

POLICY TITLE: COMPLIANCE WITH THE FEDERAL ANTI-KICKBACK STATUTE AND STARK LAW

ORIGINATED BY: COMPLIANCE OFFICER

APPROVED BY: COMPLIANCE COMMITTEE

REVIEWED/REVISED: 1/2011; 10/02/2012; 10/01/2013; 10/01/2014; 10/08/2015

Key Points:

- This Policy applies to The Christ Hospital and all of its wholly-owned subsidiaries (collectively, “TCH”).
- TCH is committed to compliance with applicable laws, rules and regulations, including the Anti-Kickback Statute and the Stark Law. These laws, while complex, relate primarily to relationships between TCH and Referral Sources, including physicians. TCH may, from time to time, develop other policies regarding these relationships.
- This Policy outlines the requirements of the Compliance Officer in maintaining and reviewing the Focus Arrangements database.
- This Policy further provides general information about the federal Anti-Kickback Statute, the Stark Law, and the regulations and other related guidance and explains how these laws relate to relationships between TCH and referral sources.

Definitions

Designated Health Services means any of the following services: clinical laboratory services; physical therapy, occupational therapy, and outpatient 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.

Focus Arrangement means every arrangement or transaction that:

1. Involves, directly or indirectly, the offer or payment of anything of value; and is between TCH and any actual source of health care business or referrals to TCH; or
2. Is between TCH and a physician (or a physician’s Immediate Family Member) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to TCH for Designated Health Services.

Immediate Family Member means 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.

Overpayment means the amount of money TCH has received in excess of the amount due and payable under any Federal health care program requirements.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.

Referral Source means (a) a physician; (b) a physician's Immediate Family Member; (c) any entity that is controlled by a physician or a physician's Immediate Family Member; or (d) any non-physician who may be capable of making referrals to TCH.

Reportable Event means any isolated event or a series of occurrences that involves:

1. A substantial Overpayment (as defined by all applicable TCH Patient Financial Services Department policies);
2. A matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
3. The employment of or contracting with a Covered Person who is an Ineligible Person; or
4. The filing of a bankruptcy petition by TCH.

Policy

1. TCH does not offer, pay, provide, or accept any remuneration, including any payment of any type, for referrals of patients. TCH is committed to ensuring that its relationships with physicians and other Referral Sources do not violate the Anti-Kickback Statute, the Stark Law, or any other applicable Federal or state laws.
2. TCH has established a Code of Conduct and policies and procedures demonstrating TCH's commitment to full compliance with all federal health care program requirements, including the Anti-Kickback Statute and Stark Law. TCH's Compliance & Organizational Ethics policies and procedures and other policies that govern transactions with Referral Sources are on the TCH intranet. The Agreements with Physicians and Other Potential Referral Sources: General Policy outlines specific requirements for entering into a Focus Arrangement that ensures that all transactions with Referral Sources comply with the applicable Federal and state laws.

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3. The Division of Compliance & Organizational Ethics maintains a database of all contractual relationships with Referral Sources that are considered Focus Arrangements.
 4. Any known or suspected violations of the Anti-Kickback Statute and Stark Law must be reported, investigated, and remediated in accordance with TCH's Compliance Reports, Consults and Investigations Policy.
 5. The Attachment to this Policy provides an overview of the Anti-Kickback Statute and Stark Law which may be amended or modified from time to time.

Procedures

1. The Compliance Officer shall review at least annually the Focus Arrangements database, TCH's internal review and approval process, and certain other procedures to monitor TCH's compliance with the requirements of the Corporate Integrity Agreement between the Office of the Inspector General ("OIG") of the Department of Health and Human Services and The Christ Hospital and The Christ Hospital, Inc.
2. The Compliance Officer shall report the results of the review to the TCH Compliance Committee and the TCH Board of Directors.
3. The Compliance Officer or the Compliance Officer's designee shall regularly track remuneration to and from all parties to Focus Arrangements, including tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement.
4. The Compliance Officer or the Compliance Officer's designee shall monitor the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement.
5. All TCH employees, medical staff members and, where appropriate, others who provide services to or on behalf of TCH shall become familiar with the requirements of the Anti-Kickback Statute and the Stark Law through training and through the attached overview of the laws. Any individual who becomes aware of any activity that may be a violation of the Anti-Kickback Statute or the Stark Law should report the potential violation in accordance with TCH's Compliance Reports, Consults and Investigations Policy.
6. If the Compliance Officer becomes aware of any activity that may violate the Anti-Kickback Statute or the Stark Law, the Compliance Officer, in coordination with the appropriate departments, shall conduct an appropriate review or investigation of the activity in accordance with TCH's Compliance Reports, Consults and Investigations Policy.
7. If at any time, TCH identifies an Overpayment, TCH shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within thirty days after identification of the Overpayment and take remedial steps within sixty days after identification (or such additional time as may be agreed to by the payor) to correct the

problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within thirty days after identification, TCH shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies. Notwithstanding the foregoing, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

