

Stark Law and Anti-Kickback Statute Reform:

What Does the Future Look Like?

Responses to CMS's June 2018 Request for Information Hold Clues

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October 4, 2018

It's a safe bet that in the coming year reforms will be made to two central laws governing physician compensation – the Stark Law and the Anti-Kickback statute. Whether through amendment to each law, revised regulations, or both, the Centers for Medicare and Medicaid Services (CMS) have left no doubt those changes are inevitable. As a result, providers should be aware that certain arrangements for payment may become available that previously either have not been permitted or have been deemed too risky to implement. It is likely, of course, that the safe route for physicians and providers will be to enter into practice alignments that are based upon alternative payment methods designed to transition from fee-for-service (FFS) to value-based payment methods. This will require, ultimately, the adoption and sharing of risk.

The Stark Law and the Anti-Kickback Statute

Just short of three decades old, the Stark Law (passed as the Ethics in Patient Referrals Act) has morphed from the simple concept of banning a physician's referral to a lab he or she owns, to a large web of regulations that set forth an array of exceptions to the law with byzantine and complex requirements. The gist of the Stark Law is to combat overutilization by physicians who refer patients to entities owned in whole or in part by the referring physician. If a physician, or a physician's family member, has a financial relationship with an entity, then the physician may not refer a Medicare or Medicaid patient to that entity and may not submit a bill for an item or service defined as a designated health service (DHS), unless the physician can satisfy a Stark exception. Because it is a "strict liability" law, any financial arrangement that runs afoul of its requirements, regardless of a provider's "intent," can lead to severe penalties.

At its core, the Anti-Kickback statute (AKS), a criminal statute, prohibits the unlawful acceptance or diversion of remuneration of any kind into influencing medical decision making. The AKS seeks to eliminate abuse and fraud by making criminal the deliberate acceptance or offering of anything of value for the referral of a patient for items or services covered by a federal health care program. Congress has crafted so-called "safe harbors" that define payment arrangements immune from prosecution. Although failure to fall squarely within a particular safe harbor does not necessarily invalidate the arrangement, attention must be paid to each element of a particular safe harbor in order to come as closely as possible to avoiding trouble.

The exceptions to the Stark Law and the safe harbors available under the AKS share many of the same components, although the former have become increasingly complex. For

each law, enforcement increasingly has been exercised through the False Claims Act, by which penalties of up to three times per violation may be assessed.

Inherent Tensions between the Stark Law and APMs

The goals envisioned in new “alternative payment arrangements” (APMs) are at odds with the goals of the Stark Law. In essence, the Stark Law, enacted in 1989, was intended to maintain financial separation between providers, and focuses on overutilization created by the economic interests of referring physicians. Congress expressly enacted it to comport with the then traditional silo model of health care reimbursement. In one silo, physicians received FFS payments, were incentivized to deliver higher volumes of care, and bore no financial responsibility for the cost of quality of ordered services. In the adjacent silo, hospitals were provided “diagnostic-related group” payments, were themselves incentivized to discharge patients as quickly as possible, and bore little financial responsibility for the cost or quality of post-discharge services. To the extent that collaboration may have been desired in order to reduce costs and improve quality, this need remained in express tension with the Stark Law which was designed to keep hospitals and physicians at arm’s length.

APMs, by contrast, are designed to integrate providers clinically and financially, in order to foster coordinated care and quality outcomes without overutilization of resources. In a value-based payment system, providers are rewarded for delivering higher outcomes at lower costs without regard to the number of services, or volume of services, furnished by the provider. In short, as payments to providers transition away from FFS to value-based, the necessity of the Stark Law is under scrutiny because its provisions impede the development of APMs that reward quality and cost-effectiveness in the delivery of medical services.

