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Patrick A. Sutton  
*Chuhak & Tecson*

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## The Stark Law in Retrospect

*Patrick A. Sutton, J.D., LL.M\**

*Well, you are not familiar with the way we go about things here. But you will have noticed the impenetrability of the official organization.<sup>1</sup>*

-Franz Kafka

The above extract, a bit of dialogue between an enigmatic bureaucrat and a land surveyor uninitiated in the ways of the local governing body, taken from Franz Kafka's unfinished last novel *The Castle*, is perhaps an appropriate introduction to a discussion of the Ethics in Patient Referral Act of 1989, commonly known as the "Stark Law,"<sup>2</sup> seeing as much of Kafka's work features labyrinthine prose, inscrutable authority, and abstruse regulations administered by a vast, creaking bureaucratic machine situated in a world that seems to operate on a peculiar sort of dream-logic. Originally enacted in 1989, the Stark Law has evolved from its humble beginnings as a relatively narrow proscription involving physician referrals for clinical laboratory services to an entity in which the physician has a financial interest,<sup>3</sup> into a law of much broader scope, covering a wide range of health-related services and financial arrangements, in turn spawning numerous volumes of complex rules, regulations and exceptions in the process, even including a rather Kafka-esque exception to the exception to the exception.<sup>4</sup>

Today, opinion regarding the necessity for, and the efficacy of, the Stark Law remains sharply divided, with many critics citing the difficulty in complying with the law as their chief complaint.<sup>5</sup> The controversy surrounding the law prompted the American Health Lawyers Association to

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\* The author is an Associate at Chuhak & Tecson, P.C.; LL.M. in Health Law, Loyola University Chicago School of Law, 2010. He would especially like to thank Professor Larry Singer for his guidance during the process of writing this article.

1. FRANZ KAFKA, *THE CASTLE* 232 (Anthea Bell trans., Oxford Univ. Press, 2009) (1926).

2. The law is named after California Congressman Fortney "Pete" Stark, who sponsored the initial bill.

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

4. 42 U.S.C. § 1395nn(b)(2) (2010).

5. Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition On Physician Self-Referrals*, 27 *LAW & PSYCHOL. REV.* 1, 21 (2003).

publish a White Paper in 2009 discussing the unintended consequences of the legislation and lobbying the government to consider alternative approaches to addressing the issue of physician self-referral.<sup>6</sup> In a somewhat ironic twist, Representative Fortney “Pete” Stark, the original sponsor of the legislation and for who it is named, recently lamented the Byzantine turn that the legislation has taken stating, “It gave every shyster and promoter a loophole. . . We now have to keep rewriting the laws like the tax code.”<sup>7</sup> And so, after more than twenty years since its genesis, the question still remains: is the Stark Law good policy?

Stated another way, considering the ultimate goals of preventing the over-utilization of medical services and protecting the Medicare program, are the numerous phases of the Stark Law and their concomitant regulations effective; or, conversely, has the legislation served to impede entrepreneurialism among physicians to the detriment of innovations and better integration in the delivery of medical treatment? This paper will endeavor to answer the above question through an analysis of the policy goals behind the legislation, the evolution of its regulations, its effect on competitiveness in the field of medicine, and the ethical considerations implicated by the issue of physician self-referral.

Part I of this paper will explore studies documenting inappropriate physician self-referral and the legislative responses thereto. Part II will provide an overview of the current state of the Stark Law and explore how it operates.<sup>8</sup> Part III will analyze its effects upon the healthcare system and the practice of medicine, and evaluate arguments in favor of and against limiting the scope of the legislation. Part IV will offer some proposals that attempt to address the problem of physician self-referral abuse, while at the same time reducing the complexity and breadth of the Stark Law and its regulations.

## I. DOCUMENTING SELF-REFERRAL ABUSE & THE LEGISLATIVE RESPONSE

“Self-referral” refers to the practice of physicians referring their patients for medical treatment or services to an entity in which either the physician

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6. Am. Health Lawyers Ass’n, Pub. Interest Comm., *A Public Policy Discussion: Taking Measure of the Stark Law* (Aug. 10, 2009), <http://www.healthlawyers.org/Resources/PI/Policy/Documents/Stark%20White%20Paper.pdf>.

7. David Whelan, *Stark Regrets: I Shouldn’t Have Written That Law*, FORBES BLOG, (Nov. 30, 2007, 1:52 PM), <http://blogs.forbes.com/sciencebiz/2007/11/30/stark-regrets-i-shouldnt-have-written-that-law/>.

8. The Stark Law should be contrasted with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b), which prohibits individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid or any other federally funded program and imposes criminal as well as civil penalties for violations. *See* 42 U.S.C. § 1320a-7(b) (2010).

or an immediate family member of the physician has a financial interest.<sup>9</sup> In practice, these arrangements are typically found where physicians have invested in non-hospital facilities such as clinical laboratories, ambulatory surgery centers, outpatient diagnostic imaging centers and durable medical equipment companies.<sup>10</sup> Usually, these investments take the form of either ownership of corporate stock or partnership interests in a corporation or partnership that operates a healthcare entity.<sup>11</sup>

It has been postulated that the aforementioned types of arrangements became prevalent in the 1980's as a result of the restructuring of payment systems in the healthcare industry aimed at cost containment, with many citing the advent of the Medicare program's prospective payment system (which fixes reimbursement for particular treatments or services at a predetermined amount) as creating competitive pressures for physicians, hospitals and other healthcare providers to develop new strategies to raise revenues.<sup>12</sup> Additionally, as medical technology has improved rapidly in the past few decades, the site of treatment has increasingly shifted from hospitals to outpatient care facilities, further facilitating the rise in joint ventures and physician entrepreneurialism.<sup>13</sup>

In a 2007 interview in which he reflected on the current state of the law and the widespread dissatisfaction expressed by many, Rep. Stark admitted that prior to 1989, he did not see physician self-referral as a big problem, stating: "I didn't think there was such a big deal. So the doctors wanted to make some extra money."<sup>14</sup> Though the bill that would eventually become the Stark Law was introduced in 1988, it was not until the Office of the Inspector General for the Department of Health and Human Services issued a special report in 1989 that empirical evidence suggested physicians were abusing the referral process in order to financially benefit themselves.<sup>15</sup> Additionally, Rep. Stark credits a former staffer who was both a physician and a lawyer for providing the inspiration for pushing for comprehensive legislation that would provide bright-line definitions and clarifications of what would constitute an impermissible referral.<sup>16</sup> It was the staffer's

9. Theodore N. McDowell, Jr., *Physician Self-Referral Arrangements: Legitimate Business or Unethical Entrepreneurialism*, 15 AM. J.L. & MED. 61, 109 n.105 (1989).

10. *Id.* at 62.

11. *Id.*

12. *Id.* at 63-64; See generally Morgan R. Baumgartner, *Physician Self-Referral and Joint Ventures Prohibitions: Necessary Shield Against Abusive Practices or Overregulation?*, 19 J. CORP. L. 313 (1994).

13. McDowell, *supra* note 9, at 64.

14. See Whelan, *supra* note 7.

15. Office of Inspector General, U.S. Dep't of Health & Human Servs., *Financial Arrangements Between Physicians and Health Care Businesses*, (1989) [hereinafter *Financial Arrangements*].

16. See Whelan, *supra* note 7.

opinion that the penalties provided by the Anti-Kickback Law, a \$50,000 fine and/or five years in prison, did not provide a sufficient deterrent for inappropriate self-referral, especially in light of the difficulties in enforcing the law thanks to its requirement of proving intent.<sup>17</sup>

#### *A. OIG Financial Arrangements Report*

In Section 203(c)(3) of the Medicare Catastrophic Coverage Act of 1988, Congress mandated the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) to conduct a study on physician ownership and compensation from healthcare entities to which they make referrals.<sup>18</sup> The results of this study were published in May 1989, in a report entitled *Financial Arrangements Between Physicians and Health Care Businesses*. Utilizing surveys of both physicians and independent clinical laboratories, the study first undertook to determine the prevalence of physician financial involvement with these entities, ultimately finding that “twelve percent of physicians who bill Medicare have ownership or investment interests in entities to which they make patient referrals.”<sup>19</sup> Additionally, the study found that eight percent of the physicians that bill Medicare have compensation arrangements such as rental agreements, employee arrangements, consulting agreements, and management services contracts with entities to which they refer patients.<sup>20</sup>

The bulk of physician ownership and investment, the study found, was concentrated in the area of independent clinical laboratories (ICL) and independent physiological laboratories (IPL) (approximately twenty-five percent of which were owned by referring physicians either in whole or in part), and durable medical equipment supply companies (approximately eight percent of which were referring physician-owned).<sup>21</sup> While the study focused primarily upon physician referrals to independent clinical laboratories, another major finding of the study was that referring physicians invest in a wide range of healthcare entities in addition to clinical laboratories, including home health agencies, hospitals, nursing homes, ambulatory surgical centers, and health maintenance organizations.<sup>22</sup>

The second major undertaking of the study was to analyze claims information from the Health Care Financing Administration (now re-titled the Center for Medicare and Medicaid Services [CMS]) in order to assess

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17. *Id.*

18. *See Financial Arrangements, supra* note 15, at 1.

19. *Id.* at ii-iii.

20. *Id.* at iii.

