Health Policy Update

Physician Refer Thyself: Is Stark II, Phase III the Final Voyage?

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The United States spends more of its wealth on healthcare than any other developed country, and that share is rising. Supporters of the free market system point to the regulatory burden on the healthcare industry. Estimates of the regulatory costs of US healthcare range from $58 billion to $339 billion. A recent report indicates that approximately $8 billion of the US healthcare budget of $1.9 trillion is spent on physicians' extra income derived from their ownership in outpatient facilities, such as ambulatory surgery centers, diagnostic imaging centers, and diagnostic testing and procedure laboratories.

It is essential for an interventionalist to understand fraud and abuse, self-referrals, and the implications of the Stark law and anti-kickback statutes, among a maze of other regulations. It is important for interventionalists to understand and also be able to invest in protected and approved investments and also be involved in business dealings which are within the law. Various reasons include: decreasing reimbursements by Medicare, Medicaid, managed care, and all other third-party payors; increased competition in providing interventional pain management; increasing costs of overhead and doing business; the popularity of interventional pain management, leading each and every pain physician to want to provide the service; concerns in multiple settings, including offices, ambulatory surgery centers (ASCs), hospitals, private practices, and academic settings; and finally, the failure to develop strategies to remove oneself from questionable investments and business associations.

Self-referrals occur when physicians refer to medical facilities in which they have financial interest. Multiple concerns related to self-referral, including conflict of interest and increased costs to the Medicare program, resulted in a ban on self-referral arrangements for clinical laboratory services under the Medicare program in 1989 known as Stark I. In 1993, the Stark I prohibition on self-referrals by physicians expanded to include 10 additional healthcare services known as designated health services or DHS. The 1993 expansion of Stark I was enacted in 1995 as Stark II. In 2007, CMS adopted Phase III of the regulations interpreting Stark II. Phase III made multiple changes and clarified many previous issues, and it becomes effective December 4, 2007.

While it is mandatory to obtain expert legal advice and this manuscript in no way provides the extensive navigation required through the maze of Stark laws and other anti-kickback statutes, it is incumbent on interventionalists in all settings of practice to have appropriate knowledge of the Stark laws and exceptions and of the anti-kickback statute and safe harbors. Penalties for violating the Stark laws are severe, including fines of up to $15,000 per service and the economic threat of exclusion from participation in federal healthcare programs, which may result in exclusion of any type of healthcare program and loss of privileges at hospitals and surgery centers.

This manuscript reviews physician practices in general, physician payments, and self-referral patterns in particular, the evolution of the Stark law and regulations and its implications for physician practices. This article is not, and should not be, construed as legal advice or an opinion on specific situations.

Key words: Self-referral, Stark I, Stark II, Phase I, Phase II, Phase III, regulations and laws, imaging services, ambulatory surgery centers, incident-to services, in-office ancillary services, anti-kickback statute

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The $2.2 trillion-a-year medical complex of the United States is considered enormously wasteful, ill-targeted, inefficient, and unfair (1). The function of any healthcare system is to promote health among the country's citizens. In designing any healthcare system, a nation has to aim to satisfy 3 competing requirements: first, ensuring that all people have adequate access to the benefits of healthcare; second, making certain that the system delivers care of consistently high quality; and third, achieving all this at a sustainable level of cost (2). Everything else is secondary. Evaluation of the cost of healthcare in the United States showed that the US spends more of its wealth on healthcare than any other developed country, and that share is rising (3). In 2005, the United States spent $1.9 trillion, or 16% of the gross domestic product (GDP), on healthcare, up from $1.7 trillion or 15% of the GDP in 2003. Consequently, the United States spends more on healthcare than it does on food, an astounding statistic (3). In a recent *New England Journal of Medicine* article, Hacker (4) attempted to describe mechanisms to heal our healthcare system. The movie *Sicko* by filmmaker Michael Moore attempted to explicitly show the deficiencies of the healthcare system in the United States (4-6). Hacker (4) describes that we do not find the answer in Moore's movie — and that is its great limitation. He continued, "the golden age of documentary has demonstrated the medium's clout. Along with Al Gore's global-warming warning, *An Inconvenient Truth*, *Sicko* may well be remembered as our generation's *Silent Spring* or *The Jungle* — propaganda, in the best sense of the word, that pricks our collective conscience about problems that are hidden in plain sight."

Many studies have attempted to explain why the United States spends disproportionately more on healthcare — some popular theories include the high price of drugs, the abundance of new medical technology, and the private nature and administrative complexity of the system — but none has fully justified why it costs so much, or why it seems to have fallen short in delivering the expected value (3). Supporters of the free market system point to the regulatory burden on the healthcare industry, which is sizeable, often viewed as among the most heavily regulated sectors of the US economy, with incurred regulatory costs that may exceed $1 trillion (7). Using a "bottom-up" approach, it is estimated that the total cost of health services regulation exceeds $339 billion. This figure takes into account the regulation of health facilities, health professionals, health insurance, drugs and medical devices, and the medical court system. Conover (7) contends that the annual net cost of health services regulation dwarfs other costs imposed by government intervention in the health care sector, exceeding the annual consumer expenditures on gasoline and oil in the United States. Further, healthcare regulatory costs are twice that of the annual output of the motion picture and sound recording industries. The estimated total cost of health services regulation of $339 billion offers only $170 billion in provided healthcare benefits; $169 billion is wasted, outweighing the benefits and costing the average household over $1,500 per year. In essence, the high cost of health services regulation is described to be responsible for more than 7 million Americans lacking health insurance (i.e., 1 in 6 of the average daily uninsured).

In a major research publication on the US healthcare system comparing the healthcare systems in the United States, the United Kingdom, and Germany, a holistic view of the system was taken (3). Arguably, there is no clear optimal amount that the United States should spend on healthcare — every country makes its own societal choices. In this report, the authors developed a measure called Estimated Spending According to Wealth (ESAW), which adjusts healthcare spending according to GDP per capita and is anchored in the fact that countries spend more on healthcare (or any good or service) as their prosperity increases (3). Sadly, based on this report, even after adjusting for its higher per capita income levels, the United States spends some $477 billion — $1,645 per capita — more on healthcare than peer countries. One might simply propose a solution to eliminate the regulations, which would reduce healthcare spending $1,500 to $3,000 per capita based on the regulatory burden (7).

However, the situation is much more complex than a simple surgical strike. The report of *Accounting for the Costs of Health Care in the United States* (3) describes that the US system is intrinsically more expensive, showing more expenses in 5 of the 7 healthcare categories — hospital care, outpatient care, drugs, administration and insurance, and public investment in health, but showing lower expenditures in two categories, namely long-term care and durable medical equipment. This report demonstrates that a higher disease burden in the US is not to blame for the US's higher spending on healthcare (3). Of the $477 bil-

lion that the United States spends above ESAW, $224 billion are spent in hospital care, compared to $178 billion spent for outpatient care. Together, these two figures account for 80% of the US spending above the level of ESAW. In excess costs spent on hospital care and outpatient care, $147 billion are spent on operational expenses and support functions, $100 billion for medical labor, $75 billion goes to the profits made and taxes paid by private payors and providers, and $49 billion for supplies.

