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STARK LAW REFRESHER

Physicians and hospitals are always looking at methods to increase profitability and to add new sources of revenues. When physicians consider adding “ancillary services” to their practices, or when hospitals and physicians consider undertaking a joint venture to provide ancillary services, many of these discussions stop dead in their tracks because of a well-known, but sometimes misunderstood law known as the “Stark Law”.

The Stark Law, which derives its name from its chief proponent, Congressman Pete Stark of California, is actually a provision of the Social Security Act known as the “Physician Self-Referral Law”. The regulations adopted by The Centers for Medicare and Medicaid Services (“CMS”) provide literally hundreds of pages of analysis of the nuances of the Stark Law. Physicians, physician practice managers, accountants, hospital executives and finance department personnel often express frustration regarding the breadth of the Stark Law. The purpose of this article is to provide a refresher on the basic points of the Stark Law for those involved in the financial management of health care providers.

What is prohibited? Under the Stark Law, if a physician has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of Designated Health Services for which payment may be made under the Medicare or Medicaid program, and the entity may not file a claim or bill for such Designated Health Services furnished pursuant to the referral. The theory behind the Stark Law is that if a physician has a financial interest in an entity that furnishes a specific type of “ancillary” service, this financial interest can affect a physician’s decision about what medical care to furnish a patient and who should furnish that care. Congressional research found that physician owned facilities performed more procedures and charged higher prices than non-physician owned facilities.

What is a financial relationship? There are two types of **financial relationships**: 1) **ownership or investment** interests; and 2) **compensation arrangements**. An **ownership or investment** interest includes an equity or debt interest in the entity. A **compensation arrangement** means any arrangement involving any remuneration between a physician and an entity. Remuneration includes any remuneration, direct or indirect, in cash or in kind. A **referral** includes the request by a physician for an item or service.

What is a Designated Health Service? The term **Designated Health Service (“DHS”)** includes clinical laboratory services, physical therapy, occupational therapy and speech-language pathology services, radiology and certain other imaging services, 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 and inpatient and outpatient hospital services. A DHS does not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgery center services or SNF Part A payments).

What are the consequences if the Stark prohibition applies? The Stark Law is an outright prohibition. Unless a specific statutory **exception** applies, a physician who has a **financial relationship** with an entity may not make a **referral** to the entity for the furnishing of a **DHS**. The penalties for violation of the Stark Law include denial of payment, civil fines and exclusion from the Medicare/Medicaid program.

What are the relevant exceptions? Although this is not an exhaustive list, some arrangements can be structured to meet certain exceptions which include:

Exceptions Related to Both Ownership/Investment Interests and Compensation Arrangements: Physician services; in-office ancillary services; services provided by an academic medical centers; implants furnished in an ambulatory surgery center; EPO and other dialysis related drugs; preventive screening test, immunizations and vaccines; eyeglasses and contact lenses provided following cataract surgery; and intra-family referrals.

Exceptions Related to Ownership/Investment Interests: Interests in publicly traded entities; interests in mutual funds; interests in rural providers; and interests in whole hospitals.

Exceptions Related to Compensation Arrangements: Rental of office space and/or equipment; employment relationships; personal services arrangements; physician recruitment arrangements; isolated transactions; charitable donations by physicians; 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 bona fide underserved areas; and community-wide health information systems.

If an exception is met, the physician may be able to make a referral of DHS to the entity with which the physician has the financial relationship. Each of the exceptions has many precise requirements, and meeting the exceptions can hinge on specific facts. Navigating through these requirements takes a team approach.

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