



COMPLIANCE PROGRAM REVIEW GUIDANCE

New York State Social Services Law Section 363-d
and Title 18 New York Codes of Rules and Regulations Part 521

Compliance Program Review Guidance

October 26, 2016

This Compliance Program Review Guidance (“Guidance”) will assist the Medicaid Required Provider (“Required Provider”) community in developing and implementing compliance programs that meet the requirements of Social Services Law Section 363-d (“SSL 363-d”) and title 18 New York Codes of Rules and Regulations Part 521 (“Part 521”).

PURPOSE OF THIS COMPLIANCE GUIDANCE

This Guidance is intended to inform Required Providers what the New York State Office of the Medicaid Inspector General (“OMIG”) looks for when it assesses compliance programs required under SSL 363-d and Part 521. In some cases, this Guidance provides examples of OMIG’s suggestions on how Required Providers can best meet the statutory and regulatory requirements. This Guidance does not constitute rulemaking by OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person. Furthermore, nothing in this Guidance alters any statutory or regulatory requirement. In the event of a conflict between statements in this Guidance and either statutory or regulatory requirements, the requirements of the statutes and regulations govern.

This Guidance does not encompass all the current requirements for compliance programs to meet the requirements of SSL 363-d and Part 521 and therefore are not a substitute for a review of the statutory and regulatory law. A Required Provider’s legal obligations are determined by the applicable federal and state statutory and regulatory law.

This Guidance may be amended at any time at OMIG’s sole discretion without prior notice.

The scope of this Guidance is not intended to be definitive guidance for managed care organizations (“MCOs”) that are Required Providers. Although this Guidance may provide some insights into New York’s statutory and regulatory requirements for MCOs, there are additional requirements that exist under federal law and regulation that must be considered by MCOs in the development and operation of their compliance programs.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

Table of Contents

| | |
|---|----|
| Abbreviations:..... | 3 |
| Definitions:..... | 3 |
| SSL ASSESSMENT GUIDANCE: ALL AFFECTED INDIVIDUALS | 5 |
| Who is subject to your compliance program? | 5 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 1 | 6 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 2 | 9 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 3 | 14 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 4 | 18 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 5 | 20 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 6 | 23 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 7 | 26 |
| SSL ASSESSMENT GUIDANCE: ELEMENT 8 | 29 |
| Seven Areas | 31 |
| 18 NYCRR 521.3 (a)(1): Billings..... | 31 |
| 18 NYCRR 521.3 (a)(2): Payments | 31 |
| 18 NYCRR 521.3 (a)(3): Medical necessity and quality of care..... | 32 |
| 18 NYCRR 521.3 (a)(4): Governance | 32 |
| 18 NYCRR 521.3 (a)(5): Mandatory reporting | 32 |
| 18 NYCRR 521.3 (a)(6): Credentialing..... | 32 |
| 18 NYCRR 521.3 (a)(7): Other risk areas that are or should with due diligence be identified by the provider. | 33 |

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

Abbreviations:

| | |
|----------------|---|
| 18 NYCRR | Title 18 of the New York Codes of Rules and Regulations |
| ACA | Affordable Care Act: 42 USC § 1320a-7k(d) |
| BOC | OMIG's Bureau of Compliance |
| CO | Compliance Officer (See "Definitions" table for further information.) |
| DOH | NYS Department of Health |
| DRA | Deficit Reduction Act of 2005 as codified in 42 USC § 1396a(a)(68) |
| Eight Elements | SSL 363-d subsection 2.'s and 18 NYCRR § 521.3(c)'s Eight Elements that are required for all compliance programs. |
| NYS | New York State |
| OMIG | NYS Office of Medicaid Inspector General |
| Part 521 | 18 NYCRR Part 521 |
| SSL | New York State Social Services Law |
| SSL 363-d | New York State Social Services Law § 363-d |
| Seven Areas | 18 NYCRR § 521.3(a)'s list of Seven Areas that compliance programs must be applicable to. |

