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# Physician Self-Referral : An Overview and Discussion

David M. Mack

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PHYSICIAN SELF-REFERRAL:  
AN OVERVIEW AND DISCUSSION

David M. Mack

B.S., Northeastern University, 1993

A Thesis

Submitted in Partial Fulfillment of the

Requirements for the Degree of

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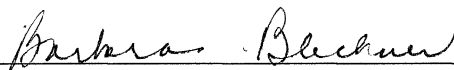
Master of Public Health Thesis

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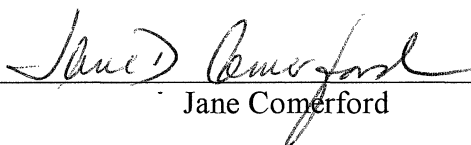
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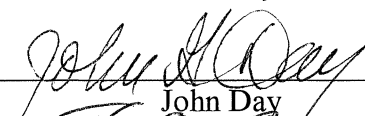
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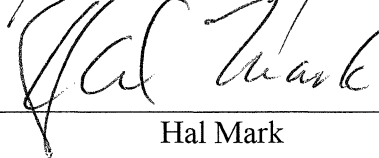
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## I. INTRODUCTION

Congress enacted law in 1989 and 1993, known as Stark, to prohibit physician self-referral.<sup>1</sup> Self-referral is the referral of patients by a physician to a health care entity in which the physician has a financial interest.<sup>2</sup> There was concern that the physician may place more weight on financial gain than on the best medical care for the patient. To counter this possible abuse, the government passed complicated legislation and regulations.

This paper describes the Stark I and II legislation and regulations (collectively known as “Stark”).<sup>3</sup> Congress enacted Stark in response to a growing and serious suspicion of fraud in government health care programs, which many believe was a significant cause of excessive health care spending.<sup>4</sup> First, the paper describes the premise underlying Stark including, analytical studies that show a correlation between self-referral and increased cost, the promulgation of ethical guidelines prohibiting self-referral, and the failure of other federal laws to prevent fraudulent self-referral schemes. Next, the paper presents a number of concerns and unintended consequences caused by the complexity of Stark and the law’s adverse impact on the

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<sup>1</sup> The prohibition against physician self-referral is a subset of health care fraud and abuse law. This paper does not specifically address fee splitting with other professionals, anti-kickback, false claims, or any other type or kind of health care fraud and abuse.

<sup>2</sup> See *Generally*, BARRY R. FURROW ET AL., *HEALTH LAW* (3d ed. 1997); BARRY R. FURROW ET AL., *HEALTH LAW HORNBOOK* (1995).

<sup>3</sup> Stark I and II are codified at 42 U.S.C. § 1395nn and attached as an Appendix.

<sup>4</sup> The estimated cost caused by self-referrals was \$28 million to the Medicare program in 1989. The projected costs from increased utilization were expected to be \$103 million in 1995. Operation Restore Trust was introduced in 1995 to fight health care fraud in, and to recover health care dollars from, abuse in four of the most vulnerable areas: home health care, nursing facilities, durable medical equipment, and hospice care. This initiative now operates in 24 states and recovers \$23 for every \$1 it spends on enforcement. RICHARD P. KUSSEROW, OFFICE OF INSPECTOR GENERAL, *FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES: REPORT TO CONGRESS* (1989).



health care environment.<sup>5</sup> Because of these concerns and unintended consequences, the Department of Health and Human Services proposed Stark II regulations and Congress proposed two new legislative initiatives. After analyzing these proposals, this paper concludes with an alternative proposal.

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<sup>5</sup> See, Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest?* 87 GEO. L. J. 499 (1998).

## **II. SUPPORT FOR THE PROHIBITION ON SELF-REFERRAL**

Congress promulgated the Stark prohibition on self-referral, and then expanded the prohibition through Stark II, in response to a growing and documented suspicion that physicians were increasing health care costs by profiting from the self-referral of patients. Three grounds supported the government's suspicion of fraud. First, results of analytic studies showed a correlation between physicians referring patients to their own businesses and increased cost. Second, ethical guidelines prohibiting self-referral documented the medical profession's consensus that self-referral was a problem. Third, the government realized that the anti-kickback statute might not prohibit fraudulent self-referral arrangements.

### **A. Studies from professional literature**

More than a dozen studies published in professional literature and other sources starting in 1989 concluded that self-referrals are a common occurrence and appear to be very costly. These studies found a correlation between self-referral and increased cost. Because these studies formed a major basis for introduction and expansion of laws prohibiting self-referral, six of these studies are briefly outlined here.

Congress mandated that the OIG conduct a study on physician ownership of, and compensation from, health care entities to which the physician makes referrals. The results of the OIG study were published in 1989 and formed a major basis for the promulgation of Stark I.<sup>6</sup> Of the 2690 physicians who responded to the survey, 12%

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<sup>6</sup> *Id.*

had an ownership interest and 8% had a compensation arrangement with the facility to which they referred. Further, based on HCFA Medicare data files regarding responding physicians' utilization, 25% of independent clinical laboratories, 27% of independent physiological laboratories, and 8% of durable medical equipment suppliers were owned in some part or in whole by referring physicians. Patients referred to facilities in which the physician had an ownership or financial interest received 45% more clinical laboratory services and 34% more independent clinical laboratory services than patients in general.

A 1990 study published in the New England Journal of Medicine studied the frequency and use of diagnostic imaging for physicians with in-office equipment as compared to physicians who referred patients to outside facilities.<sup>7</sup> The study concluded that the physicians with in-office equipment ordered imaging four to four-and-a-half times more often than physicians who referred to outside facilities. The study also found that the charges were higher for in-office imaging. Interestingly, this study found that the differences could not be attributed to the patient population, specialties of the physician, or the complexity of the imaging procedures performed.<sup>8</sup>

A 1992 study by the same investigators extended and confirmed the 1990 research. The 1992 study concluded that physicians who owned imaging technology employed diagnostic imaging in their evaluation significantly more often and

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<sup>7</sup> This study and the subsequent studies are considered to be a major basis for the expansion of Stark and the promulgation of Stark II.

<sup>8</sup> Bruce J. Hillman et al. *Frequency and Costs of Diagnostic Imaging In Office Practice – A Comparison Of Self-Referring and Radiologist-Referring Physicians*. 323 N. E. J. M. 1604 (1990).

generated higher imaging charges than did physicians who referred to independent radiologists.<sup>9</sup>

The Florida Health Care Cost Containment Board published its findings on self-referral in 1991.<sup>10</sup> The Board studied access, cost, utilization, and quality. The study found that 93% of diagnostic imaging facilities in Florida were joint ventures with physicians. When compared with non-physician affiliated facilities, doctor-affiliated clinical laboratories, diagnostic imaging facilities, and physical therapy facilities performed more procedures on a per-patient basis, charged higher prices, and were not located in under-served areas.

The New England Journal of Medicine published a study in 1992 that assessed utilization of physical therapy, psychiatric evaluation, and magnetic resonance imaging (MRI).<sup>11</sup> The study concluded that self-referring physicians initiated physical therapy more than two times more often than the non-referring group, but the cost per visit was lower for the self-referring group. Doctors referred psychiatric patients in the self-referral group for more visits per patient than the non-referral group, thus yielding significantly higher (26%) costs for psychiatric evaluation services in the self-referral group. Self-referring physicians ordered MRI scans about 10% more often than physicians making referrals to a facility in which they had no financial arrangement, with no significant difference in cost. The study concluded that self-referral increased costs in three ways: by increasing the number of patients receiving

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<sup>9</sup> Bruce J. Hillman et al. *Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population*. 268 JAMA 2050 (1992).

<sup>10</sup> STATE OF FLORIDA HEALTH CARE COST CONTAINMENT BOARD, JOINT VENTURES AMONG HEALTH CARE PROVIDERS IN FLORIDA. September, 1991.

physical therapy, by increasing the number of psychiatric evaluations performed without increasing the number of patients, and by increasing the frequency of requests for MRI scans.

Another 1992 study published in the Journal of the American Medical Association concluded that physical therapy and rehabilitation facilities owned by referring physicians resulted in higher utilization, per patient charges, and revenue per patient. Joint venture physical therapy clinics performed fifty percent more visits per year than non-joint venture clinics, including forty-five percent more visits per patient resulting in thirty-two percent more revenue per patient, even with significantly lower per visit costs. Joint venture physical therapy clinic staff spent significantly less time with patients and substituted unlicensed therapists to perform physical therapy more often. Also, joint venture facilities generated more revenue from patients with private insurance, rather than Medicare or Medicaid. Results for rehabilitation facilities owned by referring physicians were similar.<sup>12</sup>

The General Accounting Office published an analysis of 2.4 million diagnostic-imaging services ordered by 17,900 physicians in the state of Florida.<sup>13</sup> The study concluded that physicians with a financial interest in the diagnostic imaging service produced higher referral rates than physicians without a financial interest. The study further found that the disparity between referral rates was greater for more costly services. Also, physicians with in-office imaging facilities referred more frequently

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<sup>11</sup> 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 N.E.J.M. 1502 (1992).

<sup>12</sup> Jean M. Mitchell and Elton Scott. *Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics*. 268 JAMA 2055 (1992).

(two to five times more often, depending on the service) than those physicians required to refer to an outside facility.

Although these studies provide support for the law to prohibit physicians from referring patients to entities in which they have a business interest, the studies may not be sufficient to draw such a firm conclusion. There is no direct proof that the increased services provided to patients were unnecessary, only that patients were referred to facilities where a physician had an ownership or financial interest more often than patients of physicians who had no ownership or financial interest. It is unknown whether the items ordered were medical necessary. Further, it is unknown whether the patients received better care because of the self-referral. The studies generally do not eliminate or account for confounding factors that may have influenced a physician to use more services, such as sickness of the patient population or physician familiarity or proximity with the service. Generally, these studies do not determine directly the extent to which financial incentives are responsible for costly over-utilization or unnecessary care. They merely suggest a correlation between self-referral and increased utilization or cost. Based on these deficiencies, further research is needed to determine whether the prohibition on self-referral actually controls over-utilization caused by physician self-referral. Nonetheless, these studies provided a strong rationale for the government's intervention into medical practices to prohibit self-referral.

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<sup>13</sup> GAO REPORT. MEDICARE: REFERRALS TO PHYSICIAN-OWNED IMAGING FACILITIES WARRANT HCFA'S SCRUTINY. No. B-253835, October, 1994.

## **B. Professional Ethics**

The prohibition against the referral of patients to an entity in which the referring physician has a financial interest is often based on the ethical principals of the Hippocratic Oath and the fiduciary duty arising from the physician-patient relationship.

The Hippocratic Oath requires each physician to protect patients from harm and injustice. If a physician's referral is motivated by economic gain there is a violation of this Hippocratic principle and a conflict of interest. A patient might be subjected to unnecessary medical tests and costs based on the physician's financial gain rather than the best interests of the patient.

The conflict of interest created by self-referral also violates a professional fidelity or loyalty that exists between physician and patient. The professional fidelity or loyalty gives the patient's interests priority.<sup>14</sup> Ethical principles require that self-interest be eliminated in any conflict, with the patient's interests taking priority over others' interests. Changes in the American health care system have created conflicts of fidelity and loyalty in many areas, including areas where physicians have a financial or business interest in the care they render. Physicians have always been paid for their services, but corporate arrangements have not always existed where the opportunity was so readily available for the financial interests of the physician to override the best interests of the patient. The physician's fidelity to the patient is threatened because referral to entities that are self-owned can lead to the provision of

unnecessary or unnecessarily expensive care. “A divided loyalty can only be reconciled by giving up or seriously modifying one or more of the conflicting loyalties.”<sup>15</sup> Most commentators agree that “avoidance of self-referral should not be considered an option, but rather a firm obligation of fidelity and a necessary condition of moral integrity.”<sup>16</sup>

Accordingly, professional medical organizations have adopted ethical principles to reconcile the divided loyalties inherent with self-referral. These principles generally prohibit self-referral, although the adoption of these principles has been difficult. The development of ethical guidelines by the profession has guided lawmakers as they created laws prohibiting self-referral.<sup>17</sup> Guidelines developed by the American Medical Association, the American College of Radiology, the American College of Physicians, and the American Occupational Therapy Association are given as examples.

Initially, the American Medical Association (AMA) refused to prohibit self-referrals.<sup>18</sup> Eventually, the AMA issued ethical guidelines rendering it unethical for physicians to refer a patient to a health care facility outside of their office practice at which they do not directly provide care or services, but in which they have an investment interest. The AMA guidelines allow a physician to refer to such a facility

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<sup>14</sup> See generally, TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 431 et seq. (4<sup>th</sup> ed. 1994).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> See also, Paul W. Armstrong and Virginia M. Hughes, *BME Defines Public Policy in Physician Self-Referral*, 94 N. J. MED. 49 (1997)(outlining the New Jersey Board of Medical Examiners rule that a physician may not make a referral for the furnishing of health care services to a health care entity in which the physician or an immediate family member has a significant beneficial interest.).

