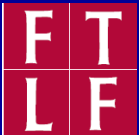


Region II Conference  
July 13, 2009

Corporate Compliance in an Era of  
Accountability and Transparency:  
If You Thought It Was Voluntary,  
*Think Again!*

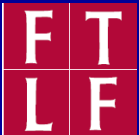
Presented by:  
Jacqueline C. Leifer  
Senior Partner



# Compliance Programs: Why Now?

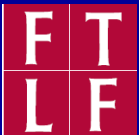
## American Recovery and Reinvestment Act

- Signed into law on February 17, 2009
- Includes \$2 billion in grants to health centers to:
  - Support comprehensive primary and preventive health care to an increasing number of patients
  - Create or retain thousands of health center jobs
  - Support pressing capital improvement needs, such as construction, repair, renovation, and equipment purchases (including health information technology – HIT – systems)
- Transparency and accountability are critical elements of ARRA
  - Health centers should anticipate a high level of scrutiny and be able to respond to a high level of accountability in their use of these funds



# American Recovery and Reinvestment Act

- ARRA funds are one-time only awards available for two (2) year project periods – not added to base grants
- Federal grant recipients and 1<sup>st</sup> tier sub-recipients must maintain current registrations in the Central Contractor Registration (CCR) database
- Funds can be used in conjunction with other funding as necessary to complete projects, but must be tracked and reported separately
  - Separate Notice of Grant Award, Payment Management System Account
  - Internal tracking – examples include time and effort reports, cost centers, ledgers, *etc.*



# American Recovery and Reinvestment Act Tracking and Reporting

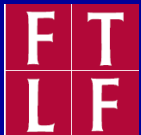
- **Separate internal tracking**
  - Appropriate “time and effort” reporting (*e.g.*, time cards/sheets and other methods to apportion time) in order to properly allocate costs (*e.g.*, salaries, benefits) between ARRA and other projects
  - Separate cost centers, general ledgers or other accounting books/records in order to properly segregate expenditures and programmatic outcomes related to ARRA funds



# American Recovery and Reinvestment Act

## Tracking and Reporting

- Existing A-133 audit requirements apply to ARRA funds; however –
  - Must maintain records that identify adequately the source and application of ARRA funds
  - Separate identification of ARRA-related expenditures on the *Schedule of Expenditures of Federal Awards* (SEFA) and the *Data Collection Form* (SF-SAC)



# American Recovery and Reinvestment Act

## Tracking and Reporting

- A-133 audit requirements (cont.)
  - March 2009 Supplement –
    - Not updated for ARRA – as necessary, OMB will issue addenda to the Supplement to provide additional guidance (including compliance with government-wide reporting requirements)
    - OMB advises auditors to
      - Review award documents for ARRA-specific terms and conditions
      - Check OMB website for addenda
      - Use framework of Supplement as guidance to identify ARRA compliance requirements that are material to the federal program being audited



# American Recovery and Reinvestment Act

## Tracking and Reporting

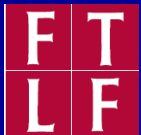
- **Two types of quarterly reporting requirements**
  - **Government-wide reporting**
    - Congressionally mandated by statute
  - **Program-specific reporting**
    - Requirements developed by HRSA that are specific to each type of ARRA funding awarded
    - Included in the funding application and the Notice of Grant Award (NGA) for each ARRA award
  - **Receipt of ARRA funds is contingent on meeting all government-wide and program-specific reporting requirements**
  - **Reporting requirements extend to subrecipients and contractors**



# American Recovery and Reinvestment Act

## Self-Disclosure and Whistleblower Protections

- Mandatory reporting of false claims and violations of law:
  - Recipients must disclose credible evidence that a principal, employee, agent, contractor, sub-recipient, subcontractor or other person has (in connection with ARRA funds)
    - Submitted a false claim under the False Claims Act
    - Committed a criminal or civil violation of laws pertaining to fraud, conflict of interest, bribery, gratuity, similar misconduct
- Whistleblower protection for disclosures of fraud, waste, abuse, mismanagement, and endangerment of public health
  - Employees must disclose information that they reasonably believe is evidence of:
    - Gross mismanagement or gross waste of funds
    - Substantial and specific danger to public health / safety
    - Abuse of authority
    - Violation of law, rule or regulation



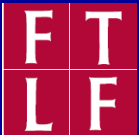


# Key Compliance Risks

**Caution!**

## High Risk Compliance Areas

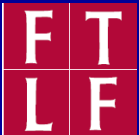
- Procurement Standards
- Federal Anti-Kickback Statute
- Patient Rewards



