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## **Medicare: Physician Self-Referral (“Stark I and II”)**

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# Medicare: Physician Self-Referral (“Stark I and II”)

## Summary

“Self-referrals” occur when physicians refer patients to medical facilities in which they have a financial interest. This interest can be in the form of ownership or investment interest in the entity; it may also be structured as a compensation arrangement between the physician and the entity.

Critics of self-referral arrangements state that they pose a conflict-of-interest since the physician is in a position to benefit financially from the referral. They suggest that such arrangements may encourage overutilization of services, which in turn drives up health care costs. They also contend that such arrangements create a captive referral system, which limits competition among health care providers. Others respond to these concerns by stating that while problems may exist, they are not widespread. Further, these observers contend that in many cases physician investors are responding to a demonstrated need which would not otherwise be met, particularly in a medically underserved area.

Congressional concern with the implications of self-referral arrangements led to the inclusion in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) of a provision barring self-referral arrangements for clinical laboratory services under the Medicare program. This provision, known as “Stark I” (after Congressman Pete Stark, the chief congressional sponsor), became effective January 1, 1992. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) extended the ban, effective January 1, 1995, to an additional list of services and applied it to Medicaid at the same time. The OBRA 1993 provision is referred to as “Stark II.” The Social Security Amendments of 1994 (P.L. 103-432) included several technical changes to the self-referral provisions. More recently, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) included a temporary provision related to referrals to specialty hospitals that focus on one category of care (e.g., orthopedic care).

It took a number of years for most of the implementing regulations to be issued for the self-referral ban. In part, this reflected the fact that Congress on several occasions considered, and in a few cases enacted, significant modifications to the original law. More important however, the delay reflected the very complicated and continually evolving nature of business relationships in the health care industry. The Centers for Medicare and Medicaid Services (CMS, the agency that administers Medicare) tried to develop regulations which on the one hand were consistent with the intention of the law while at the same time not interfering unduly with legitimate business practices. The final phase of the implementing regulations were issued March 26, 2004.

The major focus of legislative attention in the near future is likely to be the 18-month moratorium, added by MMA, on referrals to specialty hospitals and whether the ban will be extended, perhaps in modified form, after the June 8, 2005, ending date. This report will be updated as events warrant.

## Contents

Introduction .....	1
Legislative History .....	1
Omnibus Budget Reconciliation Act of 1989 (OBRA 1989):	
“Stark I” Provisions .....	1
Enactment .....	1
Summary .....	2
Studies .....	2
Response of the Medical Profession .....	3
Omnibus Budget Reconciliation Act of 1993 (OBRA 1993):	
“Stark II” Provisions .....	4
1992 Legislation .....	4
1993 Legislation .....	4
1994 Legislation .....	5
Activities in the 104th Congress .....	5
Concerns with Implementation of Stark II .....	5
Balanced Budget Act of 1995 (BBA) .....	6
Specialty Hospitals; Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) .....	7
Specialty Hospitals .....	7
MMA .....	7
Regulations .....	8
Stark I .....	8
Stark II .....	8
Other Anti-Fraud Provisions .....	10
Prospects .....	10
Appendix: Summary of Law and Regulations .....	11
In General .....	11
Sanctions .....	11
Exceptions .....	11
Definitions .....	12
Designated Health Services .....	12
Referral; Referring Physician .....	13
Financial Relationship .....	13
Ownership or Investment Interest .....	13
Compensation Arrangement .....	14
Fair Market Value .....	15
Volume or Value of Referrals .....	15
Group Practice .....	15
General Exceptions .....	17
Physicians’ Services Exception .....	17
In-office Ancillary Services Exception .....	17
Prepaid Plans Exception .....	19

Electronic Prescribing Exception .....	19
Other exceptions .....	20
Academic Medical Centers (AMCs) Exception .....	20
Implants Furnished by an Ambulatory Surgical Center (ASC) Exception .....	21
Erythropoietin (EPO) and Other Dialysis-related Drugs Furnished in or by an End-stage Renal Disease (ESRD) Facility Exception .....	21
Preventive Screening Tests, Immunizations, and Vaccines Exception .....	21
Eyeglasses and Contact Lenses Following Cataract Surgery Exception .....	21
Intra-family Rural Referrals Exception .....	22
Exceptions Relating Only to Ownership or Investment Prohibition .....	22
Ownership of Publically Traded Investment Securities Exception ...	22
Hospitals in Puerto Rico Exception .....	22
Hospital Ownership Exception .....	22
Rural Providers Exception .....	23
Exceptions Relating Only to Other Compensation Arrangements .....	23
Rental of Office Space and Equipment Exception .....	23
Bona Fide Employment Relationships Exception .....	24
Personal Service Arrangements Exception .....	24
Remuneration Unrelated to the Provision of Designated Health Services Exception .....	25
Physician Recruitment Exception .....	25
Isolated Transactions Exception .....	26
Group Practice Arrangements with a Hospital Exception .....	26
Payments by a Physician for Items and Services Exception .....	26
Other Exceptions .....	27
Charitable Donations By a Physician Exception .....	27
Non-Monetary Compensation Up to \$300 Exception ....	27
Fair Market Value Compensation Exception .....	27
Medical Staff Incidental Benefits Exception .....	27
Risk-Sharing Arrangements Exception .....	28
Compliance Training Exception .....	28
Indirect Compensation Exception .....	28
Referral Services Exception .....	28
Obstetrical Malpractice Insurance Subsidies Exception ...	28
Professional Courtesy Exception .....	28
Retention Payments in Underserved Areas Exception ....	29
Community-Wide Health Information Systems Exception .	29
Other Provisions .....	30
Advisory Opinions .....	30
Reporting Requirements .....	30

# Medicare: Physician Self-Referral ("Stark I and II")

## Introduction

"Self-referrals" occur when physicians refer patients to medical facilities in which they have a financial interest. This interest can be in the form of ownership or investment interest in the entity; it may also be structured as a compensation arrangement between the physician and the entity.

Critics of self-referral arrangements state that they pose a conflict-of-interest since the physician is in a position to benefit financially from the referral. They suggest that such arrangements may encourage overutilization of services, which in turn drives up health care costs. They also contend that such arrangements create a captive referral system, which limits competition among health care providers. Others respond to these concerns by stating that while problems may exist, they are not widespread. Further, these observers contend that in many cases physician investors are responding to a demonstrated need which would not otherwise be met, particularly in a medically underserved area.

Congressional concern with the implications of self-referral arrangements led to the inclusion in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) of a provision barring self-referral arrangements for clinical laboratory services under the Medicare program. This provision, known as "Stark I" (after Congressman Pete Stark, the chief congressional sponsor), became effective January 1, 1992. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) extended the ban, effective January 1, 1995, to an additional list of services and applied it to Medicaid at the same time. The OBRA 1993 provision is referred to as "Stark II." The Social Security Amendments of 1994 (P.L. 103-432) included several technical changes to the self-referral provisions. More recently, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) included a temporary provision related to referrals to specialty hospitals.

## Legislative History

### **Omnibus Budget Reconciliation Act of 1989 (OBRA 1989): "Stark I" Provisions**

**Enactment.** For several years, a number of articles appeared in magazines, newspapers, and professional journals concerning the substantial profits that physicians could make by becoming partners in providers to which they referred their patients. In 1989, the Office of the Inspector General (OIG) of the Department of

Health and Human Services (DHHS) reported that patients of referring physicians who owned or invested in independent clinical labs received 45% more lab services than Medicare patients in general and 34% more services directly from clinical labs than Medicare patients in general. This increased utilization cost Medicare an estimated \$28 million in 1987.<sup>1</sup>

While several types of arrangements were the subject of both the press and OIG studies, the most significant findings related to referrals to independent clinical laboratories. The Congress responded to these reports by enacting the “Stark I” ban as part of OBRA 1989. The Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) included technical amendments.

**Summary.** The 1989 law established a ban, effective January 1, 1992, on certain financial arrangements between physicians and clinical laboratories. Specifically, a physician could not make a referral to a lab for services for which Medicare would otherwise pay if the physician (or immediate family member) had an ownership or investment interest in, or a compensation arrangement with, the lab. Further, the lab could not bill for such services. For purposes of the ban, an ownership or investment interest could be through equity, debt, or other means. A compensation arrangement was defined as any arrangement involving remuneration between a physician (or immediate family member) and an entity.

