Why Stark, Why Now?

Suggestions to Improve the Stark Law to Encourage Innovative Payment Models

A Senate Finance Committee Majority Staff Report

Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models

Senate Committee on Finance, Majority Staff
Chairman Orrin Hatch (R-Utah)

I. INTRODUCTION

On December 10, 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral law, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also known as the Stark law.

The Stark law prohibits a physician from referring Medicare patients for "designated health services" (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.[1] Financial relationships include both ownership and investment interests, as well as compensation arrangements. In addition, the law prohibits an entity from billing the Medicare program for services provided pursuant to an impermissible, or tainted, referral.

Support for Stark law reform has grown in recent years, and, following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger. The strict liability regime, huge penalties, and the breadth, complexity, and ambiguities of the Stark law and its regulations have created what is often referred to as a minefield for the health care industry. With this backdrop, attempts by Congress, the Centers for Medicare & Medicaid Services (CMS), and the private sector to encourage value-based payment models have not effected change as quickly as some had hoped. While many providers would like to move toward alternative payment models, most are reluctant to do so because they must contend with the tension between the Stark law and alternative payment models and the possibility of devastating penalties if they guess wrong.

The round table participants discussed whether changes to the law were necessary to implement MACRA and, if so, what options would work best in a system that includes both the fee-for-service (FFS) payment model and alternative payment models. After the meeting, the Committees invited the round table participants and others to share their views on the Stark law.[2]

The round table participants and the groups that submitted comments for the Committees' review included Stark law experts, academics, attorneys in private practice who work with

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[1] Section 1903 of the Social Security Act, 42 U.S.C. § 1396b, prohibits payment of the federal share of Medicaid to states for services paid under Medicaid that would have constituted a prohibited referral under Medicare.

[2] In 2009, the Public Interest Committee of the American Health Lawyers Association (AHLA) sponsored a "Convener on Stark law" (Convener Session) held on April 24 and June 30, 2009, in Washington, D.C. A white paper was published entitled, A Public Policy Discussion: Taking the Measure of the Stark Law, which summarizes the discussion and proposals for changing the

hospitals and/or physicians, attorneys in the private sector who previously served in government regulatory and enforcement agencies, hospital systems, electronic health record providers, as well as associations representing hospitals, physicians, medical device manufacturers, accountable care organizations, and several types of ancillary service providers.

II. EXECUTIVE SUMMARY

Congress enacted the Stark law to limit the influence of financial relationships on physician referrals. If a physician (or an immediate family member) has a financial relationship with an entity, then the physician may not make a referral to the entity for the furnishing of DHS under Medicare and, to some extent, Medicaid, unless an exception applies. 42 U.S.C. § 1395nn; 42 U.S.C. § 1396b. A "financial relationship" is defined as any direct or indirect (1) ownership or investment interest or (2) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the DHS. An entity may not bill for DHS provided as the result of a tainted referral.

Congress intended the Stark law to provide a bright line test to curb physician self-referral. But despite CMS's efforts to provide clear rules and interpretations to address the strict liability regime, the Stark law's breadth, complexity, and impenetrability have created a minefield for the health care industry. As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit noted last year, "even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act." United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Before Congress passed health care reform, the health care industry recognized that the Stark law would be an obstacle to hospitals' and other providers' efforts to align incentives with physicians for certain alternative payment models, including pay-for-performance, gainsharing, bundled payment or outcomes measures. During the American Health Lawyers Association's (AHLA) 2009 Stark discussion, many participants noted that alternative payment programs inevitably link physician payments to

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law itself or its administration or enforcement. Although the topics covered do not overlap precisely, our December 2015 round table was an effort to look at what changes had taken place since 2009, given the passage of the Affordable Care Act in 2010 and MACRA in 2015. The views shared by the round table participants and subsequent commenters reflect the changing legal landscape between 2009 and the present, but they also echo many of the underlying issues discussed in the 2009 AHLA session.

the volume or value of physician referrals[3] – a payment formula that generally will not pass muster under the compensation arrangement exceptions to the Stark law.[4]

Congress also recognized that alternative payment models would be difficult or impossible to establish in the current FFS enforcement environment. As a result, the Affordable Care Act (ACA) included an authorization for the Health and Human Services (HHS) Secretary to issue regulatory waivers from the Stark law and other fraud and abuse laws for innovative payment and service delivery models.[5] Under that authority, the Secretary has issued waivers from fraud and abuse laws for participants in the Medicare Shared Savings Programs (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI), the Comprehensive Care for Joint Replacement (CJR), and other Accountable Care Organization (ACO) programs.

MACRA's modification of the Civil Monetary Penalties (CMP) law, 42 U.S.C. § 1320a-7a, (specifying that the gainsharing prohibition applies only to inducements made to reduce or limit medically necessary services to beneficiaries) has removed some barriers to gainsharing and pay-for-performance programs. Nevertheless, as the waivers for CMS demonstrations illustrate, the Stark law continues to pose significant risks for implementation of such programs. Importantly, Medicare waivers do not protect all alternative payment models under MACRA or with commercial payers, undercutting hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations.

The Committees invited the round table participants to consider an array of known issues, including the current Stark law environment, health care reform implementation, costs associated with compliance and disclosures, possible fixes under both FFS and alternative payment models, and CMS's limited authority to create exceptions and to issue advisory opinions. Round table participants were then asked to specifically focus on (1) changes to the Stark law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.

