



Anti-Kickback Statute Policy

(Revision Date: December 11, 2019)

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 Vendors.

PURPOSE:

Sightpath is committed to compliance with applicable laws, rules and regulations, including the Federal Anti-Kickback Statute. This policy provides general information about the Federal Anti-Kickback Statute; and implements relevant policy as applied to relationships between Sightpath and referral, or direct business sources, where payment may be paid under a federal healthcare benefit program.

FEDERAL HEALTHCARE ANTI-KICKBACK STATUTE

Relevant Purpose

The Federal Anti-Kickback Statute generally prevents companies such as Sightpath from encouraging customers, directly or indirectly, to recommend, prescribe, or purchase Sightpath services based on a financial incentive or “kickback” rather than sound medical and business judgment.

Summary of the Law

As it applies to Sightpath, the Anti-Kickback Statute generally makes it illegal to directly or indirectly offer or pay any “remuneration” to any entity (including vendors, customers, and potential customers) to induce that entity to recommend, prescribe, or purchase Sightpath services when those services are being paid for by the federal government.

“Remuneration” can be anything of value, such as discounts, rebates, grants, vouchers, cash, gifts, services, coupons, lottery tickets, trips, or free products. The government may view remuneration as a kickback even if one among many other appropriate reasons you provided it was to encourage your customer to utilize Sightpath services.

Similarly, the Anti-Kickback Statute generally makes it illegal for Sightpath customers and vendors to accept any improper remuneration in exchange for prescribing or influencing prescribing Sightpath services. Thus, there is a common interest between Sightpath and those individuals and entities with whom we do business to avoid an arrangement that might appear to be a “kickback.”

“Safe Harbors”

Not all discounts, grants, and gifts are illegal. The government has established “safe harbors” to protect certain conduct. If a company fully complies with a safe harbor, it will not be liable under the Anti-Kickback Statute. For example, the Personal Services Safe Harbor allows Sightpath to enter into contracts with healthcare professionals for services such as speaking engagements, consultancies, and advisory boards. It is important to note that this safe harbor requires that the services be “bona fide”, that any fees paid for such services represent the “fair market value” for such services, and that an agreement is set out in writing signed by both parties. Further, a safe harbor also exists for bona fide employees. The specifics of these safe harbors are extremely complex. For this reason, all arrangements with possible antikickback risk must be approved by the Compliance Department.

Penalties

It is a felony to violate the Anti-Kickback Statute. Violators may be fined substantial penalties for violations, and may also face probation (for organizations) or prison (for individuals). Additionally, violation of the Anti-Kickback Statute may result in exclusion from the federal healthcare programs such as Medicare and Medicaid. Likewise, there are state-based anti-kickback statutes under which Sightpath could face penalties for activities deemed to be kickbacks.

POLICY – GIFTS, MEALS, ENTERTAINMENT AND CHARITABLE CONTRIBUTIONS

Gifts, Meals, and Entertainment

It is never appropriate to provide a gift, meal, or entertainment in order to encourage a customer or prospective customer to purchase or order Sightpath services or to be a source of referrals for Sightpath.

Sightpath employees or sales representatives may not give gifts, provide meals, or entertainment to a prospective customer, current customer, relative, or close associate of the customer unless they have been approved by the Compliance Department and Senior Director and are:

- Offered only occasionally
- Are nominal in value
- Are not price terms or in place of a price concession

Non-Sightpath funds may never be used to provide gifts, meals, or entertainment to a prospective customer, relative, or close associate of the customer.

Charitable Contributions

Sightpath may support certain charitable organizations through appropriate donation of products, services, and funds. All charitable contributions must be approved in accordance with the Charitable Contributions Policy which can be found on the Sightpath Intranet under the Compliance tab, number ten.

http://intranet.sightpathmedical.com/?page_id=26591

Notwithstanding the above, participating in a mission trip that includes a customer or potential customer, is allowed provided it does not violate any of the principles listed below.

Charitable donations of products, services, funds, or participation in a mission trip, may never be made:

- To encourage anyone to purchase or recommend Sightpath services
- In exchange for an agreement to purchase or order Sightpath products, or
- In lieu of a discount or price concession or as part of a contract negotiation

POLICY – FOCUS ARRANGEMENTS

General Focus Arrangement Policy

Definitions:

- *Focus Arrangements (FA)* – An arrangement between Sightpath and any actual source of healthcare business or referrals paid for by a government program that involves the payment or provision of anything of value
- *Covered Person*
 - All owners, officers, directors, and employees
 - All persons who furnish patient care items/services or billing coding functions for Sightpath or perform functions related to sales and marketing on behalf of Sightpath; excluding vendors whose sole connection with Sightpath is selling or providing medical supplies or equipment to Sightpath; and
 - The Management Committee of TLC Holdings LLC Series 3.5

New, Existing and Renewed Focus Arrangement Policies

- New, existing and renewed FA's will be maintained in the FA Centralized Tracking System (CTS)
- Remuneration to and from all parties to the FA will be tracked
- As applicable, service and activity logs will be maintained for FA's to ensure parties to a FA are performing services required under the FA
- As applicable leased space, medical supplies, medical devices, equipment or patient care items will be monitored to ensure use is consistent with the terms of a FA.
- All new, existing, and renewed FA will be reviewed by counsel with expertise in the Anti-Kickback Statute and Stark Law, have business rationale documented, and have Fair Market Value (FMV) review documented.