The law established a series of exceptions to the ban. Some were general exceptions to both the ownership and compensation arrangement prohibitions. For example, there were exceptions for services provided by another physician in the same group practice or for in-office ancillary services. Other exceptions related *only* to the ownership or investment prohibition or *only* to the compensation prohibition.

**Studies.** The issue of physician self-referrals continued to be of concern to policymakers after enactment of the 1989 law. Several subsequent events focused continuing attention on this issue. These included issuance of a Florida study, and several follow-up studies, which added substantially to the body of evidence on the implications of self-referrals.

The Florida study was issued by Florida State University in September 1991. It was prepared under contract with the state’s Health Care Cost Containment Board pursuant to a mandate by the Florida legislature. The authors of the study grouped the 10 types of facilities surveyed into three categories based on the effect of joint venture arrangements on access, charges, and utilization of services. The authors concluded that joint venture arrangements had no apparent negative effects on hospital and nursing home services. For the second category of facilities, (ambulatory surgical centers, home health services, durable medical equipment suppliers, and radiation therapy centers) some potential problems were identified, but the data did not allow the authors to draw definitive conclusions. However, for the third category (clinical laboratories, diagnostic imaging services, and physical therapy

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<sup>1</sup> U.S. Department of Health and Human Services, Office of the Inspector General, *Financial Arrangements Between Physicians and Health Care Businesses*, OAI-12-88-01410, May 1989.

services) the results indicated significantly higher utilization and significantly higher charges at joint venture facilities. Further, joint venture arrangements did not increase access to rural or underserved patients.<sup>2</sup>

A follow-up analysis of the impact of physician ownership on physical therapy and rehabilitation services showed that visits per patient were 39% to 45% higher in joint venture facilities. Further, gross and net revenues per patient were 30% to 40% higher in facilities owned by referring physicians.<sup>3</sup> A follow-up examination of radiation therapy centers showed that joint ventures provided less access to poorly served populations (rural counties and inner cities) than nonjoint venture facilities; further, the frequency and costs of radiation therapy treatments in free-standing centers in Florida were 40% to 60% higher than in the rest of the U.S. where the prevalence of joint venture arrangements was substantially lower.<sup>4</sup>

A follow-up analysis by GAO, showed that physician owners of diagnostic imaging services referred their patients more frequently, for more expensive services, than nonowners. Overall, MRI owners referred their patients for MRI scans twice as often as nonowners. This evidence was presented to the Congress during its consideration of OBRA 1993.<sup>5</sup> The final report, issued subsequent to enactment of OBRA 1993 provided additional evidence. That report found that physicians who had ownership interests in some type of imaging facility ordered 54% more MRI scans, 27% more computed tomography (CT) scans, 37% more nuclear medicine scans, 27% more echocardiograms, 22% more ultrasound services, and 22% more complex X-rays. The study also found that imaging patterns for physicians with imaging facilities in their offices, group practices, or other practice affiliations ordered tests more frequently than physicians who referred patients outside of their practices.<sup>6</sup>

**Response of the Medical Profession.** Beginning in the mid-1980s, many in the medical profession reexamined the appropriateness of self-referral arrangements. The primary focus for this discussion was within the American Medical Association (AMA). The organization's 1986 Council on Ethical and Judicial Affairs report (cited during consideration of the 1989 law) took the position

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<sup>2</sup> U.S. Congress, House, Committee on Ways and Means, Subcommittee on Health, *Joint Ventures Among Health Care Providers in Florida*. Statement presented at hearing by Jean Mitchell and Elton Scott, Hearing on Physician Ownership/Referral Arrangements, 102<sup>nd</sup> Cong., 1<sup>st</sup> sess., Oct. 17, 1991, (Washington, GPO, 1991).

<sup>3</sup> Jean M. Mitchell and Elton Scott, "Physician Ownership of Physical Therapy Services," *JAMA*, vol. 268, no. 16, Oct. 21, 1992, pp. 2055-2059.

<sup>4</sup> Jean M. Mitchell and Jonathan Sunshine, "Consequences of Physicians' Ownership of Health Care Facilities — Joint Ventures in Radiation Therapy," *The New England Journal of Medicine*, vol. 327, no. 21, Nov. 19, 1992.

<sup>5</sup> Testimony by Janet Shikles, in U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Medicare: Physicians Who Invest in Imaging Centers Refer More Patients for More Costly Services*, Apr. 20, 1993 (Washington: GAO, 1993).

<sup>6</sup> U.S. General Accounting Office, *Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA's Scrutiny*, GAO/HE'S-95-2, Oct. 1994.

that physician ownership in a commercial venture was not itself unethical; potential conflict-of-interest situations were to be addressed through certain safeguards such as informing patients of the ownership interests.

In December 1991, the AMA Council, citing evidence of continuing problems, recommended a new approach. It stated that, in general, physicians should not refer patients to a health care facility outside their office practice at which they do not directly provide care or services when they have an investment interest in the facility. However, physicians could invest in and refer to an outside facility, if there was a demonstrated need in the community for the facility and alternative financing was not available.

Six months after the Council's report, the AMA's House of Delegates went on record against the Council's recommendation; it approved a policy stating that referrals were ethical if the patient was fully informed of the financial interest and the existence of available alternate facilities. However, in December 1992, the House of Delegates reversed its position and affirmed the December 1991 policy of the AMA Council. This general policy remains in effect today.<sup>7</sup>

The divergence of opinion within the AMA reflected the divergence of opinion across the profession at the time. Some physicians strongly rejected the connotation that referrals in and of themselves were unethical, while others supported the AMA position.

## **Omnibus Budget Reconciliation Act of 1993 (OBRA 1993): “Stark II” Provisions**

**1992 Legislation.** The 102<sup>nd</sup> Congress passed H.R. 11, the Revenue Act of 1992, which was vetoed by President George H.W. Bush on November 4, 1992. This legislation would have included several Medicare amendments including several technical modifications to the Stark ban. Included were exemptions for facilities shared by more than one physician practice (under specified conditions), modifications in the definition of group practices, and clarification of permissible compensation arrangements.

**1993 Legislation.** Modifications to the Stark ban were again considered during 1993. The concern continued to be a balance between the concerns of legitimate business arrangements with the goal of effective implementation of the referral ban. The range of the discussion expanded considerably from that which had occurred during 1992. Several issues were of particular concern including the scope of the ban, the definition of group practice, and clarification of the definition of compensation arrangements.

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<sup>7</sup> American Medical Association, Code of Medical Ethics, Current Opinions of the Council on Ethical and Judicial Affairs, E-8.032, *Conflicts of Interest: Health Facility Ownership by a Physician*, at [<http://www.ama-assn.org/ama/pub/category/print/8472.html>], accessed June 15, 2004.



During consideration of the bill, some attempts were made to extend the ban to a broad range of additional services and to additional payers. The final law did extend the ban to an additional list of “designated health services” beginning in 1995; it also extended the ban to Medicaid. The legislation gave physicians over two years to divest themselves of ownership interests; however, some groups had pushed for a later start-up date.

A second area of concern was the definition of group practice; this definition is important because referrals to other members within the same group practice are exempt from the referral ban. There was agreement that the existing law required technical improvements. However, many were also concerned that the definition had to be sufficiently tight to exclude sham groups whose primary purpose was to circumvent the referral ban. The final definition was modified to include a number of additional requirements. However, it did not include a controversial proposal that group practices maintain an average of five physicians per site.

OBRA 1993 also included significant modifications to the in-office ancillary services exception. Under the revised version this exemption is provided for the furnishing of clinical laboratory services by a lab even though it has multiple office locations. However, for all other services the exception for group practices applies only if the services are provided in a centralized location. The question of the treatment of Medicare ancillary services in multiple stand-alone facilities was left to the Secretary to address in regulations.

OBRA 1993 did not include an exception for facilities which are shared by physicians who are not part of a formal group practice. A shared facility exception for laboratory services had been included in the 1992 bill which was vetoed.

OBRA 1993 also contained significant clarifications in the language relating to permissible compensation arrangements and to remuneration.