<sup>18</sup> American Medical Association, Council on Ethical and Judicial Affairs. *Conflicts of Interest: Physician Ownership of Medical Facilities*. 267 JAMA 2366 (1992).



if that physician will actually provide the service to the patient at the facility in which the physician has an investment or ownership interest or if the facility is needed in the community and no alternative source is available to provide the service and the investment interest is disclosed to referred patients.<sup>19</sup> The AMA noted that

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<sup>19</sup> AMA CODE OF ETHICS:  
Section 8.03 Conflicts of Interest: Guidelines

Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician unnecessarily to hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.

#### Section 8.032 Conflicts of Interest: Health Facility Ownership by a Physician

Physician ownership interests in commercial ventures can provide important benefits in patient care. Physicians are free to enter lawful contractual relationships, including the acquisition of ownership interests in health facilities, products, or equipment. However, when physicians refer patients to facilities in which they have an ownership interest, a potential conflict of interest exists. In general, physicians should not refer patients to a health care facility which is outside their office practice and at which they do not directly provide care or services when they have an investment interest in that facility. The requirement that the physician *directly* provide the care or services should be interpreted as commonly understood. The physician needs to have personal involvement with the provision of care on site.

There may be situations in which a needed facility would not be built if referring physicians were prohibited from investing in the facility. Physicians may invest in and refer to an outside facility, whether or not they provide direct care or services at the facility, if there is a demonstrated need in the community for the facility and alternative financing is not available. Need might exist when there is no facility of reasonable quality in the community or when use of existing facilities is onerous for patients. Self-referral based on demonstrated need cannot be justified simply if the facility would offer some marginal improvement over the quality of services in the community. The potential benefits of the facility should be substantial. The use of existing facilities may be considered onerous when patients face undue delays in receiving services, delays that compromise the patient's care or affect the curability or reversibility of the patient's condition. The requirement that alternative financing not be available carries a burden of proof. The builder would have to undertake efforts to secure funding from banks, other financial institutions, and venture capitalists before turning to self-referring physicians.

When there is a true demonstrated need in the community for the facility, the following requirements should also be met: (1) physicians should disclose their investment interest to their patients when making a referral, provide a list of effective alternative facilities if they are available, inform their patients that they have free choice to obtain the medical services elsewhere, and assure their patients that they will not be treated differently if they do not choose the physician-owned facility; (2) individuals not in a position to refer patients to the facility should be given a bona fide opportunity to invest in the facility on the same terms that are offered to referring physicians; (3) the opportunity to invest and the terms of investment should not be related to the past or expected volume of referrals or other business generated by the physician investor or owner; (4) there should be no requirement that a

“physicians are not simply businesspeople with high standards. Physicians are engaged in the special calling of healing, and, in that calling, they are the fiduciaries of their patients. They have different and higher duties than even the most ethical businessperson.”<sup>20</sup>

The American College of Radiology (ACR) holds that self-referral arrangements lead to inappropriate utilization of medical services and that no justification for these arrangements outweighs the risks inherent in the arrangement.<sup>21</sup> The ACR advocates the ethical principle that physicians should not have a direct or indirect financial interest in facilities to which they refer patients. ACR further does not agree with the argument that the current trend toward managed care decreases the need for self-referral prohibitions. Managed care arrangements contain over-utilization protections that theoretically would protect patients from unnecessary care

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physician investor make referrals to the entity or otherwise generate business as a condition for remaining an investor; (5) the return on the physician’s investment should be tied to the physician’s equity in the facility rather than to the volume of referrals; (6) the entity should not loan funds or guarantee a loan for physicians in a position to refer to the entity; (7) investment contracts should not include “noncompetition clauses” that prevent physicians from investing in other facilities; (8) the physician’s ownership interest should be disclosed to third party payers upon request; (9) an internal utilization review program should be established to ensure that investing physicians do not exploit their patients in any way, as by inappropriate or unnecessary utilization; (10) when a physician’s commercial interest conflicts to the detriment of the patient, the physician should make alternative arrangements for the care of the patient. AMERICAN MEDICAL ASSOCIATION. COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS. CODE OF MEDICAL ETHICS (1999).

<sup>20</sup> *Id.*

<sup>21</sup> The practice of physicians referring patients to health care facilities in which they have a financial interest is not in the best interest of patients. This practice of self-referral may also serve as an improper economic incentive for the provision of unnecessary treatment or services. Even the appearance of such conflicts or incentives can compromise professional integrity. Disclosing referring physicians’ investment interests to patients or implementing other affirmative procedure to reduce, but not completely eliminate, the potential for abuse created by self-referral is not sufficient... The American College of Radiology believes that radiologists and radiation oncologists should make efforts to restructure the ownership interests in existing imaging or radiation therapy facilities because self-referral may improperly influence the professional judgments of those physicians referring patients to such facilities. *Medicare Physician Referral Laws. Testimony Before the Subcommittee on Health of the House Committee on Ways and Means*. 1999 WL 304843 (1999)(statement of J. Bruce Hauser, M.D., FACR, on behalf of American College of Radiology).

caused by physician profit motives. However, over 80% of Medicare beneficiaries still belonged to fee-for-service care as of 1998 and the health care environment has not shifted enough to eliminate the costs of self-referral.

The American College of Physicians requires the physician seek to ensure that medically appropriate levels of care take primacy over financial considerations. Physicians should not refer patients to an outside facility in which they invest and at which they do not directly provide care. Physicians, may, however, invest in or own health care facilities when capital funding and necessary services are provided that would otherwise not be available. In such situations, in addition to disclosing these interests to patients, safeguards must be established to protect against abuse, impropriety, or the appearance of impropriety.<sup>22</sup>

The American Occupational Therapy Association believes that the act of referral does not constitute an ethically reimbursable professional service because the responsibility of health care professionals is to place the health care needs of patients first. A financial relationship creates a potential conflict of interest; an economic inducement that can result in referrals when services are not needed or referrals for a wider range of services or greater frequency and longer duration of treatment than is actually necessary.<sup>23</sup>

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<sup>22</sup> American College of Physicians, *Ethics Manual: Fourth Edition*, 128 ANNALS OF INTERNAL MEDICINE 576 (1998).

<sup>23</sup> American Occupational Therapy Association, *Referral for Profit (White Paper)*, 44 AM. J. OF OCCUPATIONAL THERAPY 852 (1990).

### C. Failure of the Anti-Kickback Statute to Prohibit Self-Referral

The OIG assumed that the Medicare and Medicaid anti-kickback statute would prohibit self-referral when they notified a physician-corporation owned laboratory joint venture in 1989 that their self-referral scheme violated the anti-kickback statute.<sup>24</sup> The anti-kickback statute, which existed prior to Stark, prohibits the knowing and willful payment, solicitation, or receipt of remuneration in the form of kickbacks, bribes, or rebates for the referral, or the inducement of a referral, for services covered by Medicare or Medicaid.<sup>25</sup> Safe harbors exist to provide immunity for certain arrangements.<sup>26</sup> It was clear to the OIG after an adverse administrative decision in 1989 that the anti-kickback statute would not adequately prohibit self-referral.

The anti-kickback intent requirement, that the provider have a “knowing and willful” intent to violate the law, created difficulties in the prosecution of self-referral under the anti-kickback statute. In *Hanlester Network v. Shalala*,<sup>27</sup> the government attempted to prosecute physician partners in a general partnership, The Hanlester Network (“Hanlester”). Hanlester consisted of corporations and physicians that

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<sup>24</sup> *Hanlester Network v. Shalala*, 51 F.3d 1390 (9<sup>th</sup> Cir. 1995)(note that the enforcement process for this matter lasted until 1995).

<sup>25</sup> 42 U.S.C. § 1320a-7b(b).

<sup>26</sup> Differences between the anti-kickback statute and Stark include: violation of the self-referral law can only result in denial of payment, civil penalties, and exclusion from federal health care programs, while violation of the anti-kickback laws can result in criminal felony prosecution and imprisonment of up to five years, civil sanctions up to \$25,000 and exclusion from participation in Medicare and Medicaid; self-referral laws are said to be self-enforcing or preventative because the mere existence of a prohibited relationship is subject to loss of Medicare payment or a civil fine, creating an incentive to comply, without the necessity of showing intent. Further, the self-referral laws only cover items and services financed by Medicare and Medicaid, while the anti-kickback laws cover items covered by other federally financed health programs. In general, anti-kickback is broader than the self-referral law.

<sup>27</sup> *Hanlester Network v. Shalala*, 51 F.3d at 1390.

entered into a laboratory service agreement with SmithKline BioScience Laboratories to provide management services to all joint venture laboratories in which Hanlester had an ownership interest. Hanlester offered limited partnership shares in the joint venture laboratories. The government attempted to prove that Hanlester violated the anti-kickback statute by offering and paying remuneration to physician investors to induce them to refer laboratory tests for Medicare and Medicaid patients to the laboratories. The government also attempted to show that the joint venture physicians received payments in return for referrals and should be excluded from participation in Medicare and Medicaid. The court held that the OIG had to show that the defendants specifically knew about the anti-kickback statute and specifically intended to violate the statute. The court held that substantial evidence did not exist to prove this scienter requirement.

Thus, it became clear that it was unrealistic to rely on anti-kickback laws to control self-referral. The anti-kickback law requires a burden of proof establishing intent that is difficult to prove. Further, the federal courts have adopted, depending on jurisdiction, three different interpretations of the term “willful.”<sup>28</sup> *Hanlester Network* outlines one of the difficulties with using the anti-kickback laws to enforce self-

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<sup>28</sup> Contrast, *Hanlester Network v. Shalala*, 51 F.3d 1390 (9<sup>th</sup> Cir. 1995)(holding that to find a violation of the statute, the court must find that the defendant knowingly and willfully engaged in prohibited conduct with specific intent to disobey the law), *U.S. v. Jain*, 93 F.3d 436 (8<sup>th</sup> Cir. 1996)(holding that a heightened mens rea requirement applies where the defendant must know the conduct is wrongful); *U.S. v. Starks*, 157 F.3d 833 (11<sup>th</sup> Cir. 1998)(holding that the law does not require knowledge that the arrangement for referrals violated the statute. The law only requires knowledge that the conduct was unlawful.). See also, Douglas A. Blair, *The “Knowingly and Willfully” Continuum of the Anti-Kickback Statute’s Scienter Requirement: Its Origins, Complexities, and Most Recent Judicial Developments*, 8 ANNALS HEALTH L. 1 (1999).

referral prohibitions and the need to establish a separate and distinct law prohibiting physician self-referral.<sup>29</sup>

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<sup>29</sup> Thomas S. Crane, *The Problems of Physician Self-Referral Under the Medicare and Medicaid Antikickback Statute*, 268 JAMA 85 (1992).

### III. THE LAW OF SELF-REFERAL<sup>30</sup>

#### A. Stark I and II

In 1989, Congress established the Ethics in Patient Referrals Act, otherwise known as Stark I, in an effort to control increased spending caused by physician self-referrals. This law regulates a physician's referrals to an entity in which the physician has an ownership or investment interest. Stark I prohibits physicians from referring Medicare patients to a clinical laboratory in which the physician or a family member has a financial interest and prohibits billing Medicare for such a referral.

Stark II, promulgated in 1993, expanded the referral and billing prohibitions of Stark I<sup>31</sup> to include laboratories and ten new designated health services<sup>32</sup> in which a physician or family member has an ownership or investment interest or from which the physician receives compensation.<sup>33</sup> Stark is an exceptions statute. First, it declares all referrals to entities in which a physician has a financial interest to be illegal. Then, the statute allows for certain self-referrals if they fit within an exception. The exceptions attempt to allow for legitimate investments, arrangements with legitimate social objectives, and realities of practice. Exceptions fall into three basic categories: 1) general exceptions, 2) ownership or investment interest

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<sup>30</sup> A summary of Stark I and II and corresponding regulations are attached as Table I.

<sup>31</sup> Stark II also makes the self-referral prohibition applicable to services paid by Medicaid. No payment will be paid to a state for a service furnished upon referral if Medicare would not cover the service if it were paying for the service directly.

<sup>32</sup> No payment will be made for illegal referrals covered by eleven designated health services, namely: clinical laboratory services; physical therapy services; occupational therapy services; radiology, MRI, CAT and ultrasound; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.

<sup>33</sup> A compensation arrangement is more specifically defined as any arrangement involving any remuneration between a physician and an entity except for certain refunds and administrative or cursory

exceptions, and 3) compensation arrangement exceptions.

## 1. General Exceptions

There are three general self-referral exceptions. These exceptions relate to physician services, in-office ancillary services and prepaid plans. The physician services exception<sup>34</sup> allows a physician to refer an otherwise prohibited designated health service to himself, if the physician personally provides the designated health service, or to an affiliated group member, if the service is personally supervised by a group member.<sup>35</sup> The in-office ancillary service exception allows otherwise prohibited designated health services to be provided personally by the referring physician, by a physician who is a member of the same group practice as the referring physician, or by individuals who are directly supervised by such a physician. In order to qualify for the in-office ancillary service exception, certain location and billing requirements must be met, such as the same-building and group billing number requirements.<sup>36</sup> The prepaid plan exception allows a physician to refer patients for a

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charges. Remuneration is defined as any remuneration, directly or indirectly, overtly or covertly, in cash or in kind. 42 U.S.C. § 1395nn(h)(1).

<sup>34</sup> 42 U.S.C. § 1395nn(b)(1).

