Good Intentions Are Not Enough: How to Re-Energize Your Compliance Program Through Focus, Support, and Accountability

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For legal advice, you should consult a qualified attorney.
LEARNING OBJECTIVES

After completing the training, participants will be ready to:

- Implement an organizational strategy for an effective compliance program
- Create organizational incentives that reward compliance outcomes and connect compliance to organizational initiatives
- Promote accountability for compliance from top to bottom of the organization

GOOD INTENTIONS? NOT A DEFENSE

- False Claims Act liability based on conduct organizations should have known (but did not)
- Medicaid payment suspensions for credible allegations of fraud (but not proven)
- False Claims Act / whistleblower lawsuits based on self-audit documentation (conducted for the purpose of identifying compliance risks)
DON’T BE ONE OF THE HEADLINES!!

- Health center pays $825,000 to settle allegations it billed Medicaid for visits to non-health center patients, by non-health center providers
- Health center settles False Claims Act allegations related to excluded employee for $270,000
- Former CEO charged in scheme to defraud health centers of $14 million
- Former mental health clinic owner sentenced for role in $3.4 million Medicaid fraud scheme
- COO of nonprofit pleads guilty to stealing more than $34,000
- Former operator of mental health care facility receives five years in prison for Medicaid fraud
- Former health center CEO sentenced to 19 months, restitution of over $100,000 and debarred for five years

OIG WORK PLAN

FY2015 to FY2016

- OIG will review Affordable Care Act-funded capital development grants for compliance with grant requirements, including:
  - Having adequate financial management controls over capital development grant funds
  - Following procurement standards in accordance with federal requirements
  - Meeting reporting requirements in accordance with the grant’s terms and conditions
  - Claiming allowable costs for construction
  - Meeting grant-established project milestones

- HRSA oversight of vulnerable health center grantees (i.e., health centers with documented compliance issues), focusing on HRSA’s award of funds to grantees with serious, ongoing compliance or performance issues
OIG WORK PLAN

In the current fiscal year, OIG has released six reviews:

- Two health centers were found out of compliance with federal requirements:
  - Inadequate financial management system
  - Insufficient equipment records
  - Failed to meet procurement standards (documentation, competitive bidding, contract provisions)
  - Failed to provide services consistent with grant application
- In both of these cases, the OIG recommended that HRSA require the return (or disposition of property in order to refund) the grant funds ($35,000 and $897,000). OIG recommended HRSA work to strengthen financial, property management and procurement controls over grant funds.

- One health center was found to have generally complied
- Three health centers were found to have complied

WHAT IS THE BEST DEFENSE?

Knowledge is at the core of a high-performing compliance program.

- Educating boards and staff on their legal requirements and obligations.
- Experience of a seasoned Compliance Officer.
- Information gathered from reports of potential non-compliance.
- Learning of non-compliance from audits and monitoring.
- Analyzing the reasons that led to non-compliance.
- Solving the business challenge of “operationalizing” compliance requirements.
MANDATORY COMPLIANCE PROGRAMS

The Affordable Care Act requires, as a condition of enrollment in Medicare, Medicaid, and CHIP, that providers establish a compliance program

- Core components of compliance program to be established by the Secretary of HHS in consultation with the OIG
- Will be specific to particular industry or category of supplier or provider
- Effective after HHS issues regulations

PROBLEM #1: UNFOCUSED PROGRAMS

Common symptoms:

- Lack a method of assessing and prioritizing compliance risk areas
- Get distracted by the problem “de jour”
- Does not establish a compliance program work plan to guide activities and allocate resources.
- Fail to tailor compliance program to the size and budget of the organization
**RE-FOCUS YOUR COMPLIANCE PROGRAM**

Focus on “big-ticket” compliance matters that will offer the best return on investment.

- Conduct an objective compliance risk assessment to identify the organization’s highest risks.
- Develop a compliance program work plan based on the results of the compliance risk assessment.
- Monitor (and report) progress of completing activities on the compliance program work plan.