Other categories in which the United States spends above ESAW, amounting to $174 billion, include $98 billion incurred in administration and insurance, $57 billion in outpatient drugs, and $19 billion in public investment. However, it appears that in long-term and home care, the United States spent $85 billion less than ESAW, and in therapeutic and durable equipment, $14 billion less than ESAW (3). Further analysis of accounting for the higher spending illustrates that inefficiencies and complexity in the system's operational processes and structure account for the second largest spending above ESAW of $147 billion. Finally, administration, regulation, and intermediation of the system costs another $98 billion in additional spending. This is in contrast to Conover's estimation (7) of regulatory burden of $339 billion.

Of importance in all these expenses, the report on *Accounting for the Costs of Health Care in the United States* (3) concludes that total physician compensation contributes spending above ESAW of $58 billion, of which $50 billion arises from their remuneration from salaries, professional fees, or a combination of these; another $8 billion stems from physicians' income from equity stakes in outpatient centers. Consequently, this report concludes that physicians' compensation on average in other countries is 4 times the GDP per capita for specialists and 3.2 times for generalists. In contrast, in the United States, these figures rise to 6.6% and 4.2% of GDP per capita, respectively.

While physicians in the United States on average see 1.6 times more patients than physicians in other countries, the report states that in addition to the fee-for-service payments for consultation and procedures, physician ownership in outpatient facilities, such as ambulatory surgery centers, diagnostic imaging centers, and diagnostic testing and procedure laboratories contributes to their income, amounting to $8 billion of US higher spending, even though $8 billion is much less than various other categories, which include provider profits and taxes of $75 billion, additional operating costs of $147 billion, $98 billion in administration, $18 billion in non-drug supplies, $50 billion in nurses and other clinical labor compensation, and $50 billion in physicians' compensation. Physician investment has been a subject of publication by the *Wall Street Journal* (8) and other media outlets, and has been critiqued by various groups opposing investment by physicians.

A recognized major trend in the healthcare over the past two decades has been the increase in services provided on an outpatient basis (9). While physicians traditionally have been relatively independent of hospitals but have used hospitals for all professional services, modern technology has changed this balance, with physicians providing many outpatient services in their offices and other facilities.

Thus, a multitude of concerns arose about whether physicians' treatment decisions would pit their potential financial rewards against the interest of their patients. These concerns led Congress to consider ethics in patient referrals and regulate them in the form of the Stark law to bar self-referral arrangements. The Stark law ban started with clinical laboratory services, and now extends to a multitude of other services known as designated health services.

Practice Of Medicine And Physician Self-referral

Self-referrals occur when physicians refer patients to medical facilities in which they have a financial interest, either in the form of ownership or investment interest in the entity or in the form of a compensation arrangement between the physician and the entity. Critics of self-referral arrangements state that they pose a conflict of interest since the physician is in a position to benefit financially from the referral and they suggest that such arrangements may encourage overutilization of services which in turn drives up healthcare costs (10). Further, critics contend that self-referral arrangements create a captive referral system which in essence limits competition among healthcare providers. Proponents of physician involvement in medical services respond to these concerns by stating that while problems may exist, they are not widespread and in many cases, physician investors are responding to a demonstrated need, which would not otherwise be met, particularly in a medically underserved area. However, thus far, no study has determined that a higher use of services associated with self-referral was inappropriate and resulted in harm to patients or pre-

vented their healthcare. Further, proponents contend that integration of ancillary services into their practices improves patient care, is more convenient for the patient and provider, provides better continuity of the care, and reduces the time required to diagnose and treat specific conditions, consequently providing better efficiency, quality, and even reduced costs in the long run (11).

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 was the genesis of Stark I, named after Congressman Fortney Pete Stark, the chief congressional sponsor of this bill. Stark I became law effective January 1, 1992 (12). Since the birth of Stark I, the restrictions on self-referrals demonstrated unprecedented growth in Stark II with OBRA of 1993 (13). The childhood and pre-teen years arrived in the development of Phases I and II of the Stark regulations beginning in 1998 and the adoption of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (14). Stark is now in its teenage period with the publication of Stark II, Phase III on September 5, 2007 (15).

How Did We Get Here?

The legislative history of antifraud regulation starts with publication of reports concerning the substantial profits that physicians could make by becoming partners and providers in entities to which they referred their patients (10). In 1989, the Office of 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 (16). Consequently, the reported increased utilization cost Medicare an estimated $28 million in 1987 (16). While multiple types of arrangements were discussed, the most significant findings related to referrals to independent clinical laboratories. Congress responded by enacting the "Stark I ban" as part of OBRA 1989 (12). The technical amendments of Stark I were included in the Omnibus Reconciliation Act of 1990 (OBRA 1990) (17).

However, the self-referral ban on clinical lab services did not stop critics. Numerous events focused continuing attention on this issue, including multiple studies performed on self-referral patterns of various outpatient services and, finally, specialty hospitals.

The first of such studies was the Florida study, which was issued by Florida State University in September 1991 and prepared under contract with the state's healthcare cost containment board mandated by the Florida legislature (18). The authors of this study grouped the 10 types of facilities surveyed into 3 categories based on the effect of joint venture arrangements on access, charges, and utilization of services. This study essentially concluded that joint venture arrangements had no apparent negative effects on hospital and nursing home services. However, for other types of services and supplies, including ambulatory surgical center services, home health services, durable medical equipment supplies, and radiation therapy center services, they expressed some concern with identification of potential problems, even though data did not allow the authors to draw definitive conclusions. Finally, for the category which included clinical laboratories, diagnostic imaging services, and physical therapy services, the results indicated significantly higher utilization and significantly higher charges at joint venture facilities, while these joint ventures failed to increase access to rural or underserved patients.

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 (19). This study also showed that gross and net revenues per patient were 30% to 40% higher in facilities owned by referring physicians.

An additional study performed examining radiation therapy centers showed that joint ventures provided less access to poorly served populations from rural counties and inner centers than non-joint venture facilities (20). In addition, the frequency and cost of radiation therapy treatments in free-standing centers in Florida were 40% to 60% higher when compared to the rest of the US with lower levels of joint venture arrangements.

A study by the US General Accounting Office also showed that physician owners of diagnostic imaging services referred their patients more frequently, for more expensive services, than non-owners (21). It was found that physicians who had ownership interests in some type of imaging facilities ordered 54% more MRI scans, 27% more computed tomography scans, 37%

more nuclear medicine scans, 27% more echocardiograms, 22% more ultrasound services, and 22% more complex x-rays.