<sup>35</sup> Where a group member is attempting to qualify for the personal services exception or the in-office ancillary service exception, group practice requirements must be met. “Group practice” means a group of two or more physicians legally organized in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides through the joint use of facilities, equipment, and personnel. Each group physician must provide substantially all of the services through the group, and the services must be billed in the name of the group. Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice. Overhead expenses and income must be distributed in accordance with methods previously determined by the group. Compensation of group members cannot be based on the volume or value of referrals. However, a physician in group practice may be paid on a share of overall profits or a productivity bonus based on services personally performed so long as the share or bonus does not take into account the volume or value of referrals. 42 U.S.C. § 1395nn(h)(4).

<sup>36</sup> The service must be provided in the building where the referring physician or another physician who is a member of the same group practice provides unrelated physician services or, if the referring



designated health service when the service is furnished by an organization receiving payments on a prepaid basis, such as a health maintenance organization.<sup>37</sup>

## **2. Ownership or Investment Interest Exceptions**

There are four ownership or investment interests exceptions. There is an exception for investment securities, rural services and two exceptions relating to hospital ownership. A physician is allowed to have an ownership or investment interest in certain publicly traded securities and mutual funds from regulated investment companies, as long as these securities were purchased on terms generally available to the public.<sup>38</sup> A rural provider may have an ownership or investment interest in an entity providing designated health services in a rural area if substantially all of the designated health services furnished by the entity are furnished to individuals residing in the rural area.<sup>39</sup> A designated health service may be provided by a hospital in which the provider has an ownership or investment interest if the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital as a whole and not merely in a subdivision of the hospital.<sup>40</sup> Physicians may have an ownership or investment interest in hospitals in Puerto Rico that provide designated health services upon referral.<sup>41</sup>

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physician is a member of a group practice, the service can be provided in another building used by the group practice for the centralized provision of some or all of the group's clinical laboratory services or other designated health services. The service must be billed by the physician performing or supervising the service, by a group practice under a group billing number or by an entity that is wholly owned by the physician or group practice. 42 U.S.C. § 1395nn(b)(2).

<sup>37</sup> 42 U.S.C. § 1395nn(b)(3).

<sup>38</sup> 42 U.S.C. § 1395nn(c)(additional shareholder equity and total assets requirements must be met).

<sup>39</sup> 42 U.S.C. § 1395nn(d)(2).

<sup>40</sup> 42 U.S.C. § 1395nn(d)(3).

<sup>41</sup> 42 U.S.C. § 1395nn(d)(1).

### 3. Compensation Arrangement Exceptions

There are nine exceptions to the prohibition against referring a patient to an entity with which the physician has a compensation arrangement. There is an exception for space and equipment rental, bona fide employment arrangements, personal services, physician incentive plans, non-designated health services, physician recruitment, isolated transactions, group practice arrangements with hospitals and payment by physicians for items or services.

The equipment and space leasing exception provides that referring physicians may receive certain compensation under a space or equipment lease from an entity providing designated health services.<sup>42</sup> Under the bona fide employment exception, an employer may pay compensation to a physician or immediate family member who has a bona fide employment relationship with the employer if the employment is for identifiable services.<sup>43</sup> Personal service arrangements are allowed under certain circumstances.<sup>44</sup> Physician incentive plans allow compensation to be determined by

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<sup>42</sup> The lease must be in writing, signed by the parties, for a term of at least one-year, specifying the space or equipment to be leased. Compensation cannot be beyond that which is reasonable and necessary for legitimate business purposes. The lease must establish the rental charge in advance, consistent with fair market value (defined as the value in arms length transactions, consistent with the general market value, 42 U.S.C. § 1395nn(h)(3)), and not taking into account the volume or value of any referrals or business generated between the parties. The lease must be commercially reasonable even if no referrals were made between the parties. Further, the space or equipment must be used exclusively by the lessee, with some exceptions for common space. 42 U.S.C. § 1395nn(e)(1).

<sup>43</sup> The amount of compensation must be consistent with the fair market value for the services and not determined by considering the volume or value of referrals. The compensation must be provided pursuant to an agreement that would be commercially reasonable even if no referrals were made. This section explicitly allows productivity bonuses based on services performed personally by the physician or an immediate family member. 42 U.S.C. § 1395nn(e)(2).

<sup>44</sup> Personal service arrangements are generally allowed if the arrangement is set out in writing, signed by the parties specifying the services covered by the arrangement, which must include all of the services to be provided by the physician. The services to be provided must not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The term of the arrangement

taking into account the volume or value of referrals or other business generated in order to reduce or limit services provided. Physician incentive plans are allowed under Stark if the physician complies with applicable law.<sup>45</sup> A physician may receive compensation from a hospital for an item or service that does not relate to the provision of a designated health service.<sup>46</sup> Further, a hospital may pay remuneration to a physician to induce the physician to relocate to a geographic area served by the hospital as long as the physician is not required to refer to the hospital and the remuneration for relocation does not take into account the volume or value of any referrals.<sup>47</sup> The isolated transaction exception allows arrangements such as a one-time sale of property or practice.<sup>48</sup> The group practice arrangement exception allows a hospital to bill for inpatient services provided by a few group practices.<sup>49</sup> Last, a physician may pay for the provision of a designated health service if the item or service is furnished at a price that is consistent with the fair market value.<sup>50</sup>

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must be for at least one year and the agreement must set out in advance the compensation arrangement which cannot exceed the fair market value and cannot take into account the volume or value of referrals or other business generated. 42 U.S.C. § 1395nn(e)(3)(A).

<sup>45</sup> No payment under such a plan may be made specifically as an inducement to reduce or limit medically necessary services and the plan must comply with regulations if the plan places the provider at substantial financial risk. 42 U.S.C. § 1395nn(e)(3)(B).

<sup>46</sup> 42 U.S.C. § 1395nn(e)(4).

<sup>47</sup> 42 U.S.C. § 1395nn(e)(5).

<sup>48</sup> The transaction must be consistent with fair market value and not determined in a manner that takes into account the volume or value of any referral by the referring physician. The one-time transaction must be provided pursuant to an agreement that would be commercially reasonable even without referrals. 42 U.S.C. § 1395nn(e)(6). “Commercially reasonable” is not defined by Stark.

<sup>49</sup> The arrangement must have begun before December 19, 1989 and continued without interruption since that date. The arrangement must be in writing specifying the services to be provided and compensation to be received. Substantially all designated health services must be provided by the group under the arrangement. The compensation must be consistent with the fair market value, not

#### 4. Reporting, Penalties, and Agency Authority

Stark requires any entity providing covered services to report concerning the entity's ownership, investment, and compensation arrangements.<sup>51</sup> Violations of Stark can result in substantial sanctions, including denial or refund of payment, civil monetary penalties and exclusion from participation in federally funded health care programs.<sup>52</sup>

Finally, Stark requires that the Secretary of the Department of Health and Human Services issue advisory opinions concerning whether a referral relating to a designated health service is prohibited.<sup>53</sup> The Secretary is authorized to promulgate regulations including the ability to define additional exceptions that do not pose a risk of program or patient abuse.<sup>54</sup>

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determined by taking into account the volume or value of referrals, and commercially reasonable even if no referrals were made. 42 U.S.C. § 1395nn(e)(7).

<sup>50</sup> 42 U.S.C. § 1395nn(e)(8).

<sup>51</sup> 42 U.S.C. § 1395nn(f).

<sup>52</sup> No payment will be made for a designated health service that is provided in violation of Stark. Any amount collected for items or services billed in violation of Stark must be refunded. Any person that presents a bill for a service that the person knows or should know is for a service for which payment is prohibited by Stark or for which refund has not been made is subject to a civil monetary penalty of \$15,000 for each service billed. If a physician or entity enters into an arrangement which the entity or physician knew or should have known had a principal purpose of assuring referrals, the physician or entity shall be subject to a civil monetary penalty of \$100,000 for each arrangement or scheme. Any person or entity that fails to comply with the reporting requirements of Stark is subject to a civil monetary penalty of not more than \$10,000 per day for which reporting was required. 42 U.S.C. § 1395nn(g)(1-5).

<sup>53</sup> 42 U.S.C. § 1395nn(g)(6).

## B. Regulatory Guidance Interpreting Stark I and II

### 1. Stark I Regulations

Regulations promulgated pursuant to Stark I<sup>55</sup> clarify the law and add regulatory exceptions to the statutory exceptions.<sup>56</sup> Stark is interpreted by the regulations to prohibit the maximum number of possible self-referral situations. For example, the regulations define ‘clinical laboratory services,’ ‘substantially all’ and ‘immediate family member’ in an attempt to maximize the number of health care self-referral arrangements that are prohibited by Stark.<sup>57</sup> The regulations also try to control the use of group practices that qualify for an exception under Stark by requiring a

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<sup>54</sup> 42 U.S.C. § 1395nn(b)(4).

<sup>55</sup> The Stark I regulations do not explicitly address Stark II and do not explicitly apply to Medicaid, however, they have been used by analogy. See *infra*, section III.B.2.

<sup>56</sup> 42 C.F.R. § 411.351 et seq.

<sup>57</sup> See *e.g.*, Clinical Laboratory Services: The regulations define clinical laboratory services to encompass every examination of any material derived from the human body. 42 C.F.R. § 411.351.

- Direct Supervision: The direct supervision requirement of the in-office ancillary services exception is defined as supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed. *Id.*
- Substantially All: The requirement that substantially all of the services of the physicians who are members of the group are furnished through the group and billed in the name of the group is clarified to mean at least 75 percent of the total patient care services of the group practice members. Patient care services means any tasks performed by a group practice member that addresses the medical needs of a patient, regardless of whether they involve direct patient encounters. Patient care services can include time spent consulting with another physician or time spent reviewing test results. The patient care services requirement is measured by the total patient care time each member spends on these services. A ratio of the total hours spent in practice versus the hours spent on patient care is utilized. This requirement does not apply if the practice is located in a health professional shortage area (“HPSA”) or for service provided in an HPSA. Members of the group include physician partners and full-time and part-time physician contractors and employees that bill in the name of the group. *Id.*
- Group practice attestation: The regulations require a group practice attestation where the group practice must submit a written statement annually or when formed or when the group meets the requirements to attest that during the last twelve months 75 percent of the total patient care services of the group practice members was furnished through the group and billed by the group. 42 C.F.R. § 411.360.
- Immediate Family Member: Immediate family member is defined as husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild; stepbrother, or stepsister; father-in-law; mother-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. 42 C.F.R. § 411.351.

group practice attestation, which requires the group to document that it satisfies the group practice requirements.<sup>58</sup>

Many exceptions, such as the rural provider, hospital ownership and physician recruitment exceptions, have been clarified.<sup>59</sup> New exceptions have been added indicating that referrals for services furnished in an ambulatory surgical center, end stage renal disease facility or by hospice are not prohibited, if payment is included in the standard rate for each.<sup>60</sup> The regulations also clarify reporting requirements<sup>61</sup> and the procedure for requesting advisory opinions from the Health Care Financing Administration (HCFA).<sup>62</sup>

## 2. Advisory Opinions

The Office of Inspector General (OIG) and HCFA issued three advisory opinions that deal with physician self-referral. The first advisory opinion, issued by the OIG pursuant to the anti-kickback provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), relates to self-referral in joint venture

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<sup>58</sup> *Id.*

<sup>59</sup> *See e.g.*, Rural Provider: The physician may refer to a rural laboratory that the physician has an ownership or investment interest in if that laboratory performs the tests on the premises of the rural laboratory or if not, the laboratory bill Medicare directly for the testing and substantially all, defined by these regulations as no less than 75 percent, of all of the tests are furnished to individuals who reside in the rural area. 42 C.F.R. § 433.356.

- Hospital Ownership: The hospital ownership exception is clarified in that the physician's ownership or investment interest must be in the entire hospital and not merely in a distinct part or department of the hospital. The regulation adds that until January 1, 1995, the referring physician's ownership or investment interest must not relate directly or indirectly to the furnishing of clinical laboratory services. *Id.*

- Physician Recruitment: The physician recruitment exception is altered by regulation in that the physician cannot be precluded from establishing staff privileges at another hospital or referring business to another entity. 42 C.F.R. § 411.357.

<sup>60</sup> 42 C.F.R. § 411.355.

<sup>61</sup> 42 C.F.R. § 411.361.

<sup>62</sup> 42 C.F.R. § 411.370 et seq.

arrangements and pre-dates Stark. HCFA issued two additional advisory opinions interpreting sections of Stark pursuant to the authority granted to it by the Department of Health and Human Services (DHHS) under the Balanced Budget Act of 1997.<sup>63</sup> The two advisory opinions issued by HCFA discuss ambulatory surgical treatment centers and referrals for eyeglasses following cataract surgery.

