Compliance, Quality and Risk Management: Structure and Focus to Meet Current Challenges

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LEARNING OBJECTIVES

- Understand the key elements of compliance, quality and risk management requirements
- Identify areas where compliance, quality and risk management efforts may overlap and conflict
- Promote accountability for compliance, quality and risk management at all levels of the organization
AGENDA

1. Definitions and requirements:
   - Compliance
   - Quality
   - Risk management
2. Top challenges and responses
3. Questions and answers

What Do We Mean by “Compliance”? 

[Image of a diagram related to compliance]
COMPLIANCE

• Conforming to a rule, policy, standard or law

• A compliance program is a proactive and reactive system to ensure that the rules applicable to an organization are followed

COMPLIANCE PROGRAMS: BACKGROUND

FEDERAL SENTENCING GUIDELINES

• Provide incentives for organizations to adopt programs designed to eliminate violations of federal law

• Corporations and their agents may receive lesser sentences and fines if their corporations have implemented effective Compliance Programs

• Even if the Compliance Program was implemented after the violation, most federal prosecutors and judges will look favorably on an organization that has implemented an effective program
COMPLIANCE PROGRAMS: BACKGROUND
THE OIG

OIG Compliance Program Guidance Documents

  - Defines seven elements of effective Compliance Programs
  - Identifies high risk areas
  - Acknowledges different expectations for different organizations
  - Recognizes limited resources of smaller organizations

Seven Elements of Compliance Programs

1. Designate a Compliance Officer/contact
2. Develop written standards and policies to implement the Compliance Program and govern operations
3. Conduct training and education programs
4. Develop open lines of communication between compliance and health center personnel
5. Conduct initial and regular internal monitoring and auditing
6. Investigate detected problems and develop corrective action
7. Publicize and enforce disciplinary standards
COMPLIANCE PROGRAMS: BACKGROUND

FEDERAL GRANTS

**Section 330:** Implementing regulations require a health center’s Board of Directors to ensure that the health center is operated in compliance with applicable federal, state and local laws and regulations (42 CFR § 51c.304(d)(3)(v)).

– Practically, this requirement is implemented by having a Compliance Program

**Uniform Grants Guidance:** Federal procurement standards require grantees that use federal funds to purchase goods and services to adopt Standards of Conduct that address conflict of interest (including organizational conflicts of interest), solicitation and acceptance of gifts, and applicable disciplinary actions.

COMPLIANCE PROGRAMS: BACKGROUND

MEDICAID

**Section 6032 of the Deficit Reduction Act (2007):** Entities that receive Medicaid payments of $5 million or more annually must, as a condition of participation:

• Establish written policies for all employees (including management), agents, and contractors that include detailed information about:
  – The entity’s policies for detecting and preventing fraud, waste, and abuse in federal health care programs
  – Federal and State False Claims Acts
  – Administrative remedies for false claims and statements
  – Whistleblower protections under such laws

• Must include in employee handbook (if applicable)
COMPLIANCE PROGRAMS BACKGROUND:
AFFORDABLE CARE ACT

- As a condition of enrollment in Medicare, Medicaid, and CHIP, providers must establish a Compliance Program.

- Core components of Compliance Programs to be established by the Secretary of HHS in consultation with the OIG:
  - Specific to particular industry or category of supplier or provider.
  - Effective after HHS issues regulations.

Potential False Claims liability:
- If a provider has a Compliance Program that does not meet the standards established by HHS; or
- If a provider fails to implement any Compliance Program.

Effective date: CMS has not yet issued regulations specific to health centers; however, regulations for other provider types/entities are affecting health centers.

COMPLIANCE PROGRAMS: BACKGROUND

- Creates a centralized source for distributing information on healthcare laws and regulations.
- Assures participation in training regarding compliance with applicable laws, regulations, policies.
- Develops a methodology that encourages employees to report potential problems.
- Develops procedures allowing prompt, thorough investigation of alleged misconduct.
- Prompts immediate, appropriate corrective action.
- Minimizes loss to the government from false claims and consequently reduces the entity’s own exposure to liability.
COMPLIANCE PROGRAMS: BACKGROUND

Helps to organize and understand the various applicable requirements through:

- Program structure: Compliance Officer, Compliance Committee, Board oversight
- Development of an annual work plan
- Written policies and procedures
- Internal monitoring and auditing
- Training and education

What Do We Mean by “Quality”?
QUALITY

• “Safe, effective, patient-centered, timely, efficient and equitable.”

