The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging

Jean M. Mitchell

The online version of this article, along with updated information and services, is available at:
http://content.healthaffairs.org/content/early/2007/04/17/hlthaff.26.3.w415.citation

For Reprints, Links & Permissions:
http://content.healthaffairs.org/1340_reprints.php

Email Alertings:
http://content.healthaffairs.org/subscriptions/etoc.dtl

To Subscribe:
https://fulfillment.healthaffairs.org

Health Affairs is published monthly by Project HOPE at 7500 Old Georgetown Road, Suite 600, Bethesda, MD 20814-6133. Copyright © by Project HOPE - The People-to-People Health Foundation. As provided by United States copyright law (Title 17, U.S. Code), no part of may be reproduced, displayed, or transmitted in any form or by any means, electronic or mechanical, including photocopying or by information storage or retrieval systems, without prior written permission from the Publisher. All rights reserved.

Not for commercial use or unauthorized distribution
The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging

Data from California suggest that physicians exploit exceptions in the Stark II law to continue to self-refer patients for imaging.

by Jean M. Mitchell

ABSTRACT: Using data from a large insurer in California, we identified the self-referral status of providers who billed for advanced imaging in 2004. Nearly 33 percent of providers who submitted bills for magnetic resonance imaging (MRI) scans, 22 percent of those who submitted bills for computed tomography (CT) scans, and 17 percent of those who submitted bills for positron-emission tomography (PET) scans were classified as “self-referral.” Among them, 61 percent of those who billed for MRI and 64 percent of those who billed for CT did not own the imaging equipment. Rather, they were involved in lease or payment-per-scan referral arrangements that might violate federal and state laws. [Health Affairs 26, no. 3 (2007): w415–w424 (published online 17 April 2007; 10.1377/hlthaff.26.3.w415)]

Under federal law, it is generally illegal for a physician to refer Medicare or Medicaid patients for designated health services in which the physician has a financial interest. Nearly half of the states have similar prohibitions that apply to the privately insured. These bans on self-referral were enacted during the early 1990s in response to several empirical studies that found that the financial incentives inherent in physician self-referral arrangements resulted in increased use of services and higher payments from third-party payers. Although none of these studies could determine whether any of the higher use associated with self-referral was inappropriate, there is no evidence indicating that it resulted in commensurate improvements in patients’ health. On the other hand, proponents contend that self-referral arrangements in which physicians integrate the provision of ancillary services into their practices improve patient care. For example, the justifications for nonradiologist physicians’ incorporating imaging into their offices include patient convenience, better continuity of care, and a reduction in the time required to diagnose and treat specific conditions.1

Jean Mitchell (mitchejm@georgetown.edu) is a professor of public policy at Georgetown University in Washington, D.C.
The federal law, also known as Stark II (named for Rep. Pete Stark [D-CA], its sponsor), prohibits many physician self-referral arrangements. It was enacted by Congress in 1993 to address many of the shortcomings of the federal antikickback statute. Under that statute, criminal, civil, or administrative liability can result if one knowingly and willfully offers to pay for, solicit, or receive any remuneration to induce referrals of items or services reimbursable under federal health programs.2 Remuneration includes the transfer of anything of value, either cash or in kind, and it covers direct, indirect, and covert as well as overt transfers. The statute ascribes liability to parties on both sides of the impermissible “kickback” transaction. Violation of the antikickback statute is a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction may also result in exclusion from federal health programs.

Although the federal prohibition on self-referral for designated health services has provided clearer guidance on referral arrangements that are illegal, the law contains a number of exceptions that could limit its effectiveness. First, physician group practices are exempt from the prohibition on self-referral for in-office ancillary services if the group practice meets specific criteria. Second, a physician may self-refer if the services are personally performed or supervised by another physician in the same group practice. Third, the federal prohibition does not apply to specific types of facilities—in particular, ambulatory surgical centers and so-called whole hospitals.3 Yet the law prohibits physicians from making referrals to a hospital department in which they have a financial stake. Some state prohibitions directly parallel the federal statute, while others are much more limited in scope.

