NEW YORK STATE DEPARTMENT OF HEALTH
Office of the Medicaid Inspector General

Compliance Program Guidance for General Hospitals

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PREAMBLE

INTRODUCTION

The New York State Office of the Medicaid Inspector General (OMIG) is committed to working with hospitals and the hospital community to proactively build integrity into the front end of Medicaid service delivery and to minimize fraud, waste, and abuse in the Medicaid program overall. Accordingly, this Compliance Guidance for General Hospitals (Guidance) is a result of an interactive process and addresses both the compliance obligations required of hospitals by the law and many of the specific requirements that hospitals must meet to be in compliance.[1] OMIG recognizes the significant efforts already taken by many within the hospital industry to develop effective compliance programs as they assess their own unique circumstances and develop compliance programs that minimize exposure to risk and maximize compliance with applicable statutes, regulations and Medicaid program requirements. OMIG's goal in publishing this Compliance Guidance for General Hospitals is to assist hospitals and their governing bodies in understanding their obligations under the New York State Medicaid program specific to compliance programs and to ensure that effective compliance programs are established. This Guidance is intended to serve as a resource to the industry and indicate how OMIG may interpret New York's mandatory compliance obligation, but it does not have the force of law or regulation.

The scope of OMIG's regulatory authority was established by Chapter 422 of the Laws of New York, 2006. Among the responsibilities created is OMIG's responsibility to oversee the requirement that Medicaid providers create and maintain effective compliance programs.[2] Without OMIG's oversight and enforcement, some Medicaid providers may disregard this requirement, and the legislative goal to reduce Medicaid fraud, waste, and abuse will not be fully realized.

N.Y. Soc. Serv. Law § 363-d and the accompanying regulations, require hospitals (providers subject to N.Y. Pub. Health Law Article 28) to adopt and implement an effective compliance program.[3] This Guidance provides detail on OMIG's expectations for the compliance program that must be adopted and implemented. When establishing a compliance program and certifying to its effectiveness, OMIG determined that providers must generally use the guidance found in the 2004 Federal Sentencing Guidelines and the amendment to those guidelines, effective November 1, 2010 and November 1, 2011, at §8 B2.1(a) when determining effectiveness. OMIG's standard for effective compliance programs shall be that the organization exercises due diligence to prevent and detect inappropriate conduct by the Medicaid provider; promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; employs a compliance program that is reasonably designed, implemented, and

[1] This Guidance is intended to apply to "general hospitals" as defined in section N.Y. Pub. Health Law § 2801. It is not intended to apply to nursing homes, rehabilitation hospitals, and diagnostic and treatment centers. For purposes of this Guidance, the term "hospital" means "general hospital."

[2] In order to meet this responsibility OMIG's Bureau of Compliance conducts effectiveness reviews to evaluate providers' compliance programs. *Compliance Alerts* are published under the Compliance tab on OMIG's Web site, www.omig.ny.gov that provide general guidance on how the Bureau of Compliance conducts effectiveness reviews, forms that could be used by providers in conducting self-assessment reviews, best practices in compliance, and other information that providers can use in developing and monitoring their compliance programs.

[3] N.Y. Soc. Serv. Law § 363-d(1), (2) and (4); 18 N.Y.C.R.R. § 521.1(a) and § 521.3(a).

enforced so that the program is generally effective in preventing and detecting conduct that is contrary to applicable Medicaid laws, regulations, and contractual obligations; and that the Medicaid provider incorporates and follows applicable industry practice or standards called for by any applicable government regulation. OMIG agrees with the position advanced in the Federal Sentencing Guidelines that the "… failure to prevent or detect the instant offenses does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct."[4]

In assessing if hospital providers have compliance programs that meet the statutory and regulatory requirements, OMIG will first assess if the provider has adopted and implemented a compliance program that meets the requirements of N.Y. Soc. Serv. Law §363-d and 18 N.Y.C.R.R. § 521.3. Once a compliance program has been determined to have been adopted and implemented, OMIG can go about the task of determining the effectiveness of the Medicaid provider's compliance program.

BACKGROUND

On March 3, 1997, with the publication of its guidance for clinical laboratories, the Department of Health and Human Services introduced compliance programs as a way for Medicare to reduce fraud, waste, and abuse by providers. Use of compliance programs in Medicare Parts A and B are voluntary. The Department of Health and Human Services' Office of Inspector General (OIG) developed compliance program guidance for various Medicare providers to "…encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations and program requirements." The OIG states that its Compliance Guidance "… should not be viewed as exhaustive discussions of beneficial compliance practices or relevant risk areas."[5]

In 2004, with the publication of the 2004 Federal Sentencing Guidelines (Sentencing Guidelines), the United States Sentencing Commission began highlighting the importance of effective compliance and ethics programs to reduce the sentencing impact of those who are convicted or plead guilty to violations of federal law and regulation. The 2010 amendments to the Sentencing Guidelines reaffirm the importance of taking action in response to self-detected criminal conduct. Congressional focus on mandatory effective compliance and ethics programs for skilled nursing facilities[6] and nursing facilities is a requirement established in Section 6102 of the Patient Protection and Affordable Care Act (ACA) (H.R. 3590, effective on March 23, 2010).[7] A similar requirement was created in ACA's Section 6401(a) for medical providers or providers of other items or services or suppliers.[8] It is expected that this focus will continue to expand to other healthcare providers in federally funded health care programs.

The 2010 amendments to the Sentencing Guidelines' commentary adds making restitution (or other forms of remediation) to the reasonable steps that should be taken to remedy the harm caused by the criminal conduct subject to the Sentencing Guidelines. ACA's Section 6402 requires that any overpayment must be reported, explained and repaid to Medicare or Medicaid by either 60 days after the date on which the overpayment was identified, or the date on which any corresponding cost report is due, whichever is later.[9]

[4] 2010 Amendment to the Federal Sentencing Guidelines at § 8B2.1(a).
[5] Department of Health and Human Services, Office of the Inspector General *OIG Supplemental Compliance Program Guidance for Hospitals,* 70 *Federal Register* 4858, January 31, 2005.
[6] Skilled nursing facilities are defined in 42 U.S.C. § 1320a-7j(a) (2010).
[7] 42 U.S.C. § 1320a-7j(b) (2010).
[8] 42 U.S.C. § 1395cc(j)(8) (2010).
[9] 42 U.S.C. § 1320a-7k(d) (2010).

Compliance guidance programs have become recognized tools to manage the efficiency of the Medicare and Medicaid programs and the efforts to reduce program fraud, waste, and abuse. Medicare Part C (Medicare benefits provided through managed care companies) and D (Medicare's prescription drug program) were the first to include a mandatory compliance program requirement. In 2006, New York was the first state to require Medicaid providers to have an effective compliance program.

BASIS FOR REGULATORY ACTION

The New York State Legislature and the Governor, when adopting N.Y. Soc. Serv. Law § 363-d, confirmed, at subsection 1, the legislative declaration that:

> … it is in public interest that providers within the medical assistance program [Medicaid] implement compliance programs. The legislature also recognizes the wide variety of provider types in the medical assistance program and the need for compliance programs that reflect a provider's size, complexity, resources, and culture… For a compliance program to be effective, it must be designed to be compatible with the provider's characteristics. … [but] there are key components that must be included in every compliance program and such components should be required if a provider is to be a medical assistance program participant. Accordingly, the provisions of this section [363-d] require providers to *adopt effective compliance program elements,* and make each provider responsible for implementing such a program appropriate to its characteristics.

[Emphasis added.]

