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GIVING DISCLOSURE ITS DUE: A PROPOSAL FOR REFORMING THE STARK LAW

Nicholas J. Diamond

ABSTRACT

While the Stark Law has been heavily criticized, calls for repeal have not been matched equally by substantive proposals for reform. I begin by revisiting criticisms of the Stark Law, so as to highlight its flawed beginnings. I then consider whether, in our era of health reform, the design of the Stark Law accords with emerging themes in the ever-changing health care regulatory environment. Concluding that it does not, I recast the oft-neglected proposal for replacing the Stark Law with a system of disclosure. I sketch how such a system might look, utilizing the recently enacted Physician Payment Sunshine Act as a model.

I. A DIFFERENT KIND OF DISCLOSURE ...........................................2
II. A BRIEF HISTORY ...................................................................5
III. MISGUIDED BEGINNINGS ......................................................7
IV. AN ANACHRONISM ................................................................10
V. A PROPOSAL FOR REFORM ..................................................13
VI. CONCLUSION ........................................................................19

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We must leave this terrifying place tomorrow and go searching for sunshine.

F. Scott Fitzgerald

I. A DIFFERENT KIND OF DISCLOSURE

Most discussions of the Stark Law begin with an acknowledgment of its immense complexity. Its labyrinthine provisions, however, belie its straightforward object, namely, financial conflicts of interest. As originally conceived, the Stark Law had a narrow focus with regard to financial conflicts of interest within the context of physician self-referrals. Early design of the Stark Law recognized that conflicts of interest were more likely to occur where a physician self-refers a patient for clinical laboratory services to an entity in which she has a financial interest. However, in the over twenty-one years since the first iteration of the Stark Law, "Stark I," went into effect, this basic theme has undergone much change. For many, the result is an untenable regulatory scheme that has, inter alia, had a “chilling . . . effect on the practice of medicine,” and an overall detrimental impact on the health care industry.

In this article, I do not intend to champion the Stark Law against such critics. Not surprisingly, the Stark Law has few proponents. Even the

1 F. SCOTT Fitzgerald, This Side of Paradise 4 (1920).

There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.

3 See 42 U.S.C. § 1395nn(a) (2013) (setting forth the basic prohibition underlying the Stark Law).
4 See Patrick A. Sutton, The Stark Law in Retrospect, 20 ANNALS HEALTH L. 15, 15 (2011) (characterizing Stark I as having “humble beginnings as a relatively narrow proscription . . . .”); see also §§ 1395nn(a)(2)(A)-(B) (defining a financial relationship of a physician, or an immediate family member of such physician, with a referred entity).
Congressman who originally conceived and subsequently shepherded its passage later expressed doubts as to its merits.\textsuperscript{7} I will, instead, argue that the Stark Law not only arose under misguided intentions, but faltered further still in its promulgation. This historical analysis finds commonality with other criticisms of the Stark Law. While such commentary is crucial to an appreciation of its flawed roots, it does not sufficiently explain why, in our era of substantial change under health reform, the Stark Law continues to make little sense.\textsuperscript{8} To this end, in the first half of this article I will argue that the Stark Law is an anachronism in the current health care regulatory environment. Such a position motivates the frequent argument for repeal.

Even if this argument is successful, a related issue remains as to whether there should be some law that stands in its place. In view of the hearty criticisms levied against the Stark Law, it stands to reason that most critics would prefer that a void remain where the Stark Law once stood. I contend, however, that this sentiment is chiefly the product of preconceived notions of the nature of a regulatory scheme that might stand in its place, namely, one that is equally complex and punitive. Before considering my argument as to a wholly different way for the law to approach physician self-referrals, two assumptions should be surfaced.

First, my arguments require acceptance that financial conflicts of interests are fundamentally problematic for the health care profession. This is not a controversial assumption. Prominent codes of conduct in the medical profession, for instance, unambiguously articulate the problematic nature of physician financial conflicts of interest.\textsuperscript{9} Second and perhaps more controversially, my arguments require recognition that physician financial conflicts of interest are proper objects of regulation. For those who subscribe to self-regulation of the medical profession, this claim will prove unpalatable. While I find such a position untenable, not least because it discounts history,\textsuperscript{10} I cannot hope to meet such a steadfast opinion in this context.

\textsuperscript{7} See Sutton, supra note 4, at 17-18 (describing Rep. Stark’s later lament toward enactment of the law that bears his name).

\textsuperscript{8} The term “health reform” is used throughout as a reference to the body of reforms implemented under the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.) [hereinafter “ACA”].

\textsuperscript{9} See, e.g., American Medical Association, Opinion E-8.0321 – Physicians’ Self-Referral, AMA CODE OF MED. ETHICS (2009), available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion80321.page (“[Physician self-referral] arrangements can also be ethically challenging when they create opportunities for self-referral in which patients’ medical interests can be in tension with physicians’ financial interests. Such arrangements can undermine a robust commitment to professionalism in medicine as well as trust in the profession.”).