## **1994 Legislation**

The Social Security Amendments of 1994 (P.L. 103-432) included technical amendments to Medicare. Several minor changes to the self-referral provisions were included in the package. These included a clarification of the definition of radiology services included in the self-referral ban and a clarification that investment and compensation arrangements are included within the reporting requirements.

## **Activities in the 104th Congress**

**Concerns with Implementation of Stark II.** Passage of Stark II raised a series of concerns on the part of many provider groups.<sup>8</sup> While Stark I and II were intended to remove potential conflicts of interest from physician decision making, a number of persons argued that the legislation, particularly parts of Stark II,

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<sup>8</sup> Many of the concerns were presented to the Congress during Ways and Means Committee hearings on the legislation on May 3, 1995. Much of the material in this section is from testimony given on that date.

represented an unwarranted intrusion into the practice of medical care. They stated that the legislation, particularly the provisions relating to compensation arrangements, were too complex and might in fact impede physicians' ability to participate in managed care networks. They suggested that while the referral prohibitions were designed primarily for a fee-for-service environment, the health care system was moving rapidly toward integrated health care networks.

Many observers also objected to implementation of Stark I and Stark II (including the potential imposition of sanctions) prior to the issuance of final regulations. They argued that the law was complex and that guidance was needed on some complex business arrangements. The Centers for Medicare and Medicaid Services (CMS, the agency that administers Medicare)<sup>9</sup> stated that it did not have leeway on the effective dates. In January 1995, CMS issued an information memorandum outlining the provisions of Stark II. While this was intended to inform physicians about prohibited referrals, many argued that it was too general to answer any specific questions. In August 1995, CMS issued final regulations on Stark I. The application of these regulations was limited to physician referrals to clinical laboratories. However, the preamble noted that the policy interpretations were generally expected to apply with respect to other "designated health services."<sup>10</sup>

Despite this statement, many groups contended that in view of the array of existing financial arrangements, more guidance was needed.. They raised a series of concerns about the potential application of the referral ban in specific situations.

**Balanced Budget Act of 1995 (BBA).** In 1995, an attempt was made to significantly scale back the application of the self-referral ban. On November 20, 1995, Congress gave final approval to the conference report on H.R. 2491, the Balanced Budget Act of 1995 (BBA 95). The President vetoed the measure on December 6, 1995, in part because of the size of the proposed Medicare savings (attributable primarily to reductions in the growth rate of payments to health care providers). BBA 95 included several amendments to the physician self-referral provisions. Many of the changes were in response to the objections raised by various provider groups. There were two major changes. The first would have repealed the self-referral prohibitions based on compensation arrangements. The second change limited the application of the prohibition to the following designated services: (1) clinical laboratory services; (2) parenteral and enteral nutrients, equipment and supplies; (3) radiology services, including magnetic resonance imaging and computerized tomography and ultrasound services; and (4) outpatient physical or occupational therapy services.

A modified version of BBA 95 was considered and ultimately passed as the Balanced Budget Act of 1997 (BBA 97). As part of the effort to develop a compromise measure, several of the items which were included in the 1995 bill were not considered as part of the 1997 bill. As a result, major physician self-referral changes were not considered during the 1997 debate. However, the legislation did

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<sup>9</sup> CMS officially came into existence on July 1, 2001. Prior to that date the agency was known as the Health Care Financing Administration (HCFA).

<sup>10</sup> 60 *Federal Register* 41916, Aug. 14, 1995.

include a provision which requires the Secretary of HHS to issue written advisory opinions concerning whether physician referrals relating to designated health services (other than clinical lab services) were prohibited.

## **Specialty Hospitals; Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)**

**Specialty Hospitals.** Recent years have seen the growth of specialty hospitals. These generally for-profit entities focus on one category of care, such as cardiac care or orthopedic surgery. Proponents of specialty hospitals contend that the focused mission improves quality and reduces costs. Other observers suggest that these hospitals are siphoning off the more lucrative cases from nearby general community hospitals, thus having an adverse impact on the latter's viability and ability to deliver a range of services including emergency care.<sup>11</sup>

A related concern is the impact of physician ownership of specialty hospitals on physicians' clinical behavior and referral patterns. While a physician is barred from referring patients for inpatient or outpatient hospital services to entities in which the physician has a financial interest, the law includes an exception if the ownership interest is in the entire facility, and not merely a subdivision. This means that a physician can refer patients to specialty hospitals even if the physician has an ownership interest in the facility. Some observers have characterized this as a serious loophole in the self-referral ban. They state that while referrals to a general hospital would have little economic impact for an individual physician, the same is not true in the case of smaller specialty hospitals.

An April 2003 GAO report focused on these concerns. It noted that specialty hospitals, while only 2% of the market had tripled in number since 1990. In 2000, they accounted for about 1% of Medicare spending for inpatient services. Approximately 70% of specialty hospitals in existence or under development had some physician owners, with total physician ownership averaging slightly more than 50%. In about 10% of hospitals with physician owners, physicians in a single group practice owned 80% or more of the hospital. The report also noted that these hospitals tended to treat less sick patients.<sup>12</sup>

**MMA.** Section 507 of MMA placed a temporary, 18-month moratorium (beginning December 8, 2003) on physician referrals to specialty hospitals in which the physician has an ownership or investment interest. The ban does not apply to hospitals already in operation before November 18, 2003 or under development as of such date, provided certain conditions are met. During this time, both the Medicare Payment Advisory Commission (MedPAC) and HHS are to conduct studies on these entities and submit reports to Congress by March 8, 2005, containing recommendations for any legislative or administrative changes.

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<sup>11</sup> U.S. General Accounting Office, *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance*, Report to Congress, GAO-04-167, Oct. 2003.

<sup>12</sup> U.S. General Accounting Office, *Specialty Hospitals: Information on National Market Share, Physician Ownership and Patients Served*, GAO letter report GA-03-683R, Apr. 12, 2003

The specialty hospital (sometimes labeled “boutique hospital”) issue is controversial. It is likely that it will continue to be the subject of debate during the moratorium period.

## Regulations

It took a number of years for most of the implementing regulations to be issued for the self-referral ban. In part, this reflected the fact that Congress on several occasions considered, and in a few cases enacted, significant modifications to the original law. More important, however, the delay reflected the very complicated and continually evolving nature of business relationships in the health care industry. HHS tried to develop regulations which, on the one hand, were consistent with the intention of the law while, at the same time, not interfering unduly with legitimate business practices.

**Stark I.** The Stark I provision was effective January 1, 1992. Proposed implementing regulations were published March 11, 1992.<sup>13</sup> Both independent laboratories and physicians raised concerns with respect to several items in the proposed rules. Final regulations were not issued until August 14, 1995<sup>14</sup> and were effective September 13, 1995. As noted earlier, the application of these regulations was limited to physician referrals to clinical laboratories. However, the preamble noted that the policy interpretations were generally expected to apply with respect to other “designated health services” until Stark II regulations were issued.

**Stark II.** Proposed Stark II regulations were issued January 9, 1998.<sup>15</sup> On January 4, 2001, final regulations (with comment period) were issued.<sup>16</sup> These covered major portions of Stark II, including many of the Medicare-related issues raised in comments to the proposed rules. These regulations are referred to as Phase

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<sup>13</sup> HHS, HCFA, “Medicare Program; Physician Ownership of and Referrals to Health Care Entities That Furnish Clinical Laboratory Services; Proposed Rule,” *57 Federal Register* 8588, Mar. 11, 1992.

<sup>14</sup> HHS, HCFA, “Medicare Program; Physician Financial Relationships With, and Referrals to Health Care Entities That Furnish Clinical Laboratory Services; Financial Relationship Reporting Requirements; Final Rule,” *60 Federal Register* 41915, Aug. 14, 1995.

<sup>15</sup> HHS, HCFA, “Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Proposed Rule,” *63 Federal Register* 1659, Jan. 9, 1998.

<sup>16</sup> HHS, HCFA, “Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule,” *66 Federal Register* 855, Jan. 4, 2001.

I. Most of the remaining provisions were addressed in Phase II interim final regulations (with comment period) issued March 26, 2004.<sup>17 18</sup>

As noted by CMS, most of the public comments made in response to the 1998 proposed rules asserted that the agency's interpretation of the statute was too conservative. CMS responded by noting that the final rule in Phase I was substantially revised in order to provide more flexibility. It reported that, in general, it interpreted the prohibition narrowly and the exceptions more broadly. For example, major changes were made in the definitions of group practice, in-office ancillary services, and academic medical centers. As a result of the numerous changes made by the final regulations, CMS stated that physicians should find it easier to comply with the laws and regulations. In general, the effective date for Phase I was delayed for one year, to January 4, 2002, to allow any affected individuals and entities enough time to restructure their business relationships.

