POLICY TITLE:  COMPLIANCE REPORTS, CONSULTS, AND INVESTIGATIONS

APPROVED BY:  COMPLIANCE COMMITTEE

ORIGINATED BY:  COMPLIANCE OFFICER

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Key Points

- This Policy applies to The Christ Hospital and all of its wholly-owned subsidiaries (collectively, “TCH”).

- This Policy explains the confidential process for reporting potential violations of TCH’s Code of Conduct, TCH policies, laws and regulations relating to Federal health care programs, including, but not limited to, the Anti-Kickback Statute and the Stark Law, criminal, civil, or administrative laws, or 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. (“CIA”).

- This Policy explains the process for requesting a Compliance Consult.

- This Policy provides guidelines for conducting investigations in response to reports of potential violations of TCH’s Code of Conduct, TCH policies, laws and regulations relating to Federal health care programs, including, but not limited to, the Anti-Kickback Statute and the Stark Law, criminal, civil, or administrative laws, or the CIA and ensuring that all such reports are acted upon in a timely and thorough manner, including, where applicable, appropriate reporting of Reportable Events and refunding Overpayments in accordance with the requirements of the CIA.

Definitions

Compliance Consult means a request for information or advice regarding a particular compliance-related matter.

Compliance Hotline means a service provided by an off-site, third-party vendor that allows for anonymous reporting of potential compliance issues (1-800-398-1496).

Compliance Report means a report of an actual or potential violation of TCH’s Code of Conduct, TCH policies, laws and regulations relating to Federal health care programs, including, but not limited to, the Anti-Kickback Statute and the Stark Law, criminal, civil, or administrative laws, or the CIA.
Covered Persons includes:

A. Owners, officers, directors, and employees;

B. 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

C. 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.

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

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

A. A substantial Overpayment (as defined by all applicable TCH Patient Financial Services Department policies);

B. 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;

C. The employment of or contracting with a Covered Person who is an Ineligible Person; or

D. The filing of a bankruptcy petition by TCH.

Policy

A. Compliance Consults

1. Purpose. All TCH Covered Persons may request information or advice regarding compliance-related matters directly from the Division of Compliance & Organizational Ethics (“Division”). Compliance Consults are especially advisable prior to implementing new polices or revising existing policies that may have compliance implications.
2. **Request Methods.** Requests for Compliance Consults may be communicated to the Division by whatever means are most convenient, whether verbally or in writing.

3. **Information Collected.** When requesting a Compliance Consult, the following minimum information should be provided:
   
   a. The name, title, and department of the requestor;
   
   b. The date of the request, if not readily ascertainable;
   
   c. The general subject matter of the request;
   
   d. An explanation of the nature of the request including all pertinent facts; and,
   
   e. An evaluation of the urgency of the request.

   The Division may request additional information during the initial intake or anytime during the review process.

4. **Response.** Upon receiving a request for a Compliance Consult, the Division will acknowledge receipt of the request, and, depending on the complexity of the matter, will attempt to provide an answer in a timely manner.

B. Compliance Reports

1. **Duty to Report.** TCH Covered Persons have a duty to make Compliance Reports on a prompt basis to ensure the timely identification and resolution of all potential or suspected wrongdoing involving TCH. Corrective action may be taken against any Covered Person who fail to make a Compliance Report as required by this Policy. Patients, community members, and others are also encouraged to make Compliance Reports.

2. **Open Door Policy.** TCH will maintain an “open-door policy” at all levels of management to encourage Compliance Reports directly through the chain of command or to the Division in accordance with this Policy.

3. **Priority.** Activities surrounding the investigation and resolution of Compliance Reports shall be prioritized based on the nature of the report.

4. **Anonymity.** Compliance Reports may be submitted anonymously to the Compliance Hotline via a toll-free telephone number, fax, mail, or electronically.
5. **Confidentiality.** All information related to Compliance Reports and follow-up investigations, including the reporter’s name (if known), will be kept confidential to the extent allowed by law.

6. **No Retaliation.** TCH prohibits any adverse action against a person for making a Compliance Report in good faith. TCH management must ensure that Covered Persons are allowed to report problems and concerns without fear of retaliation.

7. **False Reports.** Corrective action may be taken against Covered Persons who knowingly make false Compliance Reports.