In recent years, specialty hospitals have occupied the center of controversy with their unprecedented growth. Proponents of specialty hospitals contend that the focused mission improves quality and reduces costs, whereas opponents suggest that these hospitals are siphoning off more lucrative cases from nearby general community hospitals, leading to an adverse impact on the hospitals' ability to deliver various services, including emergency care, and adversely impacting the viability of hospital systems (22). Specialty hospitals create issues distinct from those raised by outpatient treatment. While a physician is unable to refer 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 of the facility. Consequently, this means that a physician can refer patients to specialty hospitals in which the physician has an ownership interest which is criticized as a loophole in the self-referral ban. An April 2003 GAO Report noted that specialty hospitals tripled in number since 1990 even though they occupied only 2% of the market (23). However, while specialty hospitals accounted for only 1% of Medicare spending for inpatient services in 2002, approximately 70% of the specialty hospitals in existence or under development had some physician owners, with total physician ownership averaging slightly more than 50%. Further, this report noted that these hospitals tended to treat less sick patients. This resulted in Section 507 of MMA placing a temporary, 18-month moratorium on physicians' referrals to specialty hospitals in which the physician has an ownership or investment interest (14). While the moratorium has expired, the FY 2008 Hospital Inpatient Prospective Payment System Regulations require providers to inform patients if the hospital is physician-owned and that patients have a right to request a list of physician investors. Further, patients must be given written notice if a physician is not present in the hospital 24/7 and the notice must describe how the hospital will handle a medical emergency if no physician is present (24).

Changing Landscape of Medical Practice

It is no secret that medical care is migrating from inpatient to outpatient and from hospitals to non-hospital settings. Consequently, the American Hospital Association (25) contends that a growing number of increasingly complex procedures are moving from the inpatient to the outpatient environment, and out of hospital settings into physician's offices and free-standing ambulatory surgery or diagnostic facilities. The Hospital Association also contends that many of these care settings involve physician ownership and self-referral. The hospital industry is not only concerned about services controlled by the self-referral ban, but they are also concerned about ambulatory surgery centers, as well as specialty hospitals.

From 1997 to 2004, the volume of ASC procedures provided to Medicare beneficiaries rose 145% while the number of ASCs climbed 67% — on average, 240 additional ASCs per year between 1998 and 2004 (25). However, ASC services are not subject to the Stark self-referral ban if they are reimbursed by Medicare as part of a composite rate. As shown in Fig. 1, the share of outpatient surgeries performed in hospitals has fallen

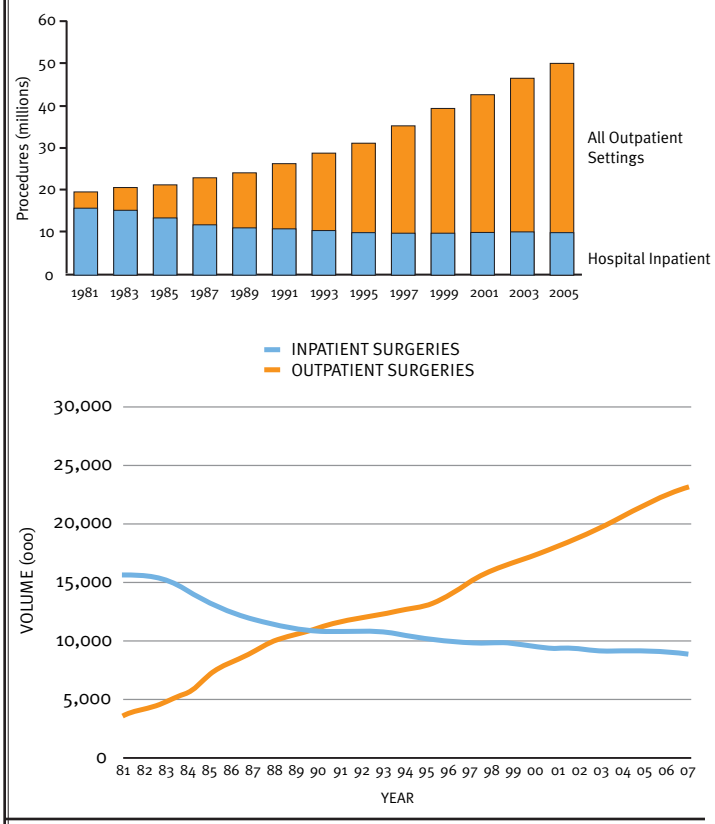


Fig. 1. *Surgical trends in the United States.*
Adapted and modified from ref. 24.

from over 90% to 45% since the early 1980s, while the share performed in ASCs and physician offices has grown from less than 5% to 38% and 17%, respectively (26). Figure 2 illustrates the migration of outpatient surgical procedures to non-hospital settings.

Figure 3A illustrates the volume of Medicare imaging services delivered from 1996 to 2004. Figure 3B shows a linkage between increased utilization of diagnostic services and self-referrals (27).

