Health Care Compliance Professional's Manual, ¶ 30,875 , Hospital Compliance Guidance

¶30,875 and ¶30,880 are draft documents issued by The New York Office of Medicaid Inspector General. They will be replaced with the final drafts in a future report.

Appendix 3-6A: New York Hospital Compliance Guidance

NEW YORK STATE DEPARTMENT OF HEALTH

Office of the Medicaid Inspector General

Compliance Program Guidance for Hospitals

DATE: February 24, 2009

Compliance Program Requirements

The following is a list of all requirements and elements of a compliance program. They are presented here for reference without additional guidance. They are derived directly from and are required by N.Y. Social Services Law § 363-d.

Requirement 1: Written Policies and Procedures

Element 1: Code of conduct or code of ethics embodies compliance expectations

Element 2: Written policies and procedures describe compliance expectations

Element 3: Written policies and procedures describe how the compliance program is implemented

Element 4: Written policies and procedures provide guidance to employees and others on dealing with potential compliance issues

Element 5: Written policies and procedures describe how potential compliance problems are investigated and resolved

Requirement 2: Designation of a Compliance Officer

Element 1: Compliance officer is an employee of the hospital

Element 2: Compliance officer is responsible for the day-to day oversight of compliance program operations

Element 3: Compliance officer's duties may solely relate to compliance or may be combined with other duties as long as compliance responsibilities are satisfactorily carried out

Element 4: Compliance officer reports directly to the hospital's chief executive or other senior administrator

Element 5: Compliance officer periodically reports directly to the hospital's governing body on the activities of the compliance program

Requirement 3: Training and Education

Element 1: All employees and persons associated with the hospital, including executives and governing body members, receive training and education on compliance issues, expectations, and the operation of the compliance program

Element 2: Training on compliance issues, expectations, and the compliance program operation is part of orientation and occurs periodically for employees, appointees, associates, and executive or governing body members.

Requirement 4: Communication Lines to the Compliance Officer

Element 1: Communication lines to the compliance officer are accessible to employees, persons associated with the hospital, executives, and governing body members

Element 2: Communication lines to the compliance officer include a method for anonymous and confidential good-faith reporting of potential compliance issues

Requirement 5: Disciplinary Policies

Element 1: Disciplinary policies exist to encourage good-faith participation in the compliance program by affected individuals

Element 2: Disciplinary policies articulate expectations for reporting compliance issues

Element 3: Disciplinary policies articulate expectations for assisting in resolution of reported compliance issues

Element 4: Disciplinary policies outline sanctions for failing to report suspected compliance problems

Element 5: Disciplinary policies outline sanctions for participating in non-compliant behavior

Element 6: Disciplinary policies outline sanctions for encouraging, directing, facilitating, or permitting non-compliant behavior

Element 7: Disciplinary policies are fairly and appropriately enforced

Requirement 6: Identification of Compliance Risk Areas and Non-Compliance

Element 1: A system exists for routine identification of compliance risk areas specific to hospitals

Element 2: A system exists for self-evaluation of risk areas, including internal audits and as appropriate external audits

Element 3: A system exists for evaluation of potential or actual non-compliance as a result of self-evaluations and audits

Requirement 7: Responding to Compliance Issues

Element 1: A system exists to timely respond to compliance issues as they arise

Element 2: A system exists for investigating potential compliance problems

Element 3: A system exists for responding to compliance problems identified in the course of self-evaluations and audits

Element 4: A system exists to correct compliance problems promptly and thoroughly

Element 5: A system exists to implement procedures, policies, and systems as necessary to reduce the potential for recurrence of identified compliance problems

Element 6: A system exists to identify and report compliance issues to the New York State Department of Health or the Office of the Medicaid Inspector General

Element 7: A system exists to track and refund overpayments

Requirement 8: Policy of Non-Intimidation and Non-Retaliation

Element 1: Hospital policies and practices prohibit intimidation or retaliation for good-faith participation in the hospital's compliance program

Element 2: The policy protects individuals involved in good-faith reporting of potential issues, investigating issues, self-evaluations, audits, remedial actions, and reporting to appropriate officials as provided in N.Y. Labor Law §§740 and 741 (False Claims Act)

Compliance Program Guidance

The requirements for a compliance program are found in N.Y. Social Services Law § 363-d. These statutory requirements are contained in the Requirements and Elements listed below. Compliance guidance is contained beneath each element. The guidance is intended to assist hospitals in creating and maintaining effective compliance programs. While hospitals are not required to adopt the particular recommendations contained in the guidance, hospitals are required to take appropriate measures to create effective compliance programs that meet all delineated requirements and elements.

Requirement 1: Written Policies and Procedures

Element 1: Code of conduct or code of ethics embodies compliance expectations.

Recommendations:

a. Code is approved by the governing board
b. Code is clear, non-technical, and easily understood
c. Code of conduct or code of ethics includes compliance expectations with regard to:

    i. Ethical behavior
    ii. Billing/claim filing
    iii. Quality of care
    iv. Governance
    v. Conflicts of interest
    vi. Patient care and patient rights

Element 2: Written policies and procedures describe compliance expectations[1]

Recommendations:

a. Policies and procedures are written, reviewed and updated with consideration given to laws, regulations, government reports, and appropriate industry guidance.
b. Sources to identify substantive policy standards include, but are not limited to:

    i. Laws, regulations, and official guidance concerning the medical assistance program, hospitals, and relevant professions
    ii. Medicaid reports, such as New York State Department of Health Office of Health Insurance Program's (NYS DOH OHIP) Medicaid Update[2] and other programmatic newsletters and publications from Centers for Medicare and Medicaid Services (CMS) and NYS DOH
    iii. The Joint Commission
    iv. Medical journals
    v. Individual Peer Review Organization (IPRO) reports,[3] including Program for Evaluating Payment Patterns Electronic Reports (PEPPER)[4] published by IPRO that compare hospitals' coding compliance for Medicare
    vi. Statewide Planning and Research Cooperative System (SPARCS) reports[5] published by NYS DOH
    vii. Internal and external monitoring and auditing
    viii. Hospital compliance guidance issued by the federal government;
    ix. Items identified in corporate integrity agreements created by the federal OIG
    x. Standards and guidelines issued by national organizations of relevant professions
    xi. Information from the Office of Professional Discipline Medicare conditions of participation
    xii. DOH opinion letters/DOH "Dear Chief Executive Officer" letters
    xiii. Resources from the American Health Lawyers Association or the Health Care Compliance Association;
    xiv. Publications related to billing compliance
c. Policies and procedures are organized logically for easy identification
d. Policies and procedures are conveniently located

    i. On hospital intranet systems
    ii. In hard copy in multiple locations
e. Policies and procedures address compliance expectations with regard to:

    i. Billing/claim filing
    ii. Payment
    iii. Quality of care

iv. Governance
v. Mandatory reporting
vi. Credentialing

f. Policies and procedures are periodically reviewed and updated[6]
g. Effective mechanisms exist to convey new policies and procedures to all individuals associated with the hospital, educate those individuals on the purpose, and measure adherence to the standards imposed[7]

Element 3: Written policies and procedures describe how the compliance program is implemented

Recommendation: At a minimum, policies should address:

a. Structure
b. Responsibilities
c. Communication/reporting mechanisms

Element 4: Written policies and procedures provide guidance to employees and others on dealing with potential compliance issues

