

Health Care Compliance Professional's Manual, ¶30,880 , Supplemental Guidance

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¶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 3-6B: Supplemental Guidance

NEW YORK STATE DEPARTMENT OF HEALTH

Office of the Medicaid Inspector General

Supplemental Guidance to the Compliance Program Guidance for Hospitals

I. The Compliance Program and Governance

Governing bodies are responsible for the quality of patient care services, the conduct and obligations of the hospital as an institution, and for ensuring compliance with all federal, state, and local laws.¹ To ensure appropriate professional practice and patient care, boards must establish, cause to implement, maintain, and, when warranted, revise policies, practices, and procedures for the ongoing evaluation of the services operated or delivered by the hospital and for the identification, assessment, and resolution of problems that may develop in the conduct of the hospital.² A hospital's compliance program should ensure that comprehensive governance processes are in place and functioning effectively. The compliance officer need not be substantively responsible for governance, nor should the hospital be required to create a new governance system in addition to that which is compliant with existing requirements. Rather, a compliance program should ensure that the board and CEO are fully cognizant of their responsibilities and of ongoing hospital operations; and that meaningful oversight systems are in place throughout the institution, and that effective corrective action plans are implemented as necessary.

II. Governing Body

As not-for-profit organizations, New York's hospitals are subject to legal and regulatory governance requirements. Among these are the Internal Revenue Service's (IRS's) requirements for all tax-exempt organizations, the New York State Not-for-Profit Corporation Law, the relevant New York State regulations on hospital governance, and the Center for Medicare and Medicaid Service's Conditions of Participations.³

In addition, there is relevant guidance in governmental discussion papers including the OIG/AHLA Discussion Paper, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors*,⁴ and the IRS Position Paper, *Governance and Related Topics for 501(c)(3) Organizations*.⁵

A. Hospital Governance:

1. Board composition - When structuring and operating hospital Boards, the Office of the Medicaid Inspector General (OMIG) recommends that hospitals consider the following:
 - a. Boards should include diversity and expertise in:
 - i. clinical care and performance improvement to oversee the provision of patient centered care focused on quality of care and patient satisfaction
 - ii. financial performance to oversee fiscal integrity and organization viability
 - iii. billing/coding to oversee reimbursement procedures/practices
 - iv. systems/information to oversee the interoperability and integrity of data
 - v. legal/regulatory to oversee compliance

- vi. business management to provide oversight/guidance in the area of governance
 - b. To ensure diversity and expertise, boards should consider the following:
 - i. establish regional panels or committees to either serve on multiple hospital boards or to serve as adjunct resources for multiple hospitals in the region
 - ii. include *ad hoc* members with particular areas of expertise as the need arises
 - iii. develop expertise by training board members in required areas
- 2. Adherence to required principles of governance⁶ Different models of oversight may be appropriate for different types and sizes of hospitals. Boards should:
 - a. Ensure a balance between governance level oversight and day-to-day operations
 - b. Ensure that effective systems are in place to manage and improve operations
 - c. Determine the type and scope of information it is interested in receiving
 - i. Actively review reports from high-level management
 - ii. Strike a balance between receiving certain types of data and the need to protect confidential information to preserve privileged communications or records.
 - iii. In determining the type and scope of information it receives, the board should consider the following:
 - Findings of claim reviews and resulting actions
 - A summary and description of Compliance officer's non-compliance job responsibilities
 - An opinion from Compliance officer as to whether adequate time and resources are provided to perform the required compliance duties
 - Compliance Officer's identification of all areas in need of improvement or correction, impediments to compliance, and steps taken to effectuate change
 - Identification of risk areas and measures in place to address these areas
 - A summary of information maintained on the logs retained by the compliance officer
 - Frequency and effectiveness of hotline use
 - The number and percentage of individuals associated with the hospital who:
 - # Have completed a Code of Conduct or Code of Ethics Certification
 - # Were required to be trained, and who have completed all required training, identifying the topics covered
 - Actions taken in response to the screening and removal process regarding individuals associated with the hospital
 - A description of the disclosure program
 - Actions taken to identify quantify, and repay any overpayments to the medical assistance program relating to items or services furnished, ordered, or prescribed by excluded persons
 - Summary of retaliation and intimidation, including the following:
 - # number and type of allegations of retaliation or intimidation
 - # number of verified allegations
 - # hospital responses to the verified allegations
 - # current employment status of such staff
 - d. Create benchmarks to establish expectations and measure performance
 - i. Progress regarding benchmarks previously identified, and identification of additional suggested benchmarks

- ii. A summary of quality of care issues, plans to address deficiencies, and achievement status of benchmarks
 - e. Consider principles of Sarbanes-Oxley
 - f. Adhere to the principles in the federal sentencing guidelines
- 3. Board Compliance Obligations
 - a. Acknowledge its role in and support of compliance program
 - b. Ensure new members and all members receive training on compliance program duties on a recurring basis
 - c. Emphasize the importance of employee participation and training
 - d. Receive sufficient information to evaluate compliance and effectiveness of compliance program⁷
 - e. Ensure a system exists to implement procedures, policies, and systems to effect appropriate handling of identified compliance problems and reduce the potential for recurrence
 - f. Meet with compliance officer at least quarterly (may be accomplished through an appropriate subcommittee) and at least once per year in a prescheduled executive session
- 4. Oversight of fiscal integrity
 - a. Take appropriate measures to ensure sufficient capitalization to provide for quality functioning of the hospital
 - b. Determine executive compensation through proper procedures⁸
 - c. Maintain internal controls to ensure financial system integrity
 - d. Ensure hospital is able to and does promptly repay overpayments or penalties to the Medicaid program
- 5. Conflict of interest: Boards
 - a. Require all board members to disclose potential conflicts of interest through a written disclosure form upon joining the board, annually, and as they arise: disclosure should be shared with board members and with the board's audit and compliance committee
 - b. Maintain written requirements addressing potential conflicts of interest relevant to each hospital committee and each board committee
 - c. Ensure that systems exist that minimize/manage conflicts of interest
 - i. A potentially conflicted board member is prudently uninvolved in any vote and does not attempt to influence the outcome of the board's consideration
 - ii. Should the board consider establishing a relationship with an entity in which a board member has a conflict of interest, the board may obtain an independent evaluation of factors involved in the board's decision and obtain an independent entity to assess the fair market value of the transaction and the consistency of the transaction with governing laws, including laws governing charitable institutions
 - iii. The board may also establish a competitive bidding process without involvement of the conflicted board member.
- 6. Oversight of quality of patient care services⁹

Boards ensure the quality of patient care services by:

 - a. Ensuring compliance with all federal, state, and local laws
 - b. Establishing, causing to implement, maintaining, and revising policies, practices and procedures for evaluating services operated or delivered and for the assessment, identification, and resolution of problems that may develop in the conduct of the hospital¹⁰
 - c. Taking sufficient action to ensure patient care practices and standards exist and that appropriate medical staff criteria are in place

7. Contracts: Ensuring that contractors comply with applicable codes, rules and regulations and provide services in a safe and effective manner¹¹

The following charts outline the basic governance requirements for New York hospitals. These charts highlight the most significant elements in this area but do not set forth the regulatory requirements in their entirety.

