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The Stark Law, post-pandemic

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When our nation's hospitals and health professionals found themselves on the front lines in the battle against the 2019 Novel Coronavirus (COVID-19) pandemic, the United States Department of Health and Human Services (HHS) acted quickly and decisively to issue an array of temporary regulatory waivers and new rules designed to give the health care system "maximum flexibility" to respond to the crisis.[1]

Among the temporary waivers issued were partial waivers of sanctions under Section 1877 of the Social Security Act, otherwise known as the physician self-referral law or the "Stark Law."

The waivers of sanctions under the Stark Law have allowed hospitals and other providers to support the physician community, and vice versa, and allowed the reshaping of financial relationships in ways that might otherwise have opened the door to major liability.

These waivers provided welcome regulatory relief, but they are limited in scope, applicability and, importantly, duration. Looking beyond the pandemic, the Stark Law, as well as the Anti-Kickback Statute, will continue to influence how physician financial arrangements are structured.

Before the pandemic arrived at our doorsteps, HHS made two promises that could meaningfully alter the compliance landscape. First, HHS promised to address "well-meaning anti-fraud protections" — like the Stark Law and Anti-Kickback regulations — that "may actually be impeding useful coordination and integration of services."[2]

Second, HHS committed to reforming the Stark Law advisory opinion process to issue actionable decisions and guidance to parties trying to understand how the physician self-referral law applies in an evolving and innovative marketplace.

Together, these two regulatory actions have the potential to open up new opportunities for the health care community to align to better serve patients and remove some of the compliance risk for those interested in taking advantage of the new flexibilities.

THE STARK LAW: AN 'OUTDATED LAW POISED FOR MODERN REFORM'

Fueled by a 1989 study by the HHS Office of the Inspector General linking physician ownership and investment to increased utilization of laboratory services,[3] the Ethics in Patient Referral Act of 1989 was passed with the purpose of prohibiting physicians from referring Medicare patients to clinical labs in which the physician had some financial relationship.[4]

Another wave of studies conducted on the heels of the 1989 OIG study produced more fodder for reform, finding additional instances outside of the clinical laboratory context where physician financial interests appeared to be driving increases in utilization.[5]

The law and its implementing regulations embody a regulatory scheme that has been referred to as "a booby trap rigged with strict liability and potentially ruinous exposure."

Moved by these studies, Congress expanded the law in 1993 to ban self-referrals for a vast array of services, including inpatient and outpatient hospital services.

The law and its implementing regulations embody a regulatory scheme that has been referred to as "a booby trap rigged with strict liability and potentially ruinous exposure."[6] Indeed, even the law's creator has expressed regret over rules that have become so complex that it has been a bonanza for lawyers.[7]

In general, the Stark Law prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship, unless an applicable exception applies, and prohibits an entity from filing claims with Medicare for designated health services furnished pursuant to a prohibited referral.[8]

The implementing regulations, which currently take up over 50 pages in the Code of Federal Regulations, contain 38 exceptions, each with multiple elements that must be satisfied.[9]

The Stark Law is often referred to as a "strict liability" law, because even an unintentional violation triggers the prohibition on Medicare payment. Noncompliance over a long period of time can result in large overpayment liability.

The Centers for Medicare & Medicaid Services (CMS) is the HHS agency responsible for administering and enforcing the Stark Law, though most Stark Law enforcement happens through False Claims Act (FCA) lawsuits.

FCA exposure arises when a party knowingly, or with reckless disregard or deliberate ignorance, submits a claim that arises from a prohibited referral, or retains Medicare reimbursement that the party later learns it should not have been paid.

The law and the current exceptions are designed around a fee-for-service health care system, where physicians can increase their income by simply performing more services. But this manner of paying for care based on volume has grown unpopular over the last couple of decades.

As our health system inches away from fee-for-service based payment, and toward "value-based" payment systems, laws like the Stark Law have been identified as barriers to progress.[10]

Congress has at times shown interest in reforming the law, including most recently in 2016 when then-Senate Finance Committee Chairman Orrin Hatch (R-Utah) released a white paper making the case for legislative change, calling the Stark Law an "outdated law poised for modern reform."[11]

Four years later, the law still remains largely as it was in 1993.

THE COVID-19 PANDEMIC: BLANKET WAIVERS OF STARK LAW SANCTIONS

On January 31, 2020, Secretary Alex M. Azar declared a public health emergency pursuant to section 319 of the Public Health Service Act, and on March 13, the President issued a proclamation pursuant to the National Emergencies Act, declaring that the COVID-19 outbreak in the United States constitutes a national emergency.

