



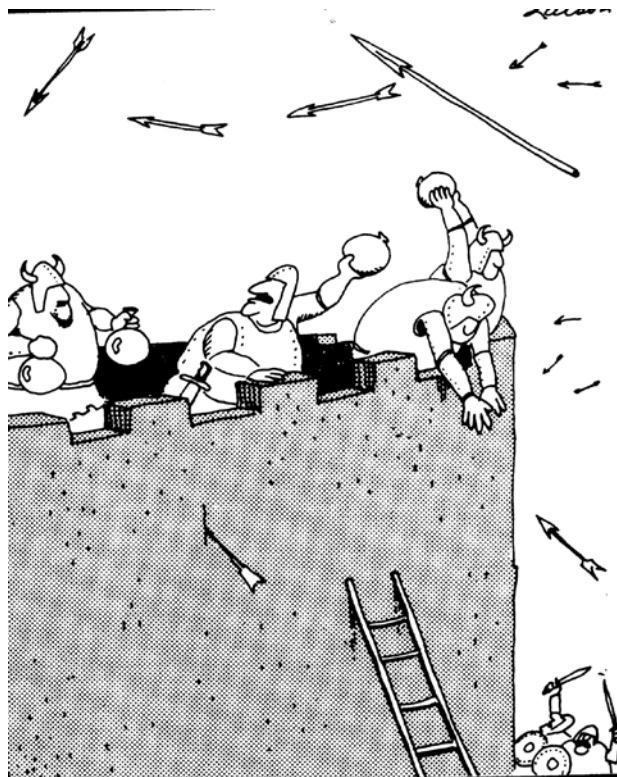
The Rising Bar of Corporate Compliance for Community Health Centers

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The “Rising” Bar of Corporate Compliance



“Forget the water balloons! Hot oil. We need hot oil!”

Background

Over the past several years, community health centers (“CHCs”) have come under increased scrutiny by governmental regulators and whistleblowers for compliance with a variety of laws and regulations that govern the healthcare industry.

- Anti-Kickback and Fraud and Abuse
- Stark and State Anti-Referral Laws
- False Claims Laws
- HIPAA Patient Privacy and Securing Laws
- Nonprofit Tax Laws
- Antitrust Compliance
- California Nonprofit Integrity Act
- Aggressive Audits by DHCS Audits & Investigations

Background

As a result of this increased scrutiny, CHC providers face increased risk of sanctions for non-compliance including:

- Overpayments and Recoupments
- Fines for Billings Implicated by FCA
- Payment of Prosecutor's Attorneys Fees
- Penalties for billing violations under the FCA
- Potential **exclusion** from participating in the federally funded programs

To assist healthcare providers in responding to this increased legal risk, the federal government and industry trade associations have developed and encouraged the adoption of Corporate Compliance Programs.

Background

In addition to compliance issues faced by traditional healthcare providers, CHCs face unique compliance challenges as they must carefully navigate often contrary regulatory schemes between the state and federal government. These additional regulatory constraints render “*template*” compliance programs of little value in addressing the specific compliance issues facing CHCs.

Special regulatory issues for CHCs exist in the areas of:

- Licensing and Certification
- Billing and Payment
- Medi-Cal Reconciliation Payment Requests
- Qualifications for Status as FQHC
- Scope of Service Approvals and Cost-Based PPS Rates

CHCs also face serious resource constraints that require a devotion of critical revenues to patient care and community service obligations.

Why is Compliance Important?

- The CHC's reputation as a respected health care provider.
- The status of the CHC as a provider organization and a nonprofit public benefit corporation.
- Both the CHC and its employees can be held accountable for compliance violations which may expose both the organization and its employees to criminal violations and civil fines and penalties.
- Ethical Conduct is a key factor in the CHC's commitment to remaining a "*Workplace of Choice*".
- Ethical Conduct ensures that the CHC has adopted "best practices" along with its peer organizations.
- Compliance is simply "*the right thing to do*".