8. If after a reasonable opportunity to conduct an appropriate review or investigation of an activity that may violate the Anti-Kickback Statute or the Stark Law TCH determines that there is a Reportable Event, the Compliance Officer shall be responsible for notifying the OIG of the Reportable Event, in writing, within thirty days after making the determination that the Reportable Event exists.
9. Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of the Stark Law shall be submitted by TCH to the Centers for Medicare & Medicaid Services ("CMS") through the self-referral disclosure protocol ("SRDP"), with a copy to the OIG. Further, the repayment requirement within thirty days of identification of the Overpayment shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

References:

- 42 U.S.C. § 1320a-7b(b), 42 CFR § 1001.952
- 42 U.S.C. § 1320a-7a(a)(7)
- 42 U.S.C. § 1395nn; 42 CFR § 411.350 et seq.

ATTACHMENT

The Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving anything of value as an inducement or reward to refer items or services for which payment is available under the federal or state healthcare programs, such as Medicare and Medicaid. Violations of the Anti-Kickback Statute are classified as felonies and are punishable by fines of up to \$25,000 and up to 5 years in prison. Violations of the Anti-Kickback Statute may also cause participants to be excluded from participating in federal health care programs or from working for entities that participate in federal healthcare programs.

The Department of Health and Human Services Office of Inspector General (“OIG”) is the federal governmental agency responsible for interpreting and enforcing the Anti-Kickback Statute. The OIG has issued regulations that contain “safe harbor” provisions describing various payment and business practices that the OIG has deemed acceptable. Unless all elements of a safe harbor are met, these practices might otherwise be viewed to implicate, and potentially violate, the Anti-Kickback Statute. Compliance with a safe harbor is not mandatory; rather, arrangements that could violate the Anti-Kickback Statute which do not fit into a safe harbor are evaluated by the OIG on a case-by-case basis.

Guidance Related to the Anti-Kickback Statute

To assist health care providers in complying with the Anti-Kickback Statute, the OIG has, and continues from time to time, to publish guidance.

1. **Advisory Opinions.** The OIG issues advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the federal and state healthcare programs, including (a) what constitutes prohibited remuneration under the Anti-Kickback Statute and (b) whether an arrangement or proposed arrangement falls within a safe harbor. Advisory opinions provide guidance, but they only apply to the parties requesting them. However, they offer meaningful advice on the application of the Anti-Kickback Statute. Additional information about the OIG’s advisory opinion process and a link to all published advisory opinions is located at <http://oig.hhs.gov/fraud/advisoryopinions.asp>.
2. **Other Guidance.** The OIG periodically develops and issues guidance, including Special Advisory Bulletins, Fraud Alerts, and other industry guidance to alert and inform the health care industry about potential problems or areas of special interest. The OIG posts its guidance to its website at <http://oig.hhs.gov/fraud/fraudalerts.asp>.

The Limitation on Certain Physician Referrals (The Stark Law)

The Stark Law 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. It 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. Notably, DHS includes all inpatient and outpatient hospital services. Sanctions for violating the Stark Law include disallowing all Medicare payments for any DHS provided pursuant to a referral from the physician and possible penalties of up to \$15,000 per DHS item or service plus three times the amount claimed for payment from Medicare; circumvention schemes can result in a penalty of up to \$100,000 and exclusion from participation in federal health care programs.

The Centers for Medicare and Medicaid Services (“CMS”), the federal agency responsible for interpreting and enforcing the Stark Law, has issued regulations that contain exceptions for relationships with physicians that will be deemed not to violate the statute. Unlike the Anti-Kickback Statute, a physician’s financial relationship with the entity providing DHS must fit within an exception to the Stark Law and meet all of the criteria of the exception. If it does not, the entity may not bill for any DHS provided pursuant to a referral from the physician.

Guidance Related to the Stark Law

CMS issues advisory opinions to outside parties regarding whether a physician’s referrals relating to certain DHS are prohibited under the Medicare program. While the advisory opinions are only binding on the person or entity who requested the opinion, the advisory opinions offer meaningful advice on the application of the Stark Law. Additional information about CMS’s advisory opinion process, a link to CMS’s published advisory opinions, and other Stark Law guidance is located at <http://www.cms.gov/PhysicianSelfReferral>.