Recommendations:

a. Employees and non-employee staff can identify potential compliance issues
b. Policies and procedures enable every individual to report suspected compliance issues to the compliance office or another manager
c. Employees and staff are expected to refuse to participate in unethical or illegal conduct
d. Contracts require provisions allowing the entity to terminate contracts and affiliations for failure to adhere to compliance obligations

Element 5: Written policies and procedures describe how potential compliance problems are investigated and resolved

Recommendations:

a. Stress confidentiality and anonymity of reporting within the bounds of the law
b. Identify who will be responsible for conducting investigations
c. Explain the hospital's standard investigative process, acknowledging that particular situations may trigger alternate processes as necessary
d. Provide for disclosure of an overview of the investigation to reporting individuals
e. Explain how the compliance officer obtains investigation specific resources, documents efforts and activities, issues reports, and closes investigations

Requirement 2: Designation of a Compliance Officer

Element 1: Compliance officer is an employee of the hospital

Recommendations:

a. The compliance officer has the skills and character to effectively perform the role of compliance officer

i. Compliance officer has relevant experience, which may include hospital operations, patient care, medicine, law, compliance, risk management, audit or other background, that ensures the compliance officer will be effective
ii. Compliance officer understands, through training and experience, the business process of compliance and has access to, and expertise in, laws, regulations, and standards applicable to the hospital's activities
iii. Compliance officer periodically attends educational conferences, meetings, or seminars designed to help the compliance officer understand how to more effectively develop and maintain a compliance program and understand the substantive risks related to the hospital's activities
iv. Compliance officer effectively communicates to hospital constituents at all levels

Element 2: Compliance officer is responsible for the day-to day oversight of compliance program operations[8]

Recommendations:

a. Compliance officer promotes quality, compliance, and adherence to Code of Conduct and other applicable policies, standards and laws
b. Compliance officer provides compliance-related guidance to hospital departments and facilitates communication and activities throughout the hospital on compliance-related issues
c. Compliance officer has the resources necessary to effectively design, lead and monitor an effective compliance program. The compliance officer has:
    i. Sufficient information about the hospital to assess hospital compliance and identify vulnerabilities and risks
    ii. Access to all relevant documents, systems, and records necessary to effectively execute responsibilities[9]
    iii. Access to internal and external expertise related to risk areas and compliance issues relevant to the hospital
    iv. Sufficient hospital resources to support and maintain an effective monitoring and auditing program that addresses risk areas and compliance issues
    v. Has support from the CEO and board for compliance initiatives including well-publicized recognition of the importance of addressing and reporting compliance concerns and reassurance that there will not be reprisal for raising potentially difficult issues
    vi. Appropriate autonomy, reporting lines outside the authority of in-house counsel and discretionary access to outside counsel
d. Compliance officer advises hospitals on compliance-related contract provisions
e. Compliance officer attends quality assurance committee meetings and receives information about quality of care
f. Compliance officer takes sufficient steps to document efforts to meet mandated requirements and resigns if the hospital engages and persists in illegal activity:[10]
    i. Endeavors to obtain necessary resources, programming and support for compliance program
    ii. Advises management and the board about difficulties achieving compliance and implications of non-compliance
g. Compliance committee exists to provide support and oversight of compliance program
    i. The committee should include a broad cross-section of hospital functions and departments in a hospital, including, for example:
        1. chief executive officer
        2. chief operating officer
        3. chief financial officer
        4. chief medical officer
        5. chief nursing officer
        6. chief information officer
        7. general counsel
        8. director of internal audit
        9. billing and payment representative
        10. case manager
        11. risk services manager
    ii. The committee should meet at least quarterly with compliance officer
        1. committee assists compliance officer in analysis of technical or medical information

2. committee offers cross-expertise assessments and assists in identifying risk areas
3. committee assists with compliance implementation planning

Element 3: Compliance officer's duties may solely relate to compliance or may be combined with other duties as long as compliance responsibilities are satisfactorily carried out

Recommendations:

a. The Board and management are aware that compliance officer's non-compliance duties involving responsibility for the hospital's financial success may present a conflict to the independence of an effective compliance program.[11]
b. Board and supervisor of compliance officer ensure that compliance officer who has additional duties is provided the time and resources necessary to perform all duties associated with the compliance officer function

Element 4: Compliance officer reports directly to the hospital's chief executive or other senior administrator

Recommendations:

a. Compliance officer has a leadership role in hospital that is recognized and promoted by senior management
b. Compliance officer's supervisor is knowledgeable, supportive, and committed to compliance
c. Compliance officer is positioned within the hospital to be effective
    i. Compliance officer participates regularly in senior management meetings as necessary
    ii. Compliance officer should not report to the general counsel/legal department but should work closely with hospital legal counsel
    iii. Compliance officer should not report to the chief financial officer/finance department

Element 5: Compliance officer periodically reports directly to the hospital's governing body on the activities of the compliance program

Recommendations:

a. Compliance officer meets at least annually with the board
b. Compliance officer meets annually in an automatically prescheduled executive session with the board
c. Compliance officer attends all meetings and meets at least quarterly with the board's audit/ compliance committee
d. Compliance officer provides regular written reports and board approved dashboard metrics that measure the Hospital's compliance effectiveness

Requirement 3: Training and education

Element 1: All employees and persons associated with the hospital, including executives and governing body members, receive training and education on compliance issues, expectations, and operation of the compliance program

Recommendations:

a. An effective mechanism exists to convey relevant policies and procedures to individuals associated with the hospital
b. Hospitals assess staff adherence to policies and procedures
c. Contracts with external parties anticipate the hospital's ability to ensure that non-employee staff receive appropriate training
d. Effectiveness of training is periodically assessed. Assessments may include:
    i. tests
    ii. competency in areas where training was provided

iii. evaluating, monitoring and auditing

e. Employees and other individuals who receive compliance training are informed of when and how to obtain additional assistance when necessary

Element 2: Training on compliance issues, expectations, and compliance program operation is part of orientation and occurs periodically for employees, appointees, associates, and executive or governing body members.

Recommendations:

a. All individuals, including voluntary physicians, receive training in hospital's compliance program and code of conduct
b. Individuals receive specific training relevant to specialized areas of work
c. Training is provided regarding relevant legal requirements, including, but not limited to:

    i. The Federal False Claims Act
    ii. Federal administrative remedies for false claims and statements established under 31 U.S.C. §§ 3801-3812.
    iii. State laws pertaining to civil or criminal penalties for false claims and statements
    iv. Whistleblower protections under such federal and state laws
    v. The hospital's policies and procedures for detecting and preventing fraud, waste and abuse
    vi. Information in this subsection is included in an employee handbook, if an employee handbook exists

d. Individuals are identified as responsible to ensure adequate training occurs at appropriate and convenient times and locations, such as:

    i. At regular staff meetings
    ii. Incorporated into the corrective action plans
    iii. When individual or group errors or vulnerabilities are identified
    iv. As identified by surveys of staff, patients and other stakeholders

e. Training is provided by qualified individuals and entities

Requirement 4: Communication Lines to the Compliance Officer

Element 1: Communication lines to the compliance officer are accessible to employees, persons associated with the hospital, executives, and governing body members

Recommendations:

a. Hospital sufficiently publicizes and encourages use of communication lines to compliance officer so potential reporters are aware of the communication lines

    i. Compliance officer's contact information is conspicuously posted prominently throughout the hospital in appropriate places, such as:

        1. high traffic areas
        2. hospital's intranet and internet sites
        3. hospital's television station
        4. along with patient bill of rights
        5. hospital newsletters
        6. employee paychecks
        7. admitting/registration areas
        8. at nurse's station

    ii. Compliance contact information is included in the following materials:

        1. new staff orientation
        2. any compliance-related training
        3. any vendor, subcontractor, and affiliate training

b. Access to translation services exists to facilitate communication between the compliance officer and individuals who are deaf or are not fluent in English, consistent with state Limited English Proficiency (LEP) regulations and guidelines
c. Hospital staff forwards any compliance-related information or reports they receive to appropriate compliance personnel
d. Knowledgeable individuals are available to answer questions that arise on the job that may affect compliance

Element 2: Communication lines to the compliance officer include a method for anonymous and confidential good-faith reporting of potential compliance issues

Recommendations:

a. Reports of potential noncompliance may be made to the compliance officer at all times
b. Telephone hotlines exist to receive reports of potential compliance issues
c. Compliance officer has a method of receiving reports from anonymous reporters that allows anonymous reporters, at appropriate points in time, to receive information about the progress and disposition of the report
d. Compliance officer publicizes the mailing address and location of locked drop boxes as alternative methods of making reports

Requirement 5: Disciplinary Policies[12]

Element 1: Policies exist to encourage good-faith participation in the compliance program by affected individuals

Recommendations:

a. Staff are aware of the disciplinary policies
b. Collective bargaining agreements cannot include provisions that are inconsistent with this obligation
c. Contracts with vendors and subcontractors cannot include provisions that are inconsistent with this obligation

Element 2: Policies articulate expectations for reporting compliance issues

Recommendations:

a. Staff is aware of the types and levels of issues that must be reported[13]
b. Staff is aware of how to report compliance issues
c. Performance expectation plans for managers and supervisors include compliance goals

Element 3: Policies articulate expectations for assisting in resolution of reported compliance issues.

Recommendation:

a. Policy articulates requirement for employees' good-faith participation in investigations
b. Policy recites obligation to be truthful with investigators.
c. Policy describes employee obligation to preserve documentation or records relevant to any ongoing investigations

Element 4: Policies outline sanctions for failing to report suspected compliance problems

Recommendation: Staff is aware of potential consequences for failing to report suspected compliance problems

Element 5: Policies outline sanctions for participating in non-compliant behavior

Recommendation: Staff is aware of potential consequences for participating in non-compliant behavior

Element 6: Policies outline sanctions for encouraging, directing, facilitating, or permitting non-compliant behavior

Recommendation:

a. Policy makes clear that it is impermissible to direct employees to engage in inappropriate or unlawful conduct
b. Policy makes clear that management at all levels have an obligation to respond appropriately to suspected or identified misconduct or non-compliance
c. Staff is aware of consequences of causing, participating in or permitting non-compliant behavior

Element 7: Policies are fairly and appropriately enforced

Recommendations:

a. Prior to a decision to discipline, the hospital assesses whether the breach was caused by a lack of effective training or insufficient resources and does not discipline if either was the principal cause
b. Corrective action plans are implemented concurrent with discipline
c. Level of discipline imposed is consistent with past practice for similar infractions
    i. Disciplinary decisions are centralized to ensure consistency of level of discipline
    ii. Level of discipline is consistent regardless of status within hospital
d. Vendors, subcontractors, and affiliate staff are held accountable for meeting the hospital's compliance standards through appropriate channels

Requirement 6: Identification of Compliance Risk Areas and Non-Compliance

Element 1: A system exists for routine identification of compliance risk areas specific to hospitals[14]

Recommendations:

a. Each hospital has written procedures and policies delineating a system to routinely identify compliance risk areas specific to that hospital
b. Hospitals conduct periodic risk assessment designed to identify the hospitals principal risks. At a minimum, these risk assessments consider:
    i. Risk areas delineated in guidance to hospitals issued by the New York State Office of the Medicaid Inspector General (OMIG). The OMIG has identified compliance risk areas specific to hospitals, in addition to those identified by the Office of the Inspector General (OIG), in Attachment A, appended to this Guidance issued by the federal Department of Health and Human Services (DHHS) federal OIG. The OIG hospital guidance is available at 63 Fed. Reg. 8987 (Feb. 23, 1998) and 70 Fed. Reg. 4858 (Jan. 31, 2005)
    ii. Work plans issued by the OMIG
    iii. Work plans issued by the OIG

Element 2: A system exists for self-evaluation of risk areas, including internal audits and as appropriate external audits

Recommendations:

a. Hospitals ensure routine monitoring of significant compliance risk areas identified by the hospital
    i. Compliance plan includes monitoring of identified risk areas
    ii. Corrective action plans are monitored for implementation
b. Auditors have relevant training and/or expertise
c. Audits are conducted with sufficient frequency and thoroughness to effectively identify non-compliance
    i. Audit plan is created and revised as necessary, at least annually. Audit plan is created:

1. assessing compliance data from previous year (audits, statistics, etc.) to identify high risks areas for the coming year
2. identifying corrective action plans that require auditing to confirm compliance
3. including measurements, timetables and individuals responsible for addressing each risk area

ii. Hospitals without appropriate staff retain external auditors/consultants to periodically audit, provide tools for self-assessment and review compliance plans

d. Audit results are shared with compliance officer and the board or board audit compliance committee

Element 3: A system exists for evaluation of potential or actual non-compliance as a result of self-evaluations and audits[15]

Recommendations:

a. Self-evaluations and monitoring efforts are analyzed to identify risk areas and non-compliance, and to benchmark achievement

i. Findings of non-compliance through monitoring and self-evaluations are further analyzed for scope and breadth of problem and forwarded for auditing as appropriate
ii. Negative trends are further investigated and monitored to enable the hospital to characterize as risk areas or as areas of non-compliance
iii. Monitoring efforts taking place as part of corrective action plans continue until the hospital is assured that compliance benchmarks are met and problem will not recur

b. Audit findings are reviewed to identify risk areas and non-compliance

i. Findings are compared with publicly available statistics, prior audits, and benchmarks
ii. Trends are identified as risk areas and incorporated into performance improvement plans
iii. Findings of non-compliance are further investigated and analyzed for breadth and scope of compliance problem and included in corrective action plans

c. Affected departments are involved in creating and implementing of corrective action plans and those plans are shared with the compliance officer

Requirement 7: Responding to Compliance Issues

Element 1: A system exists to timely respond to compliance issues as they arise

Recommendations:

a. Compliance officer follows protocols and procedures to timely receive and process reports of possible compliance issues
b. Procedures include taking immediate action to secure the health and safety of current patients if affected by the issue raised

Element 2: A system exists for investigating potential compliance problems

Recommendation:

a. Policies exist delineating procedures for detecting and preventing fraud, waste, abuse[16] and other compliance obligations
b. Potential compliance problems are promptly, fairly, and thoroughly investigated by impartial investigator(s)
c. Compliance officer oversees investigations

i. Compliance officer is trained to conduct investigations

ii. Investigation is assisted by staff within the hospital as needed by compliance officer
iii. Compliance officer engages external resources to assist with investigations as appropriate
iv. Investigations are directed independently of department(s) implicated by the allegations
v. Documentation and evidence related to the investigation is secured

d. Individuals who may have relevant information are promptly interviewed

i. Measures are taken to protect the integrity of the interview process including asking interviewees to refrain from discussing the topic and questions asked during the interview
ii. Legal rights of employees are considered and assured during investigatory interviews
iii. Individuals are reminded of nonretaliation and nonintimidation protections of the law

e. An investigatory report is prepared and retained by the compliance officer. At a minimum, the investigative report includes

i. A description of the allegations or suspected misconduct
ii. The identity of the persons interviewed (if any)
iii. A general description of the evidence reviewed and secured
iv. Observations/findings of fact
v. Recommendations for discipline or corrective action, if any