Compliance Lessons

- Community Health Centers (“CHCs”) are “*big game*” targets for regulators and relators
- Doing “*God’s Work*” will not protect you
- The most dangerous threat to a CHC is people that work or worked for you
 - Dismissed, disciplined or “disappointed” employees pose a risk of becoming a whistleblower
- Governmental enforcement agencies do NOT understand the complexity of the regulatory environment under which CHCs must operate
- Conducting a self-investigation and making a self-disclosure can secure an improved bargaining position with regulators and help to mitigate the application of penalties and the requirement to undertake compliance obligations

Compliance Lessons

- What to Expect in an Investigation:
 - Investigations can drag out for several years
 - Wear a CHC down organizationally and individually
 - Cost tens or even hundreds of thousands of dollars in legal fees and experts fees
- Investigators are looking to make their case and not necessarily to find the truth and often need an outcome to justify their audits or interventions
- Do **not** hire inexperienced or untrustworthy people in high risk areas
- Get legal advice rather than debate legality of billing practices among the staff as this can often be used against the CHC as evidence of a known “wrongdoing” and suggest the existence of a false claim
- The law is still not clear on the issue of “implied certification” of the accuracy of a payment claim that can provide the basis for a False Claims action

Compliance Lessons

- High Risk Compliance Areas, include the following:
 - Coding and Billing
 - ❖ Insufficient Documentation to Support “Medical Necessity”
 - ❖ Billing for Services not Performed
 - Substandard Care
 - Improper Inducements, Kickbacks and Self-Referrals
 - Treatment by Excluded, Unlicensed, or Un-credentialed Providers
 - False Statements on Reconciliation Reports
 - Most significant risks come from the existence of a system business practice: (i) that is exposed through a government investigation or *qui tam* lawsuit, and (ii) the aggregate amount of which is sufficient to put the financial viability of the CHC at risk
 - Failure to encrypt or encode “*protected health information*”
 - Wage and Hour collection actions under PAGA

Question:

What are the key components to a Corporate Compliance Program for CHC?

Compliance Actions – Selecting a Chief Compliance Officer

Selection of a Chief Compliance Officer is one of the most significant actions that can be taken to put into place a Compliance Program. To be successful, the selection should have the following:

- Input and support of the CHC Board of Directors
- Have a dual reporting relationship to both the Executive Director and the CHC Board of Directors
- Sufficient authority and resources to enable the Chief Compliance Officer to carry out his/her compliance responsibilities

Currently there is a limited supply of professionals that have sufficient expertise and experience with CHCs to have each CHC hire or engage a Chief Compliance Officer. It is both possible and prudent for CHCs (i) to collaborate in the hiring of a Corporate Compliance Officer and (ii) to operate a Joint Compliance Program.

Compliance Actions – Selecting a Chief Compliance Officer

- **Compliance Program.** The selection of a qualified Chief Compliance Officer is one of several elements of an effective Compliance Plan.
- **Core Elements.** There are seven (7) core elements of a Corporate Compliance Program:
 1. Designating a Chief Compliance Officer
 2. Internal monitoring and periodic auditing
 3. Development of written compliance standards
 4. Training and education programs
 5. Communicating compliance commitment to employees and affiliates
 6. Investigations and Corrective Action Plans
 7. Enforcing disciplinary standards
- **Shared Elements.** Even though there are seven (7) core elements of a Corporate Compliance Program, some of these key elements can be effectively and efficiently operated jointly.

Compliance Actions

There are several activities and techniques that can be employed by a CHC to address compliance risk:

- Develop model plans and auditing techniques to assess the high risk business practices of the CHCs
- Conduct targeted audits and assessment of its high risk business practices
- Adopt policies and procedures to implement the Corporate Compliance Program
- Develop and implement a Code of Conduct for all officers, directors, employees and independent contractors ("Staff Member(s)") of the CHC
- Train Staff Members in the Code and ask each Staff Member to certify compliance with the Code
- Establish a system to monitor and enforce the Code
- Respond to allegations of non-compliance

Compliance Actions

Auditing and Monitoring Plans and Techniques. CHCs should focus on business practices that are most likely problematic from a compliance point of view such as:

1. Coding/billing
2. Claims submission for both PPS payments and reconciliation reports
3. Licensing and federal certification issues
4. Employment practices and human resource issues
5. Federal 330 compliance obligations
6. Regulatory compliance including documentation and records retention issues
7. Legal issues such as confidentiality issues and conflicts of interest

Compliance Actions – Educational Programs

Training and Education Programs. CHCs should develop education and training programs to educate new and existing employees on compliance requirements for the CHC.