Element	State Requirements	Federal Requirements
Governing body, generally	10 NYCRR § 405.2	42 CFR § 482.12
Governing body legally responsible for directing hospital operations.	10 NYCRR § 405.2(b)(1)	
Governing body establishes and causes to be implemented necessary policies and procedures.	10 NYCRR § 405.2(b)(2)	
Governing body appoints CEO who manages hospital.	10 NYCRR § 405.2(d)	42 CFR § 482.12(b)
Training of board members	10 NYCRR § 405.2(b)(3)	
Orientation and continuing education programs should address topics including patient rights and quality assurance program.	10 NYCRR § 405.2(b)(3)	
Board oversight, generally	10 NYCRR § 405.2(c)(2)	
Board shall take actions to monitor and restore compliance when hospital compliance deficiencies are identified, including monitoring of all plans of correction.	10 NYCRR § 405.2(c)(2)	
CEO shall be responsible for development and implementation of all plans to correct operational deficiencies identified by regulatory agencies and report to the governing body.	10 NYCRR § 405.3(a)	
Board oversight, finances	10 NYCRR § 405.3(f)(3)(ii)	42 CFR § 482.12(d)
The governing board shall not delegate independent control of a hospital books and records.	10 NYCRR § 405.3(f)(3)(ii)	
The institution must have an overall institutional plan that includes an appropriate budget.	10 NYCRR § 405.3(f)(3)(i)	42 CFR § 482.12(d)
Executive compensation shall be reasonable and fixed pursuant to Internal Revenue Service requirements. Hospitals are strongly encouraged to rely on the IRS's "rebuttable presumption test."	NY NOT-FOR-PROFIT CORP. LAW § 515	IRC § 4958; http://www.irs.gov/charities/charitable/article/0,,id=173697,00.html ; 26 CFR § 53.4958-6
Physical plant	10 NYCRR § 405.2(g)	42 CFR § 482.41
Board is responsible for providing an appropriate physical plant.	10 NYCRR § 405.2(g)	42 CFR § 482.41

Contracts	10 NYCRR § 405.2(h)	42 CFR § 482.12(e)
Board shall ensure that a contractor of services furnishes services that permit hospital compliance with all applicable codes, rules, and regulations.	10 NYCRR § 405.2(h)	42 CFR § 482.12(e)
Board shall ensure that all contracted services are safe and effective.	10 NYCRR § 405.2(h) (1)	42 CFR § 482.12(e)(1)
Hospital shall maintain a list of all contracted services, including scope and nature of services provided.	10 NYCRR § 405.2(h) (2)	42 CFR § 482.12(e)(2)

III. Governance and quality

Specific requirements concerning the board's role in quality are outlined below. The quality portion of this Guidance discusses the New York State quality requirements, particularly the QA program, in greater detail.

Element	State Requirements	Federal Requirements
Board oversight, quality of care	10 NYCRR § 405.2(f)	
Board ensures that all patients receive care that meets generally acceptable standards.	10 NYCRR § 405.2(f)(1)	42 CFR § 482.12(c)
Board ensures that hospitals conducting human research shall adopt and implement appropriate policies and procedures for the protection of human subjects.	10 NYCRR § 405.2(f)(6)	
Board ensures that hospitals have sufficient personnel to meet patient care needs at all times.	10 NYCRR § 405.2(f)(7)	
The governing body establishes a coordinated program to review all hospital services for the purpose of enhancing quality of patient care and identifying and preventing malpractice.	10 NYCRR § 405.2(b) (6)	
Board oversight, medical staff	10 NYCRR § 405.2(e)	42 CFR § 482.12(a)
Board shall have oversight of medical staff in a range of operational areas, specified in the text of the regulation.	10 NYCRR § 405.2(e)	42 CFR § 482.12(a)

(See the portion of this Guidance discussing credentialing for additional discussion of these requirements.)

QUALITY

I. The Compliance Program and Quality

The medical assistance program requires providers to meet professionally recognized standards in delivering care, supplies, and services to medical assistance program recipients.¹² As such, quality of care standards are inextricable from billing and payment compliance issues in the medical assistance program. The Office of the Medicaid Inspector General (OMIG) believes a strong correlation exists between efforts devoted to quality and an organization's commitment to compliance, and that hospitals would benefit from an integration of compliance and quality assurance functions.

A hospital's compliance program should ensure that quality processes are in place and functioning effectively. The compliance officer need not have substantive responsibility for quality or patient-care decision-making. Quality and clinical experts are more appropriate substantive leaders. Nor should the hospital be required to create a new quality system in addition to that which is compliant with existing requirements. Rather, the compliance program should ensure that the necessary quality assurance (QA) system and related functions proceed effectively, that quality-related data is collected and reported as required, and that the facility engages in continuous, proactive quality improvement processes to address gaps in the current system or other areas for improvement.

