Strictly Speaking: The Misalignment of the Policy Goal and Practical Impact of the Stark Law

Juliette Stancil, LLM, JD, CHC
I. **Introduction**

The Stark law was supposed to target actions with bad intentions.¹ This is purportedly the view of from former United States Representative Pete Stark nearly thirty years after the passing of what was initially titled the Ethics in Patient Referrals Act (EPRA).² However, over the last twenty-five years the Stark law has become the subject of scores of Medicare billing regulations, impacted likely hundreds of thousands of physician employment contracts and leases, and generated an incalculable number of headaches from physicians and hospital administrators.

This paper will address the Stark law’s shortcomings through research of its legislative history, the discussion of the earlier and significant legislative birthing process of its sister regulation, the Anti-kickback Statute,³ and the adverse effects the strict liability nature of the law has on health care transactions. Although the original legislative goal of the Stark law was to combat health care fraud and attempt to slow the rate of inflation for health care costs, it has failed to achieve its goal because as a strict liability law it does not act as a deterrent to fraudulent health care billing practices.

Over the years, the EPRA has transformed into the Physician Self-Referral law, commonly known as the Stark law.⁴ The Stark law is a strict liability law that intends to punish adverse behavior with no consideration of the wrongdoer’s intent.⁵ Despite the comment from Representative Stark, the law does not make a distinction between

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² 134 Cong. Rec E 2724; H.R. 939; the bill’s current title is the Physician Self-Referral law, but it is most commonly known as the Stark law, in recognition of its House Sponsor, California Representative Fortney “Pete” Stark.
³ 42 U.S.C. § 1320a-7b
⁴ 42 U.S.C. § 1395nn, *et seq*; throughout this paper, the Physician Self-Referral law will be referred to as both the Stark law and the Physician Self-Referral law interchangeably.
⁵ *See*, 42 U.S.C. § 1395nn
wrongdoers whose intentions were malicious and those who were attempting to comply with the cumbersome law in good faith, but failed on technical non-compliance. As a strict liability law, Stark also imposes an onerous burden on the health care industry to cross every ‘T’ and dot every ‘I’, because even a missing signature is enough to be subjected to monetary penalties in excess of $10,000 for a single violation. Because a strict liability law is meant to punish regardless of the intent, the Stark law is also ineffective at deterring the adverse physician conduct that fraud and abuse laws are intended to prevent.

In 2010, Medicaid and Medicare purchased over $925 Billion in health care goods and services, which accounted for 36 percent of total health care spending. Through Accountable Care Organizations (ACOs), the Affordable Care Act (ACA) is implementing a managed care model of health care delivery and it is a drastic change for many health care providers because health care payment has traditionally been fee-for-service. In an effort to be better prepared for the change, many providers are consolidating. Likewise, the industry is seeing more efforts on behalf of physicians and hospitals to enter into mutually beneficial financial employment relationships.

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6 See 42 U.S.C. § 1395nn (g)(3)-(5); civil monetary penalties may total $15,000 for submission of improper claims, $100,000 for arranging schemes intended to circumvent the law, and $10,000 for failing to report known violations.
7 Id. at 3
9 See generally, Jim Yanci et al., What Hospital Executives Should Be Considering In Hospital Mergers and Acquisitions, 1-12, 3 Dixon Hughes Goodman (2013), available at: http://www.dhglp.com/res_pubs/Hospital-Mergers-and-Acquisitions.pdf (last visited April 5, 2014) (indicating the number of hospital consolidations has increased steadily since 2010).
Stark law provides that if a physician (or a member of his or her immediate family member) has a financial relationship with an entity the physician may not make referrals to the entity for the furnishing of designated health services (DHS)\textsuperscript{11} and the entity may not submit a claim for those services to a federal health care program.\textsuperscript{12} A financial relationship is an ownership or investment interest in the entity, or a compensation arrangement between the physician and the entity.\textsuperscript{13} DHS includes radiology and other diagnostic imaging services as well as inpatient and outpatient services.\textsuperscript{14} For specialty physician practices which primarily deal in DHS, such as those of the orthopedic specialty, the Stark law’s prohibition poses a significant legal and administrative hurdle.\textsuperscript{15}