These actions triggered section 1135 of the Social Security Act, which authorizes the Secretary of the Department of Health and Human Services (the Secretary) to waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act of 1996 requirements.[12]

Under section 1135 of the Act, the Secretary may grant waivers to ensure that, during an emergency period, in affected areas of the nation

(1) there are sufficient health care items and services are available to meet the needs of individuals in the emergency area enrolled in the Medicare, Medicaid, and CHIP programs; and

(2) health care providers that furnish such items and services in good faith, but that are unable to comply with certain enumerated requirements, may nonetheless be reimbursed for such items and services and exempted from sanctions for such noncompliance — including sanctions under section 1877(g) of the Act — absent any determination of fraud or abuse.[13]

Pursuant to this authority, on March 30, 2020, CMS issued a number of waivers, including a waiver of sanctions under the Stark Law for COVID-19 Purposes.[14] These waivers, according to CMS, were designed to "provide vital flexibility for physicians and providers in the fight against COVID-19."[15]

Importantly, CMS issued these waivers as "blanket waivers," meaning that individual parties do not need to apply for the relief unless they seek something the blanket waiver did not address.

The blanket waivers are self-implementing, meaning that no additional action is required for health care providers to avail themselves of the protection.

The issuance identified 18 types of compensation and ownership remuneration and referrals that would be exempt from sanctions under the Stark Law if adopted during the national emergency to address a "COVID-19 Purpose."[16]

> The Stark Law is often referred to as a "strict liability" law, because even an unintentional violation triggers the prohibition on Medicare payment.

Under these waivers, a hospital could, for instance, pay physicians more than what an existing services agreement might call for in order to compensate for the added hazards and challenges associated with furnishing care to COVID-19 patients, or to provide continued income to employed physicians that saw their patient volume drop.

It also allows hospitals to provide free space, telehealth and other equipment, meals, transportation, and other nonmonetary benefits to physicians, and forgives the failure to obtain signed agreements for otherwise compliant arrangements.

Where hospitals leased space to physicians, the hospitals were able to do as other landlords have done during the pandemic – provide rent relief.[17]

While the blanket waiver approach enabled the agency to quickly provide broad immunity from 1877(g)'s sanctions, it was not designed to anticipate or address every fact pattern.

The waivers only extended to certain elements of the regulatory exceptions, and financial relationships or referral relationships must still satisfy all non-waived elements of an applicable exception to avoid sanction under Section 1877(g).[18]

The blanket waivers did not permit things like the extension of existing physician recruitment arrangements with income guarantees. In other words, the blanket waivers are limited in scope.

Furthermore, the waivers only apply to the sanctions authorized under Section 1877(g), which include denial (or

recoupment) of payment and civil monetary penalties for intentional conduct.

The waivers do not immunize parties from liability under the Anti-Kickback Statute, nor would they preclude a relator from bringing a qui tam suit under the FCA.

The Office of Inspector General (OIG) issued a Policy Statement on April 3rd indicating that it will not impose administrative sanctions under the Exclusion Statute and the Civil Monetary Penalty Statute that correspond to the first 11 of the Stark blanket waivers.[19]

And the Secretary has said he will work with the Department of Justice to address FCA suits brought by relators where parties using the blanket waivers have a good faith belief that their remuneration or referrals are covered by a blanket waiver.[20]

These statements of enforcement policy are important, and while they do not completely guard against the possibility that a relator may still file an FCA action, they may serve to deter such lawsuits.

Finally, the waivers are limited in duration. The Secretary's authority to waive sanctions under 1877(g) expires upon:

- the termination of the President's declaration of emergency or disaster pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act;
- the termination of the Secretary's declaration of public health emergency pursuant to section 319 of the Public Health Service Act; or
- the termination of a period of 60 days from the date of the waiver, absent an extension by the Secretary.[21]

As of the date of this article, the Secretary's declaration of a public health emergency is set to expire on July 25, 2020, but HHS has indicated that it expects to renew the declaration prior to this date.

THE STARK LAW POST-PANDEMIC: HHS PROMISES NEW EXCEPTIONS AND MORE ADVISORY OPINIONS

Before COVID-19 upended our world, regulatory reforms to the Stark Law were already underway at HHS. In a March 2018 speech to the Federation of American Hospitals, newly-confirmed HHS Secretary Azar announced value-based payment reform as one of his four top priorities, and noted that "well-meaning fraud and abuse laws" would need to change.

