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Still Useful? Senate Finance Evaluates Possible Stark Law Changes, Including Repeal



BY KATHERINE A. LAUER, JOSEPH C. HUDZIK, AND MICHAEL DREYFUSS

Has the Stark Law outgrown its usefulness? Originally enacted to prevent overutilization by physicians with financial interests in the entities to which they refer, the Stark Law's breadth and technical complexity have become an impediment to the adoption of new payment models that are necessary to make health-care reform a reality.

And, of course, there are the Stark Law's wildly disproportionate penalties for providers who fail to successfully navigate the minefield of ambiguous—if not impenetrable—rules. ''[E]ven 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.''[1]

Katherine A. Lauer is a partner in the San Diego office of Latham & Watkins LLP and can be reached at katherine.lauer@lw.com . Joseph C. Hudzik is counsel in the Washington, D.C., office of Latham & Watkins and can be reached at joseph.hudzik@lw.com . Michael Dreyfuss is an associate in the Washington, D.C., office of Latham & Watkins and can be reached at michael.dreyfuss@lw.com .

The Senate Finance Committee (the ''Committee'') has taken notice, and in a recent Committee report discusses possible modifications to the Stark Law designed to reduce regulatory hurdles to health-care reform and to provide a greater distinction between technical and substantive violations of the law.

Although the Report does not draw any conclusions or make any final recommendations, its discussion is informative to providers and suppliers as Congress considers options to push the health-care industry and Medicare further toward Value-Based Payment (''VBP'') and pay-for-performance models, and it provides a glimmer of hope for Stark Law reform.

Background

On June 30, the Committee released a report titled ''Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models,'' which reflected on a round-table discussion with industry representatives and described several possible reforms for the Stark Law (also known as the ''physician

[1] *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, No. 13-2219, 2015 BL 212865, 26 (4th Cir. July 2, 2015) (Wynn, J., concurring).

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self-referral law''),[2] ranging from modification of certain exceptions, to expanded advisory opinion authority for the Secretary of the Department of Health and Human Services (the ''Secretary'' of ''HHS''), to repeal of the law in whole or in part (the ''Report'').

The genesis of the Report was, in part, the Medicare Access and CHIP Reauthorization Act of 2015 (''MACRA'') and other reform measures that are driving the health-care system from its historical Fee-For Services (''FFS'') payment model to a VBP model. In the view of the round-table participants, the Stark Law's prohibition on compensation arrangements that vary with the value or volume of business generated between the parties, fact-based Fair Market Value analysis, ambiguous exceptions and strict liability regime poses an impediment to the adoption of VBP methodologies.

The Stark Law

The Stark Law prohibits physicians who have a financial relationship with an entity from referring patients to the entity for the provision of certain Designated Health Services (''DHS'').[3]

The law further prohibits such entities from seeking payment from Medicare for services provided based on a prohibited referral. Payment from Medicare for such services is available only if the financial arrangement between the physician and the entity fits within one or more statutory safe harbors or regulatory exceptions. Payments received from Medicare that are not in compliance with the law (i.e., where the underlying financial arrangement does not fit within an applicable exception) are overpayments, which may trigger Medicare's 60-day overpayment report and return requirement.[4]

The Stark Law is in many ways similar to the federal Anti-Kickback Statute (''AKS'') but it differs in a few meaningful respects.

First, the Stark Law is a civil law rather than a criminal law.

Second, the Stark Law is a strict liability statute; meaning the government is not required to prove intent to show a violation.

Third, the Stark Law presumes that all financial relationships between a physician and an entity that provides DHS are improper and places the burden on the DHS entity to prove that the relationship does not trigger the law's prohibition or that the relationship meets every element of an applicable exception.

The Stark Law works best when payments are linked to specific services. It doesn't work well under value-based purchasing models where payments are tied to efficiencies and savings obtained through the coordinated provision of health care by groups of individuals and entities.

The Stark Law, having been enacted and implemented under a FFS regime, works best when payments are linked to specific services. The law does not work well under VBP models where payments are tied to efficiencies and savings obtained through the coordinated provision of health care by groups of individuals and entities, including physicians who refer patients for DHS.

Facilitating such coordination and distributing earned savings involves establishing financial ties between the various participants—hospitals, physicians, pharmacies, home health providers and others—which necessarily implicate the fraud and abuse laws, including the Stark Law.