This paper will first detail the unique legislative history of Stark’s predecessor, the Anti-kickback Statute. In that discussion it will also reference the turning point early in the law’s forty year history which laid the foundation for the modern version of the law. Next, this paper will discuss the type of unethical physician conduct the Stark law was enacted to prevent and the health care fraud and abuse landscape present before its passing. Because Stark, as a strict liability law has direct impacts on the growing push for mergers and acquisitions within the health care industry, this paper will then discuss the effects of the laws on health care transactions. This paper will also look at two health care acquisitions involving Stark and Anti-kickback violations and how purchasers dealt with those issues differently. Finally, this paper will discuss why the Stark law is an unnecessary redundancy.

\textsuperscript{11} Some insight as to why the law was made applicable to DHS can be found at 134 Cong. Rec E 2724, where Representative Stark states that the most common services involved in the business organizations created to circumvent the Anti-kickback Statute included diagnostic and therapeutic radiology, clinical labs, durable medical equipment, home health care, and home infusion therapy.
\textsuperscript{12} 42 U.S.C. § 1395nn (a)(1)(A)-(B).
\textsuperscript{13} Id. at (a)(2)(A)-(B).
\textsuperscript{14} Id. at (h)(6).
of the Anti-kickback Statute in light of the liberal judicial interpretation of the terms “kickbacks” and “bribes” within the Anti-kickback Statute.

II. PHYSICIAN FINANCIAL RELATIONSHIPS THAT THREATEN PATIENT CARE LEAD TO THE ENACTMENT OF THE STARK LAW

The Stark law was passed as a way to safeguard patients of federal health care programs whose physicians may have been inappropriately incentivized to utilize services or admit patients unnecessarily. In fact, Representative Stark urged “everyone who is concerned about inflation in the health sector [to] support [the] legislation.” Unlike the Anti-kickback Statute, the Stark law is a civil, strict liability law. The Stark law was passed as a way to punish a specific type of activity, which the government became dissatisfied with the impact and application of the Anti-kickback Statute.

The Stark law, as a strict liability law, is misplaced in the health care industry because it does not adequately deter fraudulent conduct as it relates to health care billing practices, just as Congress came to that realization with the original Anti-kickback Statute, the same is true of the Stark law. Although health care compliance programs educate hospital and physician practice staff about fraud and abuse laws, the idea that certain violations are punishable simply by their action escapes even the most well educated practitioners. Stark’s sister regulation, the Anti-kickback Statute has managed to solidify itself as a fraud deterrent regulation because it is punishable by incarceration and its liberal interpretation would allow it to be applicable to typical Stark law scenarios.

17 135 Cong. Rec E 686 (March 8, 1989).
18 Compare 42 U.S.C. § 1320a-7(b) (the Anti-kickback Statute) with 42 U.S.C. § 1395nn (the Physician Self-Referral Law).
19 Fed. Sent. Guidelines § 8B2.1 (detailing the requirements of an effective compliance program as one which has an active education and training component).
In March 1989 there was also an article about physician owned labs in the Wall Street Journal.20 The article detailed a story of a radiologist from California who was threatened by his colleagues that he would be effectively ousted form the medical group because they would refuse to refer to him unless he started to share a portion of his profits with them.21 Although the physician did not act on the threat, later that year his colleagues opened up a separate radiology practice in the building next door where they each owned investment shares.22 That action effectively nullified the referrals the partners would make to the radiologist. According to the article, that type of activity was growing in popularity in response to physician practice consultants.23