The Phase II final regulations cover items not addressed in Phase I, including the exceptions relating to ownership and investment interests and exceptions related to compensation arrangements. In certain instances, changes are made in the Phase I rules in response to public comments. Phase II regulations are effective July 26, 2004. As noted in the preamble, CMS followed the same approach as with Phase I. CMS stated that it attempted to clarify and simplify the rules; further it added additional exceptions for financial relationships that posed no risk of fraud and abuse when all of the conditions of the exception are met.

CMS noted that the Phase I and Phase II regulations are intended to be read together. It therefore printed the entire regulation for the self-referral provisions as part of the Phase II issuance. The only part of the self-referral ban not addressed by Phase II is the ban on Medicaid referrals; this is expected to be addressed in subsequent rule-making.

The Appendix provides an overview of the self-referral law and regulations as they exist today.

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<sup>17</sup> HHS, CMS, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule," 69 *Federal Register* 16052, Mar. 26, 2004.

<sup>18</sup> A technical glitch resulted in a couple of sections being omitted from the preamble to the regulations. The omitted language was subsequently published on Apr. 6, 2004. HHS, CMS, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) Correction; Correction of Interim Final Rule," 69 *Federal Register* 17933, Apr. 6, 2004.

## **Other Anti-Fraud Provisions**

It should be noted that the law contains a variety of provisions, in addition to the self-referral ban, which are designed to address potentially fraudulent or abusive activities against federal health care programs. These include: (1) Section 1128 of the Social Security Act (SSA) which establishes, for individuals and entities convicted of health care crimes, mandatory and permissive exclusions from participation in federal health care programs; (2) Section 1128A of SSA which establishes civil monetary penalties for false claims and similar activities; and (3) the “anti-kickback” statute (Section 1128B of the SSA) which establishes criminal penalties for individuals and entities submitting false statements or soliciting or receiving a kickback. Federal criminal prosecutions may also be brought under other anti-fraud statutes.

Civil money penalties, assessments, and exclusions for health care violations are administered by the HHS Office of Inspector General (OIG), while criminal provisions are administered by the Department of Justice. The law also requires the Secretary of HHS to issue and modify “safe harbors” which identify legitimate business practices which would not be considered in violation of the anti-kickback law.

## **Prospects**

In the first few years following enactment of the self-referral ban, a number of efforts were made to significantly modify or lessen the impact of the legislation. This effort has waned in recent years. It is, however, likely that the health care community will continue to recommend additional modifications to the regulations to accommodate additional business relationships.

The major focus of legislative attention in the near future is likely to be the 18-month moratorium on referrals to specialty hospitals and whether the ban will be extended, perhaps in modified form, after the June 8, 2005, ending date.

## Appendix: Summary of Law and Regulations

This Appendix provides an overview of the self-referral law and regulations as they exist today. **This summary should not serve as a basis for determining whether an individual financial relationship is in violation of the ban or fits one of the exceptions. Only an attorney familiar both with the Stark provisions as well as the circumstances of an individual case is in a position to make such a determination.**

### In General

The law establishes a ban on certain *financial arrangements* between a *referring physician* and an entity. Specifically, if a physician (or immediate family member) has a financial relationship with an entity, the physician is prohibited from making a referral to the entity for designated health services (*DHS*) for which Medicare would otherwise pay. Further, the entity may not bill Medicare for such services.

A financial relationship is defined as an *ownership or investment interest* in or a *compensation arrangement* with the entity. For purposes of the ban, an ownership or investment interest may be through equity, debt, or other means. An interest in an entity that holds such ownership or investment interest is included in the definition. A compensation arrangement is generally defined as any arrangement involving any remuneration between a physician (or immediate family member) and an entity.

### Sanctions

The law prohibits payments for a DHS provided through a prohibited referral and requires refunds for any amounts improperly billed and collected. It provides for a civil monetary penalty (up to \$15,000 per service) and exclusion from Medicare in any case where a person submits an improper claim that such person knew or should have known was provided through a prohibited referral or who has not refunded the payment. Civil monetary penalties of up to \$100,000 for each arrangement or scheme and exclusion from Medicare are also provided for circumvention schemes. These occur in cases where a physician or other entity enters an arrangement or scheme (such as a cross-referral arrangement) which the entity or person knew or should have known had the principal purpose of assuring referrals, which if they had been directly made would have been prohibited.

Civil money penalties, assessments, and exclusions for health care violations are administered by the HHS Office of Inspector General (OIG). The OIG sanctions regulations for such violations include sanctions relating to the self-referral ban (42 C.F.R. 1003).

### Exceptions

The law includes a series of exceptions to the ban. Some are general exceptions to both the ownership and compensation arrangement prohibitions, while others relate only to ownership or only to compensation arrangements.

Implementing regulations add an exception for a claim by an entity for a DHS when the entity is unaware of the referring physician's identity and did not act in reckless disregard or deliberate ignorance of such identity.

The regulations further add an exception for certain temporary arrangements involving noncompliance. If the entity has a financial relationship with an entity that complied with one of the general, ownership, or compensation exceptions for the previous 180 days, it is allowed 90 days to come into compliance provided certain conditions are met. The relationship must have fallen out of compliance for reasons beyond the control of the entity and the entity must take prompt steps to rectify the noncompliance. This exception can be used by an entity only once every three years.

The following is a summary of the self-referral law (Section 1877 of the Social Security Act) and related regulations (42 C.F.R. 411.350 - 411.361)

## Definitions

The law and regulations contain a series of terms which are key to application of the self-referral provision. The definition of terms is particularly important to determine whether a particular referral falls within the prohibition, and if so, is eligible for an exception. The following highlights the definitions for key terms used throughout the law and/or regulations. Additional concepts, primarily applicable to a single exception are defined in subsequent sections.

### **Designated Health Services.**

**Law.** The self-referral ban applies to designated health services (DHS). These are defined as: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) radiology services, including magnetic resonance imaging (MRI), computerized axial tomography (CAT scans) and ultrasound services; (5) radiation therapy services and supplies; (6) durable medical equipment (DME) and supplies; (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) home health services; (10) outpatient prescription drugs; and (11) inpatient and outpatient hospital services.

**Regulations.** DHS do not include services that are reimbursed by Medicare as part of a composite rate for a service that is not a DHS. For example, radiology services paid as part of the facility fee for ambulatory surgical center services are not considered DHS.

Certain services are defined by reference to a list of specific CPT (Current Procedural Terminology) and HCPCS (Health Care Financing Administration Procedure Coding System) codes. The specified services are clinical laboratory services, physical therapy, occupational therapy and speech language pathology services, radiology and certain other imaging services, and radiation services and supplies. The associated codes are in an Appendix to the March 24, 2004 regulations and will be updated annually in an appendix to the physician fee schedule update.



**Referral; Referring Physician.**

**Law.** Referrals include a request by a physician for an item or service, 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). Also included is a request by a physician, or establishment of a plan of care, that involves the furnishing of DHS. Physician requests are defined as physician referrals.

The law specifies that requests by pathologists for clinical diagnostic lab services and pathological examination services are not “referrals” if they are furnished by (or under the supervision of) such pathologist pursuant to a consultation request by another physician. Requests by radiologists for diagnostic radiology services and by radiation oncologists for radiation therapy would not constitute referrals.

**Regulations.** The regulations state that a “referral “ does not include services performed or provided personally by the referring physician. A service is not considered to be personally performed or provided if it is performed or provided by another person, including the referring physician’s employees, independent contractors, or group practice members. The definition of referring physician specifies that such physician and the professional corporation of which he or she is the sole owner are the same for purposes of the self-referral provisions.

The preamble to the regulations notes that while some services may not be considered to be personally performed, they may fall into the in-office ancillary services or other exceptions (discussed below).

Further, the preamble also notes that a referral is not considered to have taken place if a physician personally provides durable medical equipment to a patient. Similarly there is no referral if a physician personally fills an implantable pump or when a physician prepares an antigen and furnishes it to a patient.