As with all elements of a compliance program, hospitals may try various approaches to integrate quality and compliance in their efforts to obtain effective results for their organizations. At a minimum, hospitals should ensure purposeful and regular communication between their QA systems and the compliance officer. Quality assurance incident reporting and other performance measures should be shared with the compliance officer. Consideration should be given to compliance officer presence at quality assurance committee meetings to focus the committee on quality-related compliance issues and underscore the importance of the inter-play between compliance and quality. Regardless of the organizational structure and approach, a hospital must assure appropriate quality of patient care and should consider the following general quality-related issues as part of an effective compliance program:

A. Access to Care

1. Provide care for patients and treat patients equally regardless of the type of insurance coverage
2. Disability-related issues: Hospitals provide reasonable accommodations and modifications for patients with disabilities¹³
3. Emergency room care: Except when appropriately on diversion status, hospitals assure that all persons arriving at the emergency department are promptly seen for emergent needs and protocols exist and are known by staff for assessment, stabilization, and transfer of patients to previously designated hospitals who have needs for specialized equipment, staff, or services not present in the hospital¹⁴
4. Operating room assignment and scheduling: Hospitals assess and plan for availability of operating rooms for emergent care needs

B. Hospitals meet recognized standards of patient care

1. Establish treatment guidelines for common conditions to ensure consistent care
2. Consider protocols for new services and highly specialized services requiring special attention and periodic external expert review and monitoring
3. Establish appropriate internal controls that safeguard patient safety and new program services

C. Preventing and addressing deficiencies: Hospitals should:

1. Establish measures to ensure that patients do not receive medically unnecessary care, services or supplies
2. Self-assess to identify deficiencies in patient care
3. Respond to identified problems including findings in surveys conducted by New York State Department of Health (NYSDOH) including prohibiting or withdrawing billing for substandard or medically unnecessary care, services, or supplies

4. Routinely monitor orders for off-label prescription and devices as a potential quality indicator of inappropriate physician prescribing

D. Patient Rights

1. Communication with patients: Hospitals ensure:
 - a. Staff explains information to patients using words and concepts that patients understand
 - b. Appropriate informed consent has been properly obtained¹⁵
 - c. Protocols exist to assess patient capacity
 - d. Guardianship orders are obtained upon admission
 - e. Hospitals identify, obtain, retain, and follow directions contained in health care proxies and do not resuscitate orders (DNRs) Appropriate translation services are available for patients who are deaf or who have limited English proficiency.¹⁶ All hospital documents are available in each foreign language represented by at least 1% of the community served by the hospital.
 - f. Patient privacy requirements are codified in policy and procedure, which staff adhere to, and systems exist to detect, deter, and respond to breaches
2. Dietary and nutritional issues: Patients are delivered and receive nutrition appropriate to their medical needs and other requirements
3. Ensure the physical security of patients
4. Permit adequate visitation so long as it does not compromise the physical or emotional well-being of patients
5. Prohibit retaliation against patients
6. Medical research
 - a. Is restricted within ethical and legal requirements
 - b. Appropriate protocols and internal controls are in place
 - c. Informed consent has been obtained¹⁷

E. Staffing Issues (for employed and non-employed individuals):

1. Staff caring for the same patient timely and adequately share patient information
2. Use of contractors does not violate Stark, self-referral, kickback, or other laws
3. Staff perform work within scope of licensure, ability, and experience
4. Staff are accountable for providing high-quality care
5. A sufficient number of qualified staff is available to care for patient needs
6. Staff are trained to proficiency and tested as needed

F. Conflicts of Interest

1. Implement appropriate safeguards for medical staff relations with drug companies and medical industry
2. Develop a process to identify and manage existing and potential conflicts
3. Manage individuals/monitor involvement of pharmaceutical and therapeutics (P&T) committee members/entities who have financial relationships with drug companies and the medical device industry
 - a. Exclude members or entities with conflicts from any vote or opportunity to inappropriately influence decisions
 - b. Seek external expert opinions/guidance as necessary

G. Facilities Issues

1. Physical plant — Hospitals maintain physical facilities in working order and with sufficient cleanliness as required by law, regulation, and code
2. Internal controls/Inventory control: Hospitals maintain sufficient inventory procedure and practice to meet patient needs
3. Equipment: Owned or rented equipment is inspected for function and safety standards and undergoes timely maintenance and replacement

II. Quality Assurance Processes

New York hospitals are required to engage in certain quality assurance and performance improvement operations pursuant to state regulations and the Medicare Conditions of Participation (COPs). Specifically, the hospital is expected to have its own QA process, as summarized below.

Element ¹⁸ , ¹⁹	State Requirements	Federal Requirements
Quality Assurance Program; Quality Assessment and Performance Improvement	10 NYCRR § 405.6	42 CFR § 482.21
Governing body establishes and oversees QA program, which includes malpractice prevention; identification of problems concerning patient care; implementation of actions necessary to correct problems; and documentation of all relevant measures. At least one member of the quality assurance committee shall be a member of the governing body of the hospital.	10 NYCRR § 405.6(a)	42 CFR § 482.21(e)
QA committee reviews care provided by all healthcare practitioners employed by or associated with the hospital. QA review includes maintenance and collection of negative health care outcomes data.	10 NYCRR § 405.6(b) (1)-(6)	42 CFR § 482.21(b)-(c)
Hospital must conduct performance improvement projects		42 CFR § 482.21(d)
QA committee oversees and coordinates staff privileging review procedure	10 NYCRR § 405.6(b) (7)(i)-(vi)	42 CFR § 482.22
QA committee oversees and coordinates educational programs including patient safety, patient rights, injury prevention, and related topics.	10 NYCRR § 405.6(b) (7)(viii)	
QA committee oversees and coordinates continuing education programs in areas of specialty.	10 NYCRR § 405.6(b) (7)(ix)	

¹⁸ The charts in this document highlight the most significant elements in this area but do not set forth the entire set of regulatory requirements.

¹⁹ Hospitals are also subject to regulatory requirements articulating the role their governing boards play in quality of care. The governance portion of this Guidance summarizes those obligations.

III. Infection control

In addition to the QA functions and oversight, hospitals must establish certain infection control processes. These infection control requirements, summarized below, also overlap with data reporting requirements, as summarized separately in this Guidance.