Element 3: A system exists for responding to compliance problems identified in the course of self-evaluations and audits

Recommendations:

a. Compliance officer is aware of self-evaluation and audit results

i. Compliance officer attends meetings of board audit committee
ii. Compliance officer meets with auditors
iii. Compliance officer receives results of self-evaluations and audits

b. Compliance problems identified in self-evaluations or audits are investigated further to clarify the breadth and scope of the problem
c. Management creates a corrective action plan with benchmarks and deadlines, and provides a copy to the compliance officer[17]
d. Board is apprised of significant compliance deficiencies and their corresponding corrective action plans

Element 4: A system exists to correct compliance problems promptly and thoroughly

Recommendations:

a. Hospital management ensures affected areas implement the corrective action plan

i. Individual responsibility is assigned for each aspect of the corrective action plan and included in performance expectation plans
ii. Regular reports are made to compliance officer regarding progress of the corrective action.

b. Board is advised of progress of the corrective action plans
c. Follow-up testing and monitoring takes place to verify that the problem is corrected
d. The board and management explore other hospital operations that are similar or interrelated to assess whether such operations have the same or similar vulnerabilities, thereby determining the limits of the identified vulnerability and correcting concurrent vulnerabilities;

Element 5: A system exists to implement procedures, policies, and systems as necessary to reduce the potential for recurrence of identified compliance problems

Recommendations:

a. Corrective action plans include revisions to procedures, policies and systems as needed
b. Current policies are periodically reviewed when noncompliance is identified for outdated information, and the need for new or updated policies and procedures exist

Element 6: A system exists to identify and report significant compliance issues to the NYS DOH or the OMIG

Recommendations:

a. Mandatory reporting is done in compliance with governing law
    i. staff understands what is subject to mandatory reporting requirements
    ii. staff is aware of how to and is able to initiate, through designated individuals, the hospital's mandatory reporting process

Element 7: A system exists to track and refund overpayments

Recommendations:

a. A process is in place to ensure identified inaccurate claims are promptly voided or overpayments are promptly repaid
b. When appropriate, timely reporting is made to the OMIG. Self-disclosures are appropriate for the following:
    i. A pattern of inappropriate coding, billing, claiming or unethical or illegal behavior
    ii. Significant compliance issue in terms of size, scope or ethical or legal implications
    iii. Conduct meeting the definition of an "unacceptable practice" as defined by 18 NYCRR § 515.2
c. The compliance officer maintains a record of refunded overpayments

Requirement 8: Policy of Non-Intimidation and Non-Retaliation

Element 1: Hospital policies and practices prohibit intimidation or retaliation for good-faith participation in the hospital's compliance program

Recommendations:

a. Policy is distributed to all individuals associated with the hospital and incorporated into any employee and staff handbooks
b. Policy contains procedures for individuals to report all alleged or suspected intimidation or retaliation
c. Preventative steps are taken to deter retaliation or intimidation against participants in the compliance program
    i. High-level manager approves terminations before they are effectuated for individual(s) involved in identified compliance concerns
d. Allegations of intimidation or retaliation are promptly, thoroughly and objectively investigated and addressed
    i. Compliance officer oversees investigation
    ii. Compliance officer receives assistance from hospital staff as needed
    iii. Human resources department is not involved if it participated in act(s) alleged to be retaliatory
    iv. Compliance officer obtains assistance from external resources on an as-needed basis
    v. Documents and other relevant evidence is secured
    vi. Investigative files are not kept in staff personnel files

e. Board is advised of frequency and types of alleged retaliation or intimidation and of changes in frequency of allegations over time

Element 2: The policy protects individuals involved in good-faith reporting of potential issues, investigating issues, self-evaluations, audits, remedial actions, and reporting to appropriate officials as provided in N.Y. Labor Law §§ 740 and 741 (False Claims Act)

Recommendations:

a. Policy specifies each activity of the compliance program and protects all individuals participating in good-faith in any of the activities from retaliation or intimidation
b. Policy prohibits all individuals associated with the hospital from retaliating or intimidating
c. Policy provides for ability to terminate contracts and affiliations as a result of retaliation or intimidation

COMPLIANCE PROGRAM GUIDANCE

The requirements for a compliance program are found in N.Y. Social Services Law § 363-d. These statutory requirements are listed below as Requirements and Elements. Compliance guidance is contained beneath each element. The guidance is intended to assist hospitals in creating and maintaining effective compliance programs. While hospitals are not required to adopt the particular recommendations contained in the guidance, hospitals are required to take appropriate measures to create effective compliance programs that meet all delineated requirements and elements

REQUIREMENT 1: Written Policies and Procedures

Element 1: Code of conduct or code of ethics embodies compliance expectations

Recommendations

A. Code is approved by the governing board
B. Code is clear, non-technical, and easily understood
C. Code includes compliance expectations with regard to:
    1. ethical business conduct
    2. quality of care
    3. governance
    4. conflicts of interest
    5. patient care and patient rights, access to and provision of medically necessary care, confidentiality
    6. raising compliance questions and reporting compliance concerns
D. Code applies to all governing board members, employees and persons associated with the hospital
E. Code reflects the hospital's commitment to standards of ethical business conduct
F. Code is reviewed annually
G. Code is posted on the hospital's intranet site; summary of code is posted on the hospital's internet site; written summary of code is provided upon request

Element 2: Written policies and procedures describe compliance expectations[1]

Recommendations

A. Policies and procedures are written, reviewed, and updated[2] with consideration given to applicable laws, regulations, and, as appropriate, reports, including government reports, and government and industry guidance
B. Hospitals shall refer to the following sources to develop policy standards:
    1. laws
    2. regulations
    3. official guidance from the New York State Department of Health Office of Health Insurance Programs (NYS DOH OHIP) concerning the Medicaid program including the

Medicaid Update (*http://www.health.state.ny.us/health_care/medicaid/program/update/main.htm*)

4. programmatic newsletters and publications from the Centers for Medicare and Medicaid Services (CMS) (*http://www.cms.hhs.gov*) and NYS DOH OHIP (*http://nyhealth.gov/health_care/managed_care/index.htm*)
5. NYS DOH opinion letters and other documents, including NYS DOH "Dear Chief Executive Officer" letters
6. eMedNY Provider Manual *http://www.emedny.org/Provider Manuals/index.html*)