**Financial Relationship.**

**Law.** As noted above, a financial relationship is defined as an ownership or investment interest in or a compensation arrangement with the entity.

**Regulations.** The interest may be direct, in which case the remuneration passes between the referring physician and the entity furnishing the DHS without any intervening persons or entities. It may also be indirect.

**Ownership or Investment Interest.**

**Law.** An ownership or investment interest may be through equity, debt, or other means. An interest in an entity that holds such ownership or investment interest is included in the definition

**Regulations.** An indirect ownership or investment interest exists if there is an unbroken chain of persons or entities with ownership and investment interests

between the referring physician (or immediate family member) and the entity. Common ownership in an entity does not in and of itself establish an indirect ownership. There must be an unbroken chain of interests between the referring physician and the entity furnishing the DHS, such that the physician has an interest in the entity furnishing the DHS.

### **Compensation Arrangement.**

**Law.** A compensation arrangement is generally defined as any arrangement involving any remuneration between a physician (or immediate family member) and an entity. The following types of remuneration are excluded from the definition: (1) the forgiveness of amounts owed for inaccurate or mistakenly performed tests and procedures or correction of minor billing errors; and (2) the provision of items used solely to collect, transport, process, or store specimens or order or communicate the results of tests.

In addition, there is an exclusion for payments made by an insurer or 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 covered by a policy with that insurer or self-insured plan. The following requirements must be met for this exclusion: (1) the services may not be furnished and the payment may not be made pursuant to a contract or other arrangement between the insurer or the plan and the physician; (2) the payment is made to the physician on behalf of the covered individual and would otherwise be made to the individual; (3) the amount of the payment is set in advance, does not exceed fair market value, and is unrelated directly or indirectly to the volume or value of referrals; and (4) the payment meets any other requirements imposed by the Secretary to prevent abuse.

**Regulations.** An “under arrangements” contract between a hospital and an entity providing DHS “under arrangements” to the hospital is considered a compensation arrangement. An arrangement consisting solely of items excluded from the definition of remuneration is not considered a compensation arrangement.

An indirect compensation arrangement exists if: (1) there exists between the referring physician and the entity an unbroken chain of persons or entities that have financial relationships between them; (2) the aggregate compensation, of the referring physician (or immediate family) from the person or entity with which the physician has a direct financial relationship, must vary with or otherwise reflect the volume or value of referrals or other business generated for the DHS entity; and (3) the DHS entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated for the DHS entity.

If an indirect compensation arrangement exists, an exception may apply if, among other things, the physician’s compensation from a bona fide employer is set in advance; is consistent with fair market value (which may include unit-based or time-based compensation); otherwise complies with a general or compensation exception (as discussed below); and complies with certain conditions ensuring patient choice, insurer’s choice, and a physician’s independent medical judgment.

**Fair Market Value.**

**Law.** The law defines fair market value as the value in an arms length transaction, consistent with general market value. In the case of rentals or leases, it includes the value of the rental property for general purposes. In the case of leased space, the value is not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity to the lessor where the lessor is a potential source of patient referrals.

**Regulations.** General market value is generally defined as the price that an asset would bring, or the compensation that would be included in a service agreement, as a result of bona fide bargaining between the parties. The regulations specify that hourly payment for a physician's professional service is to be considered fair market value if it is determined using one of two methodologies. Under the first method, the hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing such services in the area. Under the second method, the hourly rate is determined by averaging the fiftieth percentile national compensation level for physicians in the same speciality in at least four of six specified surveys and dividing by 2,000 hours. If a specialty is not identified in a survey, the general practice amount can be used.

**Volume or Value of Referrals.**

**Law.** A number of exceptions in the compensation sections specify that the compensation not take into account the volume or value of referrals. Certain exceptions impose the further requirement that the compensation not take into account other business generated between the parties.

**Regulations.** The regulations permit time-based or unit-based payments, even when the physician receiving the payment has generated the payment through a DHS referral, provided the payment is set at fair market value at the inception of the arrangement and does not subsequently change during the term of the arrangement in any manner that takes into account DHS referrals. For those exceptions that prohibit taking into account other business generated between the parties, the arrangement may not take into account any other business, including non-federal health care business generated between the parties. Not included are personally performed services.

**Group Practice.**

**Law.** The law contains a definition of group practice for purposes of the self-referral provision. A group practice is defined as a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association in which: (1) each physician group member furnishes substantially the full range of services the physician routinely provides through the joint use of office space, facilities, equipment, and personnel; (2) substantially all of the services of the physician group members are provided through the group and billed under a billing number assigned to the group with billing receipts treated as receipts of the group; (3) the overhead expense and

practice income are distributed in accordance with methods previously determined; (4) members of the group practice must personally perform no less than 75% of the physician-patient encounters of the group practice; and (5) the group meets other standards imposed by the Secretary.

In addition, no physician who is a member of a group may directly or indirectly receive compensation based on the volume or value of referrals. However, a physician may be paid a share of the overall profits of the group, or a productivity bonus, based on personally-performed services or services incident to such services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of the physician's referrals.

The law also specifies that faculty practice plans operated by a hospital, an institution of higher education, or a medical school with an approved medical residence training program fall within the definition of a group practice only for services provided within the faculty practice plan.

**Regulations.** The regulations specify that the practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the state including (but not limited to) a partnership, professional corporation, limited liability company, foundation, not-for-profit corporation, faculty practice plan, or similar association. The entity may be owned, in whole or in part, by another medical practice, provided it is not an operating physician practice. A single entity does not include informal affiliations of physicians formed substantially to share profits from referral or separate group practices under common ownership or control. A group practice that is a single legal entity may own subsidiary entities. A group practice operating in more than one state is considered a single legal entity if: (1) the states in which the group are operating are contiguous; (2) the legal entities are absolutely identical as to ownership, governance, and operation, and (3) the organization into multiple entities is necessary to comply with state licensing laws.

The practice must have two or more physicians who are members of the group (either as employees or direct or indirect owners). Each physician group member must furnish substantially the full range of patient care services that the physician routinely furnishes through the joint use of space, facilities, equipment, and personnel. The total time each member spends on patient care services must be documented to determine whether the group meets the test that substantially all (i.e., 75%) of total patient care services must be furnished through the group. A group practice adding a relocating physician will have 12 months to come back into compliance with the "substantially all" test, if the addition of such new member would otherwise mean the entity failed the test.

The group practice must be a unified business with centralized decision making and consolidated billing and financial reporting.

The group practice is required to meet the prohibition on compensating a physician based on the volume or value of referrals. However, the definition of a group practice permits a group to pay physicians a share of the overall profits. They can allocate the overall profits on an equal per capita basis or on a basis related to

revenues for non-DHS services. The practice may also pay a productivity bonus provided it is calculated in a reasonable and verifiable manner not directly related to the volume or value of referrals. The bonus can be based on total patient encounters or relative value units (used for the purpose of paying for services under the physician fee schedule) or compensation not related to DHS services. In both cases the requirements are met if revenues from DHS are less than 5% of total revenues.

## General Exceptions

The law specifies the following *general exceptions to both the ownership or investment and the compensation bans*.

### Physicians' Services Exception.

**Law.** Physicians' services are defined as those services provided personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

**Regulations.** The regulations extend the exception to services provided as "incident to" physicians services (such as those provided by nurses), provided they meet the definition of physicians services. This exception does not extend to other "incident to" services, such as diagnostic tests, or physical therapy.

### In-office Ancillary Services Exception.

**Law.** This exception applies to all designated health services except for durable medical equipment (other than infusion pumps) and parenteral and enteral nutrients, equipment, and supplies. In-office ancillary services are defined as services furnished by the referring physician, another physician in the same group practice, or personally by individuals directly supervised by the physician or another physician in the group practice.

The services must be furnished in: (a) a building in which the referring physician or other member of the group practice provides services unrelated to the furnishing of designated health services; or (b) in another building used for the centralized provision of the group's designated health services. For clinical lab services only, the exception applies if such services are furnished by a group practice with multiple locations. For other designated health services, the group practice exception only applies if they are provided in a centralized location. The Secretary is permitted to establish other terms and conditions where the provision of services at more than one location do not present a risk of program or patient abuse.