Recent newspaper articles provide anecdotal evidence that these exceptions have resulted in new forms of referral arrangements for advanced diagnostic imaging procedures—arrangements specifically designed to take advantage of these exceptions.4 Such arrangements, which generate additional income for referring physicians, often require them to make minimal or no financial investment. The typical referral arrangement is structured as either a lease agreement or payment per scan performed. Under a so-called lease or time-sharing arrangement, referring physicians rent an imaging center (with equipment and employees) part time, for a specific day of the week or for part of that day. The referring physician sends the patient to the facility on that designated day and then submits a global bill to the insurer for the scan. (The global bill includes a fee for the technical component of the scan as well as the doctor’s professional interpretation fee.) To comply with the Stark rules, such part-time arrangements must be with a facility in the same building as the physician’s primary practice office. In addition, other Medicare rules require the physician or a member of his or her group practice to supervise the test. The level of supervision required, either direct, general, or personal, depends on the type of test involved.5

Alternatively, the referring physician may send his or her patients to a desig-
nated imaging provider and pay this provider a set fee for each scan performed. In this situation, the referring physician submits a global bill to the insurer for each scan referred; the difference between the amount reimbursed by the insurer and the “payment per click” represents pure profit to the referring physician. The legality of both types of arrangements, however, is questionable under both the antikickback statute and the federal self-referral law. Physicians have also avoided the prohibition on self-referral by incorporating advanced imaging machines in their offices, which is permissible under the in-office ancillary exception.6

Despite anecdotal evidence on referral arrangements tailored to fit existing exceptions, the extent of such arrangements is unknown. There is no empirical evidence documenting the prevalence and scope of physician self-referral arrangements in this post-Stark era either within particular states or at the national level. Because considerable research documents the fact that physician self-referral arrangements result in increased use of services and third-party payments, both within-office imaging and referral arrangements that involve little financial risk for referring physicians should be of particular concern to insurers, employers, policymakers, and consumers.7

Using billing records from a large private insurer in California, I and my colleagues collected information to identify the prevalence and scope of physician self-referral arrangements for three types of advanced imaging technologies: magnetic resonance imaging (MRI), computed tomography (CT), and positron-emission tomography (PET). By directly contacting each provider who billed the insurer for these procedures, we were able to distinguish self-referral situations in which physicians own equipment that is located in their offices from those in which physicians refer and bill for the procedure but do not own the equipment.

California merits examination for at least three reasons. First, California law prohibits self-referral for designated health services, regardless of type of insurance coverage. Second, until 1 January 2007, the California law as it pertains to diagnostic imaging services was more comprehensive than the federal prohibition because it encompassed nuclear medicine and PET scans.8 Third, as an innovator in the delivery of health care services, California serves as a bellwether for the rest of the United States.

**Study Data And Methods**

- **Data source.** Data consist of providers’ billing records for ambulatory services rendered to people covered by a large private health insurer in California. In January 2005, the insurer covered more than 5.8 million people, and 2.7 million were enrolled in large employer-group preferred provider organization (PPO) plans. Large-group enrollees represented 67 percent of those who were covered under these types of plans.

- **Identifying imaging providers.** Providers who bill for advanced diagnostic imaging procedures include hospitals, radiologists, nonradiologist physicians, inde-
pendent diagnostic testing facilities (IDTFs), and radiation oncologists. Physicians (radiologists, nonradiologists, and radiation oncologists) typically submit bills under their group practice’s tax identification number. We obtained from the insurer a comprehensive list of providers who during 2004 submitted claims for either the technical component or the global fee (professional and technical components) by procedure type for MRI, CT, and PET scans. By applying this selection criterion, we attempted to screen out radiologists who only billed for the professional fee for the interpretation of the scan. Since these physicians typically work out of hospitals, the technical component billed by the hospital would capture each imaging procedure performed.

The provider lists frequently were missing or had limited contact information and therefore required a considerable amount of editing to incorporate accurate contact information obtained from Internet searches. Once this phase was completed, we contacted each provider by telephone to obtain information on whether the provider offered the imaging procedure of interest, ownership, specialty of physicians if applicable, and details on imaging equipment for providers who owned the equipment. Exhibit 1 depicts graphically the series of questions asked of each provider who billed the insurer for imaging procedures. Between Internet searches, multiple telephone calls, and analysis of claims to ascertain a count of each procedure type performed and amount billed during each given year, we spent an average of two hours per case to obtain complete information on each provider. The final database contains each provider’s name, address, and telephone number; Web site if available; ownership/self-referral status; and machine

EXHIBIT 1
Determining Self-Referral Status Of Providers Who Billed One Large Insurer For Advanced Imaging Procedures In California, 2004

