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Brief Insight

Modernizing Stark

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> The guiding principle for the self-referral laws was to prevent physicians from inappropriately referring patients based on the potential for financial gain. Yet, the health care delivery system has changed profoundly since passage of the first self-referral laws. Since 1989, the health care system has rapidly moved away from the traditional fee-for-service way of delivering medical care. Today, the health care system has moved towards a more coordinated, integrated approach.[1]

At a time when the health care industry grapples with the transition to value-based payment, the above quote reads like it could have been written yesterday. Yet, this statement about the federal physician self-referral prohibition commonly known as the Stark Law was made almost two decades ago by Rep. Bill Thomas (R-CA) in a congressional committee hearing. The question of how to modernize the Stark Law has vexed policymakers for years, but the need for action has become urgent. Under the direction of Sen. Orrin Hatch (R-UT), the Senate Finance Committee has taken on the mantle of Stark Law reform, organizing a roundtable discussion of experts and industry stakeholders, releasing a whitepaper that outlines the problem and highlights a range of

1 *Medicare Self-Referral Laws: Hearing Before the Subcomm. on Health of the Comm. on Ways & Means*, 106th Cong. 2 (1999) (statement of Dwight S. Cenac, Home Care Association of America), *available at* www.gpo.gov/fdsys/pkg/CHRG-106hhrg65695/html/CHRG-106hhrg65695.htm.

potential solutions, and convening a hearing to probe the issue.[2] Still, the law remains unchanged.

Why is it that, despite broad, longstanding agreement that a problem exists, we do not yet have a solution? Several factors might explain. For one, we simply do not know the many forms value-based payment models may take, much less how industry will respond to them. Without a complete understanding of the types of financial relationships that providers may develop in response to alternative payment models, it is difficult to craft a suitable exception. Relatedly, the range of potential solutions offered by policymakers and stakeholders is so broad as to cause the discussion to become unfocused. The menu of options offered by the Senate Finance Committee runs the gamut, from modest expansions of program-specific waivers to outright statutory repeal. Without consensus as to whether to pursue incremental reform or wholesale policy change, it's no wonder progress has been slow. Finally, relaxing an anti-fraud law[3] is politically unpopular, particularly in the absence of a cogent justification.

To advance the discussion, we contend there needs to be a sharper focus on a narrower solution. There is a simpler, politically feasible approach: amend the statute to permit the Centers for Medicare and Medicaid Services (CMS) to create regulatory exceptions to the Stark Law where it determines that doing so does not pose a *significant* risk of program or patient abuse.

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2 Staff of S. Comm. on Fin., Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models, *available at* www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf; *Examining the Stark Law: Current Issues and Opportunities: Hearing Before the S. Comm. on Fin.* (2016), *available at* www.finance.senate.gov/hearings/examining-the-stark-law-current-issues-and-opportunities.

3 While we hesitate to characterize the Stark Law as anti-fraud law, as the parties' intent is generally not relevant to a determination of liability, we note that the law's origins reflect concern about intentional misconduct. In introducing the Ethics in Patient Referrals Act, Rep. Pete Stark (D-CA) stated as follows: "Unfortunately, clever deal makers have found a loophole [to the federal anti-kickback statute]. Referral schemes are being disguised as legitimate business arrangements, most commonly as partnerships involving referring physicians, but also as consulting or similar arrangements. The intent generally is quite clear: to lock-in referrals by creating a web of financial relationships binding the referring physicians to the provider . . . . Frankly, it's hard to believe that partnership managers do not routinely keep [referral] statistics, and such a manager would have to be a saint not to use this information to encourage more referrals from physician investors." 135 Cong. Rec. H240 (1989).

CMS's authority to establish new exceptions to the Stark Law is rooted in Section 1877(b)(4) of the Social Security Act.[4] Under that section, the Secretary of the Department of Health and Human Services is given the authority to exempt from the Stark Law's prohibition "any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse."[5] In other words, exceptions beyond those specified in the statute must pose no risk of abuse, no matter how small or remote.[6]

This limitation on CMS's authority is a major obstacle to the creation of safe space for innovative arrangements intended to further the objectives of value-based payment initiatives. Indeed, CMS cited this limitation when, in 2008, it proposed but declined to finalize an exception for incentive payment and shared savings programs.[7] The agency observed that, "in order to ensure that we did not exceed this authority, the proposed exception was targeted and relatively narrow," and, as a result, "it was unlikely to cover as many arrangements as interested stakeholders would like."[8] Ultimately, citing a lack of "sufficient information or agreement among commenters regarding possible modifications to the proposal to allow us to finalize an exception that expands the proposed exception in any meaningful way," and reiterating the difficulty of "craft[ing] a 'one-size-fits-all' set of conditions that are sufficiently 'bright line' to facilitate compliance and enforceability," CMS declined to move forward with the exception.[9] Two years later, in an announcement regarding a public workshop on legal issues related to accountable care organizations, CMS again