Although the comments that we received were wide-ranging, there were many recurring themes. To implement health care reform, many comments focused on potential new waivers or exceptions, expansion of existing waivers or exceptions, broadening CMS's regulatory authority, repealing the compensation arrangement prohibition, or repealing the law in its entirety. Comments also concentrated on other important non-MACRA issues, including changes to standard Stark law definitions, like fair market value, the volume and value of referrals, and commercial reasonableness. In distinguishing technical and substantive violations, comments centered on documentation requirements and harm to beneficiaries or federal health care programs.

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[3] Reducing unnecessary FFS procedures or services reduces costs but increases profit (*i.e.*, value).

[4] AHLA, A Public Policy Discussion: Taking the Measure of the Stark law, at 9 (2009) (hereinafter, AHLA 2009 White Paper).

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

Some commenters submitted other suggestions for improving the law, including changes or clarifications to in-office ancillary services exception, the physician-owned hospital exception, documentation requirements, and others. This white paper focuses on potential changes to the Stark law to remove hurdles to implementing health care reform and on how to distinguish technical and substantive violations. The other issues that are not addressed in detail in this white paper may be considered by the Committee at a future point in time.

III. STARK LAW BACKGROUND

Under an FFS payment model, physicians have a financial incentive to provide more services. When a physician has a financial interest in an entity to which he or she refers patients, the incentive extends to ordering tests, procedures, or referring patients to that entity. The issue received attention in the 1980s, and, by 1989, the HHS Office of Inspector General found that physician self-referral related to laboratory tests was associated with a marked increase in utilization.[6]

That year, Congress passed the Ethics in Patient Referrals Act of 1989 (Stark I) prohibiting a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. Stark I also prohibited the lab from billing for any services furnished pursuant to a tainted referral. To prevent the law from being circumvented by contractual structures that did not involve equity but gave physicians the benefits of ownership, Congress also prohibited circumventions schemes and compensation arrangements. Stark I became effective January 1, 1992. Congress soon expanded the clinical laboratory prohibition to ten "designated health services" in the Omnibus Budget Reconciliation Act of 1993 (Stark II), which became effective January 1, 1995. Stark I and Stark II each included exceptions to the general prohibition.

CMS has published a series of regulations implementing the Stark law, beginning in 1992.[7] The final rules, listed below, are codified at 42 C.F.R. § 411.350–411.389.[8]

- Stark I regulations, August 14, 1995.
- Stark II Phase I regulations, January 4, 2001 (interim final rule).
- Stark II Phase II regulations, March 26, 2004 (interim final rule).
- Stark II Phase III regulations, September 5, 2007.
- Stark II Phase IV, Inpatient Prospective Payment System (IPPS) regulations, August 19, 2008.
- Stark II Phase V, IPPS regulations, October 30, 2015.

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[6] OIG-Office of Analysis and Inspections, Report to Congress, Financial Arrangements Between Physicians and Health Care Businesses, 3 (May 1989).

[7] AHLA's 2009 White Paper includes a chart with a helpful description of the regulatory changes from 1992 through 2009, at pages 4-5.

[8] The CMS website has a list detailing the Stark law's significant regulatory history.

Several commenters stated that the Stark law is not a "fraud" statute, but a regulation of payment. There is no requirement of an intent to violate the statute and compliance is a straightforward condition of payment. These commenters noted that Congress intended to provide a bright line rule, which would encourage hospitals and other providers to self-police their arrangements with physicians.

Even with regulatory exceptions and guidance, the result has been an extremely broad prohibition on physician referrals. If a physician has a financial relationship with an entity, any referrals by the physician to that entity are prohibited unless the financial relationship fits within one or more exceptions.[9] But the round table participants characterized the exceptions as illusory because the three key standards in most exceptions—fair market value, "takes into account" volume or value of referrals, and commercially reasonable—are factual, which means parties must prove that their arrangement fits into the exception at trial. Moreover, the participants and commenters noted that the three standards are ambiguous, and thus lead to unpredictable outcomes. The unpredictability is especially frustrating given the enormous penalties under the Stark law, which can be much higher than penalties for fraudulent activity.[10]

Commenters also noted the high cost and difficulty of complying with the Stark law. Even tracking non-monetary compensation issues can cause headaches for hospitals and physicians. For instance, if a physician agrees to join an ACO, it makes sense to provide access to the same electronic health record system used by the rest of the network. While the current MSSP waivers address this concern, if the physician leaves the ACO, or when the waivers expire, the physician may face Stark liability, which is just one additional hurdle to physicians joining ACOs and other integrated health care entities.

Some participants noted the law's inflexibility, as it prohibits any financial arrangement with a physician that does not fit within an exception. This inflexibility is underscored as providers attempt to implement alternative payment models like ACOs, pay-for-performance, shared savings, and bundled payments, which do not always fit into existing exceptions. Participants and commenters generally agreed that the Stark law does not have a place in the pay-for-value world because it was created to address overutilization in an FFS environment. Many participants and commenters believe that the law is disruptive to the development and implementation of value-based models.

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[9] The requirement that the financial relationship fit within an exception is different than the option to fit a relationship within a safe harbor to the Anti-Kickback Statute (AKS). Under the AKS, financial relationships that do not fit squarely within a safe harbor do not necessarily violate the AKS.

[10] If a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services from that physician are "overpayments" and must be returned, regardless of the amount of the "tainted" transaction or nature of the payment. In contrast, even the new authority in the ACA expanding the false claims liability for violations of the AKS is limited to claims "resulting from" the kickback.

