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Stark Law Summary

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Background

The Federal physician self-referral law was enacted in 1989 and became effective on January 1, 1992. This law, commonly referred to as "Stark I" after the California Congressman who sponsored the initial bill, prohibited physicians from referring Medicare and Medicaid patients to clinical laboratories in which they or their immediate family members had an ownership or other investment interest. In 1993 ad 1994, Congress amended the law, commonly referred to as "Stark II", by expanding the list of prohibited services to cover more than just clinical laboratories. This expanded list is referred to as "Designated Health Services" or "DHS". The physician self-referral law is included in Section 1877 of the Social Security Act and is codified at 42 USC 1395nn. Section (g)(6) of the law authorizes the Secretary of the Department of Health and Human Services to promulgate regulations interpreting the Stark law.

The Centers for Medicare and Medicaid Services ("CMS") is the division of DHHS that is responsible for publishing regulations under the Stark Law. In 1995, regulations were published for the physician self-referral prohibition as it applied to clinical laboratory services. In 1998, a proposed revision to the rule was published to incorporate the additional DHS. The final rule was adopted in three phases beginning in January 2002 ("Phase I"). The Phase II regulations were released in March 2004 and became effective July 26, 2004. The Phase III regulations were published in September 2007. In addition, in 2006, CMS began to introduce changes to the Stark regulations through the rulemaking cycle of the physician fee schedule. Additional amendments to the Stark Law were included as part of the Patient Protection and Affordable Health Care Act ("PPACA").

The Rule

The general rule under Stark is as follows: A physician may not refer a Medicare patient to a Designated Health Services provider with which the physician has a financial relationship unless an exception is met. This can be broken into four distinct elements:

1. Physician
2. Medicare Patient
3. Designated Health Services
4. Financial Relationship

These distinct elements require further definition:

1. Physician – The Stark law only applies to physicians. However, physician extenders, such as physician assistants and nurse practitioners (collectively Licensed Independent Provider or "LIP"), can be implicated in a Stark violation depending upon the level of independence they have to refer patients. If the LIP works under the direct supervision of the physician, any referral of a patient by the LIP could be imputed to the physician, thereby implicating the Stark law. Similarly, if the LIP is directed by the physician regarding referrals or is required by the physician to refer patients to specific entities, then referrals by the LIP will likely be considered to have come from the physician. Put another way, if an LIP has independent decision-

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making authority on when and where to refer a patient, then referrals by the LIP will likely not trigger a Stark analysis.

2. Medicare Patient – The Stark law explicitly applies only to Medicare patients. However, the Stark II regulations applied the Stark prohibition to the Federal payment portion of Medicaid payments. As a result, the self-referral of patients for services that would be prohibited under Medicare are also prohibited for Medicaid patients.
3. Designated Health Services (DHS) – The Stark law only applies to referrals of patients to the following specific services:
    a. Clinical laboratory services;
    b. Physical therapy services;
    c. Occupational therapy services;
    d. Radiology services;
    e. Radiation therapy services and supplies;
    f. Durable medical equipment and supplies;
    g. Parenteral and enteral nutrients, equipment, and supplies;
    h. Prosthetics, orthotics, and prosthetic devices and supplies;
    i. Home health services;
    j. Outpatient prescription drugs; and
    k. Inpatient and outpatient hospital services.
4. Financial Relationship – Under the Stark law, a financial relationship exists when a physician, directly or indirectly, has a compensation arrangement or an investment interest in an entity that provides designated health services. A financial relationship can be attributed to a physician through an immediate family member, meaning 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, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. In some limited circumstances, a financial relationship may be specifically excluded from the Stark prohibition. These exceptions are narrow and limited and specific guidance from legal counsel should be obtained before relying on an exception to the financial relationship element.

The Exceptions

There are thirty-five exceptions to the Stark law that are defined by either law or regulation. Some of the exceptions include:

1. Physician services;
2. In-office ancillary services;
3. Indirect compensation;
4. Risk sharing arrangements;
5. Academic Medical Centers;
6. Publicly traded securities;
7. Space/equipment leases;
8. Bona fide employment;
9. Personal services;
10. Physician recruitment;
11. Fair market value comp;

12. Non-monetary compensation;
13. Compliance training;
14. Community Health Info Systems; and
15. Obstetric malpractice insurance subsidy;

Each of these exceptions contains specific requirements that must be carefully examined to determine whether the exception applies to a specific set of facts and circumstances. To apply an exception, all of the requirements for the exception must be met. Before concluding that an exception applies, consult your legal counsel with your specific facts.

Advisory Opinions

CMS has issued Advisory Opinions in response to requests for guidance regarding specific arrangements. The published Advisory Opinions provide insight as to how the government would evaluate the arrangements in question. However, the Advisory Opinions may not be relied upon for legal guidance except by the party that requested the Advisory Opinion. As a practical matter, however, practitioners typically review the Advisory Opinions to help assess whether a particular situation is more likely or less likely to meet the government's approval. Put another way, the Advisory Opinions aid practitioners in establishing soft boundaries for complying with the Stark law.

What if I violate the Stark law?

If an arrangement between a physician and DHS provider is determined to violate the Stark law, then a penalty of $15,000 may be imposed for each inappropriate referral and claim submitted as a result of that referral, plus an assessment of up to three times the amount of each claim submitted. In addition, the physician and/or the DHS provider may be excluded from participation in federal health care programs for violating the Stark law. If the government determines that the arrangement is a "circumvention scheme", a civil penalty of $100,000 may be imposed. A circumvention scheme is one in which the physician or the DHS provider knows, or should know, the arrangement has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of the Stark law.

The Stark law does not include criminal penalties. However, if the arrangement is deemed to result in an unlawful kickback, the Federal Anti-Kickback Statute can be triggered, which contains both civil and criminal penalties.

Many states have self-referral laws and laws that prohibit fee-splitting arrangements. These laws impose additional restrictions and requirements on physicians who refer patients, regardless of payer, for designated health services in which they have an ownership interest.