# Key Compliance Risks

## Procurement Standards

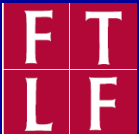
- Circular A-110 and Circular A-122
  - Contracts executed by nonprofit health centers paid for in whole or in part by Federal funds are subject to administrative requirements in 45 CFR Part 74 (incorporating OMB Circular A-110 and A-122)



# Key Compliance Risks

## Procurement Standards

- Written standards of employee conduct (including conflict of interest)
- Open and free competition
  - Review for bid or offer that is responsive to solicitation and most advantageous to health center
  - Health center should reserve right to reject any and all bids
- Written procurement procedures
- Maintenance of procurement records, including cost and price analysis and justification for contractor and award selection
- Contract administration system that ensures contractor compliance and includes monitoring and oversight of contractor performance



# Key Compliance Risks

## Procurement Standards

### Procurement Standards

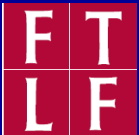
- Specific Provisions Required in Federally Funded Contracts Entered Into By Health Centers
  - Contractor's record-keeping and reporting responsibilities
  - Notice and prior approval of health center if material change in scope of work or approved budget
  - Remedial actions available to health center in event of contractor violation/breach of contract
  - Circumstances justifying termination of contract by health center, including default by contractor and circumstances beyond the contractor's control
  - Contractor's compliance with certain Federal laws



# Key Compliance Risks

## Procurement Standards

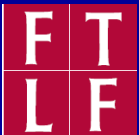
- Compliance with procurement standards does not:
  - Make the Federal government a party to the contract
  - Affect the health center's overall responsibility for the federally sponsored project or its accountability to the government for Federal funds



# Key Compliance Risks

## Federal Anti-Kickback Law

- Purpose: prohibits persons and entities from
  - Knowingly or willfully ...
    - Person or entity knows or has reason to know that what he/she/it is doing constitutes prohibited conduct and
    - Person or entity continues to engage in the activity
  - Soliciting or receiving ...
  - Remuneration directly or indirectly, in cash or in kind ...
    - Includes the transfer of anything of value, including monetary savings through the use of discounts, rebates and free goods and/or services ...
  - To induce patient referrals or the purchase or lease of equipment, goods or services ...
  - Payable in whole or in part by a Federal health care program



# Key Compliance Risks

## Federal Anti-Kickback Law

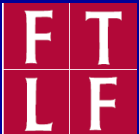
- Safe Harbors – arrangements deemed by Congress / DHHS to present a low risk of fraud and abuse
  - Must meet all requirements to be protected automatically
  - However, if an arrangement does not meet all requirements, does not necessarily mean that it is illegal
  - case-by-case analysis



# Key Compliance Risks

## Federal Anti-Kickback Law

- Violations of the statute can result in
  - Criminal liability:
    - Felony conviction - \$25K fine, imprisonment up to 5 years, or both
  - Civil penalties
    - Up to \$50K fine and damages of 3x amount of remuneration
  - Administrative proceedings
    - Suspension or exclusion from participating in Federal health care programs

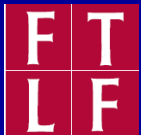




# Key Compliance Risks

## Grant Funded Health Center Safe Harbor

- Issued October 4, 2007
- Purpose: protect from prosecution under the federal anti-kickback law
  - Certain arrangements between health center grantees and providers/suppliers of goods, items, services, donations and loans ...
  - That contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided ...
  - To the health center's medically underserved patients
- Does not apply to FQHC look-alike entities



# Key Compliance Risks

## Safe Harbor Word of Caution ...

- To ensure compliance with the health center safe harbor, health centers should
  - Ensure that arrangements involving donations and/or low or no cost goods, items, services, loans, etc., comply with all regulatory requirements of the underlying safe harbor
  - Ensure that the health center does not enter into arrangements with partners who condition business on value or volume of referrals

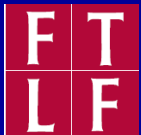
**AND, MOST OF ALL - DO NOT GUARANTEE ANY REFERRALS UNDER ANY ARRANGEMENT**



# Key Compliance Risks

## Patient Gifts: Beneficiary Inducement Prohibition

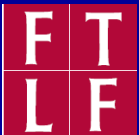
- Purpose: prohibits the offering or transferring of remuneration and/or inducements (including waivers or reductions of coinsurance and deductible amounts, and items or services for free or for other than fair market value) ...
  - To beneficiaries of Medicare, Medicaid and other State health care programs receiving federal funds from Maternal and Child Health programs, Social Services programs, or State Children's Health Insurance Program ...
  - Which are likely to influence the beneficiaries ...
  - To choose good or services from a particular supplier or provider ...
  - Paid for in whole or in part by such programs
- Impacts both actual and potential patients