Although many areas for improvement were discussed, especially those to usher in health care reform, round table participants and commenters also recognized that the Stark law has been effective in restricting physician ownership and investment in entities such as free-standing imaging centers and other providers of ancillary services. The law has also encouraged the industry to focus on compliance because of the need to closely scrutinize physician relationships, but several commenters noted that in practice the burden of compliance falls upon hospitals. Round table participants praised the establishment of the Self-Referral Disclosure Protocol, which enables providers to disclose Stark violations and permits CMS to compromise repayment amounts. Some participants noted that the settlements under the Protocol have been fair and reasonable. But several participants believe that the process is too time consuming and does not provide certainty to disclosing parties. Some commenters point to exceptionally high settlements for disclosures of technical violations based on documentation issues alone.

IV. STARK LAW IN CONTEXT

Round table participants and commenters discussed the Stark law in the context of other enforcement authorities and reimbursement rules that may also address physician self-referral practices.

Anti-Kickback Statute. Many commenters noted the imperfect and often confusing overlap between the Anti-kickback statute (AKS), 42 U.S.C. § 1320a-7b, and the Stark law.[11] Relationships that are permissible under the Stark law may violate the AKS, which some commenters said means the Stark law occasionally undermines the enforcement of the AKS. When Congress passed the Stark law, there was no civil liability for anti-kickback violations under the CMP law, and it was unclear whether the government could use an anti-kickback violation as a predicate for a False Claims Act (FCA) case.

With the expansion of the scope and application of the AKS over the years, however, many participants and commenters argue that the Stark law is no longer needed. The AKS can now be enforced in the civil context through the FCA and the CMP law. Not all participants agreed that the Stark law was no longer needed, in part because the FFS payment model would still be used to some extent for years to come.

Compounding the complicated overlap between these two statutes, is the disproportion in penalty levels. Penalties are smaller for AKS violations, which require knowing and willful intent, meaning the underlying conduct is arguably much more egregious.

False Claims Act. The FCA has become the primary enforcement mechanism of the Stark law. 31 U.S.C. § 3729–3733. While the Stark law prohibits physician referrals to an entity based on non-compliant financial relationships, from an FCA perspective, the focus is on the prohibition on billing for services furnished pursuant to a tainted referral. FCA exposure is created if the claims were submitted with the requisite intent (reckless disregard or deliberate

[11] While this may be an area that would benefit from further examination by Congress, the AKS is outside the Finance Committee's jurisdiction, and while we may refer to comments that mention the AKS, we are unable to address those concerns at this time.

ignorance of their truth or falsity). The Fraud Enforcement and Recovery Act of 2009 (FERA) expanded the potential for FCA exposure by revising the definition of a claim to include the knowing and improper retention of an overpayment.[12] 31 U.S.C. § 3729(a)(1)(G). In 2010, the ACA added the "60-day rule" requiring providers to "report and return" a Medicare or Medicaid overpayment within 60 days "after the date on which the overpayment was identified." 42 U.S.C. § 1320a-7k(d)(1)–(3). Thus, under the FCA's reverse false claims provision, an entity that submits a claim with no knowledge that it may be prohibited by the Stark law may face FCA exposure if (1) the entity later discovers the Stark violation and (2) fails to report and return any reimbursement associated with the tainted claim within the 60-day period.[13]

Some commenters expressed concerns with recent FCA litigation, noting that certain aspects of the Stark law have led to a number of recent FCA settlements that threaten the development of integrated delivery systems. The commenters pointed to several recent FCA settlements based on a *qui tam* theory that an accounting loss for hospital-owned physician practices is *ipso facto* evidence that the employed physicians are paid more than fair market value and that the arrangement is not commercially reasonable. The commenters acknowledge that the complaints for some of the recent settlements may involve extreme facts but are nonetheless concerning as potential examples of bad facts making bad law.

Reimbursement. Some round table participants noted that reforming reimbursement rules may address the Stark law's underlying concern of overutilization. Some suggestions included decreasing reimbursement for ancillary services provided through a physician's group practice, bundling the payment for physician office visits and ancillary services, and adopting bundled payment plans that promote shared risk among providers involved in an episode of care.[14] Although we did not receive comments in direct opposition to these suggestions, we received numerous comments both in favor of and against any changes to the in-office ancillary services exception which could serve as an alternative to payment changes for such services.

V. IMPLEMENTING MACRA AND OTHER ALTERNATIVE PAYMENT MODELS

As noted above, the Committees invited round table participants and others to share their perspectives on what changes to the Stark law might be necessary to implement health care reforms promoting alternative payment models, such as MACRA. Participants were asked to

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[12] Prior to FERA, liability for retention of an overpayment required an affirmative step to evade repayment through a false record or statement and only if it could be established that repayment was an "obligation." This provision became known as a reverse false claim.

[13] In rejecting two motions to dismiss, the District Court for the Southern District of New York recently addressed what it means to "identify" an overpayment and start the clock for the 60-day rule under the FCA. *U.S. ex rel. Kane v. Healthfirst, Inc., et al.*, No. 11 CIV 2325, 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

[14] For additional reimbursement suggestions shared during AHLA's Convener Session, see, AHLA 2009 White Paper, at 12.

include in their suggestions options that would work in a payment environment that includes both FFS and alternative payment models.

The comments generally focused on potential new waivers or exceptions, expansions of existing waivers or exceptions, changes to standard Stark law definitions, broadening the Secretary's authority, or repealing the law or the compensation arrangement prohibition. The relevant comments are summarized by category below.

Repeal. Many commenters suggested that the Stark law has outlived its utility. These commenters argue that the AKS in its current form can address the conduct that the Stark law seeks to curtail. However, some commenters noted that the Stark law addresses conduct that may not fall under the AKS. Additionally, while the FFS payment model is being phased out, it will continue in some form for many years. With this in mind, some commenters advocating repeal recommended that the Stark law be sunset once Medicare had transitioned to alternative payments to a meaningful extent.

