferable approach.
- Suggested definitions for an enumerated list of terminology in relation to health care delivery, payment reform, and the Stark Law, including care coordination, clinical integration, financial integration, risk, risk sharing, a physician incentive program, gainsharing, and an integrated delivery system, as well as any additional terminology and definitions in relation to the comments elicited in the RFI.
- Potential approaches to defining "commercial reasonableness" and modifying the "fair market value" definition consistent with the statute with regard to the Stark Law exceptions.
- When compensation should be considered to "take into account the volume or value of referrals" by a physician or "take into account other business generated" between parties in the context of both the Stark Law and alternative payment models. CMS has also requested examples of compensation models that do not take into account the volume or value of referrals by a physician or other business generated between parties.

- Whether and which barriers exist to qualifying as a "group practice" under the Stark Law regulations and whether any additional provisions, definitions, and/or exceptions could benefit from additional clarification.
- Potential role and value of transparency safeguards related under the Stark Law (e.g., disclosures regarding financial arrangements to beneficiaries), whether such transparency would reduce or eliminate the program harms that the Stark Law seeks to mitigate, and whether and how CMS could design a model to test whether new transparency safeguards could effectively address the impact of financial self-interest on physician medical decision-making.
- Compliance costs for entities subject to the Stark Law, studies assessing the Stark Law's impact on the health care industry, and whether CMS should measure the effectiveness of the Stark Law in preventing program abuse.

Although all of the above requests for comments could impact care coordination and participation in alternative payment models, many of the above requests are very significant with respect to Stark Law compliance generally. All health care providers subject to the Stark Law should consider the opportunity to providing comments to this RFI, regardless of their participation in new payment models. Comments are due to CMS by no later than 5:00 p.m. on August 24, 2018.

Notes:
[1] CMS, Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 29,524 (June 25, 2018).
[2] *See generally* 42 USC § 1395nn.
[3] *Id.*
[4] *See*, e.g., CMS, Medicare Program; FY 2018 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update, 36,771, 36,784 (proposed rule, Aug. 7, 2017).
[5] 42 C.F.R. § 411.357(n).
[6] 42 C.F.R. § 411.357(d).
[7] 42 C.F.R. § 411.357(g).

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