In recognition of potential difficulties the Stark Law poses under VBP models, Congress gave the Secretary of HHS the authority to issue regulatory waivers of the Stark Law for certain innovative payment and service delivery models implemented under the Affordable Care Act (''ACA''). The Secretary has issued waivers for various programs, including the Medicare Shared Savings Programs (''MSSP''), the bundled Payments for Care Improvement (''BPCI'') Initiative, the Comprehensive Care for Joint Replacement (''CCJR'') Model, and the various Accountable Care Organization (''ACO'') programs. These waivers and statutory changes, however, represent a patchwork approach to addressing the Stark Law's effect on VBP.[5]

Enforcement. Although intended to be self-enforcing by encouraging entities such as hospitals to police their own financial arrangements with physicians, the government has leveraged the *qui tam* provisions of the federal False Claims Act (''FCA'') to enforce the Stark Law. The government and FCA relators have argued successfully that the FCA prohibits billing for services tainted by noncompliance with the Stark Law, where evidence shows that the claim for reimbursement was submitted in reckless disregard or deliberate ignorance of the truth or falsity that the provider complied with applicable law.

These cases have led to significant recoveries by the government, even though they were typically in situations where the underlying healthcare services were provided as claimed and were medically necessary.

[2] Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn; 42 C.F.R. §§ 411.350–411.389.

[3] 42 U.S.C. § 1395nn(h)(6) (defining DHS as clinical lab services; physical or occupational therapy services; radiology services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient and outpatient hospital services; and outpatient speech-language pathology services).

[4] Section 1128J(d) of the Social Security Act.

[5] Under MACRA, Congress modified the Civil Monetary Penalties (CMP) law to remove barriers to gainsharing for VBP programs, but left the Stark Law untouched. Instead, Congress requested recommendations on how the various fraud and abuse laws could be modified to support health-care reform.

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FCA liability may also attach to a violation of the Stark Law through the obligation to pay or refund an overpayment to the government, known as a ''reverse'' false claim. The ACA clarified the meaning of ''obligation'' by directly linking the retention of overpayments to false claims liability. The nuanced compliance challenge presented by the Stark Law leaves providers exposed to unwitting violations of Medicare's 60-day overpayment report and return obligation and thus further FCA liability.

Proposed Stark Law Changes, Modifications

The Report summarizes various recommendations from the round-table participants on how the Stark Law might be modified to ease implementation and adoption of health-care reforms promoting alternative payment models (''APMs''), such as VBP models. The participants offered proposals ranging from new and expanded waivers or exceptions, to changes to Stark Law definitions, to repealing all or a portion of the law.

While it is not possible to say with certainty which, if any, proposal will ultimately be adopted, the Report suggests that Congress may be willing to consider incremental changes to the Stark Law in the near term given the push to increase the proportion of Medicare payments made through APMs.

Repeal the Stark Law in Whole or in Part. The most dramatic, but also least likely, change would be the outright repeal of the Stark Law. The Report noted that certain roundtable participants suggested that the AKS serves a sufficiently similar role and would fill any enforcement void left by repeal of the Stark Law.

A more moderate approach would sunset the Stark Law after Medicare meaningfully transitions to VBP models and away from FFS; however, the Report acknowledged difficulties in identifying the point at which meaningful transition would have occurred.

Sun-setting the Stark Law when it serves no further purpose is a reasonable proposal.

Although full repeal of the Stark Law prior to VBP models fully supplanting FFS models, or even significantly replacing FFS payments, is unlikely, sun-setting the Stark Law when it serves no further purpose is a reasonable proposal.

Unfortunately, this approach does little to help providers manage the law's weighty compliance burden and significant potential liability in the interim.

Short of full repeal, roundtable participants advocated for a repeal of the compensation arrangement prohibition. As the Report notes, however, the prohibition on compensation arrangements was intended to prohibit schemes designed to circumvent the Stark Law's ownership and investment prohibition. Repeal of the compensation arrangement prohibition would relieve providers of a significant regulatory burden, but it would make it more difficult for the government to address abusive arrangements.

Only the Stark Law's civil monetary penalty for circumvention schemes, which is rarely affirmatively enforced, would remain a viable authority under which to pursue arrangements structured to provide the benefit of an improper ownership or investment interest while avoiding the prohibition. This change to the law seems unlikely prior to VBP becoming an entrenched payment model given the difficulties in proving a knowing violation of the CMP.

New or Modified Waivers and Exceptions. The Report listed recommendations by roundtable participants to enact new waivers or exceptions or to modify existing waivers or exceptions to support and protect arrangements between physicians and providers linked to APMs, or risk-sharing or gainsharing arrangements, which generally reduce or eliminate the risk of abusive overutilization.