#### **a. Joint Venture Arrangements Advisory Opinion**

In 1989, the OIG issued a joint venture advisory opinion under the anti-kickback statute before the initiation of any formal legal prohibition on self-referral. The anti-kickback statute is a federal law that makes it a crime to solicit, receive or pay any remuneration for the referral of a patient or to induce the referral of a patient.<sup>64</sup> The OIG raised concern about situations when physicians become investors in a joint venture entity and thereafter refer patients to that entity, benefiting financially from their referrals. The OIG identified three areas of a joint venture that would be reviewed for suspect activity. First, the manner in which investors are selected and retained should be reviewed to ensure that investors are not required to refer or in a position to make referrals. Second, the nature of the business structure of the joint venture should be reviewed to ensure that the joint venture is not merely a shell to cover for kickbacks and referrals. Third, the financing and profit distributions of the joint venture should be reviewed to ensure that returns are proportionate to the

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<sup>63</sup> 42 U.S.C. § 1395nn(g)(6); 63 Fed. Reg. 1646 (Final Rule implementing Stark law advisory opinion process).

<sup>64</sup> See, 42 U.S.C. § 1320a-7b.

financial risk of the investor.<sup>65</sup> The OIG sent the advisory opinion to every provider of health care services in the Medicare program as a warning to those engaged in abusive self-referral arrangements.<sup>66</sup>

### **b. Joint Venture Ambulatory Surgical Treatment Center Advisory Opinion**

Under Stark, HCFA issued an advisory opinion that interpreted the rural provider exception of Stark II as applied to an ambulatory surgical treatment center (ASTC). ASTC investors requested advice on whether or not a proposed joint venture violated Stark. HCFA found that an ASTC that planned to offer investors up to 49 percent of the company's interest in profits, losses, and cash flow, in exchange for capital contributions, created an ownership or investment interest.<sup>67</sup> Therefore, Stark prohibited the arrangement unless it fit within an exception. HCFA found that the rural provider exception applied. The rural provider exception requires that services provided by the proposed ASTC actually be furnished in a rural area and that substantially all of the services furnished by the ASTC be furnished to individuals

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<sup>65</sup> Investors should not be chosen because they are in a position to make referrals or based on their capacity to make referrals. Divestiture of a physician's interest based on the failure to make referrals or for moving out of the practice area are indicators of a violation of the anti-kickback statute. If the joint venture tracks sources of referral and distributes this information to investors, the arrangement may be suspect. Business structures that are only shell joint ventures for the purpose of covering for kickbacks for referrals are not allowed. If the amount of capital invested by the physician is disproportionately small and the returns on investment disproportionately large when compared to the typical investment, the financing and profit distribution or disproportionate returns in comparison with financial risk makes the venture suspect for violation of the fraud and abuse statute.

<sup>66</sup> *Medicare Physician Referral Laws: Testimony Before the Subcommittee on Health of the House Committee on Ways and Means*, 1999 WL 304835 (1999)(statement of D. McCarty Thornton, Chief Counsel to the Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services).

<sup>67</sup> HCFA-AO-98-001. OBER KALER, HEALTH LAW ALERT, Fall 1998/Winter 1999.



residing in the rural area.<sup>68</sup> HCFA decided that this ASTC satisfied the rural provider exception. Therefore, because the rural provider exception covered this ASTC, any physician, including a non-surgeon physician investor, could refer patients to the ASTC without violating Stark.

### **c. Referrals for Eyeglasses Following Cataract Surgery Advisory Opinion<sup>69</sup>**

Ophthalmologists and physicians proposed to form a partnership to provide eyeglasses to their patients following cataract surgery with intraocular lens implants.<sup>70</sup> Technically, the referral of a patient to a partnership in which the referring physician is a partner is a prohibited self-referral under Stark. It is a prohibited self-referral because the physician has an investment interest in the partnership and has a compensation arrangement with the partnership to which the physician is referring patients. However, HCFA approved the proposed partnership. HCFA determined in the advisory opinion that the partnership qualified as a group practice<sup>71</sup> and determined that the arrangement would satisfy the in-office ancillary service

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<sup>68</sup> A rural area is any area that is not an urban area. An urban area is an area within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or an area recognized as urban by regulation. The area of the proposed ASTC was considered a rural area because it was not listed as an urban area. HCFA referenced the Stark II proposed regulations to define 'substantially all' as 75%. HCFA clarifies that the substantially all requirement is an ongoing requirement in order to remain within the rural provider exception. *Id.*

<sup>69</sup> HCFA-AO-98-002. OBER KALER, HEALTH LAW ALERT, Spring/Summer 1999.

<sup>70</sup> Although not relevant to the self-referral issue, the partnership will also provide services to non-patients. *Id.*

<sup>71</sup> In order to determine whether the proposed partnership qualified as a group practice, HCFA analyzed the five key elements of the definition of group practice, including: 1) does each member of the group provide substantially the full range of services, 2) will substantially all (75%) of the members' services be provided through the group and billed by the group, 3) will overhead expenses and income from the practice be distributed in accordance with methods determined prior to the time period the group has earned the income or incurred the cost, 4) will no physician member be compensated directly or

exception.<sup>72</sup> Additionally, HCFA utilized the proposed Stark II regulations, although they do not yet have the force of law, when analyzing this issue because “it reflects [HCFA’s] current interpretation of the law.”

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indirectly based on the volume or value of referrals and, 5) will members of the group, physician owners and employees, provide at least 75 percent of the physician patient encounters. *Id.*

<sup>72</sup> First, the services of the group would be furnished or directly supervised by the referring physician or by a member of the same group practice. Second, the services would be furnished in a location where the group practice provides services unrelated to designated health services or a broader range of services than those considered to be designated health services or if the designated health services are furnished in another building that is used by the group for the centralized provision of designated health services. And, third, the services would be billed under the group practice’s group billing number. *Id.*

#### **IV. DIFFICULTIES AND UNINTENDED CONSEQUENCES OF STARK**

Even though Stark has substantially succeeded in prohibiting health care arrangements that allow self-referral and lead to over-utilization and inappropriate medical care, a number of concerns and unintended consequences for health care providers resulted from its application. These problems are created by specific unintended consequences, the problem of complexity, adverse effects on appropriate health care arrangements, and overzealous prosecution.<sup>73</sup>

##### **A. A Specific Example of Unintended Consequences**

One of many examples of Stark's unintended and negative consequences involves Extracorporeal Shock Wave Lithotripsy (ESWL). ESWL is one of the most effective and widely used urology services for the non-invasive treatment of kidney stones. At the time of its introduction in 1984 many hospitals were unable to purchase the extraordinarily expensive machinery. As a result, urologists created joint venture facilities to raise capital to purchase this equipment. ESWL is considered by HCFA to fall within a designated health service and self-referral is prohibited unless excepted by the statute. As such, physicians may not be able to treat patients at the facility in which they have a financial interest. This causes disruptions for patient access by forcing patients to travel to another facility not owned by the physician. In some states, the patient may actually have to travel outside of the state to receive this care. Continuity of care may also be compromised if the physician cannot easily follow the

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<sup>73</sup> See generally, AMERICAN HEALTH LAWYERS ASSOCIATION. FRAUD AND ABUSE: DO CURRENT LAWS PROTECT THE PUBLIC INTEREST? A Report on the 1999 Public Interest Colloquium Held January 29-30, 1999. Washington, D.C.

patient. Further, non-urologist owned facilities could become flooded with Medicare and Medicaid patients, creating delays of service for only one category of patients, thereby creating a two-tiered health care system.<sup>74</sup>

Because this form of raising capital is inhibited by Stark, the law may actually compromise access to health care.<sup>75</sup> Patient access may be compromised if a physician cannot refer a patient or is afraid to refer a patient to the best provider merely because a questionable financial relationship may lead the physician to believe that that referral may be prohibited. Physicians may also be prohibited from bringing the latest technology to their patients if no other investors are available.

## **B. The Problem of Complexity**

The law is complex and difficult to interpret.<sup>76</sup> Although Stark meant to be a “bright line” test to determine acceptable conduct, many of its terms are broad or ambiguous. In addition, the voluminous regulations designed to clarify the law only compound the problem. Even prominent lawyers in the field of health care fraud and

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<sup>74</sup> Another example involves new therapies such as those to treat benign prostatic hyperplasia, or enlarged prostate, which could be in jeopardy by self-referral prohibitions. The equipment needed to treat this disease requires a large capital investment. A joint venture would inevitably be required to establish a facility, but Stark would prevent many potential investors from joining in the venture and potentially prohibit the venture from occurring. Accordingly, no treatment for certain diseases in certain areas of the country will be available. *Id.*

<sup>75</sup> The law alters the natural state of market competition. The law allows designated health services to compete on the basis of cost and services rather than on the basis of whether a financial relationship exists with the referring provider. However, it may be harmful to prevent referring physicians from entering their health care market as competitors because access and quality of care may suffer. If these providers are allowed to enter the market as competitors and self-referral is allowed, it would prevent competitors from entering the market because there would be no business to acquire.

<sup>76</sup> Duplicity of laws creates further complexity, which is not discussed by this paper. If a provider complies with the anti-kickback law, which is apparently more strict than Stark, the provider may not be in compliance with Stark. It is very difficult to ensure that an arrangement satisfies each fraud and abuse law.

abuse find Stark extremely ambiguous and confusing.<sup>77</sup> The exceptions and regulations are so vast and puzzling that a bright line no longer exists. Providers spent six years without guidance from HCFA. During the six years, many activities began that now would be prohibited and many activities that would have been useful were not begun. It is not clear if lawyers will be able to give providers clear and unqualified advice to enable providers to comply with the law.

The laws on fraud and abuse are so confusing that two lawyers charged with fraud and abuse violations because of advice to their clients regarding how to operate under health care fraud and abuse laws were later exonerated.<sup>78</sup> The absolving judge criticized the complexity of the health care fraud laws by stating that “no reasonable jury could find beyond a reasonable doubt that the lawyers willfully committed any of the criminal acts charged in the indictment.” The court found that the law was in a state of flux and that the lawyers had adapted their advice as the law changed in an attempt to facilitate legal transactions. However, charges still stand in the matter against two doctors and three former hospital executives.<sup>79</sup>

The government contends that the laws cannot possibly be confusing because 89 percent of audits were found to be unwarranted. They argue that this high rate of compliance leads to the conclusion that providers are able to comply with the law. However, it is possible that 89% of audits are unwarranted not because of compliance but merely because normative physician behavior is adverse to self-referral. In other

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<sup>77</sup> *Medicare Physician Referral Laws. Testimony Before the Subcommittee on Health of the House Committee on Ways and Means.* 1999 WL 304837 (1999)(statement of Sanford V. Teplitzky, Partner Ober, Kaler, Grimes & Shriver).

<sup>78</sup> All defendants were indicted for conspiracy to solicit and pay bribes of \$2 million and for making false claims for referring nursing home patients to certain hospitals.

words, the 11% of ‘warranted audits’ may not be due to an overt failure to comply, but rather the result of positive attempts to alter the health care environment without understanding the complexity of the government prohibition on certain self-referral arrangements.

### **C. Adverse Effects on Appropriate Health Care Arrangements**

As health care transactions and relationships become more complex and sophisticated, it is not always clear when Stark applies or whether Stark’s protection is necessary.

Medical practice is becoming increasingly complex as more cost effective and efficient health care arrangements, such as managed care, emerge. Managed care reduces the opportunity for physicians to make referrals based on personal gain.<sup>80</sup> These complex arrangements are designed to realize cost-effective care and may cause no self-referral concerns, but none-the-less remain questionable under Stark.

Stark fails to adequately address the complexity of relationships among providers and sometimes applies in an ambiguous manner to particular types of business arrangements. The law was written at a time when most providers organized as independent practitioners instead of today’s group practices and most entities were not part of a health care system. The intent of the law was to make it more difficult to structure business relationships in the health care environment and it has succeeded because questionable joint ventures are much less common today. However, the

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<sup>79</sup> *United States v. Anderson*, No. 98-20030 (D. Kan. 1998)

statute may prohibit arrangements that would not cause concerns over self-referral, such as those depicted in the specific examples, discussed supra. Further difficulty is created in attempting to apply Stark to complex corporate structures in light of OIG's policy of collapsing complex corporate structures.<sup>81</sup>

Many complex health care business structures are difficult to create and utilize under the current law.<sup>82</sup> The law may be impeding efforts to create more efficient initiatives that provide the same or better quality of care. Integrated organizations such as a joint venture PHO in which a hospital and a group of physicians are equal partners create issues of self-referral violations. The PHO is generally organized to negotiate and administer managed care contracts. At first glance, participation in a PHO appears to present no issue because no relationship exists between the physicians and the hospital whereby physicians would be referring patients to an entity in which the physician had a financial interest. However, the hospital's large capital investment and low risk of financial loss may lead to fraud and abuse issues if it can be shown that there is an indirect form of illegal remuneration to physicians when the physician refers a patient to the partner hospital. It is uncertain whether this is covered exclusively under the anti-kickback statute or additionally under Stark.

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<sup>80</sup> *Medicare Physician Referral Laws. Testimony Before the Subcommittee on Health of the House Committee on Ways and Means*. 1999 WL 304870 (1999)(statement of The Honorable William M. Thomas, Chairman).

<sup>81</sup> For example, complex relationships involving PHOs or other marketing entities or MSOs employing physicians and leasing physician practice space generally engage in business purposes with no perception of referral inducement but may be considered within the referral scheme if they are part of the corporate structure that is involved in the referrals.

<sup>82</sup> Leonard C. Homer, *How New Federal Laws Prohibiting Physician Self Referrals Affect Integrated Delivery Systems*, 11 HEALTH SPAN 21 (April, 1994).

