CHRISTIANA CARE
HEALTH SYSTEM

Corporate Compliance Program

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1. Introduction

a. Foreword from Ron Sherman

i. ***SUBTEXT****:Christiana Care's mission is to serve our community. Our community expects us not only to provide excellent patient care, but to do it in a way that is commercially reasonable and ethical. In the spirit of commercial reasonableness/ethics, we need to go beyond the excellent care we provide and ensure that everyone in our organization complies with the laws, regulations and rules set by Medicare, Medicaid and commercial insurers which affect the claims development and submission process. As healthcare providers, we have a responsibility to make sure we are doing things the right way when it comes to billing, accounting, purchasing, business transactions and vendor selection. Following the requirements of our Code of Organizational Ethics helps every one of us do it*

b. Course Background and Objectives

Christiana Care has created a document called the "Code of Organizational Ethics". All employees, contractors, active medical staff members and Board Members connected with CCHS must read and understand its provisions and prohibitions. It is a guide that sets out the principles for ethical business conduct that affect us personally, particularly with respect to the development and submission of claims to payors for the services we provide, as it applies in our work day-to-day business operations. It is a roadmap that describes the behavioral principles that serve as the foundation of our Corporate Compliance program.

The objectives of this training are to enable participants to:

i. Become familiar with the CCHS Corporate Compliance Program
ii. Describe the requirements of our Corporate Integrity Agreement
iii. identify common forms of illegal and/or unethical conduct
iv. Utilize in-house compliance misconduct reporting systems
v. Understand the consequences of violating the Code of Organizational Ethics

The Federal Medicare/Medicaid programs provide health insurance to nearly 100 million Americans with an annual cost to taxpayers of about 1 trillion dollars. As custodian of these

assets, the government has a responsibility to act in the best interests of the American public, ensuring that money is spent as these Programs intend (i.e. the requirements of the regulations) and in the most cost-effective manner possible - hence the extreme focus on value-based purchasing, pay-for-performance, and standardized, evidence-based clinical practice.

Conversely, having been entrusted by the American people to provide healthcare in exchange for taxpayer funds, it is incumbent upon the healthcare industry to provide the best possible cost-effective care while upholding the highest ethical standards, especially when it concerns billing government payors. A major driver of the rise in health care costs has been a significant degree of fraud committed against government health care programs. Billions of dollars in health care fraud have been identified through the efforts of powerful surveillance technologies and whistleblowers acting under Federal and State False Claims Acts.

This is why the Government Accounting Office regards both the Medicare and Medicaid programs as among the highest-risk programs for fraud in the country. As a result, the government has taken major steps to escalate and increase the effectiveness of healthcare fraud prosecutions, and to hold providers accountable for submitting accurate and truthful claims for services.

2. CCHS Corporate Integrity Agreement

a. What is a Corporate Integrity Agreement?

As of February 24, 2010, CCHS entered a Corporate Integrity Agreement (CIA) with the Office of the Inspector General for a term of 5 years. A CIA is an agreement that imposes requirements, mostly on a provider's Compliance program, that remedies the conduct that resulted in the prosecution and civil settlement. CIAs are generally tagged onto monetary settlements of prosecutions under the False Claims Act, the government's most effective weapon against healthcare fraud. In exchange for the provider's agreement to implement the requirements of the CIA, the OIG agrees not to exclude the provider from participation in the Medicare and Medicaid Programs. "Exclusion" means that a provider is prohibited from billing for services provided to Medicare/Medicaid patients, on average about 45% of a provider's revenue.

While the requirements of CIAs are focused on preventing and monitoring the particular provider behavior that lead to

violation of Federal healthcare fraud law, CIAs also usually contain the following common elements:

i. The hiring of a Compliance Officer/appointment of a Compliance Committee;
ii. Development of written standards, policies and, procedures for claims development and submission and a Code of Conduct
iii. Implementation of a comprehensive employee and contractor training program;
iv. retaining an Independent Review Organization to conduct annual audits of the things specifically set out in the Agreement;
v. Establishing a confidential compliance violation reporting program;
vi. Checking the OIG sanctions/exclusion lists and avoiding employment of ineligible persons;
vii. Timely submission of Implementation Reports and Annual Reports on the organizations fulfillments of the requirements of the CIA.