C. Hospitals should consider, where appropriate, the following sources to develop policy standards:

1. The Joint Commission
2. Medical journals
3. IPRO reports,[3] including Program for Evaluating Payment Patterns Electronic Reports (PEPPER)[4] published by IPRO comparing hospitals' coding compliance for Medicare
4. Statewide Planning and Research Cooperative System (SPARCS) reports[5] published by NYS DOH
5. Internal and external monitoring and auditing
6. Hospital compliance guidance issued by the Department of Health and Human Services Office of Inspector General (OIG) (*http://www.oig.hhs.gov*)
7. Items identified in corporate integrity agreements created by the (OIG) and the New York State Office of the Medicaid Inspector General (OMIG) (*http://www.omig.state.ny.us*)
8. Standards and guidelines issued by national organizations of relevant professions
9. Information from relevant professional disciplinary agencies
    i. NYS DOH (*http://nyhealth.gov*)
    ii. New York State Department of Education (*http://www.nysed.gov*)
10. Medicare conditions of participation
11. Resources from relevant professional associations including, the American Health Lawyers Association or the Health Care Compliance Association
12. Publications related to billing compliance

D. Policies and procedures are organized logically for easy reference

E. Policies and procedures are conveniently located and readily accessible to all employees

F. Policies and procedures address, at a minimum, compliance expectations with regard to:

1. access to and provision of medically necessary care
2. billing
3. credentialing
4. credit balances/overpayments
5. rights of patients with disabilities and chronic conditions
6. patient grievance, appeal and fair hearing procedures
7. governance
8. mandatory reporting
9. NYS DOH quality reports
10. quality of care
11. reporting of events and costs affecting payment from the Medicaid program
12. timely and accurate claims payment
13. protection of patients against balance billing

G. Hospitals ensure that policies and procedures are in place, that policies and procedures explain the obligation to report compliance concerns, and that policies and procedures set forth expectations of compliance officer[6]

H. Material changes to policies and procedures are conveyed to governing board members, applicable employees and persons associated with the hospital within a reasonable period of time

I. New changes to policies and procedures are conveyed to governing board members, employees and persons associated with the hospital within a reasonable period of time

Element 3: Written policies and procedures describe how the compliance program is implemented

Recommendations

A. Policies and procedures describe at a minimum:

    1. the structure of the compliance program including how substantive requirements relating to legal obligations and risk areas are developed, and how the code of conduct/ethics meets such obligations
    2. responsibilities of governing board members, employees and person's associated with the hospital
    3. communication/reporting mechanisms

Element 4: Written policies and procedures provide guidance to employees and others on dealing with potential compliance issues

Recommendations

A. Policies and procedures provide guidance to employees and others to assist in identifying potential compliance issues
B. Policies and procedures provide guidance to employees and others on how to report suspected compliance issues to the compliance officer, a senior manager with authority to address the issue, or a supervisor
C. Policies and procedures set forth expectation that employees and others will act in accordance with the code of conduct/ethics and must refuse to participate in unethical or illegal conduct
D. Contracts include provisions allowing the hospital to terminate for contractor or affiliate failure to adhere to compliance obligations

Element 5: Written policies and procedures describe how potential compliance problems are investigated and resolved

Recommendations

A. Policies and procedures ensure confidentiality where warranted and appropriate
B. Policies and procedures identify who will be responsible for conducting investigations
C. Policies and procedures explain the standard investigative process and that particular situations may trigger alternate processes, as necessary
D. Policies and procedures explain how the hospital obtains investigation specific resources, documents efforts and activities, issues reports, and closes investigations
E. Policies and procedures provide for feedback to reporting individuals, as appropriate

REQUIREMENT 2: Designation of Compliance Officer

Element 1: Compliance officer is an employee of the hospital

Recommendations

A. Compliance officer has the experience, training and integrity to perform the responsibilities associated with the position of compliance officer

    1. compliance officer has relevant experience, which may include experience in areas such as compliance, operations, patient care, nursing, medicine, law, risk management, or auditing
    2. compliance officer is trained and has experience in the affect of hospital operations on compliance and has an understanding of the laws, regulations, and standards applicable to the hospital
    3. compliance officer periodically attends educational conferences, meetings, or seminars designed to help the compliance officer understand how to more effectively develop and maintain a compliance program and understand the substantive risks related to the hospital's activities

B. Compliance officer has a leadership role that is recognized and promoted by senior management

1. Compliance officer participates regularly in senior management meetings

C. Compliance officer is a high level position within the hospital

Element 2: Compliance officer is responsible for the day-to-day operation of the compliance program[7]

Recommendations

A. Compliance officer promotes quality, compliance and adherence to code of conduct/ethics, laws, regulations, and other applicable policies
B. Compliance officer provides compliance-related guidance and facilitates communication and activities on compliance-related issues
C. Compliance officer has the resources necessary to effectively design, implement and monitor the compliance program, including:

1. sufficient information to assess compliance questions and concerns and to identify vulnerabilities and risk areas
2. access to all documents and other information relevant to compliance activities[8]
3. access to sources with expertise in relevant compliance concerns and risk areas
4. sufficient time, staff and budget to maintain and support an effective monitoring and auditing program that addresses risk areas and compliance issues
5. support from the chief executive and governing board for compliance initiatives including well-publicized recognition of the importance of addressing and reporting compliance concerns and assurance that there will not be reprisal for raising potentially difficult issues
6. appropriate autonomy, reporting lines outside the authority of the chief financial officer and in-house counsel, and discretionary access to independent counsel or other expertise, as necessary

D. Compliance officer advises on compliance-related contract provisions
E. Compliance officer is advised of meetings affecting the compliance program such as quality assurance committee meetings and attends as appropriate
F. Compliance officer is provided information about patterns or significant concerns related to quality of care
G. Compliance officer takes sufficient steps to document efforts to meet statutory requirements, advises management and the governing board about difficulties achieving compliance and implications of non-compliance, and resigns if the hospital engages and persists in illegal activity[9]
H. Compliance committee exists to provide support to and oversight of the compliance program

1. Compliance committee shall include one or more of the following:

a. chief executive officer
b. chief operating officer
c. chief financial officer
d. chief information officer
e. general counsel
f. chief medical officer
g. director of internal audit
h. billing and payment representative
i. case manager
j. risk services manager
k. human resources manager
l. chief nursing officer

2. Compliance committee meets at least quarterly with the compliance officer

a. compliance committee members offer the compliance officer assessments in their areas of expertise and assist in identifying risk areas
b. compliance committee assists compliance officer with compliance program implementation and planning

I. Compliance officer effectively communicates with board members, employees and persons associated with the hospital

Element 3: Compliance officer's duties may solely relate to compliance or may be combined with other duties as long as compliance responsibilities are satisfactorily carried out

Recommendations

A. Governing board and supervisor of compliance officer ensure that compliance officer who has responsibilities in addition to compliance is provided the time and resources necessary to perform all duties associated with the compliance officer function
B. Governing board and management understand that compliance officer's responsibilities outside of compliance duties which involve responsibility for the hospital's financial success may present a conflict to the independence of an effective compliance program.[10]

Element 4: Compliance officer reports directly to the chief executive or other senior administrator

Recommendations

A. Compliance officer's supervisor is knowledgeable and supportive of, and committed to compliance
B. Compliance officer works closely with the legal department, but does not report to the general counsel
C. Compliance officer does not report to the chief financial officer/finance department

Element 5: Compliance officer periodically reports directly to the governing board on the activities of the compliance program

Recommendations

A. Compliance officer reports at least annually with the governing board
B. Compliance officer meets at least quarterly with the governing board's audit/compliance committee
C. Compliance officer meets annually at a prescheduled executive session of the governing board in the absence of the chief executive and others who report to the chief executive
D. Compliance officer provides to the governing board regular written reports and metrics that measure the effectiveness of the compliance program

