

POLICY TITLE: AGREEMENTS WITH PHYSICIANS AND OTHER
POTENTIAL REFERRAL SOURCES: GENERAL POLICY

ORIGINATED BY: COMPLIANCE OFFICER

APPROVED BY: COMPLIANCE COMMITTEE

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

Key Points

- This Policy applies to The Christ Hospital and to all of its wholly-owned subsidiaries (collectively, "TCH").
- This Policy provides a general statement of policy and guiding principles for Focus Arrangements, as defined below, to ensure that all such Focus Arrangements comply with the Anti-Kickback Statute and Stark Law, and to establish a process for approval of Focus Arrangements.

Definitions

Covered Persons includes:

1. Owners, officers, directors, and employees;
2. Contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of TCH *excluding* vendors whose sole connection with TCH is selling or otherwise providing medical supplies or equipment to TCH and who do not bill the Federal health care programs for such medical supplies or equipment; and
3. Physicians and other non-physician practitioners who are members of TCH's active medical staff.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individual shall become a Covered Person at the point when they work more than 160 hours during the calendar year.

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.

Division means the TCH Division of Compliance & Organizational Ethics.

Fair Market Value means the value in arm's-length transactions, consistent with the general market value. 'General market value' means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referral.

Physician Development Committee means the Physician Development Committee of the TCH Board of Directors.

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.

Ineligible Person shall include an individual or entity who:

1. Is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or
2. Has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

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:

1. A physician;
2. A physician's Immediate Family Member;
3. Any entity that is controlled by a physician or a physician's Immediate Family Member; or
4. Any non-physician who may be capable of making referrals to TCH.

TCH Authorized Representative means the person with signature authority for a Focus Arrangement with a Referral Source as specified in any applicable TCH policy.

Policy

1. TCH will, from time to time, develop policies and procedures regarding various types of Focus Arrangements with Referral Sources. The provisions set forth in this Policy apply to all Focus Arrangements, including routine renewals and amendments; however, to the extent another TCH policy applies to the specific type of Focus Arrangement contemplated by the parties, the more specific policy shall also be followed as well.
2. In addition to complying with applicable policies and procedures established by the Division, each new Focus Arrangement, renewal or amendment of an existing Focus Arrangement with a Referral Source shall:
 - a. Be set forth in writing and signed by a TCH Authorized Representative and the other party(ies) to the Focus Arrangement;
 - b. Specify all of the items or services provided by either party to the other;
 - c. Specify the duration of the Focus Arrangement;
 - d. Specify the amount of remuneration (e.g., rent, purchase price, compensation, etc.) to be paid under the Focus Arrangement;
 - e. Include a requirement that each party to the Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required under the Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and TCH. Additionally, TCH shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures;

- f. Include a certification by the parties that they shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Focus Arrangement; and
 - g. Satisfy all other applicable legal requirements as determined by the Division and/or legal counsel.
3. Remuneration paid pursuant to any Focus Arrangement shall be consistent with the Fair Market Value of the items or services provided and shall be determined without regard to the volume or value of referrals or other business generated between the parties.
4. TCH shall contract only for services that are reasonable and necessary and serve a legitimate business purpose. TCH shall not contract for services that involve counseling or promotion of activities that violate Federal or state law.
5. Side agreements or arrangements (whether written or oral) not covered by the Focus Arrangement are prohibited, unless they are made as a formal amendment or additional agreement reviewed by legal counsel and signed by both parties.
6. All Focus Arrangements and any amendment or related agreement thereto shall be retained in TCH's master contract files.
7. All payments made pursuant to a Focus Arrangements must be consistent with the terms of the Focus Arrangement.
8. All remuneration to and from parties to a Focus Arrangement shall be tracked and completed time sheets shall be a prerequisite to receiving payment to ensure that the parties to a Focus Arrangement are performing the services required under the Focus Arrangement, as applicable.
9. TCH shall not enter into a Focus Arrangement with a Referral Source who is an Ineligible Person and will terminate any Focus Arrangement with a Referral Source who becomes an Ineligible Person.
10. Arrangements between TCH and a Referral Source that satisfy the following Stark Law exceptions shall not be considered a Focus Arrangement and are not subject to this Policy:
 - a. Ownership or investment interests - 42 C.F.R. § 411.356;
 - b. Remuneration unrelated to the provision of designated health services - 42 C.F.R. § 411.357(g);
 - c. Payments by a physician for items and services - 42 C.F.R. § 411.357(i);
 - d. Non-monetary compensation - 42 C.F.R. § 411.357(k);
 - e. Medical staff incidental benefits - 42 C.F.R. § 411.357(m);
 - f. Compliance training - 42 C.F.R. § 411.357(o);