N.Y. Soc. Serv. Law § 363-d subsection 2 requires OMIG to "create and make available" guidance for compliance programs for providers who participate in the Medicaid program. This Compliance Program Guidance for Hospitals is the first in a series to be developed and published by OMIG as guidance for Medicaid providers.

APPLICABILITY

New York ***requires*** specified Medicaid providers (OMIG recommends all Medicaid providers) to have an effective compliance program in order to participate in the Medicaid program. This mandatory requirement is the most stringent in the country, and reflects the Legislature's determination that even enhanced external policing of providers by government agencies alone cannot completely address the fraud, waste, and abuse in New York's Medicaid program. Those Medicaid providers required to adopt and implement an effective compliance program are enumerated in N.Y. Soc. Serv. Law § 363-d and 18 N.Y.C.R.R. Part 521. Those providers include:

> those subject to the provisions of articles twenty-eight[10] and thirty-six[11] of the public health law, articles sixteen[12] and thirty-one[13] of the mental hygiene law, *and certain* other providers of care,

[10] N.Y. Pub. Health Law Article 28 providers include hospitals, clinics, diagnostic and treatment centers, nursing homes, and other providers as included in the definition of hospital and nursing home in N.Y. Pub. Health Law § 2801(1), (2).
[11] N.Y. Pub. Health Law Article 36 providers include home care services providers as defined in N.Y. Pub. Health Law § 3602.
[12] N.Y. Mental Hyg. Law Article 16 governs the operations of programs, provision of services, and facilities for individuals with developmental disabilities.

> services and supplies under the medical assistance program for which the medical assistance program is a substantial portion of their business operations.[14]

[Emphasis added.]

New York State regulations at 18 N.Y.C.R.R. § 521.2(b) address additional providers that must have effective compliance programs when it defines "substantial portion of business operations" to mean any of the following:

> (1) when a person, provider, or affiliate claims or orders, or has claimed or has ordered, or should be reasonably expected to claim or order at least $500,000 in any consecutive 12-month period from the Medical Assistance Program;
> 2) when a person, provider, or affiliate receives or has received, or should be reasonably expected to receive, at least $500,000 in any consecutive 12-month period directly or indirectly from the Medical Assistance Program; or
> (3) when a person, provider, or affiliate submits or has submitted claims for care, services, or supplies to the Medical Assistance Program on behalf of another person or persons in the aggregate of at least $500,000 in any consecutive 12-month period.

Since the hospital providers in New York State (to which this Guidance is primarily directed) are subject to Article 28 of the N.Y. Pub. Health Law, they are required to have compliance programs that meet the requirements of N.Y. Soc. Serv. Law § 363-d and the accompanying regulations regardless of how much they claim, order, or receive from Medicaid. For hospitals located outside of New York State (who may not be subject to N.Y. Pub. Health Law Article 28) that provide services to Medicaid beneficiaries, the "substantial portion of business operations" test will be applied in determining if those out-of-state hospitals are required to have a compliance program meeting New York State's requirements.

IMPLICATIONS OF FAILURE TO HAVE AN EFFECTIVE COMPLIANCE PROGRAM

The failure of a provider to have an effective compliance program has consequences for a provider which may include being ineligible to bill or receive Medicaid payments, or revocation of the provider's participation status in the Medicaid program. N.Y. Soc. Serv. Law § 363-d 3(b) provides that:

> In the event that the commissioner of health or the Medicaid inspector general finds that the provider does not have a satisfactory program …the provider may be subject to any sanctions or penalties permitted by federal or state laws and regulations, including revocation of the provider's agreement to participate in the medical assistance [Medicaid] program.

Additionally, 18 N.Y.C.R.R. § 521.1 provides that:

> To be eligible to receive medical assistance [Medicaid] payments for care, services, or supplies, or to be eligible to submit claims for care, services, or supplies for or on behalf of another person, the following persons shall adopt and implement effective compliance programs:…

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[13] N.Y. Mental Hyg. Law Article 31 providers include entities required to be certified under N.Y. Mental Hyg. Law § 31.02 to provide services to mentally disabled Medicaid beneficiaries.

[14] N.Y. Soc. Serv. Law § 363-d(4).

DEVELOPMENT OF THIS GUIDANCE

OMIG undertook a comprehensive effort to develop Medicaid compliance guidance for hospitals serving New York's Medicaid enrollees. First, OMIG began by reviewing the most recent compliance guidance documents for hospitals developed by the Office of Inspector General of the United States Department of Health and Human Services (HHS/OIG). These included:

- the 1998 Publication of the OIG Compliance Program Guidance for Hospitals
  http://www.oig.hhs.gov/fraud/complianceguidance.asp
- the 2005 OIG Supplemental Compliance Program Guidance for Hospitals
  http://www.oig.hhs.gov/fraud/complianceguidance.asp
- the three documents on hospital governance developed by HHS/OIG together with the American Health Lawyers Association
  1. *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors.*
     http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf
  2. *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*
     http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf
  3. *An Integrated Approach to Corporate Compliance A Resource for Health Care Organization Boards of Directors*
     http://oig.hhs.gov/fraud/docs/complianceguidance/Tab%204E%20Appendx-Final.pdf

Although these compliance documents primarily address compliance issues identified in connection with the Medicare program, they reflect a compliance strategy developed by HHS/OIG over the past ten years in a variety of health care professions and organizations, and have been revised to reflect provider and beneficiary concerns over that time period.

Second, OMIG conducted a review of the literature relating to compliance and the role of governmental agencies and private organizations.

Third, OMIG conducted a review of the 2004 Federal Sentencing Guidelines and the amendments to the Guidelines, effective on November 1, 2010, as well as ACA and regulations proposed under ACA.

Fourth, OMIG consulted with national compliance organizations, seeking current materials and implementation issues for compliance professionals.

Fifth, starting in 2007, OMIG organized an advisory committee comprised of individuals with interest and expertise in the goals and issues relating to hospital compliance. This committee held multiple all-day meetings to discuss compliance issues, policy, and specific draft language for the compliance guidance and provided comments on earlier versions of the Guidance. The committee included national experts on compliance issues, patient advocates, individuals with experience in hospital executive management, finance, board oversight, and advocates for Medicaid enrollees. The committee also included outside counsel, hospital association representatives, and hospital consultants. OMIG appreciates and recognizes the contributions of the Hospital Compliance Advisory Committee. Their ideas, suggestions, and constructive criticism were invaluable in the development of this Guidance. Not all ideas, suggestions,

and constructive criticisms were incorporated into the final version, nor should the final product be considered to be a consensus document. Ultimately, this Guidance is the work product of the Office of the Medicaid Inspector General and is provided in accordance with the requirements of N.Y. Soc. Serv. Law § 363-d.

Sixth, OMIG developed an internal advisory committee to discuss compliance issues, policy, and to review the draft guidance, focusing on lessons learned from hospital audits and investigations, and consistency with governing laws and regulations.

Finally, OMIG met with representatives from the state agencies with responsibilities for oversight of the Medicaid program, enrollment of Medicaid providers, and licensing of health care professionals and facilities. These representatives offered suggestions and reviewed the proposed text for consistency with governing law and program requirements.

COMPONENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

OMIG worked with various Medicaid providers to identify factors indicative of an effective compliance program. This Guidance provides OMIG's views on the eight elements required under New York's laws and regulations for effective compliance programs and highlights specific recommendations related to each element. Likewise, it provides insight into OMIG's expectations related to the application of compliance activities required under 18 N.Y.C.R.R. § 521.3 including: billings, payments, medical necessity and quality of care, governance, mandatory reporting, credentialing, and other risk areas that are or should with due diligence be identified by the provider. A hospital should use this Guidance to evaluate its compliance program. The Medicaid provider must be able to demonstrate to the New York OMIG that its compliance program meets the requirements of N.Y. Soc. Serv. Law § 363-d and 18 N.Y.C.R.R. Part 521. OMIG is currently developing criteria to measure compliance program effectiveness.

Hospitals with effective compliance programs maximize their opportunities to prevent fraud, waste, and abuse in an environment where the governing body, staff, and management support the compliance officer and compliance structures implemented to support the compliance program. Effective compliance programs exist in cultures that value continuous performance improvement and support individuals who in good faith identify potential areas of non-compliance and opportunities for improvement. A culture that supports continuous performance improvement promotes ongoing review and revision of policies and procedures in order to address changes in operating environments, prevent and detect errors, and react to identified cases of non-compliance through correction, self-reporting, and repayment.

Developing an organizational culture of integrity is essential to the development of an effective compliance program. Creating an effective compliance program requires a commitment beyond drafting a compliance plan document and having it approved by management and the governing body. Additionally, hospitals cannot assume that once a compliance officer is appointed, they have met all their compliance responsibilities. The governing body and senior management must take the lead in supporting the compliance function and demonstrate to everyone connected with the hospital, (employee and contractor alike) that the hospital is committed to compliance and that sufficient resources will be dedicated to ensure that the compliance function is effective. Everyone in the hospital must be educated on and appreciate

their compliance obligations.[15] The compliance officer serves to focus the hospital's efforts and ensure that risk areas are properly assessed and appropriate action to address those risks is implemented. The hospital must allocate sufficient resources to this effort which include, but should not be limited to, establishing a leadership level position that serves as the compliance officer; allocating adequate financial, staff, auditing, risk management and infrastructure resources essential to an effective compliance program and providing appropriate communication linkages between the compliance officer and the governing body so that compliance activities interact collaboratively with senior management. This also includes making resources and educational opportunities available to the compliance officer and appropriate staff which can include attending OMIG Webinars; receiving OMIG communications via OMIG's listserv; reviewing OMIG *Compliance Alerts*; reviewing *Medicaid Updates* published by the New York State Department of Health (DOH), among many other resources and opportunities.

An effective compliance program requires commitment from the governing body and senior management to operate in an ethical, legal and compliant manner. The commitment "from the top" must be communicated to all employees and contractors of the hospital. It must be evident in the structures the hospital creates to support the compliance officer and in a business philosophy that compliance is not just a department, but rather is a shared responsibility for the entire hospital. The compliance office and its staff cannot be seen as solely responsible for compliance within the hospital.

Notwithstanding the prior statements, the Legislature recognizes that a compliance program required by N.Y. Soc. Serv. Law § 363-d "… may be a component of more comprehensive compliance activities by the…[Medicaid] provider so long as the requirements of…[§ 363-d] are met."[16]

Hospitals that consider statutory and regulatory requirements as a baseline for compliance but aspire to exceed those requirements will be most successful in their compliance programs' effectiveness, will integrate compliance into their routine business processes, and will realize additional benefits in their business operations. Incorporating the compliance function into the routine business activities of the hospital can serve as a vehicle to strengthen day-to-day operations and encourage organizational integration. This promotes development of hospital-wide solutions which consider the impact on all stakeholders rather than individualized solutions that are developed without such consideration. The level of integration of the compliance function into hospital operations is a measure of the importance that the governing body and management place on compliance and the compliance officer's responsibilities.

CONCLUSION

Many hospitals have already implemented policies, procedures, and systems that support the goals established by the New York State Legislature when enacting Chapter 422 of the Laws of 2006. Those efforts deserve recognition and acknowledgement, even if they are not labeled as compliance programs. OMIG does not suggest that compliance programs that are working be dismantled in order to conform to the specifics of this Guidance, but to the extent that hospitals determine that existing programs could be enhanced as a result of this Guidance, OMIG encourages hospitals to make those enhancements.

[15] In developing their compliance education curriculum, it is recommended that hospitals take into account their prior compliance history, compliance risk assessments, job responsibilities of those attending training, and other reasonable factors.
[16] N.Y. Soc. Serv. Law §363-d(2) and 18 N.Y.C.R.R. § 521.3(a).

This Guidance serves as one of the tools that OMIG will use to determine the effectiveness of compliance programs related to Medicaid laws, regulations, and program requirements.[17] Compliance structures implemented by hospitals following this Guidance may also positively impact other regulatory obligations, but this Guidance is not intended to preempt other New York State or federal agencies' oversight of hospitals. OMIG recognizes and acknowledges the roles of other state and federal agencies and hopes that this Guidance will complement those agencies' regulatory activities. Finally, OMIG hopes that this Guidance will assist the various trade and professional associations that are involved in promotion and improvement of Medicaid compliance programs and awareness.

[17] OMIG's Web site, www.omig.ny.gov, includes other resources that have been developed to assist providers in determining the effectiveness of their compliance programs. *Compliance Alerts* are published on OMIG Web site and include a recommended self-assessment tool, as well as a listing of materials that OMIG uses when it conducts its compliance effectiveness reviews.

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Compliance Program Obligations

Every provider that is required to adopt and implement an effective compliance program as a condition of their Medicaid participation must meet the requirements of N.Y. Soc. Serv. Law § 363-d and 18 N.Y.C.R.R. § 521.3. The required compliance program must apply to billings, payments, medical necessity and quality of care, governance, mandatory reporting, credentialing, and other risk areas that are or should, with due diligence, be identified by the provider.

The following is a list of all elements and requirements of a compliance program. They are presented here for reference without guidance. They are derived directly from and are required by N.Y. Soc. Serv. Law § 363-d and 18 N.Y.C.R.R. § 521.3.

Element 1: Written Policies and Procedures

Requirement 1: Code of conduct or code of ethics embodies compliance expectations.
Requirement 2: Written policies and procedures describe compliance expectations.
Requirement 3: Written policies and procedures describe how the compliance program is implemented.
Requirement 4: Written policies and procedures provide guidance to employees and others on dealing with potential compliance issues.
Requirement 5: Written policies and procedures describe how potential compliance problems are investigated and resolved.

Element 2: Designation of a Compliance Officer

Requirement 1: Compliance officer is an employee of the hospital.
Requirement 2: Compliance officer is responsible for the day-to-day operation of the compliance program.
Requirement 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.
Requirement 4: Compliance officer reports directly to the chief executive or other senior administrator.
Requirement 5: Compliance officer periodically reports directly to the governing body on the activities of the compliance program.

Element 3: Training and Education

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

Element 4: Communication Lines to the Compliance Officer

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

Element 5: Disciplinary Policies

Requirement 1: Disciplinary policies encourage good faith participation in the compliance program by all affected individuals including policies that articulate expectations for reporting compliance issues and for assisting in their resolution.
Requirement 2: Disciplinary policies outline sanctions for failing to report suspected problems, for participating in non-compliant behavior, and for encouraging, directing, facilitating, or permitting non-compliant behavior, and are fairly and appropriately enforced.

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

Requirement 1: A system exists for routine identification of compliance risk areas specific to hospitals.
Requirement 2: A system exists for self-evaluation of risk areas, including internal audits and. as appropriate, external audits.
Requirement 3: A system exists for evaluation of potential or actual non-compliance as a result of self-evaluations and audits.