REQUIREMENT 3: Training and Education

Element 1: All affected employees and persons associated with the hospital, including executives and governing body members, receive training and education on compliance issues, expectations, and the operation of the compliance program

Recommendations

A. Effective mechanisms exist to convey relevant policies and procedures to governing board members, employees and persons associated with the hospital
B. Hospital assesses adherence to policies and procedures
C. Contracts with contractors and affiliates anticipate the hospital's ability to ensure that non-employee staff receive appropriate training
D. Effectiveness of training is periodically assessed through:

    1. testing
    2. competency of individuals in areas where training was provided
    3. evaluating, monitoring, and auditing of compliance with policies and procedures

E. Governing board members, employees and persons associated with the hospital who receive training are informed of when and how to obtain additional assistance
F. Training materials:

    1. are evaluated on an annual basis
    2. consider results of audits and investigations
    3. include a variety of teaching methods
    4. are provided in different languages, as appropriate

5. are developed at appropriate reading levels

G. Training information is disseminated through such means as:

1. compliance newsletters
2. compliance section in existing newsletters
3. notices of significant legal or regulatory developments
4. notices identifying new risk areas
5. intranet website that provides links to other websites
6. posters
7. FAQs

H. Training conveys the hospital's commitment to compliance and standards for integrity
I. Training explains the purpose and importance of complying with applicable laws and regulations
J. Training addresses potential fear of retaliation
K. Training provides a mechanism for obtaining anonymous information from governing board members, employees and persons associated with the hospital regarding potential compliance issues
L. Training for all employees is mandatory

1. sanctions for failure to attend training are explained

M. Training is documented:

1. on sign-in sheets
2. in minutes from meetings
3. by electronic or manual tracking

N. Procedures are established providing the opportunity to comment on training

Element 2: Training on compliance issues, expectations, and compliance program operation occurs periodically and is part of orientation for new employees, appointees or associates, executives, and governing body members

Recommendations

A. Initial orientation of all employees, including voluntary physicians, includes training on code of conduct/ethics
B. General training is provided on an annual basis
C. Specific training is provided for specialized areas of work
D. Training is provided regarding relevant legal requirements, including, but not limited to:

1. Federal False Claims Act as required by the Deficit Reduction Act
2. Federal administrative remedies for false claims and statements established under 31 U.S.C. §§ 3801 - 3812
3. State laws pertaining to civil or criminal penalties for false claims and statements
4. whistleblower protection under such federal and state laws
5. the hospital's policies and procedures for detecting and preventing fraud and abuse
6. information in this subsection is included in an employee handbook, if any

E. Training occurs at appropriate and convenient times and locations, such as:

1. at regular staff meetings
2. when individual or group errors or vulnerabilities are identified
3. when identified by surveys of staff, patients and other stakeholders

F. Training is incorporated into corrective action plans
G. Training is provided by qualified individuals and entities

REQUIREMENT 4: Communication lines to the compliance officer

Element 1: Communication lines to the compliance officer are accessible to all employees, persons associated with the hospital, executives, and governing board members to allow compliance issues to be reported

Recommendations

A. Communication lines to the compliance officer are sufficiently publicized to:

    1. ensure awareness that the communication lines exist
    2. encourage reporting

        a. compliance officer's contact information is conspicuously posted:

            - in high traffic areas
            - on the hospital's intranet and internet sites
            - in the hospital's newsletters
            - on the hospital's television station
            - along with patient bill of rights
            - in admitting/registration areas
            - at nurse's station

        b. b. compliance officer's contact information is included with the following materials:

            - new staff orientation
            - compliance-related training
            - contractors and affiliate training, if any

B. Hospital ensures that services exist to facilitate communication between compliance department and individuals with physical and cultural barriers consistent with law, regulations and guidelines
C. Compliance-related information or reports are forwarded to appropriate compliance staff
D. Compliance staff are available to answer questions that arise on the job that may affect compliance
E. Hospital fosters organizational culture that encourages open communication without fear of retaliation

Element 2: Communication lines to the compliance officer include a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified

Recommendations

A. Reports of potential compliance issues may be made at any time to the compliance officer, a senior manager or a supervisor who has the authority to review or address the question or concern
B. Telephone hotlines exist to receive reports of potential compliance issues

    1. hotline calls are logged and tracked

C. Compliance officer has a method of receiving anonymous reports and provides feedback to reporting individuals, as appropriate
D. Compliance officer publicizes alternative methods of reporting, such as mailing address and location of locked drop boxes
E. Several independent reporting paths exist
F. Governing board, employees and persons associated with the hospital are advised of reporting mechanisms in a variety of ways
G. Governing board, employees and persons associated with the hospital are advised of their responsibility and obligation to report compliance-related concerns
H. Procedures are established to provide an opportunity to make suggestions about the reporting process
I. Procedures are established to provide an opportunity to seek clarification of the hospital's policies, practices or procedures regarding anonymous and confidential good faith reporting of potential compliance questions and concerns

REQUIREMENT 5: Disciplinary Policies[11]

Element 1: Disciplinary policies encourage good faith participation in the compliance program by all affected individuals

Recommendations

A. Disciplinary policies articulate expectations for reporting compliance issues

    1. training is provided to all persons associated with the hospital on:

        a. disciplinary policies
        b. the types and levels of issues that must be reported[12]
        c. how to report compliance issues including the information that should be disclosed

    2. Collective bargaining agreements cannot include provisions that are inconsistent with the obligation to encourage good faith participation in the compliance program
    3. Contracts with contractors and affiliates cannot include provisions that are inconsistent with the obligation to encourage good faith participation in the compliance program

B. Disciplinary policies articulate expectations for assisting in the resolution of reported compliance issues

    1. all persons associated with the hospital shall:

        a. participate in good faith in investigations
        b. be truthful with investigators
        c. preserve documentation or records relevant to ongoing investigations

    2. performance expectation plans for managers and supervisors include compliance goals

Element 2: Disciplinary policies outline sanctions and are fairly and firmly enforced

Recommendations

A. Disciplinary policies outline sanctions for:

    1. failing to report potential compliance issues
    2. participating in non-compliant behavior
    3. encouraging, directing, facilitating, or permitting non-compliant behavior

        a. employees receive training on sanctions that are imposed for encouraging, directing, facilitating, or permitting non-compliant behavior
        b. disciplinary policies make clear that management at all levels has an obligation to respond appropriately to suspected or identified non-compliant behavior

B. Before initiating disciplinary action, the hospital considers the cause of the alleged violation
C. Corrective action initiatives are considered concurrent with disciplinary actions
D. Sanctions are consistent

    1. disciplinary decisions are centralized to ensure consistency
    2. level of discipline is consistent regardless of status within the hospital

E. Disciplinary policies encourage fair and impartial treatment of all affected individuals
F. Contractors and affiliate staff are held accountable for meeting the hospital's compliance standards

REQUIREMENT 6: Identification of Compliance Risk Areas and Non-Compliance

Element 1: A system exists for routine identification of compliance risk areas specific to hospitals[13]

Recommendations

A. Written policies and procedures delineate processes to routinely identify compliance risk areas specific to the hospital
B. Periodic assessments designed to identify the hospital's risk areas are conducted, and, as applicable, consider:

    1. work plans issued by the OMIG

2. work plans issued by the OIG
3. NYS OMIG audits
4. NYS DOH surveys
5. Risk areas identified in attachment A to this guidance
6. Risk areas identified in guidance issued by the OIG.