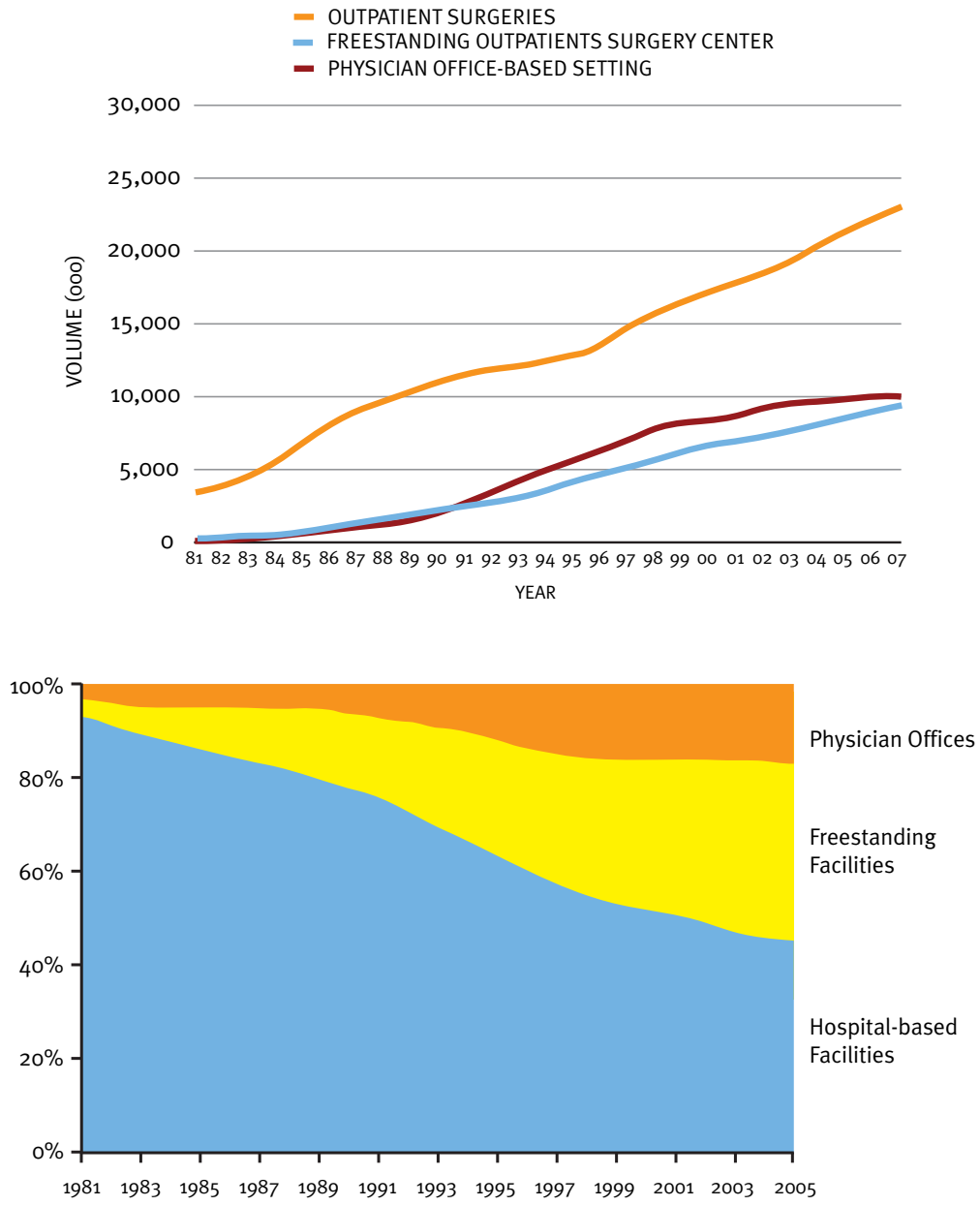
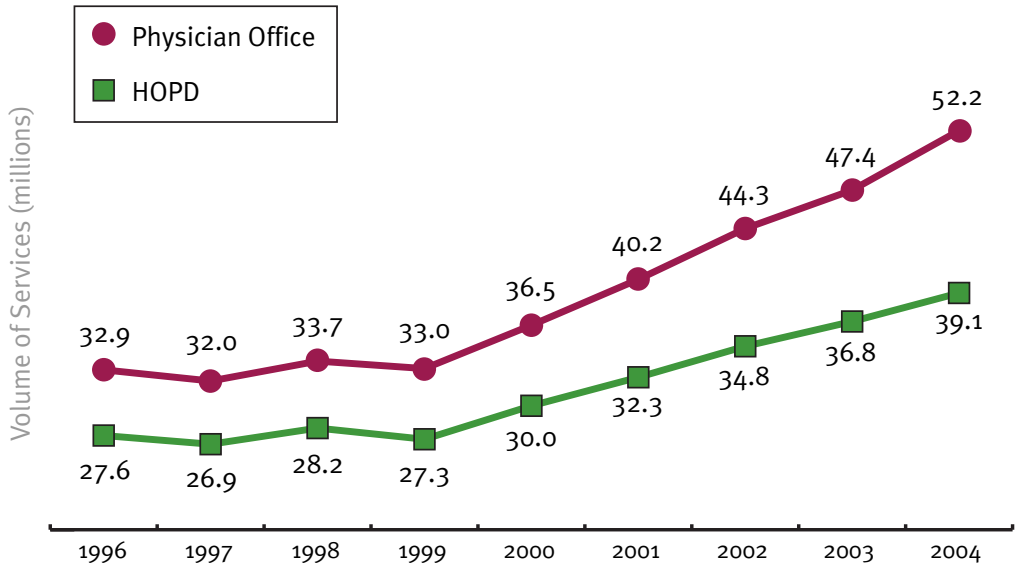
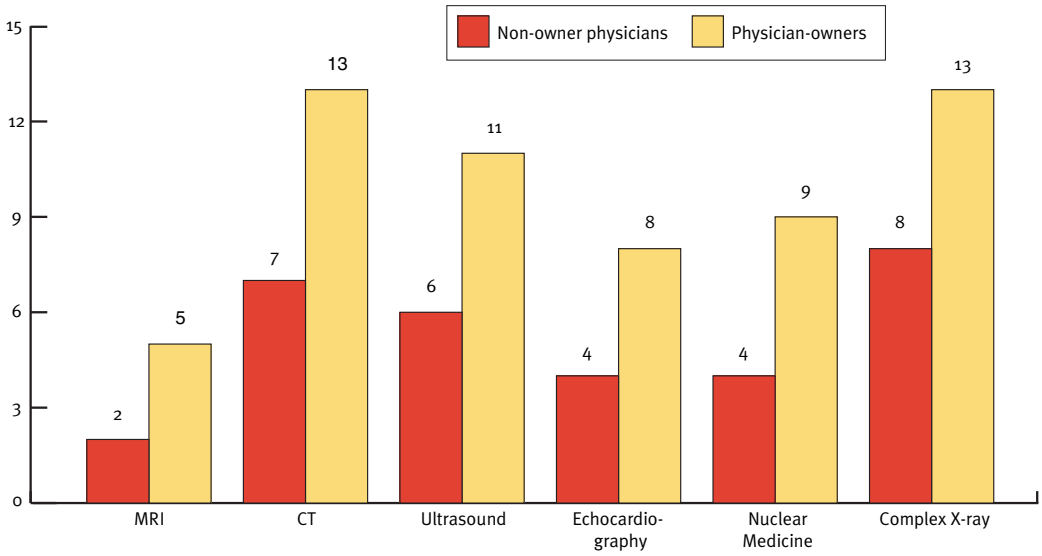


Fig. 2. *Migration of outpatient surgical procedures to non-hospital settings.*



A. Volume of Medicare imaging services delivered, 1996 – 2004
Adapted and modified from ref. (25).



B. Number of imaging services ordered per physician
Adapted from ref. (27).

Fig. 3. *Changing landscape of imaging services.*

The Legislative History

OBRA 1989

The OBRA of 1989 (12) included a provision barring self-referral arrangements for clinical laboratory services under the Medicare program, known as Stark I. This law established a ban, effective January 1, 1992, on certain financial arrangements between physicians and clinical laboratories. This law provided that, a physician could not make a referral to a lab for services for which Medicare would otherwise pay to an entity in which the physician or an immediate family member had an ownership or investment interest in, or a compensation arrangement with the lab, and the lab could not bill for such services.

OBRA 1993

The OBRA of 1993 (13) considered multiple changes with regards to the business arrangements of physicians and their ability to refer patients to these businesses. The final law extended the ban to an additional list of "designated health services" beginning in 1995. In addition, the ban extended to services and supplies provided to Medicaid beneficiaries. OBRA 1993 also included significant modification to the in-office ancillary services exception.

1994 Legislation

The social security amendments of 1994 (PL 103-432) (28) included technical amendments to Medicare laws, which incorporated several minor changes to the self-referral provisions. 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.

104th Congress

The passage of Stark II raised a series of concerns on the part of provider groups. Essentially, Stark II was considered as intruding into the practice of medical care.

Balanced Budget Act of 1997

The Balanced Budget Act of 1997 postponed major physician self-referral changes (29).

MMA

The MMA (14) substantially limited specialty hospitals.

The Healthcare Financing Administration (HCFA) and later on, Centers for Medicare and Medicaid Services (CMS) released Stark I and II regulations and Phases I, II, and III (15,30-36).