1. Education programs are a specific requirement of the Deficit Reduction Act (“DRA”).
2. Compliance programs are now mandatory for CHCs with \$5 million in annual revenue and best practices for CHCs with less than \$5 million.
3. Policies and procedures must be established to provide compliance training and information about (i) false claims laws, (ii) remedies and penalties for non-compliance, (iii) whistleblower protections and (iv) the Clinic’s compliance policies.
4. Training, including whistleblower protections, must be extended to all Staff Members.
5. DRA became effective January 1, 2007 and is currently in place.

Compliance Responses

- **Staff Member review as an element of compliance**
 - Require Staff Members to commit to Code including providing any information or allegation of non-compliance
 - Perform an exit interview before ending the relationship
 - Carefully check that they are not taking or transferring any CHC data or documents with them
- **Develop a specific “*investigative protocol*” and use when allegations of non-compliance are raised including a rule that prohibits the destruction or removal of documents**
- **Perform pro-active audits and investigations in the “high risk” business practice areas so that you are not the “last” to know**
- **Consider the use of the 60-Day Rule Disclosure Protocol even if the self investigation identifies only the possibility of any overpayment**

Question:

Can CHCs collaborate to jointly operate certain elements of a Corporate Compliance Program and share the costs and data from such a collaboration?

Answer:

CHCs can organize into a Joint Compliance Program arrangement to help make a CHC Compliance Program more effective and less costly:

1. Select a qualified Legal Counsel to support the Joint Program and the Chief Compliance Officer(s).
2. Establish a clear Joint Operating Agreement that outlines what compliance functions will remain with the CHC and what compliance functions will be jointly operated.
3. Operate within Joint Operating Agreement to avoid issues with waiving legal privileges and the sharing of data and information prohibited by HIPAA and privacy laws.
4. Provide continuity of legal support to achieve integrated corporate compliance program functionality.

Joint Compliance Program

Compliance Activities at CHC. There are several elements of a Corporate Compliance Program that should be reserved specifically to the CHC:

1. Selection of Chief Compliance Officer
2. Reporting relationship of Chief Compliance Officer to the CHC Board of Directors
3. Role of Chief Compliance Officer as focal point of compliance for the CHC
4. Relationship with employees and requirements of Code of Conduct for each CHC
5. Investigations of non-compliance of law and billing practices
6. Employee disciplinary matters
7. Legal issues such as confidentiality issues and conflicts of interest

Joint Compliance Program

Collaborative Support. There are several elements of a Corporate Compliance Program that can be best served by Joint Program Collaboration such as:

1. Supporting, auditing and monitoring plans and techniques
2. Identifying high risk activities for review
3. Designing model policies and procedures
4. Developing and conducting training and educational programs
5. Maintaining important benchmark data so that the participating CHCs can see how their performance compares to others in the Joint Program
6. Managing “hot lines” and expanding lines of communication

Joint Compliance Programs

- **Auditing and Monitoring Plans and Techniques.** Groups can play an important role in the development of audit plans that are most likely to be problematic from a compliance point of view such as:
 - Baseline audits
 - Probe audits
 - New provider audits
 - Compliance audits
 - High risk areas focused audits
- **Design Model Policies and Procedures.** Groups can contribute to better and more complete policies and share the cost of preparation by legal counsel and experts.
- **Training and Education Programs.** There is value for Groups to develop and conduct training programs and to disseminate protocols to new and existing employees on compliance priorities.

Compliance Preparedness

Compliance Policies

CHCs may wish to present a Corporate Compliance Plan and recommended policies and procedures to its board of directors for adoption, which includes the following elements:

1. Compliance Plan Overview
2. Compliance Officer Responsibilities and Authority
3. Compliance Committee Responsibilities
4. Code of Conduct
5. Ethical Conduct Policy
6. Compliance Training Program
7. Disclosure Program
8. Compliance Plan Policies and Procedures
9. Employee Screening Requirements
10. Overpayments Policy

Compliance Plan Overview

Purpose: to establish standards of conduct and written policies and procedures for the staff of CHC

- Focus on compliance with laws regulating CHC's operations
 - Ensures staff performs duties in ethical and legal manner
 - Creates specific Code of Conduct to follow
 - Provides guidance and direction to staff in meeting legal, ethical and professional obligations
- Designed to prevent misconduct
 - Provide early detection of potential violations
 - Risk identification is ongoing process
 - Annual review of policies and procedures
 - Under leadership of Compliance Officer and Compliance Committee

