Development and Implementation of Corporate Compliance for FQHC’s

Louisiana Primary Care Association

Annual Continuing Education Conference

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Compliance Presentation Goals

- This Compliance Presentation is intended to assist Attendees with:
  - Recognizing the benefits of maintaining an updated and tailored compliance program;
  - Understanding how the elements of an effective compliance program work together to foster a “culture of compliance”;
  - Recognizing the purpose of key laws and regulations for the healthcare industry and how to use the Compliance Plan to help ensure compliance with these laws and regulations; and
  - Understanding how to use the Compliance Plan to help detect and correct mistakes through direct action, open communication or internal anonymous reporting using the Compliance Hotline.
What is a Compliance Program?

• A Compliance Program is an effective, practical and integrated management tool that establishes clear and defined goals and procedures designed to create a culture of compliance, reduce the occurrence of mistakes and prevent intentional violations of the applicable health care statutes and regulations.
Compliance Goals

• Goal: to create a “Culture of Compliance” throughout the FQHC by showing a commitment from the top and enforcing compliance standards throughout the entity.

• Benefit: by focusing attention on processes and reinforcing clinical standards through audits and training, Attendees can maintain and improve its high quality of care.

• Benefit: by minimizing potential compliance errors; detecting and correcting any errors that do occur, Attendees will help keep such errors from becoming significant and crippling civil fines and penalties.
Key Elements for the Compliance Plan

• Conducting internal monitoring and auditing;
• Implementing compliance and practice standards;
• Designating a compliance officer or contact;
• Conducting appropriate training and education;
• Responding appropriately to detected offenses and developing corrective action;
• Developing open lines of communication; and
• Enforcing disciplinary standards through well-publicized guidelines.

http://oig.hhs.gov/authorities/docs/physician.pdf
Elements: Internal and External Audits

- Internal and External auditing and monitoring is an essential element of an effective Compliance Program and consists of periodic audits conducted by the Compliance Department and/or external independent legal counsel and consultants.
- Audits are designed to help you ensure you provide high-quality medical care in a professional, safe, effective and efficient manner that is in full compliance with clinical guidelines, professional standards, contractual requirements, and statutory and regulatory requirements.
Elements: Policies and Procedures

• The purpose of written compliance policies and procedures is to provide a clear explanation of the your compliance and quality goals and provide clear and understandable mechanisms and procedures designed to enable the you and your Personnel to achieve those goals in compliance with Federal, state and other program requirements and standards.

• Effective policies and procedures should be relevant to day-to-day responsibilities, distributed to relevant personnel and reviewed periodically to evaluate effectiveness.
Elements: Education and Training

- An effective Compliance Program is rooted in an active and adaptive education and training program for Personnel.
- Inadequate training significantly increases the risks of compliance issues and possible violations of the applicable statutes and regulations.

- Education can take the form of:
  - Active Education and Training
  - Adaptive Education and Training
Active Education and Training

• Active education and training is designed to teach each person how to carry out their responsibilities effectively, efficiently and in compliance with statutory and regulatory compliance requirements.

• The department managers and Compliance Department are responsible for evaluating the effectiveness of the existing education and training methods and information utilized by Personnel.
Adaptive Education and Training

• Adaptive education and training is designed to be responsive to the educational needs of Personnel identified through internal and/or external reviews, audits, or compliance assessments or by government notices, alerts, and/or other advisory statements.

• As an example, if internal monitoring or auditing identified an issue with documentation or other matters relating to a specific service, you would develop additional training materials and procedures, if necessary, and conduct adaptive education and training with affected Personnel designed to address and prevent a reoccurrence of the identified compliance issue.
Elements: Open Communications

- Open Communication is the environment in which everyone is encouraged to express their compliance, quality and other concerns and/or suggestions for improvement without fear of retaliation. It is the fostering of an engaged dialogue meant to improve your operations.
- Open Communication is essential to maintaining an effective Compliance Program by increasing your ability to internally identify and respond to potential and/or actual compliance issues, quality issues or performance improvement suggestions.
- Open Communication is an essential element for establishing a Culture of Compliance among Personnel as well as contractors and others.
Open Communication: Compliance Hotline