<table>
<thead>
<tr>
<th>Do you offer imaging (CT, MRI, PET) at this site?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
<tr>
<td>Provider refers patients for imaging services</td>
</tr>
<tr>
<td>Determine where patients are referred:</td>
</tr>
<tr>
<td>- Facility name(s)</td>
</tr>
<tr>
<td>- Facility type(s)</td>
</tr>
<tr>
<td>- Physician specialty</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Provider offers on-site imaging services</td>
</tr>
<tr>
<td>Determine type of facility:</td>
</tr>
<tr>
<td>- Hospital</td>
</tr>
<tr>
<td>- Radiology group</td>
</tr>
<tr>
<td>- Nonradiologist physician group</td>
</tr>
<tr>
<td>- Independent diagnostic testing facility</td>
</tr>
<tr>
<td>Obtain equipment details:</td>
</tr>
<tr>
<td>- Manufacturer</td>
</tr>
<tr>
<td>- Model</td>
</tr>
<tr>
<td>- Year</td>
</tr>
<tr>
<td>- Image quality</td>
</tr>
</tbody>
</table>

SOURCE: Protocol developed by the author.
NOTES: CT is computed tomography, MRI is magnetic resonance imaging, PET is positron-emission tomography.
manufacturer, model, and year.

Classification of self-referral status. Each provider who billed for either the technical component or a global fee for each advanced imaging procedure was classified as follows: (1) equipment owned or leased by nonradiologist physicians (fewer than 100 physicians in group); (2) equipment owned or leased by large multispecialty group of physicians with 100 or more members; (3) equipment owned or leased by radiologists; (4) equipment owned or leased by hospital; (5) equipment owned as a joint venture between radiologists and hospital providers; (6) equipment owned or leased by radiation oncologists; and (7) equipment owned by an independent diagnostic testing facility. Physicians in group 1 were in a position to refer patients for diagnostic imaging procedures and thus were classified as “self-referral.” This group is of particular interest, given concerns about the conflict of interest and financial incentives associated with self-referral arrangements. Group 1 providers were further classified by type of self-referral. Some nonradiologist physician providers who worked in small to medium-size groups submitted global bills for imaging procedures, and the equipment was located within their practices. However, many other nonradiologist physician providers did not own the equipment, nor were the machines located on site. Rather, they either leased time on another provider’s machine or paid another provider a set fee per scan and then submitted a global bill to the insurer for each scan ordered.

Large multispecialty physician practices (those with 100 or more members) were also deemed to be “self-referral.” The original intent of the group-practice exception was to recognize that physician-members of large group practices routinely make most referrals internally for a wide array of services. The presumption behind this exception was that any financial gain that accrues to an individual physician from making referrals is small. Unlike smaller groups of nonradiologist physician providers, the large multispecialty practices owned the imaging equipment, and it was located on site.

Because radiologists were not in a position to refer patients for diagnostic imaging procedures, this provider group was classified as “not self-referral.” For hospital providers, the imaging equipment was either owned or leased by the hospital and was located on the facility grounds. Since physicians, not hospitals, refer patients for imaging procedures, hospitals were categorized as “not self-referral.” If however, the hospital was a specialty facility owned by referring physicians, it was classified as “self-referral.”

Under Stark II, radiation oncologists are considered to be non-self-referral physicians. Yet radiation oncologists may refer patients for CT scans to be used in planning the course of radiation therapy treatments. For this reason, the self-referral status of radiation oncologists was classified as “indeterminate.” IDTFs represent a diverse group of providers; their variable structure and ownership defy simple classification with respect to self-referral status. Although IDTFs submitted global bills to the insurer, anecdotal information indicates that some have estab-
lished personal services contracts (that is, medical directorships, interpretation agreements, or consulting arrangements) with referring physicians to ensure that these physicians refer their patients to the IDTF. Whether or not an IDTF had established such contractual agreements with referring physicians was impossible to ascertain from the claims submitted to the insurer. Rather, one would need to scrutinize the financial records of each IDTF to determine if the entity has established such contractual agreements with nonradiologist physicians. In light of these considerations, IDTFs were classified as having “indeterminate” self-referral status.

The insurer records the names, license numbers, and specialties of physicians affiliated with the each provider tax identification number (billing number). We used these records to cross-check and verify the specialties and self-referral status assigned to each case classified as “self-referral.” Despite incomplete information in each of the original provider lists, with significant effort we were able to correctly classify the ownership and self-referral status for 100 percent of the potential provider entries.

- **MRI providers.** Of the original 1,335 MRI providers, we identified 66 duplicate cases, 125 entries that were deemed “low-volume providers,” and 121 radiology practices that worked out of hospitals and therefore only billed for their professional services (interpretation of the MRI scan). Altogether, these exclusions resulted in a list of 1,023 valid providers that billed the insurer for either the technical component or a global fee for MRI procedures.