b. CCHS Corporate Integrity Agreement

The CCHS Compliance Program focuses on the detection and correction of claims development and submission practices that do not conform to Federal and State law and regulations. Thus, aside from protecting government healthcare programs from fraud, it also serves to minimize the organization's exposure to damages and penalties imposed by government agencies related to alleged fraudulent or abusive practices However, claims development practices relate not only to how we document the services we provide, and whether they are medically necessary, but to our relationships and interactions with providers and vendors. To the extent these relationships involve financial transactions and/or arrangements that affect the ordering or prescribing of items or services covered by government healthcare programs, they are the focus of government fraud prevention efforts. It is this part of the government's enforcement efforts that is the focus of our CIA.

The following is a brief overview our responsibilities under the CIA. Please familiarize yourself with them:

i. Train our employees, physicians and contractors on the requirements of the CIA
ii. Comply with all Stark/Anti-Kickback laws and regulations
iii. Generate policies to ensure compliance with Stark and Anti-Kickback laws and regulations

iv. Maintain a database of all Arrangements (contracts) with referral sources or recipients
v. Track payments made to, or received from all referral sources or recipients
vi. Respond appropriately to probable violations of the Stark/Anti-kickback law
vii. Engage an Independent Review Organization to annually evaluate our compliance with terms of the CIA
viii. Maintain a disclosure program to enable individuals to report suspected violations

3. Corporate Compliance Agreement

a. Overview

The Corporate Compliance Program focuses on certain areas of health-care claims development/submission practice that are considered to be at high risk for fraud and abuse:

- Overcoding or lack of documentation to support claims submitted to government payors;
- Lack of medical necessity, and documentation thereof, for the services represented in the claims;
- Encouragement of referrals of patients or other healthcare business through financial incentives offered to physicians or other referral sources, or by recipients of referrals;
- Conflicts of Interest i.e. physician financial relationships with pharmaceutical or medical device manufacturers which compromise objective medical decision making or result in over-utilization of services billed to government payors;
- Acceptance of kickbacks in various forms from vendors for referrals of business;
- Mismanagement of financial and/or medical records
- Violations of EMTALA (Emergency Medical Treatment and Active Labor Act)

The Compliance Program is designed to improve the ability of staff to recognize and remedy abusive and illegal practices at the individual and organizational levels. The Program focuses on things like proper coding, medical necessity, adequate documentation to support services billed, recognizing and reporting improper practices, and corrective action plans to eliminate those improper practices. The Compliance Program

is also responsible for policy development, organizational response to civil or criminal violations, and disciplinary consequences for misconduct.

b. *Compliance in Billing Practices*

i. *False Claims*

The **False Claims Act** , also called the "**Lincoln Law**" imposes liability on individuals and organizations that defraud governmental programs. It was passed in 1863 during the Civil War to curtail government contractor fraud in the form of fraudulent claims. Today, it is the government's major weapon against all forms of healthcare fraud. Recent revisions called the "FERA" provisions have expanded its capabilities in fraud prevention.

ii. *Your Name is on the Claim*

Gone are the days when physicians could simply rely on their coders to monitor their compliance in billing. Enforcement authorities today are equipped with powerful software that enables them to readily identify improper claims development/submission practices. Individual practitioners are held accountable for the accuracy of all information on the claims submitted on their behalf, and are often held personally responsible for improper claims development or submission practices.

iii. *Liabilities and Consequences*

Liabilities and consequences for violation of the False Claims Act can include damages of up to 3 times the amount of the total payment received on the false claims submitted, and penalties ranging from $500 to $11,000 for each false claim submitted. The Patient Protection and Affordable Care Act of 2010 has enhanced the power of the False Claims Act by authorizing penalties of $50,000 for the submission of false statements or records that are material to a false claim. Violation of the False Claims Act can also lead to exclusion from the Medicare or Medicaid Programs, as discussed above. The government yield on the prosecution of healthcare fraud is approximately a $ 7.90 return for every dollar spent, virtually ensuring that government efforts to recover funds and curtail fraudulent practices will continue.

c. *Common Billing Issues*

i. *Documentation*

Medical record documentation is required to record information that justifies the diagnosis and treatment of the

patient. Medical necessity applies not only to assigning accurate diagnoses to justify treatment, but to performing the correct tests and examinations used to determine the diagnoses. Coding is an integral part of justifying payment for diagnostic and therapeutic services billed to government or commercial payors. Correct coding is completely dependent on the quality of documentation. Thus, an appropriately documented medical record can reduce many of the difficulties associated claims development, and the prevention of claims denials and fraud investigations. Under Federal Law, providers have an independent responsibility to prepare and maintain adequate documentation to support their claims for services. While there is no direct authority in the Law for this, the government continues to maintain the position that a service that was not documented was not performed.