These consultants would travel to physicians informing them of the benefits of ownership and investment relationship interests in ancillary service centers, such as diagnostic imaging and clinical lab services.24 At times, investment returns of 50% in a year would be promised on initial $10,000 investments.25 This practice continues today in the area of in-office ancillary services.26 It has led to a move in Congress to repeal the Stark law exception allowing physicians to bill for ancillary services provided in the office which are incident to diagnosis or treatment.27

III. THE IMPACT OF A STRICT LIABILITY LAW ON HEALTH CARE MERGERS AND ACQUISITIONS TRANSACTIONS

20 135 Cong. Rec. E610.
21 Id. at E610.
22 Id. at E610.
23 Id. at E610.
24 Id. at E610.
25 Id. at E610.
Together, the Anti-kickback Statute, Stark law and the False Claims Act\(^\text{28}\) make up a triton of government health care industry regulation. In 2012 alone health care outlays totaled over \$2.8\ trillion,\(^\text{29}\) so the mechanisms of combatting fraud must be scoped to deter considerable instances of fraud. Over the years, the Anti-kickback Statute has undergone numerous revisions which have transformed the misdemeanor strict liability law into the intent based felonious criminal law it is today. Moreover, despite the legislative indications that the Stark law would be an intent based law used to plug the hole left by the Anti-kickback Statute, it was enacted as a strict liability law. This misinterpretation of the Stark law’s original goals into its codification has led to the misalignment of its policy goals and enforcement within the industry.

1. ACA Changes to the Payment Model Affect Traditional Health Care Delivery Models

Because of the ACO shared savings payment model, there are advantages to being a larger provider. First, to even qualify as an ACO, the network must be able to support at least 5,000 Medicare beneficiaries.\(^\text{30}\) The opportunity to share in the savings also gives providers impetus to create a complete continuum of care throughout the organization. For the organization, this means the ability to retain more of the base rate funds because there is greater control over the services provided.

With an increase in specialty providers who are employed directly with the hospital, there is also a less pressure to ensure that its relationship with the referring physician is

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\(^{28}\) 31 U.S.C. § 3729; although the False Claims Act has not been mentioned in this paper, its significance on health care fraud and abuse is not unnoticed.


compliant. Both Stark law and the Anti-kickback Statute allow for a bona fide employment relationship between the hospital and referring physicians. Because Stark exceptions are mandatory, if one of the exception’s requirements is not met it could result in a technical violation. Punishment for technical violations is no less severe than those of willful conduct intended to violate the law. These violations also threaten the integrity of a program because egregious violations could lead to exclusion from federal health care programs. An effective contract management system monitored by the organization’s compliance program is a necessity to prevent these violations.

Instances of fraud and abuse also affect the growing number of acquisition deals the health care industry has seen in the last few years. Because of the changes in the reimbursement models, there is a move on both the behalf of hospitals and physicians to buy and sell, respectively. Physicians are motivated to sell private practices and become employed by hospitals because of the added financial security. Physicians will see a significant cut in their reimbursement rates under the Medicare program. Becoming a

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35 Helen Adamopoulos, Q3 Healthcare Merger and Acquisition Activity Up 20%, Becker’s Hospital Review, available at: http://www.beckershospitalreview.com/hospital-transactions-and-valuation/q3-healthcare-merger-and-acquisition-activity-up-20.html (last visited April 2, 2014) (numbers put the merger and acquisition process in health care at an increase of 20% in the third quarter of 2013 as compared to that same time one year prior).
salaried employee of a hospital is a safer financial decision because the income is guaranteed and not contingent on patient payor mix.39

The move from private practice also has its drawbacks. Specialty physicians in private practice will no longer have the in-office ancillary service stream of income available.40 In-office ancillary services refers to Stark’s exception which allows a physician to both refer and bill to an entity with which he or she has a financial interest when that service is incident to treatment or diagnosis of the patient’s presenting condition.41 This exception allows Medicare beneficiaries to have quick access to services. Rather than a patient having to schedule a subsequent appointment with a separate unaffiliated facility to have an MRI conducted, and then have to reschedule an appointment with their specialty physician, this exception allows the specialty physician to conduct the MRI in office and speed up the delivery of care to the patient. Likewise, the motivation for the hospitals is the desire to expand service lines and maintain a care structure that is keyed to preventative treatment.