Repeal Compensation Arrangement Prohibitions. A larger group of commenters believed that repealing the compensation arrangement requirements would address many of the concerns not only with implementing health care reform but with the Stark law's most difficult provisions. They recommend limiting the Stark law to ownership and investment interests, which they believe was Congress's original intent. However, as some commenters noted, prohibitions on compensation arrangements have been in the law from the beginning and were included to avoid schemes to circumvent the law with creative arrangements that would give physicians the benefits, and dangers, of ownership but that did not involve equity.[15] Other commenters argued that the compensation arrangement prohibitions are no longer necessary because the AKS can now be enforced in a civil context through both the FCA and the CMP law.

New Risk Revenue Waiver/Exception. To lessen the burden of health care entities making the transition from FFS to alternative payment models, two commenters recommended creating a waiver from the Stark law once a health care entity's risk revenue reaches a certain majority percentage of its total revenue. Health care entities receiving such a waiver would be required to meet certain criteria, for example, having the governing board of the ACO entity approve applicable financial relationships through a process that validated Triple Aim[16] principles and shows no motivation to increase utilization. Noting that some health care entities would never reach this level of risk based revenue, one of the commenters acknowledged that entities that did not reach such a level of risk engagement would still be required to meet a Stark

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[15] AHLA 2009 White Paper, at 12.

[16] *See* Donald M. Berwick, et al., The Triple Aim: Care, Health, And Cost, Health Affairs, May/June; 2008, 27(3) at 759-769. "The Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions, which we call the "Triple Aim": Improving the patient experience of care (including quality and satisfaction); Improving the health of populations; and Reducing the per capita cost of health care." IHI website, Triple Aim Initiative.

exception for certain arrangements. The other commenter framed the exception in terms of health care systems that derive no less than 50 percent of their health care revenue from alternative payment methodologies, and recommended that such systems receive a broad waiver from the Stark law similar to those now in effect for ACOs.

The commenters believe that enforcement agencies could use the AKS and the gainsharing CMP to address problematic arrangements. This idea accommodates the incremental transition to value-based payment models. However, some round table participants questioned how health care entities could reach a threshold percentage without being at risk, arguing that this type of fix would simply shorten the period of exposure for a subset of providers.

Create New or Expand Currently Restricted Waivers. Most commenters suggested extending the waivers that are currently highly limited to CMS-run programs to all payers. Many commenters believed that expanding the waivers for the MSSP to qualifying alternative payment model participants would be the best solution.[17] Some urged that the same protections be provided to physicians operating in alternative payment models that were provided through ACOs eligible for MSSP, including the pre-participation period. Those commenters believe this would recognize the variety of alternative payment models that use different mechanisms and structures to encourage efficient care. One commenter stated that, ideally, Congress would make the current Center for Medicare & Medicaid Innovation (CMMI) waivers permanent and available to all new adopters of similar models in the future, as well as permanent programs established under the CMMI's authority.

Commenters agreed not only that Congress should create waivers to address the problem but also that Congress should give HHS broader authority to create regulatory waivers. While commenters generally agreed that some new waivers could be created through existing but limited CMS rulemaking authority, most agreed that Congress should give CMS express authority to create broader waivers than currently authorized by law.[18]

Some commenters argued for consistency in fraud and abuse laws' applicability to ACO programs for all government-supported innovative payment models. One suggestion to accomplish such consistency was the creation of a new Stark law exception at 42 U.S.C. § 1395nn(b) that would apply to MIPS, physician-focused payment models, and payments associated with alternative payment models. Another suggestion was to create a waiver that would apply to MIPS, alternative payment models, and ACOs, modeled on current Stark exceptions for Medicare prepaid plan enrollees. These type of waivers could address issues in an environment that includes both FFS (MIPS) and alternative payment models.

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[17] CMS and OIG, HHS, Medicare Program; Final Waivers in Connection With the Shared Savings Program, 80 Fed. Reg. 66,726 (Oct. 29, 2015) (codified at 42 C.F.R. Chs. IV and V).

[18] Recommendations to expand the Secretary's authority to create waivers and exceptions are discussed below.

Create New Exceptions. Many commenters suggested the creation of a new exception to enable financial arrangements that involve risk-sharing and gainsharing in alternative payment models when appropriate safeguards are in place. Some recommended that such an exception (the "APM Exception") apply to all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and that it not impose a fair market value requirement. At least one commenter recommended a new exception for quality-based payments to physicians, provided that such payments are not tied to the volume or value of referrals.

Other commenters stated that a new exception should be available for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care (referring to integrated delivery systems, accountable care, team-based care, or value-based payment arrangements). Some commenters, concerned that an exception may focus on institutional providers, expressed the need for an exception that took into account the breadth and scope of providers and entities necessary for truly integrated health care. Other commenters emphasized that the new exception should be available for truly clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. Commenters also noted the need to protect shared savings and incentive programs, as well as any arrangement start-up or support contribution, when certain conditions are met.

One commenter suggested an approach to accommodate alternative payment models, either under MACRA or more broadly, that would involve adding an additional statutory exception for alternative payment models that promote and advance accountability for quality, cost/risk, care coordination, patient experience, and outcomes. To qualify for the exception, which could be added to the compensation arrangement exceptions at 42 U.S.C. § 1395nn(e), arrangements would need to meet conditions that are already used to qualify ACOs and other risk-sharing arrangements under the Stark law and AKS. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.