21. *Id.*

22. *Id.*

utilization patterns and estimate the costs self-referral imposed upon the system.<sup>23</sup> The conclusions were startling: 1) patients of physicians who own or invest in ICLs received forty-five percent more clinical lab services than average Medicare patients; 2) patients of physicians who own or invest in IPLs received thirteen percent more physiological testing than average Medicare patients; and 3) the costs of the increased utilization of just clinical lab services cost the Medicare program approximately \$28 million in 1987.<sup>24</sup>

Consequently, the OIG report identified six distinct options for policymakers and Medicare administrators in order to address the over-utilization of healthcare services due to inappropriate self-referral.<sup>25</sup> These included: 1) implementing a post payment utilization review program by insurance carriers for physicians that own or invest in other healthcare entities; 2) require physicians to disclose financial interest to patients; 3) improve enforcement of the Anti-Kickback Law; 4) institute a private right of action for kickback cases; 5) prohibit physicians from referring patients to certain types of entities in which they have a financial interest; and 6) prohibit physicians from referring patients to all entities in which they have a financial interest.<sup>26</sup>

Influenced by this report, Congress included a provision designed to provide limitations on certain physician referrals of Medicare patients in the Omnibus Budget Reconciliation Act of 1989, which was passed in December of that year to become effective on January 1, 1992.<sup>27</sup> This provision, commonly referred to as “Stark I”, focuses exclusively on prohibiting a physician from referring a Medicare patient for clinical laboratory services to an entity in which the physician, or the immediate family member of the physician, has a financial relationship, as well as prohibiting the entity from submitting a claim for payment pursuant to a prohibited referral.<sup>28</sup> In addition to providing several exceptions to the prohibition, the law imposed disclosure requirements on healthcare entities concerning physician ownership and/or investment and commissioned the Comptroller General to conduct a study on the ownership of hospitals by referring physicians and joint ventures between hospitals and referring physicians.<sup>29</sup>

Besides having a profound effect on the legislation, which would

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23. See *Financial Arrangements*, *supra* note 15, at iii.

24. *Id.*

25. *Id.* at iv.

26. *Id.*

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

28. *Id.*

29. *Id.*

ultimately become the first iteration of the Stark Law, the 1989 OIG study in turn inspired several more studies on the issue of physician self-referral by both governmental agencies and professional journals that not only supported, but expanded upon, the OIGs conclusions.<sup>30</sup>

*B. Additional Documentation of the Self-Referral Problem  
and the Expansion of the Stark Law*

Between 1989 and 1994, nine more influential studies examining both the prevalence and impact of the practice of physician self-referral on the healthcare system appeared in professional journals such as the *New England Journal of Medicine* and the *Journal of the American Medical Association* as well as in state and federal government reports.<sup>31</sup> While Stark I focused exclusively on referrals for services at clinical laboratories, the following studies indicated not only that clinical labs were not sole area subject to self-referral abuse, but the studies resulted in a renewed call for a wider and more comprehensive ban on the practice of physician self-referral.

In a 1990 article appearing in the *New England Journal of Medicine*, a comparison study was performed on the practice patterns of fifteen doctors at Health Stop, a chain of ambulatory care centers, before and after it changed its compensation system from flat-fee to a variable salary dependent on how much income a doctor could generate individually.<sup>32</sup> The study found that: physicians increased the number of laboratory tests they ordered by twenty-three percent; the number of x-ray films per visit increased by sixteen percent, and that total charges per month, adjusted for inflation, grew twenty percent; leading the study's authors to conclude that physicians indeed change the way they practice medicine when financial incentives rewarding individual performance are introduced.<sup>33</sup> Further studies documented similar increases in utilization of services across a wide variety of specializations where physicians had financial incentives to do so.

In another article appearing in the same volume of the *New England Journal of Medicine*, a similar comparison study was described that measured the frequency of the use of diagnostic imaging as performed by physicians who used imaging equipment in their offices and as ordered by

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30. *Medicare Self-Referral Laws: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 106th Cong. 20 (1999) (statement of D. McCarty Thornton, Chief Counsel to the Inspector Gen., Office of the Inspector Gen., U.S. Dep't of Health & Human Servs.).

31. *Id.* at 22-25.

32. David Hemenway et al., *Physicians' Responses to Financial Incentives – Evidence from a For-Profit Ambulatory Care Center*, 322 *NEW ENG. J. MED.* 1059, 1059 (1990).

33. *Id.* at 1060, 1062.

physicians who referred patients to outside radiologists.<sup>34</sup> The study revealed not only that self-referring physicians utilized diagnostic imaging services at least four times more often than their counterparts who referred to outside radiologists, but also that the charges from the self-referring physicians were higher on average - a difference that the authors found could not be attributed to differences in the patient mix, the specialties of the physicians, or the complexity of the services performed.<sup>35</sup>

Similar results were reported regarding physical therapy and rehabilitation facilities in a study published by the *Journal of the American Medical Association* in 1992.<sup>36</sup> Through analyzing information from these facilities concerning profits, charges, and utilization obtained under a legislative mandate from the State of Florida, the authors concluded that patient referrals were thirty-nine to forty-five percent higher in facilities owned by the referring physician and these facilities generated significantly higher revenues than facilities not owned by physicians.<sup>37</sup> Interestingly, the study also found that licensed physical therapists employed in facilities not owned by physicians spent an average of sixty percent more time treating patients than their peers did in facilities wholly or jointly owned by physicians.<sup>38</sup>

Additionally, results were reported in the case of freestanding radiation therapy centers in Florida, where the frequency and costs of treatment were between forty and sixty percent higher when compared with the rest of the United States where referring physicians had ownership interests.<sup>39</sup> Similarly, California researchers found that the practice of self-referral had significant effects on the utilization of high-cost medical services covered under the state's workers compensation program.<sup>40</sup> In comparing the patterns of physicians who engaged in self-referral and physicians who referred to independent facilities, this study revealed that self-referring physicians initiated physical therapy 2.3 times more often than their

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34. Bruce J. Hillman et al., *Frequency and Costs of Diagnostic Imaging in Office Practice – A Comparison of Self-Referring and Radiologist-Referring Physicians*, 322 NEW ENG. J. MED., 1604, 1604 (1990).

35. *Id.* at 1606.

36. Jean M. Mitchell & Elton Scott, *Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics*, 268 JAMA 2055, 2055 (1992).

37. *Id.*

38. *Id.*

39. Jean M. Mitchell & Jonathan H. Sunshine, *Consequences of Physicians, Ownership of Health Care Facilities – Joint Ventures in Radiation Therapy*, 327 NEW ENG. J. MED. 1497, 1497 (1992).

40. Alex Swedlow et al., *Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self Referral by Physicians*, 327 NEW ENG. J. MED. 1502, 1504 (1992).



independent counterparts, incurred over twenty-six percent higher costs associated with psychiatric evaluation, and ordered significantly more MRI tests, thirty-eight percent of which were deemed by the authors to be medically inappropriate.<sup>41</sup>

### C. OBRA 93 & The Advent of Stark II

Perhaps the most influential study addressing the topic of physician self-referral, published in Marc Rodwin's 1993 book *Medicine, Money and Morals: Physicians' Conflicts of Interest*, which essentially argues that physicians' financial conflicts of interest exist in every area and specialty of medicine, and are more pervasive than commonly acknowledged.<sup>42</sup> In the foreword to the book, Dr. Arnold S. Relman, a professor from Harvard Medical School and editor-in-chief of the *New England Journal of Medicine*, states the crux of the problem:

If our health care system faces a cost-crisis - and there is nearly universal agreement that it does - the proximate cause of that crisis must be sought in the behavior of physicians...The medical care has become a competitive, revenue-seeking industry in which many physicians have an economic interest that goes beyond their personal services. This development undoubtedly affects many of the decisions doctors make, and it certainly adds to the cost of medical care.<sup>43</sup>

In April 1993, not long after the book was published, Rodwin testified before the Ways and Means Health Subcommittee at a hearing concerning the problems created by inappropriate physician self-referral.<sup>44</sup> Shortened versions of the key findings and recommendations from this testimony were subsequently read into the congressional record on the floor of the House of Representatives by Rep. Stark and included the following salient points: 1) physicians' financial conflicts of interest existed as far back as the 1890's, including kickbacks, self-referral, and ownership of pharmacies and other medical supply businesses; 2) while other professional groups are subject to strict conflict of interest regulations and high fiduciary standards, doctors (with the notable exception of doctors practicing within the Veteran's Administration) generally are less accountable to patients; 3) current laws (e.g., Stark I, Anti-Kickback) form a patchwork of regulation that is *ad hoc*,

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41. *Id.*

42. MARC A. RODWIN, *MEDICINE, MONEY AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST* (1993).

43. *Id.* at ix - x.

44. *The Comprehensive Physician Ownership and Referral Act 1993: Hearing on H.R. 345 Before the Subcomm. on Health of the H. Comm. On Ways and Means, 103rd Cong. (1993)* (statement of Marc Rodwin, Associate Professor, School of Public and Environmental Affairs, Indiana University).

inconsistent, and incomplete; and 4) the current system of financing and organizing medical care has led to uncontrolled increases in medical spending, and provided perverse financial incentives for doctors.<sup>45</sup> Further stating that Professor Rodwin's findings are supported by numerous published studies, cases, and financial documents, Rep. Stark concluded:

For physician self-referral, the most effective, least costly and easiest approach is to enact a broad federal prohibition such as that proposed in H.R. 345. Extensive monitoring of doctors through utilization review and quality assurance programs would be very costly and not a particularly effective way to cope with conflicts of interest. Disclosure would do more to protect doctors than patients. Using penalties for misconduct to deter improper actions would offer little protection to patients because of the difficulty of detecting and prosecuting suits, and detection would be costly, too. This holds whether the sanctions are for violating the Medicare anti-kickback statute, antitrust laws, state laws or other legislative and common law prohibitions.<sup>46</sup>

Originally introduced by Rep. Stark in January 1993, H.R. 345, "The Comprehensive Ownership and Referral Act of 1993" was designed to make illegal any referral by a physician, no matter what the source of payment was expected to be, to other providers with which the referring physician has a financial relationship.<sup>47</sup> Citing the decision by the American Medical Association's Council on Ethical and Judicial Affairs, which found unethical the practice of referring patients to providers with which the physician was financially associated, Rep. Stark argued that the only way to protect healthcare consumers from unnecessary referrals is to impose a comprehensive, across-the-board ban on self-referral as well as providing physicians a bright-line rule to make clear which arrangements are not allowed.<sup>48</sup> To this end, the proposed bill extended the ban on physician self-referral contained in Stark I to all payers, including Medicare, Medicaid, Blue Cross/Blue Shield, commercial carriers, and health maintenance organizations.<sup>49</sup>

Furthermore, the bill extended the ban contained in Stark I, which only applied to referrals for clinical laboratory services, to an enumerated list of "Designated Health Services" including: physical therapy services, occupational therapy services, radiology services (including magnetic resonance imaging (MRI), computerized axial tomography, and ultrasound

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45. 139 CONG. REC. E1116, E1116-E1117 (daily ed. May 3, 1993) (statement of Rep. Stark).