New waivers or exceptions could take various forms, such as a designated APM exception or broadened waiver authority for the Secretary of HHS. For example, the Report referenced suggestions to make permanent existing waivers for entities engaged in qualifying APMs (e.g., ACO and MSSP participants), and a variation requiring compliance with regulations in their current form until the provider exceeds a certain level of risk-based revenue.

A new exception could be based on the risk-sharing exception at 42 C.F.R. § 411.357(n)[6] and could protect downstream bundled payments, shared savings and other financial arrangements between the parties participating in the various APM models operated by the Centers for Medicare & Medicaid Services (''CMS''), so long as the protected arrangement was reasonably related to the purpose of the respective program.

Proposals to modify existing Stark Law exceptions included expanding the statutory exception for prepaid plans at 42 U.S.C. § 1395nn(b)(3) so the prohibition on referrals of DHS would not apply to services rendered by an entity participating in an APM with CMS, and protecting DHS furnished to a Medicare beneficiary assigned to an MSSP, Pioneer ACO, or any ACO model established by CMS.

Although these modifications may provide greater certainty to providers participating in such programs, because the prohibition would remain in effect for FFS beneficiaries, existing compliance obligations would not likely be reduced and may increase if providers are required to adjust or revise arrangements to account for populations of beneficiaries subject to different regulatory obligations.

Roundtable participants also advocated for aligning the Stark Law exceptions with conduct permitted under the CMP law, such as the anticipated gainsharing safe harbor.[7] Other recommendations focused on clarifying the indirect-compensation arrangement exception and

[6] 42 C.F.R. § 411.357(n) (''*Risk-sharing arrangements*. Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the [AKS], or any Federal or State law or regulation governing billing or claims submission. . .'').

[7] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing 79 Fed. Reg. 59717, 59719 (proposed Oct. 3, 2014), *available at* http://oig.hhs.gov/

deeming percentage-based compensation arrangements to be consistent with Fair Market Value and commercially reasonable (or at least easing the Fair Market Value and commercial reasonableness criteria for such arrangements).

Given the Stark Law's perceived utility in limiting overutilization in the FFS context, Congress may authorize a limited permanent waiver or exception to align the Stark Law with the CMP law and to protect arrangements established under authorized VBP models. The extent to which any exception or waiver would protect downstream financial arrangements is impossible to say at this juncture, but may mirror existing waivers granted by the Secretary.

Unless Congress expressly provides otherwise, any new or modified exception will likely include significant documentation obligations given CMS's authority to establish new exceptions only where there is no risk of program or patient abuse.

Expand the Secretary's Authority to Provide Waivers, Exceptions, Advisory Opinions. Roundtable participants referenced in the Report proposed expanding the Secretary's authority to issues waivers, exceptions, and advisory opinions. This approach has the advantage of introducing greater regulatory and enforcement flexibility while leaving the status quo largely unchanged.

However, the disadvantages of this approach are significant. As noted above, the issuance of additional waivers or exceptions may result in an overlapping patchwork of inconsistent compliance obligations affecting a provider's interactions with different physicians and beneficiaries. The burden of compliance may be exacerbated, not eased.

Expansion of the Secretary's authorities may only serve as half-measures of reform.

Further, expansion of the Secretary's authorities may only serve as half-measures of reform. If Congress leaves in place the strict liability regime, the reforms may not sufficiently ease compliance obligations to achieve the Committee's goal of encouraging transition to VBP.

The issuance of additional advisory opinions would be of limited utility to the health-care community because, although generally informative as to CMS's view of a particular arrangement, only the requesting party may rely on the advisory opinion. Further, the advisory opinion process may not offer providers sufficient flexibility to adjust arrangements in a changing reimbursement landscape; thereby further delaying transition to VBP models.

Roundtable participants also suggested broadening the Secretary's authority to create new Stark Law exceptions. CMS has been historically conservative in adopting new exceptions, because current law permits new exceptions only if the Secretary determines that the change would ''not pose a risk of program or patient abuse.''

Participants suggested that authorizing exceptions that do not pose ''an undue or significant risk of program or patient abuse'' may give the Secretary latitude to revise the law's complicated regulatory structure and broaden exceptions, without significantly increasing the risk of program abuse. However, it is unlikely that new exceptions would significantly ease provider compliance obligations if the law remains a strict liability prohibition. Any new Stark Law exception would likely continue to have stringent documentation, Fair Market Value, commercial reasonableness and volume and value criteria.

The relative success of the HHS Office of the Inspector General's (''OIG's'') broad authority to implement new safe harbors to the AKS should not be seen as evidence that a similar approach would work in the Stark Law context.