Definitions:

| | |
|-----------------------------|--|
| Affected Individuals | <p>Includes:</p> <ul style="list-style-type: none"> ● All affected employees, ● Affected Appointees, ● Executives, and Governing Body members. ● any person or affiliate who is involved in any way with the Required Provider, such that the person or affiliate contributes to the Required Provider's entitlement to payment under the Medical Assistance Program and who is not an employee, Executive, or Governing Body member of the Required Provider (e.g., independent contractors, interns, students, volunteers, and vendors). Individuals who are at least a 5 percent owner of the Required Provider shall be considered persons associated with the Required Provider. |
| Compliance Officer | For the purposes of this document, refers to the employee vested with responsibility for the day-to-day operation of the compliance program that is required under SSL 363-d subsection 2(b) and 18 NYCRR 521.3 (c)(2). |
| Executive | An Executive is any member of senior management staff regardless of specific title. |

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

| | |
|-----------------------|---|
| Governing Body | <p>In a corporate entity, this is the board of trustees, board of directors, or similar body regardless of the name used.</p> <p>In a partnership entity, this is the partner or partners who are responsible for making policy determinations for the partnership (i.e., not necessarily the day-to-day management of the partnership).</p> <p>For Required Providers that are not corporations, partnerships, or government entities (e.g., sole proprietors), the Governing Body is the owner(s) of the Required Provider.</p> |
| Insufficiency | Failure to meet one or more of the Eight Elements for compliance, or one or more of the requirements under the Eight Elements. |
| Periodic/Periodically | A regular interval which is no less frequently than annually, but the context may require a more frequent interval. |
| Required Provider | See 18 NYCRR § 521.2(a). |

General Statement:

1. **In order to satisfactorily meet the requirements of SSL 363-d and Part 521, a compliance program must:**
 - a. be appropriate to the Required Provider's characteristics (see item 5 for further information);
 - b. meet all the requirements of each of the Eight Elements;
 - c. **apply to each of the Seven Areas;**
 - d. be implemented; and
 - e. produce results that can be reasonably expected of an operating compliance program that meets the Eight Elements and applies to the Seven Areas.
2. The standard for meeting the requirements of SSL 363-d and Part 521 is that there must be no Insufficiencies in any of the Eight Elements and the compliance program must be operating relative to each of the Seven Areas.
 - a. SSL 363-d subsection 2 provides: "A compliance program shall include the following elements: ..."
 - b. 18 NYCRR 521.3 (c) provides: "... compliance program shall include the following elements ..."
 - c. 18 NYCRR 521.3 (a) provides: "... compliance programs shall be applicable to: ..." the Seven Areas.
3. **All of the requirements under each of the Eight Elements for mandatory compliance programs must apply to all Affected Individuals.** BOC's Assessment will consider each requirement's applicability to all Affected Individuals.
4. A compliance program that is appropriate to the Required Provider's characteristics should "... reflect a provider's size, complexity, resources, and culture" (SSL 363-d subsection 1.).
5. The compliance program may be a component of more comprehensive compliance activities by the Required Provider as long as the requirements of SSL 363-d and Part 521 are met.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

GUIDANCE: ALL AFFECTED INDIVIDUALS

Who is subject to your compliance program?

18 NYCRR 521.3 (c):

18 NYCRR 521.3 (c)(1) states “employees and others.” BOC interprets this to be “all affected individuals,” as used in 18 NYCRR 521.3 (c)(5), which is consistent with requirements found in other elements that address **all affected employees, appointees, and persons associated with the Required Provider, Executives, and governing body members.**

Assessment form questions:

Is your compliance program applicable to all Affected Individuals?

All of the following elements and requirements for mandatory compliance programs must apply to all Affected Individuals. BOC’s Assessment will consider each requirement’s applicability to all Affected Individuals. If a mandatory compliance program does not apply to all Affected Individuals, Insufficiencies in multiple elements may result.

