

CRS Report for Congress

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

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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. A number of studies found that self-referral arrangements posed a conflict-of-interest since the physician was in a position to benefit financially from the referral. They found that such arrangements tended to encourage overutilization of services, which in turn drives up health care costs. They also contended that such arrangements create a captive referral system, which limited competition among health care providers. Some persons responded to these concerns by stating that while problems might exist, they were not widespread. Further, these observers contended that in many cases physician investors were 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 Centers for Medicare and Medicaid Services (CMS, the agency that administers Medicare) has issued a series of implementing regulations. “Phase III” of the final regulations were issued September 5, 2007.

Recently attention has focused on the growth of specialty hospitals, namely hospitals that focus on one category of care (e.g., orthopedic care). 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. The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) included a temporary 18-month moratorium (beginning December 8, 2003) on referrals to such hospitals. The ban did not apply to hospitals already in operation or under development as of November 18, 2003. On August 1, 2007, the House passed the Children's Health and Medicare Protection Act of 2007 (CHAMP, H.R. 3162) containing a number of Medicare provisions. CHAMP would modify the current “whole hospital exception” which permits referrals by physicians to hospitals in which they have a financial interest. Only hospitals experiencing no increase in the number of operating rooms and beds at any time on or after the date of enactment could continue to be eligible. The Senate has not taken action on any self-referral measure this year. This report will be updated as events warrant.

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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. A number of studies found that self-referral arrangements posed a conflict-of-interest since the physician was in a position to benefit financially from the referral. They found that such arrangements tended to encourage overutilization of services, which in turn drives up health care costs. They also contended that such arrangements create a captive referral system, which limited competition among health care providers. Some persons responded to these concerns by stating that while problems might exist, they were not widespread. Further, these observers contended that in many cases physician investors were 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 ban (which has since expired) related to referrals to specialty hospitals.

The Centers for Medicare and Medicaid Services (CMS, and its predecessor the Health Care Financing Administration) issued a series of implementing regulations. On August 27, 2007, CMS announced the issuance of the third phase (Phase III) of final implementing regulations; they were published in the *Federal Register* on September 5, 2007. The Phase III rule finalizes and responds to public comments regarding the Phase II final rules. CMS notes there are no new exceptions, but rather refinements in certain areas which could permit or, in some cases require, restructuring of some existing arrangements.

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 1987.¹

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.

¹ 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.

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 between physicians and health facilities 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 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.²

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.³ 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.⁴

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 1993.⁵ 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

² 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, 102nd Cong., 1st sess., October 17, 1991, (Washington, GPO, 1991).

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

⁴ 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, November 19, 1992.

⁵ 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*, April 20, 1993 (Washington: GAO, 1993).

ordered tests more frequently than physicians who referred patients outside of their practices.⁶

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 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. In such cases, physicians must disclose their investment interests to patients when making a referral. Patients must be given a list of effective alternative facilities if such facilities become reasonably available, informed they have an option to use one of the alternative facilities, and assured that they will not be treated differently by the physician if they do not choose the physician owned facility.⁷ This general policy remains in effect, though revisions have been made to conform to subsequent legislation and additional clarifications are under review.

Omnibus Budget Reconciliation Act of 1993 (OBRA 1993): "Stark II" Provisions

1992 Legislation. The 102nd 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.

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

⁷ [http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_ci91.pdf]

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 During the 104th Congress

Passage of Stark II raised a series of concerns on the part of many provider groups.⁸ 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, represented an unwarranted intrusion into the practice

⁸ 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.

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. CMS stated⁹ 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."

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 1997 (BBA 97, P.L.105-33)

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 include a provision which requires the Secretary of HHS to issue written advisory

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

opinions concerning whether physician referrals relating to designated health services (other than clinical lab services) were prohibited.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

MMA contained two self-referral provisions. The first related to electronic prescribing, the second to specialty hospitals (discussed below).

MMA provided for the establishment of an electronic prescription program for the new Medicare drug program. It authorized 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.