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**RISK ASSESSMENTS**

- **Severe**
- **Serious**
- **Moderate**

**SEVERITY OF CONSEQUENCES**

**Remote**  **Possible**  **Probable**

**LIKELIHOOD OF OCCURRENCE/ENFORCEMENT**

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COMPLIANCE PROGRAM WORK PLANS

Address risk areas by developing a work plan

- A work plan is a list of projects or actions that are conducted in response to a risk area
- Potential work plan “actions”:
  - Training and education
  - Review and development of policies and procedures
  - Audits / assessments
  - Monitoring
- Disperse responsibility for work plan activities among senior management.

Federal Civil False Claims Act (31 U.S.C. § 3729-3733)

The FCA forbids *knowingly*:

- Presenting or causing the presentation of, a false claim for reimbursement by a Federal health care program, including Medicare or Medicaid;
- Making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim;
- Repaying less than what is owed to the Government;
- Knowingly and improperly avoiding or decreasing an obligation to pay the Government*; and
- Conspiring to defraud the Federal Government through one of the actions listed above.

*Knowingly* means:

- Actual awareness of falsity
- Deliberate ignorance of the truth or falsity
- Reckless disregard of truth or falsity

*Note: Knowing retention of overpayment beyond due date (i.e., 60 days from identification or when applicable cost report is due) is considered an “obligation” under the False Claims Act.*
RISK AREA: BILLING, CODING & DOCUMENTATION

Return of Overpayments: CMS New Final Rule

• “Identified an overpayment”: When the person has or should have, through the exercise of reasonable diligence, determined that an overpayment was received and quantified the amount of the overpayment.

• Reverse false claim: Any overpayment retained by a person after the deadline for reporting and returning the overpayment is an obligation for purposes of the False Claims Act.

Whistleblower/Qui Tam Lawsuits

• Protects employees and contractor whistleblowers from “retaliation”

• If successful, relator receives 15-30% of proceeds.

Penalties

• Under the new rule published on June 30, 2016, the FCA penalties rise to a minimum of $10,781 and a maximum of $21,563 per false claim plus three times the amount of the overpayment. (New penalties are effective August 1, 2016 and will be applied for violations occurring after Nov. 2, 2015.)

• OIG can also impose civil monetary penalties (CMPs) or exclude a provider from participation in Federal health care programs.

IMPROPER LICENSURE OR CERTIFICATION

• **Licensure**: In order for a practitioner’s services to be billable, the practitioner must be:
  – Licensed
  – Performing services that are permitted within the scope of his/her license
  – Adequately supervised, if applicable for the type of license held by the practitioner

• **Certification**: Providers must comply with state certification requirements.

• **Credentialing**: Many payors require that all practitioners be credentialed/enrolled with the payor for the provider to bill for their services.

• **Exclusion**: No Federal health care program payment may be made for any items or services furnished by an excluded individual or entity (or referred by an excluded individual or entity).
Available at: https://www.supremecourt.gov/opinions/15pdf/15-7_a074.pdf.

Key Facts
• In 2009, a 17 year-old patient died from an adverse reaction to a prescribed bipolar disorder medication.
• During the five years leading up to her death, the patient received counseling services from a satellite mental health facility owned and operated by Universal Health Services.
• Massachusetts investigated and issued a report detailing violations of over a dozen Medicaid regulations related to the qualifications and supervision required for staff at the mental health facilities.
• The patient’s parents filed a qui tam suit alleging that Universal Health Services violated the False Claims Act under an implied false certification theory of liability.
• They contended that every submission of a claim implicitly represents that the provider is entitled to payment and that failing to disclose violations of material legal requirements makes the claim misleading or false.