Evolution Of Stark Law

Stark I became effective January 1, 1992. In 1993, the Stark prohibition on "self-referrals" by physicians expanded to include 10 additional health care services, known as designated health services (DHS). Congress believed physicians might cause patients to overutilize these DHS if physicians had a financial stake in the DHS (37). The 1993 amendments, known as "Stark II," became effective January 1, 1995 (37). Today, the list of DHS includes 12 services

Table 1. *Designated health services under Stark law.*

- clinical laboratory services
- physical therapy services
- occupational therapy services
- speech-language pathology services
- radiology services (including MRI, CT, ultrasound, and nuclear medicine)
- radiation therapy services and supplies
- durable medical equipment and supplies
- parenteral and enteral nutrients, equipment, and supplies
- prosthetics, orthotics, and prosthetic devices and supplies
- home health services
- outpatient prescription drugs
- inpatient and outpatient hospitalization services

The first six categories listed above are limited to CPT and HCPCS codes published each year in the physician fee schedule final rule and on the CMS' website.

as shown in Table 1.

Since Stark I was enacted, the Centers for Medicare and Medicaid Services (CMS) has worked to develop several sets of regulations that interpret Stark I and Stark II. Stark I proposed regulations were published in 1992 and finalized in 1995 (30,31). Stark II proposed regulations were published in 1998 (32). Phase I of the Stark II final regulations was released January 4, 2001, and was effective one year later (33). Phase II of the Stark II regulations was released on March 26, 2004, and became effective on July 26, 2004 (34,35). On September 5, 2007, CMS issued Phase III of the final regulations for Stark II (15). The Phase III final rule responds to comments on Phase II, and addresses the entire regulatory scheme. The Phase III regulations become effective December 4, 2007.

The Stark Statute

The Stark law states that if a physician or an immediate family member of the physician has a financial relationship with an entity, the physician cannot refer a Medicare or Medicaid patient to that entity for a DHS unless an exception applies. In addition, the DHS entity may not present or cause to be presented a claim for DHS if the physician (or an immediate family member) has a financial relationship with the entity and that financial relationship is not authorized by the statute (15,36-38).

The statute identifies two types of financial relationships: (a) ownership or investment interests, and (b) compensation arrangements. An ownership interest includes a direct or indirect ownership or investment interest in the DHS entity. A physician may have an ownership or investment interest in the DHS entity through equity, debt, or other means. An ownership or investment interest includes an interest in an entity that holds an ownership interest in the DHS entity (39). An ownership interest includes loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue (15). A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or the physician's immediate family member) and the DHS entity (15, 40). Thus, if a physician's spouse has a catering contract with a hospital to which the physician refers, that is a compensation arrangement, and the contract must be analyzed to see if it fits within a Stark law exception. A physician's "immediate family member," as defined in the Stark regulations, includes the physician's husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law; grandparent or grandchild; and spouses of grandparents or grandchildren (15).

The reality of the Stark law is that many contracts and business transactions that physicians and their immediate family members enter into fall under the "self-referral" prohibition. Congress realized that because of the prohibition, physicians and their immediate family members would not be able to enter into many common business transactions without incurring liability, so a series of exceptions to the Stark law prohibition were developed. If a financial relationship exists between the DHS entity and the referring physician or an immediate family member, it must fit within an exception, or Stark is violated. Exceptions are broken down into 3 broad categories: ownership and compensation exceptions, ownership exceptions, and compensation exceptions. An ownership or investment interest requires an ownership exception. A compensation arrangement requires a compensation exception. Listed in Table 2 are the current exceptions to the Stark law. Be aware that each exception has several elements that must be met in order for the exception to apply. Also, a general exception applicable to ownership and investment interests or compensation arrangements includes certain arrangements involving temporary compliance (41).

The Intersection of Stark and the Anti-kickback Statute

The federal anti-kickback statute (42) makes it a crime to offer, pay, solicit, or receive remuneration to induce or in exchange for (a) a referral of a patient for an item or service payable under federal health care programs, or (b) purchasing, leasing, ordering, or arranging for, or recommending purchasing, leasing, or ordering any good, facility, service, or item payable under a federal health care program. This statute prohibits payments for referrals and has been interpreted broadly. The Office of Inspector General has promulgated many "safe harbors" to protect business arrangements that meet all the safe harbor criteria. In contrast to the Stark law, where an exception must be met in order to avoid liability, failure to meet all the criteria for a particular safe harbor does not result in an automatic violation of the anti-kickback statute (43).

Table 2. Exceptions under Stark law.

Exceptions to Ownership Or Investment Interests Only	Exceptions to Both Ownership/ investment and Compensation	Exceptions to Compensation Arrangements Only
• Publicly-traded securities	• Physician services	• Rental of office space
• Mutual funds	• In-office ancillary services	• Rental of equipment
• Rural providers	• Services furnished by an organization (or its contractors or subcontractors) to enrollees in a prepaid health plan	• Bona fide employment relationships
• Hospitals	• Academic medical centers	• Personal service arrangements
• Puerto Rican hospitals	• Implants furnished by an ASC	• Remuneration by a hospital to a physician if the remuneration does not relate to the provision of DHS
	• EPO and other dialysis-related drugs furnished in or by an ESRD facility	• Physician recruitment
	• Preventive screening tests, immunizations, and vaccines	• Isolated transactions
	• Eyeglasses and contact lenses following cataract surgery	• Certain arrangements with hospitals
	• Intra-family rural referrals	• Group practice arrangements with a hospital
	• Electronic prescribing (note that the Phase III regulation classifies this exception as applicable to compensation arrangements only)	• Payments by a physician for items and services
		• Charitable donations by a physician
		• Non-monetary compensation
		• Fair market value compensation
		• Medical staff incidental benefits
		• Risk-sharing arrangements
		• Compliance training
		• Indirect compensation arrangements
		• Referral services
		• Obstetrical malpractice insurance subsidies
		• Professional courtesy
		• Retention payments in underserved areas
		• Community-wide health information systems
		• Electronic prescribing items and services

It is more important to understand that many common business transactions must be analyzed for compliance with Stark and the anti-kickback statute, as many of the Stark law exceptions and anti-kickback safe harbors overlap but do not necessarily mirror one another. Further, some Stark law exceptions require compliance with the anti-kickback statute and some anti-kickback safe harbors incorporate Stark law requirements (43).

Stark law exceptions and safe harbors under the anti-kickback statute are different (15,30-43). Under the safe harbors of the anti-kickback statute, a financial relationship outside a safe harbor is not necessarily illegal, whereas under Stark, any relationship that does not meet all the elements of an exception is illegal. Thus, an interventionalist should look at both the Stark law and anti-kickback statute and devise plans to meet safe harbors under the anti-kickback statute and also fall into one of the exceptions under the Stark law, while planning and improving the economic efficiency of the medical practice and also increasing its income. It is crucial to understand the law carefully and avoid any irregularities as it is essential for interventionalists to improve economic efficiency with rising practice expenses, including healthcare insurance, office overhead expense, and malpractice premiums, coupled with declining reimbursements, as shown in Fig. 4.