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.¹⁰

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 "whole hospital exception" 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 because physician ownership in a specialty hospital is comparable to ownership in a subdivision of a community hospital. 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

¹⁰ U.S. General Accounting Office, *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance*, Report to Congress, GAO-04-167, October 2003.

practice owned 80% or more of the hospital. The report also noted that these hospitals tended to treat less sick patients.¹¹

MMA Moratorium. Section 507 of MMA placed a temporary, 18-month moratorium (December 8, 2003- June 5, 2005) on physician referrals to specialty hospitals in which the physician had an ownership or investment interest. The ban did not apply to hospitals already in operation before November 18, 2003 or under development as of such date, provided certain conditions were met. During this time, both the Medicare Payment Advisory Commission (MedPAC) and CMS were to conduct studies on these entities and submit reports to Congress by March 8, 2005, containing recommendations for any legislative or administrative changes.

MedPAC Report. MedPAC submitted its report on March 8, 2005.¹² The report found¹³ that physician-owned specialty hospitals treat patients who are generally less severe cases (and therefore more profitable than average) and concentrate on particular diagnosis groups. In 2002 (the time period studied) the hospitals did not have lower costs for Medicare inpatients than community hospitals, although their inpatients had shorter lengths of stay. Further the financial impacts on community hospitals was limited in that year. It further stated that many of the differences in profitability across and within diagnosis-related groups (DRGs, the units that determine inpatient hospital payments) could be reduced by improving the payment system including refining the DRGs to more fully capture the severity of illness.¹⁴

CMS Report. CMS issued its report on May 12, 2005.¹⁵ Because the ownership data was not collected by CMS, the agency relied on a sample approach. It found significant differences between cardiac hospitals and orthopedic/surgery hospitals. Cardiac hospitals tended to resemble full service hospitals because of their size, the presence of emergency departments, and their community outreach programs. Medicare inpatient days represented 67% of total inpatient days. Typical ownership patterns were 49% physicians' share, 51% corporate/hospital share with the average physician ownership share 0.9%. On the other hand, orthopedic/surgery hospitals tended to resemble ambulatory surgical centers, lack active emergency departments, and focus on outpatient services. Medicare inpatient days represented

¹¹ U.S. General Accounting Office, *Specialty Hospitals: Information on National Market Share, Physician Ownership and Patients Served*, GAO letter report GA-03-683R, April 12, 2003

¹² [http://www.medpac.gov/documents/Mar05_SpecHospitals.pdf]

¹³ [http://www.medpac.gov/publications/congressional_testimony/20050512_TestimonySpecHospEC.pdf]

¹⁴ A subsequent MedPAC report issued in August 2006 (*Physician-Owned Specialty Hospitals Revisited*) contained findings similar to those presented in 2005; however, the statistical significance of some of the findings increased due to having a larger number of specialty hospitals to examine.

¹⁵ [<http://www.cms.hhs.gov/MLNProducts/Downloads/RTC-StudyofPhysOwnedSpecHosp.pdf>]

36% of total inpatient days. Typical ownership patterns were 80% physicians' share, 20% corporate/hospital share with the average physician ownership share 1.1%.

The report found that Medicare referrals to physician-owned hospitals came primarily from physician owners. Its sample did not see a consistent pattern of preference for referring to specialty hospitals among physician owners relative to their peers. Medicare cardiac patients treated in competitor hospitals were more severely ill than those treated in physician-owned specialty hospitals in most of the study sites.

The report found that the quality of cardiac care delivered at specialty hospitals was as good or better than competitor hospitals. It was not able to draw any conclusions with respect to orthopedic/surgery hospitals.

Following the MedPAC and CMS May reports, CMS submitted recommendations concerning the inpatient hospital prospective payment system, similar to those which had been recommended by MedPAC. It further noted that physicians may be participating in ownership of small orthopedic or surgical hospitals rather than ambulatory surgical centers (ASCs) in part to take advantage of the differences in payments between the two. It noted upcoming changes in payments to ASCs which are intended to remove the financial incentives for performing services in these facilities rather than in hospital outpatient departments.