\textsuperscript{10} See, e.g., Sylvia R. Cruess & Richard L. Cruess, The Medical Profession and Self-Regulation: A Current
If these assumptions are well taken, the question becomes, how would a law that speaks to physician self-referrals look, if it is not to resemble the Stark Law? Substantial treatment of this inquiry is confusingly lacking in the literature on the Stark Law. This dearth should not be construed as evincing disagreement with the assumptions articulated above. The literature does contain a few proposals for reform,\textsuperscript{11} which suggests that there is at least some receptiveness to the assumption that physician financial conflicts of interest are proper objects of regulation. In comparison to ample criticisms of the Stark Law, however, a relative paucity of attention has been directed toward further developing these proposals for reform as an appropriate companion to such criticisms.

To this end, I will consider one proposal for reform that has not received its due. Various commentators have dismissed the merits of replacing the Stark Law with a system of disclosure. Under existing proposals, such a system would require physicians to directly disclose to their patients any financial interests in entities to which they make referrals.\textsuperscript{12} This option exhibits various flaws, which I will delineate below. It would be hasty, however, to dismiss the value of a system of disclosure, though cast in different terms, as an alternative to the Stark Law. I will argue that the recently enacted Physician Payment Sunshine Act ("Sunshine Act"),\textsuperscript{13} which addresses potential conflicts of interest in the health care profession under different yet fundamentally related conditions, can serve as a model for developing a system of disclosure as an appropriate alternative to the Stark Law.

\textit{Challenge, 7 VIRTUAL MENTOR 1, 1 (2005), at 1, stating:}

Standards were considered to be weak, variable, and inconsistently applied, and physicians were further accused of using collegiality as a means of shielding poorly performing peers. Medicine was further criticized for its lack of openness and transparency in regulatory procedures and for the absence of public involvement in them. In short, the system appeared to lack accountability, and it was suggested that an informed public should participate in medicine's regulation. Many of these criticisms proved to be accurate and had an impact on both public policy and on the level of trust that the profession enjoyed.


11 See, Jo-Ellyn Sakowitz Klein, Note, \textit{The Stark Law: Conquering Physician Conflicts of Interest?} 87 GEO. L.J. 499, 528-29 (1998) (arguing for a broad solution that would first study the relationship between physician self-referrals and overutilization of services, and then evaluate the whole of health care fraud and abuse laws to assess their shortcomings); see generally E. Haavi Morreim, \textit{Blessed Be the Tie That Binds? Antitrust Perils of Physician Investment and Self-Referral}, 14 J. LEGAL MED. 359 (1993) (arguing for physician self-referrals to be regulated under an array of existing laws, such as those directed toward informed consent, fiduciary duties, and antitrust matters).

12 See, e.g., Klein, \textit{supra} note 11, at 527-28.

II. A BRIEF HISTORY

During the 1980s, the health care industry underwent significant change, ushered in by a newfound focus on cost containment.\(^{14}\) Pressures to curb expenditures in the provision of care surfaced following implementation of Medicare’s Prospective Payment System (PPS), which set reimbursement according to a predetermined amount that reflected the average treatment cost in a specific diagnostic-related group,\(^{15}\) rather than according to the actual cost of treatment.\(^{16}\) This radical shift in reimbursement methodology fostered competition amongst providers, who sought new ways to curb expenditures, such as shifting the provision of some health care services to less expensive nonhospital settings.\(^{17}\) The emergence of new medical technologies also contributed to increased provider competition, as new advancements offered the promise of streamlining previously expensive health care services.\(^{18}\)

The proliferation of care in nonhospital settings and the advent of new medical technologies in toto resulted in an increased level of financial involvement by physicians in the various mechanisms associated with the provision of care.\(^{19}\) The reasons for this increase were fairly uncomplicated. Because physicians have an intimate understanding of which health care services are most needed in their communities, they were able to draw from this firsthand knowledge to identify profitable investments.\(^{20}\) Moreover, confronted with the pressing need to curb expenditures, physicians were motivated to develop unorthodox strategies to mitigate losses resulting from increased marketplace competition.\(^{21}\)

Increased physician investment in health care services brought about a more pronounced culture of so-called “self-referrals,” where a physician


\(^{15}\) Social Security Amendments of 1983, Pub L. No. 98-21, § 601, 97 Stat. 65, 149 (codified as amended at 42 U.S.C. § 1395 (1983)); see Tironi, supra note 6, at 236 (explaining the importance of the shift affected by implementation of the PPS); see also McDowell, supra, at 64 (describing how the PPS and other cost containment measures brought about significant competition in the health care marketplace).