Element	State Requirements	Federal Requirements
Infection Control	10 NYCRR § 405.11	42 CFR § 482.42
The hospital provides a sanitary environment and establishes an effective infection control program.	10 NYCRR § 405.11	42 CFR § 482.42
The hospital designates an infection control professional who is responsible for the hospital-wide program.	10 NYCRR § 405.11(a)	42 CFR § 482.42(a)
The hospital-wide program includes processes to reduce the risk of infections and communicable diseases in patients and hospital personnel.	10 NYCRR § 405.11(b)	42 CFR § 482.42(a)(1)
There shall be written policies and procedures for identifying, reporting, and investigating infections and communicable diseases of patients and hospital personnel.	10 NYCRR § 405.11(c)	42 CFR § 482.42(a)(2)
The hospital-wide infection control program shall be integrated with the hospital's quality assurance program.	10 NYCRR § 405.6; 10 NYCRR § 405.11(d)	42 CFR § 482.42(b)(1)
The hospital requires compliance with written requirements for orientation and ongoing education.	10 NYCRR § 405.11(e)	
The hospital implements acceptable corrective action plans related to infection control as necessary.	10 NYCRR § 405.11(f)	42 CFR § 482.42(b)(2)

IV. Patients' rights

Hospitals are responsible for ensuring that patients' rights are protected. Relevant regulatory requirements are summarized below.

Element	State Requirements	Federal Requirements
Patients' Rights	10 NYCRR § 405.7	42 CFR § 482.13
Hospital ensures that all patients are afforded their rights; hospitals shall provide patients with a copy of these rights and provide assistance to patients to understand and exercise these rights.	10 NYCRR § 405.7	42 CFR § 482.13(a)(1), (b)
Communication with patients.	10 NYCRR § 405.7(a)(1)-(6)	42 CFR § 482.13(a)(2)

Language Assistance program/ Coordinator.	10 NYCRR § 405.7(a)(7)	
Disability rights; language rights.	10 NYCRR § 405.7(b)(1)	
Nondiscrimination	10 NYCRR § 405.7(b)(2)	
Limited use of physical restraints.	10 NYCRR § 405.7(b)(5)	42 CFR § 482.13(e), (f), (g)
Refusal of treatment.	10 NYCRR § 405.7(b)(10)	42 CFR § 482.13(b)(2)
Privacy and confidentiality rights.	10 NYCRR § 405.7(b)(12), (13)	42 CFR § 482.13(d); 45 CFR pts. 160, 164
Discharge planning.	10 NYCRR § 405.7(b)(15), (16)	
Refusal to participate in research or human experimentation.	10 NYCRR § 405.7(b)(18)	
System for patient complaints.	10 NYCRR § 405.7(b)(22)	42 CFR § 482.13(a)(2)
Necessary supportive services for special needs...	10 NYCRR § 405.7(b)(25)	
Patient's Bill of Rights.	10 NYCRR § 405.7(c)	

MANDATORY REPORTING OF ADVERSE INCIDENTS

I. The compliance Program and Adverse Incident Reporting

A hospital's compliance program should ensure that any mandated adverse incident reporting processes, summarized below, are in place and functioning effectively. The compliance officer need not be substantively responsible for incident reporting, nor should the hospital be required to create a new adverse incident reporting system in addition to what is compliant with existing requirements. Rather, the compliance program should ensure that systems exist to facilitate effective reporting.

Mandatory reporting requirements include reports to the following:

- NYSDOH NYPORTS²⁰ - for certain types of events within hospitals
- FDA - for problems with FDA-approved devices.
- Elder abuse
- Child abuse
- State and Local Authorities - for domestic violence, assaults, and other crimes
- National Practitioners Data Bank and/or state licensing board - for malpractice and other events

The Office of the Medicaid Inspector General (OMIG) is aware that frequent discrepancies exist between reporting by hospitals and the actual number of occurrences that should be reported. Hospitals with excellent quality of patient care may file a greater number of mandatory reports than hospitals with poor quality of care as a result of effective systems in place to identify and investigate these incidents and more effective performance of the mandatory reporting functions. Hospitals implementing compliance systems that have not historically focused on quality of care may notice a sharp increase in mandatory reports. In such instances, spikes in mandatory reporting may be a sign of a hospital's greater attention to improvement in quality of care. Hospitals are encouraged to share best compliance and reporting practices with one another and to collaborate on appropriate solutions.

II. Adverse Incident Reporting Requirements in New York

New York State has a mandatory incident reporting requirement, as outlined in New York Public Health Law § 2805-l and § 2819, and 10 NYCRR Article 405.8. Moreover, the New York Patient Occurrence Reporting and Tracking System (NYPORTS) was developed in 1998 to specifically define the types of incidents that are reportable and the process for review and subsequent action. Hospitals should ensure that they are properly reporting the necessary information through NYPORTS.

A. Mandatory Reporting

1. Staff is aware of the types of matters that must be reported, the parameters for reporting and the process including how and to whom reports should be made²¹
2. Medical staff bylaws must include a standard of conduct that requires medical staff to report these incidents to a designated hospital administrator immediately when any medical staff member learns of the occurrence of such an incident²²
3. Reports and corrective action plans are timely and accurately made to required federal and state authorities^{23, 24}
4. Hospitals establish methods of measuring and checking these systems to assess the effectiveness of mandatory reporting systems²⁵
5. Adverse patient events are identified and timely and thoroughly investigated, analyzed, and incorporated into hospital performance improvement plans

The following charts outline the regulatory authority for incident reporting. In addition, the NYPORTS guidance materials are accessible at <https://commerce.health.state.ny.us/nyports/cgi-bin/applinks/nyports/login.aspx> (accessible to those with HPN accounts and NYPORTS permissions.) These charts highlight the most significant elements in this area but do not set forth the regulatory requirements in their entirety.

Element	State Requirements
Incidents to be reported	10 NYCRR § 405.8(b)
Patient deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards.	10 NYCRR § 405.8(b)(1)
Injuries and impairments of bodily functions, in circumstances other than those related to natural course of illness, disease or proper treatment in accordance with generally accepted medical standards and necessitate additional or more complicated treatment regimens or result in significant change in patient status.	10 NYCRR § 405.8(b)(1)
Poisoning occurring within the facility.	10 NYCRR § 405.8(b)(4)
Patient elopements and kidnappings.	10 NYCRR § 405.8(b)(5)
Disasters or other emergency situations external to the hospital environment which affect facility operations.	10 NYCRR § 405.8(b)(7)
Unscheduled termination of any services vital to the continued safe operation of the facility or to the health and safety of its patients and personnel.	10 NYCRR § 405.8(b)(8)
Specific elements of the mandatory reports	10 NYCRR § 405.8
The hospital shall conduct an investigation of the incidents described in this section and those deemed appropriate by DOH.	10 NYCRR § 405.8(c)