- **CT providers.** Of the 1,525 potential providers that billed the insurer either for the technical component or globally for CT procedures, 399 were deemed ineligible because they were either out of state (104); duplicates (39); low-volume providers (204); or obstetricians or dentists (52) who billed for one CT procedure code but did not provide CT or refer patients for CT. We further eliminated 162 radiology groups that work at hospitals and thus only billed for professional services. The final list of providers that billed for CT scans contained 964 providers.

- **PET providers.** The insurer identified 206 potential providers that billed for either the technical component or global reimbursement for PET scans during 2004. Twenty low-volume cases, two duplicates, and ten radiology groups that only billed for professional services were eliminated. These exclusions yielded a list of 174 providers that billed the insurer for PET scans performed during 2004.

**Study Results**

Exhibit 2 shows providers who billed either globally or for the technical component for the three types of advanced diagnostic imaging procedures, classified by ownership and self-referral status in 2004. Approximately 33 percent of providers who submitted either global or technical bills for MRIs were nonradiologist physicians practicing in small to medium-size groups and involved in self-referral. Physicians who were members of large multispecialty group practices...
EXHIBIT 2
Prevalence Of Diagnostic Imaging Providers Who Billed For The Technical Component Or Globally For Privately Insured People In California In 2004, By Self-Referral Status

<table>
<thead>
<tr>
<th>Provider type</th>
<th>Self-referral status</th>
<th>Providers who billed for MRI (N = 1,023)</th>
<th>Providers who billed for CT (N = 964)</th>
<th>Providers who billed for PET (N = 174)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Number</td>
<td>Percent</td>
<td>Number</td>
</tr>
<tr>
<td>Nonradiologist physician (small or medium-size group)</td>
<td>Self-referral</td>
<td>340</td>
<td>33.2</td>
<td>210</td>
</tr>
<tr>
<td>Nonradiologist physician (large group)</td>
<td>Self-referral</td>
<td>37</td>
<td>3.6</td>
<td>24</td>
</tr>
<tr>
<td>Radiologist, owned equipment</td>
<td>Not self-referral</td>
<td>291</td>
<td>28.4</td>
<td>280</td>
</tr>
<tr>
<td>Hospital, owned equipment</td>
<td>Not self-referral</td>
<td>276</td>
<td>27.0</td>
<td>402</td>
</tr>
<tr>
<td>Radiology-hospital joint venture</td>
<td>Not self-referral</td>
<td>10</td>
<td>1.0</td>
<td>-a</td>
</tr>
<tr>
<td>Independent diagnostic testing facility</td>
<td>Indeterminate</td>
<td>69</td>
<td>6.8</td>
<td>24</td>
</tr>
<tr>
<td>Radiation oncologist, owned equipment</td>
<td>Indeterminate</td>
<td>-a</td>
<td>-a</td>
<td>24</td>
</tr>
</tbody>
</table>

**SOURCE:** Provider records from the insurer, 2004.

**NOTES:** MRI is magnetic resonance imaging. CT is computed tomography. PET is positron-emission tomography.

*Radiation oncologists did not bill for either MRI or PET scans.*

(100-plus physicians) accounted for 3.6 percent; IDTFs accounted for nearly 7 percent. The remaining 56 percent of providers were classified as “not self-referral.”

Nonradiologist physician providers who were members of small to medium-size groups and engaged in self-referral accounted for almost 22 percent of the providers who submitted global bills for CT scans during 2004. Large multispecialty groups of physicians, also classified as “self-referral,” constituted 2.5 percent. IDTFs and radiation oncologists, viewed as having indeterminate referral status, together accounted for 5 percent of CT providers. The remaining providers did not engage in self-referral.

Slightly more than 17 percent of the 174 providers who billed either globally or for the technical component for PET scans were members of small to medium-size physician groups who engaged in self-referral. Close to 5 percent of PET providers were large multispecialty physician groups. IDTFs represented almost 20 percent; the remaining 58 percent were not involved in self-referral.

**Further classification of self-referral cases.** Exhibit 3 depicts self-referral providers who were affiliated with small to medium-size group practices, stratified by type of self-referral arrangement. Almost 61 percent of the 340 nonradiologist physician providers who submitted global bills for MRIs did not own the equipment, nor was the machine located on site. Nearly 64 percent of the self-referral CT providers who worked in small to medium-size groups billed the insurer but had ei-
ther a lease or payment-per-click arrangement. Thus, only 39 percent of MRI providers and 36 percent of CT providers who engaged in self-referral had the machines located at their practices. In contrast, nearly 70 percent of PET providers classified as self-referral actually had the machines on site.