Special Compensation Rule. The majority of comments touched on potential changes to how the Stark law treats compensation arrangements. As an alternative to an integrated delivery system waiver, some commenters recommended changing the fair market value requirement or the fair market value definition to accommodate alternative payment models. One commenter suggested a special compensation rule related to MACRA alternative payment model financial arrangements that would automatically deem such arrangements to (1) not take into account the volume or value of referrals, or other business generated between the parties, and (2) constitute fair market value, provided all MACRA alternative payment model programmatic requirements were otherwise met.

Modify Existing Exceptions. Commenters also suggested modifying existing statutory or regulatory exceptions to the Stark law to promote integrated care and aligned incentives.

Most Stark law exceptions protect a "financial relationship" and except the relationship from triggering the prohibition on DHS referrals. Other exceptions, like the prepaid plan exception at 42 U.S.C. § 1395nn(b)(3), only protect the services that would otherwise be

prohibited DHS referrals. The prepaid plan exception, for example, only protects referrals of services to the prepaid plan but still prohibits FFS referrals to the same party. Several commenters recommended Congress broaden the statutory prepaid plan exception so that the prohibition on referrals for DHS would not apply to services rendered by an entity that has a contract with CMS or its agent that contemplates the use of alternative payment models. Alternatively, the exception could be framed so that it protects DHS furnished to a Medicare beneficiary who is assigned to an MSSP, Pioneer, or Next Generation ACO, or any other ACO model established by CMS or tested under CMMI. Either scenario should protect services that would otherwise be prohibited DHS referrals; FFS referrals to the same party would still be prohibited. These commenters argue that this would provide more certainty for the regulated community than an extension of the regulatory waiver approach for ACO arrangements.

Several commenters recommended Congress expand the risk-sharing exception at 42 C.F.R. § 411.357(n) to apply to Medicare and Medicaid FFS programs. Other commenters would expand the exception to incentive payment arrangements between a DHS entity and a physician participating in a qualified alternative payment model (others framed this as applying to compensation arrangements involving integrated care organizations). Some commenters recommended that a new exception be created based on the risk-sharing exception that would apply to MSSP, Pioneer, Next Generation ACO, or other CMS or CMMI ACO models, as long as the arrangement is reasonably related to one of the purposes of the respective program. The exception would explicitly cover payment arrangements that are downstream of bundled payments, shared savings, and other alternative payment programs implemented by governmental or private payers. Commenters advocated for consistency between the Stark law and the CMP law, stating that the Stark law should not prohibit any arrangement presently permitted under the CMP law, as amended by MACRA, specifically the modifications to the gainsharing prohibition. They also recommended a clarification that the volume and value standard under the Stark law is not implicated when a physician is incentivized to follow a standard hospital quality measure (*e.g.*, a care protocol) that includes ordering an item or service for a patient that will not result in any additional reimbursement to the hospital.

One commenter recommended Congress codify the existing exception applicable to services furnished by an organization (or its contractors or subcontractors) to enrollees set forth at 42 C.F.R. § 411.355(c), and modify it to incorporate alternative payment models, including those involving integrated care organizations, as being eligible for protection.[19]

Another commenter noted that although the current Stark rules do not pose major obstacles for parties to enter into bundled payment or gainsharing arrangements, some legislative changes or clarifications to the Stark law could provide much needed comfort for parties who are uncertain how to proceed or fear inappropriate enforcement efforts.

One area the commenter identified for clarification is the definition of an indirect compensation arrangement, which, along with the exception for indirect compensation

[19] For purposes of consistency, the commenter recommended that the definitions of health plan and enrollees under 42 C.F.R. § 1001.952(1) be modified to contemplate ownership and compensation relationships arising out of alternative payment models.

arrangements, is one of the most complex and frustrating areas of Stark regulation. The definition includes three components. One of those components is based on the referring physician's receipt of aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. *See* 42 C.F.R. § 411.354(c)(2)(ii). The commenter recommends that Congress clarify that where the physician's compensation from an entity with which he or she has a direct compensation arrangement does not necessarily rise as a direct result of more referrals or higher paying referrals, the aggregate compensation test is not met.

Additionally, the commenter notes that although arrangements where physicians are paid a percentage of savings are common, CMS has never expressly recognized that a percentage of savings can be fair market value and commercially reasonable. To resolve uncertainty and to promote non-abusive shared savings arrangements, the commenter recommended that Congress adopt CMS's deeming provision for per-click compensation arrangements, 42 C.F.R. § 411.354(d)(2), and extend it to percentage compensation arrangements. The commenter also recommended that Congress amend the Stark law to state that an arrangement under which a physician receives a percentage of saving realized by a provider can satisfy the fair market value and commercial reasonableness requirements of an applicable exception. Alternatively, Congress could provide that an arrangement under which a physician would receive a percentage of savings realized by the hospital or other provider or supplier will be presumed (or deemed) to satisfy the fair market value and commercial reasonableness requirements of an applicable exception if the parties relied in good faith on an opinion from a nationally recognized appraisal firm. To prevent opinion shopping, the statute must provide that all opinions (draft or otherwise) of fair market value and commercial reasonableness would be taken into account when determining whether the parties relied in good faith on a favorable opinion. One commenter suggested that such a change should include some standard to govern the amount that can be shared with physicians, such as a cap or threshold.

Expand the Secretary's Authority: Waivers, Exceptions, and Advisory Opinions. Some commenters noted that the Stark law and regulations are payment regulations that providers must comply with to receive payment. An effective regulatory regime requires that the regulated community be able to obtain timely and clear guidance. Commenters offered a number of suggestions in this regard.

Commenters generally agreed that Congress should expand the Secretary's authority to create waivers, exceptions, and advisory opinions. Although some commenters suggested that the authority be limited to expanding waivers for participants in MSSP and other CMMI models, most recommended that the Secretary be given express waiver authority that would apply to innovative payment models under MACRA and other health care reform laws.