Deficit Reduction Act. On June 9, 2005, the end of the moratorium period, CMS instituted a six-month suspension in the processing of Medicare enrollment applications submitted by specialty hospitals. It stated that during the suspension period, it intended to undertake a review of its existing standards for participation and payment. Subsequently, CMS issued extensions to the suspension.

The Deficit Reduction Act of 2005 (DRA, P.L.109-171) extended the suspension until the earlier of the date that the Secretary submitted a final report on physician investment in specialty hospitals (as required by DRA) or August 8, 2006. The Secretary could extend the deadline for an additional two months if the required report had not been issued. The temporary suspensions did not apply to those specialty hospitals that submitted an enrollment application prior to June 9, 2005, or that requested prior to that date an advisory opinion from CMS as to their status under the specialty hospital moratorium.

The final required DRA report was issued August 9, 2006.¹⁶ It reviewed a number of items including investment in specialty hospitals, compensation arrangements, provision of care to Medicaid patients and charity care, and payer mix. Based on its review, it outlined a strategic and implementing plan which includes continuing to make improvements in the DRG and ASC payment systems, aligning physician and hospital incentives, issuing guidance on patient safety measures,

¹⁶ [http://www.cms.hhs.gov/PhysicianSelfReferral/06a_DRA_Reports.asp#TopOfPage]. Note that this report provides additional background information on the specialty hospital issue and the various government reports issued on the subject.

promoting transparency of investments, and enforcement activities.¹⁷ The report did not make any legislative recommendations.

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, 1992.¹⁸ Both independent laboratories and physicians raised concerns with respect to several items in the proposed rules. Final regulations were not issued until August 14, 1995¹⁹ and were effective September 13, 1995. 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, 1998.²⁰ On January 4, 2001, final regulations (with comment period) were issued²¹ These regulations

¹⁷ One component of the plan was a disclosure requirement. Pursuant to regulations issued August 22, 2007, beginning in FY2008, all hospitals (not just specialty hospitals), will be required to describe to patients whether they are physician owned and, on request, the names of the physician owners. (*HHS, CMS, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Final Rule, 72 Federal Register, 47129, August 22, 2007.*)

¹⁸ HHS, HCFA, “Medicare Program; Physician Ownership of and Referrals to Health Care Entities That Furnish Clinical Laboratory Services; Proposed Rule,” *57 Federal Register* 8588, March 11, 1992.

¹⁹ 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, August 14, 1995.

²⁰ HHS, HCFA, “Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Proposed Rule,” *63 Federal Register* 1659, January 9, 1998.

²¹ HHS, HCFA, “Medicare and Medicaid Programs; Physicians’ Referrals to Health Care (continued...)

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 I. Most of the remaining provisions were addressed in Phase II interim final regulations (with comment period) issued March 26, 2004.^{22 23} Phase III of the final regulations, containing some further modifications, were issued September 5, 2007.²⁴

Phase I. 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.

Phase II. The Phase II interim final regulations covered 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 were made in the Phase I rules in response to public comments. Phase II regulations were 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 were intended to be read together. It therefore printed the entire regulation for the self-referral provisions as part of the Phase II issuance.

Phase III. On September 5, 2007, the third phase of final implementing regulations were published in the *Federal Register*. They will be effective December 7, 2007. As was the case for Phase II, the entire regulation for self-referral provisions

²¹ (...continued)

Entities With Which They Have Financial Relationships; Final Rule,” 66 *Federal Register* 855, January 4, 2001.

²² 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, March 26, 2004.

²³ A technical glitch resulted in a couple of sections being omitted from the preamble to the regulations. The omitted language was subsequently published on April 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, April 6, 2004.

²⁴ HHS, CMS, “Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III); Final Rule,” 72 *Federal Register* 51012, September 5, 2007.

was printed. Again, CMS states that Phases I, II, and III are intended to be read together. Providers should read all three phases (including the preambles) to fully understand the exceptions and how they may be applied in specific cases.