Minimum Requirements—the following must be met:

BOC considers the following information when defining all Affected Individuals:

- 1. Individuals receiving 1099 forms are considered independent contractors.** This does not necessarily include such independent contractors as landscaping and maintenance companies, or others who have no involvement in delivery of or billing for Medicaid care, services, or supplies.
2. It is possible that there are no Affected Appointees and Persons Associated with the Required Provider. However, most Required Providers have at least some Affected Appointees and Persons Associated with the Required Provider.
3. Corporations, partnerships, or government entities typically maintain a control function that is above the Executive level of the organization. For the purposes of this Guidance, this control function is referred to as the Governing Body.
4. Sole proprietors are not corporations, partnerships, or government entities; therefore, BOC looks to the owner(s) of the Required Provider as the Governing Body.

GUIDANCE: ELEMENT 1

Element 1 - Written policies and procedures

18 NYCRR 521.3 (c):

... (1) written policies and procedures that describe compliance expectations as embodied in a code of conduct or code of ethics, implement the operation of the compliance program, provide guidance to employees and others on dealing with potential compliance issues, identify how to communicate compliance issues to appropriate compliance personnel and describe how potential compliance problems are investigated and resolved;

Assessment form questions:

- 1.1 Written policies and procedures in effect that describe compliance expectations as embodied in a code of conduct or code of ethics.
- 1.2 Written policies and procedures in effect that implement the operation of the compliance program.
- 1.3 Written policies and procedures in effect that provide guidance to all Affected Individuals on dealing with potential compliance issues.
- 4.1 Written policies and procedures in effect that identify how to communicate compliance issues to appropriate compliance personnel.
- 7.1 Written policies and procedures in effect that provide guidance on how potential compliance problems are investigated and resolved.

Minimum Requirements—the following must be present for each requirement in Element 1:

1. For Element 1, policies and procedures must be in writing.
2. Evidence must exist that the written policies and procedures are in effect, which may include one or more of the following, but is not limited to:
 - a. The compliance plan and related policies and procedures are approved or adopted by the appropriate governance (e.g., board of directors) or leadership group (e.g., CEO, COO).
 - i. BOC considers who would normally approve or adopt similar enterprise-level policies and procedures within the organization.
 - ii. BOC looks to see if the compliance plan and related policies and procedures have been approved or adopted by the governing body and/or senior management (e.g., resolution, meeting minutes, signature on the policy with an appropriate statement, or statement on distribution indicating approval).
 - b. There is evidence that the compliance plan and related policies and procedures are known by all Affected Individuals, and that they have been implemented.
 - c. There is evidence that action is being taken consistent with the terms of the policies and procedures.

Guidance:

1.1 Written policies and procedures in effect that describe compliance expectations as embodied in a code of conduct or code of ethics.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

1. Compliance expectations must include statements that the:
 - a. Required Provider and all Affected Individuals will, at all times, act in a way to meet the requirements of the mandatory compliance program law and regulation; or
 - b. Required Provider expects to conduct business in a manner that supports integrity in operations.
2. Compliance expectations must also include statements that conduct contrary to this expectation will be considered a violation of the compliance program, and related policies and procedures.
3. A code of conduct or code of ethics is preferred, but if policies and procedures are complete, that will suffice.

1.2 Written policies and procedures In effect that implement the operation of the compliance program.

1. BOC looks for the Required Provider to identify written policies and procedures that support the operation of their compliance program.
2. Evidence that the compliance program is operating may include one or more of the following but is not limited to:
 - a. The Required Provider and all Affected Individuals act in a way to meet the requirements of the mandatory compliance program law and regulation.
 - b. The written policies and procedures have been distributed to all Affected Individuals. Distribution may consist of:
 - i. handing out a hard copy;
 - ii. a hard copy being made available in a public area; or
 - iii. a digital copy being made available on an intranet or Internet.
 - c. There is work product that demonstrates the written policies and procedures are operating. For example:
 - i. Work plans exist.
 - ii. Evidence that investigations have commenced and been completed, and action has been taken in response.
 - iii. Budgets for the compliance function exist.

1.3 Written policies and procedures In effect that provide guidance to all Affected Individuals on dealing with potential compliance issues.