A. DETROIT MEDICAL CENTER AND CONDELL MEDICAL CENTER ILLUSTRATE THE INDUSTRY’S REACTION TO THE IMPENDING CHANGES IN PAYMENT MODEL AND THE PROBLEMS FRAUD AND ABUSE LAWS HAVE ON COMPLETING THE TRANSACTION

The ACA prescribed incentives for Medicare providers to establish ACOs.42 These organizations are meant to better manage patient care because they will include an intricate mix of primary care and specialty services with a large patient base. Ideally, in this model of health care delivery, those providers with more resources will be better able to handle patient loads and spread the risk of high utilization patients.

39 Alexander, supra.
40 Kutscher, supra.
41 42 U.S.C. § 1395nn (b)(2).
42 See, discussion, supra Section II.
For small hospitals, medical groups and some single-specialty practices, this change in reimbursement system could mean trouble. These providers must become part of a larger system with a diverse service line to remain profitable and competitive in the future health care market. As a result, large provider networks are acquiring smaller providers across the country in an effort to get ahead of the change. This move benefits the larger providers by increasing their mass to handle a larger patient base, and it places the smaller providers in a network where care can occur on a continuum.

During the acquisition process, purchasers are ultimately interested in whether the possible revenue streams will be worth the liabilities. To determine that risk, purchasers hire transaction counsel to conduct due diligence. Due diligence is the process by which providers undergo intricate review the potential purchase. Specific to the health care industry, the items of importance include of the review of patient medical records, conducting audits of these medical records and assessing the physician employment contracts and lease arrangements. These items have direct implications to the value of the entity to be acquired. For this reason, purchasing providers are likely to use caution because any potential fraud and abuse issues could result in a walking away from the deal.

Sometimes the due diligence process does not reveal major liability issues. Other times, however, significant fraud and abuse issues come to light which could pose lethal to the transaction. How purchasers proceed once the issue is exposed could make all the difference even after the transaction has been closed. Vanguard and Tenet, then two of the largest health care companies in the United States, dealt with those similar issues.

1. Detroit Medical Center
Detroit Medical Center (DMC), based in Detroit, Michigan, was acquired by Vanguard Health System in early 2011. Through the due diligence efforts during the course of the acquisition, Stark and Anti-kickback Statute violations surfaced dating back almost ten years. According to the Settlement Agreement entered into by Detroit and OIG, several of the violations involved physician leases that had expired and not been renewed. Detroit voluntarily disclosed the issues to OIG resulting in a Settlement Agreement.

In the end, as part of the acquisition, Vanguard paid $30 million to OIG and a total of $368.1 million to complete the deal. Notably, the acquisition was contingent on settling the fraud and abuse issues and Vanguard was made a party to the agreement. This means that Vanguard retained any liability that was still present in the DMC system as a result of fraud and abuse issues that were present prior to the execution of the acquisition and not already disclosed to OIG. Vanguard is protected by the terms of this settlement agreement.

The compliance issues at DMC were numerous. Some of the arrangements with referring physicians were not reduced to writing, as required by Stark and Anti-kickback Statute regulations, and those that were memorialized still failed to incorporate some of the regulatory safe harbor and exception requirements. Lease arrangements with physicians also did not meet the requirements of Stark and the Anti-kickback Statute.