Under Deputy Secretary Eric Hargan's leadership, HHS advanced a plan to modernize the Stark Law regulations, as well as the Anti-Kickback Statute safe harbors and certain privacy rules, which were acting as barriers to physicians and health care institutions finding new and economical ways to work together to better coordinate care for patients.

This initiative has been dubbed the "Regulatory Sprint to Coordinated Care."[22]

The first major milestones in the Regulatory Sprint were hit last fall. On October 17, 2019, CMS published a proposed rule entitled "Modernizing and Clarifying the Physician Self-Referral Regulations."[23]

In it, the agency proposed new exceptions to the Stark Law for certain types of value-based compensation arrangements between or among physicians, providers and suppliers.

It also proposed new exceptions for donations of cybersecurity technology and related services, and an amendment to the existing exception for electronic health records and related items and services.

> Importantly, CMS issued these waivers as "blanket waivers," meaning that individual parties do not need to apply for the relief unless they seek something the blanket waiver did not address.

Finally, the rule proposed to add clarification to several key terms found throughout the Stark Law and implementing regulations — i.e., how CMS interprets what it means for an arrangement to be "commercially reasonable"; how it interprets and applies the "volume or value" and "other business generated" standards; and how it interprets "fair market value."

These proposals enjoy broad support across the health care provider community, and represent a major leap forward toward a more modern approach to regulating physician financial relationships.

Once these regulations are finalized (if they are finalized), accessing the new flexibilities may mean more work for the throngs of attorneys, consultants and valuation experts that typically attend the creation of new financial arrangements in this highly regulated space.

This could put smaller facilities and practices at a disadvantage. But HHS has recently signaled a willingness to revamp its advisory opinion process as a means of providing more timely compliance guidance and, ultimately, greater certainty to regulated entities.

In the Calendar Year 2020 Physician Fee Schedule Final Rule, CMS made some important changes to the regulations governing the Stark Law advisory opinion process that were intended to both clarify the process and remove limitations and restrictions that might be unnecessarily serving as obstacles to a more robust process.[24]

Section 1877(g)(6) of the Act requires the Secretary to issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act.

On January 9, 1998, the Secretary issued a final rule with comment period in the Federal Register to implement and interpret section 1877(g)(6) of the Act (the 1998 advisory opinion rule). (See Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions (63 FR 1646).)

In the 20 years since this process was put in place, CMS has issued just over 30 opinions, 15 of which focus narrowly on questions related to an 18-month moratorium on physician-owned specialty hospitals, which was in effect from December 8, 2003, through June 7, 2005.

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CMS itself acknowledged that this process "has not been widely utilized by stakeholders." In the final rule, CMS stated:

We agree that a well-functioning advisory opinion process could aid in advancing two of the Department's top priorities — reducing regulatory burden on providers and encouraging adoption of alternative payment models and coordinated care arrangements.

A faster and more robust advisory opinion process facilitates the shift to value-based care arrangements by providing more guidance for parties trying to understand how the physician self-referral law applies in an evolving and innovative marketplace.

This will help to reduce provider burden by providing insight into what does and does not comply with the law, which encourages innovation.[25]

Changes such as the new user fee structure will enable the agency to handle a greater volume of advisory opinion requests and issue opinions in a shorter time frame.[26]

And removal of the limits on who may reasonably rely on a published advisory opinion shows that CMS hopes that issued opinions will serve as a practical compliance tool for regulated entities, even if they are not parties to a specific opinion.

Regulatory uncertainty can be crippling. A high-functioning advisory opinion process, accessible to every individual and entity, regardless of practice size, carries the promise of bringing more certainty to Stark Law compliance.

Notes

[1] *See* CMS, Press Release, Trump Administration Makes Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge (Mar. 30, 2020), available at https://go.cms.gov/3edx81p (last accessed June 28, 2020).

[2] Remarks on Value-Based Transformation to the Federation of American Hospitals, March 5, 2018, available at https://bit.ly/323cWNc (last visited June 28, 2020).