The Stark law permits the Secretary to create regulatory exceptions that the Secretary determines do "not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). CMS has taken a cautious approach in issuing Stark exceptions.[20] Commenters believe that many of

[20] Although CMS recently provided additional guidance on the Stark law, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70885, 71300-71341 (Nov. 16, 2015), at least one commenter

the existing exceptions are too narrow or complicated to be useful but that more practical exceptions could be issued if the Secretary were given authority to create exceptions where an arrangement does not pose an undue or significant risk of program or patient abuse. Commenters also noted that HHS has greater authority and flexibility to create safe harbors to the AKS, a criminal statute, than it has to create exceptions to the Stark law, a regulation of Medicare payment.

Several commenters also urged Congress to strengthen the Secretary's authority to issue Stark advisory opinions and promote timely agency guidance. One commenter noted that if an exception for innovation arrangements were adopted, it could permit the submission of a request through the CMS advisory opinion process, which would provide added comfort to both CMS and the industry. The commenter noted that Congress could direct CMS to modify its current regulations to accommodate the review process and set forth other requirements CMS considers necessary to organize, facilitate, and fund the analysis and the timely issuance of advisory opinions dealing with innovation arrangements that promote the Triple Aim. This commenter noted that such advisory opinions should not be required, but that they should be available to provide added comfort to the industry in a time of innovation and change.

The participants and commenters agreed that the creation of the Self-Referral Disclosure Protocol (SRDP) and the expansion of the Secretary's authority to compromise Stark repayment obligations were positive developments in Stark law enforcement. Nevertheless, some said the process was too lengthy and left providers in limbo while they waited for a disposition. Many commenters argued Congress should give CMS more discretion to settle Stark law violations, such as providing CMS with the explicit authority to impose CMPs in lieu of compromising repayments based on the total repayment amount.[21] One commenter suggested Congress give CMS discretion to determine whether to prohibit billing for violations, which could have far-reaching implications, including taking Stark law violations out of the realm of FCA litigation.

Some commenters were not enthusiastic about creating additional waivers or exceptions to the Stark law because they believe that regulatory environment is already overly complex. These commenters also believed it would not be effective to simply strengthen the Secretary's advisory opinion authority to promote timely agency guidance because, based on 25 years' worth of rule-making, they believe Congress should revise the law entirely. In their view, advisory opinions only help at the margins, and, in almost all cases, very slowly.

VI. DEFINING TECHNICAL VIOLATIONS

Commenters generally agreed that "technical" violations should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment

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believed that the agency could be more hesitant to issue exclusions after the recent decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). This concern underscores the importance of consideration of an explicit grant of authority to the Secretary.

[21] Recommendations concerning a revised penalty structure are discussed below.

liability.[22] Several commenters noted that Congress recognized the disparity between technical and substantive violations when it created the SRDP and authorized the Secretary to reduce amounts owed. In distinguishing technical and substantive violations, comments focused on documentation requirements, adherence to fair market value, the volume or value of referrals, or harm to beneficiaries or federal health care programs. But some commenters questioned whether drawing such a distinction would be helpful because it would be difficult to determine penalty provisions and enforcement priorities in an already hyper-technical environment. Their solution to the complexity would be to eliminate the compensation arrangements prohibition. As for penalties for technical violations, all commenters recommended that CMPs be assessed in lieu of penalties or that no penalty be assessed. Some commenters recommended further reducing the CMP if a party self-disclosed a violation within 60 days of discovery.

Documentation Requirements. Commenters generally agreed that technical violations were those involving the form, not substance, of an arrangement. Commenters and round table participants pointed to Representative Charles Boustany's proposed legislation, the Stark Administrative Simplification Act of 2015, as a move in the right direction, specifically in terms of its definition of technical violations.[23] The proposed legislation defines "technical noncompliance" as arrangements that violate the law's prohibition of self-referral "only because (i) the arrangement is not set forth in writing; (ii) the arrangement is not signed by 1 or more parties to the arrangement; or (iii) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement."[24]

Several commenters added that technical violations are those that pose a low risk of affecting the Medicare fisc and are unlikely to result in increased use of medically unnecessary services.

Arrangements That Do Not Incentivize Referrals or Unduly Influence Health Care Decision-Making. In describing technical violations, some commenters included along with documentation requirements violations that are irrelevant to whether an arrangement incentivizes referrals. Outside the context of ownership, they only consider "substantive" violations of the Stark law to be compensation structures that induce or reward referrals (*i.e.*, the physician is paid for referrals). Some of these commenters recommended eliminating any technical violations that do not harm patients or Medicare and authorizing the Secretary to impose a CMP for each arrangement to reduce the impact of technical violations. One commenter suggested that a financial arrangement that a reasonable person would conclude creates a significant incentive to a physician to refer to a particular entity is substantive.

Fair Market Value. Some commenters suggested dividing violations into two categories: (1) those where compensation is in excess of fair market value (and perhaps commercial reasonableness) and/or is determined in a manner that takes into account the volume

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[22] AHLA 2009 White Paper, at 16.

[23] Stark Administrative Simplification Act of 2015, H.R. 776, 114 Cong. (2015).

[24] Stark Administrative Simplification Act of 2015, H.R. 776, 114 Cong. (2015).

or value of referrals; and (2) those where compensation is not. However, commenters recognized that the division is not clear cut in practice due to the technical nature of the rules on fair market value and volume or value of referrals. Many commenters and participants agreed that any meaningful change to the Stark law must address volume and value, and, to a lesser extent, fair market value.[25] One suggestion was to define technical violations to include any violation that does not involve fair market value (and perhaps commercial reasonableness) or the volume or value prohibition; and that, depending on the facts and circumstances, technical violations may include violations that involve fair market value, commercial reasonableness, or the volume or value prohibition.