\(^{16}\) See Christian D. Humphreys, Comment, Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient? 30 SAN DIEGO L. REV. 161, 162 (1993) (“Prior to the 1983 Amendments [to Medicare reimbursement], hospitals were reimbursed by the federal government for the actual dollar amount incurred in the treatment of a Medicare patient.”)

\(^{17}\) McDowell, supra note 14, at 64.

\(^{18}\) Id.; see William R. Kucera, Jr., Note, Hanlester Network v. Shalala: A Model Approach to the Medicare and Medicaid Kickback Problem, 91 NW. U. L. REV. 413, 424 (1996); see also Tironi, supra note 8, at 236.

\(^{19}\) McDowell, supra note 16, at 64.


\(^{21}\) McDowell, supra note 14, at 64.
refers a patient to a secondary entity in which she holds a financial interest. These referrals encompassed a swath of circumstances, including services performed in separate locations and various in-office technologies. Interestingly, physician self-referrals were "fairly common" in the 1970s. With the shift toward nonhospital care settings in the 1980s, however, the increasingly close relationship between care and investment interests brought about a heightened potential for abuse. Put plainly, "[p]hysicians who invested in health services were accused of controlling both supply and demand."  

Some characterize self-referrals as "a natural outgrowth of the competitive health care industry and the physician's unique position in the industry," whereas others argue that self-referrals exhibit a fundamental conflict of interest. Both positions are partially correct. The mere fact that a physician stands to personally profit from the provision of care is, ceteris paribus, unobjectionable. That physicians might avail themselves of the prospect of increased profitability because of opportunities presented by new trends in the health care field is equally unremarkable. In the financial industry, for instance, the law does not broadly curb professionals' ability to invest according to their investment acumen or market experience. It is only when, for example, personal profits result from trading on "insider information" that the law asserts itself to eradicate unfairness in the marketplace.  

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22 Morreim, supra note 11, at 362.  
23 Id.  
24 Tironi, supra note 6, at 236; see Morreim, supra note 11, at 361-62, stating: Historically, such physician referrals have not been controversial. Hospital choice was usually fairly simple. Even if there were more than one hospital in town, the physician often only had staff privileges at one of them, and thus the choice of hospital was obvious. Similarly, when a subspecialist medical consultant was needed, the physician would select a trusted colleague. So long as physicians were mainly in solo or in small-group, single-specialty practices, a referral to a consultant of another specialty carried no possibility of financial gain for the referring physician. [Citation omitted] Only rather recently have groups of physicians begun to join together in large, multispecialty group practices and to share in the revenues of keeping consultant referrals within the group.  
25 Kucera, supra note 18, at 424-25.  
26 Tironi, supra note 6, at 237.  
27 McDowell, supra note 14, at 64-65.  
28 See, e.g., Jennifer A. Hanson, Note, The Academic Medical Center Exception to the Stark Law: Compliance By Teaching Hospitals, 61 ALA. L. REV. 373, 374-75 (2010) (describing Rep. Stark's objections to physician self-referral arrangements); see also Wales, supra note 22, at 13-14 (summarizing common arguments against the physician self-referrals based on inherent conflicts of interest).  
29 See 15 U.S.C. § 78j (2013) making it: unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange ... [t]o use or employ, in connection with the purchase or sale of any security ... any manipulative or deceptive device or contrivance in contravention of such rules and
Yet, as opponents of self-referrals would contend, the degree of closeness between the provision of care and investment interests seems ethically problematic. Broadly, some have criticized how health care became intertwined with commercial concerns beginning in the 1980s which, some argue, interfered with the ethical and social duties required of physicians in caring for their patients. More specifically, the American Medical Association’s Code of Medical Ethics, for instance, characterizes self-referrals as “ethically challenging” and asserts that they should be permitted only under specific conditions including, *inter alia*, ensuring that financial benefit is not dependent on the volume of referrals and providing for mechanisms to review referral practices. That a lengthy list of sometimes onerous conditions should first be satisfied does not augur well for the ethical permissibility of physician self-referrals.

III. MISGUIDED BEGINNINGS

Despite the absence of a widely accepted ethical objection to physician self-referrals, economic objections gained strength in the late 1980s. A 1989 report published by the Office of Inspector General (OIG) of the Department of Health & Human Services (HHS) proved to be a watershed moment in the turn toward comprehensive regulation of physician self-referrals. The report findings were both expected and highly controversial. Not surprisingly, the report found that physicians had investment interests in a gamut of health care businesses, from clinical and physiological laboratories, to nursing homes and ambulatory surgical centers.

More controversially, the report found that eight percent of physicians who billed Medicare had compensation arrangements, ranging from space rental agreements to consulting agreements, with entities to which they referred patients. Nationally, the report found that many

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regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

*see also* 17 C.F.R. § 240.10b-5 (2013) (promulgating requirements pursuant to section 10(b) of the Securities Exchange Act of 1934).