#### **D. Law Enforcement in Health Care**

Overzealous prosecution creates an unsuitable environment for health care providers because they live in fear that a simple mistake may trigger an investigation or even prosecution. Unclear laws and regulations leave providers in constant confusion over whether they are complying with the law. Prosecutorial discretion makes compliance difficult because each investigator interprets and applies the law differently. Also, many investigators interpret and apply the law in a different manner than health care providers who attempt to work within the ever-changing framework of health care. Providers are required to expend money and time to undertake compliance efforts and often are afraid to contest allegations because the penalties can be so high.

Prosecutorial problems are in part due to the astounding number of government groups (more than fifteen) that are assisting in the investigation of health care fraud and abuse.<sup>83</sup> Each group competes for political status and funding by seeking to enforce health care fraud and abuse.

However, it appears that the concern about overzealous prosecution may be, for the most part, rhetoric. No case has ever been successfully brought under Stark, only a few dozen providers faced criminal sanctions under the anti-kickback statute and the government has assured providers in writing that innocent business mistakes will not be prosecuted. However, some believe it is clear that the investigatory body,

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<sup>83</sup> These groups include: Congress, Department of Health and Human Services, Healthcare Financing Administration, Office of Program Integrity, Office of Inspector General, Department of Justice, Federal Bureau of Investigation, Medicare contractors, Peer Review Organizations, Department of Labor, Department of Veteran Affairs, Department of Defense, State Attorneys General, Medicaid



or group of bodies, must be simplified and communication must be increased between these groups in order to ensure a streamlined and understandable enforcement mechanism. Simplification is necessary because even though no case has ever been successfully brought under Stark, enforcement still continues.

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Fraud Control Units, private payors, and private citizens. Further, a new Health Integrity and Protection Data Bank will collect and store information on fraud and abuse enforcement actions.

## V. PROPOSED CLARIFICATIONS TO STARK

### A. Proposed Stark II Regulations

HCFA plans to issue final regulations (otherwise known as rules) based on Stark II by May of 2000.<sup>84</sup> The rules were first proposed on January 9, 1998 and attempt to make it easier for physicians to work in an integrated health system. HCFA is currently reviewing the more than 12,800 comments received on these proposed regulations.<sup>85</sup> Although the proposed regulations are meant to clarify the law and create more flexibility, they are nearly four hundred pages long and reflect the complexity of the self-referral prohibitions they are meant to clarify.<sup>86</sup>

#### 1. Discussion

The proposed rules clarify and define many terms used in the Stark legislation.<sup>87</sup> Footnote 87 gives an example of seven definitions and clarifications of

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<sup>84</sup> Medicare and Medicaid Programs; Physicians; Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659 (1998)(to be codified at 42 C.F.R. pt 411, 424, 435, and 455)(proposed January 9, 1998).

<sup>85</sup> See generally, Andrew B. Wachler & Phyllis A. Avery. *Stark II Proposed Regulations: Rule Offers Additional Guidance While Regulators Seek More Input From Health Care Community*. THE HEALTH LAWYER. January 1998; NHLA/AAHA. *Spotlight on the Stark II Regulations*. HEALTH LAWYERS NEWS. February 1998; JOANNE SINSCHMEIMER & SANFORD TEPLITZKEY. AMERICAN HEALTH LAWYERS ASSOCIATION. FRAUD AND ABUSE: COMPLIANCE AND ENFORCEMENT. October, 22-23, 1998. Arlington, VA.

<sup>86</sup> *Medicare Physician Referral Laws. Testimony Before the Subcommittee on Health of the House Committee on Ways and Means*. 1999 WL 304833 (1999)(statement of Kathleen A. Buto, Health Care Financing Administration).

<sup>87</sup> See e.g., Entity: Entity means any entity that provides designated health services, without qualifications or limits. A physician or group of physicians is referring to an entity even when they are referring to, or among, themselves. These types of self-referrals must meet an exception, such as the personal service exception or the in-office ancillary service exception. Medicare and Medicaid Programs; Physicians; Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659, 1685 (1998)(to be codified at 42 C.F.R. pt 411, 424, 435, and 455)(proposed January 9, 1998).

- Financial Relationship: The term financial relationship is clarified. A referral alone does not create a financial relationship. *Id.* at 1686. The rule clarifies that indirect financial relationships of any degree

words used in Stark II. This paper briefly discusses several regulatory clarifications regarding various Stark exceptions, including group practice, in-office ancillary services, durable medical equipment, prepaid plan, personal services, and provision of designated health services exceptions are outlined. In addition, three new compensation arrangement exceptions are discussed. Finally, reporting, sanction and advisory opinion clarifications are mentioned.

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are covered by the rule just as direct financial relationships are. In other words, if a physician refers a patient to an entity for the provision of services that will be referred out to an entity in which that physician has an ownership or investment interest, Stark will be violated. This interpretation fulfills the intent of the statute in preventing physicians from evading the prohibition by establishing holding companies rather than investing directly in the entity furnishing the designated health service. In short, “the number of layers of ownership is irrelevant, as long as the physician or family member has established an indirect interest.” Further, payment received as a return on an investment is not compensation prohibited by the Act. *Id.* at 1687.

- Referral: The rule clarifies the definition of referral, which is now defined as the request by a physician, directly or through a plan of care, for a designated health service for which payment may be made under Medicare or Medicaid, including the request for a consultation with another physician and any test or procedure ordered by, or to be performed by or under the supervision of that other physician. *Id.* at 1692.

- Service: The term ‘service’ is now used in place of ‘services and items,’ and the term ‘service’ includes ‘items.’ *Id.*

- Remuneration: The rule revises the definition of remuneration to meet the requirements of the statute. Remuneration does not include fee for service payments made by an insurer to a physician, so long as they meet the requirements of the statute and do not take into account other business generated by the parties. *Id.*

- Fair Market Value: The term fair market value is used in most of the compensation-related exceptions. Most of the compensation discussed must be based on the fair market value, consistent with the general market value. General market value is defined by the rule as “the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement.” *Id.* at 1686.

- Volume or Value of Referrals: The rule clarifies that anywhere the statute refers to the ‘volume or value of referrals,’ HCFA will also evaluate business generated between the parties. Although arrangements predicated on the volume or value of referrals are prohibited, a physician can on his or her own or at the request of a patient refer patients within a network as long as compensation is not directly predicated on the volume or value of referrals to in-network providers. *Id.* at 1699.

## 2. Group Practices

HCFA's regulation construed Stark's group practice requirements contained in the physician service and in-office ancillary service exceptions.<sup>88</sup> The regulations prevent many groups from joining together for the sole purpose of taking advantage of the exceptions.<sup>89</sup> The regulations also require that each member of a group provide substantially the full range of patient care services that the individual physician routinely furnishes. The definition of patient care services is broadened by this rule.<sup>90</sup> For example, substantially all patient care services must be furnished through the group and be billed under a billing number assigned to the group.<sup>91</sup> The definition of member is expanded to include all owner physicians, regardless of their ownership interest, and employee physicians.<sup>92</sup> Under the proposed rule, independent contractors

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<sup>88</sup> To qualify as a group, physicians must be legally organized as one legal entity. However, the group may contain physicians who are individually incorporated and provide services to group patients because this is not a conglomeration of multiple physician groups but is rather a true group practice. Also, as a practical matter, the group practice may now bill with more than one billing number and still qualify as a group practice, so long as the billing numbers used are assigned to the group. This acknowledges that group practices with many different locations may bill separately. *Id.* at 1687.

<sup>89</sup> *Id.* at 1687.

<sup>90</sup> It includes any patient care tasks including tasks that address the medical needs of patients in general or that generally benefit the practice. This can include time spent training staff, arranging for equipment or performing administrative or management tasks, but not teaching in a medical school or doing outside research. This requirement ensures that the physician member is actually practicing medicine and not simply part of the group so that the group will qualify for the exception while acknowledging that physicians can furnish other kinds of services than just patient care. Accordingly, time spent performing these tasks will count toward the calculation of patient care services time. But if a physician spends patient care time in another setting, that will count toward the time spent providing patient care time for the group. *Id.* at 1688.

<sup>91</sup> Substantially all of the physician-patient encounters must occur between owner or employee physicians and patients. "Substantially all" means that at least 75% of the patient care services (as defined supra) must be personally conducted by a member of the group. The proposed rule outlines some guidelines in calculating the 75% limit. In sum, at least 75% of all patient care services, must occur between owner or employee group physicians and patients, and not provided by non-members of the group. The ban against payments based on volume or value of referrals would remain, but a bonus or profit sharing based on services personally performed would be allowed. In determining who is a group member when making 75% determinations, independent contractors will not count as qualifying group members. This assists the group in meeting the substantially all requirement by excluding specialist contractors who may spend a small amount of time providing group patient care services. *Id.*

<sup>92</sup> *Id.* at 1687, 1689.

no longer qualify to directly supervise in-office ancillary services.<sup>93</sup> Also, the group may use a management service organization to administer billing for the group, as long as the arrangement satisfies a separate regulation.<sup>94</sup> The distribution of overhead and expenses requirements section of the regulation provides that overhead expenses and practice income must be distributed in accordance with methods that are “previously determined” and follows an established plan indicating that the group is a unified business.<sup>95</sup>

### 3. In-Office Ancillary Services Exception

The in-office ancillary service exception section of the statute establishes that direct supervision means that the physician must be present in the office suite in which the services are being furnished, at the time they are being furnished.<sup>96</sup> The term “direct supervision” is construed so narrowly that even simple in-office lab services performed by technicians would not qualify as an in-office ancillary service if performed during periods before or after the physician’s regularly scheduled office

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<sup>93</sup> *Id.* at 1689.

<sup>94</sup> *Id.*

<sup>95</sup> “Previously determined” is as determined prior to the time period during which the group has earned the income or incurred the costs. The group must have an established plan rather than distributing on an ad hoc basis. Distribution must be made in a manner that indicates that the practice is a unified business, reflecting centralized decision making, pooling of expenses and revenues, and a distribution system that does not treat each satellite office as if it were a separate enterprise. Distribution of profits or compensation cannot be made based on volume or value of referrals, but a physician can receive a portion of the pooled profit as long as the physician’s portion is not determined using information regarding the volume or value of that physician’s referrals or the volume or value of designated health services performed. Profit may be distributed based on an investment interest, number of hours worked or difficulty of work. Productivity bonuses based on services personally performed, but not based on the volume or value of any referrals, are allowed. Profits from services other than designated health services may be distributed in any way the group sees fit. *Id.*

<sup>96</sup> Although the physician must actually be physically present, the physician will be considered present during brief and unexpected absences as well as routine absences of short duration. If the physician is only available by phone or is only physically present somewhere in the building, the in-office ancillary

hours, or when the physician is out doing hospital rounds or providing care in an outpatient clinic or another suite within the same building. The rule indicates that in-office ancillary services are those that are integral to the physician's own practice and conducted within his or her own sphere of activity and not a service that is a separate profit-making enterprise.<sup>97</sup> The rule also narrowly defines the same location requirement of the in-office ancillary service exception. Same building means one physical structure, with one address and not connected by tunnels or walkways. The same location requirement does not permit mobile structures that can be utilized near the building, such as mobile x-ray vans.<sup>98</sup> Further narrowing is found where the regulation provides that a service is actually furnished where the procedure is actually performed on a patient or at the location in which the patient receives and begins using the ancillary service. Under this rule, services given to a patient to be used at home or outside the physician's office have not been furnished in the physician's office and, therefore, would not qualify for the in-office ancillary service exception.<sup>99</sup>

#### **4. Durable Medical Equipment Exceptions**

The rule provides that the in-office ancillary service exception does not apply to durable medical equipment, other than infusion pumps, or to parenteral and enteral

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service exception will not apply. The physician must be otherwise scheduled and ordinarily be expected to be present. *Id.*

<sup>97</sup> *Id.* at 1684.

<sup>98</sup> The group practice can meet an alternative centralized location requirement if the location provides designated health services for more than one group office in one or more centralized locations. The group, however, would have to have a physician member present to perform or directly supervise the designated health service. *Id.*

<sup>99</sup> *Id.* at 1695 – 1696.

nutrients, equipment, and supplies.<sup>100</sup> Although crutches are considered durable medical equipment, the regulations add crutches to the in-office ancillary service exception. The rule was created because it would be inconvenient for the patient to have to obtain crutches elsewhere after having a bone cast at the doctor's office. Further, the physician is not expected to see a profit from the crutches.

### **5. Prepaid Plan Exception**

The prepaid plan exception is interpreted in a way that attempts to safeguard against abuse while facilitating the evolution of integrated delivery and other health care delivery systems. The exception applies to health maintenance organizations and other prepaid medical plans that have a contract with Medicare even if these organizations do not furnish services directly. The rule proposes to create an additional exception for services provided by analogous Medicaid organizations. However, no exception is created for hybrid systems, typically those utilizing both fee-for-service and capitated billing, because there is no guarantee that all of these systems minimize the risk of patient or program abuse.<sup>101</sup> Although capitated payments may prevent over-utilization, fee-for-service billing allows a physician to increase revenue every time a referral is made.

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<sup>100</sup> *Id.* at 1675.