Because government payors have a legislative obligation to cover the cost for care to beneficiaries, they continually review claims for reasonable documentation that services were performed and/or were medically necessary and consistent with the coverage provided before paying for them. They may request information to validate:

a. The medical necessity and appropriateness of the diagnostic or therapeutic services provided;

b. that the services provided have been accurately reported;

c. the site of the services.

The Civil Monetary Penalty Laws, which apply to the Medicare and Medicaid Programs, provide civil sanctions for the presentation of a claim for an item or service based on a code the person knows will result in a greater payment than is warranted. However, the evidence required to sustain an action under the False Claims Act usually requires the government to establish that the provider has engaged in a pattern of submitting false claims related to a particular service or item, rather a than single false claim.

It is important to recognize that physician documentation in the hospital chart, especially documentation to support the medical necessity of every procedure or treatment, not only supports professional claims submitted on behalf of the physician, <u>but is critical to driving the legitimacy of facility claims.</u>

It is of paramount importance that physicians justify the medical necessity for the treatment they provide, or the procedures they perform, with comprehensive chart documentation before providing the services, especially if the treatments or procedures involve expensive drugs or medical devices. The government will recoup the physician's fees, as well as the cost for the drugs or devices from the hospital, if the medical necessity documentation is inadequate.

The Compliance Department has implemented structures and processes in high-risk clinical departments to internalize ongoing auditing and education with respect to physician chart document-tation to minimize claims development risks.

ii. *Medical Necessity*

"Medical necessity" means that the services provided, in the independent and objective judgment of the provider, are necessary the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and are:

a. In accordance with generally accepted standards of medical practice;
b. Clinically appropriate with regard to type, frequency, extent, site and duration, and are considered effective;
c. Not more costly than an alternative service as likely to produce equivalent therapeutic or diagnostic results;
d. Consistent with the requirements of national coverage determinations (NCDs) or local coverage determinations (LCDs) developed by Medicare, which are statements of medical necessity for certain treatments/procedures through the use of evidence based clinical standards.

Documentation in the medical record must support the medical necessity of every service provided that is billed to a government or commercial payor.

iii. *Improper Claims Development*

a. duplicate billing
b. improper coding leading to higher payment
c. billing for services not provided
d. billing for services not supported by documentation
e. billing for medically unnecessary or non-covered services
f. billing separately for services required to be billed together (unbundling)

g. billing based on inappropriate admissions
h. not returning credit balances
i. not refunding known overpayments to payors
j. following proper accounting rules that affect reimbursement.

iv. Other

Obtaining correct patient information during the registration process is critically important in properly entering charges and in ensuring that all of the services provided will be reported on claims forms. If any of this information is missing or incorrect, claims may be submitted in error.

One way providers can monitor missing or incorrect information is to routinely review denials from Medicare and Medicaid. Denials are notices sent by payers to providers to let them know why a service will not be paid.

Information that can be identified through review of denials includes:

- System documentation issues.
- Need for updating of policies and/or procedures.
- Areas for further education and training.
- Situations warranting compliance investigation.

When denials are received, the billing department should immediately share this information with other relevant departments to improve processes and make corrections if needed.

d. Examples of Violations

i. Inflating Payments by Improper Coding

a. August 2013: Justice Department announced that a Long Island, N.Y. orthopedic surgeon, will pay the government $388,000 to settle allegations that he violated the False Claims Act by submitting false claims to Medicare for minimally invasive spine procedures that were allegedly coded as more complicated, invasive procedures.
b. August 2013: A health system in Florida will pay $26 million to settle allegations that six of its health care facilities submitted false claims to Medicare, Medicaid and other federal health care programs for inpatient procedures that should have been billed as outpatient services.