46. *Id.* at E1117.

47. H.R. 345, 103rd Cong. (1993).

48. 139 CONG. REC. E84 (daily ed. Jan. 6, 1993) (statement of Rep. Stark).

49. *Id.*

services), the furnishing of durable medical equipment, the furnishing of parenteral and enteral nutrition equipment and supplies, the furnishing of outpatient prescription drugs, ambulance services, home infusion therapy, and inpatient and outpatient hospital services (including rehabilitation and psychiatric hospital services).<sup>50</sup>

Despite the fact that H.R. 345 did not pass, most of the language of the bill was subsequently adopted (albeit much diluted) in Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93).<sup>51</sup> Signed into law by then-President Clinton on August 10, 1993, section 13562 of OBRA 93 (Stark II) extended the self-referral ban to include the list of ten “Designated Health Services” (DHS or DHS Services) proposed in H.R. 345 and also extended the prohibition to cover Medicaid patients, but fell short of Rep. Stark’s vision of a broad ban on the practice of physician self-referral extending to private payors as well.<sup>52</sup> This iteration of the law became known colloquially as “Stark II” and marks the point at which the rules and regulations intended to clarify the law began to be issued in numerous phases and took on a life of their own.

In 1998, just over five years after Stark II was introduced, the Health Care Financing Administration issued a proposed rule to revise the regulations to cover the additional DHS services and extend the prohibition to Medicaid patients.<sup>53</sup> Public comments received in the period subsequent to the proposed rule led to the adoption of a bifurcated rulemaking process whereby the final rules would be promulgated in two separate phases: Phase I primarily addressed general definitions, general prohibitions, and the clarification of what constitutes a financial relationship between physicians and entities providing DHS, and Phase II primarily addressed regulatory exceptions, reporting requirements, and public comments relating to Phase I.<sup>54</sup> The Phase I Final Regulations were not released until 2001,<sup>55</sup> while the Phase II Final Regulations were not released until three years later, in 2004.<sup>56</sup>

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50. *Id.*

51. Morey J. Kolber, *Stark Regulation: A Historical and Current Review of the Self-Referral Laws*, 18 HEC FORUM 61, 63-64 (2006).

52. *Id.*

53. Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships, 63 Fed. Reg. 1,659, 1,672 (proposed Jan. 9, 1998) (to be codified at 42 C.F.R. pts. 411, 424, 435 and 455).

54. *See* 139 CONG. REC. E84.

55. Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships (Phase I), 66 Fed. Reg. 856, 856 (Jan. 4, 2001) [hereinafter Physicians’ Referrals (Phase I)] (to be codified at 42 C.F.R. pts. 411 and 424).

56. Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054, 16,054 (Mar. 26, 2004) [hereinafter Physicians’ Referrals (Phase II)] (to be codified at 42 C.F.R. pts. 411 and 424).

Finally, in September 2007, Phase III Final Regulations were published which sought to address public comments received after the publication of the Phase II rules and to reduce some of the regulatory burdens imposed on the healthcare industry by clarifying and modifying some of the exceptions related to financial relationships between physicians and DHS entities where there is little risk of abuse to either the patient or to the Medicare or Medicaid programs.<sup>57</sup>

While the three aforementioned “phases” represent the bulk of the Stark Law regulations, they are by no means the only official CMS pronouncements on the legislation. Recently, changes made by CMS to the Medicare Physician Fee Schedule and Hospital Inpatient Prospective Payment System rules (which provide billing codes, the levels at which particular services will be reimbursed, and other program policies) affected significant portions of the regulations contained in all three phases of the Stark II rulemaking.<sup>58</sup> While these regulations aimed to clarify the Stark Law as well as to close a number of perceived loopholes, the approach taken by CMS in implementing the Stark Law can be perhaps accurately described as *ad hoc*, resulting in lengthy delays, inconsistent interpretations, and considerable trepidation on the part of a healthcare community faced with expending considerable amounts of time and energy complying with an ever-changing law.<sup>59</sup>

## II. THE CORE ELEMENTS OF THE STARK LAW’S PROHIBITION ON SELF-REFERRAL

The core of the Stark Law is its prohibition on self-referral, which can be stated succinctly as: a physician is prohibited from referring a patient for an item or service that is included in the list of ten DHS services<sup>60</sup> to an entity in which the physician (or an immediate family member) has a financial interest, unless an exception applies.<sup>61</sup> Additionally, entities providing DHS services are prohibited from submitting any claims for reimbursement or billing to either the Medicare or Medicaid programs, or to any other

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57. Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012, 51,012 (Sept. 5, 2007) [hereinafter Physicians’ Referrals (Phase III)] (to be codified at 42 C.F.R. pts. 411 and 424).

58. Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 48,434, 48,688 (Aug. 19, 2008) (to be codified at 42 C.F.R.411-413, 422, and 489).

59. Irvin Wagner, *The Difficulty of Doing Business with Stark in an Ever-Changing and Overly Complex Regulatory Environment: After Twenty Years, Where Are We Heading?* 19 ANNALS HEALTH L. 241, 245 (2010).

60. 42 U.S.C. § 1395nn(h)(6)a-k (2006).

61. 42 U.S.C. § 1395nn(a)(1)(A).

person or entity pursuant to a prohibited referral.<sup>62</sup> By itself the prohibition is a fairly straightforward proposition. However, due to the fact that the Stark Law covers all DHS referrals unless an exception applies, the chief difficulties in achieving compliance with the statute lie in the complex, protean definitions to terms such as “financial relationship,” as well as those terms contained in the numerous exceptions to the statute.

### *A. Physician*

Commonly, performing a Stark analysis involves breaking down the statute’s self-referral prohibition into a seven-step inquiry. First, it is necessary to determine whether the party making the referral is a “physician” as defined by the regulations. For purposes of the prohibition, “physician” means a doctor of medicine or osteopathy, dentist, podiatrist, optometrist, or chiropractor.<sup>63</sup> Providers such as nurse practitioners, physician’s assistants, and physical therapists are not included within this definition. If the individual qualifies as a “physician” under the above definition, the next necessary step is to determine whether a “referral” occurred.

### *B. Referral*

As provided in the regulations, “referral” includes: any physician request (in any form, whether written, oral, or electronic) for a service, item or good that is reimbursed under Part B of the Medicare program; a request for a consultation with another physician, as well as all of the services ordered as a result of that consultation; and the establishment of a plan of care using DHS.<sup>64</sup> While this definition does not expressly include any DHS personally performed or provided by the referring physician, it does implicate referrals made within a physician’s group practice.<sup>65</sup> If the request for services qualifies as a “referral” under the regulations, the next determination that must be made is whether the referral is for Designated Health Services.

### *C. Designated Health Services*

Currently, “Designated Health Services” include: 1) clinical laboratory services; 2) physical therapy; 3) occupational therapy; 4) radiology and certain other imaging services; 5) radiation therapy services and supplies; 6) durable medical equipment and supplies; 7) parenteral and enteral nutrients,

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62. 42 U.S.C. § 1395nn(a)(1)(B).

63. 42 C.F.R. § 411.351 (2009).

64. *Id.*

65. *Id.*

equipment and supplies; 8) prosthetics, orthotics, and prosthetic devices and supplies; 9) home health services; 10) outpatient prescription drugs; and 11) inpatient and outpatient hospital services.<sup>66</sup>

If the referral is for one of the services or items listed above, the next inquiry that must be made is whether the individual being referred is a Medicare or Medicaid patient. Despite Rep. Stark's intention that the self-referral ban apply broadly to include private payors as well as the Medicare and Medicaid programs, the language relating to the extension of the ban was deleted from the OBRA 93.<sup>67</sup>

#### D. Entity

Additionally, it is also necessary to consider the definition of what constitutes an "entity" (i.e., the other end of the referral), to which physicians may not make certain referrals, as its meaning is no longer self-evident. Under the Phase I regulations, only the person or entity that actually billed Medicare or Medicaid was considered an "entity" for the purposes of the statute's self-referral prohibition.<sup>68</sup> The limited scope of this definition led directly to the proliferation of what are known as "under arrangements," a term which denotes an arrangement where a hospital would contract or enter into some form of joint-venture with a third party (e.g., a physician or physician group practice) to provide services for the hospital that the hospital would then bill for under its provider number, thus avoiding the Stark Law self-referral prohibition.<sup>69</sup>

CMS expressed concern over this practice in a proposed rulemaking in 2007, stating: "It appears that the use of these arrangements may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries."<sup>70</sup> Consequently, in August 2008, the agency published a revised definition of "entity" to take effect on October 1, 2009, which expanded the term to include any person or entity that performed DHS services that are billed as DHS in addition to those who actually billed DHS.<sup>71</sup> The result of this

66. See Physicians' Referrals (Phase II), *supra* note 57, at 51,080.

67. See 139 CONG. REC. E84 (daily ed. Jan. 6, 1993) (statement of Rep. Stark).

68. See Physicians' Referrals (Phase I), *supra* note 55, at 943.

69. Daniel Murphy, *New Stark Regulation Will Eliminate Most Under Arrangements Joint Ventures*, Birmingham Medical News 13 (Sept. 2008), [http://www.balch.com/files/Publication/058ed7e0-1527-4091-9736-56189d08eeb6/Presentation/PublicationAttachment/c5872501-8efd-47f7-9f02-639fa749c49d/MurphyDM%20Under%20Arrangements%20Article%20\(2\).pdf](http://www.balch.com/files/Publication/058ed7e0-1527-4091-9736-56189d08eeb6/Presentation/PublicationAttachment/c5872501-8efd-47f7-9f02-639fa749c49d/MurphyDM%20Under%20Arrangements%20Article%20(2).pdf).

70. Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38,122, 38,186 (proposed Jul. 12, 2007) (to be codified at 42 C.F.R. pt. 411).

71. See Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, *supra* note 58, at 48,434.

change is that physicians or physician group practices that perform DHS must now meet an exception to the Stark Law.

### *E. Financial Relationship*

Perhaps the most important concept involved in analyzing a referral under the Stark Law is determining whether a “financial relationship” exists between the referring physician and the entity to which the referral has been made. Under the statute, a “financial relationship” is specified as one of three possibilities: 1) an ownership interest; 2) an investment interest; or 3) a compensation arrangement between the physician (or a physician’s immediate family member) and the entity.<sup>72</sup> The regulations break down the concept of financial relationship further, adding that the ownership or investment interest as well as the compensation arrangement may be either direct or indirect.<sup>73</sup>

The regulations specify that:

A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).<sup>74</sup>

Due to the breadth of this definition, the concept of “direct financial relationships” is relatively straightforward and does not require overly complex analysis. Additionally, provisions contained in the Phase III Final Rules serve to eliminate some of the semantic differences resulting from physician practice organizations being understood as intervening between the referring physician and the entity performing DHS by forcing physicians to “stand in the shoes” of their organizations for purposes of determining whether a direct financial relationship exists.<sup>75</sup> Under the Phase III Final Rule, “a physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity . . . is his or her physician organization.”<sup>76</sup>

On the other hand, “indirect financial relationships” can be a more complex concept to understand and in the case of indirect compensation agreements, involve a multi-step analytical process. Under the regulations, an indirect ownership or investment interest exists where there is an unbroken chain of owners between the referring physician and the entity

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72. 42 U.S.C. § 1395nn(a)(2) (2010).

73. 42 C.F.R. § 411.354(a)(1) (2010).

74. 42 C.F.R. § 411.354(a)(2).

75. Physicians’ Referrals (Phase III), *supra* note 57, at 51,028.

76. *Id.*

furnishing DHS, and the entity furnishing DHS has actual knowledge of (or acts in reckless disregard or deliberate ignorance of) the fact that that the referring physician has some ownership or investment interest in the entity furnishing the DHS.<sup>77</sup> For example, an indirect ownership interest would exist where a physician owns a physician practice group and the group in turns owns an interest in a medical imaging company, which has knowledge of the physician's ownership interest in the practice group.

Although they are similar to indirect ownership or investment interests in that they involve the unbroken chain and knowledge elements as well, indirect compensation arrangements involve a slightly more detailed and complex analysis. Three conditions must be satisfied for an indirect compensation arrangement to exist. First, there must exist an unbroken chain of persons or entities that have financial relationships between the referring physician and the entity furnishing DHS.<sup>78</sup> Second, the referring physician receives aggregate compensation that varies with or takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity (i.e., the total amount of compensation is higher or lower based on referrals to the DHS entity).<sup>79</sup> Finally, the entity furnishing DHS must have actual knowledge (or act in reckless disregard or in deliberate ignorance of) the fact that the referring physician's aggregate compensation varies in the prohibited manner described directly above.<sup>80</sup> Arrangements between medical device companies and orthopaedic surgeons where the device company provides a financial interest in devices the physicians help develop often raise indirect compensation issues. For example, physician referrals of DHS to a hospital purchasing the devices could create an indirect financial relationship if the entity is aware of the relationship. Furthermore, the "stand in the shoes" provision of the Phase III Final Rules applies equally to the indirect compensation arrangement analysis as well, with the effect that many arrangements that were previously considered indirect compensation arrangements will have to be re-evaluated as direct compensation arrangements and tailored accordingly to fit within an established statutory exception.

#### *F. Exceptions*

If it has been determined that a physician has made a referral for DHS to an entity with which he or she has a financial relationship, the Stark Law's prohibition on referrals applies and the final step in the analysis is to

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77. 42 C.F.R. § 411.354(b)(5)(i).

78. 42 C.F.R. § 411.354(c)(2)(i) .

79. 42 C.F.R. § 411.354(c)(2)(ii).

80. 42 C.F.R. § 411.354(c)(2)(iii).



determine whether any exception to the prohibition exists. Generally speaking, the exceptions to the Stark Law can be placed into three categories: 1) all-purpose exceptions, which apply to both ownership and compensation arrangements; 2) ownership and investment exceptions; and 3) direct and indirect compensation arrangement exceptions. As the prohibition contained in the Stark Law, as well as the definitions of the key terms contained therein, are relatively broad and cover most referral arrangements involving Medicare or Medicaid patients, the exceptions have become the focal point of the statute as well as a frequent target for critics who cite the exceptions as proof of the Stark Law's complexity.<sup>81</sup>

Indeed, the regulations relating to the exceptions require substantial investments of time and energy spent analyzing matters such as: whether physicians in a group practice spend the requisite number of hours with patients per week furnishing non-DHS services;<sup>82</sup> whether the amount of space rented or leased exceeds the amount "reasonable and necessary" for legitimate business purposes;<sup>83</sup> and finally whether any amount of remuneration (which includes "any payment or benefit made directly or indirectly"<sup>84</sup>) exceeds "fair market value."<sup>85</sup>

The general exceptions include: physician services where referrals are between members of the same group practice;<sup>86</sup> certain ancillary services performed within the same office of a group practice;<sup>87</sup> and certain prepaid health plans, such as HMOs.<sup>88</sup> For physician groups, the in-office ancillary services exception is the most commonly used exception to the Stark Law and is also one of the broadest exceptions available. In order to qualify for this exception, the physician must be a member of a qualifying "group practice"<sup>89</sup> and must also meet various requirements related to supervision of the physician furnishing the services,<sup>90</sup> the physical location and characteristics of the building housing the practice,<sup>91</sup> and billing.<sup>92</sup> If the various requirements prescribed by the regulations are met, physicians are permitted to furnish certain DHS services (excluding the furnishing of some items of durable medical equipment and parenteral and enteral

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81. Paula Tironi, *The "Stark" Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?*, 19 ANNALS HEALTH L. 235, 238 (2010).

82. 42 C.F.R. § 411.355(b)(2)(A)(2) (2009).

83. 42 C.F.R. § 411.357(a)(3).

84. 42 C.F.R. § 411.351.

85. 42 C.F.R. § 411.357(c)(2)(i).

86. 42 U.S.C. § 1395nn(b)(1) (2010).

87. 42 U.S.C. § 1395nn(b)(2).

88. 42 U.S.C. § 1395nn(b)(3).

89. 42 C.F.R. § 411.352 (2009) (defining group practice).

90. 42 C.F.R. § 411.355(b)(1).

91. 42 C.F.R. § 411.355(b)(2).

92. 42 C.F.R. § 411.355(b)(3).

nutrients) in the group's office without triggering the Stark Law's prohibition on self-referral.<sup>93</sup>

Exceptions relating to ownership or investment interests include: ownership interests in publicly traded securities or mutual funds;<sup>94</sup> ownership and investments interests in healthcare facilities located in rural areas;<sup>95</sup> healthcare facilities located in Puerto Rico;<sup>96</sup> and ownership and investment interests in hospitals meeting certain requirements.<sup>97</sup>

Finally, the direct and indirect compensation arrangement exceptions include: the rental of office space and equipment;<sup>98</sup> bona fide employment relationships;<sup>99</sup> personal services arrangements (used when physicians are not employed but instead are independent contractors);<sup>100</sup> remuneration unrelated to the provision of DHS;<sup>101</sup> physician recruitment activities;<sup>102</sup> isolated transactions (e.g., the one-time sale of a practice);<sup>103</sup> group practice arrangements with a hospital subject to numerous requirements;<sup>104</sup> and payments by physicians for certain items and services.<sup>105</sup>

The numerous exceptions listed above serve as a major point of contention in the debate over the effectiveness of the Stark Law, with some critics arguing that the exceptions limit the prohibition's effectiveness and provide loopholes through which providers can avoid the reach of the statute by entering into indirect arrangements.<sup>106</sup> On the other hand, it has been argued that it is these exceptions that make the law complex to the point of incomprehensibility, with one critic pointing out that while the definitions of key terms in the statute require a little over two pages, the exceptions fill over nine pages of the statute, and in turn spawned a guidebook for doctors and lawyers that devoted eighteen pages and over seventy footnotes to offer clarification.<sup>107</sup>

Additionally, the changes made to the exception relating to physician ownership interests in hospitals (commonly known as the "whole hospital

93. 42 C.F.R. § 411.355(b).

94. 42 U.S.C. § 1395nn(e) (2010).

95. 42 U.S.C. § 1395nn(d)(2).

96. 42 U.S.C. § 1395nn(d)(1).

97. 42 U.S.C. § 1395nn(d)(3).

98. 42 U.S.C. § 1395nn(e)(1).

99. 42 U.S.C. § 1395nn(e)(2).

100. 42 U.S.C. § 1395nn(e)(3).

101. 42 U.S.C. § 1395nn(e)(4).

102. 42 U.S.C. § 1395nn(e)(5).

103. 42 U.S.C. § 1395nn(e)(6).

104. 42 U.S.C. § 1395nn(e)(7).

105. 42 U.S.C. § 1395nn(e)(8).

106. Anne W. Morrison, *An Analysis of Anti-Kickback and Self-Referral Law in Modern Healthcare*, 21 J. LEGAL MED. 351, 378 (2000).