Compensation Arrangements That Do Not Violate the AKS. Several commenters recommended defining technical violations as compensation arrangements that do not otherwise violate the AKS. In other words, as suggested above, prohibited ownership violations would be substantive noncompliance, and problematic compensation arrangements would be enforced through the AKS or the CMP law. One commenter suggested that any arrangements that do not confer a financial benefit to the referring physician should not be considered substantive and that technical violations should not carry Stark penalties.

Create Bright Line Requirements For Substantive Noncompliance. One commenter suggested first creating bright line requirements to improve clarity and then considering all noncompliance with those bright line requirements to be substantive. The commenter recommended that Congress direct CMS to specify, on a regular basis *(e.g.,* through Medicare Physician Fee Schedule rule making), compensation practices that are not permitted based on the agency's experience. Only noncompliance with such specifically non-permitted compensation practices should be viewed as substantive noncompliance. As discussed below, concerns have been raised about Congress's or CMS's ability to create a list that would effectively cover all financial arrangements that may involve self-referral concerns.

Clarify Compensation Arrangement Terms. Several commenters recommended clarification of the three key terms in the compensation arrangement exceptions: fair market value (FMV), "takes into account" the "volume or value" of referrals, and commercially reasonable. The comments we heard echoed those raised during the AHLA discussion, including concerns about the difficulty of establishing and documenting FMV.[26]

Some commenters recommended allowing physician compensation for providing high-quality and efficient care without violating the Stark law's FMV standard, even if the compensation is related to the volume or value of the referrals. These commenters argue that the statutory definition of FMV simply reflects the clear rule that arrangements must reflect arm's length bargaining and that the "volume or value" standard was a regulatory addition created by CMS. Another commenter also rejected CMS' definition of FMV and recommended that Congress clarify that intent is not material in the strict liability law, and bar CMS from defining

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[25] We received many comments recommending changes to terms associated with compensation arrangement exceptions. They are discussed in Section VI, below.

[26] *See* AHLA 2009 White Paper, at 11-12.

essential terms (*i.e.*, FMV, commercially reasonable and volume or value of referral standards) in a purportedly circular, interconnected manner.

One commenter suggested amending the statute to provide that the FMV requirement is met where the compensation paid to the physician does not exceed FMV. Some commenters noted the confusion caused by the regulations' ambiguity on whether an arrangement that is FMV at its inception, but later falls out of FMV, continues to meet the FMV requirement. Long leases should not enjoy exception for years and short leases should not be punished if the lease falls out of FMV in six months. To address this concern, one commenter suggested that Congress could provide that arrangements that are FMV at their inception are presumed or deemed to be FMV throughout their life, up to some maximum period, such as two to three years. Alternatively, if a party obtains an FMV appraisal from a qualified, independent appraisal firm, it is entitled to rely on the appraisal for the life of the appraisal, up to a maximum of two to three years. A variation would be to specify that, in order to gain the protection of the FMV presumption or deeming, the appraisal be obtained before the arrangement begins. The commenter also recommended a similar provision for an appraisal regarding whether an arrangement is commercially reasonable.

A few commenters sought Congress's explicit confirmation that certain practices are acceptable and do not necessarily violate the Stark law. For instance, one commenter suggested that Congress confirm that DHS entities can base compensation on market surveys of similar arrangements without regard to whether those surveys involve actual or potential referral sources – given that the only available surveys involve entities (*e.g.*, medical practices, hospitals and other employers) and physicians who are in a position to make referrals. The commenter also suggested that the Stark law be amended to clearly state that nothing in the law prohibits a DHS entity from developing and using management, financial, and other reports that may include productivity or other data in their internal operations as consistent with typical business practices, so long as such reports are not used in decision-making regarding the compensation to be paid to individual physicians. Several participants at the round table suggested that Congress remove the "commercially reasonable" requirement from the employment and other compensation exceptions or clarify that operating losses in DHS entity-owned physician practices are not commercially unreasonable.

Others suggested changes to other definitions. One commenter recommended that the definition of "group practice" be revised by removing the current volume or value standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark law. Virtually all of the exceptions to the existing Stark law impose restrictions on compensation based on "volume or value" of referrals; however, inclusion of this language in the group practice definition creates enormous confusion and opportunities for technical non-compliance. Another commenter suggested that the Stark law's definitions of remuneration and compensation arrangement be narrowed so that FMV exchanges do not implicate the Stark law.[27]

[27] *See* AHLA 2009 White Paper, at 12 (similar suggestion that compensation arrangement prohibitions apply only when payments vary with the volume or value of referrals).

Another commenter suggested Congress amend the Stark law to define reasonable safe harbors that would provide predictable refuge for hospitals that reasonably evaluate and document fair market value.

Intent. While not always tying the suggestion to the definition of technical violations, several commenters recommended that an intent requirement be added such that purely accidental omissions were not in violation of the Stark law. Some participants believed this would make the Stark law duplicative of the AKS rather than a payment rule.[28] Others recommended adding a harm to programs requirement to limit fines to situations where the prohibited referrals result in some demonstrable harm to the government or the patients served, with the burden of proof on the government.

Create Exception for Technical Noncompliance. One commenter recommended creating an exception for technical noncompliance based on the regulatory exception for certain arrangements involving temporary noncompliance at 42 C.F.R. § 411.353(f), but with fewer restrictions. The commenter did not specify how to differentiate between technical and substantive violations, but emphasized the importance of such an exception.