ii. *Duplicate Billing*

a. August 2013: a major University Hospital in Atlanta paid 1.5 million to settle an FCA investigation alleging that the University billed government payors for services already covered by a clinical trail sponsor resulting in the University being paid twice for the same service

iii. *Unbundling of Services*

a. In many cases, government health care programs have special reimbursement rates for groups of procedures that are typically performed together, such as laboratory tests. One common type of fraud has been to "unbundle" these procedures or tests and bill each one separately, which results in greater reimbursement than the bundled reimbursement rate.

iv. *Billing for Inappropriate Admissions*

a. July 2013: A major Boston teaching hospital paid $5.3 million to settle alleged FCA violations for inpatient admissions that should have been billed as lower paid outpatient or observation services.

v. *Failure to Return Overpayments by Vendors*

1. Federal statutes deem retention of a known overpayment a violation of the False Claims Act. This means that once a provider suspects it may owe the government a refund on any claims submitted, it must with all due speed, investigate to determine if a refund is actually due, calculate the refund, and return the refund. The 60 day statutory reporting requirement begins to run once the refund is calculated.

   August 2013: A major Maryland acute care hospital paid $750,000 to settle FCA allegations failed to repay the overpayments in connection with cardiac testing after financial managers discovered them.

e. **Compliance with Referral Prohibitions**

i. *The Stark Law*

The Stark Law prohibits a hospital from submitting any Medicare claims related to services provided to patients who were referred by a physician while that physician and the

hospital had an "improper" financial relationship as defined by the Stark Law. The Stark Law prohibits referrals only for certain "designated healthcare services" but those include all hospital inpatient and outpatient services. Financial relationships between hospitals and physicians are deemed "improper" when they are designed to compensate physicians based on the volume or value of referrals to the hospital, notwithstanding medical necessity.

These relationships usually occur in the form of payment for clinical or administrative services or for lease of space. In enacting the law, Congress found that these kinds of improper financial relationships (e.g. the hospital charging less than the going rate for office space leased to a referring physician group) often compromise independent and objective judgment regarding the medical necessity of referrals made, and lead to overutilization of the Medicare program. Academic studies have shown that physicians who have improper financial relationships with hospitals use more of the hospitals' services than their peers on the Medical Staff who do not have such relationships.

Payment made by the hospital for the services of a referring physician will generally be exempted from the Stark referral prohibition if a written contract is in place between the parties that describes an arrangement where payment is at the market rate i.e. "fair market value" (FMV) for the particular services (or lease) provided, and the arrangement makes sense from an economic point of view for both parties (i.e. is "commercially reasonable"). Also, the payments must not vary with the volume or value of referrals of patients or other healthcare business made by the physician.

The central requirement of our CIA is that there be a contract management system in place composed of certain "arrangements procedures" which are defined in the CIA. These procedures are designed to continually monitor whether there is a written contract in place for each arrangement; whether the arrangement is at FMV and commercially reasonable; whether and how the contract was reviewed and approved; whether and how the payment is tracked; and whether the payment is backed up by documentation that describes and quantifies the services performed.

In order to track all financial arrangements with physicians, the hospital is required to maintain an "Arrangements Database" which contains each contract as well as data on how FMV and commercial reasonableness was determined. Critical

to the creation of each contract is the information contained in a "Contract Request Form" which must be completed by each clinical department and sent to the Legal Department, every time a new financial arrangement is established with a physician.

"Fair Market Value" ("FMV") means the price the services would bring on the open market in a negotiation between parties of equal bargaining power who are not otherwise in a position to generate healthcare business for each other.

"Commercial Reasonableness" generally involves an assessment of things like legitimate need for the services by the recipient of the referrals, the anticipated volume of business to be referred and its bearing on the arrangement, and whether the arrangement make sense from a business perspective for both parties.

Even if a physician is employed by the hospital, the requirements of Stark must still be met if the physician is in a position to make referrals to the hospital. The payment to the physician must be at FMV, commercially reasonable, and not vary with the volume or value of referrals made by that physician. As opposed to other Medical Staff physicians, however, employed physicians can be required to refer all of their patients to the hospital.

Determination of FMV is particularly difficult for physicians who provide administrative or educational services rather than clinical services (e.g. medical directors). Because excessive payment for these services has so often been the basis for government prosecution of hospitals under Stark, it is particularly important that accurate records be kept of the activities performed by medical directors and the amount of time spent at each activity.