Ruling Highlights
• The Supreme Court held that implied false certification can, in some circumstances, provide a basis for liability under the FCA.
• Those circumstances are:
  1. the claim does not merely request payment, but also makes specific representations about the goods or services provided; and
  2. the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading.
• The Supreme Court remanded the case back to the lower court for further proceedings.
ADDRESSING KEY RISK AREAS

- Track licensure, credentialing / enrollment
- Know scope of practice for each licensed practitioner (and ensure that license is not exceeded!)
- Train practitioner staff (anyone who enters information in the medical record)
- Train billing staff (anyone who participates in the claims submission process)
- Monitor for changes to payor billing requirements
- Conduct billing and coding audits
- Screen for exclusion (and document!)

PROBLEM #2: UNSUPPORTED COMPLIANCE PROGRAM

Common Symptoms:
- Board of Directors has little interaction with Compliance Officer
- Management team does not invite Compliance Officer’s participation in meetings
- Employees do not seek guidance from Compliance Officer
HOW TO BUILD SUPPORT FOR THE COMPLIANCE PROGRAM

Build support by supporting others:

- **Board of Directors**: Explain how the compliance program helps fulfill fiduciary duties
- **Management**: Help management team fulfill their compliance responsibilities.
- **Staff**: Direct staff to applicable policies; earn trust to protect confidentiality, not police employees

BOARD RISK AREA: BREACH OF FIDUCIARY DUTIES

- Personal liability may result from breach of fiduciary duties
  - *In re Lemington Home for the Aged Comm. Of Unsecured Creditors*, 777 F.3d 620 (3rd Cir. 2015).
  
  - Directors breached duty of care by failing to exercise reasonable diligence and prudence over the institution and its poorly performing management team.
    - Allowed CEO to work on part-time basis in violation of state law
- Compliance programs assist the board in ensuring the organization complies with applicable rules
MANAGEMENT AND STAFF RISK AREA:
SLIDING FEE DISCOUNT PROGRAM

- HRSA released PIN 2014-02 related to the sliding fee discount and related billing and collections program requirements
- Clarifies several aspects of the sliding fee discount program, including:
  - Use of multiple sliding fee discount schedules
  - Application of discounts to patient cost sharing amounts and supplies/equipment
  - Cash/prompt payment discounts
  - Role of the governing board in establishing and approving the sliding fee discount program
- Compliance Officer can assist:
  - Review and revision of sliding fee policies and procedures
  - Training of employees on new policies and procedures
  - Auditing documentation requirements

RISK AREA: CONFIDENTIALITY OF MENTAL HEALTH INFORMATION

HHS released new guidance on Feb. 22, 2014 related to mental health information

Clarifies when HIPAA permits communications
  - With a patient’s family members, friends, or caregivers
  - With a parent of a minor patient
  - About an individual’s harm to self or others

Compliance Officer can assist:
  - Review and revision of existing BAA, NPP, and privacy policies for compliance with HIPAA and Part 2
  - Training of employees and volunteers on confidentiality
  - Resolving specific confidentiality issues that arise
PROBLEM #3: UNACCOUNTABLE COMPLIANCE PROGRAM

Common Symptoms:

– Exists on paper only
– Fails to clearly assign responsibility for tasks
– Fails to engage in any audits to identify non-compliance
– Devotes few resources or time to training and education

INTEGRATING ACCOUNTABILITY INTO YOUR COMPLIANCE PROGRAM

The Seven Elements

1. Designate a compliance officer
2. Develop written standards and policies to implement the compliance program and govern operations
3. Implement training and education programs
4. Establish effective, clear, open lines of communication (internal reporting)
5. Conduct internal monitoring and regular audits
6. Respond to detected issues
7. Publicize and enforce disciplinary standards
1. Designate a Compliance Officer

Designate an employee with responsibility for the day-to-day operation of the compliance program

- Employee’s duties may solely relate to compliance or may be combined with other duties so long as compliance responsibilities are satisfactorily carried out
  - Employee should not hold financial, billing/coding or legal/counsel responsibilities
- Employee must report directly to the organization’s chief executive, or senior administrator designated by the chief executive