CMS’s Request for Information Issued on June 18, 2018

While the signals pointing to CMS’s drive for reform of Stark have been clear for some time, CMS’s formal request for information from health care industry stakeholders, titled the “Regulatory Sprint to Coordinated Care,” issued on June 18, 2018 demonstrates the government’s now absolute priority to transition to value-based payments.¹ CMS’s June request for public comments on how to reform the Stark Law, and the responses received, are but the latest sign that the law will be revised in some fashion. CMS’s push to transition physician reimbursement to a new world of value-based payments in lieu of FFS simply cannot be undertaken without revision to the regulatory regime embodied in the current Stark Law. When inevitable changes arrive, there may be significant opportunities for physicians to enter into new

¹ 83 Federal Register 29524, published June 25, 2018

alternative payment arrangements without fear of subjecting themselves to the draconian penalties contained within the law.²

CMS set a deadline for responses to its RFI by August 24. Immediately thereafter, on August 27, the Office of Inspector General (OIG) released its own request for information about revisions to the current Anti-Kickback statute and its safe harbors to encourage APM advancement.³ In this RFI, the OIG seeks stakeholder input concerning the AKS and comments regarding the existing safe harbors, or the addition of new ones, in order to identify regulatory provisions governed by the AKS that act as barriers to coordinated care, and to assess whether these provisions are themselves regulatory obstacles to coordinated care. Comments to this RFI are due October 27.

Precursors to Stark Law Reform and the Push to “Alternative Payment Arrangements”

Since the passage in 2010 of the Patient Protection and Affordable Care Act (ACA), Congress and CMS have publicly demonstrated a desire to reform the Stark Law, not because of its complexity but rather to align the law with CMS’s public goal to shift from FFS payment models - by which volume of service is the basis for payment, to value-based payment models - where efficiency and quality are factored in provider reimbursement. Indeed, the ACA commenced the process of statutorily encouraging new “alternative payment arrangements” to foster the development of value-based payments. These include the establishment of the Centers of Medicare & Medicaid Innovation (“CMMI”) to test new delivery models through a variety of programs relating to the Medicare and Medicaid programs. Other prominent programs have included the Medicare and Medicaid Shared Savings Program (MSSP) and establishment of Accountable Care Organizations (ACO), the Comprehensive Care for Joint Replacement Model, and the Bundled Payment for Care Improvement Initiative. All seek to shift provider payment from a fee-for-service model to a value-based one.

The 2016 enactment of the Medicare Access and CHIP Reauthorization Act (MACRA) and its on-going efforts to reward quality, resource use, EHR adoption, and clinical practice improvement activities further demonstrate Congress’ intent to move Medicare payments away from FFS to APMs. MACRA establishes a time-table for physicians to transition away from pure FFS payments to either a Merit-Based Incentive Payment System (MIPS) or APMs. These two options and their incentives are phased in over time. Although MACRA represents a concrete step to push away from the traditional FFS model and towards a value-based payment system, policy makers both in the Congress and at CMS do not believe they are sufficient to push payment reform fast enough. The problem? With the exception of waivers from Stark for

² Recently, the Balanced Budget Act of 2018 (enacted in February, 2018) raised the maximum money penalties related to improper claims to up to \$100,000, depending on the violation. Penalties for Stark Law violations continue, of course, to include denials of payments and refunds of payments, in addition to the imposition of severe money penalties.

³ 83 Federal Register 43607, published August 27, 2018

certain ACO participants in the MSSP, the ACA left the Stark Law untouched and MACRA's few protections protect all APMs.

Moreover, in 2016 the Senate Finance Committee issued a forceful report criticizing the Stark Law. The report pulled no punches. Conceived as a result of a Senate round-table convened by the Committee, it characterized the law as increasingly unnecessary for, and a significant impediment to, value-based payment models, stating that the risk of overutilization, which drove the passage of the Stark Law, is largely or entirely eliminated in APMs.⁴

It should be no surprise that as 2019 approaches, the Stark Law is destined for change.

Five Themes from the Responses to CMS's June 2018 Request for Information

Stakeholders have submitted detailed and numerous comments to CMS's RFI. While it is impossible to predict the revisions with absolute certainty, the comments reveal prominent and similar appeals. Five are discussed below. Assuming their inclusion in statutory amendments or new regulation, implementation of these themes into law will result in increased opportunities for providers to enter into APMs and new compensation opportunities for physicians.

