

Title: Compliance with Law (COMP – 4)
Scope: Network
Manual: COMPLIANCE POLICIES AND PROCEDURES MANUAL
Origination Date: 10/01/2014
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Review Dates:

I. Purpose

St. Luke’s University Health Network and its subsidiaries and affiliates (SLUHN) is committed to providing the highest quality of care to our patients and conducting our business with integrity and in compliance with federal and state laws and regulations. Vendors are required to comply with SLUHN policies and procedures, as well as applicable federal, state and local laws, regulations, guidelines, orders, and accreditation standards.

II. The Deficit Reduction Act of 2005 (DRA)

Requires all Medicaid recipient entities to develop and distribute policies, such as this one, outlining federal and state false claims acts, as well as information regarding whistleblower protection and the entities’ policies to reduce fraud and abuse. In accordance with the DRA, below are summaries of major federal and state laws outlining potential liability for presenting false claims and making false statements in order to obtain payments from federal and state health care programs. These summaries are intended to be instructive only; they are not intended to identify all potentially applicable laws, alter any legal definitions or provisions therein, or imply that any summarized law applies to a particular set of circumstances. Rather, potential issues that arise must be investigated and properly resolved under applicable law based on individual circumstances.

III. Major Federal Laws

A. Federal False Claims Act (FCA) – The FCA prohibits, among other things, knowingly presenting or causing to be presented to the Federal government a false or fraudulent claim for payment. Knowingly means that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate

ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required. Violations may result in civil, criminal and administrative actions punishable by substantial monetary penalties, fines, imprisonment and exclusion from federal and state health care programs.

1. **Overpayments** - If an overpayment is identified, it must reported and the overpayment must be returned 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.

B. Qui Tam Actions – In addition to its substantive provisions, the FCA provides that private parties may bring an action on behalf of the United States. These private parties, known as “qui tam relators,” may share in a percentage of the proceeds from an FCA action or settlement. The FCA provides protection to qui tam relators who are discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of their employment as a result of their furtherance of an action under the FCA. Remedies include reinstatement with comparable seniority as the qui tam relator would have had but for the discrimination, two times the amount of any back pay, interest on any back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys’ fees.

C. Federal Program Fraud Civil Remedies Act (PFCRA) – This federal law makes it illegal for a person or entity to make, present or submit (or cause to be made, presented or submitted) a “claim” (i.e., a request, demand or submission) for property, services, or money to an “authority” (i.e., an executive department of the federal government, e.g., the U.S. Department of Health and Human Services which oversees Medicare and Medicaid programs) when the person or entity “knows or has reason to know” that the claim: (i) is false, fictitious or fraudulent; or (ii) includes or is supported by any written statement which asserts a material fact which is false, fictitious or fraudulent; or (iii) includes or is supported by any written statement which omits a material fact, is false, fictitious or fraudulent because of the omission and is a

statement in which the person or entity has a duty to include such material fact; or (iv) is for the provision of items or services which the person or entity has not provided as claimed. In addition, it is illegal to make, present or submit (or cause to be made, presented, or submitted) a written "statement" (i.e., a representation, certification, affirmation, document, record, or accounting or bookkeeping entry made with respect to a claim or to obtain the approval or payment of a claim) if the person or entity "knows or has reason to know" such statement: (i) asserts a material fact which is false or (ii) omits a material fact making the statement false, fictitious or fraudulent because of the omission.

1. Similar to the Federal False Claims Act, the PFCRA broadly defines the terms "knows or has reason to know" as (1) having actual knowledge that the claim or statement is false, fictitious, or fraudulent; (2) acting in deliberate ignorance of the truth or falsity of the claim or statement; or (3) acting in reckless disregard of the truth or falsity of the claim or statement. The law specifically provides that a specific intent to defraud is not required in order to prove that the law has been violated. The PFCRA provides for civil penalties of up to \$5,000 for each false claim paid by the government, and in certain circumstances, an assessment of twice the amount of each claim. In addition, if a written statement omits a material fact and is false, fictitious or fraudulent because of the omission and is a statement in which the person or entity has a duty to include such material fact and the statement contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, the law provides for a penalty of up to \$5,000 to be imposed for each such statement.

D. Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) – The HIPAA Privacy and Security Rules provide, among other things, privacy and security standards protecting the confidentiality and integrity of "individually identifiable health information." HIPAA calls for severe civil and criminal penalties for noncompliance. The imposition of the penalties is tiered and ranges from \$100 to \$1.5 million depending on the severity of the violation.

E. Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, is to promote the adoption and meaningful use of health information technology. The HITECH Act addresses the privacy and security concerns associated with the

electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA rules.