• Goals of a quality program:
  • To encourage higher standards of care
  • To improve the average level of practice
  • To eliminate or educate poor practitioners and providers
  • To detect and correct issues when they occur
  • To prevent problems from occurring

PRINCIPLES OF A QUALITY IMPROVEMENT/ASSURANCE PROGRAM

1. Considers the systems and processes:

2. Focuses on patients
   – Are patient needs and expectations being met?

3. Team-based
   – Assemble individuals with diverse perspectives and skillsets to tackle complex QI problems

4. Use of data
   – Data describes how current systems are functioning, how changes impact functioning, and provides documentation of success
Health Center Program Compliance Manual
Quality Improvement/Assurance (QI/QA)

• Health center must have an ongoing quality improvement/assurance (QI/QA) system that includes clinical services and [clinical] management, and that maintains the confidentiality of patient records.

The health center’s ongoing QI/QA system must provide for all of the following:

• Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care; and

• Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments must:
  • Be conducted by physicians or by other licensed health professionals under the supervision of physicians;
  • Be based on the systematic collection and evaluation of patient records;
  • Assess patient satisfaction, achievement of project objectives, and include a process for hearing and resolving patient grievances; and
  • Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.
HRSA QUALITY REQUIREMENTS

• The health center must maintain the confidentiality of patient records, including all information as to personal facts and circumstances obtained by the health center staff about recipients of services. Specifically, the health center must not divulge such information without the individual’s consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary of HHS or his/her designee with appropriate safeguards for confidentiality of patient records.

HRSA QUALITY REQUIREMENTS

Demonstrating compliance

a. The health center has a board-approved policy(ies) that establishes a QI/QA program that addresses the following:
   • The quality and utilization of health center services;
   • Patient satisfaction and patient grievance processes; and
   • Patient safety, including adverse events.

b. The health center designates an individual(s) to oversee the QI/QA program established by board-approved policy(ies). This individual’s responsibilities would include, but would not be limited to:
   • Ensuring the implementation of QI/QA operating procedures and related assessments;
   • Monitoring QI/QA outcomes;
   • Updating QI/QA operating procedures.
c. The health center has operating procedures or processes that address all of the following:
   • Adhering to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable;
   • Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary;
   • Assessing patient satisfaction;
   • Hearing and resolving patient grievances;
   • Completing periodic QI/QA assessments on at least a quarterly basis to inform the modification of the provision of health center services, as appropriate; and
   • Producing and sharing reports on QI/QA to support decision-making and oversight by key management staff and by the governing board regarding the provision of health center services.

d. The health center’s physicians or other licensed health care professionals conduct QI/QA assessments on at least a quarterly basis, using data systematically collected from patient records, to ensure:
   – Provider adherence to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable; and
   – The identification of any patient safety and adverse events and the implementation of related follow-up actions, as necessary.

e. The health center maintains a retrievable health record (for example, the health center has implemented a certified EHR) for each patient, the format and content of which is consistent with both federal and state laws and requirements.

f. The health center has implemented systems (for example, certified EHRs and corresponding standard operating procedures) for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with federal and state requirements.
HRSA QUALITY MEASURES

• Access to prenatal care
• Childhood immunization
• Cervical cancer screening
• Adolescent weight screening and follow-up
• Adult weight screening and follow up
• Tobacco use screening and cessation
• Asthma treatment
• Cholesterol treatment
• Ischemic Vascular Disease
• Colorectal cancer screening
• Depression screening and follow up
• HIV linkage to care
• Oral health