<sup>101</sup> These hybrid plans, such as preferred provider organizations and physician hospital organizations, would normally find an exception under the personal services exception so that referrals within the organization would be allowed. *Id.* at 1697.

## **6. Unrelated Remuneration Exception**

The new rule clarifies the exception for remuneration unrelated to the provision of designated health services and narrows it. The rule states that the exception does not apply to remuneration from entities other than hospitals and does not apply to payments to a physician's family member. The remuneration must not in any direct or indirect way involve a designated health service or relate to the volume or value of referrals for designated health services. For example, a physician may be paid a rental fee for allowing visiting faculty to use the physician's residence or the physician might receive compensation for teaching or providing utilization review or administrative services. The physician may not be paid for technology developed by the physician because that technology might be used in the furnishing of a designated health service. The hospital may not provide malpractice insurance or other general costs that enable the physician to provide a designated health service.<sup>102</sup>

## **7. New Compensation Arrangement Exceptions**

Three new compensation arrangement exceptions are created by the rule. First, a discount exception is created whereby discounts to physicians that are passed on in full to the patient or the patient's insurer would be exempt if the referring physician retained no benefit. The discount is allowed if in "an arm's length transaction an entity offers it to all similarly situated individuals, regardless of whether they make

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<sup>102</sup> *Id.* at 1702.



referrals to the entity, the discount does not reflect the volume or value of any referrals and the discount is passed on to Medicare or other insurers.”<sup>103</sup>

Second, a new fair market value exception covers any compensation arrangements between a physician or a family member or group of physicians if the agreement meets certain criteria.<sup>104</sup> This exception attempts to recognize compensation arrangements that are legitimate and commercially reasonable without taking into account the volume or value of any referrals. In other words, this exception is designed to exempt many financial arrangements involved with integrated delivery systems that have been difficult to realize because of Stark.<sup>105</sup>

Third, a new *de minimis* compensation exception is proposed for *de minimis* compensation of less than a \$50 value per gift, \$300 year aggregate, including free samples, training, free coffee mugs, or pens, etc.<sup>106</sup> as long as the compensation is available to all similarly situated individuals regardless of whether they would refer and the compensation does not take into account the volume or value of any referrals.<sup>107</sup>

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<sup>103</sup> *Id.* at 1693.

<sup>104</sup> The criteria include a written agreement covering all items and services to be provided specifying the period of time the arrangement is effective, specifying the compensation that will be provided consistent with the fair market value, explaining the commercial reasonableness of the transaction and the legitimate business purpose that is furthered by the arrangement, and that the arrangement is in compliance with the anti-kickback laws. *Id.*

<sup>105</sup> *Id.* at 1699.

<sup>106</sup> Cash equivalents, such as gift certificates, stocks or bonds, and airline frequent flier miles, do not qualify. *Id.*

<sup>107</sup> *Id.*

## 8. Reporting, Penalties, and Agency Authority

The regulations simplify the Stark reporting requirements.<sup>108</sup> Physicians will no longer be required to submit the amount of information they were previously required to submit under Stark I regulations. Physicians need only keep on file the kind of information that they would normally maintain to meet Internal Revenue Service, Securities Exchange Commission, and other Medicare and Medicaid rules. HCFA feels this would be sufficient to prove compliance with the self-referral laws.

In addition, the sanctions are changed. The rule limits the sanctions applicable to wrongful referrals involving Medicaid beneficiaries. The only sanction applicable to a Medicaid provider is that the Act prohibits the payment of federal funds to a state for services furnished pursuant to a prohibited referral. States must impose their own sanctions in situations where state law should prevail.

Lastly, HCFA advisory opinion authority is clarified. Advisory opinions can be requested from HCFA to determine whether a referral relating to a designated health service is prohibited under Stark. Stark II regulations provide that no advisory opinion will be issued on whether the fair market value is being paid or whether an individual is a bona fide employee. Making individualized determinations of this kind would be too burdensome.

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<sup>108</sup> *Id.* at 1703 et seq.

## **B. Proposed Legislation**

Congress introduced two bills in Congress in an effort to modify and clarify Stark II. The Thomas bill relaxes the self-referral prohibition and the Stark bill maintains, updates, and clarifies the self-referral prohibition.<sup>109</sup>

### **1. Thomas Bill**

Rep. Bill Thomas (R. Cal.) introduced the Physician Self-Referral Amendments of 1999.<sup>110</sup> The bill eliminates the prohibition on referrals based on compensation arrangements. Rep. Thomas is concerned with HCFA's difficulty in enforcing the Stark self-referral laws. He believes that doctors are the best protectors of quality health care and are adequate to ensure that Medicare patients get the care they need. Physicians, he believes, are an effective tool in the fight against fraud and abuse.<sup>111</sup> Thomas would make ownership or investment interest the sole criteria for barring referrals, thus deleting the confusing compensation arrangement exceptions. The Thomas bill would repeal the site of service requirement of the in-office ancillary service exception. Thomas does not believe that the site-of-service requirement serves any purpose in combating fraud. Thomas would also modify the physician supervision requirement for ancillary services. An individual is considered to be under the "general supervision" of a physician if the physician is legally responsible for the services performed by the individual and for ensuring that the individual meets licensure and certification requirements, if any, regardless of whether or not the

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<sup>109</sup> A summary of the Thomas and Stark bills is attached as Table II.

<sup>110</sup> 1999 Cong. U.S. HR 2651.

<sup>111</sup> CCH MEDICARE AND MEDICAID GUIDE, No. 1069 p.3 (1999).

physician is physically present when the individual furnishes the item or service.<sup>112</sup>

Implementation of the Thomas bill would not be allowed until final regulations were promulgated.

## **2. Stark Bill**

Rep. Stark criticizes the Thomas bill as an attempt to repeal the heart of the physician self-referral law. Stark is concerned that the Thomas bill encourages the type of abuse by doctors that the Stark law was enacted to rectify and prevent. Stark fears a return to the days when self-referral cost Medicare hundreds of millions of dollars and diminished the trust implicit in the doctor-patient relationship. Stark called the Thomas bill “pro-fraud” with the potential to increase Medicare spending by \$500 million dollars over seven years.

Stark introduced his own legislation entitled the Medicare Physician Self-Referral Improvement Act of 1999.<sup>113</sup> The bill creates an expansive fair market value exception for providers who have compensation relationships with entities to which they refer. The exception allows compensation arrangements unless payment to the provider exceeds the fair market value.

Similar to Thomas’s bill, the Stark bill indicates that direct supervision of in-office ancillary services will no longer be required so long as the physician or group member assumes full and direct legal, financial, and professional responsibility for the

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<sup>112</sup> The bill defines member of a group practice as an owner or bona fide employee, or both, in a purported effort to prevent HHS from regulating the definition. Intraocular lenses, eyeglasses, and contact lenses are excluded from the designated health service of prosthetics, orthotics and prosthetic devices, and supplies. Pathologists who supervise or direct the provision of clinical laboratory services for a group practice are deemed to be members of such group practice. *Id.*

services that are provided and for those who provide these services. Also, the prepaid plan exception is expanded to include Medicaid managed care organizations.

In addition, Stark's bill adds four new general exceptions for capitated payments, communities with no alternative providers, ambulatory surgical centers, and hospice. The prohibition on self-referral does not apply if a designated health service is included in the services for which a physician or group is paid only on a capitated basis by a health plan or insurer pursuant to a written arrangement. The bill does not prohibit a referral for a designated health service furnished in any area where it is determined that the individuals residing in the area do not have reasonable access to such designated health services. Also, the bill does not prohibit referrals for designated health services furnished in ambulatory surgery centers or by a hospice program.

The compensation arrangement exception section is replaced in the Stark bill. The Stark law requires that a compensation arrangement fit within one of nine exceptions in order to be legal. The bill replaces the nine compensation arrangement exceptions with a general exception and two additional exceptions for certain arrangements. The general exception requires the following eight criteria for permissible compensation arrangements: 1) in writing, 2) signed, 3) for a specified period of time, 4) covering all of the services to be provided or incorporating by reference any other arrangements, 5) consistent with fair market value, 6) specifying the compensation to be provided set in advance not determined in a manner that takes

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<sup>113</sup> 1999 Cong. U.S. HR 2650.

into account the volume or value of any referrals, 7) that is commercially reasonable, and 8) furthers the legitimate business interests of the parties.

Two specific arrangements are excepted from the prohibition on compensation arrangements under the Stark bill: physician recruitment and *de minimis* payments. Remuneration provided to induce a physician to relocate to the geographic area served by a hospital in order to become a member of the hospital's medical staff is not a compensation arrangement under the Act. Under this exception, the physician must not be required to refer patients to the hospital. In addition, the arrangement must not take into account the volume or value of referrals. Under the *de minimis* payment exception, remuneration for items or services not exceeding \$50 per gift or \$300 per year that does not take into account the volume or value of referrals will not be considered a compensation arrangement.

## VI. CONCLUSION AND RECOMMENDATIONS

Congress enacted the prohibition on self-referral to control over-utilization and protect the best interests of the patient by limiting referrals to entities in which a physician has a financial interest. However, there are legitimate reasons that a provider might have a financial interest in such entities. These reasons include 1) ensuring that quality and continuity of care is provided, 2) providing a necessary but unavailable service to the community, and 3) ensuring that care is provided in a cost-efficient manner.<sup>114</sup> However, the problems of a physician making a decision based upon financial incentives rather than best medical practice, as discussed in this paper, must be addressed. The law must reduce potentially harmful incentives of physician financial interest while preserving the benefit of such interests. In addition, the development of efficient health care arrangements must be addressed and encouraged.

One answer is to allow the health care market to evolve on its own. However, the health care market will not control itself. Consumer choice is not an appropriate vehicle by which to control health care referrals because the consumer is not in a position to make an informed choice about where to have services performed. Consumers do not have enough information to make this type of decision. Even if such information was available, the consumer is not in a position to evaluate and make decisions based on this information. In addition, the patient's concerns focus on whether they can be diagnosed, treated, and cured rather than on the efficacy of the referral.

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<sup>114</sup> *Fraud in Medicare Programs. Testimony Before the Senate Government Affairs Permanent Subcommittee on Investigations*. 1997 WL 360721 (1997)(statement of Pamela H. Bucy, University of Alabama School of Law).

The current law and regulation does not realize an optimal balancing of these competing considerations. In addition, it has created many concerns and unintended consequences that must be addressed. As Senator Stark stated, “Stark’s original concern was with referrals outside the doctor’s office where the doctor merely sat back, having nothing to do with the quality of services, and waited for the distribution checks to roll in.” The law must play a role in ensuring that medical decisions are based on what is best for the patient and not what is best for the physician. On the other hand, health care must be allowed to evolve toward a more efficient system and physicians should not be prevented from providing better care merely because of the potential for a conflict of interest.

The concern and solution should focus on quality care and not only pecuniary interest. For example, group practice members often refer exclusively within their group. Under the current law, this is allowed, but the patient is probably not receiving care from the most appropriate provider, rather the provider that can retain the most profit for the group. Considering the importance of self-determination in health care, this is not the most appropriate method of referral. Further, even though profit is maximized for the group, there is no evidence that any savings occurs for the health care system or that there is any increase in the quality of care for the patient. Therefore, the problem is not self-referral in a vacuum but rather self-referral that is increasing costs while decreasing quality of care.



## **Proposed Law Against Self Referral**

The following is the author's proposal to clarify and simplify Stark I and II.

The proposal attempts to prevent the over-utilization that leads to increased health care cost while allowing the health care system to evolve and protecting the quality of patient care.<sup>115</sup> Like Stark, the proposal prohibits self-referral schemes unless they fit within an exception. However, the exceptions are vastly different than Stark. More specifically:

A physician may not make a referral to an entity for the furnishing of any health care service and the entity may not cause to be presented a claim for the service if the physician or immediate family member has an ownership or investment interest in that entity different than that available to the general public or receives compensation from that entity greater than the fair market value, unless one of the following is satisfied:

- 1) the physician directly provides or directly supervises the provision of the health care service; or
- 2) the referral is to or from another member of the referring physician's group practice and;
  - a) the group does not require referral to another group member or penalize for referrals outside the group and,
  - b) the patient is offered referral to an appropriate provider outside the group, if available and,
  - c) the group maintains and reports data to the Board, established infra, on the percent of patients referred within the group and the percent of patients referred outside the group. If the group refers less than **[40%]** of patients outside the group, exclusive of those patients enrolled in a plan that requires the provision of care within the group, an audit will result to ensure compliance with a and b; or
- 3) there is a demonstrated need for the entity and no alternative investors exist
  - a) the burden is on the proposed investor to identify and notify all alternative investors within the area where care will be provided and all known investors outside that area.
  - b) an alternative investor is one who will not refer to the entity; or

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<sup>115</sup> Unless otherwise noted, terms are defined as defined in Stark II regulations.