Determining the Penalty. Some commenters also advocated for the inclusion of mitigating factors when determining the penalties associated with technical violations, sometimes referring to the factors in the legislation creating the SRDP. Some commenters suggested that Congress give the Secretary explicit authority to reduce penalties or apply CMPs in lieu of penalties, and those commenters also recommended that certain factors be considered with determining the penalty amount. Suggested factors included: (1) whether the violation is technical or substantive; (2) whether the parties' failure to meet all of the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; (3) the corrective action taken by the parties; (4) whether the services provided were reasonable and medically necessary; (5) whether access to a physician's services was required in an emergency situation; and (6) whether the Medicare program suffered any harm beyond the statutory disallowance. A variation of a suggestion discussed in the previous section would be for Congress give CMS discretion to determine whether to prohibit billing for technical violations, which would allow CMS to compromise repayment amounts, to impose CMPs, or not to impose any penalty.

VII. GENERAL RECOMMENDATIONS BEYOND MACRA IMPLEMENTATION AND DEFINING TECHNICAL VIOLATIONS

Commenters noted general frustrations with Stark law compliance and explained the difficulties hospitals and other providers face in complying with the law. Several commenters noted that even if a provider fits its arrangements squarely within certain exceptions, the provider could still face lengthy and expensive legal battles because many exceptions are fact-specific. For instance, for challenges based on any Stark law exceptions with AKS/Claims Requirements, a hospital would not be able to prevail on a motion to dismiss or a motion for summary judgment because resolving the Stark law claims requires the court to also determine whether the financial relationship at issue satisfies the highly fact-specific AKS/Claims Requirements. As discussed

[28] *See* AHLA 2009 White Paper, at 12 (similar comments on intent).

above, the same is true of each of the three standards (FMV, volume/value, commercial reasonable). The commenters believe that including requirements of separate laws stacks the deck against hospitals trying to obtain predictability with respect to their Stark law compliance. Although the concerns discussed below are not unique to implementing health reform, they create a chilling effect because both hospitals and physicians are wary not only of the difficulties associated with complying with the Stark law but also of the costs associated with defending even compliant arrangements.

Align Stark Law with AKS. As discussed above, many commenters believe Congress should align the Stark law and AKS. Congress (or for regulatory exceptions, HHS) could accomplish this by replacing certain Stark law exceptions with AKS exceptions. For instance, one commenter suggested that the Stark law bona fide employee exception should be made identical to the AKS bona fide employee exception, which unlike the Stark exception does not include a fair market value component. The commenter reasoned that if the concern giving rise to this exception is that part-time employees are more subject to abuse, then the Stark law's fair market value component could be limited to persons who are dually employed by a provider of DHS and a physician practice, but not be applied to physicians whose only employer is a provider of DHS. The commenter also noted that for all tax-exempt entities, there already are substantial constraints on compensation paid to employees. The commenter suggested that any compensation arrangement that satisfies an AKS safe harbor should also be exempt from the Stark law. Rather than maintaining two parallel, but not identical, sets of regulations that outline permitted practices, the commenter believes it would be better to rely on the AKS safe harbors and eliminate the separate, but not identical, exceptions to the compensation arrangements provisions of the Stark law.

Tax Exempt Exception for Compensation Arrangements. One commenter noted that the Internal Revenue Service (IRS) already limits compensation arrangements entered into by tax exempt entities, and that in light of such limitations, a potential carve out to the Stark law could be an exception applicable to any compensation arrangement that is entered into by a tax exempt enterprise. That commenter suggested that clearer, broader exceptions for bona fide co-management arrangements, professional courtesy, reasonable gifts or rewards for patient referrals, and free screenings would be helpful.

Reverse the Premise and Change the Burden of Proof. One commenter recommended reversing the premise of the Stark law to specify types of particular compensation arrangements that are "strict liability" and place the burden on government to show a violation. The commenter also recommended that penalties be made commensurate with the harm to the Medicare program. Although the structure of the Stark law has long been debated, the main argument against reversing the premise is the difficulty in defining a list of all illegal arrangements that could mask self-referrals.[29]

Simplify/Clarify. Many of the participants suggested that the Stark law's definitions and exceptions should be streamlined and simplified. Some commenters suggested eliminating or modifying the signature requirement. One commenter recommended removing the limitation on

[29] *See* AHLA 2009 White Paper, at 13.

the number of times a hospital may use the late signature rule, or in the alternative, modifying the signature requirement to simply require evidence of assent between the parties.

Other commenters recommended that the Stark law should be amended to codify CMS policy confirming that payments to physicians for personally performed services are permissible under the Stark law, even if the personally performed services are related to DHS ordered by the physician. These commenters suggest an amendment identifying the following as permissible forms of payment for personally performed services: (1) hours worked in performing such services; (2) revenues billed, collected or collectible for such services; (3) wRVUs for such services; (4) patient encounters; (5) average daily patient census; or (6) any other approach that measures the clinical or administrative services actually furnished by the physician. For every physician (whether or not in a group practice), services that are billable as "incident to" the physician's services are deemed to be personally performed by the physician.

VIII. CONCLUSION

The Stark law was created to address a risk in an FFS payment model. The financial incentives that trigger overutilization concerns in an FFS payment model are largely or entirely eliminated in alternative payment models. Although the FFS payment model still exists, the comments show that the Stark law and its regulations have presented challenges to providers attempting to implement health care reform. Many commenters cited the Stark law's strict liability standard and significant penalties as serious obstacles to implementing MACRA and other alternative payment reforms. The Committee appreciates all of the comments submitted and will be considering them all as we evaluate and develop potential changes to the Stark law.