1. Guidance on dealing with potential compliance issues is covered in other areas (e.g., requirements 1.1, 1.2, 4.1, and 7.1). Assessment of the guidance on dealing with compliance issues will be done in requirements 1.1, 1.2, 4.1, and 7.1. As a result, the main topic of this question is the applicability of the compliance program to all Affected Individuals.
2. The written policies and procedures identified in 1.1, 1.2, 4.1, and 7.1 must be applicable to all categories of Affected Individuals.

4.1 Written policies and procedures In Effect that identify how to communicate compliance issues to appropriate compliance personnel.

1. The written policies and procedures must identify the appropriate compliance personnel to receive the communication. It need not be the CO, but it must be compliance personnel.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- a. Policies and procedures can include direction to report to supervisors and management as long as there is also a requirement for supervisors and management to report issues to appropriate compliance personnel.
 - b. Reporters must also have a clear reporting path to appropriate compliance personnel.
 - c. It is acceptable for the Required Provider to use a hotline service as long as reports from the hotline service are not filtered and are provided directly to appropriate compliance personnel. The Required Provider is responsible to ensure that the vendor does not have a conflict of interest related to the provision of such services.
 - d. It is acceptable for the Required Provider to use a drop box for communication as long as the drop box is used to report compliance issues, and is monitored and controlled exclusively by appropriate compliance personnel.
2. **Communication methods may vary** for different categories of Affected Individuals under the compliance program's policies and procedures. In those instances, **the compliance program's policies and procedures should identify how each category of Affected Individuals can communicate to appropriate compliance personnel.**

7.1 Written policies and procedures In effect that provide guidance on how potential compliance problems are investigated and resolved.

1. **There must be a written commitment to investigate potential compliance problems.** Examples of activities for the investigation of potential compliance problems may include but are not limited to:
 - a. Identification of the investigator.
 - i. It is permissible for investigations to be conducted by people outside of the compliance function.
 - ii. To the extent that someone outside the compliance function is investigating, the results of the investigation will be shared with appropriate compliance personnel.
 - iii. Results from investigations should not be filtered by someone outside of the compliance function.
 - b. How the investigation will be conducted (e.g., interviews, documentation reviews, and root cause analyses).
 - i. Identification of investigative steps from start to finish.
 - ii. Sufficiently detail the results of investigations and analyses to identify who the participants are and who may be encouraging, directing, facilitating, or permitting Non-Compliant Behavior.
 - c. Documentation of results.
2. **There must be a written commitment to resolve confirmed compliance problems.** Examples of activities for the resolution of confirmed compliance problems may include but are not limited to:
 - a. implementation of plans of correction;
 - b. reporting results to the chief executive and Governing Body;
 - c. monitoring the effectiveness of implemented plans of correction; or
 - d. updating, correcting, or modifying policies, procedures, and business practices.

GUIDANCE: ELEMENT 2

Element 2 - Designate an employee vested with responsibility

18 NYCRR 521.3 (c):

... (2) designate an employee vested with responsibility for the day-to-day operation of the compliance program; such employee's duties may solely relate to compliance or may be combined with other duties so long as compliance responsibilities are satisfactorily carried out; such employee shall report directly to the entity's chief executive or other senior administrator designated by the chief executive and shall periodically report directly to the governing body on the activities of the compliance program;

Assessment form questions:

- 2.1 Designate an employee that is vested with responsibility for the day-to-day operation of the compliance program.
- 2.2 Are the designated employee's (referred to in 2.1) duties related solely to compliance?
- 2.3 Are the compliance responsibilities satisfactorily carried out?
- 2.4 Does the designated employee (referred to in 2.1) report directly to the entity's chief executive or other senior administrator?
- 2.5 Does the designated employee (referred to in 2.1) Periodically report directly to the Governing Body on the activities of the compliance program?

