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CMS Continues to Eye Reforms to Stark Law, Requests Public Input

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The Centers for Medicare and Medicaid Services (CMS) issued a Request for Information (RFI) on June 20, 2018 seeking input from the public on how to address "any undue regulatory impact and burden" of the physician self-referral law (the "Stark law"), particularly how aspects of the Stark law may present barriers to coordinated care under value-based payment models.[i] Two pieces of major health care reform legislation adopted within the last decade, the Patient Protection and Affordable Care Act (ACA) and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), were intended to transform the health care delivery system in part by encouraging development of new payment models. These new models represent a shift away from the traditional fee-for-service (FFS) model that pays providers based on the number of items and services they offer patients, in favor of alternative payment models (APMs) that provide incentives for improving the quality of care provided and reducing duplicative and unnecessary costs. Since enactment of the ACA and MACRA, stakeholders have repeatedly voiced concerns that the Stark law's prohibitions and complexity would prevent patient care innovation and widespread adoption of APMs.

In general, the Stark law prohibits a physician from making a referral for the provision of certain "designated health services" (DHS) to any entity with which that physician (or his or her immediate family member) has a financial relationship, unless an exception applies.[ii] The Stark law further prohibits the entity receiving an impermissible referral from billing Medicare for services provided pursuant to that referral. At the time of its enactment, the Stark law was intended to create a "bright line" test limiting physician self-referrals to prevent physicians from ordering unnecessary or excessive items or services from which they would profit. However, over the last 30 years, the Stark law has evolved to include more than three dozen exceptions containing various technical and subjective terms that often have mystified health care providers and left them subject to substantial risk of unintentionally violating the law's prohibitions. Stark law violations result in significant penalties, from the obligation on the entity that provided the DHS pursuant to an impermissible referral to refund all Medicare payments received for those services to possible liability and treble damages under the False Claims Act. As a result, health care providers are hesitant to enter into arrangements which regulatory agencies later may determine violate the Stark law.

The Stark law's prohibition is rooted in the FFS model, which enables health care providers to generate income based on the quantity of services provided to patients. Value-based APMs, like those made possible under the ACA and MACRA, base reimbursement not on the number of services provided, but on the quality of the care provided and the patient outcomes achieved. Improving quality and outcomes requires a greater level of care coordination between physicians and other health care providers, such as hospitals and post-acute care facilities. Complying with the Stark law's requirements while obtaining physician buy-in on these new APMs is nearly impossible—a fact that had not escaped Congress at the time it adopted the ACA. The ACA permitted CMS to issue waivers of compliance with the Stark law and other fraud and abuse laws for providers participating in APMs.[iii] To this end, CMS has issued waivers covering participants in Medicare Shared Savings Programs, Bundled Payments for Care Improvement Initiatives, Compressive Care for Joint Replacement, and certain Accountable Care Organization (ACO) programs. Unfortunately, these waivers all expire, and similar authority enabling CMS to grant such waivers was not provided for APMs that are implemented pursuant to MACRA. Without long-term certainty surrounding the requirements for compliance with Stark and other fraud and abuse laws when participating in APMs, many health care providers are hesitant to make the shift from volume-based care to APMs.

The reluctance of health care providers to embrace APMs, along with the importance of APMs to real reform of our health care delivery system, have refocused criticism of the Stark law as an impediment to innovation, rather than as a means of protecting against improper cost increases. In December 2015, the U.S. Senate Committee on Finance and the U.S. House Committee on Ways and Means convened a round-table discussion of subject matter experts to discuss whether changes in the Stark law were necessary to implement APMs made possible under health care reform legislation.[iv] This meeting led to a June 2016 report outlining suggested reforms that will encourage providers to participate in APMs.[v] The Senate Committee on Finance then held a hearing in July 2016 which featured further discussion about possible Congressional action, including a full or partial repeal of the Stark law.[vi] Despite seeming agreement among hearing participants that Congressional action on the Stark law was a prerequisite for the long-term success of APMs, to date Congress has made no move to reform the law.

In the absence of such Congressional action, CMS appears to be considering a broad range of possible regulatory changes that may address health care provider apprehensions about and facilitate wider adoption of APMs. The RFI released on June 20, 2018 calls for comments on possible exceptions necessary to protect ACOs and bundled payment models. CMS also seeks input on the utility of existing Stark law exceptions, including those for ownership or investment interests, as well as compensation, risk-sharing, and personal service arrangements. However, CMS's authority to adopt new exceptions or drastically alter current ones is limited. Such action is permitted only if CMS determines that such changes would "not pose a risk of program and patient abuse."[vii] In the current environment where both FFS and APMs exist, relaxing requirements under current Stark law exceptions could pose such risks, and new exceptions related solely to APMs could be used to hide abusive arrangements which take advantage of the ongoing FFS environment. CMS has traveled this path before when, in 2009, it proposed a gainsharing exception to the Stark law, which would have assisted health care providers in adopting APMs.[viii] Following public responses to the proposed exception, which included criticism of CMS's limited ability to revise it, the gainsharing exception was not finalized.

Assuming that the issuance of the RFI does not rekindle a movement within Congress urging repeal of the Stark law, the RFI ultimately may have its greatest chance of impacting future regulatory changes to the Stark law through its call for comment on possible approaches to modifying the definition of "fair market value" and to defining "commercial reasonableness." These two terms are used throughout the Stark law and are key to several exceptions.[ix] Despite the pervasiveness and critical importance of these terms, however, what constitutes "fair market value" under the existing definition is not always clear, and "commercial reasonableness" is not defined anywhere. Pinpointing definitions for these terms that would accommodate APMs and provide more "bright line" rules could go a long way toward creating additional certainty under the Stark law.

CMS's RFI is expected to be published in the Federal Register on June 25, 2018, after which the public comment period will remain open for 60 days. Although it is difficult to predict what changes to the Stark law, if any, will emerge through this RFI process, its issuance offers some indication that CMS is willing to consider further regulatory action to eliminate some of the inherent conflicts and complexity of the Stark law that have been developed over years of iterative legislative and rulemaking efforts. Health care providers and other industry stakeholders should seize this opportunity to add their concerns, perspectives, and possible solutions to the discussion.

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[i] CMS, "Medicare Program; Request for Information Regarding the Physician Self-Referral Law" Request for Information (June 25, 2018) available at https://www.federalregister.gov/documents/2018/06/25/2018-13529/medicare-program-request-for-information-regarding-the-physician-self-referral-law; see also, CMS,"CMS seeks public input on reducing the regulatory burdens of the Stark Law" Press Release (June 20, 2018) available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-06-20-2.html; Seema Verna, Administrator CMS, "Working Together for Value" The CMS Blog (June 20, 2018) available at https://blog.cms.gov/2018/06/20/working-together-for-value/.

[ii] 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a).

[iii] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, (2010).

[iv] See, U.S. Senate Finance Committee, "Why Stark, Why Now?" Majority Staff Report (June 30, 2016) available at https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf.

[v] Id.

[vi] U.S. Senate Finance Committee, "Examining the Stark Law: Current Issues and Opportunities" Hearing (July 12, 2016) available at https://www.finance.senate.gov/imo/media/doc/26440.pdf.

[vii] 42 U.S.C. § 1395(b)(4).

[viii] 73 Fed. Reg. 38502, 38548-58 (July 7, 2008).

[ix] See e.g., 42 C.F.R.§ 411.354(d) and (e); 42 CFR § 411.357(a)-(h),(j), (l)-(n), (p), (r)-(t), and (v)-(y).

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