Element 7: Responding to Compliance Issues

Requirement 1: A system exists to respond to compliance issues as they are raised.
Requirement 2: A system exists for investigating potential compliance problems.
Requirement 3: A system exists for responding to compliance problems as identified in the course of self-evaluations and audits.
Requirement 4: A system exists to correct compliance problems promptly and thoroughly.
Requirement 5: A system exists to implement procedures, policies, and systems as necessary to reduce the potential for recurrence of identified compliance problems.
Requirement 6: A system exists to identify and report compliance issues to the New York State Department of Health or the New York State Office of the Medicaid Inspector General.
Requirement 7: A system exists to refund overpayments.

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

Requirement 1: A policy of non-intimidation and non-retaliation protects individuals in their good-faith participation in the compliance program, including reporting potential issues, investigating issues, self-evaluations, audits and remedial actions, and reporting to appropriate officials as provided in N.Y. Labor Law §§ 740 and 741 (False Claims Act).

COMPLIANCE PROGRAM GUIDANCE

The obligations for a compliance program are found in N.Y. Soc. Serv. Law § 363-d and 18 N.Y.C.R.R. Part 521. The statutory and regulatory obligations are restated in summary form and listed in the portion of the Guidance that follows as "Elements" and "Requirements." OMIG's compliance guidance is labeled as "Recommendations" and follows the Elements and Requirements to which the Recommendations apply. This 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 Elements and Requirements.

In OMIG's view, an effective compliance program can be part of an institutional control structure that plays a part in all the critical functions of a hospital. An effective compliance program promotes program integrity in the Medicaid program, which may also impact other lines of business of the hospital. It provides hospital management and the governing body with the organizational framework necessary to promote compliance with laws and regulations governing not only finance and administration, but also those governing clinical services.

While a compliance program may impact clinical services and may even overlap with a facility's quality management program, the compliance program should not be considered a substitute for an effective quality management program. Compliance and quality management are distinct disciplines that require different expertise. The compliance program promotes adherence to laws and regulations, including those that relate to patient care (e.g., credentialing, adverse event reporting, establishment of a quality management program, etc.). By contrast, the quality management program promotes compliance with the standard of care. It applies the regulations, best practices, clinical protocols, and other strategies to prevent, identify and correct deficiencies in clinical processes, decisions and technique.

ELEMENT 1: Written Policies and Procedures

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

Recommendations:

A. Code is approved by the governing body.
B. Code is written in clear, concise, non-technical, language so as to be easily understood.
C. Code includes compliance expectations with regard to:
    1. ethical business conduct;
    2. patient care and patient rights, access to and provision of medically necessary care, and confidentiality;
    3. conflicts of interest;
    4. billing and coding accuracy;
    5. payments and collections;
    6. quality of care;
    7. governance;
    8. credentialing;
    9. raising compliance questions and reporting compliance concerns; and

10. other matters as may evolve under the compliance program.

D. Code applies to all governing body members, employees, and persons associated with the hospital (for example, volunteers, contractors, medical staff, and vendors).
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 internal employee website; summary of code is posted on the hospital's public website; written summary of code is provided upon request. Copies of the code are distributed to all governing body members, employees, and persons associated with the hospital.

Requirement 2: Written policies and procedures describe compliance expectations.[18]

Recommendations:

A. Compliance policies and procedures are written, reviewed, and updated[19] with consideration given to applicable laws, regulations, and, as appropriate, reports, including government reports, and government and industry guidance and requirements established by applicable regulatory authorities.
B. Hospitals shall refer to the following sources to develop policy standards:
   1. laws;
   2. regulations;
   3. official published guidance from DOH:
      a. Office of Health Insurance Programs (NYS DOH OHIP) concerning the Medicaid program;
      b. Office of Health Systems Management; and
      c. *Medicaid Updates* (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 publicly distributed documents, including NYS DOH "Dear Chief Executive Officer" and "Dear Administrator" letters;
   6. eMedNY Provider Manual http://www.emedny.org/Provider Manuals/ index.html);
   7. terms of any settlement agreements in force with OIG, OMIG, or the New York State Attorney General;
   8. Medicaid's or Medicare's conditions of participation;
   9. directives issued by OMIG relative to compliance programs; and
   10. issues that may evolve under their compliance programs.

C. Hospitals may also consider, where appropriate, the following sources to develop compliance-related policy standards. In relying on sources such as professional journals or associations or publications of accrediting bodies, hospitals should be careful to ensure that such sources do not conflict with statutory or regulatory requirements.
   1. The Joint Commission and other accrediting bodies;
   2. professional journals;

[18] *See* 10 N.Y.C.R.R. §405.2(c).
[19] *See* 10 N.Y.C.R.R. § 405.3(d)(6)

3. IPRO reports;[20]
4. Statewide Planning and Research Cooperative System (SPARCS) reports[21] published by NYS DOH;
5. standards for and results from 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. terms of corporate integrity agreements issued to hospitals and other providers by the OIG and OMIG (http://www.omig.ny.gov);
8. standards and guidelines issued by national organizations of relevant professions and professional organizations such as the American Health Lawyers Association and Health Care Compliance Association;
9. information from relevant professional disciplinary agencies:
   a. NYS DOH (http://nyhealth.gov);
   b. New York State Department of Education (http://www.nysed.gov); and
10. publications, including appropriate newsletters, manuals and guidelines, related to billing compliance.

D. Policies and procedures are organized logically for easy reference.
E. Policies and procedures are conveniently located and readily accessible.
F. Policies and procedures address, at a minimum, compliance expectations with regard to:[22]
   1. accurate billing and coding, including exhausting all existing benefits prior to billing the Medicaid program;
   2. payments and collections, including patients' access to financial assistance; [23]
   3. credit balances/overpayments;
   4. access to and provision of medically necessary care;
   5. quality of care;
   6. DOH quality reports and adverse incident reports;
   7. governance (i.e., how management and the governing body interface with the compliance program or how conflicts of interest of directors or officers are to be addressed, among others);
   8. mandatory reporting;
   9. credentialing;
   10. patients' rights, including, but not limited to treatment without discrimination as to race, color, religion, sex, national origin, disability, sexual orientation, age or source of payment;
   11. *Your Rights as a Hospital Patient in New York State*; patient grievance, appeal and fair hearing procedures;
   12. reporting of events and costs affecting payment from the Medicaid program;
   13. timely and accurate claims submission and payment;
   14. protection of patients against balance billing;
   15. other risk areas that are or should with due diligence be identified by the hospital; and

[20] IPRO, http://www.ipro.org/
[21] Statewide Planning and Research Cooperative System, http://www.health.state.ny.us/statistics/sparcs/
[22] It should be noted that the provider's compliance plan is not required to specifically address each of these in the formal document, unless that is how the provider wishes to address these points. The policies referred to may exist elsewhere within in the provider's policies and procedures and can be relied upon and referenced in the compliance plan.
[23] N.Y. Pub. Health Law § 2807-k(9-a).

16. accurate reporting and attestation to qualify for, and receive payment through, the Medicaid and Medicaid Electronic Health Records Incentive programs.

G. Policies and procedures explain reporting obligations related to compliance concerns, and the policies and procedures set forth expectations and role of compliance officer in addressing those concerns.
H. Material changes to policies and procedures are conveyed to governing body as appropriate, applicable employees and persons associated with the hospital within a reasonable period of time.

Requirement 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 body, employees, and persons associated with the hospital;
    3. communication/reporting mechanisms; and
    4. frequency of meetings and connection between the compliance function and the governing body and senior management.