State of Reimbursement

While hospitals oppose self-referrals, they have not been affected with declining reimbursements by Medicare and third-party payors, as illustrated in Fig. 5. In fact, Medicare and other insurers have been balancing their budgets by cutting physician payments, at the same time adding yearly increases to several sections

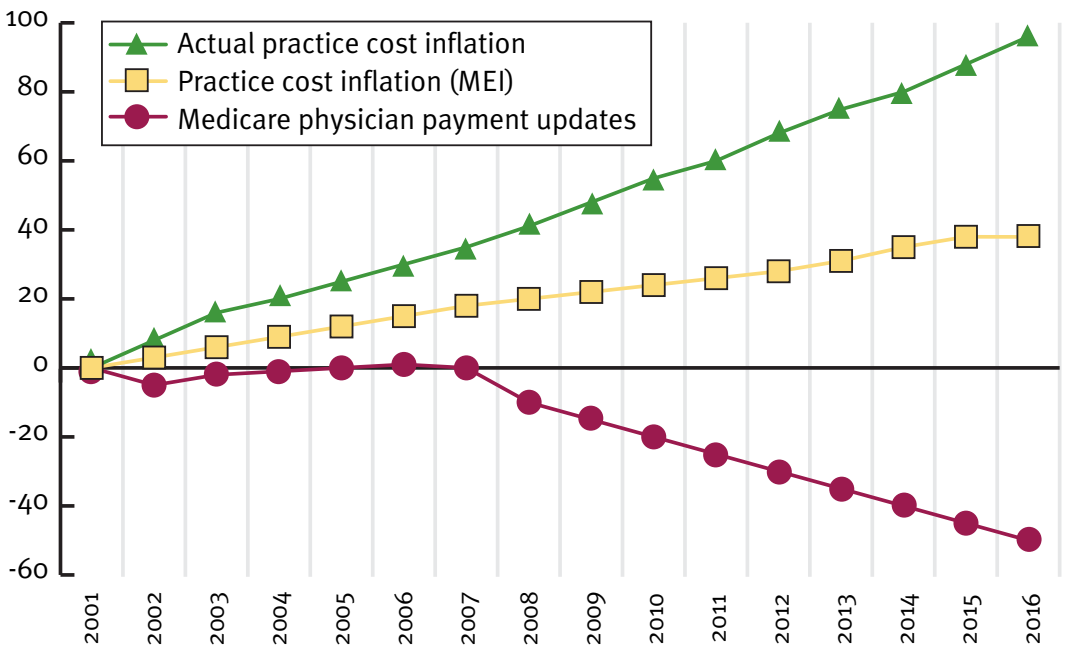


Fig. 4. *Comparison of health care payments by Medicare.*

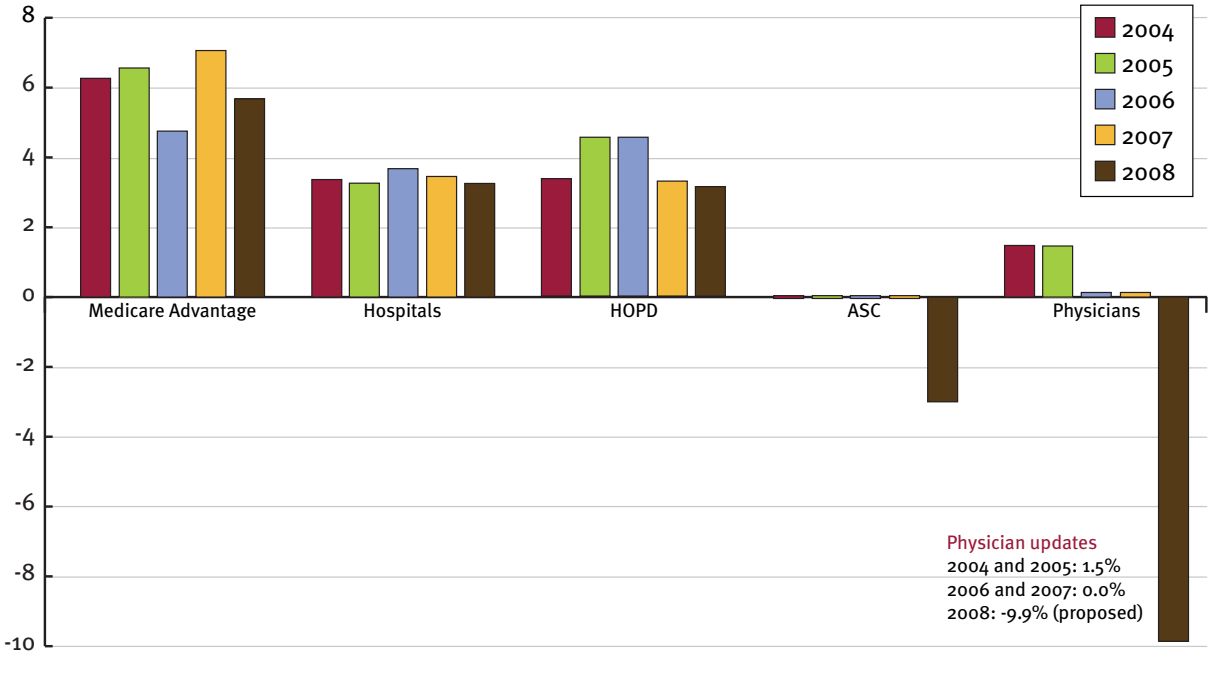


Fig. 5. *Illustration of reductions in physician payments and flat payments for ASCs and projected payment cuts for ASCs*

of the healthcare system, including hospitals, nursing homes, and Medicare Advantage Plans. Private insurers are reaping the benefit of double-digit yearly profit percentages, while maintaining increased percentages in their premiums (5). As illustrated in Fig. 5, not only the physician payments are reduced, but ASC payments are flat and projected to face significant cuts in the future. Many other sectors of healthcare are seeing increases, including the hospitals.

What is concerning is that CMS Office of Actuary report illustrates a lack of contribution of physician services to increased spending in recent years (44). The 2006 rate of growth in physician expenditures — that is the percentage by which the total annual spending on physician services increased over the previous year — fell to its lowest point in 7 years. Approximately 21% of US healthcare costs in 2005 were spent on physician and clinical services, reflecting an average growth in spending for physician and clinical services of 7.9% per year since 2000. Based on projections (45-47) and data from the CMS Office of Actuary (44,45), approximately $447 billion was spent on physician and clinical services in 2006 — just over 6% or approximately $26 billion more than what was spent on these services in 2005. Not surprisingly, the primary cause for this is an unusual reduction in services provided by physicians. Further, some have speculated that the decline in growth in physician payments was related to relatively stagnant reimbursements by Medicare. Private insurers rode Medicare's coattails and utilized Medicare schedules as a benchmark or even a ceiling in healthcare payment contract negotiations (5).

Stark II, Phase III Regulations

The following summarizes some of the most important changes and additions made by Phase III (15,37,46).

Independent Contractors As "Physicians in the Group Practice"

Phase III modified the definition of "physician in a group practice." For an independent contractor to count as a physician in the group practice for purposes of the in-office ancillary services exception, the contractor must have a contract directly with the group practice (the independent contractor cannot be employed by a staffing entity which has a contract with the group practice). Further, an independent contractor physician must perform services in the group's facilities to be considered a "physician in the group practice."