30 See, e.g., Arnold S. Relman, 325 NEW ENG. J. OF MED. 854, 858 (1991) (“In my view, that means we should not only be competent and compassionate practitioners but also avoid ties with the health care market, in order to guide our patients through it in the most medically responsible and cost-effective way possible.”).

31 American Medical Association, *supra* note 11, at §§ 3(a)-(b).


33 Id.

34 See OFFICE OF INSPECTOR GENERAL, *supra* note 34, at 11.
referring physicians held whole or partial ownership interests in independent clinical laboratories (ICLs) (25 percent), independent physiological laboratories (IPLs) (27 percent), and durable medical equipment suppliers (DMEs) (8 percent). More controversial still, it found that patients of referring physicians who own or invest in ICLs received forty-five percent more clinical laboratory services, irrespective of place of service, as well as thirty-four percent more direct services from ICLs, as compared with all Medicare patients. Similarly, patients of physicians who invest in IPLs utilized thirteen percent more IPL services compared with all Medicare patients. Cautioning that the "actual effect is probably higher," the report concluded that this level of utilization cost Medicare $28 million in 1987 alone.

As proponents of self-referrals have argued, this report admits of a few flaws. Chiefly, the report does not make the crucial distinction between overutilization and increased utilization of services. While it demonstrates that physicians with investment interests in entities to which they refer patients tend to utilize a greater amount of services, it does not show that these services were more than would be medically necessary under the circumstances. More importantly, the report fails to connect an increased volume in provided services with a lower quality of care or poor health outcomes. Finally, the report does not conduct a comparative analysis to determine whether physicians without investment interests in the entities to which they refer patients might be underutilizing services.

Despite these weaknesses, the report served as a tipping point for Congressional action. In particular, Representative Fortney Stark of California believed that robust legislative action would prevent physicians from defrauding federal health care programs by engaging in what he deemed "referral schemes." More specifically, Representative Stark believed that the Anti-Kickback Statute (AKS), which requires a showing of intent, was too weak to adequately regulate self-referrals. To countermand this weakness, he advocated for the creation of a bright line test to determine whether, irrespective of intent, an impermissible conflict

35 Id.
36 Id.
37 Id.
38 Id.
39 Tironi, supra note 6, at 237.
40 Humphreys, supra note 16, at 172.
41 Kucera, supra note 18, at 426.
42 Klein, supra note 11, at 508.
43 Wagner, supra note 6, at 243-44.
44 42 U.S.C. § 1320a-7b(b) (2013); Wagner, supra note 6, at 243-44.
of interest existed in self-referral arrangements. Such a test, Representative Stark opined, would combat the negative ramifications of physician self-referrals, namely, compromising patient care, billing federal health care programs for unnecessary services, and engendering unfair competition in the marketplace through physician kickbacks from suppliers.

In 1993, the second iteration of the Stark Law, "Stark II," arose in the wake of influential studies on the ramifications of physician self-referrals, some of which persuasively argued that physician conflicts of interest were far more pervasive than originally thought. Though it had similar motives to its predecessor, Stark II expanded the comparably humble scope of Stark I to include a gamut of health care services and financial arrangements. This expanded scope contributed to a torturous implementation timeline. Even though Stark II was enacted in 1993, HHS did not promulgate final regulations for Stark I until 1995. Stark II regulations would not be published until 1998. Similar delays plagued the release of various phases of Stark II regulations during the period from 2001 to 2008.

Critics cite these chronological delays and inconsistencies as problematic for legal counsel, who must contend with conflicting and generally uncertain provisions, which require constant restructuring of agreements to ensure continued compliance. The complexity of the regulations themselves, as I have noted above, further exacerbates this difficulty. For instance, despite the numerous exceptions carved out in subsequent revisions, the changing dynamics of the health care industry

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45 Hanson, supra note 28, at 374.
46 Wagner, supra note 6, at 244.
47 Sutton, supra note 4, at 22.
48 See Klein, supra note 11, at 511 ("Although the Stark laws have changed considerably over time, the rationale invoked to justify them remained relatively constant.").
53 Wagner, supra note 6, at 245.
often result in new financial relationships that do not fall cleanly under delineated Stark Law exceptions. This has the effect of both cultivating confusion and thwarting earnest industry efforts toward maintaining compliance. Consequently, providers must devote significant time and resources to retaining and working with legal counsel to forestall inadvertent violations. As one critic concludes, “Stark soundly fails to fulfill its mission of providing easily understood bright line tests.”

Critics also rightly aver that penalties for violations are particularly severe, not least because the Stark Law is most frequently enforced through the False Claims Act (FCA). As one critic states, by prosecuting potential violations of the Stark Law under the FCA, the federal government unfairly takes advantage of qui tam mechanisms, thereby creating a “bounty system.” Significant expansion of the FCA exacerbates this worry because a claim may be brought not only for presenting a false claim to the federal government, but also for submitting a false claim to any federal funds recipient.

