



Stark Law Policy

(Effective Date: November 1, 2017)

SCOPE:

This policy applies to all Sightpath Medical LLC (“Sightpath”) employees worldwide, including part time, temporary contract employees, Management Committee Members, Corporate Integrity Agreement (CIA) Covered Persons, and Vendor’s.

PURPOSE:

Sightpath is committed to compliance with applicable laws, rules and regulations, including the Stark Law. This policy provides general information about the Stark Law and implements relevant policy.

STARK LAW

Relevant Purpose

The Stark Law’s purpose is to regulate physician referrals where the physician has a financial interest in the entity on the receiving end of the referral. Stark, by limiting these types of “self-referrals,” helps avoid overutilization of referred services and ensures competition by other providers, driving down healthcare costs.

Summary of the Law

The Stark Law prohibits physicians from referring Medicare/Medicaid patients to an entity for “designated health services” (DHS) if the physician or an immediate family member of the physician has a “financial relationship” with the entity receiving the referral. The Stark Law further prohibits the entity receiving a prohibited referral from presenting a claim to Medicare or Medicaid for the designated health service furnished under the prohibited referral.

The Stark Law is not an intent based statute. Thus, receipt of a referral from a physician where a financial relationship exists results in a violation of the Stark Law, regardless of intent.

Penalties

Penalties for violation of Stark include:

- Overpayment/refund obligation
- Federal False Claims Act liability
- Civil monetary penalties (CPM) and federal program exclusion for knowing violations
- Potential for \$15,000 CPM for each service
- Civil assessment of up to three times the amount claimed

POLICY

Designated Health Services

Under the Stark Law, under certain circumstances Sightpath will not be able to accept/provide referrals for “designated health services” to/from a physician with whom Sightpath has a “financial relationship.” Some of the “designated health services” covered by the Stark Law include radiology services (e.g., A-scans and B-scans); prosthetic devices and supplies (e.g., post-cataract eyewear, and IOL’s); outpatient prescription drugs; and inpatient and outpatient hospital services.

Financial Relationships

A “financial relationship” is deemed to exist if a physician (or an immediate family member of the physician) holds an ownership or investment interest in, or is a party to a “compensation arrangement” with the entity receiving the referral. A “compensation arrangement” is defined broadly to include any arrangement involving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind between a physician (or an immediate family member) and an entity. Thus, a “financial relationship” could be created by a consulting agreement with a physician, the sale of product to a physician, or the provision of free goods to a physician.

Exceptions

Certain exceptions have been created where relationships with a physician will not be deemed to create a “financial relationship” under the Stark Law. Exceptions include, but are not limited to:


- a. The “personal services exception” to the Stark Law protects fair market value payments to a physician for legitimate, commercially reasonable and necessary services that are provided pursuant to a written services agreement, subject to the satisfaction of certain additional requirements.
- b. The Stark Law also has an exception for payments made by a physician for items or services if the items or services are furnished at a price that is consistent with fair market value.
- c. Other exceptions to the definition of “financial relationship” may be available for a particular business arrangement.

RESPONSIBILITY FOR COMPLIANCE WITH STARK LAW POLICY

It is the Compliance Officer’s responsibility along with input from the Compliance Committee and Legal Counsel to maintain compliance with Stark. As of the effective date of this policy, Sightpath is not aware of any relationship that currently implicates Stark. However, the Compliance Officer will continue to monitor Sightpath’s relationships and if Stark becomes applicable, will work with Legal Counsel to structure such relationships so as to meet Stark requirements. Further, as needed, additional policy, procedure, and controls will be developed in order to ensure ongoing compliance with Stark.

POLICY – SUSPECTED VIOLATION

All suspected violations of the Stark Law must be reported to the Compliance Officer who will investigate the incident and take appropriate remedial steps to address the issue. The Compliance Officer will also determine if the incident meets the definition of a reportable event per Sightpath’s Corporate Integrity Agreement.



Benjamin N. Wright
Compliance Officer

11/01/2017

Date