Theme 1: Expansion of Waivers from the Stark Law Provisions

We may see the expansion of waivers from the Stark Law's strict requirements that until now have been available only to ACOs eligible for the Medicare Shared Savings Program. The current regulations, finalized in 2015, explicitly recognize that the MSSP rewards care coordination between providers that are referral sources for each other. By design, however, these waivers are program-specific and limited in scope to particular providers in the MSSP or specific programs established by CMMI. It is possible that waivers of certain Stark Law requirements may be extended from CMS-run programs to all payers. In order to accelerate the adoption of alternative payment methods (and by extension boost Congress's goal of fostering value-based payments systems through MACRA), Congress may grant CMS authority to establish broad waivers applicable to a variety of APMs.

Notably, some responses to the RFI have commented that a "plethora" of new APMs can be expected to surface as value-based payments are developed.⁵ In order to protect these payment methods and the providers who design them, CMS should establish a "core set of waivers for all APMs," thus allowing physicians and providers to satisfy themselves that the payment arrangement is immune from civil penalties.

⁴ Senate Finance Committee Majority Report, "Why Stark? Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Model," (Senate Finance Committee Report) available at <https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf> (last visited September 20, 2018)

⁵ Health Care Information Task Force, letter of August 24, 2018 to Seema Verna, Administrator, CMS <https://hcttf.org/wp-content/uploads/2018/08/CMS-Stark-RFI-HCTTF-Response-082418.pdf> (last visited September 29, 2018)

Result: If the current waivers are expanded and made applicable to a wide variety of APMs, or if new waivers are made available, physicians will have greater opportunities to participate in non-MSSP and other private payer APMs that reward them for care coordination, care integration, and quality outcomes and to receive payment for such outcomes, without concern of running afoul of the Stark Law’s prohibitions.

Theme 2: Revision of Certain Key Stark Law Definitions

i. “Commercial Reasonableness”

Eight of the existing exceptions under the Stark Law require that a compensation arrangement be “commercially reasonable.” Reams of paper have been used to explain the nuances of this requirement. The current subjective and vague definition of “commercial reasonableness” (“a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals”) affords little protection from the strict-liability nature of the Stark Law, and as a result providers are hesitant to enter into compensation arrangements where commercial reasonableness may be suspect. The technical requirements of this standard burden common business arrangements that pose no threat of self-referral (such as a hospital holding office space for a group practice awaiting to-be-recruited physicians). Of greater significance to the transition to value-based payments, however, is that the current definition serves as an impediment to the integration of different types of providers. Coordination of care is thus stymied. Responses to the RFI advocate revisions to the definition to make it broader and more lenient in order to provide for flexibility and allow collaboration among various providers and physicians.

ii. “Fair market value and “volume or value of referrals”

Under Stark, remuneration to physicians must be set at fair market value and not determined in a way that “takes into account” the volume or value of referrals to the entity. At present, despite voluminous regulatory and sub-regulatory guidance issued over the years, “fair market value” (FMV) and “volume or value” remain concepts that are vague, are frequently the source of debate, and are entirely fact-based. The result is that providers and physicians have been unwilling to enter into financial transactions in which these terms are in question, even where the goals of such arrangements are to reduce utilization and improve quality. Therefore, a common theme in response to the RFI includes a needed review and re-definition of FMV and manifests a need to allow APMs to provide some portion of payment as an acknowledgment of the successful coordination of care coupled with quality outcomes derived as a result of the volume of referrals within an integrated delivery system.

Result: If the regulatory exceptions to the Stark Law are modified to broaden the types of arrangements considered “commercially reasonable,” physicians can expect greater flexibility in entering into financial arrangements where physicians are compensated for patient outcomes even if the arrangement does not initially generate positive financial returns. Similarly, a new

definition of “FMV” or a narrowing of the definition of “compensation arrangements” to make clear that exchanges based on FMV do not implicate the Stark Law will permit providers greater flexibility to enter onto APMs.