Equally troubling for providers, the Stark Law is a strict liability statute and, thus, the government need not demonstrate a knowing and willful violation as is required under the AKS. For entities struggling to navigate the complexities of the Stark Law, strict liability only serves to further aggravate difficulties by punishing inadvertent violations. Finally, with the availability of the FCA, the AKS, and various antitrust protections, it is unclear what equitable or practical purpose the added liability of the Stark Law serves.

IV. AN ANACHRONISM

While these flaws do much to weaken the merits of the Stark Law, their implications cut much deeper when viewed against the backdrop of health reform under the Affordable Care Act (ACA). The Stark Law arose as a response to changes in the climate of the health care industry

54 Sutton, supra note 4, at 35-36.
55 Id.
56 Klein, supra note 11, at 517.
57 Wagner, supra note 6, at 245-46.
58 Tironi, supra note 6, at 239; see 31 U.S.C. §§ 3729-3733 (2013).
59 Klein, supra note 11, at 525.
60 See § 3729(b)(2)(a)(ii) (defining “claim” to include those made to a “contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest . . . .”).
61 Compare 42 U.S.C. § 1320a-7b(b)(2) (requiring knowing and willful conduct) with 72 Fed. Reg. 51,026 (explaining that “[t]he physician self-referral law is a strict liability statute”).
62 Klein, supra note 11, at 524.
following implementation of the PPS. That climate, compared with the current Medicare reimbursement landscape under the ACA, looks markedly different. The current landscape under the ACA is marked not by a parochial focus only on cost containment, as was the case under the PPS, but sweeps broadly to incorporate equal concern for both access to and quality of care. Health reform operates under the assumption that anything less than such a comprehensive approach would be insufficient to “bend the cost curve.” This assumption can be witnessed, for instance, in the ACA’s so-called “three-legged stool,” which takes a multi-pronged approach to reforming private health insurance markets.

More specifically, on the public health insurance side, Medicare reimbursement today looks far beyond the ambit of the PPS to incorporate broader payment calculi that speak to the tripartite aims of cost, quality, and access. This focus is emblematic of the broader shift away from the fee-for-service system toward a system that promotes and rewards high-value care, as opposed to an increased volume of services, which has long been thought to create perverse incentives in the system. The Value-Based Payment Modifier which, by 2015, will adjust payments under the Medicare Physician Fee Schedule to a physician or groups of physicians based on the quality of care provided relative to cost during a performance period, represents just one instance of a reimbursement system that is shifting toward promoting value, conceived as an optimal balance of cost and quality.

63 The ACA contains innumerable provisions that speak to the quality of and access to care. See, e.g., Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 Fed. Reg. 12,834 (Feb. 25, 2013) (to be codified at 45 C.F.R. pts 147, 155, and 156) (requiring that all health plans offered in the individual and small group markets cover at minimum a specified list of essential health benefits); see also 42 U.S.C.A. § 18091 (2013) (requiring individuals, subject to certain exceptions, to maintain “minimum essential” health insurance coverage or pay a penalty).

64 See, e.g., Ezekiel Emanuel, et al., A Systematic Approach to Containing Health Care Spending, 367 NEW ENG. J. OF MED. 949, 949 (2012) (describing the notion of “bending the cost curve” as a comprehensive effort to reduce the rate of growth of health care spending in the United States relative to gross domestic product).

65 See, e.g., Jonathan Gruber, Health Care Reform Is a “Three-Legged Stool”: The Costs of Partially Repealing the Affordable Care Act, CENTER FOR AMERICAN PROGRESS 1, 2 (2010), http://www.americanprogress.org/issues/2010/08/pdf/repealing_reform.pdf (“At the [ACA]’s core is a “three-legged stool” approach to reforming these markets: new rules that prevent insurers from denying coverage or raising premiums based on preexisting conditions, requirements that everyone buy insurance, and subsidies to make that insurance affordable.”).


Various other programs with similar goals are already in place. For instance, the Hospital Value-Based Purchasing Program, which took effect in fiscal year 2013, evaluates hospitals under performance metrics designed in the aggregate to promote high-value care and then provides incentive payments, funded by a variable-percentage reduction in diagnosis-related group payments across all hospitals, to high performers. As a further example, the Hospital Readmissions Reductions Program, which took effect in fiscal year 2012, withholds a percentage of Medicare reimbursement for hospitals with too many avoidable readmissions for certain medical conditions within thirty days of discharge.

Other programs with similar goals focus specifically on the provision of care. Accountable Care Organizations (ACOs) and related programs, such as Medicare Shared Savings and the Advance Payment ACO Model, endeavor to create provider groups that coordinate care to both improve health outcomes and reduce costs. The group of thirty-two Pioneer ACOs experienced moderate success at improving quality and producing shared savings in 2012. Future programs aimed at better coordinating care to help improve quality and lower costs include episode-based payments, such as bundled payments, which incentivize quality improvement by paying providers based on the entire episode of care, rather than for individual services.