- g. Referral services - 42 C.F.R. § 411.357(q);
- h. Professional courtesy - 42 C.F.R. § 411.357(s);
- i. Community-wide health information systems - 42 C.F.R. § 411.357(u); or
- j. Any exception to the Stark Law (42 U.S.C. § 1395nn) enacted after October 27, 2010 that does not require a written agreement.

Procedures

1. When a Focus Arrangement is contemplated, the TCH Authorized Representative, or his or her designee, shall complete and forward the relevant portions of the Contract Checklist Form attached hereto as Exhibit A to the Office of General Counsel and shall provide such information as is necessary for efficient and timely preparation of the Focus Arrangement.
2. General Counsel will review the proposed terms of the Focus Arrangement for compliance with all applicable legal requirements. If General Counsel determines that the proposed arrangement is a Focus Arrangement, General Counsel will forward the Contract Checklist Form to the Division. The Division will review for compliance and will then notify the TCH Authorized Representative of approval to proceed with drafting the Focus Arrangement or advise of deficiencies.
3. The TCH Authorized Representative, or his or her designee, shall not make a commitment (whether written or oral) to any Referral Source regarding the terms of a proposed Focus Arrangement until such terms have been reviewed and approved by the Division and legal counsel with expertise in the Anti-Kickback Statute and Stark Law.
4. If, at any time, it appears that there have been discussions or an agreement indicating intent to reward past or obtain future referrals by way of a Focus Arrangement, the Focus Arrangement will not be approved and shall not be implemented.
5. Prior to implementation, signing a Focus Arrangement on behalf of TCH or presenting the Focus Arrangement to the Referral Source for signature, the TCH Authorized Representative, or his or her designee, must obtain review and approval of the Focus Arrangement.
6. Utilizing the form attached hereto as Exhibit B, the TCH Authorized Representative, or his or her designee, must certify as to the following:
 - a. The items or services reflected in the written Focus Arrangement are reasonable and necessary and satisfy a legitimate business purpose;

- b. The remuneration to be paid under the Focus Arrangement is consistent with the Fair Market Value of the items or services to be provided and was determined without regard to the volume or value of referrals or other business generated between the parties;
 - c. The Referral Source is not an Ineligible Person; and
 - d. Other conditions determined by the Division and/or legal counsel to be necessary for the Focus Arrangement to satisfy applicable legal requirements, have been met.
7. The TCH Authorized Representative shall provide documentation of the Fair Market Value of remuneration to be paid under the proposed Focus Arrangement. Depending on the nature of the Focus Arrangement, such documentation may include a copy of independently published data (e.g., market or salary surveys), market comparables, a valuation opinion from a duly qualified independent third party or other objective and reliable sources of information approved by the Division. Subject to legal limitations, in determining the appropriate value to be paid from within the established range of industry benchmark data, the TCH Authorized Representative shall thoroughly analyze and consider all facts and circumstances of the proposed Focus Arrangement. For example, factors such as limited physician experience or space that is below standard condition for the market may result in remuneration at the low end of the established range. Focus Arrangements involving payment above the 75th percentile of applicable industry benchmark data (as determined by the Division in consultation with TCH Authorized Representative) must be supported by a valuation opinion from a duly qualified third party. Fair market value documentation shall be maintained in TCH's master contract files.
8. The Division will then notify the TCH Authorized Representative that the Focus Arrangement may proceed to legal counsel with expertise in the Anti-Kickback Statute and Stark Law for preparation and/or review, or will advise of any deficiencies.
9. After legal counsel has approved the proposed agreement, the TCH Authorized Representative, or his or her designee, will forward to the Division documentation that the Focus Arrangement has been reviewed by legal counsel.
10. Upon receipt of the signed certification, Fair Market Value documentation and legal review, the Focus Arrangement shall be approved by the Division, except for Focus Arrangements involving payment above the 75th percentile of applicable industry benchmark data (as determined by the Division in consultation with TCH Authorized Representative), which shall be submitted to the Physician Development Committee of the Board for review.