Theme 3: EHR System Buildouts and Payments

To achieve success, APMs require data and information sharing. Electronic health records are central to the integration of care delivery and coordination of care. The benefits of robust EHR systems are evident; what has been a problem, however, are the Stark Law prohibitions applicable to the financial benefits that accrue to physicians resulting from a separate entity’s purchase of a technology on behalf of a physician, as, for example, a hospital’s purchase of an EHR system that directly benefits an affiliated or independent group’s practice.. While an exception for adoption of EHRs does exist, it is narrowly tailored and, in addition to cumbersome technical requirements, requires that physicians pay for a significant portion of the EHR’s costs. In addition to EHRs, new technologies to advance telemedicine have the potential to increase access to, and coordination and collaboration of, patient care. Because the Stark Law presents inherent limitations on how physicians can financially benefit from the adoption of these technologies, several responses to CMS’s RFI have urged the development of a “straight-forward, broad-scale exception to protect financial arrangements that support the adoption and use of technologies that promote care coordination, value-based payment, and access to care.”⁶

Result: If enacted, such an exemption will permit physicians to benefit from and utilize technology for which they have not paid in their clinical practices without concern of violating the Stark law’s exceptions on compensation. In turn, physicians will have the opportunity to financially benefit through APMs that utilize such technology in a manner that rewards them for care coordination and quality of care.

Theme 4: Removal of Strict Liability

As noted, the Stark Law is a “strict liability” statute and can be violated without any intent to commit an infraction. The slightest non-conformance with the statute can be financially crippling. Coupled with its draconian penalties, this strict liability aspect poses a significant barrier to entering into collaborative arrangements. Several responses to the RFI reflect the finding of the 2016 Senate Finance Committee Report that the law “has become increasingly unnecessary for, and a significant impediment to, value-based models that Congress, CMS, and commercial health insurers have promoted.”⁷ Moreover, APMs specifically are designed to discourage overutilization, and therefore eliminate to a great extent this risk.

⁶ Letter of Bruce Siegel, MD, President and CEO, America’s Essential Hospitals, August 24, 2018 , to Seema Verna, Centers of Medicare & Medicaid Services, available at https://essentialhospitals.org/wp-content/uploads/2018/08/AEH-STARK-RFI_8.24.18.pdf (last visited September 29, 2018)

⁷ Senate Finance Committee Report

Result: Removal of the law’s strict liability attribute will encourage providers to venture forward in the design of new APMs that, even if such efforts somehow run afoul of the law, will not result in steep penalties.

Theme 5: Creation of a New “Gainsharing” Exception

“Gainsharing” describes arrangements between hospitals and physicians in which the hospital agrees to share with the physicians any reduction of the hospital’s costs for the treatment of patients attributable in part to the efforts of the physicians. The OIG has issued several advisory opinions addressing “gainsharing arrangements” based upon specific facts, and while they provide guidance they cannot be considered affirmative blessings of all potential arrangements which reward physicians for medical decisions that are effective, safe, and less expensive. Responses to the RFI highlighted the positive incentives to control costs and improve quality that gainsharing arrangements offer, and noted that incentive payments serve to drive best practices. At the same time, these responses also pointed out that the Stark Law does not contain express protections which align with cost-saving financial incentive programs between hospitals and physicians.⁸

Result: Although a new exception that enlarges and permits greater participation in gainsharing may likely include specific guidelines and requirements, the expansion of gainsharing opportunities will result in additional and innovative ways for physicians to be rewarded for their cost-cutting measures.

Conclusion

CMS has yet to announce when it may issue recommendations to Congress or a notice of proposed rule-making in response to the comments received to the RFI. CMS may wait for the OIG to review comments to the Anti-Kickback statute, which are due in late October, and the two agencies then may issue joint recommendations. What is clear is that both CMS and the OIG are now poised to reform the fraud and abuse laws to promote payment arrangements in an effort to accelerate the adoption of APMs and ultimately to “bend the cost curve.” Stay tuned.

⁸ Letter from Melinda Reid Hatton, General Counsel, American Hospital Association, to Seema Verna, CMS, August 3, 2018, available at <https://www.aha.org/system/files/2018-08/180803-letter-stark-rfi.pdf> (last visited September 15, 2018).