The Stark Law, therefore, is an anachronism in the present regulatory climate. Having its roots in an era where cost was considered independent of both access to and quality of care, the Stark Law speaks to a way of thinking about health care that is fast becoming outdated. This contention differs from saying that, despite its parochial focus on cost, the Stark Law can still play a more modest role in the trajectory of health reform. Rather, the point is that the Stark Law proceeds from a faulty starting position because it considers only cost, while ignoring the related and crucial issue of whether self-referrals have a negative effect on the quality of care. This can be witnessed, for instance, in the OIG report. By wholly ignoring a concern that is of central import to health reform, the Stark Law distances

68 § 1395ww(o).
69 § 1395ww(q).
itself from the present foci of the health care regulatory environment. Instead, the Stark Law needs to be recast to bring a wider gamut of timely considerations to bear on how the law addresses physician self-referrals.

V. A PROPOSAL FOR REFORM

A proposal for a system of disclosure as an alternative to the Stark Law has not been given its due consideration. The conventional proposal for such a system goes thus: before making a referral, the physician must disclose to her patients whether and to what extent she holds an investment interest in the entity to which the referral would be made. It is unclear, however, what would occur after the patient receives this information. The notion seems to be that the patient could determine of her own accord whether there is a significant financial conflict of interest present, which would in turn bear on whether she grants consent to performance of the referred service. Presumably, the patient would likewise be able to weigh personal cost concerns based on factors like insurance coverage and any related out-of-pocket costs. In some instances, where the nature of the referred service carries a degree of personal physical risk, the patient could also weigh whether the perceived benefits outweigh the attendant risks.

This proposal has obvious flaws. First, it is unclear why the burden of disclosure should be placed on the individual physician, as opposed to the institution or practice group that employs the physician. Direct disclosure by the physician would likely harm the physician-patient relationship by casting doubt upon the trustworthiness of the physician. One can imagine how the mechanics of direct disclosure would seem to imply to the patient that something is awry. Moreover, the average patient is not equipped to assess the totality of the disclosed information. This form of disclosure, therefore, presumes an unreasonable level of medical knowledge of the average patient. There are still further practical concerns that weaken such a proposal. For instance, as is the case in other forms of disclosure in medical settings, the demands of an urgent medical emergency tend to aggravate the expected orderliness of disclosure protocols.

73 Id. at 527.
74 Klein, supra note 11, at 527.
75 Id.
76 See American College of Emergency Physicians, Code of Ethics for Emergency Physicians II(A)(2) (Apr. 2011), available at http://www.acep.org/Clinical---Practice-Management/Code-of-Ethics-for-Emergency-Physicians/ ("The unique setting and goals of emergency medicine give rise to a number of distinctive ethical concerns. Among the special moral challenges confronted by emergency physicians are the following... Second, patients in the emergency department often are unable to participate in decisions regarding their health care because of acute changes in their mental state. When patients lack decision-making capacity, emergency physicians cannot secure their informed consent to treatment...").
Disclosure need not be made directly to the patient, however. In contrast, a more workable system of disclosure would turn on disclosure to the federal government, specifically, under conditions that would further the push for transparency in health care that the ACA envisions. While disclosure would not be made directly to the patient, she would have access to the disclosed information, which could then become part of her medical decision-making process, if so desired. As for the federal government, the availability of information on physicians’ financial interests in entities to which they refer patients would provide valuable data that could be analyzed to identify and predict fraudulent conduct. Perhaps more crucially, as I discuss below, the simple act of having to disclose this information might itself serve as a valuable deterrent.

Disclosure is not an altogether new concept for the Stark Law. For instance, the ACA makes a significant addition with regard to self-disclosure under the Stark Law. Section 6409(a) of the ACA requires the Department of Health & Human Services (HHS) to establish a self-referral disclosure protocol (SRDP) that sets out a process by which providers may self-disclose actual or potential violation of the Stark Law. HHS later articulated this process. The SRDP affords providers the opportunity to avoid the otherwise harsh penalties that accompany a Stark Law violation through settlement mechanisms with reductions in amounts owed for actual violations. The Centers for Medicare & Medicaid Services’ (CMS) Division of Technical Payment Policy has recently confirmed that the SRDP has been popular amongst providers.

77 The ACA contains innumerable provisions that promote health care transparency. See, e.g., Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 Fed. Reg. 18,310, 18,341 (to be codified at 45 C.F.R. pts 155, 156, and 157) (explaining that Health Insurance Marketplace “policies and protocols must be consistent with the principle of 'Openness and Transparency,' which states that there should be openness and transparency about polices, procedures, and technologies that directly affect individual and/or their personally identifiable health information.”).