11. Upon approval, the parties may execute the Focus Arrangement.
12. The Division shall retain the TCH master contract files which shall include: (a) the original of the fully executed Focus Arrangement, (b) the completed Contract Checklist Form, (c) the completed Proposed Agreement Certification Form, (d) documentation of Fair Market Value, and (e) documentation of legal review.
13. Following execution of the Focus Arrangement, time sheets shall be submitted to the Division pursuant to the terms of the applicable Focus Arrangement. The Division shall review and approve the time sheets. Following approval of the time sheets, the Division shall authorize payment pursuant to the terms of the applicable Focus Arrangement.
14. Exceptions to this Policy shall be rare and permitted only upon approval of the Finance Committee of the TCH Board of Directors, based upon the particular facts and circumstances and pursuant to procedures adopted by the Finance Committee, in consultation with the Division and legal counsel.

EXHIBIT A

The Christ Hospital Contract Checklist Form																													
Contract Name:																													
Contract Originator/Sponsor:																													
Legal/Compliance																													
Vendor/Other Party:		Contract Type:																											
Job Title / Services Needed:																													
Effective Date:		Auto Renewal: ___Y ___N																											
Expiration Date:		Section:																											
Focus Arrangement (FA) ___Y ___N ___NA	Covered Person(s) - ___Y ___N (List covered person(s) to the right - If >2, please attach list)																												
Please describe Legitimate Business Purpose:																													
Is a Fair Market Value opinion required? ___Y ___N	If FMV is required, please describe method used below: (attach documentation)																												
HIPAA applicability:	Is a Business Affiliate Agreement (BAA) required?	___Y ___N ___NA																											
Financials																													
Compensation: - section # :	Total Amount:																												
Accounting/Financial Reporting: - section #	ARO applicability? ___Y ___N Long term unconditional commitment? ___Y ___N Market valuation? ___Y ___N Tax/Form 990/UBIT applicability? ___Y ___N Community Benefit reporting applicability? ___Y ___N Other accounting issues:																												
Other noteworthy sections?																													
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EXHIBIT B

Proposed Focus Arrangement Certification Form

Please complete this form prior to signing any Focus Arrangement with a physician or other referral source and forward to the Compliance Officer along with a copy of the Focus Arrangement and any attachments. A completed copy of this form should also be attached to any applicable contract execution form(s) as may be used in the process.

Date:
TCH Authorized Representative:
Physician or other referral source:
Type of arrangement:

I hereby certify that the following is true and correct to the best of my knowledge:

- a. The items or services reflected in the Focus Arrangement are reasonable and necessary and satisfy a legitimate business purpose;
- b. The remuneration to be paid under the Focus Arrangement is consistent with the Fair Market Value of the items or services to be provided and was determined without regard to the volume or value of referrals or other business generated between the parties;
- c. The Referral Source is not an Ineligible Person; and
- d. Other conditions determined by the Division of Compliance & Organizational Ethics and/or legal counsel to be necessary for the Focus Arrangement to satisfy applicable legal requirements, have been met.

TCH Authorized Representative Signature: _____

Date: _____

Reference

Policy: Agreements with Physicians and Other Referral Sources