# Key Compliance Risks

## Patient Gifts: OIG Special Advisory Bulletin Guidelines

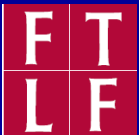
- August 2002: OIG Special Advisory Bulletin describes **scope of acceptable practices** for offering gifts or other inducements to Medicare and Medicaid beneficiaries
  - Inexpensive (“de minimis”) gifts or services (other than cash or cash equivalents) that have a retail value of no more than
    - \$10 individually AND
    - \$50 in the aggregate annually per patient



# Key Compliance Risks

## Patient Gifts: OIG Special Advisory Bulletin Guidelines

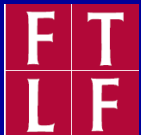
- Scope of acceptable practices (cont.)
  - More expensive items or services that fit within certain statutory exceptions
    - Non-routine, unadvertised waivers of cost-sharing amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts
    - Properly disclosed differentials in a health plan's copayments or deductibles
    - Waiver by health centers of coinsurance and deductible amounts for patients who qualify for the center's sliding fee scale (individuals or families with annual incomes at or below 200% of FPG)



# Key Compliance Risks

## Patient Gifts: OIG Special Advisory Bulletin Guidelines

- Scope of acceptable practices (cont.)
  - Statutory exceptions (cont.)
    - Incentives to promote the delivery of preventive care
      - Items or services covered by Medicare or Medicaid and are either pre-natal / post-natal well-baby services
      - Services described in the *Guide to Clinical Preventive Services* (published by the US Preventive Services Task Force)
    - Waivers of copayment amounts that exceed the minimum copayment amount under the Medicare hospital outpatient fee schedule



# Key Compliance Risks

## Patient Gifts: Do's and Don'ts

- If you cannot meet the “de-minimis” standards or a statutory exception
  - Do not provide gifts that are only tangentially related to promoting good health and/or health care
  - Do not provide gifts/gift cards that can be redeemed for cash or for services or items provided by the health center
  - Do not provide gift cards for stores or vendors that are operated by other health care providers and/or that contain health care goods and services (such as pharmacies) OR
  - Limit items that can be purchased to non-health care related items or the departments within the store in which purchases are made



# Key Compliance Risks

## Patient Gifts: Do's and Don'ts

- Do not use gifts/gift cards to market or promote the health center organization (except for inexpensive items provided at health fairs and similar community events)
- Use gifts/gift cards in conjunction with
  - Medically necessary and appropriate treatment plans or clinical programs as a means to reward compliance and good health outcomes
  - Government-supported and approved programs, with the gifts/gift cards themselves approved as part of the scope of work and budget
  - BUT - do not provide gifts that have values disproportionate to the goals being achieved

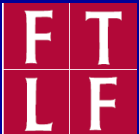




# Key Compliance Risks

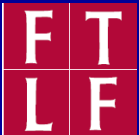
## Other Compliance Hot Topics of 2009

- Section 330-related requirements
  - Scope of Project
  - 340B drug diversion and charges/discount approach
  - FTCA issues
- Coding and Billing
  - Billing by unlicensed providers (or providers licensed in other jurisdictions)
  - Billing under another provider's name
- Employing or contracting with suspended or excluded providers
  - <http://www.oig.hhs.gov/fraud/exclusions.html>
  - <http://www.gsa.gov>
- Executive Compensation



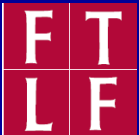
# Benefits of a Corporate Compliance Program

- **OIG emphasis of the provider's ethical and legal duty to ensure that it is not submitting false or inaccurate claims to government and private payors.**  
(See, e.g., OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399, 58400; Physician Guidance, 65 Fed. Reg. 59434, 59435)
- **Reduction in coding and billing errors is also consistent with ethical standards that apply to health care practitioners and business practices.**  
(See, e.g., American Medical Association, Second Principle of Medical Ethics ("A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception."))



# Benefits of a Corporate Compliance Program

- Demonstrate to employees and the community at large the organization's strong commitment to honest and responsible provider and corporate conduct
- Identify and prevent illegal and unethical conduct
- Improve the quality of patient care
- Create a centralized source for distributing information on health care statutes, regulations and other program directives related to fraud and abuse and related issues



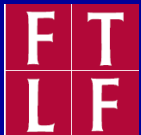
# Benefits of a Corporate Compliance Program

- Develop a methodology that encourages employees to report potential problems
- Develop procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, physicians, and other health care professionals and consultants
- Initiate immediate and appropriate corrective action
- Minimize the loss to the government from false claims through early detection and reporting, and thereby reduce the organization's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion.