The Phase III rule finalizes and responds to public comments regarding the Phase II final rules. CMS notes there are no new exceptions, but rather refinements in certain areas which could permit or, in some cases require, restructuring of some existing arrangements. It states that the regulation: (1) provides enhanced flexibility in structuring nonabusive compensation arrangements; (2) provides relief for inadvertent violations of the self-referral prohibition under certain circumstances; (3) reduces the regulatory burden for compliance with certain exceptions; and (4) clarifies the agency's interpretation of existing regulations.²⁵

The following are some of the key changes made in Phase III: (1) a new "stand in the shoes" provision eliminates the indirect compensation exception for physicians who contract with a designated health services entity through their physician organization (thereby requiring them to comply with the rules governing direct compensation); (2) changes are made in how academic medical centers determine total compensation paid to physicians; (3) a safe harbor for hourly payments to doctors for personal services is eliminated from the fair market value definition; (4) the physician recruitment exception is modified generally to ease the ability of hospitals to recruit physicians into rural and underserved areas; and (5) the whole hospital exception is revised to specify that a physician's ownership in a whole hospital or subdivision does not include a security interest the doctor may have taken in equipment sold to the entity and financed with a loan to the entity.

Additional Regulations

CMS has issued additional regulations affecting the Stark self-referral ban. The annual physician fee schedule includes an updated "list of codes" in the Federal Register for certain categories of designated health services to which the physician self-referral prohibition applies. The designated health service categories included in the list of codes are: clinical laboratory services; physical therapy services (including speech-language pathology services) and occupational therapy services; radiology and certain other imaging services; and radiation therapy services and supplies. The list of codes is published as an addendum to the annual final rule concerning physician fee schedule payment policies. Additionally, CMS may publish other rules or correction notices that may change the list of codes.

The physician fee schedule regulations may also include additional changes to the Stark regulations. For example, the final rule for calendar year 2006, published on November 21, 2005, added nuclear medicine services and supplies to the designated health service categories of "radiology and certain other imaging services" and "radiation therapy services and supplies." The proposed 2008 regulation issued July 12, 2007, contains a number of additional proposed changes; further, it seeks comment on other related issues.

²⁵ HHS, CMS, *CMS Issues Final Rule Prohibiting Physician Self-Referral*, Press Release, August 27, 2007.

On August 8, 2006, CMS issued final regulations on electronic prescribing and electronic health records.²⁶ The regulation created exceptions to the physician self-referral prohibition for certain nonmonetary remuneration related to electronic prescribing technology and electronic health records technology. This regulation has been incorporated into the Phase III rules.

The Appendix provides an overview of the self-referral law and regulations. The regulations discussion incorporates changes made by Phase III, which are effective December 7, 2007.

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 monetary 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.

Pending Changes

There are currently two activities which have the potential for modifying physician referral requirements. The first is a provision related to specialty hospitals incorporated in a House-passed bill. The second is the proposed 2008 physician fee schedule which contains proposed regulatory changes.

Children’s Health and Medicare Protection Act of 2007

Under current law, physicians are not prohibited from referring Medicare patients to whole hospitals in which they have ownership or investment interests.

²⁶ HHS, CMS, *Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Final Rule; Federal Register*; vol. 71, no.152, August 8, 2006.

(The temporary moratorium on referral to specialty hospitals expired in 2005, as discussed above.) Providers that furnish substantially all of their designated health services to individuals residing in rural areas are also exempt from the prohibition.

On August 1, 2007, the House passed the Children's Health and Medicare Protection Act of 2007 (CHAMP, H.R. 3162) which included a number of Medicare provisions. Section 651 of the bill which would modify the whole hospital exception. It specifies that only hospitals meeting certain requirements would be exempt from the referral prohibition. Hospitals eligible for the exemption would have to: 1) have a Medicare provider agreement in effect on July 24, 2007; 2) have no increase in the number of operating rooms and beds at any time on or after the date of enactment; and 3) meet requirements relating to preventing conflicts of interest, ensuring bona fide investment, and enhancing certain patient safety requirements.

All hospitals, including rural hospitals, would have 18 months from the date of enactment to come into compliance. The Secretary would be required to establish policies and procedures to ensure compliance with the requirements. The enforcement efforts could include unannounced site reviews of hospitals. The Secretary would be required to conduct audits to determine if hospitals violated the requirements.

