



Forum Session Meeting Announcement

Friday, December 14, 2007

9:00–9:30am — Breakfast

9:30–11:30am — Session

The Ethics in Patient Referrals Act: The Stark Law and the Practice of Medicine

A Discussion Featuring:

Hoangmai H. Pham, MD

Senior Health Researcher

Center for Studying Health Systems Change

Vicki Robinson, JD

Chief, Industry Guidance Branch

Office of the Inspector General

U.S. Department of Health and Human Services

William Rich, III, MD

Medical Director of Health Policy

American Academy of Ophthalmology

Location

Phoenix Park Hotel

530 North Capitol Street, NW

Ballroom

First Floor

Registration Required

Space is limited. Please respond as soon as possible.

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The Ethics in Patient Referrals Act: The Stark Law and the Practice of Medicine

OVERVIEW

The Ethics in Patient Referrals Act was intended to stop physician referrals motivated by financial gain by restricting physician ownership of certain types of facilities. Although the so-called Stark law was passed over 15 years ago, Congress and the Centers for Medicare & Medicaid Services (CMS) continue to struggle with the boundaries of the legislation. In fact, modifications to definitions of key concepts in the law will be implemented in January 2008. The Medicare Payment Advisory Commission (MedPAC) has urged CMS to strengthen several provisions to further restrict physician self-referrals, while others have argued for changes to allow for new developments in health care. This Forum session will address how the law has been modified, how the opportunities for self-referral have changed, and whether this new context requires rethinking the ethics of self-referral.

SESSION

The ability of physicians to refer patients to facilities in which they have a financial interest was curtailed with the Ethics in Patient Referrals Act, commonly known as the Stark law.¹ The Act prevents a physician with an ownership or financial interest in a facility from referring a Medicare patient to that facility and it prevents the facility from billing for the referred service. Enacted in 1989 and expanded in 1993, this law was created in response to evidence that physicians who had a financial stake in providing certain services referred their patients for those services more than other physicians.² In addition, the perceived conflict of interest was believed to contribute to physicians steering less intensive patients to their own facility to improve its revenues.

In the original law, the self-referral prohibition applied only to laboratory services. Physicians could not refer their patients to a lab in which they had an ownership interest and the lab could not bill Medicare for the referred services. In 1993 and in 1994, Congress extended the prohibition so that it now applies to ten designated health services:³ clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging (MRI), computerized axial tomography (CT) scans, and ultrasound; 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;

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and inpatient and outpatient hospital services. Since then, key concepts that affect how the law is applied have been defined in regulation, most recently in the final rule for the physician fee schedule, which will be effective January 1, 2009.⁴

Although most would agree that medical decisions should be based on clinical considerations rather than financial benefit to providers, the Stark law and associated regulations have been fraught with controversy. What was essentially a simple concept—that physicians should not have a financial conflict of interest when making referral decisions—has been difficult to implement. Exceptions in the law have allowed certain physician ownership arrangements to flourish, as well as new ventures that appear to be designed specifically to skirt the law. These and other health care delivery changes have prompted some to call for the repeal of the Stark law as others ask that it be strengthened.

EXCEPTIONS TO SELF-REFERRAL PROHIBITIONS

Ancillary services provided in the physician's office are excepted from the statute, therefore physicians can provide ancillary services, such as laboratory, radiology, or physical therapy services, in their own office and bill Medicare for them, if certain other conditions are met. Physicians may also have an ownership interest in a freestanding ambulatory surgery center (ASC), refer Medicare patients to the ASC, and bill for the entire (technical and professional) Medicare payment for the ASC procedure. Similarly, physicians are allowed to refer to a hospital in which they have an ownership interest, as long as their financial investment is in the entire facility.

These three exceptions have grown in importance. MedPAC reported that in 2006, over one-quarter of the physicians surveyed said they had expanded their ability to provide tests and lab services in their offices in the past year, over 19 percent had expanded imaging services, and almost 6 percent had expanded equipment and supplies sales.⁵ These services are some of the fastest growing components of Medicare physician spending.⁶ The number of ASCs increased over 60 percent from 1999 to 2005 to 4,500 facilities; Medicare payments more than doubled to reach \$2.7 billion over the same period. Over 90 percent of ASCs are at least partly owned by physicians.⁷ The number of physician-owned hospitals that specialize in cardiology, orthopedics, or surgery has grown rapidly, although they still remain a small component of the health care delivery system. In 2006, there were about 100 physician-owned specialty hospitals.

CHANGES IN THE HEALTH CARE LANDSCAPE

Changes in health care delivery since the enactment of the Stark law have contributed to the use of new sites of care and the continuing rise in the volume of and spending for physician services. Medical advances have broadened the conditions and diagnoses for which there are effective treatments, as well as the population of patients who could benefit from

treatment. Technology has expanded the ancillary services that can be provided in an outpatient setting at the same time that physicians have increasingly joined single-specialty groups. These larger physician practices are more likely to have the resources to purchase and support more expensive equipment and facilities that enable them to provide a wider range of services, like endoscopies or cardiac catheterizations, in-office.⁸

Some have argued that the rise in these entrepreneurial ventures by physicians are related to stagnant growth in physician income, often attributed to tighter Medicare and Medicaid fees and greater uncompensated care loads. Further, Medicare's fee-for-service payments, which are widely acknowledged to be more generous for providing procedures compared with office visits or consultations, may contribute to unwarranted growth in procedures.