The hospital shall provide a copy of its investigative report to the area administrator within 24 hours of its completion. This report shall contain all information required by the department including:

- an explanation of the circumstances surrounding the incident
- a summary of current patient status
- a chronology of steps taken to investigate the incident
- a summary of all actions taken to correct identified problems, to prevent recurrence of the incident and/or to improve overall patient care

10 NYCRR § 405.8(d)

III. Additional New York State requirements related to incident reporting

Element	State Requirements
The chief executive officer (CEO) shall oversee all plans to correct operational deficiencies identified by regulatory agencies on a timely basis.	10 NYCRR § 405.3(a)
The CEO shall report to the governing body progress in developing and carrying out plans of correction.	10 NYCRR § 405.3(a)
The hospital shall maintain and furnish to the Department of Health, immediately upon request, copies of all documents including: <ul style="list-style-type: none"> • complaints received regarding patient care and documentation of the follow-up actions taken as a result of the investigation of these complaints • copies of all incident reports completed pursuant to section 405.8 of this Part 	10 NYCRR § 405.3(d)(8)-(9)

IV. Centers for Medicare & Medicaid services (CMS)

In addition to the State requirements outlined above, the Centers for Medicare & Medicaid Services (CMS) establish certain reporting requirements for hospitals participating in the Medicare program, outlined below.

Death Reporting Requirements Related to the Use of Restraint and Seclusion

Element	State Requirements
Hospitals must report to CMS each death associated with the use of restraint or seclusion that: <ul style="list-style-type: none"> • occurs while the patient is in restraint or seclusion at the hospital; • occurs within 24 hours after the patient has been removed from restraint or seclusion; or • is known to the hospital and that occurs within one week after restraint or seclusion were utilized, where it is <i>reasonable to assume</i> that the use of restraint or placement in seclusion contributed directly or indirectly to the patient's death. 	42 CFR § 482.13(g)(1)
According to CMS, for the purpose of this regulation, <i>reasonable to assume</i> includes but is not limited to deaths related to restriction of movement for prolonged periods of time	42 CFR § 482.13(g)(1)(iii)

or deaths related to chest compression, restriction of breathing or asphyxiation.

Deaths must be reported to CMS by telephone, within one business day following knowledge of the patient's death. Medical record documentation must include the date and time the death was reported to CMS.

42 CFR § 482.13(g)(2)-(3)

CREDENTIALING

I. The Compliance Program and Credentialing

Ensuring appropriate credentialing is critical to hospitals' provision of an appropriate quality of patient care. New York State laws and regulations, the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (COPs), and hospital accreditation standards require hospitals to conduct on-going and continuous credentialing and competency reviews of clinical and non-clinical staff throughout the period of the staff member's appointment and reappointment. Credentialing requirements for clinical staff must include a series of activities designed to collect relevant data that serve as the basis for decisions regarding appointment and reappointment to the medical staff as well as for the delineation of clinical privileges. Public Health Laws § 2801(b) and § 2805(k) require hospitals to conduct reasonable credentialing investigations using due diligence of individuals associated with hospitals.

A hospital's compliance program should ensure that any required credentialing processes, summarized below, are in place and functioning effectively. The compliance officer need not be substantively responsible for credentialing, nor should the hospital be required to create a new credentialing system if an effective practice already exists. Rather, the compliance program should work with those designated by the hospital to be responsible for credentialing to ensure compliance with all associated requirements on an ongoing basis. Similarly, the compliance program should ensure that relevant information is reported internally and externally as required and check that any necessary corrective action plans are proceeding effectively.

Hospitals are encouraged to share best compliance and credentialing practices with one another and to collaborate on appropriate solutions. The Office of the Medicaid Inspector General also encourages all medical assistance program providers to share information regarding employee and staff qualification and performance of contractors. Honest, factual information shared with hospitals about prior performance and qualifications of former staff or former contractors will help other hospitals to make informed decisions and avoid hiring individuals or contracting with companies with significant deficiencies.

A. Credentialing

1. Initial credentialing

- a. Hospitals ensure reasonable credentialing reviews are conducted for all potential staff, including employee and non-employee staff, permanent and temporary staff, visiting physicians and contractors
 - i. Hospitals take appropriate measures to ensure that individuals applying for positions are actually who they represent themselves to be
 - ii. Hospitals filling positions that require licenses should ensure that staff filling those positions are in good standing and currently hold all required licenses
 - iii. Hospitals give due consideration prior to executing contracts with companies that have been recently convicted of a criminal offense or found civilly liable as a result of actions or omissions related to health care
- b. Review includes examination of the following watch lists combined with appropriate background checks²⁶ :
 - i. Office of the Inspector General (OIG)
 - ii. Office of the Medicaid Inspector General (OMIG)

- iii. General Service Administration (GSA)
 - iv. Department of Homeland Security
 - c. Job applications require applicants to disclose convictions, exclusions, terminations, suspensions, restrictions, or sanctions, disciplinary actions, terminations, settlements, findings of liability, as well as pending administrative, civil, or criminal proceedings, and prior license revocation, suspension, surrender, or restriction
 - d. Monitoring and auditing of the credentialing investigation system exists to determine effectiveness of the procedure's implementation
 - e. Hospital boards identify parameters and standards for credentialing, establish policies and procedures to ensure potential employees and staff are appropriately screened, and delineate parameters for employment
- 2. Recredentialing: Hospitals comply with the Joint Commission requirements, conditions of participation, and hospital bylaws
 - a. Board provides guidance for recredentialing procedure and specifies the information it seeks to review
 - b. Recredentialing reviews are recurring and triggered by identified events and the passage of specified time periods
 - c. Hospitals review OIG's, OMIG's, and GSA's excluded provider list at least every six months
 - d. Hospitals require all staff to promptly disclose debarment, exclusion, suspension, criminal charges or convictions, lawsuits implicating professional practice, professional practice complaints, and other events that may result in ineligibility to participate in the Medicaid program
 - e. Review allegations and findings of substandard care
 - f. Hospitals take prompt and appropriate action to limit or terminate responsibilities of staff who are excluded from the Medicaid program, have inadequate qualifications, or provide substandard care
- 3. Privileging:
 - a. Privileging limits: Hospitals have effective systems in place to limit privileges to ensure that staff practice within the scope of individual qualifications and ability
 - b. Hospitals monitor and audit care, services, and supplies rendered by credentialed staff to ensure that they are within limits of privilege and that the hospital does not bill for care, services, or supplies that are beyond privileged activities
 - c. Privileging process ensures adequate access to services including specialty care

II. Overview: Requirements for New York State Hospitals

The following charts outline the basic credentialing requirements specific to New York hospitals. These charts highlight the most significant elements in this area but do not set forth the entire set of regulatory requirements.