8. **Making Compliance Reports.** Compliance Reports may be made directly to TCH management, including the Division, or to the Compliance Hotline as follows:

   a. **To TCH Management:** TCH encourages Covered Persons to make Compliance Reports through their chain of command or, depending on the circumstances, to the Division. Members of management who receive such Compliance Reports should gather the facts and details and should contact the Division if they believe that there is a possible violation of TCH’s Code of Conduct, TCH policies, laws and regulations relating to Federal health care programs, including, but not limited to, the Anti-Kickback Statute and the Stark Law, criminal, civil, or administrative laws, or the CIA.

   b. **To the Compliance Hotline:** Anyone, including patients and community members, may make a Compliance Report via any of the Compliance Hotline mechanisms.

      i. The Compliance Hotline is available at all times. The toll-free telephone hotline will be answered by a trained person who will collect information from the caller.

      ii. Reports to the Compliance Hotline may be made without leaving a name. Phone numbers are not tracked. In some cases, it may be difficult to follow-up without the name of the caller. In these instances, callers will be asked if their names may be disclosed. If callers do not disclose their names, the difficulties in investigating the Compliance Report will be explained. The wishes of the caller, however, will be respected.

      iii. The Compliance Officer, or his/her designee, will promptly investigate any report or evidence of adverse action taken against an individual for making a Compliance Report. TCH will take
9. **Intake Process of Direct Reports.** The Division will document all incoming Compliance Reports. At a minimum, the following information will be collected:

   a. Date and time of the Compliance Report;
   
   b. Name of TCH entity, department, or business unit involved;
   
   c. Nature of the complaint or violation reported and facts and details; and
   
   d. Name and telephone number of the person making the report (unless the person does not provide a name).

The Division will ensure that all Compliance Reports are addressed in an appropriate and timely manner. A representative of the Division may contact individuals who do not wish to remain anonymous for follow-up information or to communicate the outcome of the issue raised or the results of any review, as appropriate. In some cases, certain details of the outcome of an investigation may need to be withheld in order to protect the privacy of others or to maintain a legal privilege.

10. **Compliance Hotline Intake.** The service that staffs the Compliance Hotline (1-800-398-1496) will document all Compliance Reports made to it. Callers making an anonymous Compliance Report will be assigned a confidential report number. The service that staffs the Compliance Hotline will promptly forward the information collected from all Compliance Reports to the Division. Callers not leaving a name can call back to the Compliance Hotline using their confidential report number to receive follow-up or to request the outcome of the issue raised or the results of any review. The Division will ensure any required follow-up is provided to the Compliance Hotline in a timely manner. In some cases, certain details of the outcome of an investigation may need to be withheld in order to protect the privacy of others or to maintain a legal privilege.

11. **Investigation & Reviews.** Compliance investigations will be handled in a timely and thorough manner and in accordance with this Policy. They will be conducted in a manner that endeavors to protect the confidentiality or anonymity of the individuals who make the Compliance Reports, if requested. However, such confidentiality or anonymity cannot be guaranteed. Investigations shall be conducted by persons with appropriate knowledge and expertise concerning the subject matter of the Compliance Report. TCH legal privileges (e.g., attorney-client, peer review or Quality privileges) will be maintained during reviews of matters involving possible criminal liability, substantial civil liability, or that involve patient quality of care. Appropriate remedial action, when indicated, is an integral component of the review process. The Division will collect and document information sufficient to support an investigation. If there is insufficient
information warranting an investigation, the facts supporting that decision shall be documented. If there are sufficient facts warranting an investigation, it will be completed in a timely fashion. If a Compliance Report does not involve a potential violation of TCH’s Code of Conduct, TCH policies, laws and regulations relating to Federal health care programs, including, but not limited to, the Anti-Kickback Statute and the Stark Law, criminal, civil, or administrative laws, or the CIA, the Division will refer the matter to the appropriate department for follow-up. No case file will be created.

12. **Special Investigations.** Investigations resulting from Compliance Reports that pertain to certain departments or subject matter will be conducted according to the following guidelines:

   a. **Criminal or Civil Liability.** Investigations that may involve criminal or substantial civil liability shall be conducted under the direction of legal counsel.

   b. **Patient Care.** Investigations involving patient care issues shall include a representative from a peer review or Quality committee. The investigation may be completely delegated to this representative in order to maintain any relevant privileges.

   c. **Hospital Claims/Billing.** Investigations pertaining to claims submission or billing shall include the Director of Patient Financial Services.

   d. **Cost Reports.** Investigations pertaining to Cost Reports shall include the Director of Reimbursement.

   e. **Employment or Personnel.** Investigations involving employment or personnel issues shall include a representative from Human Resources.

   f. **Financial Matters.** Investigations involving financial matters (e.g., theft, embezzlement, misappropriation of funds) shall include a representative from the Comptroller’s Office.

13. **Reports Database.** All Compliance Reports shall be entered into the Compliance Reports Database. A summary of the outcome of investigations and any corrective measures taken shall be recorded in the Compliance Reports Database except for any information that may be otherwise legally privileged.

14. **Overpayments.** 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.

15. **Reporting of Reportable Events Under the CIA.** If after a reasonable opportunity to conduct an appropriate review or investigation of the Compliance Report 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.

16. **Reportable Events Involving the Stark Law.** 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.