Compliance with every element of an AKS safe harbor is not mandatory, whereas providers must comply with every element of a Stark Law exception. In the AKS context, providers can, and frequently do, craft innovative arrangements that hew closely to the spirit of the safe harbor without satisfying every element, and may gain additional comfort from favorable advisory opinions addressing similar arrangements. This approach is not feasible in the Stark Law context because it is a strict liability statute designed to be an easily enforced bright-line prohibition.

Defining Technical, Substantive Violations of Stark

In addition to proposals intended to bolster adoption of health-care reform, the Report addressed the often discussed distinction between ''technical'' and ''substantive'' violations of the Stark Law, a distinction that has no legal impact on liability under the current rules.

Roundtable participants generally agreed that technical violations should not give rise to FCA liability or subject a provider to significant overpayment liability. Although not currently defined in the statute or regulations, technical violations are those that involve the form, not substance, of the arrangement, such as noncompliance with documentation requirements under certain exceptions, the failure with which to comply does not incentivize referrals or present any meaningful risk of overutilization or program abuse.

The proposed Stark Administrative Simplification Act of 2015[8] was viewed by the participants as a move in the right direction with respect to defining technical violations as (i) an arrangement not set forth in writing; (ii) an arrangement not signed by one or more parties to the arrangement; or (iii) a prior arrangement that expires and services continue without execution of an amendment or new arrangement. The proposed bill also provided for a single civil monetary penalty of $5,000 for technical noncompliance lasting less than one year, and $10,000 if the noncompliance lasts for greater than one year.

Although not referenced in the Report, CMS made certain modifications in the 2016 final rule for the Medicare Inpatient Prospective Payment System that should

authorities/docs/2014/Safe_Harbor_Beneficiary_Inducements_Proposed_Rule.pdf.

[8] Stark Administrative Simplification Act of 2015, H.R. 776, 114th Cong. (2015) (Rep. Charles Boustany (R-LA) and Rep. Ron Kind (D-WI)).

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reduce the compliance burden and liability for certain technical violations referenced in the Report and the Stark Administrative Simplification Act.

Although an arrangement must still be set forth in a ''writing'' to comply with most applicable exceptions, CMS clarified that the required ''writing'' may be composed of various contemporary documents reflecting the arrangement and the required ''signature'' may appear on any of such documents provided the signature reflects acceptance of the terms of the arrangement.

Further, the regulations now permit an arrangement that becomes noncompliant due to expiration to remain complaint indefinitely provided the parties continue to act consistent with the same terms and conditions as the previous arrangement. CMS acknowledged that parties must be mindful that an indefinite arrangement may not remain consistent with Fair Market Value over time, but that so long as the arrangement was determined to be within Fair Market Value when entered and the original term was commercially reasonable, the agency would not have Fair Market Value concerns during the original term.

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Relieving burdensome compliance obligations and the significant potential liability for technical violations has long been viewed by providers and their attorneys as an important fix for the Stark Law, short of repeal.

The reforms listed in the Report, such as easing documentation requirements, clarifying certain compensation arrangement terms (i.e., the Fair Market Value, commercial reasonableness and volume or value of referral standards), establishing an exception or reduced penalty for technical noncompliance, reflect the goal of reducing the potentially significant liability associated with noncompliance that has no effect on the quality or quantity of health care provided to Medicare beneficiaries.

The proposed Stark Administrative Simplification Act may have provided a good starting point when proposed, but it no longer accurately reflects the compliance burden faced by providers and suppliers. Further analysis by the Committee in light of the recent regulatory changes should be undertaken to identify statutory changes that would relieve the industry of regulatory burdens that do not protect beneficiaries or the Medicare program from abuse.

Any Changes to Stark Law Likely to be Limited, Incremental

The Committee acknowledged that the purpose of the Stark Law is largely, if not entirely, eliminated through the use of APMs, and that despite the continuation of the FFS model—for now—the law continues to pose challenges for providers seeking to implement health-care reform. Although the Committee noted that it will consider all of the various comments and recommendations it received, it seems unlikely that the law will be repealed while the FFS model remains a fixture of the Medicare program.

Providers should anticipate seeing additional proposals and recommendations to ease the compliance burden associated with Stark Law and to foster participation in health-care reform and APMs, but these changes are likely to be incremental and limited to programs directed by CMS.

In light of OIG's proposed gainsharing CMP (expected to be finalized later this year), it is feasible Congress will look to OIG's experience to guide future legislation and recommendations to CMS. It is too early to say with certainty what, if any, statutory or regulatory changes will come out of the Committee's report.

In the context of the Stark Law's hyper-technical regulatory environment, any changes to improve the law and encourage innovative payment models are likely to be slow, incremental, and welcome.