FTCA QUALITY REQUIREMENTS

PAL 2017-03: Documentation requirements

• QI/QA Plan: Plan and/or other documentation (such as 6 months of QI/QA committee minutes) to demonstrate established ongoing QI/QA program and supporting operating procedures that address:
  • Adherence to current evidence-based clinical guidelines, standards of care, and standards of practice, as applicable;
  • A process for identifying, analyzing, and addressing patient safety and adverse events and for implementing follow-up actions, as necessary;
  • A process for assessing patient satisfaction;
  • A process for hearing and resolving patient grievances;
  • Completion of periodic (for example, quarterly) QI/QA assessments;
  • A process for modifying the provision of health center services based on the findings of QI/QA assessments, as appropriate.
FTCA QUALITY REQUIREMENTS

• QI/QA Assessments: For example, QI/QA report(s), six months of QI/QA committee minutes, or QI/QA assessments performed over the past year. Such documentation must, at a minimum, demonstrate the following:
  • QI/QA assessments have been completed on a periodic (ongoing) basis (for example, quarterly) over the past year
  • QI/QA assessments over the past year that include assessing the following:
    • The quality of health center services;
    • Patient satisfaction and the outcomes of patient grievance processes;
    • The utilization of health center services, consistent with evidence-based guidelines;
    • The status of activities around any safety and adverse events, including follow-up actions, as appropriate.

• QI/QA Report: Most recent QI/QA report that has been provided to key management staff and to the governing board.

• Governing Board Minutes: Minutes that document that the report was shared with and discussed by the governing board to support decision-making and oversight regarding the provision of health center services.

• QI/QA Position Descriptions: Upload the relevant position description(s) or describe the responsibilities of the individual(s) who oversee the QI/QA program, including ensuring the implementation of QI/QA operating procedures and completion of QI/QA assessments, monitoring QI/QA outcomes, and updating QI/QA operating procedures.
FTCA QUALITY REQUIREMENTS

PAL 2017-03: Questions

- Describe how the health center’s physicians or other licensed health care professionals conduct QI/QA assessments, including their use of data collected from patient records.

- Has the health center implemented a certified EHR for all health center patients? If “No”, describe the health center’s systems and procedures for maintaining a retrievable health record for each patient, the format and content of which is consistent with both federal and state laws and requirements.

- Describe the health center’s systems and procedures for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with federal and state requirements.

- Indicate whether you currently have a grant condition related to QI/QA.

What do we mean by “risk management”?

- IDENTIFY
- ASSESS
- RISK MANAGEMENT
- ANAYLZE
- REDUCE
- CONTROL
- TRANSFER
RISK MANAGEMENT

Risk management involves understanding, analyzing and addressing risk to make sure organizations achieve their objectives. Risk management must be proportionate to the complexity and type of organization involved.

Enterprise Risk Management (ERM) is an integrated approach to managing risk across an organization and its extended networks.

FTCA RISK MANAGEMENT REQUIREMENTS

PAL 2017-03: Documentation requirements

- Policies and procedures: To demonstrate how the health center has mitigated risk for health center patient safety in these areas/activities consistent with the health center’s HRSA-approved scope of project, upload the following policies and procedures:
  - Referral tracking
  - Hospitalization tracking
  - Diagnostic tracking (x-ray, labs)

- Risk Management Position Descriptions: Upload the relevant Position Description(s) or Describe how the health center has designated an individual(s) (for example, a risk manager) who oversees and coordinates the health center’s risk management activities.
FTCA RISK MANAGEMENT REQUIREMENTS

PAL 2017-03: Questions

• Describe the health center’s ongoing risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation.

• Describe the health center’s risk management policies to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. At a minimum, specifically address the following:
  • Risk management across the full range of health center activities (scheduling, triage, intake, tracking, and follow-up);
  • Health care risk management training for health center staff;
  • Completion of quarterly risk management assessments;
  • Annual reporting to the board of: completed risk management activities; status of the health center’s performance relative to established risk management goals; and proposed risk management activities that relate and/or respond to identified areas of high organizational risk.