- 4) the referring health care provider receives prior approval from the federal Fraud and Abuse Board, which shall be established to perform the functions required by this Act.
  - a) Approval will be granted if the Board finds that there is no chance of abuse of overutilization and no chance of a decrease in quality of care caused by referrals to the entity.
  - b) Approvals and denials must be thoroughly documented in a written decision by the Board and, unless otherwise altered by Congress or by the Board in future decisions, each decision is binding authority for future referral arrangements.
  - c) Documentation must be provided to the Board for any arrangement that is created in reliance on a prior documented approval.
  - d) If an arrangement is approved or relies on a prior approval, every referring physician or the entity must annually report the amount of income from the entity and the value and volume of referrals to that entity. The Board may request a hearing on the issue of whether overutilization or a decrease in quality of care is occurring or has occurred from the approved arrangement. If the Board determines by a preponderance of the evidence that there is abuse, the Board may revoke approval for the referral arrangement. If referrals continue after approval is revoked, sanctions may be implemented. The Board may waive the reporting requirements if the Board deems it appropriate.
  - e) In addition, the Board shall cause random audits to be made of health care providers to ensure compliance with this Act. The Board shall promulgate regulations to fulfill this requirement and must delegate this audit function to a private entity if it is more efficient.
  - f) The Board shall have exclusive jurisdiction to investigate, prosecute, and adjudicate self-referral issues.
  - g) The petitioning party has the burden to prove by substantial evidence all elements necessary to attain approval by the Board.
  - h) The Board shall be composed of two physicians, two OIG personnel, and one independent consumer as chosen by Congress.
  - i) All decisions of the Board may be appealed to the Secretary of Health and Human Services and then to the federal courts.
- Sanctions
  - j) Refunds
  - k) Civil monetary penalties similar to Stark
  - l) Exclusion
  - m) Imprisonment of up to five years for any willful violation of the Act with the intent to cause overutilization or profit at the expense of, or without consideration for, the quality of patient care.

This proposal attempts to balance the need of the health care system to evolve, while protecting against overutilization and ensuring quality care. Under this

proposal, a physician may maintain any ownership or investment interest so long as the interest is one that is generally available to the general public and may retain any compensation as long as it is not greater than the fair market value. If the interest is available only to groups smaller than the public at large, such as only a group of physicians, or compensation is greater than the fair market value, any referrals to that entity will be prohibited unless an exception is met.

If the physician directly provides or directly supervises the provision of the service, the chance of overutilization is minimized because the physician cannot cause excessive overutilization by merely providing services. Also, this allows the physician to provide all necessary care in an efficient manner within his or her own office.

The group practice section allows referrals within the group so long as such referral does not decrease the quality of care offered to the patient. Forcing the group to refer outside the group a certain percentage of the time will ensure that if a better provider is available, the physician will not hesitate to refer the patient to the better provider. Further, if the group complies with the section by not requiring in-group referrals or penalties for referrals outside the group and the group offers the patient an outside provider; the group can refer inside the group as much as it wishes. However, the group may be audited. This section also acknowledges the difficulty in deciding whether an outside provider is appropriate or perhaps better by allowing in-group referrals under the circumstances outlined.

The demonstrated need section allows care to be provided by physicians receiving income from referrals to an entity in which that physician has an ownership or investment interest, as long as no alternative investors exist. The proposed investors

must identify and notify all possible alternative investors and establish that those investors are not willing to invest on similar to or better terms than those investors that will refer to the entity.

The most important part of the proposal is the establishment of the Fraud and Abuse Board. The Board will function as an approval body for the numerous arrangements in which physicians wish to have an ownership or investment interest in the entity to which they refer. This section allows the health care system to evolve in any way it wishes so long as the new arrangement will not promote overutilization or decrease quality of care. Arguably, the creation of this Board will increase expenditures to investigate and enforce the proposal. However, the Board becomes the sole entity responsible for self-referral issues, thereby eliminating the many entities that currently play a role in enforcing this type of fraud and abuse. The savings would be further enhanced if the anti-kickback laws are revised and use the same system and Board.

The sanctions in the proposal are basically the same as in Stark, except that a criminal provision is added. Criminal sanctions and imprisonment for the type of violation outlined in the proposal are necessary to ensure that health care providers do not consider attempting to work outside the proposal. Further, the type of violations that will allow criminal sanctions are quite egregious and difficult to prove, creating a good balance between upholding the purpose of the proposal and ensuring that physicians are not placed in prison or worry about imprisonment every time they make a referral. The audit feature also ensures physician compliance.

There are several problems with the proposal. The proposal may not adequately protect against self-referral. The clause that allows a physician to have investment or ownership interests as long as that interest is available to the general public and the clause that allows compensation arrangements consistent with fair market value may not prohibit arrangements that could lead to abuse. In addition, it might be argued that one governing Board might not be adequate to investigate all fraud and abuse. To be effective, the Board may have to be expansive and expensive. Perhaps intermediary boards could carry out the tasks of the Board. However, this may fragment and complicate the simplicity and uniformity of one central Board. Further, defining and measuring quality of care and “no chance” of abuse may be too difficult to be workable in determining which arrangements are prohibited. Furthermore, the use of criminal sanctions in health care fraud and abuse enforcement may not be appropriate and may cause a chilling effect on the creation of efficient health care entities. Placing the burden of proof on the petitioner may create disincentives to getting approval, thereby vitiating the usefulness of the proposal.

The author does not pretend that this proposal is the final word on how to deal with self-referral. Rather, the proposal is meant to elicit discussion and demonstrate that the issues of Stark may be dealt with in a much simpler manner. The proposal is not only simpler, but also appears to prohibit self-referral, while allowing health care to evolve and protecting quality of care. The proposal is simpler than Stark because it deals with the evolution of the health care system on a case by case basis as opposed to the current method of waiting for congressional change to the law. Further, the proposal is not as complex as Stark because it does not suffer from the effects of

powerful lobbying groups. In essence, a simple and efficient system to deal with health care fraud and abuse is necessary to ensure that access to quality care is available without causing adverse consequences to the health care market and health care entities and professionals.

## APPENDIX

### 42 U.S.C. § 1395nn

#### (1) In general

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then--

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

#### (2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is--

(A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

#### (b) General exceptions to both ownership and compensation arrangement prohibitions

Subsection (a)(1) of this section shall not apply in the following cases:

##### (1) Physicians' services

In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4) of this section) as the referring physician.

##### (2) In-office ancillary services

In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)--

(A) that are furnished--

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii)(I) in a building in which the referring physician (or another physician who is a member of the

same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice--

(aa) for the provision of some or all of the group's clinical laboratory services, or

(bb) for the centralized provision of the group's designated health services (other than clinical laboratory services),

unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice,

if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

### (3) Prepaid plans

In the case of services furnished by an organization--

(A) with a contract under section 1395mm of this title to an individual enrolled with the organization,

(B) described in section 1395l(a)(1)(A) of this title to an individual enrolled with the organization,

(C) receiving payments on a prepaid basis, under a demonstration project under section 1395b-1(a) of this title or under section 222(a) of the Social Security Amendments of 1972, to an individual enrolled with the organization, or

(D) that is a qualified health maintenance organization (within the meaning of section 300e-9(d) of this title) to an individual enrolled with the organization.

### (4) Other permissible exceptions

In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

(c) General exception related only to ownership or investment prohibition for ownership in publicly traded securities and mutual funds

Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are--

(A)(i) securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or



(ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and

(B) in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding \$75,000,000.

(2) Ownership of shares in a regulated investment company as defined in section 851(a) of Title 26, if such company had, at the end of the company's most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75,000,000.

(d) Additional exceptions related only to ownership or investment prohibition

The following, if not otherwise excepted under subsection (b) of this section, shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Hospitals in Puerto Rico

In the case of designated health services provided by a hospital located in Puerto Rico.

(2) Rural provider

In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity, if substantially all of the designated health services furnished by such entity are furnished to individuals residing in such a rural area.

(3) Hospital ownership

In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if--

(A) the referring physician is authorized to perform services at the hospital, and

(B) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

(e) Exceptions relating to other compensation arrangements

The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B) of this section:

(1) Rental of office space; rental of equipment

(A) Office space

Payments made by a lessee to a lessor for the use of premises if--

(i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,

(ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,

(iii) the lease provides for a term of rental or lease for at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Equipment

Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if--

(i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,

(ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,

(iii) the lease provides for a term of rental or lease of at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Bona fide employment relationships

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if--

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment--

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as

needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

(3) Personal service arrangements

(A) In general

Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) if--

(i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,

(ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,

(iv) the term of the arrangement is for at least 1 year,

(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and

(vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Physician incentive plan exception

(i) In general

In the case of a physician incentive plan (as defined in clause (ii)) between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(I) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.

(II) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 1395mm(i)(8)(A)(ii) of this title, the plan complies with any requirements the Secretary may impose pursuant to such section.

(III) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.

## (ii) Physician incentive plan defined

For purposes of this subparagraph, the term "physician incentive plan" means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

## (4) Remuneration unrelated to the provision of designated health services

In the case of remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.

## (5) Physician recruitment

In the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, if--

(A) the physician is not required to refer patients to the hospital,

(B) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and

(C) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

## (6) Isolated transactions

In the case of an isolated financial transaction, such as a one-time sale of property or practice, if--

(A) the requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer, and

(B) the transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

## (7) Certain group practice arrangements with a hospital

## (A) [FN1] In general

An arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if--

(i) with respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1395x(b)(3) of this title,

(ii) the arrangement began before December 19, 1989, and has continued in effect without interruption since such date,

(iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement,

(iv) the arrangement is pursuant to an agreement that is set out in writing and that specifies the services to be provided by the parties and the compensation for services provided under the agreement,

(v) the compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the compensation is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the entity, and

(vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(8) Payments by a physician for items and services

Payments made by a physician--

(A) to a laboratory in exchange for the provision of clinical laboratory services, or

(B) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

(f) Reporting requirements

Each entity providing covered items or services for which payment may be made under this subchapter shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including--

(1) the covered items and services provided by the entity, and

(2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A) of this section), or with a compensation arrangement (as described in subsection (a)(2)(B) of this section), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides services for which payment may be made under this subchapter very infrequently.

(g) Sanctions

(1) Denial of payment

No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section.

(2) Requiring refunds for certain claims

If a person collects any amounts that were billed in violation of subsection (a)(1) of this section, the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.

(3) Civil money penalty and exclusion for improper claims

Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for

which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than \$15,000 for each such service. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than \$100,000 for each such arrangement or scheme. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(5) Failure to report information

Any person who is required, but fails, to meet a reporting requirement of subsection (f) of this section is subject to a civil money penalty of not more than \$10,000 for each day for which reporting is required to have been made. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(6) Advisory opinions

(A) In general

The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) Application of certain rules

The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) of this section and take into account the regulations promulgated under subsection (b)(5) of section 1320a-7d of this title in the issuance of advisory opinions under this paragraph.

(C) Regulations

In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(D) Applicability

This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after August 5, 1997 and before the close of the period described in section 1320a-7d(b)(6) of this title.

(h) Definitions and special rules

For purposes of this section:

(1) Compensation arrangement; remuneration

(A) The term "compensation arrangement" means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).

(B) The term "remuneration" includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

(C) Remuneration described in this subparagraph is any remuneration consisting of any of the following:

(i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(ii) The provision of items, devices, or supplies that are used solely to--

(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or

(II) order or communicate the results of tests or procedures for such entity.

(iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if--

(I) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Employee

An individual is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of Title 26).

(3) Fair market value

The term "fair market value" means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(4) Group practice

(A) Definition of group practice

The term "group practice" means a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association--

(i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel,

(ii) for which substantially all of the services of the physicians who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group,

(iii) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined,

(iv) except as provided in subparagraph (B)(i), in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

(v) in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and

(vi) which meets such other standards as the Secretary may impose by regulation.

(B) Special rules

(i) Profits and productivity bonuses

A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.

(ii) Faculty practice plans

In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) shall be applied only with respect to the services provided within the faculty practice plan.

(5) Referral; referring physician

(A) Physicians' services

Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), constitutes a "referral" by a "referring physician".

(B) Other items



Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a "referral" by a "referring physician".

(C) Clarification respecting certain services integral to a consultation by certain specialists

A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician".

(6) Designated health services

The term "designated health services" means any of the following items or services:

- (A) Clinical laboratory services.
- (B) Physical therapy services.
- (C) Occupational therapy services.
- (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- (E) Radiation therapy services and supplies.
- (F) Durable medical equipment and supplies.
- (G) Parenteral and enteral nutrients, equipment, and supplies.
- (H) Prosthetics, orthotics, and prosthetic devices and supplies.
- (I) Home health services.
- (J) Outpatient prescription drugs.
- (K) Inpatient and outpatient hospital services.