[3] Office of Inspector General, U.S. Dep't of Health & Human Servs., Financial Arrangements Between Physicians and Health Care Businesses (1989). The OIG's report identified a number of possible solutions, including implementing a post-payment review program for services referred by physician owners/investors, requiring disclosure of financial interests to patients, instituting a private right of action for violations of the Anti-Kickback Statute, prohibiting physicians from making referrals to certain types of entities in which the physicians had a financial interest, and prohibiting physicians from making referrals to all entities in which the physicians had a financial interest.

[4] Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 1877, 103 Stat. 2106, 2236 (1989).

[5] *See* Patrick A. Sutton, The Stark Law in Retrospect, 20 Annals Health L. 15 (2011).

[6] *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364, 395 (4th Cir. 2015) (Wynn, J., concurring).

[7] *See, e.g.*, Pete Stark: Repeal the Stark law, Modern Healthcare, August 02, 2013. According to Congressman Stark, the main author of the initial legislation, the purpose of the law was to stop those health care providers who were being unduly influenced by financial motives, not muddy the waters for all health care providers. He lamented that the law grew more complicated with the help of "high-priced lawyers who tried to build loopholes for their clients. The original law was pretty simple. Basically it says anyone who takes a bribe or a split or a commission or a kickback in exchange for referring services gets five years or a $50,000 fine." Id.

[8] Social Security Act § 1877(a).

[9] *See generally* 42 C.F.R. §§ 411.355 - .357.

[10] U.S. Senate Committee on Finance, Why Stark, Why Now? (2016).

[11] *See* Press Release, Hatch Releases White Paper Discussing Suggestions to Improve Stark Law, Jun. 30, 2016, available at https://bit.ly/3iEBDp4.

[12] *See* Social Security Act § 1135. Two prerequisites must be met before the Secretary may invoke the waiver authority. First, the President must have declared an emergency or disaster under either the Stafford Act or the National Emergencies Act. Second, the Secretary must have declared a Public Health Emergency under section 319 of the Public Health Service Act.

[13] Social Security Act § 1135(a).

[14] CMS, Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency, available at https://go.cms.gov/2O5IYzY (last accessed June 27, 2020).

[15] https://go.cms.gov/2W5Ipvl

[16] *Id.* at 3.

[17] *See id.* at 6-7; *see also* CMS, Explanatory Guidance, March 30, 2020, Blanket Waivers of Section 1877(g) of the Social Security Act (April 21, 2020), available at https://go.cms.gov/38IlaeR (last visited June 27, 2020) (hereinafter "Explanatory Guidance").

[18] Explanatory Guidance at 2.

[19] OIG, OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency (April 3, 2020), available at https://bit.ly/38G9b1p (last visited June 27, 2020).

[20] Explanatory Guidance, at 1.

[21] Social Security Act sec. 1135(e).

[22] *See* 83 Fed. Reg. 29,524 (June 25, 2018).

[23] 84 Fed. Reg. 55,766 (Oct. 17, 2019). On the same day, the HHS Office of Inspector General published a companion proposal to modify the regulatory safe harbors under the Anti-Kickback Statute and regulatory exceptions to the civil monetary penalty rules regarding beneficiary inducements. 84 Fed. Reg. 55,694 (Oct. 17, 2019). While the OIG proposal is outside the scope of this article, it is important to recognize the overlap of the OIG and CMS regulations governing financial relationships between physicians and the entities to whom they refer.

[24] 84 Fed. Reg. at 62,937.

[25] 84 Fed. Reg. at 62,937.

[26] 84 Fed. Reg. at 62,940; 42 C.F.R. § 411.375(a).

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ABOUT THE AUTHOR

Kelly M. Cleary rejoined **Akin Gump** as a partner after serving for three years at the Department of Health and Human Services as deputy general counsel and chief legal officer for the Centers for Medicare & Medicaid Services. As an adviser to health industry participants, she supports in-house legal and business teams in structuring complex transactions and other strategic initiatives in a manner that minimizes regulatory risk. She has particular experience in matters involving state and federal fraud and abuse laws, including the federal Stark Law and Anti-Kickback Statute and their state analogs, and the Patient Protection and Affordable Care Act marketplace regulations. Cleary also has successfully represented clients before administrative and judicial tribunals on matters relating to Medicare and Medicaid enrollment and reimbursement, as well as in lawsuits arising under the False Claims Act. In addition, she advises clients on privacy, security and breach notification issues arising under state and federal laws. Based in the firm's Washington office, she can be reached at kcleary@akingump.com. This article reflects the situation at the time it was written based on the rapidly changing nature of the COVID-19 pandemic.