

Title: Reporting of Potential Compliance Issues (COMP - 2)

Scope: Network

Manual: Network Compliance Department

Origination Date: 09/05/2014

Revision Date: 07/20/2016, 09/29/2017, 10/6/2017

Review Dates:

I. Purpose:

The purpose of this policy is to establish a process to report Potential Compliance Issues associated with St. Luke's Code of Conduct as well as its policies and procedures, laws and regulations related to Federal health care programs, including but not limited to Stark Law, Anti-kickback Statute, and state laws where applicable. Also, this policy provides guidance on the expectation that issues will be promptly and thoroughly investigated and appropriate corrective actions may be implemented if there is a potential violation of criminal, civil or administrative law.

All employees, physicians and members of Boards of Trustees of St. Luke's University Health Network ("St. Luke's"), and all individuals and entities that do business with St. Luke's (collectively referred to as "Individuals"), are covered by this policy.

II. DEFINITIONS:

A. **"CMS"** means the Centers for Medicare & Medicaid Services

B. **"Compliance Hotline"** or **"Hotline"** is operated by a third party company which is in the business of providing toll-free telephonic answering, reporting and tracking of telephone calls of compliance concerns. This Hotline is an integral component of the St. Luke's Corporate Compliance Program ("Compliance Program") and is designed to assist in the identification of possible unethical, illegal or questionable behavior by employees, Board Members, physicians, individuals or organizations with which St. Luke's does business.

- C. **"Federally funded health care programs"** means Medicare, Medicaid, managed Medicare, managed Medicaid, managed Medicaid, TriCare, VA, CHAMPUS, SCHIP, Federal Employees Health Benefit Plan, Indian Health Services, Health Services for Peace Corp Volunteers, Railroad Retirement Benefits, Black Lung Program, and Services Provided to Federal Prisoners.
- D. **"OIG"** means the Department of Health & Human Services Office of Inspector General.
- E. **"Overpayment"** means the amount of money St. Luke's has received in excess of the amount due and payable under any Federally funded health care program Federal health care program requirements, including applicable Federal statutes, regulations, Medicare or other Federal health care program payment manuals, and Medicare fiscal intermediary or carrier Local Coverage Decisions. An Overpayment may be the result of not following Federally funded health care programs, Federal health care program requirements, errors by St. Luke's personnel, payment processing errors by the payer, or erroneous or incomplete information provided to St. Luke's by the patient or responsible party.
- F. **"Potential Compliance Issue"** means a potential Reportable Event or other suspected violation of St. Luke's Standards of Conduct, St. Luke's policies and procedures, or laws and regulations relating to Federally funded health care programs, including but not limited to the Anti-kickback statute and Stark law. For purposes of this policy, Potential Compliance Issues shall include but are not limited to the issues listed on the "Examples of Reportable Potential Compliance Issues" (Exhibit A).
- G. **"Reportable Event"** means anything that involves: a matter that a reasonable person would consider a probable violation of the criminal, civil, or administrative laws applicable to any Federally funded health care program, or a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care, and or the a violation may that may present an imminent danger to the health, safety, or well-being of a patient or place a patient in an unnecessarily high-risk situations. A Reportable Event may be the result of an isolated event or a series of occurrences.

III. PROCEDURE

1. Responsibility for Reporting Issues

All Individuals are expected to report Potential Compliance Issues or Reportable Events immediately upon discovery or notification of the same. Reporting can be done by following the Chain of Command, as follows:

1. Supervisor or department director or designee,
2. Human Resources,
3. Legal Services Department, Senior Management, and/or Chief Compliance & Privacy Officer ("CCPO") or
4. Hotline (1-855-9 ETHICS or 1-855-938-4427).

Any individual who receives a compliance report is expected to notify the CCPO or ensure that the CCPO is notified.

IV. Hotline Process

- A. All Hotline calls are received by a third party vendor through a dedicated number 1-855-9 ETHICS or (1-855-938-4427) or website (<https://mysaintlukes.alertline.com>) which is well publicized. To the extent possible and allowed by law, the anonymity of the caller will be protected.
- B. The Hotline Company categorizes the issues as they are received and reports all calls to the CCPO within 24 hours.
- C. The Hotline Company provides all callers with a date that they can call back to obtain information or resolution status regarding the reported issue(s).
- D. The CCPO will be designated as the primary contact with the Hotline Company. Upon receipt of the documentation from the Hotline Company, the CCPO will determine the issues involved and request assistance from personnel with the required knowledge and expertise to perform an effective investigation.