F. **Anti-Kickback Statute** – Section 1128(b) of the Social Security Act, commonly referred to as the “Anti-Kickback Statute,” provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce referrals of items or services covered, in whole or in part, by Medicare, Medicaid, or any other federally funded health care program. An offense is classified as a felony, with each violation punishable by a fine of up to \$25,000 and/or imprisonment for up to five (5) years. Violation of the Anti-Kickback Statute could also result in exclusion from government health care programs. The types of conduct and remuneration covered by the Anti-Kickback Statute include kickbacks, bribes, and rebates from providers to others in exchange for patient referrals. The Anti-Kickback Statute proscribes any such remuneration whether made directly or indirectly, overtly or covertly, or in cash or in kind. Moreover, prohibited conduct includes not only remuneration intended to induce referrals, but remuneration intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service, or item paid for by the Medicare and Medicaid programs.

1. 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.

G. **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.

- H. **Physician Payment Sunshine Act (PPSA)** – The PPSA requires pharmaceutical, medical device, biological, and medical supply manufacturers to report to Health and Human Services (HHS) any “payment or other transfer of value” to physicians and teaching hospitals. The report must include information about the amount of the payment, the date on which the payment was made, the form of payment, and the nature of the payment (e.g., gift, consulting, speaking, entertainment, research, or travel). The PPSA specifically excludes certain transfers of value from this disclosure requirement.

IV. **Major Pennsylvania Laws**

- A. **Fraud and Abuse Control under the Public Welfare Code** – This law contains provisions relating to acts prohibited by providers and other acts relating to applications for medical assistance or the receipt of benefits under the program. Several provisions of Pennsylvania statutes track the requirements under federal laws. Under Pennsylvania law, it is unlawful for providers to: knowingly or intentionally submit false information, or false claims or costs reports for furnishing services or merchandise under the medical assistance program, or claims or cost reports for medically unnecessary services or merchandise; solicit, receive or offer to pay remuneration, including kickbacks, bribes or rebates in connection with furnishing services or merchandise under the medical assistance program; submit duplicate claims for which the provider has already received or claimed reimbursement; submit a claims for services, supplies or equipment not rendered to a recipient; submit claims which include costs or charges not related to the services,

supplies or equipment rendered to the recipient; submit claims for or refer recipients to another provider for unnecessary services, supplies or equipment; submit claims which misrepresent information about such things as the services provided, the recipient, date of service, or identify of the practitioner or provider; submit claims for reimbursement higher than the provider's usual and customary charge for the service or item; submit claims for a service or item not rendered; provide a service or item without a practitioner's written order and consent of the recipient (except in emergencies); or render a service or item without making a reasonable effort to verify through a current medical assistance card that the patient is in fact currently eligible (except in emergencies). Violations can result in criminal and civil penalties, including monetary penalties and termination of participation as a provider in the medical assistance program.

1. Under Pennsylvania law, it is also unlawful for other persons to: knowingly or intentionally make false statements or fail to disclose material facts regarding eligibility for themselves or another for medical assistance benefits; fraudulently conceal knowledge of events affecting the person's initial or continued right to receive such benefits; convert benefits to a use other than for himself or the person for whom the benefits were intended; visit multiple providers for the purpose of obtaining excessive services or benefits beyond what is reasonably needed; or borrow or use a medical assistance card without entitlement to do so. Violations can result in criminal and civil penalties, including monetary penalties and restrictions on continued eligibility for medical assistance benefits.

B. **Whistleblower Law** – Pennsylvania law protects the rights of employees of public bodies, such as state or local governments, who make good faith reports about wrongdoing or waste, or who participate in an investigation, hearing or inquiry.

V. **Major New Jersey Laws**

A. **New Jersey False Claims Act (New Jersey FCA)** – The New Jersey FCA is comparable to the federal False Claims Act, making it unlawful for a person to knowingly make false or fraudulent claims, including to: present or cause to be presented to an employee, officer or agent of the State of New Jersey, or any contractor, grantee or other recipient of State funds, a false or fraudulent claim for payment or approval; make, use or cause to be made or used a false record or statement to get a false or fraudulent claim paid or

approved by the State; conspire to defraud the State by getting a false or fraudulent claim allowed or paid; or knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, increase or decrease an obligation to pay or transmit money or property to the State. Liability under the New Jersey FCA results in a civil penalty equal to the civil penalty under the Federal FCA (currently between \$5,500 and \$11,000) for each act constituting a violation, plus 3 times the amount of the damages sustained by the State (or 2 times the amount of damages if the person committing the violations provides full information and cooperation to the government officials investigation the false claims violations). In addition to its substantive provisions, the New Jersey FCA provides that private parties may bring an action in the name of the State for a violation of the FCA. These private parties may share in a percentage of the proceeds from an action or settlement. The New Jersey FCA provides protection to private parties who are discharged, demoted, suspended, threatened, harassed, denied promotion or in any other manner discriminated against in the terms and conditions of their employment as a result of their disclosure of information to the State or furtherance of an action under the New Jersey FCA. Remedies include reinstatement with comparable seniority as the party would have had but for the discrimination, two times the amount of any back pay, interest on any back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