# Seven Elements of Effective Corporate Compliance Programs

- Section 330 Implementing Regulations require a health center's **Board of Directors** to ensure that the health center is operated in compliance with all applicable Federal, State and local laws and regulations (*See* 42 C.F.R. § 51c.304(d)(3)(v))
- Implementation of a corporate compliance program is an effective means of meeting this obligation
- The Board is responsible for **oversight** and **evaluation** of the compliance program



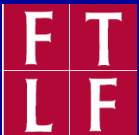
# Seven Elements of Effective Corporate Compliance Programs

- Serves as notice that all providers should implement comprehensive, effective corporate compliance programs
- *OIG Compliance Program for Individual and Small Group Physician Practices* (65 Fed. Reg. 59434 *et. seq.*, October 5, 2000)
  - Incorporates the 7 elements common to all programs
  - Recognizes need for flexibility by permitting providers to
    - Take into account each provider's facts and circumstances, *e.g.*, size, complexity, resources, type of practice, and compliance history
    - Use a multi-tiered, step by step approach



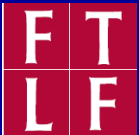
# Seven Elements of Effective Corporate Compliance Programs

- **Compliance Program Guidance for Individual and Small Group Physician Practices** (65 Fed. Reg. 59434)
  - Draws distinction between “small” and “large” health centers:
    - Flexible, step-by-step approach to implementing a formal compliance program
    - Takes into account financial and staffing constraints of smaller practices
  - However, no bright line distinction
  - Each health center must make its own determination whether Small Group Practice Guidance is applicable and appropriate for developing corporate compliance program



# Seven Elements of Effective Corporate Compliance Programs

- **Seven elements** of all compliance programs
  - Designate a compliance officer/contact
  - Conduct initial (“baseline”) internal monitoring and oversight, and regular audits thereafter
  - Develop written standards and policies to implement the compliance program and govern health center operations
  - Conduct culturally and linguistically competent training and education programs
  - Develop effective, clear, open lines of communication between compliance and health center personnel - open door policy and policy prohibiting retaliation
  - Investigate detected problems and develop corrective action
  - Publicize and enforce disciplinary standards

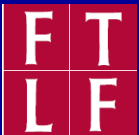




# Seven Elements of Effective Corporate Compliance Programs

## Compliance Officer Position

- Position of authority to show health center's commitment to compliance
- If compliance duties assigned to existing staff member, keep position separate from CFO, billing and coding personnel and general counsel (conflict of interest)
- Must be vested with authority necessary to conduct appropriate follow-up and report findings directly to Executive Director and Board of Directors
- Authority to conduct investigations and communicate directly with legal counsel and other outside investigative resources (through appropriate channels)



# Seven Elements of Effective Corporate Compliance Programs

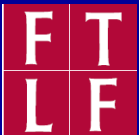
## Compliance Officer Qualifications

### ■ Personal Qualities

- Integrity
- Sound judgment
- Demonstrated leadership skills
- Assertive
- Approachable

### ■ Industry-Specific Experience

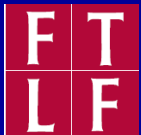
- Expertise and experience dealing with health care industry compliance issues
- Familiar with high-risk areas identified by OIG
- Familiar with activities of other government agencies with regulatory and enforcement authority over health centers



# Seven Elements of Effective Corporate Compliance Programs

## Establishing a Compliance Committee (Staff)

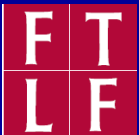
- Function: advise compliance officer and assist in the development and implementation of compliance program
- Advantage: allows compliance officer to delegate routine but essential functions of compliance programs



# Seven Elements of Effective Corporate Compliance Programs

## ■ Audits

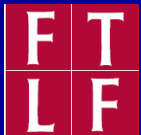
- Generally: excellent way to ascertain if problem areas exist and, if so, chart corrective action.
- In particular, audits in billing/claims area can show whether or not:
  - The health center has accurate, complete standards and procedures
  - Claims submission practices are in compliance
  - Billing is accurate
  - Documentation is correct
  - Services/items are reasonable and necessary
  - There are improper incentives for unnecessary services