It appears that at least some of the financial relationships between physicians and facilities are designed specifically to get around the ownership restrictions of the Stark law. New lease arrangements, described by CMS, may allow physicians to benefit from referrals for imaging services without having to make a significant capital investment.⁹ A physician may lease an imaging center for a period of time and refer patients during that period. The referring physician pays the center for each imaging service or "per click" for the use of the facility and then bills Medicare for the technical or facility portion of the fee, which is higher than the per-click rental payment. Thus, the physician profits from each referral. An analysis of advanced imaging in California found that between 20 and 35 percent of physicians billing for MRI, CT, or positron emission tomography (PET) scans in 2004 were nonradiologists engaged in self-referral. Further, over 60 percent of these providers who billed for MRI or CT scans did not own the imaging equipment, but had either a lease or per-click arrangement with the facility.¹⁰

For the past several years, specialty hospitals and the referral patterns of their physician owners have been under scrutiny.¹¹ If physician-owners selectively refer patients to specialty hospitals, they may be able to profit from treating Medicare patients without necessarily providing care more efficiently than other hospitals. In fact, evidence indicates that specialty hospitals tend to care for the least costly subgroup of patients receiving a particular procedure.¹² If this results in the concentration of the costlier patients in community hospitals, the growth in physician-owned specialty hospitals may impair the financial performance of hospitals that accept a wider mix of patients.

The practice of medicine involves complex relationships among physicians and other providers that are instrumental in helping to ensure access to care, test new models of care, and push for quality improvements. Recognizing the potential need for physician investment in services for rural beneficiaries, the Ethics in Patient Referral Act includes exceptions to the referral prohibitions in certain situations. Other exceptions have allowed

the growth of specialty hospitals and ASCs, with their consumer focus that has undoubtedly improved the experience of patients and has even spurred some hospitals to change the way they schedule and manage care. Physicians have also argued that the quality of care is higher when they have the control that comes with ownership. The Act and its interpretation may need to continue to evolve as the practice of medicine and these complex relationships change. Financially rewarding physicians for taking risks and trying new approaches may need to be continuously balanced with curbing opportunities to put financial gain before patient care.

SPEAKERS

This Forum session will explore new self-referral arrangements, describe the federal government's response, and discuss the implications of these changes for Medicare and the practice of medicine. **Hoangmai Pham, MD**, senior health researcher at the Center for Studying Health Systems Change (HSC), will draw upon the HSC multi-year site visit data to illustrate changes in the health care market and new physician self-referral relationships. **Vicki Robinson, JD**, chief of the Industry Guidance Branch in the Office of the Inspector General (OIG), U.S. Department of Health and Human Services, will discuss OIG enforcement activities, implications of recent changes to the Stark regulations, and considerations for the future. **William Rich, III, MD**, will bring the point of view of a practitioner and will provide observations about how self-referral has changed the practice of medicine.

KEY QUESTIONS

- Has the Stark law reduced inappropriate referrals for services? Has it stymied useful innovations in health care delivery?
- How can federal regulators keep up with innovations in health care delivery to guard against inappropriate referrals? Are some of these innovations specifically designed to get around the Stark law?
- Can conflicts of interest be eliminated in referrals for health care services? Can consumer information provide adequate protections from these conflicts? Are there other ways to mitigate conflicts of interest?

ENDNOTES

1. Section 1877 of the Social Security Act.
2. Federal Register, vol. 66, no. 3, January 4, 2001.
3. Under a separate statute, the law applies to services paid for by the Medicaid program. One of the latest changes lets hospitals offer physicians hardware that allows the receipt and transmission of electronic prescription information.

Endnotes / continued ►

Endnotes / continued

4. "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions," CMS-1385-FC, on display at the Federal Register on November 1, 2007, to be published November 27, 2007; display version available at www.cms.hhs.gov/PhysicianFeeSched/downloads/CMS-1385-FC.pdf.
5. Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, March 2007, p. 106; available at www.medpac.gov/documents/Mar07_EntireReport.pdf.
6. MedPAC, *Report to the Congress: Medicare Payment Policy*, p. 112.
7. "Ambulatory Surgery Centers; A Positive Trend in Health Care," American Association of Ambulatory Surgery Centers; available at www.aaasc.org/features/documents/ASCTrendReport118061.pdf.
8. Allison Liebhaber and Joy M. Grossman, "Physicians Moving to Mid-Sized, Single-Specialty Practices," Center for Studying Health Systems Change, Tracking Report No. 18, August 2007; available at www.hschange.com/CONTENT/941.
9. Federal Register, vol. 72, no. 133, July 12, 2007.
10. Jean M. Mitchell, "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence from Advanced Diagnostic Imaging" *Health Affairs*, Web Exclusive, 26, no. 3 (April 17, 2007): pp. w 415–w424.
11. Laura A. Dummit, "Specialty Hospitals: Can General Hospitals Compete?" National Health Policy Forum, Issue Brief 804, July 13, 2005; available at www.nhpf.org/pdfs_ib/IB804_SpHospitals_07-13-05.pdf.
12. Centers for Medicare & Medicaid Services, Study of Physician-owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, available at www.cms.hhs.gov/reports/downloads/RTCPhysSpecHosp.pdf; and MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals*, March 2005; available at www.medpac.gov/publications/congressional_reports/Mar05_SpecHospitals.pdf.



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