The House-passed CHAMP bill included both Medicare provisions and provisions relating to the state childrens' health insurance program (SCHIP). Revised SCHIP provisions were subsequently incorporated into H.R. 976 which passed both houses of Congress. As of this writing the Senate has not considered a Medicare package this year. At this time, it is unclear how the Congress will proceed on any Medicare legislation.

2008 Proposed Physician Fee Schedule

As noted, the proposed 2008 physician fee schedule contains several proposed regulatory changes to the self-referral requirements including those relating to joint ventures between doctors and hospitals. CMS will analyze the comments received in the proposed rule. Any changes will be incorporated into the final physician payment regulation issued later this year.

Appendix: Summary of Law and Regulations

This Appendix provides an overview of the self-referral law and regulations. The regulations discussion incorporates changes made by Phase III, which are effective December 7, 2007. **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 up to 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 with respect to the same referring physician.

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 - 411.370)

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 annual physician fee schedule includes an updated "List of codes" in the Federal Register for certain categories of designated health services to which the physician self-referral prohibition applies. The designated health service categories included in the list of codes are: clinical laboratory services; physical therapy services (including speech-language pathology

services) and occupational therapy services; radiology and certain other imaging services; and radiation therapy services and supplies.

The final physician fee schedule rule for 2006 added nuclear medicine services and supplies to the designated health service categories of "radiology and certain other imaging services."

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 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. However, it stated that there are few, if any situations in which a referring physician would personally furnish DME and supplies to a patient because doing so would require that the physician be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier. A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that he or she personally performed all required activities.

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. The regulations specify that an ownership or investment interest in a subsidiary company, is not an ownership or investment interest in a parent company, nor in any other subsidiary of the parent company, unless the subsidiary company itself has such interest in the parent company or such other subsidiaries. (It may however, be part of an indirect financial arrangement). Certain items are excluded from the definition of ownership and investment interests. One exclusion is security interest in the equipment of a hospital held by a physician who both sold the equipment to the hospital and financed its purchase through a loan to a hospital. (This transaction is considered a compensation arrangement.)

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.

A direct compensation arrangement exists if remuneration passes between the referring physician (or immediate family member) and the entity furnishing the DHS without any intervening persons or entities.

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 take into account 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.

Phase III of the regulations adds a new “stand in the shoes” provision which means that some arrangements previously considered indirect compensation are now defined as direct compensation (and must comply with the direct compensation rules). Specifically, a physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity is his or her physician organization; the physician is deemed to “stand in the shoes” of the physician organization. For purposes of the definition of indirect compensation arrangement, a physician will be deemed to stand in the shoes of the physician organization with which he or she has a direct financial relationship. When a physician stands in the shoes of his or her physician organization, he or she is deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization has with the DHS entity. The term parties refers to the physician organization and all of its physician members, employees, and independent contractors. In the preamble to the Phase III regulations, CMS noted that many existing arrangements may have been properly structured to comply with the indirect compensation exception. It stated that it was not the intent to require that those arrangements be reexamined and revised. Therefore, the regulations grandfather in those arrangements meeting the indirect compensation exception as of September 5, 2007 (the publication date of Phase III) during the original term or current renewal term of the arrangement.

The regulation states that a physician’s compensation from a bona fide employer or under a managed care contract or other contract for personal services may be conditioned on the physician’s referral to a particular provider, practitioner, or supplier, provided that the compensation arrangement 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 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 well-informed buyers and sellers who were not otherwise in a position to generate business for the other party. Usually the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity.

Phase II regulations established a safe harbor that specified that hourly payment for a physician's professional service was to be considered fair market value if it was determined using one of two methodologies. This safe harbor was eliminated in Phase III, in part because the survey and other information upon which the methodologies relied were not readily available.