Requirement 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 questions and concerns.
B. Policies and procedures provide guidance to employees and others on how to report potential compliance questions and concerns 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, must refuse to participate in unethical or illegal conduct and report any unethical or illegal conduct to the compliance officer, a senior manager with authority to address the issue, or a supervisor. This should include a statement as to the consequences of failures to act according to the stated expectations.
D. Contracts with subcontractors and affiliates include termination provisions for failure to adhere to hospital compliance requirements.

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

Recommendations:

A. Policies and procedures ensure confidentiality, where 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.
F. Policies and procedures address reporting results of any investigation of potential compliance problems to the governing body and senior management.

ELEMENT 2: Designation and Role of Compliance Officer

The compliance officer is an important element of the overall control structure of the hospital. The exact role of the compliance officer should be left to hospital management and its governing body to define within the context of applicable laws and regulations. However, the compliance officer should be a leader in the organization who works with senior managers and staff to minimize fraud, waste, and abuse in the Medicaid program and to promote compliance with laws and regulations generally. As noted above, in areas such as quality management and clinical issues, the compliance officer may not be in the best position to provide management, oversight and decision-making. An effective compliance program should not be a substitute for an active quality management program.

Requirement 1: Compliance officer is an employee of the hospital.

Recommendations:

A. Compliance officer is an employee, as "employee" may be defined by federal or state laws and regulations, which may apply to such topics as income tax reporting, workers' compensation coverage, pension and retirement benefits, and collective bargaining, among others.
B. Compliance officer has the experience, training and integrity to perform the responsibilities associated with the position of compliance officer, which may include, but not be limited to:
    1. compliance officer has relevant experience, which may include experience in areas such as compliance, operations, patient care, nursing, medicine, law, risk management, coding and billing or auditing;
    2. compliance officer has experience and understanding of the relationship between hospital operations and compliance and has knowledge of the applicable laws, regulations, and requirements; and
    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.
C. Compliance officer has a leadership role that is recognized and promoted by senior management:
    1. compliance officer participates regularly in senior management meetings or receives reports on compliance-related matters in areas that may include quality and risk management, billing and coding, internal audit and internal controls, credentials, and vendor contracting.

Requirement 2: Compliance officer is responsible for the day-to-day operation of the compliance program.[24]

[24] The compliance officer need not have substantive responsibility for all operational areas, but will be advised of compliance concerns and will take appropriate action based upon the information received. The NYS Office of Medicaid Inspector General recognizes that the compliance officer is not single-handedly responsible for compliance with billing, payments, governance, quality of care, and mandatory reporting requirements. Rather, the compliance officer provides a road map for the governing body and management to meet statutory and regulatory obligations and are often delegated the responsibility of designing systems, policies, and processes that give hospital management the tools needed to ensure compliance. Ultimately, the governing body and CEO are responsible for meeting statutory and regulatory requirements. *See* 10 N.Y.C.R.R. § 405.2(b), (d).

Recommendations

A. Compliance officer provides compliance-related guidance and facilitates communication and activities on compliance-related questions and concerns.
B. Compliance officer promotes, throughout the hospital, the existence of systems and processes that are reasonably effective in identifying and ensuring that appropriate action is taken to minimize fraud, waste, and abuse in the Medicaid program.
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;[25]
    3. access to resources with expertise relevant to compliance concerns and risk areas;
    4. sufficient time, staff and budget allocation to maintain and support an effective monitoring and auditing program that addresses risk areas and compliance questions and concerns;
    5. support from the chief executive and governing body 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; and
    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 promotes quality (in collaboration with others responsible for quality in the hospital), through compliance and adherence to the code of conduct/ethics, laws, and regulations.
F. Compliance officer is advised of meetings affecting the compliance program such as quality assurance, risk management, billing and coding, and credentialing committees' meetings and attends, as appropriate.
G. Compliance officer is provided information about patterns or significant concerns related to quality of care, risk management, and billing and coding.
H. Compliance officer takes sufficient steps to document efforts to meet the statutory obligations, advises management and the governing body about difficulties achieving compliance and implications of non-compliance.[26]
I. Compliance officer considers resignation in appropriate circumstances.[27,28]

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[25] There are no laws to prevent the compliance officer from obtaining access to hospital records for compliance purposes. There may be a misconception that the Health Insurance Portability and Accountability Act and other laws act to shield hospital records from compliance officers and compliance functions. Access to patient records should, however, be limited to those records and those portions of records that can be reasonably determined to be relevant to a legitimate compliance purpose.

[26] The compliance officer should document efforts the hospital takes to meet statutory requirements. Documentation will demonstrate that the hospital and the compliance officer took all reasonable steps to maximize the opportunities to have an effective compliance program. Placement of the compliance officer position sufficiently high in senior/high-level management, combined with ensuring the compliance officer has regular and direct access to the governing body, may help maintain the necessary tone from the top on compliance and reduce the likelihood of a compliance failure.

[27] Compliance officers may wish to refer to the Health Care Compliance Association's ethical standards (Principal 1, R1.4 of the HCCA Professional Code of Ethics adopted September 15, 1999); and the Society of Corporate Compliance and Ethics', *Code of Professional Ethics for Compliance Ethics Professionals* (Principal 1, R1.4 adopted August 29, 2007).

J. Compliance committee exists to provide support to and oversight of the compliance program
    1. Compliance committee shall include executives and managers with compliance-related duties, such as:
        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 manager;
        k. human resources manager; and/or
        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 and
        b. compliance committee assists compliance officer with compliance program implementation and planning.

K. Compliance officer periodically and effectively communicates with governing body, employees, and persons associated with the hospital:
    1. See Element 2 at Requirement 5 "Compliance officer periodically reports directly to the governing body on the activities of the compliance program" below;
    2. In addition to the compliance training that is addressed in Element 3, the compliance officer should communicate with employees and persons associated with the hospital at such times and in ways that make his/her communication most effective.

Requirement 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.

<u>Recommendations</u>

A. Governing body 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 body and management understand that the 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.[29]

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[28] A compliance officer's decision to resign in appropriate circumstances is an understandably difficult one to make, both professionally and personally, for the compliance officer. The hospital leadership should consider the importance of the compliance statement that the compliance officer is making through his/her resignation in the face of an unresolved compliance issue.

[29] A compliance officer may be required to make recommendations that may 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.

Requirement 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. This addresses the potential conflict between the duty of the general counsel to defend the organization (including the application of the attorney-client privilege) and the compliance program's obligations to identify risk areas and non-compliance.[30]
C. Compliance officer does not report to the chief financial officer/finance department. This addresses the potential conflict of a compliance assessment of billing and financial weaknesses of the compliance officer's supervisor when this reporting structure exists.
D. The hospital's chart of organization shows a reporting relationship between the compliance officer and the appropriate senior-level administrator.

Requirement 5: Compliance officer periodically reports directly to the governing body on the activities of the compliance program.

Recommendations

A. Compliance officer reports at least annually to the governing body.
B. Compliance officer meets at least quarterly with the governing body committee that is responsible for oversight of the hospital's compliance activities.[31]
C. Compliance officer meets annually at a prescheduled executive session of the governing body in the absence of the chief executive and others who report to the chief executive. Compliance officer may also meet with the governing body in executive session on an as-needed basis.
D. Compliance officer provides to the governing body regular written reports and metrics that have been developed by the provider to measure the effectiveness of the compliance program.
E. Governing body reviews and approves (as appropriate) any annual compliance work plan for the hospital.
F. The hospital's chart of organization shows a reporting relationship between the compliance officer and the governing body.