78 The Centers for Medicare & Medicaid Services (CMS) already utilizes a variety of analytics platforms to prevent and detect fraud. See CENTERS FOR MEDICARE & MEDICAID SERVICES, REPORT TO CONGRESS: FRAUD PREVENTION SYSTEM – FIRST IMPLEMENTATION YEAR I (2012) (reporting to Congress on the successes of the newly-developed Fraud Prevention System (FPS), which utilizes predictive analytics technologies to identify and prevent the payment of improper claims in the Medicare fee-for-service program).

79 ACA § 6409(a).


81 ACA § 6409(b).

The Stark Law contains another provision addressing disclosure, albeit of a different kind. As originally conceived, the Stark Law set forth a series of mandatory reporting requirements regarding physician "ownership, investment, and compensation arrangements." \(^{83}\) Specifically, this disclosure has two basic components. First, the entity billing Medicare has to identify the items or services that it provided. \(^{84}\) Second, the entity has to identify the names and "unique physician identification numbers of all physicians with an ownership or investment interest" or with "a compensation arrangement" in the entity. \(^{85}\) However, CMS never promulgated specific reporting requirements, likely because it recognized that enforcing these provisions would impose a heavy burden on both itself and the health care industry. \(^{86}\) Stark II later added clarifying language on the state of these requirements such that disclosure under section 1395nn(f) need only be submitted "upon request." \(^{87}\)

The first step toward setting forth a system of disclosure to replace the Stark Law would be to articulate what specifically must be reported. The requirements under section 1395nn(f) establish a reasonable scope. These requirements satisfy the *prima facie* need to identify which services have been provided and by whom, and whether the referring physician has an investment interest in the referred entity. The regulations further specify that disclosure must include "the nature of the financial relationship (including the extent or value of the ownership or investment interest or the compensation arrangement)." \(^{88}\) This level of detail helps to distinguish between minor investment interests, where the risk for abuse is likely minor, and significant investment interests, where the risk for abuse may be greater.

Second, a system of disclosure would, contrary to changes under Stark II, not be upon request, but instead be mandatory, with attendant penalties for failure to adhere. Replacing the Stark Law with a system of disclosure without mandatory reporting would hinder the federal government by limiting the availability of data for analysis, prediction, and detection of fraud and abuse law violations, namely, under the FCA and the AKS. By mandating disclosure, the objective is to strike a reasonable

\(^{83}\) § 1395nn(f).

\(^{84}\) § 1395nn(f)(1).

\(^{85}\) § 1395nn(f)(2).

\(^{86}\) *The Stark II Phase II Interim Final Rule*, CROWELL & MORING (Apr. 6, 2004), http://www.crowell.com/NewsEvents/AlertsNewsletters/Health-Law-In-The-News/The-Stark-II-Phase-II-Interim-Final-Rule#I12E.

\(^{87}\) 42 C.F.R. § 411.361(e) (2013).

\(^{88}\) § 411.361(c)(4).
balance between ensuring that the federal government has access to useful data and the reality of some degree of fraudulent billing conduct in government health care programs.

As a model for developing such a system, I propose drawing from the recently finalized Physician Payment Sunshine Act ("Sunshine Act")\(^8\) because it speaks broadly to the issue of financial conflicts of interest that may affect treatment decisions. Generally, the Sunshine Act requires manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP), and applicable group purchasing organizations (GPOs), to annually report certain payments or transfers of value made to physicians or teaching hospitals.\(^9\) It likewise establishes similar reporting requirements for physician ownership or investment interests in said manufacturers or GPOs.\(^10\) Importantly, the Sunshine Act provides for transparency of this collected information by requiring that HHS publish submitted payment and ownership information on a public website.\(^11\)

A system of disclosure that would replace the Stark Law should, in concert with mandatory reporting, develop a similar procedure for fostering transparency through online publication of reported data. As the preamble to the Sunshine Act final rule asserts, “transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts.”\(^12\) CMS has recently made other data publically available online in an effort to further promote transparency in the health care industry. Most notably, in May of 2013, CMS published a detailed spreadsheet online of hospital-specific charges for more than 3,000 hospitals that receive Medicare Inpatient Prospective Payment System payments for the top 100 most frequently billed discharges.\(^13\)

Further, as Rosenthal and Mello capture, transparency garners favor “because it buttresses rather than constrains markets, avoiding the need for more intrusive, direct regulation.”\(^14\) Particularly in the instance of

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90 Id. at 9,522.
91 Id. at 9,525.
92 Id. at 9,458.
93 78 Fed. Reg. 9,458, supra note 89, at 9,459.
GIVING DISCLOSURE ITS DUE

physician self-referrals, where intrusive regulation has been part and parcel to maintaining compliance with Stark provisions, emphasizing transparency in a new regulatory design is of special import. This form of transparency, as with the Sunshine Act, affords consumers *qua* patients the opportunity to factor such information into their medical decision-making process, if so desired.