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44 Id. at 5.
45 Id. at 7.
46 Id. at 7.
47 Id. at 7.
48 Id. at 7.
49 Id. at 7.
50 Id. at 7.
Some of those leases contained rental rates that were below fair market value and may have not been commercially reasonable either.\textsuperscript{51}

Between 2004 and 2010, DMC also provided “business courtesies” to its referring medical physicians that included tickets to sporting events, education events, charitable dinner events, and other meal and entertainment courtesies.\textsuperscript{52} DMC also provided signage and advertising for some physicians on terms that were not commercially reasonable or for prices that represented fair market value. January 2007 to September 2010, it submitted claims to Medicare and Medicaid for codes that were not supported by evidence from the medical files.\textsuperscript{53}

In all, over one hundred leases, professional service agreements and physician arrangements failed to satisfy fraud and abuse regulations.\textsuperscript{54} Likely in light of its then pending acquisition by Vanguard, the Settlement Agreement was not accompanied by a Corporate Integrity Agreement (CIA). In the time since then, Vanguard has been acquired by Tenet Health.\textsuperscript{55}

2. CONDELL MEDICAL CENTER

Similarly, during the course of Advocate’s courting for acquisition of Condell Medical Center (Condell) in 2008 uncovered several compliance issues relating to its relationships with its referring physicians.\textsuperscript{56} Among its issues were physician leases that were not memorialized, or failed to include the formalities required by Stark law and the Anti-
kickback Statute. It allowed rent abatement for rental rates that were already below fair market value and in some cases deferred collection of rental payments from referring physicians. On its cost reports, Condell incorrectly certified that the services were not provided either directly or indirectly was a kickback or otherwise illegal. Condell loaned monies to its physicians secured by promissory notes that failed to meet Stark law and Anti-kickback Statute regulation requirements. Moreover, it allowed physicians to “work off” those agreements to the amounts due and owing under the loans at hourly rates that were greater than fair market value through activities that did not benefit the community.

Without conducting a community needs assessment, Condell entered into arrangements with physicians who were already in its service area and those agreements benefited individual physicians or physician groups, rather than the community. Physician recruiters were paid bonuses and many support agreements contained restrictive covenants that did not allow the physician from obtaining admitting privileges at any other hospital.

As a result of these violations, Condell was required to pay the State of Illinois and the United States $36 million to settle those violations. At the time, Condell was the largest medical provider in Lake County, one of Chicago’s collar counties. Unlike DMC’s

57 Id. at 4.
58 Id. at 4.
59 Id. at 4.
60 Id. at 4.
61 Id. at 4.
62 Id. at 6.
63 Id. at 7.
64 Id. at 7.
65 Id. at 7.
agreement where Vanguard joined as a party to the settlement—effectively limiting its liability through the acquisition—Advocate was not made a party in Condell’s settlement.66

The move to more consolidated health systems implies that there will be more similar arrangements. Where does this leave the health care purchasers who want to remain competitive in the changing market but are fearful of the potential liability an acquisition may impose because of its strict liability? This harsh standard holds the acquiring organization to a high standard for the non-compliance issues of its predecessor and could exist as an unknown liability risk for an organization up to the statutory period.

Not only does this adverse conduct result in multi-million dollar fees for the organization, but if the compliance issues are systemic within the organization it devalues the organization and could prevent it from being enticing to a purchaser. Advocate and Vanguard approached two similar situations in different ways. Vanguard’s decision to join as a party to the deal made it a better business decision because even after acquiring the organization, the action acts as a shield for future prosecution as a result of the conduct disclosed in the Settlement Agreement. As a business decision, it helps give the organization a piece of mind about the newly acquired organization too.

Fraud and abuse regulations should be aimed at preventing adverse conduct, with a strict liability law there is no deterrent to the conduct because there is no requirement that the wrongdoer have knowledge of his or her bad acts. To that end, the Anti-kickback Statute is more effective at getting at the adverse conduct of shady physicians and hospital administrators.