Element 2: A system exists for self-evaluation of risk areas including internal audits and as appropriate external audits

Recommendations

A. Hospital ensures routine monitoring of identified compliance risk areas, as appropriate

    1. compliance program includes monitoring of identified compliance risk areas
    2. corrective action plans are monitored for implementation

B. Auditors have relevant training and/or expertise
C. Audits are conducted with sufficient frequency and thoroughness to effectively identify non-compliance

    1. audit plan is developed at least annually, revised as necessary, and

        a. assesses compliance data from previous year (audits, statistics, etc.) to identify high risk areas for the coming year
        b. identifies corrective action plans that require auditing to confirm compliance
        c. includes measurements, timetables, and individuals responsible for addressing each risk area

    2. hospital retains, as necessary, external auditors/consultants to periodically audit, provide tools for self-assessment, and review the compliance program

D. Internal and external audit results affecting compliance are shared with the compliance officer and governing board or governing board's audit/compliance committee

Element 3: A system exists for evaluation of potential or actual non-compliance as a result of self-evaluations and audits[14]

Recommendations

A. Self-evaluations and monitoring efforts are analyzed to identify non-compliance

    1. findings of non-compliance through self-evaluations and monitoring efforts are further analyzed for breadth and scope of problem and forwarded for appropriate action, as necessary
    2. negative trends are identified and further investigated and monitored
    3. monitoring efforts taking place as part of corrective action plans continue until the hospital is assured that the compliance problem will not recur

B. Audit findings are analyzed to identify non-compliance

    1. findings are compared with publicly available statistics and prior audits
    2. trends are identified and incorporated into performance improvement plans
    3. findings of non-compliance are further investigated and analyzed for breadth and scope of problem and included in corrective action plans

C. Affected departments are involved in creating and implementing corrective action plans which are shared with the compliance officer

REQUIREMENT 7: Responding to Compliance Issues

Element 1: A system exists to respond to compliance issues as they are raised

Recommendations

A. Compliance officer follows policies and procedures in response to reports of potential compliance questions or concerns in a timely manner

B. Policies and procedures ensure immediate action to secure the health and safety of current patients if affected by the issues raised

Element 2: A system exists for investigating potential compliance problems

Recommendations

A. Potential compliance issues are timely, fairly, and thoroughly investigated
B. Compliance officer oversees investigations

    1. compliance officer is trained to conduct investigations
    2. compliance officer is assisted by other departmental staff as needed
    3. compliance officer has unfettered access to information to thoroughly conduct investigation
    4. compliance officer makes every effort to ensure transparency when investigating compliance problems
    5. compliance officer assesses compliance questions or concerns for referral to general counsel, as appropriate
    6. compliance officer advises chief executive and/or governing board of investigation, as appropriate
    7. compliance officer engages external resources to assist with investigations, including independent counsel and independent board committee, as appropriate
    8. investigations are directed independently of department(s) implicated by the allegations

C. Recusal

    1. Potential compliance problems are promptly, fairly, and thoroughly investigated by impartial investigator(s) and hospitals have written policies addressing recusal of employees and persons associated with the hospital from investigations who have a conflict of interest

D. Documentation

    1. documentation and evidence related to the investigation are maintained in a confidential manner as appropriate
    2. hospitals have policies and procedures to ensure that appropriate documentation related to investigations is retained

E. Individuals who may have relevant information are promptly interviewed

    1. measures are taken to protect the integrity of the interview process, including asking individuals to refrain from discussing the topic and questions asked during the interview
    2. legal rights of individuals related to the investigation are considered and assured during investigative interviews
    3. individuals are reminded of non-intimidation and non-retaliation policies and protections of the law

F. An investigative report is prepared and retained by compliance officer. At a minimum, the investigative report includes:

    1. a description of the allegations of suspected misconduct
    2. the identities of the persons interviewed, if any
    3. a general description of the evidence reviewed and secured
    4. observation/findings of fact
    5. recommendations for discipline or corrective action, if any

Element 3: A system exists for responding to compliance problems as identified in the course of self-evaluations and audits

Recommendations

A. Compliance officer is aware of self-evaluation and audit activity, schedules and results

    1. compliance officer attends meetings of governing board's audit committee, as necessary

2. compliance officer meets with auditors
3. compliance officer receives results of self-evaluations and audits, as appropriate

B. Compliance problems identified in self-evaluations or audits are investigated further to clarify breadth and scope of problem, as appropriate
C. Management creates a corrective action plan with benchmarks and deadlines, and provides copy to compliance officer[15] , as appropriate
D. Governing board is apprised of significant compliance deficiencies and corresponding corrective action plans, as appropriate

Element 4: A system exists to correct compliance issues promptly and thoroughly

Recommendations

A. Management ensures affected areas implement corrective action plans

1. individual responsibility is assigned for each aspect of corrective action plan and included in performance expectation plans, as appropriate
2. reports are made to compliance officer regarding progress of the corrective action

B. Governing board is advised of progress of corrective action plans, as appropriate
C. Follow-up testing and monitoring takes place to verify that problem is corrected, as appropriate
D. Governing board and senior management explore other operations that are similar or interrelated to assess whether such operations have the same or similar vulnerabilities, thereby determining the limits of the identified vulnerability and correcting concurrent vulnerabilities
E. Policies and procedures provide for feedback to reporting individuals, as appropriate

Element 5: A system exists to implement procedures, policies, and systems as necessary to reduce the potential for recurrence of identified compliance problems

Recommendations

A. Corrective action plans include revisions to written policies and procedures and systems, as needed
B. When non-compliance is identified, current policies are reviewed to identify outdated information and to determine the need for new or updated policies and procedures, as appropriate

Element 6: A system exists to identify and report significant compliance issues to the New York State Department of Health or the New York State Office of the Medicaid Inspector General

Recommendations

A. Hospitals will report significant compliance issues, as required by law

1. governing board, employees and persons associated with the hospital understand mandatory reporting requirements
2. governing board, employees and persons associated with the hospital are aware of how to and are able to initiate, through designated individuals, the hospital's mandatory reporting process

Element 7: A system exists to refund overpayments

Recommendations

A. A process is in place to ensure that overpayments are identified, promptly repaid and not rebilled
B. When appropriate, timely reporting is made to the Office of Medicaid Inspector General/Office of Inspector General. Self-disclosures are appropriate for the following[16] :

1. a pattern of inappropriate coding, billing, claiming or unethical or illegal behavior
2. a significant compliance issue in terms of size, scope or ethical or legal implications
3. conduct meeting the definition of an "unacceptable practice" set for the in 18 NYCRR 515.2

C. Compliance officer reviews policies and procedures to ensure that appropriate measures are in place to maintain a record of refunded overpayments

REQUIREMENT 8: Policy of Non-Intimidation and Non-Retaliation

Element 1: A Policy of non-intimidation and non-retaliation protects individuals in their good faith participation in the compliance program

Recommendations

A. Policy addresses good faith participation in the compliance program with respect to, but not limited to:

    1. reporting of potential issues
    2. investigating issues
    3. self-evaluations
    4. audits
    5. remedial actions
    6. reporting to appropriate officials as provided in N.Y. Labor Law § 740 and § 741

B. Policy is distributed to governing board and employees and is readily available to persons associated with the hospital and is incorporated into employee handbook, if any

C. Policy contains procedures for reporting alleged or suspected intimidation and retaliation

D. Preventative steps are taken to deter intimidation and retaliation against individuals who participate in good faith in the compliance program

    1. Senior and/or Human Resources manager approves terminations before they are effectuated for individual(s) who participate in good faith in the compliance program

E. Allegations and suspicions of intimidation or retaliation are promptly, thoroughly, and objectively investigated and addressed

    1. compliance officer oversees investigations
    2. compliance officer receives assistance from other departmental staff as needed
    3. employees and persons associated with the hospital who have conflicts should recuse themselves from investigations
    4. compliance officer obtains assistance form external resources on an as needed basis
    5. documents and other relevant evidence are maintained in a confidential manner
    6. investigative files are not kept in staff personnel files

F. Compliance officer reports to the governing board the frequency and the types of alleged and suspected intimidation and retaliation, as appropriate

Footnotes

1 *See* 10 NYCRR § 405.2(b)(2).