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 of the group practice members must be furnished through the group. A group practice adding a relocating physician has 12 months to come back into full 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 provided the share is not based on the volume or value of referrals. 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 based on services personally performed by the physician, or “incident to” such personally performed services, or both, provided it is calculated in a reasonable and verifiable manner not directly related to the volume or value of referrals of DHS (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services “incident to” the physician’s personally performed services). The bonus is deemed not to relate to the volume or value of DHS referrals if: (1) it is based on total patient encounters or relative value units (used for the purpose of paying for services under the physician fee schedule); (2) it is based on compensation not related to DHS services; or (3) 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: (1) 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 (2) 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 blood glucose monitors) must be needed for ambulation or 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.
- *Direct Supervision.* The exception applies to services provided by persons directly supervised by the referring 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 any) 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 patient receiving the DHS usually receives physician services from the referring physician or members of the physician's group practice. The referring physician or the referring physician's group practice owns or rents an office that is normally open to patients at least 8 hours per 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). 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 referring physician is present and orders the DHS during a patient visit on the premises or the referring physician or a member of the physician's group is present while the DHS is furnished during occupancy of the premises. The referring physician, or his or her group practice, owns or rents 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). 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.

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 means 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 each academic medical center component to the referring physician must be set in advance and not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician. Further, the total compensation paid by all academic medical center components to the referring physician must not exceed fair market value.

- *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. For purposes of determining whether the majority of physicians on the medical staff are faculty members, the affiliated hospital must include or exclude all individual physicians with the same class privileges at 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 documents adopted by the governing body 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 implanted 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 that appear on the CMS website (which is updated annually).. 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 specifying items eligible for the exception.

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 to furnish the services in a timely manner within 25 miles or 45 minutes transportation time. The mileage or time 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 or 45 minutes transportation time 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 placed a temporary, 18-month moratorium (beginning December 8, 2003) on physician referrals to specialty hospitals in which the physician had an ownership

or investment interest. A specialty hospital was one that was 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 did not apply to hospitals already in operation before November 18, 2003 or under development as of such date provided the following conditions were met: (1) the number of physician investors after such date was no greater than on such date; (2) the specialized care categories did not change after such date; and (3) any increase in the number of beds only occurred on the hospital's main campus and did not exceed 50% of the beds as of such date or five beds whichever was greater.

Regulations. The regulations reflect the statutory language. However, the moratorium has expired.

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 provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement..

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 purposes; (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. 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. Further, holdover arrangements for up to six months immediately following an agreement of at least one year are permitted provided that the holdover arrangement is on the same terms and conditions as the immediately preceding agreement.

The regulations specify that physician incentive plans are arrangements between entities (or downstream contractors) and physicians. A downstream contractor is defined as an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor. A first tier contractor means an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services.

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. Phase III made a number of changes to the regulations. The regulations, as modified, 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 amount of remuneration to the physician based on 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 geographic area is defined as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. The geographic area may include one or more zip codes from which the hospital derives no inpatients provided that such zip codes are surrounded by zip codes in the defined geographic area from which the hospital draws at least 75% of its inpatients. Hospitals in rural areas may use an alternative test to determine the “geographic area served by the hospital”; the alternative test encompasses contiguous (or in some cases noncontiguous) zip codes from which the hospital draws at least 90% of its inpatients.

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 and into the geographic area served by the hospital; or (2) the physician moves his medical practice into the geographic area served by the hospital and physician’s new medical practice derives at least 75% of its revenues from professional services furnished to patients (including hospital inpatients) 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.

Several categories of physicians are exempted from the relocation requirements. These include (1) residents and physicians in practice less than one year; (2) physicians who for the two years immediately preceding the recruitment arrangement were employed on a full-time basis by a federal or state bureau of prisons, the Department of Defense or Department of Veterans Affairs, or facilities of the Indian Health Service, provided that such physicians did not maintain a separate private practice; and (3) those physicians whom the Secretary has deemed in an advisory opinion not to have established a medical practice comprised of a significant number of patients who are or could become patients of the recruiting facility.