Integrating Accountability: Compliance Officer

- Compliance Officer should be held accountable for:
  - Implementing a compliance program that meets OIG standards and, as applicable, legal requirements for compliance programs
  - Conducting compliance risk assessments
  - Development of annual compliance work plan
  - Preparing and revising compliance program policies and procedures
  - Periodic reporting to the Board of Directors
- Compliance Officer should not be held accountable for the organization’s compliance with all legal requirements.
2. Develop written standards

- **Purpose:** To establish and publicize standards for organization’s operations
  - Standards of Conduct / Conflicts of Interest
  - Compliance program
  - Clinical / Financial / Operational
- **Caution:** Do not adopt written standards that the organization cannot implement or with which the organization cannot comply
- Do tailor documents to your organization’s operations
- Must be accessible to those who are supposed to follow them

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**Standards of Conduct**

- All organizations should formally adopt standards of conduct applicable to all Board members, employees and agents
- **Content:**
  - Organization’s mission
  - Commitment to compliance with law
  - Business conducted in accord with highest ethical standards
  - Procedures to avoid and address conflicts of interest, including disclosure requirements, recusal by conflicted persons from deliberation and/or votes, arm’s-length procurements, etc.
  - Emphasis on fraud abuse and prevention
- **Required for grantees under federal procurement standards; Recommended by OIG**
INTEGRATING ACCOUNTABILITY INTO YOUR COMPLIANCE PROGRAM

Integrating Accountability: Written Policies

- Board of Directors should be held accountable for developing and approving written Standards of Conduct for the organization.
- CEO should hold each department accountable for development of policies and procedures to promote compliance as well as revising policies and procedures to comply with changes in legal requirements and best practices.
- Compliance Officer should be held responsible for developing compliance program policies and procedures consistent with applicable standards.

ACCOUNTABILITY FOR COMPLIANCE

3. Training and education

- Need not be formal, classroom-style training
- Objective: Effective communication of organizational policies and procedures as well as applicable legal requirements
- Can offer:
  - In-person sessions
  - On-line courses
  - Newsletters
  - Office bulletin board/ Intraweb
INTEGRATING ACCOUNTABILITY INTO YOUR COMPLIANCE PROGRAM

General Compliance Training

• Operation and importance of program
• Benefits to organization, patients and community
• Role of each individual in compliance program operation
• Standards of conduct
• Consequences of violating standards and procedures, including potential civil and criminal liability to organization

Specialized Training

• Staff should receive training on risk areas specific to their job functions (claim development and submission, procurement, grant reporting, etc.)

Targeted Training

• Use training and education as corrective action to address specific problem areas or vulnerabilities identified by the organization

Integrating Accountability: Training and Education

• Should require each employee to obtain initial and annual General Compliance Training
• Should make completion of any required training a prerequisite for receiving a raise or performance bonus
• Should require departments to establish training and education goals for each employee.
4. Open Lines of Communication

**Internal Reporting**

- Require, as a condition of continued employment, the reporting of conduct that a reasonable person would, in good faith, believe to be non-compliant
- Include provisions in written standards of conduct stating that failure to report potentially non-compliant conduct is a violation of compliance program policy
- Develop procedure for individuals to seek clarification from compliance officer if questions arise

**Whistleblower protections**

- Ensure protection (non-retaliation) of those who report or assist in investigations (whistleblowers)
- Prohibition on any form of retaliation for reporting in good faith
- Individuals affiliated with organization will not be
  - Terminated
  - Suspended
  - Demoted
  - Subject to other adverse action
- Any actual or threatened retaliation should be reported as non-compliant conduct
INTEGRATING ACCOUNTABILITY INTO YOUR COMPLIANCE PROGRAM

Integrating Accountability:
Open Communication

- Should require employee reporting of conduct that a reasonable person would, in good faith, believe to be non-compliant
  - Include flexibility of reporting to supervisor or Compliance Officer as well as anonymous reporting options
- Should require immediate reporting of loss of clinical licensure, or potential loss thereof.