107. Wales, *supra* note 5, at 11.

exception”) in the recent healthcare reform legislation highlight how the Stark Law has become politicized, straying further from its purpose of preventing fraud and abuse. Under the current law, physicians may refer Medicare or Medicaid patients to a hospital in which they have an ownership interest where the physician is authorized to perform services at the hospital and the ownership interest is in the entire hospital as opposed to a distinct part or department of the hospital.<sup>108</sup> Between 2003 and 2006, due to mounting political pressure from opponents of “specialty hospitals” (such as the American Hospital Association), Congress imposed a moratorium on Medicare certification of such hospitals with physician owners.<sup>109</sup> Furthermore, the recently passed Patient Protection and Affordable Care Act significantly limits the ability of physicians to invest in hospital facilities by prohibiting hospitals from increasing the total percentage of the total value of ownership interests held in a hospital by physicians as well as subjecting physician owners to a host of stringent new requirements.<sup>110</sup> Also, as the provision imposes a deadline of December 31, 2010 for existing arrangements to be grandfathered in, the changes made by this provision could very well have the effect of halting many ongoing hospital construction projects, as well as arresting future physician investment in hospitals.<sup>111</sup>

As noted by some attorneys in the healthcare field, the provision discussed above has more to do with the political interests of special interest groups rather than addressing fraud and abuse.<sup>112</sup> One attorney noted, “the clear intent of the provision is to maroon physician owned hospitals in a sort of regulatory purgatory until they eventually wither away entirely or they are purchased by non-physician owners.”<sup>113</sup> What is missing from this provision is a compelling justification, as the government has not identified any data that suggests that physicians who invest in hospitals have a greater conflict of interest when it comes to referring

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108. 42 C.F.R. § 411.356(c)(3) (2009).

109. Balch and Bingham LLP, *Digging Through the Rubble: What Opportunities For Physician-Hospital Joint Ventures Remain Standing?*, 1-2, [http://www.healthlawyers.org/Events/Programs/Materials/Documents/HHC09/legalresources/balch\\_resource.pdf](http://www.healthlawyers.org/Events/Programs/Materials/Documents/HHC09/legalresources/balch_resource.pdf) (last visited Dec. 5, 2010).

110. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6001, 124 Stat. 684, 685-87 (2010).

111. Craig A. Conway, *Physician Ownership of Hospitals Significantly Impacted by Health Care Reform Legislation*, 2 (Apr. 2010), [http://www.law.uh.edu/healthlaw/perspectives/2010/\(CC\)%20Stark.pdf](http://www.law.uh.edu/healthlaw/perspectives/2010/(CC)%20Stark.pdf).

112. *Id.* at 4; see also Victor Moldovan, *Will Healthcare Reform Kill Surgeon Ownership?*, ORTHOPRENEUR 32-33 (Mar./Apr. 2010), available at [http://www.ortho.world.com/site/docs/op/online/2010/marapr/editorial\\_moldovan.pdf](http://www.ortho.world.com/site/docs/op/online/2010/marapr/editorial_moldovan.pdf).

113. Moldovan, *supra* note 112, at 33.

patients than physicians who are employed by a hospital.<sup>114</sup>

### *G. Statutory Penalties*

In addition to the complexity of achieving compliance with the Stark Law, the prescribed penalties for violating it are extremely severe, especially considering that the law is a strict-liability statute. Claims for DHS submitted in violation of the Stark Law prohibition may trigger the following sanctions: denial of payment,<sup>115</sup> requiring amounts received to be refunded;<sup>116</sup> civil monetary penalties of \$15,000 per service where the violation is knowing;<sup>117</sup> and exclusion from the Medicare and Medicaid programs where a physician or entity has knowingly entered into an improper cross-referral arrangement or scheme designed to circumvent the self-referral prohibition.<sup>118</sup> Furthermore, violations of the Stark Law also potentially implicate the federal False Claims Act as Medicare providers certify upon submitting their claims for payment that the claims are submitted in conformity with federal law, including the Stark and Anti-Kickback laws.<sup>119</sup> Thus, by submitting claims to the Medicare program that are for services rendered pursuant to prohibited referrals, the claims are *per se* false, and consequently make the claimant liable for up to three times the amount of the claim plus a penalty of an amount between \$5,000 and \$10,000 per claim.<sup>120</sup>

### III. THE IMPACT OF THE STARK LAW ON THE HEALTHCARE COMMUNITY

When introducing the bill that would later become the Ethics in Patient Referrals Act, Rep. Stark stated on the floor of the House of Representatives that:

What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the arrangements that are prohibited. If the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law. The Ethics in Patient Referrals Act provides this bright line rule.<sup>121</sup>

While the original version of the Stark Law was significantly less complex due to the fact that it only covered clinical laboratory services, the

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114. *Id.* at 33-34.

115. 42 U.S.C. § 1395nn(g)(1) (2010).

116. 42 U.S.C. § 1395nn(g)(2).

117. 42 U.S.C. § 1395nn(g)(3).

118. 42 U.S.C. § 1395nn(g)(4).

119. *See generally* 31 U.S.C. §§ 3729-3733 (2010).

120. 31 U.S.C. § 3729(a).

121. 135 CONG. REC. H240-01 (daily ed. Feb. 9, 1989) (statement of Rep. Stark).

great expansion of the statute's scope as part of the OBRA 93 legislation has turned the Stark Law into a morass of unclear, frequently changing regulations with minimal guidance from the Department of Health and Human Services Office of Inspector General.

In a 2003 article appearing in the University of Alabama School of Law's *Law and Psychology Review*,<sup>122</sup> Houston lawyer Steven D. Wales compiled what amounts to an epic catalogue worthy of Homer of various published critical reactions to Stark II, which he termed "a classic example of a moving target;" "confusing;"<sup>123</sup> "complicated;"<sup>124</sup> "over-reaching, too complex, and intrusive;"<sup>125</sup> "out of synch with managed care;"<sup>126</sup> chilling "legitimate and worthwhile physician participation in the competitive healthcare marketplace;"<sup>127</sup> ambiguous;<sup>128</sup> "arcane;"<sup>129</sup> requiring "institutions and physician practices to undertake an exhausting internal . . . evaluation that may—even with the of intentions and efforts—be extremely difficult to do right;"<sup>130</sup> creating "disincentives to innovate";<sup>131</sup> burdening well-intentioned business transactions with complication, cost, and "uncertain regulatory climate";<sup>132</sup> "more of a benefit to lawyers" than an effective check on fraud and abuse;<sup>133</sup> a twisted knot of legislation where the language is so incomprehensible that regulators themselves have trouble understanding it, let alone enforcing it;<sup>134</sup> "strict and technical" with "so many elements that can trip you up" and are "impossible to meet";<sup>135</sup> with the regulations finally being described as "heaps of words in barely decipherable bureaucratese".<sup>136</sup>

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122. See Wales *supra* note 5, at 23-24.

123. Ninth Circuit Clarifies Rules in Hanlester Joint Venture Test Case, 4 Health L. Rep. (BNA) No. 15, at D-4 (Apr. 13, 1995).

124. Stark II: Health Care Groups Seek Moratorium, Major Revisions to Stark II Legislation, 4 Health L. Rep. (BNA) No. 19, at D-15 (May 11, 1995).

125. *Id.*

126. *Id.*

127. *Id.*

128. Molly Tschida, *Stark Raving Mad*, MODERN PHYSICIAN, May 1999.

129. Berkeley Rice, *Does Your Compensation Formula Pass the Smell Test? This Group's Didn't. The Doctors Were Being Paid for Referrals to Their In-House Lab-and Settled Charges for \$230,000.*, MED. ECON., Feb. 22, 2002, at 75.

130. See Tschida, *supra* note 128.

131. *Id.*

132. Mark Taylor, *Healthcare Struggles With Stark Reality*, MODERN HEALTHCARE, Jul. 5, 1999, at 30.

133. *Id.*

134. Lisa Pallatroni, *The Language Barrier: Incomprehensible Fraud and Abuse Laws*, MED. LAB. OBSERVER, Nov. 2000, at 6.

135. See Taylor, *supra* note 132, at 30.

136. Michael Pretzer, *The Final Word-Almost-on Self-Referral*, MED. ECON., Feb. 19, 2001, at 23.

Today, critics still cite similar concerns over the complexity and scope of the law, and calls for the statute to be reformed continue.<sup>137</sup> In 2009, the Public Interest Committee of the American Health Lawyers Association (AHLA) published a white paper, entitled “A Public Policy Discussion: Taking the Measure of the Stark Law,” designed to provide a frank discussion of the efficacy of the Stark Law, to assess the Stark Law’s practical impact, and “to consider what, if any, changes to the Law might be beneficial in light of both the current structure of the healthcare delivery system and pending healthcare reform proposals.”<sup>138</sup>

Finding that the statute’s broad scope as well as its strict liability provisions have yielded both positive and negative results, the white paper assessed the following as positive impacts of the law: heightened internal scrutiny of physician financial relationships leading to the development of corporate compliance programs and contract management systems; restricted physician investment in free-standing imaging centers and other providers of ancillary services prone to self-referral abuse and over-utilization; and aided enforcement due to the lack of an intent requirement in establishing a violation.<sup>139</sup> Conversely, the following negative consequences were also highlighted: complexity of exceptions and lack of a bright line rule have driven the restructuring of the healthcare delivery system, thus creating an unlevel playing field and unclear boundaries in many circumstances; impediments to the implementation of innovations in healthcare delivery and payment systems such as pay-for-performance, shared savings, and bundled payments due to the lack of flexibility with existing exceptions; and disproportionate consequences compounded by the strict-liability provisions, as well as the complexity of the law which makes non-compliance almost inevitable for many providers.<sup>140</sup>

Though participants acknowledged that opinion among AHLA members regarding the various available options for restructuring the Stark Law remains divided, a major theme found in comments made by these participants was that the structure of the statute has made it “unworkable given the dynamics of the healthcare industry.”<sup>141</sup>

The proscriptive structure of the Stark Law requires the creation of an exception for each and every permissible financial relationship. Given the dynamics of the healthcare industry, the Law is destined to impede changes that involve relationships that do not fit within existing

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137. See *Physicians’ Referrals (Phase II)*, supra note 56 at 16,054; 42 C.F.R. § 411.354(c)(2)(i) (2010).