New and Renewed Focus Arrangement Policies

- Will be set forth in a signed writing
- Include a requirement that each party to a FA who meets the definition of a Covered Person will complete one hour of Anti-Kickback Statute and Stark training
- Each party to the FA will be provided with a copy of Sightpath's Stark Law and Anti-Kickback Statute Policy
- Include a written compliance certification that each party will not violate the Anti-Kickback Statute and Stark law.

Compliance Review of CTS and FA Procedures – The Compliance Officer will review the FA CTS and FA Procedures on an annual basis and provide a report to the Compliance Committee.

Note: In addition to these general FA policies, the following sections contain policy specific to different categories of Focus Arrangements as well as reference to detailed procedural documents that implement applicable policy

Speakers, Consultants, and Advisory Committees

Sightpath may pay reasonable fees for the performance of bona fide services by healthcare professionals and customers, provided certain criteria are met.

These arrangements may include, for example, speakers, consultants, or participation on the Clinical Advisory Group. Such arrangements are permitted only if:

- Sightpath needs the services, and that need has been appropriately documented
- Participants are chosen based on their qualifications and expertise
- Participation is limited to the number of people needed to do the work
- Payment is based on the fair market value of the work or services, and
- Sightpath and the healthcare provider sign a written contract in a form approved by the Compliance Department that includes: – the legitimate business need for the services – a minimum one-year term (with some exceptions) – the participant's qualifications – a description of the services, and – fair market value compensation

These arrangements may not be made:

- To encourage healthcare professionals to purchase, or recommend Sightpath services
- To reward high volume customers

In addition, the policies in the General Focus Arrangement Policy section above are also applicable to these arrangements.

See: Clinical Advisory Group Focus Arrangement Procedures

Customer Agreements

New and Renewing Customer Agreements - Sightpath's contracts with certain customers whose services are reimbursed by a federal program and with customer's who are a source of referral business to Sightpath. For such customers, the General Focus Arrangement Policies described above, to include Fair Market Value (FMV) review, Business Justification analysis and Legal review, must be applied.

Examples of lines-of-business that must complete this process include:

- Cataract
- Mobile Femtosecond (MOFE)
- YAG
- SLT
- Refractive agreements where there is also a Cataract, MOFE, SLT, or YAG agreement with the same entity
- Sightpath Creative agreements where there is also a Cataract, MOFE, SLT, or YAG agreement with the same entity

"Dormant" Customer Agreements - It is Sightpath's policy to apply General Focus Arrangement Procedures to include Fair Market Value (FMV) review, Business Justification analysis and Legal review to Dormant Customer Agreements that return as an active customer at the time the customer reactivates its relationship with Sightpath. Reactivated Dormant Customer Agreements will follow the same contracting and FA procedures as a new account. Sightpath defines a Dormant Customer Agreement as a contract with a customer that has not utilized our services within the past 12 months.

Customer Concessions - It also Sightpath's policy to ensure "customer concessions" during the duration of the contractual relationship do not undercut FMV nor give customer's preferential treatment that could potentially implicate the Antikickback liability. All requests for a customer concession (e.g. minimum waivers, discount on invoice, etc.) must be submitted to the Sightpath Pricing Committee via the Customer Concession's form in Salesforce. The Pricing Committee with consultation from the Compliance Officer will determine if the requested concession will be given.

See the following:

- *Customer Contracting Focus Arrangement Procedures*
- *Customer Post Contracting Focus Arrangement Procedures*

Vendor Agreements

General Focus Arrangement Policies described above, to include Fair Market Value (FMV) review, Business Justification analysis and Legal review, must be applied for all vendor agreements where the vendor is a source of referral business for services reimbursed under a government program.

See : Vendor Agreement Focus Arrangement Procedures

Services and Products Purchased From Physicians Or Healthcare Service Providers

In rare instances, Sightpath may have a business need to purchase services (e.g. Technician “lease”) or products (e.g. used equipment) from a physicians or other healthcare service provider. General Focus Arrangement Policies described above, to include Fair Market Value (FMV) review, Business Justification analysis and Legal review, must be applied for all such purchases.

See: *Equipment Sales & Services Purchased From A Physician – Focus Arrangement Procedures*

Equipment Sold To Physicians Or Healthcare Service Providers

On occasion Sightpath may have a business reason to sell used equipment to a physician or other healthcare service provider. General Focus Arrangement Policies described above, to include Fair Market Value (FMV) review, Business Justification analysis and Legal review, must be applied for all such sales.

See: *Equipment Sales & Services Purchased From A Physician – Focus Arrangement Procedures*

Sightpath Creative

General Focus Arrangement Policies described above, to include Fair Market Value (FMV) review, Business Justification analysis and Legal review, must be applied to all Sightpath Creative contracts if there is also a contract with the physician for Cataract, MOFE, YAG, or SLT services. “Stand alone” Refractive accounts are not considered Focus Arrangements.

See: *Sightpath Creative Focus Arrangement Procedures*

POLICY – SUSPECTED VIOLATION

All suspected violations of the Antikickback Statute 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.



12/11/2019

Sherry Hocking
Compliance Director

Date