Productivity Bonuses, Profit Shares, and "Incident to" Services

A group practice may pay a physician in the group practice a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. Productivity bonuses, on the other hand, may be directly related to the volume or value of either services personally performed by the referring physician, his or her referrals for services that are "incident to" those personally performed services, or both. For example, a physician can be paid a productivity bonus based directly on physical therapy services provided incident to his or her services. However, the productivity bonus cannot be directly related to any other DHS referrals, such as diagnostic tests, as CMS also clarified that "incident to" services and supplies do not include x-rays or diagnostic imaging procedures that have a separate Medicare benefit category. Therefore, group practices will be precluded from directly attributing diagnostic tests that have historically been billed on an "incident to" basis to the ordering physician for purposes of calculating personal productivity bonuses.

Indirect Compensation Arrangements, "Stand in the Shoes," and Physician Organizations

The Stark regulations make a distinction between direct and indirect compensation arrangements, with different exceptions available for each type of arrangement. Under Phase III, a direct compensation arrangement will exist if anything of value passes directly between a DHS entity and the referring physician or his or her immediate family member without going through an intervening person or entity, or if the only intervening entity between the physician and the DHS entity is a "physician organization." A "physician organization" is defined as a physician, a professional corporation with a single physician as the sole owner, a physician practice, or a group practice. In Phase III, CMS made it clear it will apply a "stand in the shoes" rule to the physician's side of indirect compensation arrangements by collapsing the financial relationships when the DHS entity contracts with a "physician organization." All such arrangements must consequently meet a direct compensation arrangement exception, with the physician deemed to "stand in the shoes" of

the physician organization and have the same financial relationships with the same DHS entities as the physician organization and all of its members, employees, and independent contractors.

Existing indirect compensation arrangements in place before publication of the rule on September 5, 2007, will be grandfathered for the length of the initial or current renewal term to give physicians and other providers some time to come into compliance with this change.

In-Office Ancillary Services Exception

In Phase III, CMS states that physicians sharing a DHS facility, such as a lab, in the same building must control the facility and the staffing at the time the DHS is furnished to the patient. As a practical matter, this will necessitate a block lease arrangement for the space and equipment used to provide the DHS. CMS went on to note that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate anti-kickback statute.

Intra-family Rural Referrals

In the Phase II regulations, CMS created a new exception for referrals from a referring physician to his or her immediate family member or to a DHS entity with which the physician's immediate family member has a financial relationship. One of the requirements of the exception is that the patient resides in a rural area and that there is no other person or entity available to furnish the referred DHS in timely manner, at the patient's residence, or within 25 miles of the patient's residence. Phase III of the regulations clarifies that the meaning of "availability" must take into account the patient's condition, and that the physician may use an alternate distance test based on transportation time (45 minutes) from the patient's residence. The time determination should be made on the basis of distance, posted speeds, and weather conditions. CMS recommends physicians choosing to rely upon the 45-minute alternate transportation time test should maintain documentation, such as printouts of Mapquest driving directions listing travel time and published weather reports, that the physician used to determine transportation time.

Personal Service Arrangements Exception

Phase III allows a holdover under a professional services agreement for up to 6 months on the same terms as the expired contract following at least a one year term. Personal service agreements should not be amended to change compensation paid to physicians. Instead, the existing agreement should be terminated and a new agreement with revised compensation terms should be entered into by the parties.

Fair Market Value Safe Harbor Deleted

In the past, the Stark regulations allowed physicians and hospitals to guarantee that hourly payments did not exceed fair market value by setting the payment at a rate less than or equal to the rate for emergency room physicians in the relevant physician market (a minimum of 3 hospitals) or the average of the fiftieth percentile of national compensation levels for physicians in the same specialty in at least of 4 of 6 specific surveys. CMS decided to delete that safe harbor, noting that the payment rates hospitals and physicians would need to analyze to take advantage of the safe harbor were difficult, if not impossible, to obtain.

Physician Recruitment Exception

Congress and CMS created a physician recruitment exception to protect certain remuneration provided by a hospital to a physician as an inducement for the physician to relocate his or her medical practice into the geographic area served by the hospital. Phase III made several changes to this exception.

To qualify for a hospital recruitment incentive, physicians must establish their practices within the geographic area served by the hospital. The existing rule applied a 75% zip code test as the definition. In other words, the geographic area served by the hospital was the smallest number of contiguous zip codes from which the hospital drew at least 75% of its inpatients. CMS clarified that hospitals in general have the flexibility to decide to include zip codes from which they draw no inpatients, as long as those zip codes are surrounded on all sides by other zip codes that meet the 75% test. CMS also clarified that hospitals with far-flung service areas may not be able to configure any list of wholly contiguous zip codes meeting the 75% test; those hospitals can use the area of contiguous zip codes that gets them closest to 75%. Rural hospitals also have the option to increase the percentage to 90%.

The recruited physician must be recruited from a medical practice located outside the geographic area served by the hospital and must establish a medical

practice within the geographic area served by the hospital. The relocation requirement will not apply to physicians employed for at least 2 years on a full-time basis in one of 3 specific public service settings (serving prison populations, serving military families through employment by the Department of Defense or by Veterans' Affairs, or serving at an Indian Health Service facility). Physicians can also apply to CMS for an advisory opinion holding that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital. Hospitals located in rural areas may request an advisory opinion that confirms community need to recruit a physician to an area outside the geographic area served by the hospital.

CMS noted that the physician recruitment exception does not apply to a hospital's offer or payment of recruitment incentives to any physician already on staff in any category of privileges whether or not those privileges are active.

The Phase II physician recruitment exception limited the cost an existing practice could allocate to recruited physicians to the additional incremental cost attributable to that recruited physician. CMS clarified in Phase III that the incremental cost standard applies whenever a hospital provides an income guarantee of any type to a physician recruited to join an existing practice. However, Phase III does allow physician practices located in a rural area or health professional shortage area (HPSA) to reallocate some existing overhead as part of the recruitment arrangement to replace a physician who within the prior 12 months either retired, relocated out of the geographic area served by the hospital, or died.

The Phase II regulations were widely interpreted as prohibiting an existing practice from imposing any practice restrictions or non-competition agreements on recruited physicians. The Phase III regulations clarify that Stark only prohibits practice restrictions that "unreasonably restrict" the recruit's ability to practice in the geographic area served by the hospital.

The preamble to the Phase III regulations indicates that CMS believes the following practice restrictions may be imposed by the practice and are not unreasonable:

- No moonlighting
- No solicitation of patients or employees
- Mandatory acceptance of Medicaid and indigent patients
- Prohibiting use of confidential or proprietary information of the practice
- Requiring the recruit to repay practice losses in excess of the amount covered by hospital recruitment payments (e.g., losses not covered by an income guarantee)
- Requiring payment of reasonable liquidated damages if the recruit leaves the practice but remains in the community
- Imposing a limited "reasonable" non-compete clause. Practices should consult with counsel to determine what state statutes and state case law permit as a reasonable non-compete clause for a physician.