TABLE I – Summary of Stark I and II (with regulatory guidance)

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
<ul style="list-style-type: none"> <li>Prohibits referrals and billing for referrals to designated health services in which a physician or a family member has a financial interest</li> <li>Financial interests are ownership or investment interests or compensation arrangements</li> <li>Applies to Medicare and Medicaid</li> </ul> <p>Designated Health Services</p> <ul style="list-style-type: none"> <li>Clinical laboratory services</li> <li>Physical therapy services</li> <li>Occupational therapy services</li> <li>Radiology, MRI, CAT, and ultrasound</li> <li>Radiation therapy services and supplies</li> <li>Durable medical equipment and supplies</li> <li>Parenteral and enteral nutrients, equipment, and supplies</li> <li>Prosthetics, orthotics, and prosthetic devices</li> <li>Home health services and supplies</li> <li>Outpatient prescription drugs</li> <li>Inpatient and outpatient hospital services</li> </ul>	<p>Immediate family member is defined as husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild; stepbrother, or stepsister; father-in-law; mother-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild</p>	<p>Indirect interests are covered</p> <p>For Joint Venture guidance, see 1989 OIG Advisory Opinion.</p>
Compensation arrangement – any		

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
arrangement involving remuneration between a physician and an entity (with minor exceptions)		
Fair Market Value – value in arms length transactions, consistent with general market value		General market value is defined as the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement
Referral – request by a physician for any item or service covered by Medicare including consultation, but not special services integral to consultation with a pathologist, radiologist, or radiation oncologist	Referrals not included for ambulatory surgical center, end stage renal disease facility, or hospice, if included in standard rate	<ul style="list-style-type: none"> <li>Item or service is now referred to only as service</li> <li>In-network referrals are excepted as long as compensation does not take into account the volume or value of referrals</li> </ul>

General Exceptions	General Exceptions	General Exceptions
<b>1. Physician Services Exception</b> Services provided personally or under supervision of another physician in the same group practice		
<b>2. In-Office Ancillary Services Exception –</b> <ul style="list-style-type: none"> <li>Services furnished personally by the referring physician or personally by a physician in the same group practice or by an individual directly supervised by such physician</li> <li>Services provided in the same</li> </ul>	Direct supervision – physician must be present in the office and immediately available to provide assistance and direction throughout the time the services are being performed	<ul style="list-style-type: none"> <li>Direct supervision – must be present in office suite at time the services are being furnished. Brief or unexpected absences or routine absences of short duration are allowed</li> <li>Same building means one physical structure with one address</li> <li>Crutches are included in the</li> </ul>

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
<p>building where such physician provides services unrelated to designated health services, or in another building used for the centralized provision of a group's designated health services</p> <ul style="list-style-type: none"> <li>• Services billed by the physician performing or supervising the service under a group billing number or by an entity wholly owned by the physician or group</li> <li>• Excluding durable medical equipment (except infusion devices) or parenteral/enteral nutrients, equipment or supplies.</li> </ul>		<p>exception</p> <ul style="list-style-type: none"> <li>• Location of in-office is determined by where the procedure is actually performed or where the patient begins using the item</li> </ul> <p>See, HCFA-AO-98-002, applying the In-Office Ancillary Service Exception</p>
<p><b>Group Practice Requirements –</b></p> <ul style="list-style-type: none"> <li>• Two or more physicians legally organized</li> <li>• Each physician provides substantially the full range of services which the physician routinely provides through the joint use of facilities, equipment, and personnel</li> <li>• Each group physician must provide substantially all services through the group</li> <li>• Services billed under group billing number</li> <li>• Expenses and income must be distributed in accordance with methods previously determined</li> <li>• Compensation of group members</li> </ul>	<ul style="list-style-type: none"> <li>• Substantially all services furnished through the group – 75 percent of the total patient care services</li> <li>• Total patient care services – tasks performed by a group member that addresses the medical needs of a patient, regardless of whether it involves a direct patient care encounter (e.g. – consulting with another physician or reviewing test results) measured by the total hours spent in practice versus hours spent on patient care for group patients. Not applicable in Health Professional Shortage Area</li> <li>• Members – partners and full-time and part-time physicians and</li> </ul>	<ul style="list-style-type: none"> <li>• Physician groups cannot legally organize to qualify as a group practice</li> <li>• One group may use more than one billing number as long as the numbers belong to the same group</li> <li>• Total patient care – broadened to include tasks that address the medical needs of patients or that generally benefit the practice (e.g., training, administrative)</li> <li>• Members – will not include independent contractors</li> <li>• Members may refer to an entity that another group member cannot.</li> <li>• Previously determined – must be determined prior to the time period</li> </ul>

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
cannot be based on volume or value of referrals; productivity bonus on services personally performed allowed	employees who bill in the group name <ul style="list-style-type: none"> <li>Group attestation required</li> </ul>	during which the group has earned the income or incurred the cost by an established plan showing a unified business
3. <b>Prepaid Plan Exception</b> – Services referred to an organization receiving payment on a prepaid basis, e.g. HMO, if the organization has a contract with the individual		Broadened to facilitate integrated health care delivery but not applying to hybrid organizations

Ownership and Investment Interest Exceptions	Ownership and Investment Interest Exceptions	Ownership and Investment Interest Exceptions
1. <b>Publicly Traded Investments</b> <ul style="list-style-type: none"> <li>Listed on an exchange</li> <li>Can be purchased on open market in terms generally available to the public</li> <li>Shareholder equity or total assets of &gt; \$75 million</li> </ul>	Total Asset and Shareholder Equity requirements are clarified	<ul style="list-style-type: none"> <li>Stockholder equity is the difference in value between a corporation's total assets and total liabilities</li> <li>Excepted if could have been purchased on open market</li> </ul>
2. <b>Rural Providers</b> – <ul style="list-style-type: none"> <li>Services provided in rural area</li> <li>Substantially all designated health services provided to individuals residing in rural area</li> </ul>	Laboratory must perform tests on rural premises or bill Medicare directly for testing that is substantially (75%) furnished to rural patients	All designated health services must be actually furnished in a rural area by a rural provider  See, HCFA-AO-98-001, applying the Rural Provider exception; rural area is determined by OMB Metropolitan Statistical Area data
3. <b>Hospitals</b> – If the physician is authorized to perform services in the hospital and the interest is in the hospital itself and not in a subdivision thereof	Physician ownership or investment interest must be in the entire hospital and not merely a distinct part or department or relating to clinical laboratory services	

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
<b>4. <u>Hospitals in Puerto Rico</u></b>		

Compensation Arrangement Exceptions	Compensation Arrangement Exceptions	Compensation Arrangement Exceptions
<p>1. <b><u>Space and Equipment Leasing</u></b></p> <ul style="list-style-type: none"> <li>• In writing</li> <li>• Signed by parties</li> <li>• Term of at least one year</li> <li>• Specifying lease or space to be leased</li> <li>• Compensation not beyond that which is reasonable and necessary for legitimate business purposes</li> <li>• Establishing charge in advance, consistent with fair market value, commercially reasonable even if no referrals were made between parties, not taking into account volume or value of referrals or business generated</li> <li>• Space or equipment must be used exclusively by lessee (exception – common space)</li> </ul>		
<p>2. <b><u>Bona fide employment arrangements</u></b> –</p> <ul style="list-style-type: none"> <li>• Employment for identified services</li> <li>• Compensation is consistent with the fair market value and not determined by considering volume or value of referrals; productivity bonus for services personally performed</li> </ul>		

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
<p>allowed</p> <ul style="list-style-type: none"> <li>By an agreement that would be commercially reasonable even without referrals</li> </ul>		
<p>3. <u>Personal Services</u> –</p> <ul style="list-style-type: none"> <li>In writing, signed by the parties</li> <li>Specifying all services to be provided by the physician</li> <li>Services cannot exceed those that are reasonable and necessary for legitimate business purposes</li> <li>Term of at least one year</li> <li>Compensation set in advance, not exceeding the fair market value or taking into account the volume or value of referrals or business generated</li> </ul>		Multiple agreements are allowed
<p>4. <u>Physician Incentive Plans (PIP)</u></p> <ul style="list-style-type: none"> <li>Cannot provide specific payment to reduce or limit services</li> <li>Must comply with PIP regulations if provider is placed at substantial financial risk</li> </ul>		PIP only applies when the entity paying the physician is the kind of entity that enrolls its patients
<p>5. <u>Not a Designated Health Service</u></p>		<p>Narrowed – only applies to hospitals and does not apply to family members. Even the most remote indirect remuneration for a designated health service will fail to comply with this exception</p> <p>Physician must actually reside outside the geographic location and must actually relocate to join the hospital's staff</p>
<p>6. <u>Physician Recruitment</u> – Payment to induce a physician to relocate as long as not required to refer and remuneration for relocation does not take into account</p>	Physician cannot be precluded from establishing privileges at another hospital	

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
volume or value of referrals		
<p>7. <u>Isolated Transactions (e.g. – one time sale of practice)</u> – Amount of remuneration must be consistent with fair market value, not determined by volume or value of referrals, and by agreement that is commercially reasonable even without referrals</p>		
<p>8. <u>Group Practice Arrangements</u> –</p> <ul style="list-style-type: none"> <li>• Arrangement began before 12/19/89 and continued without interruption</li> <li>• In writing, specifying the services to be provided and compensation</li> <li>• Compensation consistent with fair market value, not determined by taking into account the volume or value of referrals, and commercially reasonable even if no referrals were made</li> <li>• Substantially all designated health services must be provided by the group</li> </ul>		<p>The arrangement may have changed with regard to the services covered and the individuals providing services</p>
<p>9. <u>Payment by physician</u> – For designated health services if service furnished at a price consistent with fair market value</p>		



STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
		<p><b>10. <u>Discount Exception</u></b> –</p> <ul style="list-style-type: none"> <li>• If a discount is passed on in full to the patient or insurer (physician receives no benefit), it is exempt</li> <li>• Discount must be offered to all similarly situated individuals, regardless of whether they make referrals and cannot reflect the volume or value of referrals</li> </ul>
		<p><b>11. <u>Fair Market Value Exception</u></b></p> <ul style="list-style-type: none"> <li>• Written</li> <li>• Specifying compensation consistent with fair market value, not taking into volume or value of referral or business generated</li> <li>• Explaining commercial reasonableness, legitimate business purpose, and compliance with Anti-Kickback laws</li> </ul>
		<p><b>12. <u>de minimis exception</u></b> –</p> <ul style="list-style-type: none"> <li>• Compensation less than \$50 per gift, \$300 per year</li> <li>• Compensation available to all similarly situated individuals regardless of whether they refer, not taking into account the volume or value of referrals</li> </ul>
Requires reporting; \$10,000 per day sanction if not compliant	Reporting requirements explained	Reporting requirements lessened

STARK I and II	STARK I REGULATIONS	STARK II REGULATIONS (in addition to that provided in Stark I regulations)
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<p>Sanctions</p> <ul style="list-style-type: none"> <li>• Denial of payment</li> <li>• Refunds</li> <li>• Civil monetary of \$15,000 for each service billed if knew or should have known prohibited by Stark, or \$100,000 for each arrangement or scheme if knew or should have known principle purpose was to assure referrals</li> </ul>		Sanctions for violations involving Medicaid beneficiaries left to states
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Advisory opinions can be issued by Secretary of Health and Human Services	Advisory opinion procedure explained	HCFA advisory opinions
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TABLE II - How the Thomas bill and Stark bill change Stark I and II

<b>THOMAS BILL</b>		<b>STARK BILL</b>
General	Financial interests would not include compensation arrangements	
Designated Health Services	<b>Definitions</b> Excludes intraocular lenses, eyeglasses and contact lenses	<b>Definitions</b> Excludes intraocular lenses, eyeglasses and contact lenses
Physician Services Exception	<b>General Exceptions</b> No Change	<b>General Exceptions</b> No Change
In-Office Ancillary Services Exception	<ul style="list-style-type: none"> <li>Site of service requirement eliminated</li> <li>Physician supervision found if the physician is legally responsible for the services performed by the individual and for ensuring that the individual meets licensure and certification requirements, if any, regardless of whether or not the physician is physically present when the individual furnishes the item or service</li> </ul>	<ul style="list-style-type: none"> <li>Direct supervision not required as long as physician or group member assumes full and direct legal, financial, and professional responsibility for the services that are provided and for whom provides these services</li> <li>Includes durable medical equipment and parenteral and enteral nutrients, equipment and supplies</li> </ul>
Group Practice Requirements	Member – owner or bona fide employee, including supervising pathologist	Expenses and income must be distributed in a manner that indicates the business is a unified entity
Prepaid Plan Exception	No Change	Includes Medicaid managed care organizations
New Exceptions	None	<b>Capitated payments</b> – Designated health service provided pursuant to a written agreement providing compensation on a capitated basis
		<b>Communities with no alternative providers</b> – If the area does not have reasonable access to the designated health service
		<b>Ambulatory Surgery Centers and Hospice</b>

<b>THOMAS BILL</b>	<b>STARK BILL</b>
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<b>Ownership and Investment Interest Exceptions</b>	<b>Ownership and Investment Interest Exceptions</b>
No Change	No Change

<b>Compensation Arrangement Exceptions</b>	<b>Compensation Arrangement Exceptions</b>
ELIMINATED	REPLACED
	<p>Fair Market Value exception becomes the general compensation arrangement exception if:</p> <ul style="list-style-type: none"> <li>• Written, signed</li> <li>• Specified period of time</li> <li>• Covering all services to be provided or incorporating other arrangements</li> <li>• Consistent with fair market value</li> <li>• Specifying compensation, set in advance, commercially reasonable, furthers legitimate business interests of parties, not taking into account the volume or value of referrals</li> <li>• Is a compensation arrangement</li> </ul> <p>Specific Exceptions:</p> <ul style="list-style-type: none"> <li>• Physician recruitment – to relocate as long as not required to refer to the hospital, not taking into account volume or value of referrals</li> <li>• de minimis – not exceeding \$50 per gift, \$300 per year, not taking into account volume or value of referrals</li> </ul>

Cannot be implemented until final regulations are promulgated.