[30] It should be noted that there is no statutory or regulatory prohibition on a compliance officer reporting to the general counsel, but such reporting relationships may limit the transparency of the compliance officer's role within the hospital.

[31] It is not expected that all hospitals have a governing body committee solely dedicated to compliance oversight responsibilities. It is also possible, in some hospitals, that the full governing body takes responsibility for compliance oversight. Hospitals must determine how they best address compliance oversight at the governing body level.

ELEMENT 3: Training and Education

Requirement 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.[32]

Recommendations

A. Effective mechanisms exist to convey relevant policies and procedures to governing body members, employees and persons associated with the hospital.
B. Hospital assesses adherence to policies and procedures.
C. Contracts with subcontractors and affiliates include provisions regarding training on compliance issues, expectations and the operation of the compliance program, as well as any hospital policies and procedures that may impact the work being performed by the subcontractor and affiliates for the hospital.
D. Effectiveness of training is periodically assessed through:
    1. testing of those attending the training (usually referred to as "post tests");
    2. observed competency of individuals in areas where training was provided;
    3. evaluating, monitoring, and auditing compliance with policies and procedures.
E. Governing body members, employees, and persons associated with the hospital who receive training are informed of when and how to obtain additional assistance (e.g., hotlines, drop boxes, e-mail addresses, etc.).
F. Training materials:
    1. are evaluated on an annual basis and updated, as appropriate;
    2. consider results of audits and investigations;
    3. include a variety of teaching methods;
    4. are provided in different languages, as appropriate; and
    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. employee intranet web site that provides links to other Web sites;
    6. posters; and
    7. frequently asked questions (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 the compliance function to obtain anonymous information from governing body 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; and

[32] It is understood that hospital providers may have collective bargaining agreements that impact on training obligations required under Element 3.

2. systems to monitor training attendance exist.

M. Training is documented. Systems may include:
   1. sign-in sheets;
   2. minutes from meetings; and
   3. electronic or manual tracking.

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

Requirement 2: Training on compliance issues, expectations, and the compliance program operation occurs periodically and is part of orientation for new employees, or associates,[33] 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 (i.e., training for billing staff will likely be different from training for medical records staff, etc.).
D. Training[34] is provided regarding relevant legal obligations, including, but not limited to:
   1. laws related to prohibitions on submission of false claims;[35]
   2. federal administrative remedies for false claims and statements established under 31 U.S.C. §§ 3801 – 3812;
   3. ACA at Section 6402 which should include, but may not be limited to, obligations to disclose overpayments;[36]
   4. State laws pertaining to civil or criminal penalties for false claims and statements;
   5. whistleblower protection under such federal and state laws; and
   6. the hospital's policies and procedures for detecting and preventing fraud and abuse.
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; and
   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.

[33] For purposes of the Compliance Program, a hospital's associates can include volunteers, independent contractors providing services on the hospital's behalf, members of the medical staff, among others.
[34] Information in this subsection may be included in an employee handbook, if any.
[35] For example, see the Federal False Claims Act, the Deficit Reduction Act of 2005 and the New York State False Claims Act, among others.
[36] 42 U.S.C. § 1320a-7k(d) (2010).

ELEMENT 4: Communication Lines to the Compliance Officer

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

Recommendations

A. Communication lines to the compliance officer are sufficiently publicized to:
    1. ensure awareness that communication lines exist;
    2. encourage reporting:
        a. compliance officer's contact information is conspicuously posted in areas that may include:
            1) in high traffic areas;
            2) on the hospital's intranet and Internet sites;
            3) in the hospital's newsletters;
            4) on the hospital's television station;
            5) along with patient bill of rights;
            6) in admitting/registration areas; and
            7) at nurse's stations.
        b. compliance officer's contact information is included with hospital materials that may include:
            1) new staff orientation and updated training;
            2) compliance-related training; and
            3) contractors and affiliate training, if any.
B. Hospital ensures that sufficient communication methods exist between the compliance department and individuals with physical and cultural communication barriers, as may be required law, regulations and guidelines.
C. Compliance-related information or reports are forwarded to appropriate compliance staff.
D. Compliance staff are available to answer compliance-related questions and respond to compliance-related concerns.
E. Hospital fosters organizational culture that encourages open communication without fear of retaliation.

Requirement 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. If reports of compliance issues are provided to anyone other than the compliance officer, the person receiving the report should provide a report to the compliance officer of the potential compliance issue in sufficient detail that the compliance officer can track and log the report and ensure that a complete investigation can be completed
B. Telephone hotlines exist to receive reports of potential compliance issues and hotline calls are logged and tracked.

C. Compliance officer has at least one accessible method of receiving anonymous reports.
D. Compliance officer shall treat reports of potential compliance issues as confidential if requested by the person making the report.
E. Compliance officer provides feedback to reporting individuals, as appropriate.
F. Compliance officer publicizes alternative methods of reporting, such as mailing address and location of locked drop boxes.
G. Several independent reporting paths exist.
H. Governing body members, employees and persons associated with the hospital are advised of reporting mechanisms in a variety of ways.
I. Governing body members, employees and persons associated with the hospital are advised of their responsibility and obligation to report compliance-related concerns.
J. Procedures are established to provide an opportunity to make suggestions about the reporting process.
K. 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.

ELEMENT 5: Disciplinary Policies[37]

Requirement 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 affected individuals on:
      a. disciplinary policies;
      b. the types and levels of issues that must be reported;[38] and
      c. how to report compliance issues, including the information that should be disclosed;
   2. collective bargaining agreements should attempt to avoid provisions that are inconsistent with the obligation to encourage good faith participation in the compliance program; and
   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 affected individuals shall:
      a. promptly report non-compliant behavior, even if it is non-compliant behavior of the reporting individual;
      b. participate in good faith in investigations;
      c. be truthful with investigators; and
      d. preserve documentation or records relevant to ongoing investigations.
   2. Performance expectation plans for managers and supervisors include supporting the hospital's compliance program.

Requirement 2: Disciplinary policies outline sanctions and are fairly and consistently enforced.

Recommendations

A. Disciplinary policies outline sanctions for:
   1. failing to report potential compliance issues;
   2. participating in non-compliant behavior; and
   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, and

[37] Support of compliance programs by affected individuals is critical to the success of a compliance program. Governing bodies and senior management should encourage participation in the compliance program. However, if incentives and affirmative efforts do not succeed, consistently applied disciplinary policies must exist to ensure participation as a last resort. Additionally, it is understood that hospital providers may have collective bargaining agreements that may impact on the disciplinary policy requirement of Element 5.

[38] Staff reporting may be over inclusive or under inclusive if staff does not receive direction as to the types of incidents a hospital considers related to compliance. Hospitals will benefit by defining the scope of issues and incidents that are considered compliance-related and reportable.

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 and conducts a root cause analysis, where appropriate.
C. Corrective action initiatives are considered concurrently with disciplinary actions.
D. Sanctions are consistent:
   1. disciplinary decisions are centralized to ensure consistency; and
   2. level of discipline is consistent regardless of status within the hospital of the offending person.
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 obligations.

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

Requirement 1: A system exists for routine identification of compliance risk areas specific to the hospital.[39]

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, among other things:
    1. work plans and publications issued by OMIG;
    2. work plans issued by the OIG;
    3. NYS OMIG audits;
    4. NYS DOH surveys and surveys by any other appropriate New York State or federal agency;
    5. risk areas identified by any appropriate New York State agencies;
    6. risk areas identified in guidance issued by the OIG;
    7. surveys by accrediting bodies; and
    8. changes to applicable laws and regulations.