4 Social Security Act § 1877(b)(4), 42 U.S.C. § 1395nn(b)(4).
5 *Id.*
6 CMS does, of course, have authority under Section 1115A(d)(1) of the Social Security Act to issue Stark Law waivers solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation. In addition, Section 1899(f) of the Act gives CMS authority to waive the Stark Law in connection with the Medicare Shared Savings Program. While CMS has used this waiver authority to protect a range of arrangements, its authority is severely limited by the requirement that waivers be program-specific.
7 *See* Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 73 Fed. Reg. 69726, 69793–98 (Nov. 19, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 413, 414, 415, 423, 424, 485, 486, & 489).
8 *Id.* at 69793.
9 *Id.* at 69794.

pointed to the "no risk" standard as an obstacle to creating a workable exception, stating its interest in comments on "how a physician self-referral exception could be designed given that any new exception under section 1877 of the Act must present no risk of program or patient abuse."[10]

Under a "significant risk" standard, rather than a "no risk" standard, the agency would have the ability to make thoughtful judgments about the range of permissible arrangements in a way that responds to the rapidly evolving dynamics of the market. It would not be foreclosed from creating a regulatory exception merely because of the possibility, however remote, that it could be exploited by unscrupulous actors—a scenario which, in all likelihood, could be adequately policed with the federal Anti-Kickback Statute. In fact, it should be noted that CMS has on numerous occasions sidestepped the "no risk" standard in the rulemaking process by including a requirement that an arrangement not violate the Anti-Kickback Statute or other fraud and abuse laws.[11] In a sense,

10 Meeting Notice, Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws, 75 Fed. Reg. 57039, 57041 (Sept. 17, 2010).

11 *See, e.g.,* Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 863 (Jan. 4, 2001) (to be codified at 42 C.F.R. pts. 411 & 424) ("As a practical matter, the statutory language authorizing exceptions leaves us two choices: (1) we can limit the exceptions to those situations that pose no risk of fraud and abuse—a very stringent standard that few, if any, of the proposed regulatory exceptions meet; or (2) we can protect arrangements that, in most situations, would not pose a risk, and rely on the anti-kickback statute or other fraud and abuse laws to address any residual risk"). *See also* Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054, 16097 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411 & 424) ("Because we are expanding this exception under our authority in section 1877(b)(4) of the Act, which authorizes the creation of new exceptions only if the excepted arrangement presents no risk of program or patient abuse, the arrangement must not violate the anti-kickback statute and must comply with all relevant claims submission and billing laws and regulations. In this context, if there is any intent unlawfully to reward or induce referrals from the physician practice whose recruitment the hospital chose to underwrite, the anti-kickback statute would be violated and the exception would not apply."). One might fairly ask whether a statutory change is necessary in light of this regulatory maneuvering. We think, however, that a statutory change would be a clearer, less cumbersome means of addressing the issue. For one, requiring compliance with the Anti-Kickback Statute and other laws does not necessarily remove *all* risk of fraud and abuse. In addition, tethering Stark Law compliance to compliance with other laws creates a clunky standard that raises more questions, such as the propriety of grafting the Anti-Kickback Statute's intent requirement onto the Stark Law's "bright line" standard. For an excellent discussion of this issue, *see* Charles B. Oppenheim, The Stark Law: A Comprehensive Analysis and Practical Guide, 38-40 (5th ed. 2014).

under a "significant risk" standard, CMS's rulemaking authority would be similar to the discretion the Office of Inspector General has to issue favorable advisory opinions where it determines an arrangement poses a minimal risk of fraud and abuse or has sufficient safeguards.[12]

To be clear, expanding CMS's regulatory authority would not, in and of itself, resolve the quagmire of updating a fee-for-service law for a value-based payment world. Difficult questions would remain regarding the scope of an exception for care coordination, clinical integration, or other innovative arrangements between physicians and entities that furnish designated health services. Any such exception would still need to deal with the challenge of, for example, assuring the *bona fides* of a provider network. However, enhancing CMS's rulemaking authority would give the agency the flexibility needed to address these issues. The Stark Law has been seen as a barrier to innovative payment initiatives for many years; adding one word to the statute could go a long way toward easing the burden. J

12 It should be noted that CMS's authority to issue advisory opinions is narrower than that of the OIG. The Stark Law advisory opinion process is limited to the issue of "whether a referral relating to designated health services (other than clinical laboratory services) is prohibited [under the Stark Law]." Social Security Act § 1877(b)(6), 42 U.S.C. § 1395nn(b)(6). Thus, it is not as if the Stark Law advisory opinion process offers a mechanism through which CMS can conclude that an arrangement poses a minimal or insignificant risk of fraud and abuse.

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