5. Monitoring and Auditing

Monitoring v. Auditing

- An audit is an organization’s retroactive assessment of compliance with applicable legal requirements
  - An internal audit or self-audit is an organization’s objective assessment, performed by internal staff or at their direction, with results not reported outside the organization
- Monitoring is a “real-time” assessment of whether on-going activities or operations are in compliance with applicable legal requirements
INTEGRATING ACCOUNTABILITY INTO YOUR COMPLIANCE PROGRAM

Conduct Audits that are Appropriate for Your Organization

Recommendations:
• Conduct comprehensive baseline self-audit of coding and billing practices
• Claims submission practices should be audited at least once per year
• Audit other functions as appropriate, considering historic high risk areas for your organization
• Conduct an “audit” of your written policies and procedures
• Conduct an “audit” of your compliance program
• Implement follow-up audits and monitoring
• Promptly communicate results to Compliance Officer, as applicable

Integrating Accountability: Auditing and Monitoring

• Should integrate compliance monitoring activities into day-to-day policies and procedures
• Should expect departments to audit compliance with legal requirements and policies/procedures
• Should establish performance goals for compliance in key risk areas
6. Responding to Detected Issues

- Organization must promptly respond to suspected non-compliance
- Response often includes an investigation to determine facts
- Engage legal counsel, outside auditors or health care experts to assist, as appropriate
- Report results and take corrective action

Integrating Accountability: Responding to Detected Issues

- Compliance Officer should maintain a confidential log of compliance issues
- Department manager should be responsible for:
  - Conducting root cause analysis to determine cause of non-compliance
  - Implementing or revising procedures to reduce potential risk of recurrence
  - Auditing issue in 60 or 90 days to determine if changes fully addressed issue
- Compliance Officer should report outcome of compliance investigation and response to CEO.
- CEO should hold department manager accountable for implementing changes to prevent compliance issue in the future.
7. Disciplinary Standards

- Establish procedures for disciplining individuals who violate law/applicable standards
- Set forth standards of conduct in governing board policies, personnel policies and contracts, including disciplinary actions that may be imposed as a result of illegal/unethical conduct
- Address guidelines in in-house training
- Necessary to add credibility and integrity to your compliance program

Integrating Accountability: Disciplinary Standards

- All employees should be held accountable for complying with applicable policies and procedures:
  - Condition of employment or contracting
  - Incorporate “compliance” in performance reviews
- Make failure to report potentially non-compliant conduct a violation of organization’s compliance program
- Make failure to report loss, or potential loss, of license a violation of organization’s compliance program
INTEGRATING COMPLIANCE THROUGHOUT YOUR ORGANIZATION

- Activate the compliance program by making it matter.
- Make it relevant to everyone’s job.
- Hold managers responsible for compliance for activities within their control.
- Include “compliance” as factor in annual performance evaluations.

ACCOUNTABILITY FOR COMPLIANCE: MANAGERS

Managers should be asked:
- How do you hold your staff accountable for compliance?
- How do you know if your department/area is in compliance?
- How do you keep staff abreast of the legal requirements your department/area is held to?
- How does your staff monitor compliance?
- How does your department audit its compliance?
- How do you measure compliance?
ACCOUNTABILITY FOR COMPLIANCE: ALL STAFF

Staff should be asked:

• What policies and procedures are you subject to?
• How do you monitor compliance with those policies and procedures?
• Have you attended mandatory compliance training?
• What are your responsibilities under the organization’s compliance program?

KEY TAKE-AWAYS

• Don’t sweat the small stuff. Focus on “big-ticket” compliance matters that will offer the best return on investment.
• Support is a two-way street. Build support for compliance by supporting others to fulfill their compliance obligations.
• Promote accountability for compliance. Activate the compliance program by making it matter to all employees.
QUESTIONS?

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