V. Identification of Potential Compliance Issues

- A. Exhibit A is a list of examples of Potential Compliance Issues or Reportable Events. This list is illustrative and not exhaustive. Any question regarding the identification of a Potential Compliance Issue should be directed to an employee's immediate supervisor, CCPO or the Hotline, as appropriate.
- B. St. Luke's also conducts compliance-related audits on a special and routine basis, and an individual may report Potential Compliance

Issues to these auditors (i.e. Internal Audit, Risk Management, Revenue Integrity reviews, Utilization/Case Management, etc.). Any departments that receive reports of Potential Compliance Issues are expected to forward these reports to the CCPO for further investigation and disclosure, if applicable.

VI. Action on Compliance Issues

- A. Upon receipt of a report of a Potential Compliance Issue or Reportable Event, the CCPO will make a preliminary, good faith inquiry into the allegations to ensure that all of the information necessary to determine whether a further review should be conducted has been obtained. Appropriate departments will be involved in investigation and resolution of reported matters.
- B. Such investigation may involve the use of outside auditors, consultants or other appropriate third parties as determined by the St. Luke's Legal Services Department, the CCPO and/or other management leaders.
- C. The CCPO or designee will complete investigations in a timely manner. The average investigation turnaround time is between thirty (30) and sixty (60) days, but complicated investigations and investigations requiring the assistance of other departments may require additional time. The CCPO or designee will notify the complainant for any investigation that exceeds sixty (60) days.
- D. Based on the results of the investigation, St. Luke's Legal Services Department and/or CCPO will determine whether a violation occurred. If the Legal Services Department and/or CCPO determine that a violation has, in fact, occurred, the Network will report to the appropriate governmental agencies and determine whether any refunds of the improper payment or any other repayments are owed.
- E. **Overpayments** - If an overpayment is identified, it must be reported and the overpayment must be returned to the payor within 60 days after the date on which the overpayment was identified, or the date any corresponding cost report was due.
 - a. An overpayment is identified by a person when they have, or should have through the exercise of reasonable diligence: (1) determined that the person has received an overpayment and (2) quantified the amount of the overpayment.
- F. Before a Compliance Issue or Reportable Event may be considered resolved, the CCPO must document the investigation and

resolution of the issue. Documentation must include evidence of refunds, corrective action plans or other evidence that the issue has been fully resolved.

- G. A summary of the Compliance Issues or Reportable Event will be presented to the Network Compliance Committee when applicable. A summary of Hotline data and all investigations will be presented to the St. Luke's Audit and Compliance Committee no less than annually, with periodic reports to the St. Luke's Board of Trustees from the Audit and Compliance Committee.

VII. Retention of Compliance Report

Hotline reports will be maintained by the CCPO for a period of ten (10) years after the date of the report.

VIII. Compliance

Compliance is everyone's responsibility. Failure to promptly report a Potential Compliance Issue will be subject to appropriate disciplinary action pursuant to all applicable St. Luke's policies and procedures, up to and including termination of employment. Such disciplinary action may also include modification of compensation, including loss of any merit or discretionary compensation awards.

IX. Attachments:

N/A

X. References

XI. Policy Responsibility

SLA-SLB-SLQ-SLM-SLMC-SLRA-SLW-SLWEEC-SLAASC-Homestar-SLPG/SLWPG-VNA	Chief Compliance and Privacy Officer	Preparer
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XII. Disclaimer Statement

This policy and procedure is intended to provide a description of a course of action to comply with legal requirements and/or operational standards. There may be specific circumstances not contemplated by this policy and procedure that may make compliance either unclear or inappropriate. For advice in these circumstances, consult with your Chain of Command, the Administrator on Call, Clinical Risk Management, Legal Services, Accreditation and Standards, or Chief Compliance & Privacy Officer, as appropriate.

XI. Approval

Network Compliance Committee every two years.