FTCA RISK MANAGEMENT REQUIREMENTS

• Describe the health center’s risk management operating procedures to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. At a minimum, specify how these operating procedures address the following:
  • Identifying the areas/activities of highest risk for health center patient safety consistent with the HRSA-approved scope of project;
  • Mitigating the areas/activities of highest risk through clinical protocols, training, and medical staff supervision;
  • Documenting, analyzing, and addressing clinically-related complaints, and “near misses” reported by employees, patients, and others;
  • Setting and tracking progress related to annual risk management goals;
  • Developing and implementing an annual health care risk management training plan for all staff members based on identified areas/activities of highest clinical risk (including, but not limited to obstetrical procedures, infection control) and any appropriate non-clinical trainings (including HIPAA medical record confidentiality requirements); and
  • Completing an annual risk management report for the board and key management.
FTCA RISK MANAGEMENT REQUIREMENTS

• Describe the development and implementation of the health center’s health care risk management training plan for staff members based on identified areas/activities of highest clinical risk for the health center. This includes the health center’s tracking/documentation methods to ensure that trainings have been completed by the appropriate staff, including all clinical staff, at least annually. Please ensure that the description incorporates how the health care risk management training plan addressed the following:
  - Obstetrical procedures (e.g., continuing education for electronic fetal monitoring (such as, online course available through ECRI Institute), and dystocia drills);
  - Infection control (e.g., Bloodborne pathogen exposure protocol, Infection Prevention and Control policies, Hand Hygiene training and monitoring program);
  - HIPAA medical record confidentiality requirements.

FTCA RISK MANAGEMENT REQUIREMENTS

• Describe how the health center provides reports to the board and key management staff on risk management activities and progress in meeting goals (at least) annually, or alternatively upload the most recent report to the board/key management staff on risk management activities, progress in meeting goals and documentation (for example, board minutes or other meeting minutes) showing that related follow up actions have been implemented.

• Has the designated individual(s) who oversees and coordinates the health center’s risk management activities completed health care risk management training this year? If “No”, please enter an explanation.
CHALLENGES AND BEST PRACTICES

Challenge #1: Time

• Meetings required for the different committees and subcommittees, include the same individuals, and seems like the same topics are covered

• Plans, policies and procedures are based on samples because there is not time to develop an individualized program
CHALLENGES AND BEST PRACTICES

Response:
• Critically evaluate the program structure
  • Who is doing what? Why?
  • Are you meeting the requirements? Are you meeting the recommendations?
  • Develop a structure that works for your organization.
• Review the foundational program documents
  • Do they reflect your organization’s structure?
  • Can policies and procedures be referenced in the program plan to keep the plan focused?
  • Consider including work plans, training plans, policies and procedures as appendices to the health center’s over-arching plans.

CHALLENGES AND BEST PRACTICES

Challenge #2: Resources
• Compliance, risk management and quality are viewed as cost centers
• One employee is responsible for all three programs
• Responsibilities are assigned to several employees but there is no ownership (or worse...conflict!)
• Can’t focus on developing the programs because the health center is busy responding to the problem “de jour”
CHALLENGES AND BEST PRACTICES

Response:
- Link compliance, quality and risk management to organization’s financial health
- Develop staff level committees to support individuals charged with compliance, quality and risk management
- Focus on the organization’s greatest risks by:
  - Conducting a risk assessment
  - Developing work plan activities that respond to the highest risks
  - Monitoring (and reporting) progress on activities in the work plan

CHALLENGES AND BEST PRACTICES

Challenge #3: Lack of Support
- Board of Directors has little involvement with the programs/does not exercise appropriate oversight
- Management team does not invite/value participation
- Employees do not understand program goals or roles of Compliance Officer, Risk Manager, etc.
CHALLENGES AND BEST PRACTICES

Response:

• Board: Explain responsibilities under Section 330 and their fiduciary duties to the organization

• Management:
  • Include compliance, quality and risk management responsibilities in job descriptions (including membership on any committee) and evaluate during annual reviews
  • Develop regular communication so programs provide value to managers

• Staff:
  • Build trust through inquiry, reporting back and honesty
  • Encourage employees to ask questions and report concerns (and provide opportunity for conversation and anonymous reporting)

QUESTIONS? COMMENTS?

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