This is not to say, however, that the success of such efforts toward transparency need hinge on how patients ultimately utilize the available information. In the context of longstanding public reporting of provider quality information, Rosenthal and Mello rightly point out that patients are often unaware of such information and, even when aware, tend to rely on other factors when choosing a provider.96 Yet, as they also note, use of such information by "expert intermediaries" may prove more fruitful.97 For instance, they reference publically available Securities and Exchange Commission filings which, though publically available, are targeted more toward institutional advisors and financial analysts with the expertise to surface and discipline violations.98 In a similar sense, while patients could obviously benefit from transparency under the proposed system of disclosure, the federal government could play the crucial role of expert intermediary, utilizing available data to detect and prosecute fraudulent conduct.

To motivate compliance, the proposed system of disclosure must be backed by penalties. The structure of penalties outlined in the Sunshine Act could serve as a sound model.99 Penalties under the Sunshine Act differentiate between a basic failure to report and a knowing failure to report.100 By adopting a similar bifurcated penalty structure, the proposed system of disclosure would make significant strides toward obviating the frequent charge of unfairness levied against strict liability under the Stark Law. As is the case under the Sunshine Act, penalties should be greater in an instance of a knowing failure to report.101 Equally important, penalties must be reasonable on the whole. The Sunshine Act caps penalties per payment, other transfer of value, or investment interest not timely or accurately reported, as well as caps them with respect to civil monetary

96 Id.
97 Id.
98 Id. at 2054.
100 Id.
101 Id.
penalties. The proposed system of disclosure should implement similar caps to mitigate against unreasonable levels of liability.

Two weaknesses of the proposed system of disclosure bear mention. First, maintaining compliance under this proposal would likely be costly for providers. For instance, providers would have to bear the financial burdens of properly tracking and reporting various physician investment interests. One estimate of the cost to comply with the Sunshine Act, for example, reached nearly $200,000 per firm, irrespective of legal fees and information technology infrastructure costs. However, it is well known that compliance with the Stark Law is extraordinarily expensive. Moreover, noncompliance with the Stark Law stands to carry much more severe penalties. In this sense, while precise cost estimates for the proposed system of disclosure are unavailable, it stands to reason that they would be less than is currently the case under the Stark Law.

The proposed system of disclosure would also, arguably, not entirely circumvent the prospect of compounded liability for claims brought concurrently under the FCA. In this sense, providers would still be exposed to added liability, much as is presently the case under the Stark Law. However, the determination of whether a violation of the Sunshine Act, or a similar system like the one proposed herein, could also implicate liability under the FCA is not readily apparent. For instance, the Sunshine Act final rule offers the predictable comment that compliance with its provisions does not result in exemption from potential liability under the FCA. Moving from this bare statement to a FCA violation, however, requires at least a few subsequent steps. One commentator has

102 Id.
104 See Klein supra note 11, at 517.
105 See LOUCKS & LAM, supra note 5, at 361 stating:

Although [Stark Law penalties] seem severe, they could be just the tip of the iceberg, as any referral arrangement in violation of the Stark prohibitions also would be subject to the anti-kickback statute’s criminal enforcement penalties. On top of these severe civil penalties, the physician, the physical therapy clinic, and its other owners can be subject to a lengthy (and costly) grand jury investigation, which could result in criminal prosecution.

106 See 31 U.S.C. § 3729(a) (setting forth the seven basic provisions upon which most health care fraud claims are brought under the FCA).
107 See 78 Fed. Reg., 9460 (Feb. 8, 2013), stating:

We also want to emphasize that compliance with the reporting requirements of section 1128G of the Act does not exempt applicable manufacturers, applicable GPOs, covered recipients, physician owners or investors, immediate family members, other entities, and other persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests (for example, potential liability under the Federal Anti-Kickback statute or the False Claims Act).
speculated that already suspicious employees with insider knowledge might be able to use published data in Sunshine Act transparency reports to catalyze a *qui tam* action, yet precisely how this would occur remains uncertain.¹⁰⁸

VI. CONCLUSION

The Stark Law admits of various weaknesses and is an anachronism in this era of health reform to boot. For these reasons, calls for repeal of the Stark Law are well founded. Yet proponents of repeal have not offered sufficient alternative proposals as to what should stand in its place. One insufficient proposal, as I have examined, suggests implementing a system of direct disclosure by physicians as to investment interests in referred entities. While such a proposal is both misguided and burdened by uncertainty as to how execution would occur, this is not to say that a system of disclosure is an altogether implausible alternative. A more propitious alternative would be shepherded by provisions in the Sunshine Act and, therefore, give disclosure its due weight.