Professional billing issues	Concern that St. Luke's employee or physician (or their relative) influenced an St. Luke's decision resulting in personal gain	Privacy violation complaint from patient or family	Lack of documentation that OIG sanctions check performed	Receipt of federal, state or other agency subpoena	Statement of deficiencies related to credentialing and privileging	Allegations of abuse by staff	ADA compliance issues	Allegation that advertising or other promotional material appear as a kickback and material has not obtained appropriate review and approval
Concerns about coding of transfer or discharge status	Employee (or relative) personal financial interest in St. Luke's supplier or contractor that does business with St. Luke's	Allegation PHI improperly used for marketing	Absence of background screening in personnel file	Receipt of notice of investigation from a federal, state or other agency of authority	Expired licenses for staff, physicians, hospital, equipment	Concerns about practitioner practices derived from: Risk Management usual occurrence system, staff complaints, patient sentinel events, help line calls	Environment-related compliance issues	a kickback and material has not obtained appropriate review and approval
Inpatient stays and same day discharge concerns	Concern that employee received (gave) personal benefit valued in excess of \$100.00 per year to a person doing business with St. Luke's	Receipt of damaged or opened package containing PHI	Denial of federal program reimbursement due to services provided by an excluded individual	Arrival at any St. Luke's location of federal, state or other regulatory agency (such as OIG, FBI, DOJ, PA DFW, etc.)	Receipt of statement of deficiencies (with conditional level deficiencies or immediate jeopardy)	Failure to meet national standards on reportable outcomes	Allegations of failure to follow-up on hazardous workplace issues	Physician engaged in advertising without a joint marketing or relocation agreement
Lab billing errors	Concern that contractor that does business with St. Luke's	Inappropriate sharing of PHI with vendor	Allegations of improper practices:	Failure to obtain informed consent for medical care or procedure	Joint Commission surveys, correspondence	Concerns about impairment of a physician	Failure to file incident as required by OSHA	Physician engaged in advertising without a joint marketing or relocation agreement
Medical record documentation issues resulting in:	Any actual or potential conflict of interest situation or allegation where an individual's interests are put ahead of St. Luke's	Media filming conducted without appropriate authorization	1) Employee bypassed for promotion due to gender, age, race, etc.	Failure to follow contractual obligations	State surveys (annual/for cause with conditional level deficiencies or immediate jeopardy)	Concerns pertaining to medical necessity issues, medical appropriateness, etc.	Thefts involving PHI	Direct mailing campaign involves use of PHI without patient consent
1) Bill hold resulting in large volume of uncoded OP diagnostic service due to incomplete documentation		Missing medical records	2) Applicant not hired due to pregnancy	Concerns about physician and referral source arrangements		Significant quality of care issues		
2) Inability to provide documentation to payers to support billed services		PHI discovered in landfill or waste disposal site	3) Employee not hired or fired due to age	All EMTALA concerns		Scope of practice issues for physicians, allied health personnel		
3) Concerns about billing without adequate documentation (i.e. physician order, progress note, etc.)		HIPAA complaint received by the Office of Civil Rights	4) Delays in processing status changes leading to over/under payment	Any occurrence which may require reporting under local, state or federal law		UR concerns: high rate of use, high rate of avoidable days, etc.		
Medicare outpatient observation charges		E-mail containing PHI sent outside protected health network	5) Complaints of impaired employee			Denials or letters from payers indicating UR problems		
Medicare Secondary Payor issues		Audits revealing inappropriate access to PHI via IS system	6) Illegal questions asked during interviews			Patient death in restraints		
Pharmacy billing errors		Any inappropriate release of PHI	7) Failure to provide appropriate accommodations under ADA					
Receipt of Probe Letters from Medicare or inquiries from Quality Improvement Organizations (billing related)		Areas that should be locked are left unsecured	8) Suspected abuse by employee against patient or co-worker					
		Electrical panels or mechanical rooms are not locked	9) Suspected criminal activity by employee					
		All other Privacy/Security violations	10) Inappropriate destruction of employee files					
			11) Missing employee files required by accrediting agencies					

St. Luke's has identified all of the above issues as potential compliance concerns. If any of these occur, you should follow your normal operating procedures. For example, notify your supervisor or the appropriate St. Luke's department. You may also contact the Chief Compliance & Privacy Officer, Nicole Huff at (484) 526-3288.