- B. New Jersey Medical Assistance and Health Services Act** – The New Jersey Medical Assistance and Health Services Act contains provisions relating to acts prohibited by persons receiving medical assistance benefits and providers receiving medical assistance payments. The law makes it a crime for a provider to knowingly receive medical assistance payments to which he is not entitled or in a greater amount than entitled. It is also a crime for a provider or other person or entity to knowingly and willfully make materially false statements in applying for payments under the medical assistance program or for use in determining rights to such payment, to conceal or fail to disclose the occurrence of an event affecting the initial or continued right to a payment with the fraudulent intent to secure payments not authorized or in a greater amount than authorized under the law, or to knowingly and willfully convert payments to a use other than the use and benefit of the provider or other person. It is also a crime for a provider or other person to solicit, offer or receive a kickback, rebate or bribe in

connection with the receipt of a payment under the Act or the furnishing of items or services for which payment is or may be made or whose cost is or may be reported in order to obtain such payments (except for lawful discounts or price reductions and payments to an employee under a bona fide employment relationship). Finally, it is a crime to knowingly and willingly make or induce, or seek to do so, the making of false statements or representations of material facts with respect to the conditions or operations of an institution or facility in order for it to qualify for certification or recertification of a hospital and thereby entitled to receive medical assistance payments. Violations can result in criminal penalties including fines and imprisonment. In addition, various civil remedies are available to the government under the Medical Assistance and Health Services Act. Persons or entities committing the crimes described in the previous paragraph are liable for civil penalties (recoverable in an administrative proceeding) including all of the following: interest on the excess payments, three times the amount of the payments unlawfully obtained, and \$2,000 per excessive claim for payments. Persons or entities who obtain medical assistance payments in amounts in excess of that to which they are entitled, but without intent to violate the Act, may be subject to a civil penalty in the amount of interest on the excess payments. Finally, the director of the Medical Assistance Program has the authority to suspend, debar or disqualify for good cause any provider (or an agent, employee or contractor of one) or other person or entity participating in the Medicaid program.

- C. **Health Care Claims Fraud Act** – This law makes it a crime for licensed health care practitioners and persons who are not practitioners to knowingly or recklessly commit health care claims fraud in the course of providing professional services. Conviction under the Health Care Claims Fraud Act subjects the person to criminal penalties as permitted under New Jersey law, fines of up to five times the pecuniary benefit received or sought, and license or certificate forfeiture. Health care claims fraud includes the making of false or misleading statements in, or omission of material facts from, a record, bill, claim or other document submitted for payment or reimbursement for health care services.
- D. **Conscientious Employee Protection Act** – This law prohibits retaliation against an employee who discloses to a supervisor or public body an activity, policy or practice by an employer that the employee reasonably believes violates a law, rule or regulation, or is fraudulent or criminal. It also prohibits retaliation against an

employee who provides information or testimony to a public body investigating a violation of law, rule or regulation by an employer, or who objects to or refuses to participate in any activity, policy or practice that the employee reasonably believes is in violation of a law, rule or regulation, or is fraudulent, or incompatible with a clear mandate of public policy. The law provides a private right of action for aggrieved employees with available remedies including injunctive relief, reinstatement, lost wages and benefits, and other compensatory damages; a defendant may also be subject to civil fines and punitive damages. An employer may, however, recover attorney's fees and costs if an employee is found to have brought an action without basis in law or fact.

VI. Compliance with SLUHN Code of Conduct

SLUHN has established a compliance program to promote an atmosphere of the highest ethical and professional standards. As part of its program, SLUHN has adopted a Code of Conduct describing SLUHN's compliance program and its role in ensuring compliance with legal and ethical standards and in detecting and preventing fraud, waste and abuse. Vendors are required to read and abide by SLUHN's Code of Conduct. SLUHN's Code of Conduct also provides information about how to raise a compliance concern (including anonymously reporting through the SLUHN Compliance Hotline) and SLUHN's policy prohibiting retaliation against people (including vendors) for raising concerns in good faith.

VII. Confidentiality of Patient and SLUHN Information: Business Associate Agreements

Vendors are required to sign SLUHN's "Observer/Vendor Memorandum of Understanding" and must keep strictly confidential all patient information and SLUHN proprietary information. All patient information is confidential, regardless of whether it is spoken in a conversation, written on a piece of paper, contained in an e-mail or stored electronically in a SLUHN computer or on a portable storage device. In addition, each vendor who is a "business associate" for purposes of the regulations implementing HIPAA is required to execute and comply with the Business Associate Agreement provided by SLUHN. Questions about Business Associates, including whether a vendor has completed a Business Associate Agreement, can be sent to SLUHN's Chief Compliance & Privacy Officer at Nicole.Huff@sluhn.org.

VIII. Non-Discrimination

Vendors are required to comply with all applicable federal and state laws regarding anti-discrimination and shall not discriminate against any person on the ground of age, race, color, national origin, religion, sex, sexual preference, gender identity and expression, disability, or any other prohibited basis under federal or state law.

IX. 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 any merit or discretionary compensation awards.

X. 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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XI. 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, Administrator on Call, Clinical Risk Management, Legal Services, Accreditation and Standards, or Chief Compliance & Privacy Officer, as appropriate.

XII. Approval

Network Compliance Committee every two years.