The services must be billed by the physician performing or supervising the service, by that physician's group practice, or by an entity entirely owned by such physician or group practice. Billings by a physician's group must use the billing number assigned to the group.

The Secretary may establish additional requirements to protect against program or patient abuse.

**Regulations.** The in-office ancillary services exception, is the key exception relied upon by physicians in their own practices. The regulations provide detailed guidance on many of the concepts noted in the law, including the following.

- *Designated health services.* The exception is expanded. Included are specified DME items (canes, crutches, walkers and folding manual wheel chairs, infusion pumps (including external ambulatory infusion pumps) and blood glucose monitors) under certain specified conditions. These items (except for infusion pumps and blood glucose monitors) must be needed for ambulation and used by the patient to depart from the office. The item must be personally furnished by the physician who ordered the DME or another physician or employee in the group practice. The physician or group practice supplying the DME must meet all the DME supplier standards.
- *Drugs.* Outpatient drugs, furnished in the office, may be covered under the exception even if they are used by the patient at home. Chemotherapy infusion drugs are also covered.
- *Direct Supervision.* The exception applies to services provided by persons directly supervised by the physician or another physician in the group practice. Supervision must meet the applicable physician supervision requirements under the applicable Medicare coverage or payment rules for the service in question. Physicians in the group include owners, employees, independent contractors, leased employees, and locum tenens physicians.
- *Same Building.* Services are considered provided in the same building (but not necessarily in the same space or part of the building) provided **one** of the following three major conditions are met:
  - The building is one in which the referring physician or his or her group practice (if applicable) has an office that is normally open to patients at least 35 hours a week, and the referring physician (and one or more members of the group) regularly practices medicine and furnishes physician services to patients in that office at least 30 hours a week. Some of the services must be physician services unrelated to DHS, although the unrelated physician services may lead to the ordering of DHS. This test generally describes buildings which are the central place of practice for physicians or their groups.
  - The building is one in which the referring physician, or his or her group practice, has an office that is normally open to their patients at least eight hours a week, and the referring physician regularly practices medicine and furnishes physician services to patients in that office at least six hours a week (including some unrelated to DHS). Services provided by members of the referring physician's group do not count toward the six-hour threshold. The patient must usually see the referring physician or other members of the group practice in the building. This test generally describes buildings where a referring physician practices medicine at least one day per week and is the principal place in which the physician's patients receive services.

- The building is one in which the referring physician, or his or her group practice, has an office that is normally open to their patients at least eight hours a week, and the referring physician or a member of the group practice, regularly practices medicine and furnishes physician services to patients in that office at least 6 hours a week in that office (including some unrelated to DHS). The referring physician must be present and order the DHS in connection with a patient visit during the time the office is open in the building or the referring physician, or a member of the group practice, must be present while the DHS is furnished during the time the office is open in the building. This test generally describes buildings where a referring physician, or member of the group, provide physician services at least one day per week and the DHSs are ordered during a patient visit or the physicians are present during the furnishing of the designated health services.
- *Special Rule for Home Care Physicians.* An exception to the same building requirement is established for physicians who do not have an office because they treat patients in their private homes. The referring physician, or qualified person accompanying the physician, such as a nurse or technician must provide the DHS contemporaneously with a physician service that is not a DHS to the patient in the patient's private home (which may include an assisted living facility or independent living facility).
- *Centralized Building.* This means part or all of a building (including for this purpose only, a mobile vehicle, van, or trailer that is owned or leased on a full time basis, i.e., 24 hours per day, seven days per week, for a term of not less than six months) by a group practice and that is used exclusively by the group practice. The term does not include space shared by more than one group practice, a group practice and one or more solo practitioners, or by a group practice and another provider or supplier. A group practice may have more than one centralized building.

### **Prepaid Plans Exception.**

**Law.** Services provided by a prepaid health plan to its enrollees are exempt. The definition of prepaid plans includes those meeting Medicare requirements or operating as prepaid plans under a Medicare demonstration project. The law includes coordinated care plans under the Medicare+Choice program, now known as the Medicare Advantage program.

**Regulations.** The exception includes Medicaid managed care organizations.

### **Electronic Prescribing Exception.**

**Law.** MMA provides for the establishment of an electronic prescription program for the new Medicare drug program. It authorizes the Secretary to establish a safe harbor from sanctions under the self-referral and other anti-fraud provisions in connection with the provision of nonmonetary remuneration necessary and used exclusively for electronic prescribing. Such remuneration could consist of hardware, software, or other information technology and training services.

**Regulations.** Implementing regulations have not yet been issued.

**Other exceptions.**

**Law.** Exceptions are provided for other financial relationships, specified by the Secretary in regulations, that do not pose a risk of program or patient abuse.

**Regulations.** The regulations include a series of additional exceptions as follows.

*Academic Medical Centers (AMCs) Exception.* AMC services qualifying for the exception must meet conditions for the referring physician. The AMC must also meet structural requirements and conditions.

- *Referring Physician.* The referring physician must:
  - Be a bona fide employee of a component of the academic medical center on a full-time or substantial part-time basis. A component includes an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or non profit support organization whose primary purpose is supporting the teaching mission of the academic medical center. The components need not be separate legal entities.
  - Be licensed to practice medicine in the state(s) in which he or she practices medicine.
  - Have a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital; and
  - Provide either substantial academic services or substantial clinical services (or a combination) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. A physician is deemed to meet the test if the physician spends at least 20% of his or her professional time or eight hours per week providing such services. Failure to meet this test does not necessarily preclude the physician from meeting the requirement.
- *Referring Physician Compensation.* The total compensation paid by all academic medical center components to the referring physician must be set in advance, not exceed fair market value, and not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician.
- *Definition of AMC.* For purposes of the exception, an AMC is defined as:
  - An accredited medical school (including a university where appropriate) or an accredited academic hospital. An accredited academic hospital is a hospital or health system that sponsors four or more approved medical education programs.
  - One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and



- One or more affiliated hospital(s) in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members. Courtesy and volunteer faculty may be counted as faculty. Faculty from any affiliated medical school or accredited academic hospital education program may be aggregated. Residents and nonphysician professionals need not be counted as part of the medical staff of the affiliated hospital.
- *AMC Standards.* AMCs are required to meet the following standards:
  - Transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research or community service.
  - The relationship of the components of the AMC must be set forth in written agreements or other written form adopted by the governing board of each component. If the AMC is one legal entity, documentation requirements are satisfied if transfers of funds between components are reflected in the routine financial reports.
  - All money paid to a referring physician for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant.
- *Anti-Fraud.* The referring physician's compensation arrangement cannot violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

*Implants Furnished by an Ambulatory Surgical Center (ASC) Exception.* Certain implants furnished by an ASC are covered by this exception. Covered implants include, but are not limited to: cochlear implants, intraocular lenses, and other implanted prosthetic devices, and DME. The implant must be implanted by the referring physician or a member of the referring physician's group in a Medicare-certified ASC with which the physician has a financial relationship. Payment is made to the ASC as an ASC procedure.

*Erythropoietin (EPO) and Other Dialysis-related Drugs Furnished in or by an End-stage Renal Disease (ESRD) Facility Exception.* This exception includes certain outpatient prescription drugs that are required for the efficacy of dialysis and identified on the list of drugs appended to the regulations. Drugs are those which are administered in an ESRD facility or in the case of EPO or Aranesep (or identified equivalent drug) are dispensed by the ESRD facility for home use.

*Preventive Screening Tests, Immunizations, and Vaccines Exception.* The items must meet Medicare frequency requirements and be on the list appended to the regulations.

*Eyeglasses and Contact Lenses Following Cataract Surgery Exception.* The exception applies to items provided in accordance with Medicare coverage and payment provisions.

***Intra-family Rural Referrals Exception.*** The exception applies to referrals to an immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, providing certain conditions are met. The patient must reside in a rural area and no other person or entity is available within 25 miles to furnish the services in a timely manner. The mileage limitation does not apply in the case of home-based services. In all cases, the referring physician or immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. These persons do not have an obligation to make such inquiries with respect to persons or entities located more than 25 miles away.

## **Exceptions Relating Only to Ownership or Investment Prohibition**

The law specifies certain exceptions relating only to the ownership or investment prohibition.