The credentialing and recredentialing requirements are integrally related to the regulatory requirements pertaining to hospital governance, and hospitals may cross-reference these obligations with those set forth elsewhere in this guidance.

III. Medical Staff, Credentialing and Administration

Element	State Requirements	Federal Requirements
Credentialing of Medical Staff.	10 NYCRR § 405.2(e)	42 CFR § 482.12(a)
Determine eligibility for appointment to the medical staff.	10 NYCRR § 405.2(e)(1)	42 CFR § 482.12(a)(1)

Appoint a physician to medical director, who shall be responsible for directing the medical staff organization.	10 NYCRR § 405.2(e) (2)	
Maintain written criteria for selection of medical staff and delineation of medical privileges. Criteria shall include individual character, competence, training, experience, judgment, and physical and mental capabilities.	10 NYCRR § 405.2(e) (3)	42 CFR § 482.12(a)(6)
Staff membership or professional privileges are not dependent solely upon certification, fellowship, or membership in a specialty body or society.	10 NYCRR § 405.2(e) (4)	42 CFR § 482.12(a)(7)
Appoint members of the medical staff with recommendations from existing members of the medical staff in accordance with written procedures.	10 NYCRR § 405.2(e) (5)	42 CFR § 482.12(a)(2)
Record in writing any actions taken on applications for medical staff appointments and reappointments including the delineation of privileges.	10 NYCRR § 405.2(e) (6)	
Ensure that the medical staff has written bylaws.	10 NYCRR § 405.2(e) (7)	42 CFR § 482.12(a)(3)
Approve medical staff bylaws and any other medical staff rules and regulations	10 NYCRR § 405.2(e) (8)	42 CFR § 482.12(a)(4)
Require members of the medical staff to abide by the rules, regulations and bylaws of the hospital.	10 NYCRR § 405.2(e) (9)	
Medical staff is accountable to the governing body for the quality of care provided to patients.	10 NYCRR § 405.2(e) (10)	42 CFR § 482.12(a)(5)
Members of the medical staff shall practice only within the scope of privileges granted by the governing body.	10 NYCRR § 405.2(e) (11)	

Particular obligations relating to the composition and responsibility of the medical staff is outlined below. These requirements overlap with the quality and governance components of this Guidance.

Element	State Requirements	Federal Requirements
Medical Staff.	10 NYCRR § 405.4	42 CFR § 482.22
Accountable to the governing body for the quality of the medical care provided to all patients.	10 NYCRR § 405.4(a)	42 CFR §§ 482.22(b), 482.12(a)(5)
Objective standards of care and conduct are followed by all practitioners granted privileges at the hospital.	10 NYCRR § 405.4(a) (1)	
Mechanisms are established to monitor the ongoing performance of practitioners granted	10 NYCRR § 405.4(a) (2)	

privileges at the hospital in delivering patient care.

Recommend to the governing body, limitation or suspension of the privileges of practitioners who do not practice in compliance with the scope of their privileges, and assure that corrective measures are taken. 10 NYCRR § 405.4(a) (3)

Examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with these provisions and the New York State Public Health Law. 10 NYCRR § 405.4(b) (4)

Adopt and enforce bylaws to carry out responsibilities, which shall be approved by the governing body and which shall set forth specified requirements for medical staff appointment and obligations of medical staff members, including their participation in malpractice prevention and quality assurance programs. 10 NYCRR § 405.4(c) (1)-(7) 42 CFR § 482.22(c)

Establish limits on working hours for eligible medical staff and postgraduate trainees to promote the provision of quality medical care. 10 NYCRR § 405.4(b) (6)

IV. Students and Assistants

Additional requirements and obligations of medical students, physician's assistants, and other clinical professionals are identified in the following regulations:

Element	State Requirements
Post-graduate trainees, post-graduate trainees who possess limited permits and medical students.	10 NYCRR § 405.4(f)
Physician's assistants and registered specialist's assistants.	10 NYCRR § 405.4(e)

V. Non-Clinical Staff Requirements

The following chart outlines the basic requirements placed upon New York hospitals to ensure the competence of both clinical and non-clinical staff members.

Element	State Requirements
Administration requirements regarding clinical and non-clinical staff	10 NYCRR § 405.3
Verification of all applicable current licensure/certification.	10 NYCRR § 405.3(b)(7)
A periodic performance evaluation, based on a written job description, of each employee.	10 NYCRR § 405.3(b)(8)

The provision of employee health services, in consultation with the medical staff. 10 NYCRR § 405.3(b)(9)

The provision for a physical examination and recorded medical history for all personnel. The examination shall ensure that no person shall assume his/her duties unless he/she is free from health impairment which is of potential risk to the patient or which might interfere with the performance of his/her duties. 10 NYCRR § 405.3(b)(10)

Reassessment of the health status of all personnel shall occur at least annually. 10 NYCRR § 405.3(b)(11)

VI. Related Reporting Requirements

Element	State Requirements
Reporting requirements for hospitals in response to a credentialing or privileging action against a licensee:	10 NYCRR § 405.3(e)
The hospital shall report, in writing, to the Office of Professional Medical Conduct (OPMC) with a copy to the Office of Health Systems Management (OHSM) within 30 days of the occurrence of denial, suspension, restriction, termination or curtailment of privileges of any physician, registered physician's assistant or registered specialist's assistant in specified cases.	10 NYCRR § 405.3(e)(1)
The hospital shall furnish to the New York State Education Department (NYSED) within 30 days of occurrence, a written report of any denial, withholding, curtailment, restriction, suspension or termination of any membership or professional privileges in, employment by, or any type of association with a hospital relating to an individual who is a health profession student serving in a clinical clerkship, an unlicensed health professional serving in a clinical fellowship or residency, or an unlicensed health professional practicing under a limited permit or a state licensee, such as an audiologist, certified social worker, dental hygienist, dentist, nurse, occupational therapist, ophthalmic dispenser, optometrist, pharmacist, physical therapist, podiatrist, psychologist, or speech-language pathologist.	10 NYCRR § 405.3(e)(2)
The report shall contain: (a) the name and address of the individual; (b) the profession and license number (c) the date of the hospital's action; (d) a description of the action taken; (e) the reason for the hospital's action or the nature of the action or conduct which lead to the resignation or withdrawal and the date thereof	10 NYCRR § 405.3(e)(2)(iii)(a)-(e)