Compliance Officer Duties

- **Compliance Officer is ultimately responsible for implementing and maintaining the Compliance Policies and ensures that:**
 - SCFHC's policies and standards are reviewed annually and findings are reported to the Board
 - Policies and standards are updated as needed
 - Staff and vendor screening mechanisms are in place
 - Staff is receiving adequate training and education, which is documented
 - Audit procedures are implemented and documented
 - Complaints are promptly (within 3 business days) investigated
 - Adequate steps are taken to correct any identified problems or violations
 - Attorneys, accountants, or consultants are retained as needed
 - A retribution-free system is in place for reporting non-compliance
 - Has specific authority to review billing practices of staff
 - Has an annual budget

Compliance Committee Duties

Compliance Committee, with the Compliance Officer, provides Compliance Plan oversight.

- Committee shall be comprised of 3-5 members of the Board, the CEO and the Compliance Officer
- Compliance Officer serves as the Chair
- Monthly meetings with records and minutes kept
- The Duties of the Committee are:
 - Reviews and acts upon the reports and recommendations of the Compliance Officer
 - Serves as appellate body for staff members contesting compliance reports
 - Evaluates performance of the Compliance Officer

Code of Conduct

- **The Code of Conduct is the foundation of the Compliance Plan and a guide to appropriate workplace behavior**
- **Each CHC and its staff share a commitment to legal, ethical and professional conduct**
 - **Care Excellence:** provide quality, clinically appropriate patient care
 - ❖ Provide same quality of care regardless of race, color, age, religion, gender, etc.
 - ❖ Patients' right to privacy and confidentiality
 - ❖ Provide only medically necessary services and maintain adequate records
 - ❖ Confirm medical services are reasonable within accepted standards
 - **Professional Excellence:** meet ethical standards of healthcare and business
 - ❖ Treat all colleagues and coworkers with equal respect
 - **Regulatory Excellence:** comply with federal and state laws and regulations
 - ❖ Ethical and honest billing practice
 - ❖ Referrals and kickbacks
- **The Code of Conduct applies to everyone**

Disclosure Program

- **All Staff is required to report their good faith belief of any violation of the Compliance Plan or applicable law.**
- **How to report a violation:**
 - Orally or in writing to their supervisor, or to another supervisor; or
 - Orally or in writing to the Compliance Officer; or
 - Directly to the CEO
- **There shall be no retaliation for reporting any suspected violation**

Audit Policies and Procedures

- **Audits are a significant part of compliance efforts**
 - To identify conduct that violates state and federal laws
 - To target and measure the effectiveness of its training efforts
 - To ensure appropriate corrective actions are taken
- **Audits to monitor accuracy of claims made to Medi-Cal/Medicare**
 - Periodic Audits of no less than 50 claims annually
 - Even an honest misunderstanding, careless mistake or accidental error can have serious consequences for an FQHC
- **Audits of new employees – for first 60 days of employment**
 - Billers or Coders
 - ❖ To ensure proper billing procedures and submission of accurate bills for services or items rendered to Federal healthcare program beneficiaries
 - Patient Care Providers

Audit Policies and Procedures

- **Compliance Audits – Compliance Officer will investigate complaints**
- Provide a detailed narrative of the concern/complaint
- Notify Compliance Committee, consult legal counsel
- Investigation initiated no more than 3 business days after the complaint
- Interview all persons with knowledge of the alleged conduct
- Review applicable laws, regulations and standards
- Identify relevant documentation
- Prepare summary report that:
 - ❖ Defines the nature of the alleged misconduct
 - ❖ States facts behind how the incident occurred
 - ❖ Identifies persons involved
 - ❖ Assess extent of civil or criminal liability
 - ❖ Estimates resulting potential overpayment
- Cease offending practice and initiate appropriate disciplinary action
- Create corrective action plan to prevent future occurrences

Overpayments Policy

- **Federal law requires that any overpayments identified shall be reported and refunded within 60 days of discovery or when the cost report is due.**
 - Overpayments include findings of up-coding, incorrect codes, insufficient documentation, services billed under the wrong provider, lack of medical necessity, duplicate payment, payment to incorrect payee or any other inaccurate or improper coding
 - Overpayments retained beyond 60 days can result in imposition of treble damages and monetary penalties
 - Self-disclosure of facts and events giving rise to overpayments along with return of overpayments and any corrective actions taken
 - Timely Self-Disclosure can prevent treble damages and penalties
 - Compliance Officer is responsible for returning overpayments

Questions or Comments?
