Stark Law

Stark law, actually three separate provisions, governs physician self-referral for Medicare and Medicaid patients. The law is named for United States Congressman Pete Stark, who sponsored the initial bill.

Physician self-referral is the practice of a physician referring a patient to a medical facility in which he has a financial interest, be it ownership, investment, or a structured compensation arrangement. Critics of the practice allege an inherent conflict of interest, given the physician's position to benefit from the referral. They suggest that such arrangements may encourage over-utilization of services, in turn driving up health care costs. In addition, they believe that it would create a captive referral system, which limits competition by other providers. (see physician self-referral)

Others respond to these concerns by stating that while problems exist, they are not widespread. Further, these observers contend that, in many cases, physician investors are responding to a demonstrated need which would otherwise not be met, particularly in a medically underserved area.

Congress included a provision in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) which barred self-referrals for clinical laboratory services under the Medicare program, effective January 1, 1992. This provision is known as "Stark I". The law included a series of exceptions to the ban in order to accommodate legitimate business arrangements. A number of observers recommended extending the ban to other services and programs. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid; this legislation, known as "Stark II," also contained clarifications and modifications to the exceptions in the original law. Minor technical corrections to these provisions were included in the Social Security Amendments of 1994.

Passage of Stark II raised a series of concerns on the part of many provider groups. While Stark I and II were intended to remove potential conflicts of interest from physician decision making, a number of persons have argued that the legislation, particularly parts of Stark II, represents an unwarranted intrusion into the practice of medicine. They have stated that the legislation, particularly the provisions relating to compensation arrangements, is too complex and may, in fact, impede physicians' ability to participate in managed care networks.

On November 20, 1995, Congress gave final approval to the conference report on the Balanced Budget Act (BBA) of 1995. President Clinton vetoed the measure on December 6, 1995. BBA included several amendments to the physician self-referral provisions. The two major changes were the repeal of the prohibitions based on compensation arrangements and the reduction in the list of services subject to the ban.

The Federal Register announced that publication of Stark III has been extended until March 26, 2008, and Phase II will remain in effect through that date.

The Phase III final rule was published on September 5, 2007, at 72 FR 51012, and became effective December 4, 2007.

The Stark Law is related to, but not the same as, the federal anti-kickback law.

Lawyers and laypersons can find Stark at [42 U.S.C.S. §1395nn] which is §1877 of the Social Security Act. Additionally, the regulations are at [42 C.F.R. §411.350 through §411.389].

Section 1877 of the Social Security Act (the Act) prohibits physicians from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician's immediate family has a financial relationship--unless an exception applies. Section 1877 also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for a DHS furnished as a result of a prohibited referral.

When enacted in 1989, section 1877 applied only to physician referrals for clinical laboratory services. In 1993 and 1994, Congress expanded the prohibition to ten additional DHS and applied certain aspects of the law to the Medicaid program. In 1997, Congress added a provision permitting the Secretary to issue written advisory opinions concerning whether a referral relating to DHS (other than clinical laboratory services) is prohibited under section 1877.

Under section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (see the provisions of section 1860D-4(e)(6) of the Act), Congress authorized an exception to the physician self-referral prohibition for certain arrangements in which the physician receives necessary non-monetary remuneration that is used solely to receive and transmit electronic prescription information.

In 2003, Congress amended section 1877 by establishing an 18-month moratorium on physician referrals to certain specialty hospitals in which the referring physician has an ownership or investment interest. Under the moratorium, specialty hospitals cannot fill or submit claims to anyone for DHS furnished as a result of a referral that is prohibited under the moratorium. The moratorium was in effect from December 8, 2003 through June 7, 2005. When the moratorium ended, CMS instituted a temporary suspension on the processing of specialty hospital applications for participation in the Medicare program. In 2006, Congress extended that suspension until the earlier of the date that the Secretary submits the final report on physician investment in specialty hospitals or August 8, 2006 (unless the Secretary extends the deadline an additional two months as authorized under section 5006(c)(2) of the Deficit Reduction Act of 2005).

On August 14, 1995, we published a final rule with comment period (60 FR 41914) incorporating into regulations the physician self-referral prohibition as it applied to clinical laboratory services.

On January 9, 1998, we published a proposed rule (63 FR 1659) that would revise the regulations to cover the additional designated health services and the Medicaid expansion. We finalized the proposed rule in three phases. On January 4, 2001, we issued the "Phase I" final rule with comment period (66 FR 856), on March 26, 2004, we issued the "Phase II" interim final rule with comment period (69 FR 16054) and, on September 5, 2007, we issued the "Phase III" final rule (72 FR 51012). To view the proposed and final rules, refer to the "Downloads" section below.

STARK LAW - Information on penalties, legal practices, latest news and advice.

Stark law, actually three separate provisions, governs physician self-referral for Medicare and Medicaid patients. The law is named for United States Congressman Pete Stark, who sponsored the initial bill. Here is a list of Stark

Guidelines and their ramifications.

Stark and physician referrals to facilities in which there is a financial interest

Physician self-referral is the practice of a physician referring a patient to a medical facility in which he has a financial interest, be it ownership, investment, or a structured compensation arrangement. Critics of the practice allege an inherent conflict of interest, given the physician's position to benefit from the referral. They suggest that such arrangements may encourage over-utilization of services, in turn driving up health care costs. In addition, they believe that it would create a captive referral system, which limits competition by other providers.

Others respond to these concerns by stating that while problems exist, they are not widespread. Further, these observers contend that, in many cases, physician investors are responding to a demonstrated need which would otherwise not be met, particularly in a medically underserved area.