Documentation, Coding and Billing

One of the primary functions of an effective compliance program is to prevent, or identify and address inappropriate documentation, coding and billing practices. Hospitals must ensure that their policies and procedures emphasize the importance of producing and maintaining appropriate records that reflect the need for service and the actual delivery of the service by appropriate personnel. Claiming for the service

must not exceed what can reasonably be supported by the documentation and must accurately capture the services rendered that meet the quality and claiming standards of the medical assistance program. Hospitals prudently give due consideration to the following when developing their compliance programs:

I. Information management

1. Medical records are timely processed, thorough, and accurate
2. Risks inherent in electronic and non-electronic medical records: Hospitals
 - a. use electronic medical record systems when possible
 - b. that do not use electronic medical records adopt measures to avoid risks associated with handwritten records
 - c. ensure timely and accurate filing of medical records
 - d. ensure appropriate availability of and privacy for medical records
3. HIPAA: Hospitals ensure that information technology systems adequately protect patient privacy rights
4. Charting accuracy and completeness: Patient charts are timely, thoroughly, and accurately completed in accordance with hospital policy and regulations
 - a. review, periodically, for completeness and accuracy
 - b. review discharge summary for accuracy
 - c. review DRG coding for accuracy
5. Signatures on records: Physicians timely sign orders and medical necessity documentation
6. Record retention:²⁷
7. Hospital compliance programs include a records retention program that:
 - a. Establish policies and procedures regarding the creation, distribution, retention, storage, retrieval and destruction of documents, encompassing:
 - i. all clinical and billing records and documentation to support payment and disclose the nature and extent of services provided,
 - ii. all records for cost-based providers receiving rates of payment, all fiscal and statistical records and reports and underlying book and documentation used for the purpose of establishing or modifying the rate or supporting the rate
 - iii. all records necessary to protect the integrity of the hospital's compliance process and confirm the effectiveness of the program, e.g., documentation that employees were adequately trained
 - b. All records relating to care, services, and supplies for patients participating in the Medicaid program are retained for a minimum of six years; for records associated with rates of payment and base year calculations, records are retained provided the base year is in effect

II. Coding, billing and payment

1. Medicaid coding
 - a. Coders are certified, whenever possible
 - b. Coders receive recurring training in coding changes
 - c. Appropriate auditing and monitoring exists of coding (awkward)
2. CDM (charge description master): All changes are accurately and promptly made. System is tested periodically and mapping to coding is accurate.
3. Computer software for billing and coding. Hospitals ensure that:
 - a. software used for billing and coding includes all features necessary for accurate submission of claims to the Medicaid program

- b. manufacturer updates that revise software programs to default values are timely reprogrammed to include necessary values for accurate submission of claims to the Medicaid program
 - c. software is customized to prevent billing for items included in hospital's base rate
- 4. Unbundling of services: Hospitals ensure that all bundled services, particularly Article 28 clinic rates, emergency department rates, and follow-up threshold visits are not unbundled
- 5. Secondary payor assurance: Hospitals ensure that all other insurer(s) are billed before billing the Medicaid program. This requires adequate policies, procedures and staffing to address post payment retroactive identification of other insurer(s) by either the Hospital or reported to the Hospital by other sources (i.e., OMIG). The Hospital must bill and/or respond to a request to bill Medicaid expenditures paid prior to such identification in a timely manner.
- 6. Cost reports: Hospitals ensure that cost reports are the result of proper calculations and allocations based on appropriate financial and statistical data including reasonable, allowable expenses actually incurred and accurately claimed during the appropriate time period. Policies and procedures should include:
 - a. Maintenance rate notices
 - b. Timely preparation and submission
 - c. Creation and maintenance of supporting work papers
 - d. Review of third-party adjustment reports
 - e. Accumulation of non-financial information for cost report preparation
 - i. Physician time studies
 - ii. Departmental statistics
 - f. Periodic review of cost reports by external sources for adherence to third party regulations
- 7. Charity care and financial assistance: Individuals participating in the medical assistance program receive appropriate consideration for charity care and financial assistance²⁸
- 8. Collection practices
 - a. Hospitals do not bill patients in excess of the amount allowed to be billed to patients
 - b. Hospitals do not use unlawful collection techniques
 - c. Collections representatives retain medical records so long as bill is in dispute or remains unpaid
- 9. Business Relations — Establish policies and procedures for physician contracts and agreements, consider the following:
 - a. Description of services
 - b. Destruction
 - c. Review of the business purpose of the joint venture
 - d. Perform a periodic review of vendor contracts to ascertain the necessity for goods or services, including the reasonableness of contract terms
 - e. Perform a periodic review of physician contracts to ascertain the necessity for the physician services, including the reasonableness of compensation
- 10. Hospitals enforce policies and procedures that preclude in-kind or other gifts, payments, or practice arrangements that may violate Stark, Self-Referral laws, or unacceptable practice requirements of the medical assistance program
- 11. Kickback prohibitions: Hospitals enforce policies and procedures prohibiting practices violating anti-kickback laws

Footnotes

¹ 10 NYCRR § 405.2(a).

² 10 NYCRR § 405.2(b)(2).

- 3 Though the OMIG does not have enforcement authority for the federal requirements, a brief recitation of these obligations may be helpful as a reminder of other obligations placed on hospitals.
- 4 OIG/AHLA Discussion Paper, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (Sept. 4, 2007), <http://www.oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>.
- 5 IRS Position Paper, *Governance and Related Topics for 501(c)(3) Organizations* (Feb. 4, 2008), http://www.irs.gov/pub/irs-tege/governance_practices.pdf.
- 6 Boards' obligations include a good-faith effort to ensure that an adequate information and reporting system exists. Systematic failure to do so may render a director liable for losses caused by non-compliance with applicable legal standards. See, e.g., *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996); *Manhattan Eye, Ear & Throat Hospital v. Spitzer*, Attorney Gen. of New York, 715 N.Y.S.2d 575 (Sup Ct, NY County 1999). Boards should make a reasonable effort to become aware of signals of system weaknesses. A board's failure to do so has been found to reflect the failure of a board to exercise required oversight. *In re Abbott Laboratories*, 325 F.3d 795 (7th Cir. 2003). Boards must also establish and maintain a coordinated program that integrates the review activities of all hospital services and ensure that appropriate legal control mechanisms are in place to monitor associated legal risks, avoid malpractice, and enhance quality of patient care. See 10 NYCRR § 405.2(b)(6).