Discussion

Laws enacted during the early 1990s to curb physician self-referral were a major step toward addressing the concerns about these arrangements; however, they contain exceptions that could enable self-referral to reappear but in a different form tailored to fit the exemption. This study is the first to document the prevalence and scope of self-referral arrangements in light of these exceptions. The findings presented here, which are based on a comprehensive list of providers who billed a large private insurer in California for advanced imaging procedures in 2004, indicate that prohibition exceptions have enabled self-referral to persist, but in new forms.

In 2004, nonradiologist physicians who were members of small to medium-size groups and engaged in self-referral accounted for 33 percent of the providers that billed the insurer for MRIs but only 11.5 of the statewide volume of this procedure performed. Such physicians represented 17 percent of providers who billed for PET in 2004, yet their share of statewide PET volume exceeded 25 percent. Moreover, for both of these highly reimbursed advanced imaging technologies, the share of statewide volume billed for by such physicians has grown dramatically since 2000. These physicians accounted for 22 percent of providers who billed for CT procedures in 2004, but their share of statewide volume was less than 7 percent. Nonetheless, the share linked to these self-referring providers had greatly increased.

These prevalence rates are probably conservative with respect to the situation in 2007 because they identify arrangements in existence during 2004 and do not reflect developments since then. Additional analyses support this contention. The
research team identified twenty new providers who billed for PET scans for the first time during 2005; half of these were classified as “self-referral.”

One aspect of the structure of today’s physician self-referral arrangements is particularly noteworthy. The in-office exception in current law was justified under the assumption that when physicians provide imaging to patients within their offices, they do so for patients’ convenience and to monitor quality of care. However, the majority of self-referral providers for MRIs and CT scans (61 percent and 64 percent, respectively) did not have the imaging equipment in their offices in 2004. Rather, physicians have figured out how to take advantage of the exemptions in existing law by establishing referral arrangements with other imaging facilities that involve minimal financial risk for the referring physician.9 The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) views these types of arrangements as an opportunity for referring physicians to bill and retain remuneration that is illicit under the antikickback statute, even thought they appear to meet the “safe harbor” guidelines.10 Moreover, these questionable referral arrangements have come under heightened scrutiny from state and federal prosecutors. In January 2007 the Illinois attorney general’s office joined a whistleblower lawsuit and charged twenty MRI centers in Chicago with concocting “sham lease agreements” to pay kickbacks to physicians for referrals.11 The OIG has filed a federal lawsuit against physicians involved in similar sham lease deals in Florida.12 Such referral arrangements raise concerns about referring physicians’ ability to monitor the quality of care provided because the referring physicians are not on site to directly supervise the provision of imaging services and the site’s operation. Finally, arguments regarding patient convenience appear to be tenuous at best, especially if the referral arrangement is structured as a “sham lease agreement.”

It is important to recognize that referral arrangements tailored to qualify as permissible under the exceptions in existing self-referral laws are not confined to the three types of advanced imaging procedures examined here. Similar referral arrangements have also been established between referring physicians and medical laboratories for clinical laboratory tests.13 Moreover, we examined providers who submitted global bills for cardiac nuclear imaging procedures; these analyses, although preliminary, indicate that self-referral arrangements are commonplace.

Although anecdotal evidence suggests that self-referral for diagnostic imaging exists in many states, it is unknown whether such referral arrangements are as prevalent elsewhere as in California. Thus, further research is needed to document the prevalence, scope, and effects of self-referral arrangements for diagnostic imaging that exist in other states. These findings should be of considerable concern to policymakers, employers, insurers, and consumers who recognize the need to control rapidly escalating health care spending. Efforts that address the exemptions in existing federal and state prohibitions on physician self-referral are likely to have major impacts on the increased use that characterizes these arrangements.
This research was supported by the California HealthCare Foundation under a grant awarded to Georgetown University.

NOTES
2. See 42 U.S. Code, sec. 1320a-7b(b).
5. The supervision requirements for diagnostic tests vary from “personal,” where the physician must be in the room, to “direct,” where the physician must be present in the office suite, to “general,” where the physician provides direction but does not need to be present.
8. The California prohibition on self referral is described in section 650.01–650.02 of the California Business and Professions Code. The Centers for Medicare and Medicaid Services (CMS) recently added nuclear medicine and PET to the list of designated health services covered under the federal self-referral prohibition, effective January 2007. Although the California law is quite similar to the federal law, some differences exist. For example, Stark II clearly defines what constitutes a referral, whereas the state law does not. Under the California law, a loan between a referring physician and the recipient of the referral is not a prohibited financial interest. Stark II contains no exception for loans. More details on differences between the California and federal laws can be obtained from the author; send e-mail to mitchejm@georgetown.edu.
12. Ibid.