The CCHS Compliance Program prohibits:

1. Offering or accepting anything in return for the referral of patients or other healthcare business.
2. Paying physicians/physician groups more or less than fair market value for services provided or paying for services that are not necessary.
3. Paying physicians more or less than fair market value for the leasing of space or equipment.
4. Establishing a financial arrangement with a provider without a written contract.

ii. The Anti-Kickback Law

The Anti-Kickback Law preceded the Stark Law, was its foundation, and is much broader in scope. It is used to prosecute fraud in the form of financial relationships (called "kickbacks") designed to induce referrals of healthcare business covered by government payors, but that don't involve physician referrals of "designated health services". Thus, the Anti-Kickback Law is used to prosecute improper financial relationships which induce referrals of all other kinds of healthcare services or business. The Anti-Kickback Law doesn't outright "prohibit" referrals while an improper relationship is in existence (like Stark), but the improper relationship is still subject to prosecution. The prosecution would be "criminal" rather than "civil" since Anti-Kickback is a criminal law, unless the government decides to use the civil False Claims Act instead (which is often the case). The Anti-Kickback Law does not prohibit financial relationships between the parties if they fit within certain "safe harbors" which are much like the exceptions under Stark.

The Anti-Kickback Law is commonly used to prosecute manufacturers of drugs and devices for schemes that induce physicians to accept payment for consulting services that are above FMV or not commercially reasonable (e.g. there is no legitimate need for the services) but serve rather as a pretext to gain the physician's "product (or brand) loyalty". This kind of loyalty can create a conflict of interest for the physician because it can compromise objective medical judgment when decisions are made about which brand of items or services to order or prescribe for patients, to recommend to the hospital for purchase, or to recommend to colleagues for their use with patients. From the government's perspective, product (or brand) loyalty interferes with objective judgment on medical necessity, effectiveness and safety, and cost-effectiveness.

The CCHS Compliance Program prohibits:

1. Accepting payments or other kickbacks from vendors meant to encourage purchase of their products by the hospital
2. Accepting excessive payments or payments for unnecessary consulting or research services from drug or medical device companies
3. Engaging in purely commercial marketing or promotional efforts for drug/device company products
4. Accepting money for attending industry sponsored seminars if no legitimate services are performed.

A physician who serves on a drug/device company speaker's bureau may be reasonably paid for his or her services but the content of the presentation must be based on his or her personal clinical experience with the products discussed rather than serve merely as a form of marketing or promotion for the company's products.

Any member of the formulary committee or any other purchasing committee is prohibited from involvement in any decision as to the purchase of the products of a company in which he or she has a financial interest or a compensation relationship. The individual must recuse him or herself from the decision making process of the committee with respect to that companies products.

Another example of a situation that could violate the Anti-kickback Law is the routine waiver of coinsurance, co-payments, and deductibles by the hospital. Patients must pay an annual deductible and for their portion of the charges, the coinsurance/co-payment amount. A hospital that routinely does not collect or waives Medicare co-payments coinsurance or deductibles may influence Medicare patients to use that provider, which could result in a violation of the Anti-kickback Law.

Providers are allowed to waive co-payments, coinsurance and deductibles in certain defined situations. An example is where co-payments, coinsurance and deductibles are waived when it is determined a patient is unable to pay due to financial circumstances.

f. Records Management

Consider the following rules:

i. There must be record of all care provided.
ii. Alteration or backdating of medical records is prohibited.
iii. All records must be current.
iv. Storage of records is regulated for reasons of security and privacy.
v. Release of any information is controlled by internal policies that are designed to comply with Federal regulations.

g. ***EMTALA***

The Federal Emergency Medical Treatment and Active Labor Act (EMTALA) requires that:

- the hospital provide a medical screening examination to every individual presenting at its emergency department who request treatment for a medical condition, and to individuals presenting on other hospital property requesting treatment for an emergency medical condition (EMC);
- if an EMC is found to exist, the hospital must provide stabilizing treatment within its capabilities;
- if the individual requires stabilization capabilities not available at the hospital, the hospital must transfer the individual to another hospital with such capabilities;
- the hospital must accept appropriate transfers of individuals with EMCs from other hospitals when it has stabilization capabilities not existing at the other hospital and has the capacity to accommodate the patient.