The following additional conditions are established when remuneration is provided by a hospital to a physician indirectly through payments to another physician practice, or directly to a physician who joins a physician practice: (1) the written agreement is also signed by the party to whom the payments are directly made; (2) all remuneration paid is passed through to or remains with the recruited physician except for actual recruitment costs incurred; (3) under any income guarantee, the costs allocated by the practice to the recruited physician do not exceed the incremental costs attributable to the recruited physician (except that a more generous standard is allowed in the case of a physician recruited to replace a deceased, retiring or relocating physician in a rural or underserved area); (4) records of actual costs and passed through amounts are kept for five years; (5) remuneration from the hospital does not take into account the volume or value of actual or anticipated referrals by the recruited physician or the practice receiving the direct payments from the hospital; (6) the practice may not impose on the recruited physician restrictions that unreasonably restrict such physician’s ability to practice medicine in the geographic area served by the hospital; and (7) the agreement does not violate anti-kickback laws or regulations.

Rural hospitals are permitted to recruit physicians into an area outside of the hospital's geographic service area if it is determined through a CMS advisory opinion that the area has a demonstrated need for the recruited physician.

The physician recruitment exception also applies to federally qualified health centers and rural health clinics.

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 those defined as services for purposes of Medicare. 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 nor offered in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and (3) the donation does not violate the anti-kickback statute or any law governing billing or claims submission.

Non-Monetary Compensation Exception. This exception covers non-monetary compensation that does not exceed an aggregate \$300 per calendar year (as adjusted each year for inflation) if the following conditions are met: (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 referring 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 2007 limit is \$329.

If an entity inadvertently provides non-monetary compensation in excess of the limit, the physician is allowed to repay the excess amount within the calendar year or 180 days following the date the excess was received, whichever is earlier (provided such excess does not exceed 50% of the limit). Further, entities are allowed to provide one medical staff appreciation function for the entire medical staff per year without regard to the limit.

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 (other than the rental of office space) either by the physician (or family member) or group of physicians to the entity or by the entity to the physician (or family member) or a group of physicians. 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 is 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 federal or state 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, as adjusted each calendar year for inflation; (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. The 2007 limit is \$28.

Risk-Sharing Arrangements Exception. This exception applies to compensation provided pursuant to a risk-sharing arrangement between a managed care organization or an independent practice 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. Compliance training includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

Indirect Compensation Arrangements Exception. Indirect compensation (as defined above, under "Compensation" in Definitions section) meets the qualifications for an exception provided that (1) the compensation received by the referring physician (or immediate family member) 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 or regulation governing billing or claims submission.

Referral Services Exception. This is defined as remuneration which fits into the anti-kickback safe harbor as defined in 42CFR1001.952(f) for referral services.

Obstetrical Malpractice Insurance Subsidies Exception. This is defined as remuneration which fits into the anti-kickback safe harbor as defined in 42CFR1001.952(o) for obstetrical malpractice insurance subsidies.

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's 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; and (5) the arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission.

Retention Payments in Underserved Areas Exception. This exception applies to remuneration provided by a hospital directly to a physician on its staff in order to retain the physician's medical practice in the geographic area served by the entity. The exception may apply to bona fide written offers or written certification from a physician. To qualify in the case of a bona fide written offer: (1) the physician must have a bona fide firm written recruitment offer or offer for employment from a hospital, academic medical center, or physician organization unrelated to the hospital making the payment, and which would require the physician to move his or her practice at least 25 miles and outside of the geographic area served by the hospital making the retention payment; (2) the payments must meet the general standards specified for physician recruitment specified above; (3) any retention payment is subject to the same obligations and restrictions on repayment or forgiveness as the written recruitment offer or offer of employment; and (4) the retention payment does not exceed the lower of: (a) 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 (b) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area to replace the retained physician.

To qualify in the case of a written certification, the certification must contain: (1) details of steps taken by the physician to effectuate the employment opportunity; (2) details of the employment opportunity; (3) a certification that the future employer is not related to the hospital making the payment; (4) the date on which the physician anticipates relocating his medical practice outside of the geographic area served by the hospital; and (5) information sufficient for the hospital to verify the information in the certification. Further: (1) the hospital must take reasonable steps to verify that the physician has a bona fide opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital; (2) the payments must meet the general standards specified for physician recruitment specified above; (3) the retention payment does not exceed the lower of: a) an amount equal to 25% of the physician's current income (measured over no more than a 24-month period); or b) the reasonable costs the hospital would otherwise have to

pend to recruit a new physician to the geographic area to replace the retained physician.