• All Personnel are encouraged to identify and report any concerns they have relating to compliance, clinical quality, personnel issues and possible areas of improvement (and re-report if their concerns haven’t been addressed) through the your internal Compliance Hotline.
  • Hotline staff shall respect a caller’s wish to remain anonymous if so desired;
  • Reports to the Compliance Hotline should be forwarded to the Compliance Department to be logged and tracked;
  • The Compliance Department shall actively review, investigate and evaluate the Hotline report and recommend a response; and
  • The Compliance Department shall submit a report to your Board of Directors.
Reporting Alternatives

• Personnel are encouraged to report any compliance concerns to their supervisor or the Hospital’s Compliance Hotline in order to permit you to identify and respond to compliance issues and improvement suggestions. However, if they so choose, Personnel may contact CMS to report concerns:
• The Centers for Medicare and Medicaid Services (CMS):
  • The phone number is 1-800-MEDICARE (800-633-4227).
  • The website is: [http://www.medicare.gov/FraudAbuse/HowToReport.asp](http://www.medicare.gov/FraudAbuse/HowToReport.asp)
  • To report Medicare and/or Medicaid fraud and abuse, call 1-800-HHS-TIPS (800-447-8477).
Responsive Audits

- In response to compliance concerns identified through a complaint, internal audit, compliance evaluation or updated guidance from legal counsel or government agency, the Compliance Officer may, in consultation with legal counsel, request legal counsel conduct an external audit of potential compliance concerns.
- Having outside legal counsel direct an external auditor will help protect the audit results under attorney-client privilege.
- Responsive audits may consist of targeted or expansive audits designed to evaluate the existence of the potential compliance issue and the potential need for adaptive education and training and/or revised compliance policies and procedures.
Building Your Compliance Program

• Conduct a Risk Assessment of Identified Compliance Priorities;

• Develop a Compliance Program with a Compliance Plan and Policies and Procedures designed to guide Attendee's operations to ensure and document compliance; and

• Implement the Compliance Program by working with Attendees personnel to integrate the compliance functions into day-to-day routines with periodic audits and assessments.
Tools for Compliance

• An effective Compliance Program provides you and your employees with tools for acting ethically and for maintaining compliance with applicable laws and regulations.

• Tools of particular use to you would be:
  • Utilizing the Compliance Officer and Compliance Committee as mechanisms for clarifying requirements and reporting potential misconduct;
  • Reviewing and understanding your written policies and procedures;
  • Maintaining effective lines of communication with management and other staff members; and
  • Participating in training and education opportunities.
Next Steps

- Appoint Compliance Officer
- Establish a Coding Hotline
- Review Compliance Guidance
- Review Compliance Plan
- Review Areas of Greatest Risk
- Perform GAP Analysis
Compliance Officer Duties/Responsibilities

• The OIG recommends that every healthcare organization designate a compliance officer to carry out and enforce compliance activities.

• The compliance officer should function as an independent and objective person that reviews and evaluates organizational compliance and privacy/confidentiality issues and concerns.

• The compliance officer’s main duties include coordination and communication of compliance plan; this involves planning, implementing, and monitoring the program.
Compliance Guidance

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Inspector General
OIG Compliance Program for Individual and Small Group Physician Practices

AGENCY: Office of Inspector General (OIG), HHS.
ACTION: Notice.
SUMMARY: This Federal Register notice sets forth the recently issued Compliance Program Guidance for Individual and Small Group Physician Practices developed by the Office of Inspector General (OIG). The OIG has previously developed and published voluntary compliance program guidance focused on several other areas and aspects of the health care industry. We believe that the development and issuance of this voluntary compliance program guidance for individual and small group physician practices will serve as a positive step towards assisting providers in preventing the submission of erroneous claims or engaging in unlawful conduct involving the Federal health care programs.