When a physician is assigned to be "on-call" to the hospitals emergency department on behalf of his/her specialty, he/she must:

- Respond immediately, or within a designated time frame, by telephone to a call from an emergency physician.
- Appear personally in the ED to further stabilize a patient if requested to do so by an emergency physician;
- As an alternative to personal appearance in the ED. move the patient to another hospital department where the patient will have more expedient access to the personal services of the on-call physician or with other superior capabilities to stabilize the patient.
- Place the ED on notice to follow the backup plan set for his or her specialty, if he/she anticipates unavailability due to circumstances beyond his/her control.

i. September 2013: A Georgia hospital paid $50,000 under a civil monetary penalty for violating EMTALA based on the hospital's refusal to accept an appropriate transfer of a patient who required its specialized capabilities.

ii. 2011: A Tennessee physician was fined $50,000 under the CMP for refusal to accept an unstable emergency patient that required the specialized capabilities available at the hospital for which he was on-call to the ED. The patient was transferred to another facility and died shortly thereafter.

h. Confidentiality

All personnel are responsible for maintaining patient and business confidentiality.

You must be aware of the procedures CCHS has in place to protect patient information. Procedures address:

- authorizing personnel and others to access patient information;
- handling requests for patient information
- transmitting information to others, including other providers;
- maintaining and protecting confidential patient information;
- handling patient information that may be included in electronic mail, voice mail, etc.

Business confidentiality is also important and includes items such as computer and voicemail passwords, pricing information, contract information, etc.

"Protected Health Information" is any information including demographic information that can be used to identify the patient. This includes information that can be used in some manner to identify the person (e.g. social security number). PHI also includes information that relates to any healthcare provided to a person, whether in the past, present or future.

Protected health information can be found in many different areas, not just patient medical records. Here are a few examples of where PHI can be found outside of patient care:

- A billing clerk processing claims.
- An accounts payable clerk process patient refund checks.
- Biomedical engineering working on equipment in a patient's room.
- Volunteers working at the information desk in the lobby.
- A housekeeper working around a nurse's station.
- Information technology staff reviewing system files to extract reports.
- Mail room clerks sending paper claims and statements to insurance companies and patients.

The privacy rules cover PHI that is contained in electronic format as well as written and oral communications. HIPAA also includes security standards to protect PHI in electronic format, such as information contained on computer systems. If you work with any

information that may contain PHI, you need to be aware of these requirements.

Updated information on HIPAA requirements can be found on the CMS website at www.cms.gov If you have any questions, you should ask your supervisor. The Compliance Officer or Privacy Officer will also be able to help you.

i. Sanction Checking

The Office of Inspector General (OIG) has the authority to exclude individuals and entities from participation in Medicare, Medicaid and other federal healthcare programs if they have engaged in fraud or abuse. Individuals and entities that are excluded from participation cannot submit bills to Medicare and Medicaid for any services that are provided.

The OIG has published the "List of Excluded Individuals/Entities". This list can be found on the OIG website at http://www.oig.hhs.gov/.

The list provides information to healthcare providers, patients, and other interested parties regarding thousands of individuals and entities that are excluded from participating in Medicare, Medicaid, and other federal healthcare programs. This list not only includes physicians and management level positions, but also nurses, technologists, therapists, billing clerks, aides, and even private citizens.

This list must be individually checked by the hospital to ensure that none of its employees, contractors, providers or others who provide items or services to its patients are excluded

j. Reporting Violations

In order to be able to recognize behaviors that violate the Code of Ethics, you must read and be familiar with its principles. You expected to report any actual or suspected violations directly to your supervisor or to Ron Sherman, the compliance officer, at 302-623-2873. Anonymous reports will be accepted on the dedicated compliance hotline (877-REPORT-0). You will not be penalized for reporting in good faith even if the suspected behavior is determined to be legitimate.'

If the complaint is appropriate, the compliance officer, Ron Sherman, will initiate an investigation and take the necessary steps to remedy the situation and prevent its recurrence. Claims deemed to be violations would be referred to Human Resources or the Medical/Dental Staff office for corrective actions that may include from warnings or termination