138. See *Public Policy Discussion*, supra note 6, at 1.

139. *Id.* at 2.

140. *Id.* at 3.

141. *Id.* at 6.

exceptions. This, in turn, creates pressure for an ever increasing number of exceptions, enhancing the complexity of the law and undermining the industry's ability to understand and comply with its provisions. The mechanical application of the Stark Law can also result in overpayment liabilities that are highly disproportionate to the conduct giving rise to the offense.<sup>142</sup>

Participants further noted that the Stark Law's structure creates greater liability exposure for hospitals than for physicians against whom enforcement is "almost nonexistent," thus further shifting the statute away from its intended focus of prohibiting physicians from engaging in inappropriate self-referral.<sup>143</sup>

This last point not only highlights the substantial burdens imposed by, and dire potential consequences of, the law, but it also raises questions regarding its effectiveness in combating fraud and abuse. While the AHLA white paper cites the development of compliance mechanisms and enhanced scrutiny of physician relationships on the part of hospitals and other institutional providers, there has been no corresponding shift toward compliance-focused behavior on the part of physicians.<sup>144</sup>

Another structural problem hampering the efficacy of the law noted by the AHLA is the lack of a procedure by which hospitals could self-report Stark Law violations to CMS, resulting in an atmosphere where providers confronted with a violation feel as though they have been "thrust into a vacuum with little practical guidance on how to best to address the situation," exacerbating the problem and potentially exposing the provider to "ruinous liability."<sup>145</sup>

Yet another concern relating to the Stark Law's efficacy is the availability of the in-office ancillary services exception, which allows physicians affiliated with qualifying group practices to perform DHS that are ancillary to the referring physician's professional services provided that certain supervision, location and billing requirements are satisfied.<sup>146</sup> Noting that the greatest financial interest physicians often have is in services provided through their group practices, the AHLA expressed concern that this exception is "inconsistent with the articulated purposes of the legislation."<sup>147</sup>

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142. *Id.* at 10.

143. *Id.*

144. *Id.* at 5.

145. *Id.* at 15-16.

146. 42 C.F.R. § 411.355(b) (2010).

147. *See Public Policy Discussion, supra* note 6, at 7.

*A. The Kosenske Case*

The Third Circuit's recent decision in *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, exemplifies the complex nuances inherent in Stark Law compliance as well as the draconian penalties that accompany even the most well-intentioned violations.<sup>148</sup> Brought as a *qui tam* action under the False Claims Act by a former member of the anesthesiology group that provided services to the hospital at issue, the relator alleged that Carlisle Hospital submitted outpatient hospital claims to the Medicare program and other federal healthcare programs, falsely certifying that such claims complied with the Stark Law.<sup>149</sup> The court found that the arrangement between the anesthesiology group practice and the hospital implicated the Stark Law and did not satisfy the personal services exception.<sup>150</sup> In 1992, Carlisle Hospital (the hospital) negotiated an Anesthesiology Services Agreement with a group of four physicians practicing as Blue Mountain Anesthesia Associates (BMAA) under which BMAA would exclusively provide all anesthesia services required by the hospital's patients as well as pain-management services to be rendered at some point in the future.<sup>151</sup>

Specifically, the agreement provided that: 1) BMAA would provide anesthesia coverage to hospital patients twenty-four hours a day, seven days a week; 2) the hospital would provide space, personnel, equipment, and supplies at no charge for BMAA to provide such anesthesiology services; 3) BMAA would use the personnel, space, equipment, and supplies solely for the practice of anesthesiology and pain-management for the hospital's patients; 4) the hospital would not allow anyone other than BMAA physicians to provide anesthesia or pain-management services at the hospital; and 5) BMAA physicians would not practice anesthesia or pain-management at any location other than the hospital or hospital-affiliated site.<sup>152</sup>

While the court noted that the agreement was "carefully drafted," it pointed out that at the time the agreement was entered into, it only covered anesthesia services provided at the hospital, as the group was not providing pain management services at the time and did not begin doing so until approximately fifteen months after the agreement was signed.<sup>153</sup> In 1998, the hospital opened a new outpatient facility approximately three miles from the hospital at which BMAA provided pain-management services to

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148. See generally *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009).

149. *Id.* at 91.

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.* at 92-93.



patients.<sup>154</sup> The hospital continued to provide space, equipment, and support personnel at the new facility at no charge to BMAA.<sup>155</sup>

At the District Court level, it was determined that the numerous benefits received by BMAA from the hospital constituted “remuneration” and evidenced a “financial relationship” under the Stark Law.<sup>156</sup> The District Court further concluded, however, that the hospital’s arrangement with BMAA fell within the scope of the “personal service” exception enumerated in §1395nn(e)(3)(A).<sup>157</sup> This exception excludes personal services arrangements from the Stark Law’s referral prohibition provided the following key requirements are met: 1) the agreement is set out in writing, signed by the parties and specifies and covers all of the services to be provided by the physician; 2) the term of the arrangement is at least one year; and 3) the compensation for the entire term is set in advance, does not exceed fair market value, and does not take into account the volume or value of referrals.<sup>158</sup> Finding the original 1992 agreement between the hospital and BMAA adequately addressed all anesthesiology and pain-management services at the clinic, the Court also found that the compensation provided to BMAA (including the provision of space, personnel, and equipment) did not exceed fair market value because it was the result of negotiation between unrelated parties.<sup>159</sup>

On review, the Third Circuit affirmed the District Court’s finding that the numerous benefits received by BMAA including the exclusive right to practice all pain-management and anesthesia services and the receipt of space, equipment, and support personnel constituted remuneration in-kind, thus establishing a financial relationship for the purposes of the Stark Law.<sup>160</sup> The Court of Appeals, however, reversed the District Court’s finding that the arrangement between the hospital and BMAA, with regard to the freestanding Pain Clinic, qualified for the personal services exception, citing several factors.<sup>161</sup>

Initially, the court stated that the personal services exception “recognizes that there can be personal service arrangements involving referrals that are beneficial,” and that the requirements of the exception protect against abuses by “insisting on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the

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154. *Kosenske*, 554 F.3d at 93.

155. *Id.*

156. *Id.* at 95.

157. *Id.* at 95-96.

158. *Id.* at 95.

159. *Id.* at 96.

160. *Kosenske*, 554 F.3d at 96.

161. *Id.*

remuneration to be received for those services.”<sup>162</sup> In finding the 1992 agreement between BMAA and the hospital deficient for purposes of the exception, the court outlined the following three factors.

First, the court held that the agreement did not apply to the provision of pain management services at the new facility as the original agreement was negotiated in 1992 in a wholly different context and as the freestanding facility did not yet exist, BMAA was not providing any pain management services at the time, and no free hospital space, staff or facilities were devoted solely to pain management.<sup>163</sup> Thus, the court concluded that the opening of the freestanding pain clinic in 1998 constituted a “very substantial change” from the circumstances contemplated in the original agreement.<sup>164</sup>

Secondly, the court noted that even if the original agreement could be read as reflecting the arrangement between BMAA and the hospital with regard to the freestanding pain clinic, it would nevertheless be deficient in that the agreement failed to include any mention of the provision of office space, equipment and staff necessary for the provision of pain management services, let alone the pain clinic itself.<sup>165</sup>

Lastly, the court stated that it was “clear that there were no arm’s length negotiations that could vouch for the fair match of service and compensation that the whole statutory scheme is designed to assure.”<sup>166</sup> As a factual matter, the court first stated that negotiations that took place in 1992 “could not possibly reflect” the fair market value of the aforementioned consideration given six years later and under the “materially different circumstances” outlined above.<sup>167</sup> As a legal matter, the court further noted that, as BMAA and the hospital were both in a position to generate business for each other, they were “interested parties,” and thus any agreement negotiated between the two does not by definition reflect fair market value.<sup>168</sup>

To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation.<sup>169</sup>

Furthermore, the court found that the addition of pain management

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162. *Id.*

163. *Id.* at 96-97.

164. *Id.* at 97.

165. *Id.*

166. *Kosenske*, 554 F.3d at 97.

167. *Id.*

168. *Id.*

169. *Id.*

services fundamentally altered the relationship between BMAA and the hospital, as the introduction of these services allowed BMAA to refer its pain clinic patients to the hospital for other diagnostic tests and treatments, unlike its arrangement to provide anesthesiology services where the referrals were being made to BMAA from the hospital.<sup>170</sup> This factor presented to the court “the same concerns” that motivated the Stark Law, thus necessitating the finding that the hospital failed to sufficiently demonstrate its right to the personal services exception.<sup>171</sup>

Apart from calling into question the common practice of hospitals providing free space, equipment and personnel to physicians, the *Kosenske* case also highlights the drastic nature of the liability that hospitals face for violating the Stark Law. Under the applicable penalties outlined in subsection (g), Carlisle Hospital would potentially be required to refund any and all amounts collected for any services billed pursuant to the tainted referrals from BMAA of pain clinic patients to the hospital,<sup>172</sup> pay a penalty of \$15,000 per each service billed pursuant to a tainted referral that has not been fully refunded,<sup>173</sup> and potentially become excluded from the Medicare and Medicaid programs,<sup>174</sup> which would be tantamount to a death sentence for a hospital.