FOR FURTHER INFORMATION CONTACT: Kimberly Brandt, Office of Counsel to the Inspector General, (202) 619–2078.

http://oig.hhs.gov/authorities/docs/physician.pdf
Components of a Compliance Program

• A Compliance Program consists of three essential elements:
  • Code of Conduct – a statement of principals;
  • Compliance Plan – establishing the framework for organizing the provider’s compliance efforts;
  • Policies and Procedures – implementing the provider’s compliance goals.

• The most effective Compliance Programs is one that is tailored to your specific operations by designing an adaptive Plan and Policies and Procedures to implement the goals expressed in the Code of Conduct while also addressing the identified compliance risks.
The central element of an effective Compliance Plan is the formal commitment to compliance embodied in the Code of Conduct, which should:

- Include a statement of your ethical and compliance principles;
- Include a summary of the broad ethical and legal standards under which the you and your administration, personnel and Medical Staff ("Personnel") should operate; and
- Reflect the your Mission, Vision and Values.

The Code of Conduct should be:

- Reviewed thoroughly with each new employee upon hire during the orientation process and annually thereafter;
- Followed by and reviewed all Personnel; and
- Updated periodically by the Compliance Department and your Board of Directors.
Important Healthcare Laws and Regulations

• Health Care is a highly regulated industry. Providers, including FQHCs must not only provide quality care to meet patient needs, but must do so in a manner that complies with:
  • Medicare and Medicaid regulations;
  • Federal Physician Self-Referral Statute (Stark II);
  • Anti-Kickback Statute;
  • False Claims Act;
  • False Statements Act;
  • Civil Monetary Penalties;
  • Mail and wire fraud statutes; and
  • HIPAA.
Risk Assessment

- The initial Risk Assessment is based on the type of services provided by Attendees and the applicable Federal and State compliance statutes, regulations, rules and agency guidance (“the Regulatory Issues”)
  - CfC – Compliance with *Conditions for Coverage* to Qualify as an FQHC
  - 340b -- Compliance with the requirements to participate in the 340b program
  - Human Resources -- Compliance with requirements for FQHC personnel
  - Financial Relationships – Compliance with Federal and State healthcare fraud and abuse statutes
  - Data integrity – compliance with Federal and State requirements to maintain the confidentiality of patient medical records and financial information
Risk Assessment: Questionnaires

- Develop questionnaires relative to each of the Risk Areas that have been defined by the Compliance Officer/Committee.
- The questionnaires are intended to gain a better understanding of Organization’s current compliance efforts and operations and how each address the Regulatory Issues.
- The questionnaires will become the Framework for the GAP analysis, and will allow the Compliance Officer/Committee to establish an Implementation Plan.
Risk Assessment (cont.)

• What will you need to do to complete the risk assessment?
  – Select who will answer the questionnaires and how they will be answered;
    • Identify the individual(s) who will answer the questionnaires (Note: the answering of the questionnaires may be outsourced to another individual or entity)
    • The individual(s) or entity should coordinate with the individual(s) and/or departments having information relevant to the questions.
  – Coordinate the completion of the Questionnaires with Compliance Officer
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Medicare/Medicaid Laws and Regulations

- FQHC’s participating in Medicare must follow Medicare regulations, for example:
  - Meet conditions of certification, such as:
    - The FQHC’s board must include a majority of active, registered users of the FQHC who are representative of the population it serves;
    - The FQHC’s core staff and overall operations must be sufficient to meet the needs of the population it serves; and
    - The FQHC must provide various services directly or by arrangement.
  - Meet standards for quality of care;
  - Not bill Medicare for unnecessary items or services or in an amount significantly higher than the usual cost or charge; and
  - Follow other rules for claims filing and billing.
- Failure to abide by Medicare regulations may result in penalties, including possible exclusion from participation in federal healthcare programs.
Stark II – 42 U.S.C. § 1395nn