In both cases the remuneration must meet the following additional requirements: (1) the physician's current medical practice is located in a rural area or health professions shortage area (HPSA), regardless of the physician's specialty or is an area with a demonstrated need for the physician, as determined by the Secretary in an advisory opinion; (2) at least 75% of the physician's patients reside in a medically underserved area or are members of a medically underserved population; (3) the hospital can not enter into a retention arrangement more frequently than once every five years with a particular physician; (4) 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; and (5) the arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission. The Secretary is permitted to waive the relocation requirement through an advisory opinion.

The retention exception also applies to remuneration provided by a federally qualified health center or a rural health clinic.

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 or regulation governing billing or claims submission.

Electronic Prescribing Items and Services.

Law. MMA provided for the establishment of an electronic prescription program for the new Medicare Part D drug program. It authorized 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. The provision applied: (1) in the case of a hospital, by the hospital to members of its medical staff; (2) in the case of a group practice, by the practice to prescribing health care professionals who are members of such practice; and (3) in the case of a prescription drug plan sponsor or Medicare Advantage organization, by such sponsor or organization to pharmacists and pharmacies participating in its network and to prescribing health care professionals.

Regulations. The regulations establish the following additional conditions: (1) the items must be provided as part of or used to access an electronic prescription drug program meeting Part D requirements; (2) the donor does not take actions limiting or restricting the use or compatibility of items or services with other electronic prescribing or health records systems; (3) the donor does not restrict or seek to limit the physician's right or ability to use the items or services for any patient; (4) neither the physician nor physician's practice makes the receipt or amount or nature of services a condition of doing business with the donor; (5) neither the eligibility of the physician for the items or services nor the amount or nature of the items or services takes into account the volume or value of referrals or other business generated between the parties; (6) the arrangement is set forth in a written agreement; and (7) the donor does not have knowledge of or act in reckless disregard that the physician possesses items or services equivalent to those provided by the donor.

Electronic Health Records Items and Services.

Law. As noted earlier, 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. A separate exception is created for nonmonetary remuneration necessary and used predominately to create, maintain, transmit, or receive electronic health records. Such remuneration could consist of software or information technology and training services. The following conditions must be met: (1) the items and services are provided by an entity to a physician; (2) the software is interoperable; (3) the donor does not take actions limiting or restricting the use, compatibility, or interoperability of items or services with other electronic prescribing or health records systems; (4) physician recipients must pay 15% of the donor's costs; (5) neither the physician nor physician's practice makes the receipt or amount or nature of services a condition of doing business with the donor; (6) neither the eligibility of the physician for the items or services nor the amount or nature of the items or services takes into account the volume or value of referrals or other business generated between the parties (with this requirement deemed met if one of certain specified conditions are met); (7) the arrangement is set forth in a written agreement; (8) the donor does not have knowledge of or act in reckless disregard that the physician possesses items or services equivalent to those provided by the donor; (9) the donor does not restrict or seek to limit the physician's right or ability to use the items or services for any patient; (10) the items and services do not include staffing of physician offices and are not used primarily to conduct business unrelated to the physician's medical practice; (11) the electronic health records software contains electronic prescribing capability; and (12) the arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission. The transfer of items or services must occur and all conditions must be met on or before December 31, 2013, the date this exception sunsets.

Other Requirements

Reporting Requirements.

Law. 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 unique physician identifier number (UPIN) or national provider identifier (NPI) 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.

Regulations. 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. Reportable relationships do not include ownership or investment interests that satisfy exceptions regarding publically traded securities and 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. Entities furnishing 20 or fewer Medicare services per year are not subject to the requirement.

Advisory Opinions.

Law. 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.

Regulations. The regulations specify that the request for an advisory opinion must involve an existing arrangement or one into which the requestor plans to enter. Advisory opinions may not address whether fair market value was or will be paid or whether the individual is a bona fide employee as that term is defined in the Internal Revenue Code.