Considered a rare judicial foray into the Stark Law, this decision has been regarded with interest by many throughout the healthcare community who see the opinion as raising several caution flags over common arrangements between physicians and hospitals, such as the provision of space, equipment, and staffing at no charge to physicians who provide services to patients in hospital departments and clinics.<sup>175</sup> Following this decision, the large looming question is whether hospitals and physicians must enter into a written agreement that complies with the Stark Law’s fair market value requirement whenever a hospital provides the use of space, equipment, and staffing to a physician, regardless of whether the physician is paid by the hospital for their services. Furthermore, this question prompts the difficult query of how to compute fair market value in light of the inclusion of these items and, in turn, whether physicians are now required to compensate the hospital for the use of hospital-provided space, equipment and staffing in order to comply with the fair market value requirement.

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170. *Id.*

171. *Kosenske*, 554 F.3d at 98.

172. 42 U.S.C. § 1395nn (g)(2) (2010).

173. 42 U.S.C. § 1395nn (g)(3).

174. 42 U.S.C. § 1395nn (g)(4).

175. Amy Lynn Sorrel, *Court issues rare Stark ruling on physician-hospital agreement*, AM. MED. NEWS, (Feb. 16, 2009), <http://www.ama-assn.org/amednews/2009/02/16/gvsb0216.htm>.

Despite the court's ruling to the contrary, there remains the interesting question as to whether the provision of space, equipment and staffing truly constitute remuneration to physicians, especially in light of the fact that under Medicare reimbursement mechanisms both the hospital and physician are paid fees based on the technical and professional components of their respective services.<sup>176</sup> Because the hospital's reimbursement under Medicare includes a "facility fee" component that includes compensation for the space, equipment and staffing utilized by physicians, and physicians cannot provide professional services to hospital patients without the use of such items, the question remains as to whether the court's decision was correct, especially in light of the significant practical effects that the decision will have on hospital-physician relationships.<sup>177</sup>

Additionally, the case highlights the intricacies of Stark Law compliance and the drastic consequences of failing to satisfy the Law's strict standards. As one practitioner in the fraud and abuse area observed, "The message is, it doesn't matter how reasonable and defensible the underlying arrangement is if you don't meet all of the requirements."<sup>178</sup> Under the sanctions made available by subsection (g) of the Stark Law, Carlisle faces potential penalties of a truly staggering and vertiginous nature, such as being forced to go back and refund every claim submitted to the Medicare program resulting from a referral of BMAA pain-clinic patients to the hospital for DHS, not to mention the possible imposition of a fine and exclusion.<sup>179</sup>

Another interesting aspect of the *Kosenske* case is the fact that it was initiated by a whistle-blower who was formerly a member of BMAA, the anesthesiology practice at issue. This is an additional liability risk for hospitals and physicians. Under the False Claims Act, providers who submit claims to Medicare for reimbursement certify that such claims are submitted in conformity with federal law, including the Stark Law.<sup>180</sup> The fact that this action was brought by a whistleblower is significant, especially in light of the fact that the government did not intervene in the case, and hospitals and physicians may find that the *Kosenske* decision may prompt more whistleblower claims based on alleged Stark Law violations under the False Claims Act.<sup>181</sup>

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176. Karl Schmitz, *Appeals Court Decision Questions Hospital Practice of Providing Free Use of Space, Equipment, Staff to Physicians*, HEALTH L. PERSP. (Hooper, Lundy & Bookman) May 2009, at 2, available at [http://health-law.com/wp-content/uploads/2009/PDF/hlp\\_05.pdf](http://health-law.com/wp-content/uploads/2009/PDF/hlp_05.pdf).

177. *Id.*

178. See Sorrel, *supra* note 175 (quoting Jeffrey P. Drummond, a healthcare regulator expert and partner with Jackson Walker LLP in Dallas).

179. See 42 U.S.C. § 1395nn(g)(2)-(4) (2010).

180. See 31 U.S.C. §§ 3729-3733 (2010).

181. See Sorrel *supra* note 175.

Despite the arguments that *Kosenske* was incorrectly decided, that it left various unanswered questions in its wake, or that it will have significant unintended consequences on the healthcare community, the decision nevertheless recognizes the crux of what the Stark Law attempts to accomplish and perhaps unintentionally provides a good focal point for efforts to reform it. While the District Court concluded that the provision of space, equipment, and staffing constituted remuneration and thus created a financial relationship between BMAA and the hospital, it found not only that the written agreement was sufficient to meet the personal services exception, but also that the arrangement did not violate the law since the original negotiated agreement reflected fair market value.<sup>182</sup>

In reversing this determination, the Third Circuit recognized that the concept of fair market value and the concomitant notion of arm's length transactions are crucial components of the Stark Law's prohibition of self-referral. It further recognized that the Stark Law is "predicated" upon the recognition that parties in a position to generate business for one another (as BMAA was by virtue of bringing its own patients into the pain-clinic) often utilize negotiated agreements as a way to disguise the payment of compensation (e.g., valuable non-monetary consideration like the provision of office space, equipment, and staff) that exceeds fair market value and evidences an unspoken understanding that these items are provided in exchange for a steady stream of referrals.<sup>183</sup>

Through this recognition, the Third Circuit may have unwittingly supplied a particularly insightful call to reform the Stark Law. First, *Kosenske* can perhaps be viewed as a microcosm of the Stark universe, as this case highlights the focus and aims of the law, the complexity and uncertainty that accompany efforts to comply with it, and the drastic consequences that follow failure to achieve strict technical compliance with the law's requirements.

At a basic level, this case concerned a dispute over whether a written agreement between a hospital and a group of providers complied with the requirements provided by an exception to the Stark Law, which was designed to ensure transparency and verifiability for referrals between a provider and an entity in which the referring provider has a financial interest.<sup>184</sup> Viewed entirely at this level, the decision appears problematic and possibly even absurd considering the severe consequences and the absence of any evidence suggesting that noncompliance resulted from willfulness or a scheme to circumvent the law.

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182. See *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 96-97 (3d Cir. 2009).

183. *Id.* at 97.

184. See *Public Policy Discussion*, *supra* note 6, at 14.

In its treatment of the fair market value concept, however, the Third Circuit demonstrates recognition of the key premise that drives the law – namely, that relationships between parties in a position to generate business for one another preclude the availability of truly arm’s length transactions that ensure compensation remains within the bounds of fair market value. This, in turn, ensures that there are no improper financial incentives present for providers to make unnecessary referrals, which have the effect of skewing a physician’s professional judgment and endangering the Medicare and Medicaid programs through the over-utilization of services.<sup>185</sup>

This recognition on the part of the Third Circuit begs the question as to whether the Stark Law is properly focused. Although much of this case focused on whether the arrangement between BMAA and Carlisle Hospital met a regulatory exception, it seems clear that the court’s determination hinged on the nature of the relationship between the parties in light of the establishment of the free-standing pain clinic. Thus, the question that *Kosenske* prompts is whether the policy concerns that underlie the Stark Law would be better served by focusing on addressing specific types of financial relationships that are prone to abuse (e.g., those that preclude the ability to transact business at arms length) rather than including all types of relationships, thereby necessitating the crafting of numerous exceptions for legitimate arrangements or those that pose a lesser risk for abuse.

#### IV. RESTRUCTURING THE STARK LAW

##### *A. Shifting the Focus of the Law*

The AHLA White Paper lists “Reverse the Premise” first and foremost among the options for restructuring the Stark Law, advocating that the focus of the Stark Law “shift from fitting all financial relationships within exceptions to defining a list of prohibited financial relationships that physicians must avoid,” and further stating that “it would be fairer and more effective for the Stark Law to define the relationships deemed to be abusive and specifically prohibit those relationships.”<sup>186</sup> While the white paper does not provide a list of specific relationships that should be prohibited due to their propensity for abuse, a few problematic arrangements can be gleaned from previous studies regarding physician self-referral abuse, including physician ownership of clinical and physiological laboratories,<sup>187</sup> outpatient diagnostic imaging facilities,<sup>188</sup> and certain ancillary services such as

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185. *See id.*

186. *See id.* at 11-12.

187. *See Financial Arrangements, supra* note 15, at 21.

188. *See Hillman, supra* note 34, at 1605-06.

durable medical equipment.<sup>189</sup>

Additionally, certain financial relationships recognized by CMS as improperly influencing physician referrals, such as “under arrangements” or “per click” lease agreements, should be prohibited as well. Although the AHLA White Paper expressed doubts regarding the ability of CMS to craft a list of problematic financial relationships,<sup>190</sup> the agency did take steps in 2008 to address several types of financial relationships prone to abuse.<sup>191</sup>

First, in the rules promulgated regarding the Medicare Inpatient Prospective Payment System for 2009, CMS revised the Stark Law’s exceptions for space and equipment leases to prohibit “per-click” arrangements,<sup>192</sup> by which either space or equipment is leased to a physician on a per service or percentage of revenue basis instead of a fixed amount.<sup>193</sup> In the preamble to the final rule, CMS noted, “such lease arrangements create the incentive for over-utilization, because the more referrals the physician lessor makes, the more revenue he or she earns.”<sup>194</sup>

Second, as described earlier in Part II, CMS also revised the definition of “entity” to prohibit “under arrangements,”<sup>195</sup> which were previously a way for physician specialists such as radiologists, oncologists, cardiologists, and urologists to share in the technical fees hospitals received via reimbursement for treatment that, under normal circumstances, only resulted in professional reimbursement.<sup>196</sup>

If the premise of the Stark Law is reversed, thus obviating the need for the myriad of exceptions to the self-referral prohibition (a fact particularly lamented by Rep. Stark),<sup>197</sup> the Stark Law can be streamlined to root out the problematic arrangements and practices that are inconsistent with the intent of the law. Although many critics have taken issue with the approach used by CMS to issuing regulations under the Stark Law (an admittedly slow process which produced a patchwork of confusing and often inconsistent regulations), these problems may be due more to the Stark Law’s over-

189. See *Financial Arrangements*, *supra* note 15, at 21.

190. See *Public Policy Discussion*, *supra* note 6, at 12-13.

191. See *generally* *Changes*, *supra* note 58.

192. *Id.* at 48,714.