- Stark II prohibits a physician from making referrals for designated health services ("DHS") to an entity that bills Medicare and with which the physician (or an immediate family member) has a financial relationship (ownership or compensation).
- That DHS entity is prohibited from billing Medicare for such prohibited DHS referrals, *unless* the financial relationship meets every element of an available exception to Stark II.
- These exceptions are numerous and highly detailed. If the relationship fails to meet *any* of the exception requirements, the entity (FQHC) will violate Stark II regardless of knowledge or intent. STRICT LIABILITY.
- A violation of Stark II will result in denial of payment and may result in penalties of $15,000 per claim and/or exclusion from the federal programs and possible False Claims Act liability.
Anti-Kickback Statute 42 C.F.R. § 1320a-7b(b)

- The Anti-Kickback Statute (“AKS”) makes it a felony to knowingly pay, offer, receive or solicit remuneration in return for referring (or arranging for the referral of business or the purchase of goods or services that are paid for by a federal program.

- Any time a hospital-based primary care physician converts his/her practice to the FQHC or the FQHC receives a grant from a hospital, the AKS is implicated, as the additional money received may be viewed as a kickback. Other common situations in which an AKS violation may exist include:
  - Paying a physician above fair market value for personal services;
  - Paying a physician above fair market value to lease space or equipment from the physician;
  - Charging a physician less than fair market value for the physician’s lease of hospital space; and
  - Giving a physician anything of value as a perk, gratuity, or any reason other than the physician’s actual provision of valuable and needed personal services that further the hospital’s mission.

- Penalties for violation of the AKS include up to five (5) years in prison, a $25,000 fine per violation, automatic exclusion from Medicare and Medicaid Programs, and potential prosecution under the Civil Monetary Penalties law which is subject to an easier burden of proof for the government.

- To avoid violating the AKS, an FQHC must endeavor to comply with the FQHC “safe harbor” to the greatest extent possible.
FQHC Safe Harbor to the Anti-Kickback Statute

• The FQHC Safe Harbor to the AKS requires that you continuously comply with each of the following:
  • Any arrangement between the FQHC and a partner must be in writing, signed, and specify all goods, services, donations or loan (“GSDLs”), etc. to be provided;
  • The GSDLs must be medical in nature or relate directly to the services provided by the FQHC, i.e. administrative services;
  • The FQHC must reasonably expect the arrangement to contribute meaningfully to its ability to maintain or increase availability or enhance the quality of the service it provides to the population it serves and must evaluate the arrangement at least annually to ensure that it still does so;
  • The partner may not require the FQHC to the partner or restrict the FQHC from referring patients to any individual or entity;
  • If the partner offers goods or services at a reduced price to some FQHC patients, it must furnish those goods and services to all patients from the FQHC who qualify therefor, regardless of the patient’s payor status;
  • The FQHC cannot be restricted from entering into other agreements for comparable goods or services or with other lenders or donors; and
  • The FQHC must notify patients of their freedom to choose any provider, and must inform a patient that inquires about its arrangement with the partner.
The False Claims Act ("FCA") prohibits knowingly filing a false, fictitious or fraudulent claim for payment to the federal government.

"Knowing" violations not only include intentional violations, but violations where the entity acted with deliberate indifference to the potential for violations.

Common situations in which the FCA is violated include:
- Incorrect coding resulting in increased reimbursement;
- Provision of services by an unlicensed or excluded individual on its behalf;
- Overpayments exist due to billing errors, non-compliant financial arrangements under Stark II or the AKS, or other reasons; and
- Failure to perform reasonable inquiry after being informed that potential overpayments exist.

To escape liability under the FCA, overpayments must be disclosed and repaid within 60 days of determining the overpayment.