Requirement 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.
B. Hospital ensures corrective action plans identified as part of any compliance inquiry or risk assessment are monitored for implementation and to ensure that the corrective action is adequately addressing the identified compliance risk areas.
C. Auditors have relevant training and/or expertise.
D. Audits are conducted with sufficient frequency and thoroughness to effectively identify non-compliance:
    1. audit plan (can also be referred to as a "work plan") is developed at least annually, revised as necessary, and
        a. assesses compliance data from previous year (audits, statistics, etc.) to identify risk areas for the coming year;
        b. includes matters that may have been the subject of a regulatory finding, observation, or recommendation;
        c. identifies corrective action plans that require auditing or monitoring to confirm compliance;
        d. includes measurements, timetables, and individuals responsible for addressing each risk area; and
        e. the audit plan and its revisions, if any, are shared with appropriate staff and leadership within the hospital.

[39] *See also* 10 N.Y.C.R.R. §§ 405.5, 405.6.

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

E. Internal and external audit results, including those affecting compliance, are shared with the compliance officer and governing body or governing body's audit/compliance committee.

Requirement 3: A system exists for evaluation of potential or actual non-compliance as a result of self evaluations and audits.[40]

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 and forwarded for appropriate action, as necessary;
   2. negative trends are identified and further investigated and monitored; and
   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; and
   3. findings of non-compliance are further investigated and analyzed for breadth and scope and included in corrective action plans.

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

D. The effectiveness of self-evaluation and monitoring efforts are periodically assessed and evaluated by the compliance officer and the chief executive officer or another member of senior management.

E. A process exists for assessing any plan of correction that has been implemented. This may include evaluating, if the plan of correction has been fully implemented, whether the correction implemented is addressing the non-compliant issue, and if the implemented plan of correction is still in effect, among other things.

[40] Reference may be made to two publications by the Association of Healthcare 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 as low-risk reveals non-compliance, a hospital may decide to change its compliance program to audit the areas potentially involved in the discovered non-compliance. See Mark P. Ruppert, Association of Healthcare Internal Auditors, , *Defining the Meaning of 'Auditing' and 'Monitoring' and Clarifying the Appropriate Use of Terms*, http://www.ahia.org/pdf/DefiningAuditingandMonitoring.pdf Debbi J. Weatherford, Association of Healthcare Internal Auditors, , *Seven Component Framework for Compliance Auditing and Monitoring Physician Contracting in Healthcare Organizations*, http://www.ahia.org/audit_library/resources/Physician Contracting.pdf .

Requirement 4: A system exists to ensure that false claims for payment are not being submitted.[41]

Recommendations

A. Establish systems of prepayment and post-payment review for claims submission with the goal of identifying false claim(s).
B. Implement a system that corrects billing and other instances of non-compliance (whether because of fraud, error, or mistake) and which includes appropriate disclosures and refunds of overpayments.

[41] Although this requirement is not specifically part of the requirements set out in N.Y. Soc. Serv. Law § 363-d or 18 N.Y.C.R.R. § 521.3, it is being included in order to address the requirements of the federal False Claims Act and New York's Fraud, Enforcement and Recovery Act, as well as the requirements of ACA. See also New York regulations on Recovery and Withholding of Payments or Overpayments at 18 N.Y.C.R.R. Part 518

ELEMENT 7: Responding to Compliance Issues

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

Recommendations

A. Policies and procedures exist that address how a potential compliance issue or concern is to be reported and investigated.
B. Compliance officer follows policies and procedures upon receipt of a report of potential compliance issue or concern in a timely manner.
C. Policies and procedures ensure immediate action to secure the health and safety of current patients if affected by the issue or concern raised.

Requirement 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 or designee is trained to conduct investigations;
    2. compliance officer is assisted by other non-compliance departmental staff, as needed;
    3. compliance officer has unfettered access to relevant information to thoroughly conduct investigations;
    4. compliance officer makes every effort to ensure transparency when investigating compliance problems to the extent that transparency does not conflict with legitimate confidentiality concerns;
    5. compliance officer assesses compliance issue for referral to general counsel, as appropriate;
    6. compliance officer advises chief executive or governing body of investigation, as appropriate;
    7. compliance officer engages external resources to assist with investigations, including independent counsel and independent board committee, as appropriate; and
    8. investigations are directed independently of department(s) implicated by allegations.
C. Recusal - Potential compliance problems are promptly, fairly, and thoroughly investigated by impartial investigator(s), and the hospital has written policies addressing recusal of employees and persons who have a conflict of interest and are associated with the hospital from investigations.
D. Documentation:
    1. documentation and evidence related to the investigation are maintained in a confidential manner, as appropriate; and
    2. hospital has 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 assured during investigative interviews; and

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 alleged compliance issues;
   2. the identities of the individuals interviewed, if any;
   3. a general description of the evidence reviewed and secured;
   4. observation/findings of fact; and
   5. recommendations for discipline or corrective action, if any.

Requirement 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 body's audit committee, as necessary;
   2. compliance officer meets with auditors;
   3. compliance officer participates, as appropriate, on risk management, quality assurance, and other management committees; and
   4. 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,[42] as appropriate.
D. Governing body is apprised of significant compliance deficiencies and corresponding corrective action plans, as appropriate.

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

Recommendations

A. Management ensures departments implement corrective action plans:
   1. individual responsibility is assigned for each aspect of corrective action plans and individuals' performance relative to the responsibility assigned is included in their personnel performance review plans, as appropriate; and
   2. reports are made to the compliance officer regarding progress of the corrective action.
B. Governing body is advised of progress of corrective action plans, as appropriate.
C. Follow-up monitoring takes place, at appropriate intervals, to verify that problem is corrected.
D. Governing body and senior management explore other hospital operations that are similar or interrelated to assess whether such operations have the same or similar vulnerabilities.
E. Policies and procedures provide for feedback to reporting individuals, as appropriate.

[42] *See also* 10 N.Y.C.R.R. §§ 405.2(c)(2), 405.3(a), 405.6(a).

Requirement 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 appropriate.
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.
C. Education and training occurs to address revisions to written policies, procedures and systems.

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

Recommendations

A. Hospital will report compliance issues, as required by law:
    1. governing body members, employees, and persons associated with the hospital understand mandatory reporting requirements; and
    2. governing body members, 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.
B. Hospital will comply with the requirements of the ACA at Section 6402[43] and such other laws and regulations as may be applicable when making self-disclosures.
C. Hospital shall use OMIG's self-disclosure protocol when returning overpayments to the New York State Medicaid Program.[44]

Requirement 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 OMIG/OIG. Self-disclosures are appropriate for the following[45]:

[43] 42 U.S.C. § 1320a-7k(d) (2010).
[44] OMIG's Self-Disclosure Guidance, dated March 12, 2009 is available at www.omig.ny.gov. OIG's self-disclosure protocol can be found at http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf
[45] See New York State Office of the Medicaid Inspector General (OMIG) Self-Disclosure Guidance, March 12, 2009 (http://www.omig.ny.gov) and the ACA at §6401 et. seq.

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. actions taken by the hospital that may be within the definition of an "unacceptable practice" set forth in 18 N.Y.C.R.R. § 515.2; and
4. overpayments as defined in 42 U.S.C. § 1320a-7k(d)(4)(B) and any applicable regulations.