66 Id. at 7-9.
The strict liability aspect of the Stark law is onerous on health care providers because it punishes the act, which could have been unintentional. Likewise, the law is redundant because the Anti-kickback Statute already sufficiently gets at the issue of health care fraud and abuse with referring physicians. When health care providers respond to the changes in Medicare and Medicaid reimbursements, the managed care models of ACOs and the private insurance industry’s response to increased risk as a result of the ACA’s provisions regarding guaranteed issue insurance plans, there are concerns for acquiring hospitals and small health systems.

IV. CONCLUSION

Although the Anti-kickback Statute is a long-living beast of government regulation in the health care industry, it has not always been the overbroad, far-reaching legislation that it is today. The amendments that it has undergone over its forty-two year history have all been incredibly drastic. Even when considered all together, these legislative amendments have made the law more favored over its strict liability sister regulation, the Stark law. Stark is a harsher law and its enactment was a misguided attempt at combatting a type of fraud that the Anti-kickback Statute could have easily reached through the developing judicial interpretation its legislative amendments have necessitated. For these reasons, there are several conclusions that can be reasonably drawn from the research conducted and addressed throughout this paper.

First, the Stark law is misplaced in the health care industry as a strict liability law intended to combat health care billing fraud. Strict liability laws are improper for health care billing activities because billing is not an action where catastrophic injury may result in the absence of the harsh standard. Other sectors are well deserving of such a standard;
nuclear energy and aviation have the capability to result in enormous loss of life if an error were to occur. However, the Stark law is unwarranted because it unduly burdens the health care industry and is redundant when compared to the Anti-kickback Statute.

Second, the birthing process of the Anti-kickback Statute from a strict liability misdemeanor criminal law to the felonious intent based criminal law it is today is yet another reason that strict liability laws do not adequately accomplish their goal of combatting fraud. The decision to change the Anti-kickback Statute to the intent-based law that it is today is one likely made in reaction to the failed prosecution attempts in the late 1970s, where defendants were prosecuted under the 1972 version of the statute. Because the terms “kickbacks” and “bribes” are construed by modern courts to encompass any form of remuneration where even one purpose of which is to induce referrals, the Anti-kickback Statute is able to apply to many situations where the Stark law is also implicated.

For that reason, the Anti-kickback Statute is a better regulatory vehicle to combat health care fraud than the Stark law. Furthermore, if the Anti-kickback Statute’s policy goal has always been to combat fraud and the legislative drafting of it lent itself to become a strict liability law, which was later amended to increase penalty and require a level of intent, then perhaps the Stark law was drafted as a strict liability law because it is civil, and no showing of intent should be required for punishment which can only result in monetary fines and penalties. In that same way, however, does that law truly deter the conduct it seeks to punish?

Although greed is a primary motivator for fraud and abuse violations, knowing that one’s liberty could be restricted because of one’s actions is often enough encouragement to refrain from such activity. It is the same theory that supports the idea that drug laws
should be tougher, because when presented with the opportunity to engage in illegal drug
related activity, the person with knowledge of the adverse punishment is less likely to
commit the act. Likewise, because physicians are generally held to higher ethical
standards, the idea that accepting or receiving any form of remuneration should
realistically be enough to deter the conduct, if not because it is unethical, then because the
punishment will imprison the person, and not just the bank account.

regulatory sector, and as unease among practicing physicians grow because of the
imminent changes in reimbursement, the government must deal with the fraud and abuse
concerns. No doubt, fraud and abuse contributes to the raising costs of health care in
America, especially considering how many Medicare beneficiaries are high utilizers of the
industry's services. Yet, combatting fraud through a strict liability law is ineffective when
looked at in conjunction with the already existing and sufficient law, the Anti-kickback
Statute. The Anti-kickback Statute provides more deterrence to health care fraud and
abuse than the strict liability law. Lastly, the truly willful conduct done in violation of the
law can be deterred by giving more teeth to the enforcement of ethical obligations of health
care professionals. These alternatives greatly reduce the inappropriate incentives for
referrals that underlie the Stark law's policy goals and they therefore better align patient
goals and physician incentives to create a more effective and innovative health care
industry.