Penalties may include up to five (5) years imprisonment and fines for criminal violations and, for civil violations, three (3) times the amount claimed plus $5,500-$11,000 per claim filed.
False Claims Act: High Risk Areas

The following are specific areas in healthcare that present a high risk of violating the False Claims Act:

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<th>Provision of Medically Unnecessary Services</th>
<th>Failure to provide claimed services</th>
<th>Mis-coding of Services</th>
<th>Failure to disclose overpayment</th>
<th>Violations of Stark II</th>
<th>Violations of the Anti-Kickback Statute</th>
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Documentation as a Risk Area under the False Claims Act

• You can avoid problems such as payment denials and FCA allegations by ensuring proper documentation regarding:
  • Services actually provided and why they were necessary;
  • By whom and when (including physician signature and date);
  • The appropriate standard and level (setting) of care;
  • The necessity of the services.
• ... and by avoiding practices such as:
  • Providing canned or overly brief descriptions in patient records; and
  • Providing untimely or insufficient documentation.
### Elements of Compliant Claims

- Claims for services are compliant when they are:
  - Documented, Charged and Billed Correctly;
  - Provided in an Approved Facility;
  - Provided while promoting Patient Rights;
  - Reimbursed correctly;
  - Provided without financial incentives;
  - Medically necessary;
  - Provided by qualified professionals and staff; and
  - Meet quality standards.
Health Insurance Portability and Accountability Act ("HIPAA")

- HIPAA contains numerous and detailed administrative, physical and technical safeguards that you must implement to govern your and your business associates use and disclose electronic protected health information.

- Examples of potential violations include:
  - Having unnecessary conversations about patients in elevators or walkways;
  - Discussing patient information in social settings such as church or neighborhood events;
  - Emailing the status of a mutual friend who is in the hospital to someone outside the hospital;
  - Calling a friend to inform them of a well-known person’s hospitalization at the Hospital; and
  - Leaving patient files where they could be viewed by the public.
HIPAA: Penalties

• Examples of potential civil penalties include:
  • If the individual did not know or would not have known he/she violated HIPAA: (1) up to $100 per violation; and (2) up to $25,000 per calendar year for repeat violations.
  • If the violation is due to reasonable cause and not due to willful neglect: (1) up to $1,000 per violation; and (2) up to $100,000 per calendar year for repeat violations.

• Examples of potential criminal penalties include:
  • Fine of up to $50,000 and jail time up to one (1) year for knowingly obtaining or disclosing protected health information (PHI);
  • Fine of up to $100,000 and jail time up to five (5) years for obtaining or disclosing PHI under false pretenses; and
  • Fine of up to $250,000 and jail time up to ten (10) years for obtaining or disclosing PHI with the intent to sell, transfer or use PHI for commercial advantage, personal gain or malicious harm.
340B Drug Pricing Program

• The 340B Drug Discount Program is a federal program that requires drug manufacturers to provide outpatient drugs to certain entities at significantly reduced prices.

• The discounts provided for by the 340B Program are critical to the financial success of Attendees.

• In order to receive the discounts, Attendees must comply with all the requirements for participation in the 340B Program.
340B Drug Pricing Program

- Attendees must continuously:
  - Enter information regarding the manufacturers it contracts with, drugs it obtains and distributes and the patients to whom those drugs are distributed into a government-run database;
  - Recertify on an annual basis;
  - Prevent duplicate discounts by maintaining reports on how it bills Medicaid drugs;
  - Prevent the sale or transfer of 340B drugs to patients that (1) do not have a relationship with the FQHC, i.e. the FQHC maintains health care records on the patient, (2) do not rely on the FQHC for responsibility of his/her care, or (3) do not rely on the FQHC or do not receive a full range of services from the FQHC.
  - Maintain records of all transactions in anticipation of an audit.
  - Failure to take these steps may not only result in Attendees being barred from participating in the 340B program, but may require it to refund any discounts.
Other Relevant Laws and Regulations

• Mail Fraud and Wire Fraud: 18 U.S.C. § 1341, 1343
  • Implicated because claims are submitted either electronically or through the mail and carries penalties of fines and up to thirty (30) years in prison.

• False Statements Act: 18 U.S.C. § 1001
  • Applies to any false or fraudulent statement (e.g. a claim for reimbursement) made to the government and carries penalties of up to five (5) years imprisonment and civil fines.