2 New York State Department of Health Office of Health Insurance Program Medicaid Update, http://www.health.state.ny.us/health_care/medicaid/program/update/main.htm (last visited June 16, 2008).

3 Individual Peer Review Organization, http://www.ipro.org/ (last visited June 16, 2008).

4 Program for Evaluating Payment Patterns Electronic Reports, http://providers.ipro.org/index/pepper (last visited June 16, 2008). *See also* Pepper Download Guide, http://www.mpro.org/hpmp/pdf/PEPPERDownloadGuide.pdf (last visited June 16, 2008).

5 Statewide Planning and Research Cooperative System, http://www.health.state.ny.us/statistics/sparcs/ (last visited June 16, 2008).

6 *See* 10 NYCRR § 405.3(d)(6).

7 *See* 10 NYCRR § 405.3.

8 OMIG recognizes that compliance officers are not single-handedly responsible for hospitals' compliance with billing, payments, governance, quality of care, and mandatory reporting requirements. Rather, they provide a road map for management to meet statutory and regulatory obligations and are often delegated the responsibility of designing a program that gives hospital management the tools

needed to ensure compliance. Ultimately, the governing board and CEO are responsible for meeting established statutory and regulatory requirements. *See* 10 NYCRR § 405.2(b), (d).

9 There are no laws that prevent the compliance officer from obtaining access to hospital records for compliance purposes. Staff and even some management employees at times have a misconception that HIPAA and other laws act to shield hospital records from compliance officers and compliance functions.

10 Documentation will show the compliance officer took all reasonable steps to effectuate their job responsibilities. Placement of the compliance officer position sufficiently high in senior management, combined with ensuring the compliance officer has regular and direct access to the board, may help avoid a compliance program's reaching this point. Compliance officers may wish to refer to the Health Care Compliance Association's ethical standards.

11 A compliance officer may be required to make recommendations that may potentially negatively impact a hospital department's potential profitability. It is important that compliance officers not only avoid positions in which a conflict exists, but also avoid responsibilities that may be perceived to impede a compliance officer's independence or performance. Perceived conflicts should be identified and managed.

12 The primary effort of hospitals to obtain participation in a compliance program should be affirmative. Staff buy-in to compliance programs is critical, and hospitals should encourage participation in the compliance program. However, if incentives and affirmative efforts do not succeed, disciplinary policies must exist to ensure participation.

13 Staff may be over inclusive or under inclusive in reporting if they do not receive direction as to the types of incidents a hospital considers compliance-related. Hospitals will benefit by defining the scope of issues and incidents that are considered compliance-related.

14 *See also* 10 NYCRR §§ 405.5, 405.6.

15 Hospitals may refer to two publications published by the Association of Health Care Internal Auditors, which discuss when auditing is appropriate and when monitoring is appropriate. Auditing and monitoring tasks are complementary, and information received as a result of one may affect the plans and approach of the other. For example, if routine monitoring of an area identified by a hospital as low-risk reveals noncompliance, a hospital may decide to change its compliance plan to audit the areas potentially involved in the discovered noncompliance.

16 Deficit Reduction Act, 42 U.S.C. § 1396a(a)(68).

17 *See also* 10 NYCRR §§ 405.2(c)(2), 405.3(a), 405.6(a).

1 *See* 10 NYCRR § 405.2(b)(2)

2 *See* 10 NYCRR § 405.3(d)(6)

3 IPRO, http://www.ipro.org/ (last visited June 16, 2008).

4 Program for Evaluating Payment Patterns Electronic Reports, http://providers.ipro.org/index/pepper (last visited June 16, 2008). *See also* Pepper Download Guide, http://www.mpro.org/hpmp/pdf/PEPPERDownloadGuide.pdf (last visited June 16, 2008).

5 Statewide Planning and Research Cooperative System, http://www.health.state.ny.us/statistics/sparcs/ (last visited June 16, 2008).

6 *See* 10 NYCRR § 405.3

7 The compliance officer need not have substantive responsibility for all operational areas of the hospital, but will be advised of compliance concerns and will follow-up as appropriate. OMIG recognizes that compliance officers are not single-handedly responsible for hospitals' compliance with billing, payments, governance, quality of care, and mandatory reporting requirements. Rather, they provide a road map for management to meet statutory and regulatory obligations and are often delegated the responsibility of designing a program that gives hospital management the tools needed to ensure compliance. Ultimately, the governing board and CEO are responsible for meeting established statutory and regulatory requirements. *See* 10 NYCRR § 405.2(b), (d).

8 There are no laws that prevent the compliance officer from obtaining access to hospital records for compliance purposes. At times there has been a misconception that HIPAA and other laws act to shield hospital records from compliance officers and compliance functions

9 Documentation will show the compliance officer took all reasonable steps to effectuate their job responsibilities. Placement of the compliance officer position sufficiently high in senior management, combined with ensuring the compliance officer has regular and direct access to the governing board, may help avoid a compliance program's reaching this point. Compliance officers may wish to refer to the Health Care Compliance Association's ethical standards.

10 A compliance officer may be required to make recommendations that may potentially negatively impact a hospital department's potential profitability. It is important that compliance officers not only avoid positions in which a conflict exists, but also avoid responsibilities that may be perceived to impede a compliance officer's independence or performance. Perceived conflicts should be identified and managed.

11 The primary effort of hospitals to obtain participation in a compliance program should be affirmative. Staff appreciation and support of compliance programs is critical, and hospitals should encourage participation in the compliance program. However, if incentives and affirmative efforts do not succeed, disciplinary policies must exist to ensure participation.

12 Staff reporting may be over inclusive or under inclusive if they do not receive direction as to the types of incidents a hospital considers compliance related. Hospitals will benefit by defining the scope of issues and incidents that are considered compliance related.

13 *See also* 10 NYCRR §§ 405.5, 405.6.

14 Hospitals may refer to two publications by the Association of Health Care Internal Auditors, which discuss when auditing is appropriate and when monitoring is appropriate. Auditing and monitoring tasks are complementary, and information received as a result of one may affect the plans and approach of the other. For example, if routine monitoring of an area identified by a hospital as low-risk reveals non-compliance, a hospital may decide to change its compliance plan to audit the areas potentially involved in the discovered non-compliance.

15 *See also* 10 NYCRR §§ 405.2(c)(2), 405.3(a), 405.6(a).

16 See New York State Office of the Medicaid Inspector General's (OMIG) voluntary disclosure guidance at (*http://www.omig.state.ny.us*)