### **Ownership of Publically Traded Investment Securities Exception.**

**Law** Ownership of certain investment securities are exempt. These securities are defined as those purchased in a corporation listed on a major stock exchange (New York, American, regional or foreign) or traded under an automated interdealer quotation system operated by the National Association of Securities Dealers. The corporation must have stockholder equity in excess of \$75 million, either at the end of its most recent fiscal year or on an average during the previous three fiscal years. The exception also applies to ownership of shares in a regulated investment company, provided the company has total assets of over \$75 million either at the end of its most recent fiscal year or on an average during the previous three fiscal years.

**Regulations.** The publically traded securities exception applies to securities that can be purchased on the open market at the time the DHS referral is made.

**Hospitals in Puerto Rico Exception.** The law and regulations provide an exception for designated health services provided by a hospital in Puerto Rico.

### **Hospital Ownership Exception.**

**Law.** The law provides an exception for designated health services provided by a hospital where the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself and not merely in a subdivision.

MMA places a temporary, 18-month moratorium (beginning December 8, 2003) on physician referrals to specialty hospitals in which the physician has an ownership or investment interest. A specialty hospital is one that is primarily or exclusively engaged in the care and treatment of one of the following: (1) patients with a cardiac condition; (2) patients with an orthopedic condition; (3) patients receiving a surgical procedure; or (4) any other service category that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment

interests in a hospital under the hospital ownership exception. The ban does not apply to hospitals already in operation before November 18, 2003 or under development as of such date provided the following conditions are met: (1) the number of physician investors after such date is no greater than on such date; (2) the specialized care categories do not change after such date; and (3) any increase in the number of beds only occurs on the hospital's main campus and does not exceed 50% of the beds as of such date or five beds whichever is greater.

**Regulations.** The regulations do not add any service categories to the statutory list of specialty hospitals.

### **Rural Providers Exception.**

**Law.** An exception is provided for designated health services provided by an entity in a rural area (using the same criteria to define rural areas as used under Medicare's hospital prospective payment system). The exception only applies if substantially all of the designated health services furnished by the entity are furnished to individuals residing in the rural area. In addition, the section includes the MMA 18-month moratorium (beginning December 8, 2003) on referrals to specialty hospitals.

**Regulations.** "Substantially all" is defined as not less than 75%.

## **Exceptions Relating Only to Other Compensation Arrangements**

The law establishes a number of exceptions relating to compensation arrangements.

### **Rental of Office Space and Equipment Exception.**

**Law.** Payments made by a lessee to a lessor are not considered a compensation arrangement if: (1) the lease is in writing, signed by the parties, and specifies the premises or equipment covered by the lease; (2) the space or 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; (3) the term of the rental or lease is at least one year; (4) the rental charges over the term of the lease are set in advance, consistent with fair market value, and are not determined by taking into account the volume or value of any referrals or other business generated between the parties; (5) the lease would be commercially reasonable even if no referrals were made between the parties; and (6) the lease meets any other requirements imposed by the Secretary to protect against abuse. In the case of office rental or lease, a lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses based on the ratio of space used exclusively by the lessee to the total amount of space (excluding common areas) occupied by persons using the common area.

**Regulations.** Leases may be terminated during the first year, with or without cause, provided the parties do not enter into another lease until after the expiration

of the lease term. Holdover month-to-month rentals for up to six months immediately following an agreement of at least one year are permitted.

**Bona Fide Employment Relationships Exception.** The law and regulations provide an exception for payments made by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer if: (1) the employment is for identifiable services; (2) the amount of the remuneration is consistent with fair market value and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals; (3) the remuneration is provided pursuant to an agreement that would be commercially reasonable without such referral; and (4) the employment meets other requirements the Secretary may impose as needed to protect against program abuse. The law and regulations permit productivity bonuses when based on services personally performed by the physician or immediate family member.

### **Personal Service Arrangements Exception.**

**Law.** The law establishes an exception for payments from an entity under an arrangement if: (1) the arrangement is written, signed by the parties, and specifies the services covered; (2) the arrangement covers all of the services to be provided by the physician (or immediate family member) to the entity; (3) the aggregate services contracted for do not exceed those that are reasonable and necessary for legitimate business purpose; (4) the term of the agreement is at least one year; (5) the compensation is set in advance, does not exceed fair market value, and (except for physician incentive plans) is unrelated to the volume or value of referrals or other business generated between the parties; (6) the services do not involve the counseling or promotion of activities counter to state or federal law; and (7) the arrangement meets other requirements imposed by the Secretary to protect against abuse.

Additionally, an exception is established for physician incentive plans. These are defined as compensation arrangements between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided to the entity's enrollees. Compensation for such incentive plans may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, provided certain conditions are met. No specific payment may be made directly or indirectly to the physician or physician group as an inducement to reduce or limit medically necessary services provided to enrollees. If the plan places the physician or physician group at substantial financial risk (as determined by the Secretary using rules developed for Medicare risk sharing contracts) it must comply with any requirements the Secretary may impose pursuant to that program. Further, the entity must provide the Secretary, on request, with descriptive information on the program.

**Regulations.** The requirement that an arrangement must cover all services to be furnished by the physician may be met by multiple contracts provided they all incorporate each other by reference or if they cross-refer to a master contract which is maintained centrally. Further, DHS entities may terminate contracts during the first year of the term, provided the parties do not enter into the same, or substantially the same, arrangement during that year.

### **Remuneration Unrelated to the Provision of Designated Health Services Exception.**

**Law.** An exception is provided in the case of remuneration, provided by a hospital to a physician, which is unrelated to the provision of designated health services.

**Regulations.** The regulations clarify that this is a narrow exception which only applies if the remuneration is wholly unrelated to the provision of DHS.

### **Physician Recruitment Exception.**

**Law.** An exception is provided for physician recruitment arrangements under which a hospital pays a physician to relocate in order to become a member of the hospital's medical staff so long as there are no requirements for the physician to refer patients to the hospital and the amount of remuneration is unrelated, directly or indirectly, to the volume or value of referrals. The Secretary may impose other requirements as needed to protect against program or patient abuse.

**Regulations.** The regulations require that: (1) the arrangement is written and signed by both parties; (2) the arrangement is not conditioned on the physician's referral of patients to the hospital; (3) the hospital does not determine directly or indirectly the volume or value of actual or anticipated DHS referrals by the physician or other business generated between the parties; and (4) the physician is allowed to establish staff privileges at another hospital or hospitals and refer business to other entities, except as otherwise restricted under a separate employment or services contract that complies with the requirements for a bona fide employment relationship (as noted above).

The remuneration is for the purpose of inducing a physician to relocate to the geographic area served by the hospital. The physician will be presumed to have relocated to the geographic area if: (1) the physician has relocated his or her medical practice at least 25 miles; or (2) the physician's new medical practice derives at least 75% of its revenues from professional services furnished to patients whom the physician did not see in the three years preceding relocation. In the first year, the 75% test is deemed to be met, if there is reasonable expectation that the requirement will be met. Residents and physicians in practice less than one year are not required to satisfy the relocation requirement.

Payments made to physicians through existing medical groups or directly to physicians recruited to existing medical groups meet the exception provided: (1) if payments are made to the group, the group is a party to the recruiting agreement; (2) all remuneration paid by the hospital to the group is passed through to the recruited physician except for actual recruitment costs incurred; (3) under any income guarantee, the hospital takes into account only the incremental costs attributable to the recruited physician; (4) records of actual costs and passed through amounts are kept for five years; (5) remuneration paid by the group does not reflect the volume or value of actual or anticipated referrals by the recruited physician or the practice receiving the direct payments from the hospital; (6) no other additional restrictions

are imposed on the physician other than those relating to quality of care; and (7) the agreement does not violate anti-kickback laws or regulations.

The physician recruitment exception is extended to federally qualified health centers (FQHCs).

### **Isolated Transactions Exception.**

**Law.** An exception is provided in the case of isolated financial transactions, such as a one-time sale of a property or practice, if: (1) the amount is consistent with fair market value and is unrelated (directly or indirectly) to the volume or value of referrals, and (2) the transaction would be commercially viable without such referrals. Again, the Secretary may impose other requirements as needed to protect against program or patient abuse.

**Regulations.** The regulations specify that there can be no additional transactions between the parties for the following six months, except for those specifically exempted under other allowed exceptions. Post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician are permitted.