193. McDermott, Will & Emery, *CMS Finalizes Stark Rule Changes in Final 2009 Inpatient PPS Rule*, Aug. 11, 2008, [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/3f62ec87-f675-438b-9de8-b97562b576c7.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/3f62ec87-f675-438b-9de8-b97562b576c7.cfm) (last visited Nov. 10, 2010).

194. Scott Becker et al., *11 Key Concepts from the Stark Law*, BECKER’S ASC REV., Mar.-Apr. 2009, at 1, 8, available at <http://www.beckersasc.com/news-analysis/11-key-concepts-from-the-stark-law.html>.

195. See *Changes*, *supra* note 58, at 48,713.

196. Daniel Murphy, *New Stark Regulation Will Eliminate Most Under Arrangements Joint Ventures*, BIRMINGHAM MED. NEWS, available at <http://www.birminghammedicalnews.com/news.php?viewStory=1164>.

197. See Whelan, *supra* note 7.

inclusive structure rather than the inability of CMS to adequately address the issue of self-referral. Concentrating on certain relationships and arrangements prone to abuse would also substantially reduce the burdens related to achieving compliance with the Stark Law for legitimate arrangements and relationships that currently have to seek the shelter of an exception due to the structure of the law.

### *B. Adjusting the Medicare Reimbursement System*

When addressing Congress in support of his bill to expand the Stark Law into a comprehensive ban on self-referral (H.R. 345), Rep. Stark stated: “Our system of financing and organizing medical care has led to uncontrolled increases in medical spending and a large ineffective utilization review bureaucracy. These problems are exacerbated because we have tolerated, even encouraged, perverse financial incentives for doctors.”<sup>198</sup> With the consideration in mind that the Stark Law addresses issues beyond that of consumer protection, namely the over-utilization of medical services that threaten the continued sustainability of the taxpayer-funded Medicare and Medicaid programs, another avenue by which to address self-referral abuse is the modification of the Medicare reimbursement system, an idea that enjoyed widespread support from the AHLA constituents involved in the white paper, as the most effective means for controlling utilization and costs.<sup>199</sup> While adjusting reimbursement mechanisms is currently touted as an integral part of arresting the continuing rapid increases in healthcare costs in the United States,<sup>200</sup> it may also be a way to address the issue of self-referral by removing financial incentives for physicians to refer patients for medically unnecessary services.

Among the possible reform options listed by the AHLA were: 1) decreasing reimbursement for all ancillary services provided through a physician’s group practice; 2) adopting a declining reimbursement formula for particular high volume services (“on the theory that the provider’s margin increases dramatically above a certain volume threshold”); 3) decreasing payments for high margin services (and service lines); 4) limiting the number of entities that are eligible to bill for certain lucrative services by implementing more stringent credentialing requirements; and 5) adopting a bundled payment system.<sup>201</sup>

While “bundled payments” are an emerging trend as well as a hot-button

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198. See *CPORA*, *supra* note 44.

199. See *Public Policy Discussion*, *supra* note 6, at 8.

200. *Public Policy Discussion*, *supra* note 6, at 8; See also Manoj Jain, *A Little Less Autonomy in Billing, Please*, WASH. POST, Mar. 9, 2010, at HE01.

201. *Public Policy Discussion*, *supra* note 6, at 8.



issue in the context of national healthcare reform that may represent a viable way of combating surging healthcare costs on a widespread scale, a more narrowly tailored solution is perhaps an appropriate way to address self-referral abuse. Despite the contention that implementing reimbursement reform globally may pose a difficult and arduous undertaking, it is nevertheless possible to bundle payments in certain areas especially prone to self-referral abuse. For instance, critics of the Stark Law often point to the in-office ancillary services exception, which permits the furnishing of certain DHS in the office of a physician's group practice that are ancillary to the referring physician's professional services where certain supervision, location and billing requirements are satisfied, as being an enormous loophole. The availability of this exception is seemingly contrary to the purposes of the Law, as it essentially permits physicians to engage in practices within the confines of a group practice that they would otherwise be prohibited from engaging in with outside entities.<sup>202</sup>

Consequently, one way to immediately address the problem of physicians over-utilizing ancillary services is to either decrease the reimbursement for certain ancillary services that are determined to be at-risk for over-utilization from a statistical standpoint or shifting to a bundled payment system for reimbursing office visits at a flat amount instead of allowing physicians to bill for ancillary services on a per-service basis.

### *C. Implementing a Self-Disclosure Protocol*

Another factor exacerbating the potentially drastic consequences that flow from a violation of the Stark Law is that there is currently no protocol by which a physician, hospital, or other entity could disclose an uncovered potential violation without becoming exposed to potentially ruinous liability. As the AHLA White Paper states: "Under existing law [CMS] believes it lacks the authority to seek less than a complete repayment of the reimbursement paid for services provided pursuant to a prohibited referral."<sup>203</sup>

Thankfully, the recent healthcare reform legislation addressed this issue by mandating that the Department of Health and Human Services

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202. Am. Coll. of Radiology, *Inappropriate Utilization of Diagnostic Medical Imaging Modalities*, available at [http://www.acr.org/SecondaryMainMenuCategories/GR\\_Econ/FeaturedCategories/congressional/FederalLegislativeIssues/InappropriateUtilizationofDiagnosticMedicalImagingModalitiesDoc2.aspx](http://www.acr.org/SecondaryMainMenuCategories/GR_Econ/FeaturedCategories/congressional/FederalLegislativeIssues/InappropriateUtilizationofDiagnosticMedicalImagingModalitiesDoc2.aspx) (last visited Dec. 5, 2010). ("While this exception is designed to protect physicians who provide certain designated health services that are generally ancillary to the medical service provided by their practice, the ACR is deeply concerned that this exception has become the rule and serves as a damaging loophole. Current data demonstrates that costs associated with the volume of diagnostic medical imaging services are increasing faster than that of prescription drugs and three times faster than all other physician services.")

203. See *Public Policy Discussion*, *supra* note 6, at 15.

implement a self-disclosure protocol for actual or potential Stark Law violations.<sup>204</sup> While the details and structure of the protocol remains to be seen, it appears that HHS will have the authority to impose fines (rather than to demand repayment in full) for violations considering such factors as the extent and nature of the violation, the timeliness of the disclosure, the cooperation of the parties involved, and other appropriate factors.<sup>205</sup> This will have the effect of somewhat lessening the liability for physicians, hospitals, and other entities that achieve less than full compliance with the Stark Law's requirements without malicious intentions.

## V. CONCLUSION

In the words of Rep. Stark,

To achieve workable healthcare reform, the United States will need to adopt new policies and institutions for physicians' conflict of interest . . . Physicians' conflicts of interest go far beyond issues of professional ethics. They are a central part of why our healthcare system needs to be reformed. Addressing such conflicts is an integral part of the federal government's responsibility to protect patients, ensure access to health care, control costs and promote quality.<sup>206</sup>

However, the broad consensus among the healthcare community is that at best, the Stark Law has become a morass that is virtually unworkable due to its breadth and complexity, and at worst, a law with drastic unintended consequences that somewhat ironically stands in the way of innovations which have the potential to enhance patient safety and reduce the cost of health care.<sup>207</sup>

Unfortunately, our experience with this piece of legislation is not unlike that of Heracles, the hero of classical Greek antiquity, and the Hydra, a terrifying nine-headed monster that grew two more heads for each one severed.<sup>208</sup> It seems that for every potentially abusive practice or relationship addressed, we have experienced not a disentanglement from, but a progressive knotting into<sup>209</sup> the difficulties the Stark Law was intended to address. As Rep. Stark himself conceded, the Stark Law's complexity is due primarily to its structure,<sup>210</sup> which necessitates even legitimate business arrangements to seek an exception. To state the matter

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204. See PPACA, *supra* note 110, at § 6409(a).

205. PPACA, *supra* note 110, at § 6409(b).

206. See CPORA, *supra* note 44.

207. See Wales, *supra* note 5, at 21-23.

208. EDITH HAMILTON, MYTHOLOGY 231 (Little Brown 1942).

209. THOMAS PYNCHON, GRAVITY'S RAINBOW 3 (Penguin 1995).

210. See Whelan, *supra* note 7.

succinctly, the Stark Law is a poor fit for the dynamic and complex healthcare industry.

This is not to say that the concern over the problem of inappropriate self-referral is illegitimate, quite the opposite. As Dr. Atul Gawande's influential piece "The Cost Conundrum" suggests, however, the wider problem of over-utilization of medical services in this country may be due more to the financial incentives offered by our current system of payment than any other factor.<sup>211</sup> It is not much of a stretch to suggest that the same logic might apply to the problem of inappropriate self-referral, which is nestled into the wider problem of over-utilization like a matryoshka doll.

Accordingly, to address this problem in the most effective manner available, as well as in the least intrusive manner possible (so as not to disproportionately affect legitimate business arrangements within the healthcare industry), the Stark Law should be reformed to prohibit only those arrangements and relationships that empirical evidence demonstrate are prone to abuse. Concomitantly, reimbursement mechanisms should be reformed so that either: 1) payments are distributed based on an episode of care rather than a separate fee for each performed; or 2) payment levels are decreased for services for which empirical evidence demonstrates are over-utilized.

If the aim of the Stark Law is to regulate the behavior of physicians with respect to inappropriately referring patients for medically unnecessary treatments, its current structure is a rather roundabout way of accomplishing it. To truly change the practice of inappropriate self-referral as well as the culture of over-utilization, it is necessary not only to target specific relationships and practices prone to abuse, but to realign the financial incentives created by our current payment mechanisms as well.

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211. See generally, Atul Gawande, *The Cost Conundrum*, NEW YORKER, June 1, 2009.