A study published by the Joint Commission on Accreditation of Health Care Organizations noted that the level of knowledge of landmark information among both CEOs and board chairs of hospitals was "remarkably low." Maulik S. Joshi & Stephen C. Hines, *Getting the Board on Board: Engaging Patient Boards in Quality and Patient Safety*, 32 JOINT COMMISSION ON QUALITY AND PATIENT SAFETY 179 (2006), available at <http://www.healthcareteamtraining.com/files/uploads/Getting%20the%20board%20on%20board%20Engaging%20hospital%20boards.pdf>. The study also reported "significant differences between the CEOs' perception of the level of knowledge of their board chairs and the board chairs' self-perception." *Id.* The importance of boards' involvement in ensuring that they are sufficiently informed cannot be overemphasized.

- 7 The OMIG highly recommends that boards familiarize themselves with the OIG/AHLA publication "*Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*," found at <http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf>.
- 8 See IRS regulations governing excess benefit transactions.
- 9 See 10 NYCRR § 405.6.
- 10 The OMIG highly recommends that boards familiarize themselves with the OIG/AHLA publication "*Corporate Responsibility and Health Care Quality — A Resource for Health Care Boards of Directors*," found at <http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>.
- 11 See 10 NYCRR § 405.2(h).
- 12 Furnishing or ordering medical care, services or supplies that are substantially in excess of the client's needs or furnishing medical care, services or supplies that fail to meet professionally recognized standards for health care or which are beyond the scope of the person's professional qualifications or licensure are unacceptable practices under 18 NYCRR § 515.2.
- 13 Individuals with disabilities may need accommodation or modification of standard approaches and procedures. A number of national help lines exist for employers and facilities with questions about accessibility. *Eg.*, Americans with Disabilities Act Home Page, <http://www.ada.gov> (last visited June 12, 2008) (ADA Compliance); FCC Consumer & Governmental Affairs Bureau Disability Rights Office, <http://www.fcc.gov/cgb/dro> (last visited June 12, 2008) (Relay Service); U.S. Access Board, <http://www.access-board.gov> (last visited June 12, 2008) (ADAAG Guideline questions); U.S. Equal Employment Opportunity Commission, <http://www.eeoc.gov> (last visited June 12, 2008) (employment-related questions or complaints).
- 14 See 10 NYCRR § 405.19.
- 15 Medical assistance program recipients may have barriers to informed consent based upon, for example, education, sophistication and knowledge of medical issues and options, foreign languages,

and capacity. These types of barriers should be thoughtfully considered in determining and assessing informed consent.

- 16 Hospitals are cautioned against using family members for translation. Use of family members as translators is not only potentially a breach of HIPAA privacy rights but is also not a reliable approach as it assumes that family members have an interest in, and the capability of, translating all information accurately. f.
- 17 See *supra* note 4.
- 20 The types of incidents that are required to be reported are listed in 10 NYCRR § 405.8(b).
- 21 Refer to Compliance Program Element 7, Requirement 6, for a discussion of the mandatory reporting obligation with regard to effectuating staff awareness of and involvement in the mandatory reporting process.
- 22 10 NYCRR § 405.4(a)(1)(i).
- 23 An investigation that identifies only the proximate cause of the adverse patient event but fails to look into possible systemic causes is not sufficient. 10 NYCRR § 405.8.
- 24 Hospitals must report adverse events to the Department of Health's Office of Health Systems Management within 24 hours of when the incident occurred or when the hospital has reasonable cause to believe that such an incident occurred but must take no more than seven calendar days to determine whether an incident is reportable. 10 NYCRR § 405.8. Reports may be made by making an initial report using a short form found at NYSDOH's Health Commerce System website at <https://commerce.health.state.ny.us/hpn/nyports/intro.html>.

Hospitals are not required to make the initial report using this website. However, if they do not, a report must be made by calling the relevant NYPORTS area office in which the hospital is located:

Buffalo (Western Region): (716) 847- 4357

Includes Counties: Niagara, Orleans, Genesee, Erie, Wyoming, Allegany, Chautauqua, Cattaraugus.

Rochester (Western Region): (585) 423-8045

Includes Counties: Monroe, Wayne, Ontario, Livingston, Seneca, Yates, Schuyler, Steuben, Chemung.

Syracuse (Central Field Office): (315) 477-8561

Includes Counties: St Lawrence, Jefferson, Lewis, Herkimer, Oswego, Oneida, Onondaga, Madison, Cayuga, Cortland, Chenango, Tioga, Broome, Tompkins

Capital District (Northeast Region): (518) 408-5329

Includes Counties: Clinton, Franklin, Essex, Hamilton, Warren, Fulton, Saratoga, Washington, Rensselaer, Albany, Schoharie, Otsego, Delaware, Greene, Columbia, Schenectady, Montgomery.

Hudson Valley (New York Metropolitan): (914) 654-7011

Includes Counties: Ulster, Dutchess, Sullivan, Orange, Putnam, Westchester, Rockland.

New York City (New York Metropolitan): (212) 417-5990

Includes Counties: Bronx, New York, Queens, Kings, Richmond

Long Island (New York Metropolitan): (631) 851-4300

Includes Counties: Nassau, Suffolk.

- 25 Effective mandatory reporting systems are one method for a hospital to identify potentially conspicuous breaches in compliance obligations. Thus, boards must not rely upon the mandatory reporting systems as its sole quality assurance system as mandatory reporting systems are designed only to capture the most severe and egregious cases or issues.

- 26 ADD links to websites here *****
- 27 The creation and retention of such documents and reports may raise a variety of legal issues, including patient privacy and confidentiality. These issues are best discussed with legal counsel.
- 28 Public Health Law §2807-k