### **Group Practice Arrangements with a Hospital Exception.**

**Law.** An exception is established for certain arrangements under which designated health services are provided by a group practice but billed by the hospital. An exception is provided if: (1) in the case of services provided to inpatients, the arrangement is pursuant to the provision of inpatient services; (2) the arrangement began before December 19, 1989 and has continued in effect without interruption since that date; (3) in the case of DHS covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement; (4) the arrangement is pursuant to a written agreement that specifies the services to be provided and the compensation for the services; (5) the compensation is consistent with fair market value, the amount per unit of service is fixed in advance and is unrelated to the volume or value of referrals or other business generated between the parties; (6) the agreement would be commercially reasonable even if there were no referrals; and (7) the arrangement meets other requirements the Secretary may impose as needed to protect against program or patient abuse.

**Regulations.** The regulation specifies that the DHS must be furnished by the group. In order for the “substantially all” test to be met, at least 75% of the DHS services furnished to hospital patients are furnished by the group under the arrangement.

### **Payments by a Physician for Items and Services Exception.**

**Law.** An exception is made for payments by a physician to a lab for clinical laboratory services. An exception is also made for payments to another entity for items and services if they are furnished at a price consistent with fair market value.

**Regulations.** The regulations specify that payments include those made by an immediate family member of the physician. Services means services of any kind, not just health care services. This exception can only be used if no other exception applies.

### **Other Exceptions.**

**Law.** Exceptions are authorized for other financial relationships, specified by the Secretary in regulations, that do not pose a risk of program or patient abuse.

**Regulations.** The regulations include a series of additional exceptions as follows.

*Charitable Donations By a Physician Exception.* This exception covers bona fide charitable donations made by a physician (or immediate family member) to an entity if: (1) the donation is made to a tax-exempt organization or to a supporting organization; (2) it is not solicited or made in any manner that reflects the volume or value of referrals or other business generated between the physician and the entity; and (3) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.

*Non-Monetary Compensation Up to \$300 Exception.* (1) The non-monetary compensation can not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; (2) the compensation may not be solicited by the physician or physician's practice; and (3) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission. The \$300 limit is to be increased each calendar year by the increase in the consumer price index-urban all items (CPI-U).

*Fair Market Value Compensation Exception.* This exception applies to compensation stemming from an arrangement between an entity and a physician (or immediate family member) or any group of physicians (whether or not they meet the definition of group practice) for the provision of items or services by the physician (or family member) or group of physicians to the entity. The following conditions must be met: (1) the arrangement is in writing, covers identifiable items or services all of which are specified; (2) the time frame is specified; (3) the compensation is specified, set in advance, consistent with fair market value and does not take into account the volume or value of referrals or other business generated by the referring physician; (4) the arrangement would be commercially reasonable; (5) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission; and (6) the services do not involve counseling or promotion of a business arrangement or other activity that violates state or federal law.

*Medical Staff Incidental Benefits Exception.* This exception applies to non-monetary compensation from a hospital to a member of its medical staff when the item or service is used on the hospital's campus. The following conditions must be met: (1) the compensation is offered to (but not necessarily accepted by) all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals or other business generated between the parties; (2) the compensation is provided during periods when the medical staff members are

engaged in services or activities that benefit the hospital or its patients; (3) the compensation is provided by the hospital and used on the campus; (4) the compensation is reasonably related to or designed to facilitate directly or indirectly the delivery of medical services; (5) the compensation for each occurrence (for example a meal) is less than \$25, increased each calendar year by the increase in the CPI-U; (6) compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; (7) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission. The exception may apply to other facilities meeting the requirements, including federally qualified health centers.

*Risk-Sharing Arrangements Exception.* This exception applies to compensation provided pursuant to a risk-sharing arrangement between a managed care organization or independent physician's association and a physician (either directly or through a subcontractor) for services provided to health plan enrollees provided that the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.

*Compliance Training Exception.* This exception applies to compliance training provided by an entity to a physician (or immediate family member or office staff) who practices in the entity's local community or service area provided the training is held in such area.

*Indirect Compensation Exception.* Indirect compensation (as defined above, under "Compensation" in Definitions section) meets the qualifications for an exception provided that: (1) the compensation is fair market value for services and items actually provided and does not take into account the volume or value of referrals or other business generated by the referring physician; (2) the arrangement is in writing and specifies the covered services (except that in the case of a bona fide employment relationship the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and (3) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.

*Referral Services Exception.* This is defined as remuneration which meets the requirements in 42CFR1001.952(f) defining permissible exceptions to activities defined as criminal for purposes of federal health care programs.

*Obstetrical Malpractice Insurance Subsidies Exception.* This is defined as remuneration which meets the requirements in 42CFR1001.952(o) defining permissible exceptions to activities defined as criminal for purposes of federal health care programs.

*Professional Courtesy Exception.* Professional courtesy (i.e., the provision of free or discounted health care items or services) offered to a physician, immediate family member, or office staff can qualify for an exception provided that: (1) the professional courtesy is offered to all physicians on the entity's bona fide medical staff or entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties; (2) the health care items and services are of a type routinely provided by the entity; (3) the entity'



professional courtesy policy is written and approved in advance by the governing board; (4) the courtesy is not offered to a physician or immediate family member who is a federal health care program beneficiary, unless there is a good faith showing of financial need; (5) the insurer is informed of any coinsurance reduction; and (6) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.

*Retention Payments in Underserved Areas Exception.* This exception applies to retention payments made by a hospital or federally qualified health center directly to a physician on its staff in order to retain the physician's medical practice in the geographic area served by the entity. To qualify: (1) the remuneration must meet the general standards specified for physician recruitment specified above; (2) the area served by the entity is a health professions shortage area (HPSA) or is an area with a demonstrated need for the physician, as determined by the Secretary in an advisory opinion; (3) the physician has a bona fide firm recruitment offer from a hospital or FQHC, unrelated to the entity making the payment, which would require the physician to move his or her practice at least 25 miles and outside of the geographic area served by the entity making the retention payment; (4) any retention payment is subject to the same obligations and restrictions on repayment or forgiveness as the bona fide recruitment offer; and (5) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission. The Secretary is permitted to waive the relocation requirement through an advisory opinion.

The retention payment is the lower of: (1) the difference between the physician's current income from physician and related services and the income the physician would receive from such services under the recruitment offer (over no more than a 24-month period); or (2) the reasonable costs the hospital or FQHC would otherwise have to expend to recruit new physicians to the geographic area. Parties are required to use reasonable and consistent methodologies for making these determinations. A hospital can not enter into a retention arrangement more frequently than once every five years and the amount may not be altered during the term of the arrangement based on the volume or value of referrals or other business generated by the physician.

*Community-Wide Health Information Systems Exception.* This exception applies to items or services of information technology provided by an entity to a physician that allow access to and sharing of electronic healthcare records and any complimentary drug information systems, general health information medical alerts, and related information for patients served by community providers and practitioners in order to enhance overall health. In order to qualify: (1) the items and services are available as necessary to enable the physician to participate in the community-wide information system; are principally used by the physician as part of that system, and are not provided in any manner that takes into account the volume or value of referrals or other business generated by the physician; (2) the community-wide systems are available to all providers and practitioners and residents of the community who desire to participate; and (3) the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.

## Other Provisions

**Advisory Opinions.** The Secretary is required to issue advisory opinions concerning whether a referral (other than to a clinical laboratory) is prohibited. Each advisory opinion is binding to the Secretary and the party or parties requesting the opinion. To the extent practicable, the Secretary is to apply the rules and take into account the regulations relating to advisory opinions for fraud and abuse sanctions.

**Reporting Requirements.** The law establishes a reporting requirement for entities providing services under Medicare. Entities are required to provide information on covered services provided by the entity and the names and provider numbers of physicians (or immediate family members) with ownership or investment interests or compensation arrangements. Sanctions may be imposed on any person who is required, but fails, to meet reporting requirements.

The regulations specify that a reportable financial relationship is any ownership or investment interest or compensation arrangement, including those meeting the criteria for an exception, except for those related to publically traded securities or mutual funds. The required information is only that information that the entity knows or should know in the course of prudently conducting business. Reportable information is to be retained by the entity and furnished upon request; routine reporting is not required.