# Seven Elements of Effective Corporate Compliance Programs

## ■ Auditing and Monitoring

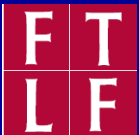
- Conduct comprehensive baseline self-audit of coding and billing practices
- Claims submission practices (under compliance officer's direction) should be audited at least once per year
- Audit other functions as appropriate, considering historic high-risk areas for your health center
- Implement follow-up audits and monitoring
- Promptly communicate results to compliance officer, contacts or committee, as applicable



# Seven Elements of Effective Corporate Compliance Programs

## ■ Written Standards and Procedures

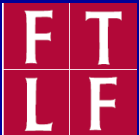
- “a central component of any compliance program”
- Purpose: to promote quality and to provide a structured approach for reducing erroneous claims, fraudulent activity and other non-compliant behavior within the organization
- Applicability: essential for all healthcare providers, regardless of size and capacity
- **Caution:** Do not adopt written standards that the health center cannot implement or with which the health center cannot comply



# Seven Elements of Effective Corporate Compliance Programs

## ■ Training and Education

- Need not be formal, classroom-style training
- Standard: effective communication
- Can offer:
  - In-person sessions
  - Newsletters
  - Office bulletin board
- Use training and education to address specific problem areas or vulnerabilities identified in audit or by health center staff



# Seven Elements of Effective Corporate Compliance Programs

## ■ Training and Education

### – Frequency

- Basic training in compliance each year
- Specialized training in functional areas upon hiring and as needed thereafter
- Targeted training ASAP after serious compliance issue is identified

### – Timing

- New employees to be trained “as soon as possible after assuming their duties”

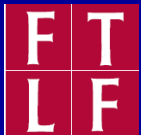




# Seven Elements of Effective Corporate Compliance Programs

## ■ Open Communication

- Establish written confidentiality and non-retaliation policies
- Develop procedure for employees to seek clarification from compliance officer if question arises
- Require employees to report conduct that a reasonable person would, in good faith, believe to be erroneous/fraudulent
- Create a user-friendly process (e.g., anonymous drop box) for effectively reporting improper conduct
- Include provisions in written standards of conduct stating that failure to report erroneous/fraudulent conduct is a violation of compliance program



# Seven Elements of Effective Corporate Compliance Programs

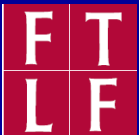
## ■ Open Communication

### – Methods:

- Open door policy assuring access to compliance officer/contacts and senior management generally
- Conspicuous notices in common areas
- Bulletin board dedicated solely to compliance
- Drop box
- Anonymous Hotline

### – Documentation:

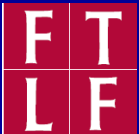
- Document all reports and action taken in response
- Maintain log of reports



# Seven Elements of Effective Corporate Compliance Programs

## ■ Investigation

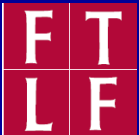
- Compliance officer must promptly investigate suspected non-compliance
- Investigation should be directed by Executive Director + compliance officer
  - Use of legal counsel
- Methods:
  - Interviews
  - Document review
  - Engage legal counsel, outside auditors or health care experts to assist, as appropriate



# Seven Elements of Effective Corporate Compliance Programs

## ■ Disciplinary Standards

- Must establish procedures for disciplining individuals who violate law/applicable standards
- Necessary to add credibility and integrity to your compliance program
- State your commitment to enforcing the law and applicable standards
- Set forth standards of conduct in board policies, personnel policies and contracts including disciplinary actions that may be imposed as a result of illegal/unethical conduct
- Disciplinary guidelines must be well publicized in personnel manuals and contracting procedures
- Address guidelines in in-house training

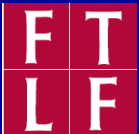


# Seven Elements of Effective Corporate Compliance Programs

## ■ Disciplinary Standards

### – Types of Actions:

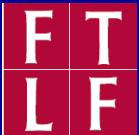
- Warnings (oral)
- Reprimands (written)
- Probation
- Demotion
- Temporary suspension
- Termination or removal (in the instance of board members)
- Restitution or damages
- Referral for criminal prosecution



# Seven Elements of Effective Corporate Compliance Programs

## ■ Risk Management:

- The OIG considers risk assessment to be a key component of an effective compliance program.
- According to the OIG, organizations should conduct a comprehensive risk analysis or obtain one from a consultant.
- The OIG believes that a properly conducted risk assessment would
  - Identify and rank the various compliance and business risks that the organization may experience in its daily operations and
  - Serve as the basis for written policies the organizations develops to mitigate those risks



# Seven Elements of Effective Corporate Compliance Programs

- **OIG Guidance to Boards of Health Care Providers**
  - Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (April 2003)
  - An Integrated Approach to Corporate Compliance (July 2004)
  - Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (Sept. 2007)



# Questions?

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