Retention Payments

The Phase III regulations changed the exception for retention payments in underserved areas in several ways. Phase III permits a hospital, rural health clinic, or federally qualified health center to offer assistance to a physician who does not have a bona fide written offer of recruitment or employment if the physician certifies in writing that he or she has a bona fide opportunity for future employment, which would require relocation of his or her medical practice at least 25 miles to a location outside the geographic area served by the hospital, rural health clinic, or federally qualified health center. If the physician provides a written certification instead of a bona fide written offer, the retention payment cannot exceed the lower of: (a) an amount equal to 25% of the physician's annual income; or (b) the reasonable costs the hospital would otherwise have to expend to recruit a new physician.

Phase III expands the exception to permit retention payments that otherwise satisfy the requirements of the exception when: (a) the physician's current medical practice is located in a rural area, a HPSA, or an area of demonstrated need determined by the Secretary of HHS in an advisory opinion; or (b) at least 75% of the physician's patients either reside in a medically underserved area or are members of a medically underserved population. The hospital does not have to be located in a HPSA.

Is Stark Effective?

The effectiveness of Stark and its implications in preventing self-referrals are not known. There are 3 elements that have to be satisfied prior to determining a violation of the Stark law has been deemed to occur. These include first, "a financial relationship"

between a physician (or an immediate family member) and an entity that provides designated health services is present; second, a "referral" by the physician to the DHS entity for provision of designated health services billed to Medicare or Medicaid has occurred; and third, no Stark law exception applies to save the referral.

Penalties for Stark violations include: Denial of payment of the tainted claim for DHS, refund of payment for the DHS claim (it is considered an overpayment), imposition of a $15,000 per service/claim civil monetary penalty and imposition of a $100,000 civil monetary penalty for each arrangement considered to be a circumvention scheme (i.e., scheme has a principal purpose of assuring referrals to the DHS entity even though the physician involved doesn't make the referrals directly but uses an entity s/he is affiliated with to do so). There is also a $10,000/day penalty for failure to produce required records.

In an evaluation of the prevalence of the physician self-referral arrangements, after the adoption of Stark II, data from California suggests that physicians exploit exceptions in the Stark II law to continue to self-refer patients for advanced diagnostic imaging. Mitchell (48), using data from a large insurer in California, identified the self-referral status of providers who billed for advanced imaging in 2004. Mitchell concluded that nearly 33% of providers who submitted bills for magnetic resonance imaging (MRI) scans, 22% of those who submitted bills for computed tomography (CT) scans, and 17% of those who submitted bills for position-emission tomography (PET) scans were classified as "self-referring." However, over 60% of those billing for MRI or CT scan did not own the imaging equipment and were involved in lease or payment-per-scan referral arrangements that might violate federal and state laws. Overall, the savings generated by the Stark prohibitions are not well known.

Ambulatory surgery centers that bill for services at a composite rate and specialty hospitals currently are not subject to the Stark law. Thus, any income attributed from these ventures will not be affected by the Stark regulations, including the Phase III regulations. However, $8 billion in excess costs for physician income includes billing for ambulatory surgical services. The regulatory costs were determined as $339 billion by Conover (7) and $98 billion by Angrisano et al (3). The cost savings attributable to the Stark regulations is unknown. There is no doubt that the Stark statute has restricted physician practices and consequently may have prolonged the life of Medicare, but what is not known at the present time is the extent of these effects. However, in spite of robust regulations, it appears that the effectiveness of Stark is only modest. The estimated excess spending in 2005 of $8 billion for outpatient centers owned by physicians, including ambulatory surgery centers, is low — approximately 0.4% of the of the $1.9 trillion healthcare budget of the United States — after years of implementation of the Stark law.

Discussion

Based on the report on *Accounting for the Costs of Health Care in the United States* (3) the conclusions reached were that of the $1.9 trillion healthcare budget $8 billion accounted for physicians' investment in outpatient centers, including ambulatory surgical centers — constituting 0.4%, a trivial amount in the large scheme of healthcare. Further, there is no evidence that by transferring these services into the hands of the hospitals, the costs will decrease. If they do, there may be savings of a small amount, probably 10% to 30% of the cost of self referrals.

While Stark regulations may have provided some savings, these will not offset the cost of regulations. Even with reductions in physician fees, healthcare expenditures are expected to reach over $4 trillion by 2016, entailing almost 20% of the GDP. Obviously, regulations and enforcement actions costing hundreds of billions of dollars have not been able to reduce healthcare costs in general or physician spending in particular. The ASC payment system is no better. ASCs were originally intended to be an alternative to hospital inpatient care; thus, the procedures performed in ASCs are quite frequently performed in hospital outpatient settings (49). Medicare has paid ASCs and HOPDs through different payment systems, which has also been followed by private insurers. Until 2000, hospital outpatient payment systems were based on charge data which was developed into the Outpatient Prospective Payment System or OPPS. ASCs continue to be paid under the old system, whereas HOPD surgical procedures are paid under OPPS. While HOPD payments are revised each year and consistently approved for increases in reimbursements. ASC payments have stayed flat. To address the issues of different payment systems, the MMA of 2003 (14) required the GAO to conduct a study that compared the relative costs of procedures

performed in ASCs to the relative costs of procedures performed in HOPDs. Based on the MMA, ASC payments are frozen until 2010. Further, based on MMA, CMS published the OPPS and ASC final rule, revising the payment system for services furnished in ASCs (49), creating a payment system with a blended formula for the first 3 years, followed by payments of 65% of HOPD after that. However, updates are not similar to the HOPD payment system. What has been ignored by Congress, CMS, and proponents of a multitude of regulations is the explosive growth of HOPD. Growth in expenditures and volume in intensity of HOPD services under OPPS from 2001 to 2008 increased by 7.8% to 12.8% on an annual basis with $17.702 billion spent in 2001 to $34.960 billion in 2008. In contrast, Medicare payments increased from $1.6 billion in 2001 to $3 billion in 2008. Thus, the phenomenal growth in expenditures under OPPS were 97.5% with an annual increase of 14%, whereas, for ASCs, the increase was 87.5%.

Even though Phase III is intended as the final phase of the CMS rule making process, it may not be the last piece of the puzzle or the final voyage of Stark. There appears to be several other significant rule-making proposals, pending legislation, and a CMS mandate regarding disclosures of hospital–physician financial relationships, any and all of which may lead to more changes to the Stark regulations and may have a profound impact on the healthcare industry (37).

Conclusion

Based on the extensive study of the report on *Accounting for the Costs of Health Care in the United States* (3), it appears that $8 billion of physician income may be attributable to equity stakes in outpatient centers, including ASCs. However, proponents of increasing regulations have not taken into account of the cost of regulations on United States healthcare and its effects. Further, all the regulations combined may not reduce any costs and, in fact, may increase the cost of healthcare as there is no single study thus far providing the data that unnecessary care has been provided or that care is adversely affected due to self-referral patterns. Contrary to this, there is evidence of increased comfort levels, convenience, ability to provide timely services with potential reductions in cost, and increased efficiency. Thus, lawmakers and CMS should look at the overall picture and actual net savings prior to embarking on expensive regulatory efforts, which have reached over $340 billion for healthcare (7).

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