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

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

Requirement 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, but not limited to:
    1. reporting of potential issues;
    2. investigating issues;
    3. self-evaluations;
    4. audits;
    5. remedial actions; and
    6. reporting to appropriate officials as provided in N.Y. Lab. Law §§ 740 and 741.
B. Policy is distributed to governing body members and employees and is readily available to persons associated with the hospital and is incorporated into the 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 managers and/or human resources managers approve terminations before they are effectuated for individual(s) who participate in good faith in the compliance program to ensure that terminations are not motivated by an attempt at intimidation or retaliation; and
    2. exit interviews of employees include questions related to if they had observed or had personally been the subject of intimidation or retaliation resulting from a good faith participation 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 recuse themselves from investigations;
    4. compliance officer obtains assistance from external resources, as appropriate;
    5. documents and other relevant evidence are maintained in a confidential manner; and
    6. investigative files are not kept in staff personnel files.
F. Compliance officer reports to the governing body the frequency and types of alleged and suspected intimidation and retaliation, as appropriate.

SELECTED REFERENCES AND AUTHORITIES

The following are some references and authorities that hospitals may want to consult on compliance programs. This is not an exhaustive list, but rather provides some basic authorities on compliance and compliance programs. Except for OMIG's Web site, OMIG does not take responsibility for the content of the references and authorities or for updating the content of the references and authorities cited below. Finally, other than OMIG's Web site and statutes and regulations, OMIG does not endorse any content on the references and authorities listed.[46]

Statutes and Regulations

NYS Provider Compliance Program Law	N.Y. Soc. Serv. Law §363-d
NYS Provider Compliance Programs Regulations	18 N.Y.C.R.R. Part 521
Patient Protection & Affordable Care Act 2010	Pub. L. 111-148
Health Care and Education Reconciliation Act of 2010	Pub. L. 111-152

Government Websites

NYS Office of Medicaid Inspector General Website
www.omig.ny.gov
- *Source for*
- *Compliance Alerts*
- Assessment Tools
- Webinars
- NYS Excluded Party List
- Corporate Integrity Agreements
- Audit Reports
- Self-Disclosure Guidance

NYS Attorney General's Website
www.ag.ny.gov

NYS Department of Health
http://nyhealth.gov
- Source for
- *Medicaid Updates*

US Dept. of HHS Office of the Inspector General (OIG)
www.oig.hhs.gov

Centers for Medicare and Medicaid Services
www.cms.gov

[46] OMIG appreciates the assistance of the Centers for Medicare and Medicaid Services for providing some of the references and cites listed.

Federal Sentencing Guidelines
www.ussc.gov/Guidelines

Compliance Associations and Other Resources
Heath Care Compliance Association (HCCA)
http://www.hcca-info.org

Society of Corporate Compliance and Ethics (SCCE)
http://www.corporatecompliance.org

"Leading Corporate Integrity: Defining the Role of the Chief Ethics & Compliance Officer (CECO)," Chief Ethics and Compliance Officer (CECO) Working Group, Ethics Resource Center
http://www.corporatecompliance.org/Content/NavigationMenu/Resources/Surveys/CECO_Definition_8-13-072.pdf

"Evaluating and Improving a Compliance Program," Health Care Compliance Association (v.1 Apr. 4, 2003)
http://corporatecompliance.org/Content/NavigationMenu/Resources/ComplianceBasics/Eval-Improve03.pdf
Daniel Levinson, "Trustee Engagement and Hospital Success," Trustees Magazine (July 2010)
http://www.trusteemag.com/trusteemag_app/jsp/articledisplay.jsp?dcrpath=TRUSTEEMAG/Article/data/07JUL2010/1007TRUviewpoint

"Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors," U.S. Dept. of Health and Human Services and The American Health Lawyers Assn. (2003)
http://oig.hhs.gov

Michael D. Greenberg, "Directors as Guardians of Compliance and Ethics Within the Corporate Citadel: What the Policy Community Should Know," RAND Corporation (2010)
www.rand.org/pubs/conf_proceedings/2010/RAND_CF277.pdf

Corporate Responsibility and Health Care Quality – A Resource for Health Care Boards of Directors, U.S. Dept. of Health and Human Services Office of the Inspector General and The American Health Lawyers Assn.
http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal9-4-07.pdf

Alan Yuspeh, Kathleen Whalen, Jerone Cecelic, Steven Clifton, Lisa Cobb,
Mark Eddy, Jill Fainter, Julie Packard, Susan Postal, Joe Steakley, and
Paula Waddey, "Above Reproach: Developing a Comprehensive Ethics and Compliance Program," (HCCA),
http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/ComplianceBasics/DevelopComprehensiveCompliancePrograms.pdf

"Driving for Quality in Long-Term Care: A Board of Directors Dashboard"
Government-Industry Roundtable -- *A Report on the Office of Inspector General and Health Care Compliance Association Roundtable on Long-Term Care Board of Directors' Oversight of Quality of Care"*
http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/ComplianceNews/FinalRoundtableReport013007.pdf

State Medicaid Agency Sanction Web sites[47]

Alabama:
http://www.medicaid.alabama.gov/CONTENT/7.0_Fraud_Abuse/7.7_Suspended_Providers.aspx

Arkansas:
http://www.dfa.arkansas.gov/offices/procurement/guidelines/Pages/suspendedDebarredVendors.aspx

California: The *Medi-Cal Suspended and Ineligible Provider List* is updated monthly and is available on the Internet at http://www.medi-cal.ca.gov/ by clicking the "References" tab, then the "Suspended & Ineligible List" link.

Connecticut: http://www.ct.gov/dss/cwp/view.asp?a=2349&q=310706

Florida: The list for Florida *Sanction & Terminated Providers* is available on the Internet at http://apps.ahca.myflorida.com/dm_web/(S(i2m4nlarklknzbldmgkvjsd0))/default.aspx. Set Document Type to FINAL ORDERS and Select "Medicaid Sanctioned Providers" as the search criterion.

Idaho:http://www.healthandwelfare.idaho.gov/AboutUs/FraudReportPublicAssistanceFraud/ReportHealthCareFraud/tabid/322/Default.aspx

Illinois: http://www.state.il.us/agency/oig/sanctionlist.asp. Links are on the right for New Additions, Browse by Name, or Download. You can also subscribe to the Mailing List.

Kentucky: http://www.chfs.ky.gov/dms/Program+Integrity.htm

Maine: http://portalxw.bisoex.state.me.us/oms/meex/meex.aspx

Maryland: http://dhmh.maryland.gov/oig/html/rellinks.htm

Michigan: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-16459--,00.html

Mississippi: http://www.medicaid.ms.gov/Documents/PI/Sanctioned_Providers_List.pdf

Nebraska: http://www.hhs.state.ne.us/med/medsanc.htm. There is no list to search. You need to contact them at Karen.cheloha@nebraska.gov

New Jersey: http://www.state.nj.us/treasury/debarred/

[47] When checking for individuals who are excluded from participation in New York State's Medicaid program, the following Web sites must, at a minimum, be consulted: New York: http://www.omig.ny.gov/data/content/view/72/52/; federal - OIG: http://exclusions.oig.hhs.gov/ and federal – EPL: http://www.epls.gov

New York: http://www.omig.ny.gov/data/content/view/72/52/

Ohio: http://jfs.ohio.gov/OHP/providers/TerminatedProviders.stm

Pennsylvania: http://www.dpw.state.pa.us/dpwassets/medichecklist/index.htm

South Carolina: http://www.dhhs.state.sc.us/dhhsnew/insideDHHS/Bureaus/BureauofComplianceandPerformanceReview.asp

Texas: Go to https://oig.hhsc.state.tx.us/Exclusions/Search.aspx to search the online database, and go to https://oig.hhsc.state.tx.us/Exclusions/DownloadExclusionsFile.aspx to download the file.