Guidance:

2.1 Designate an employee that is vested with responsibility for the day-to-day operation of the compliance program.

1. BOC considers an employee to be anyone who qualifies as an employee for NYS or federal employment tax purposes.
 - a. Independent contractors, consultants, volunteers, leased employees, persons supplied by Management Services Organizations (MSOs) or Professional Employer Organizations (PEOs), and the like are not considered employees.
 - b. If there is uncertainty as to the employment status, BOC may request evidence of an employee's W-2 or similar employment reports.
2. Tests to determine whether a CO is an employee of a Required Provider may include but are not limited to:
 - a. the CO is a "W-2 employee."¹
 - b. other objective, non-contractual obligations that determine employment status.
3. BOC refers to "Compliance Guidance 2015-02: Mandatory Compliance Program Requirement: Holding Company and Joint Venture Structures, Employee Vested with Responsibility for Day-

¹ "W-2 employee" can be found in "Compliance Guidance 2015-02: Mandatory Compliance Program Requirement: Holding Company and Joint Venture Structures, Employee Vested with Responsibility for Day-to-Day Operation of the Compliance Program."

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

to-Day Operation of the Compliance Program.” This also applies in the context of non-profit corporations when there is a sole corporate member.

4. Evidence that an employee has been vested with responsibility for the day-to-day operation of the compliance program includes but may not be limited to:
 - a. Governing Body resolution/minutes evidencing appointment of the employee and compliance-related duties and responsibilities;
 - b. letter of appointment for the employee;
 - c. job description and/or performance plan that includes day-to-day operational responsibility and management of the compliance program;
 - d. management organization charts;
 - e. communications to those covered by the compliance program; or
 - f. compliance plan document or other policies and procedures that describe compliance-related duties and responsibilities.
5. There must be consistency across documented evidence.
6. BOC recommends that the designated employee vested with responsibility for the day-to-day operation of the compliance program not be in the legal or financial departments due to the potential for a conflict of interest.
7. Please see requirement 2.3 (item 3) for a description of what constitutes day-to-day operation of the compliance program.

2.2 Are the designated employee’s (referred to in 2.1) duties related solely to compliance?

1. BOC reviews the designated employee’s job description(s) and/or performance plan(s).
 - a. There may be multiple job descriptions and/or performance plans if the designated employee has other responsibilities outside of compliance.
 - b. It is acceptable to submit an informal job description as long as it is in writing.
2. BOC reviews organizational charts to identify areas of responsibility for the designated employee.
3. BOC recommends that the designated employee vested with responsibility for the day-to-day operation of the compliance program not be in the legal or financial departments due to the potential for a conflict of interest. BOC reviews possible conflicts of interest between the designated employee’s compliance duties and the non-compliance related duties. Concerns exist if the other duties involve work in departments that have potential compliance risk areas, that create potential conflicts of interest, such as:
 - a. billing and payment obligations; or
 - b. quality management.

2.3 Are the compliance responsibilities satisfactorily carried out?

1. Evidence to determine whether compliance responsibilities are satisfactorily carried out must exist. Such evidence may include but is not limited to:
 - a. The Required Provider’s assessment of whether the compliance responsibilities are being satisfactorily carried out. This includes:
 - i. evidence of a compliance work plan and resulting logs, reports, and risk analyses;
 - ii. annual self-assessment of the compliance program and related policies and procedures, and risk analyses;
 - iii. completion of the annual SSL and/or DRA certification(s) on OMIG’s web site;

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- iv. evidence of initial and Periodic compliance training for all Affected Individuals; and
 - v. completion of investigations, including implementation and monitoring of plans of correction, for compliance issues.
- b. BOC looks for evidence that there is an objective, regular analysis of what the CO is required to perform, and if performance is being assessed and rated. This should be reflected in the annual performance plans done by the person(s) to whom the CO reports.
 - c. BOC looks for evidence that the non-compliance duties allow for sufficient time and attention for the designated employee to satisfactorily carry out compliance responsibilities.
 - d. BOC looks for evidence that sufficient resources are dedicated to the compliance function to assist the designated employee in satisfactorily carrying out compliance responsibilities. Resource analyses should include not only what the CO is given time to do, but also what support is available through other staff, outside auditors, and financial resources.
 - e. BOC looks for evidence that the designated employee is attending/leading meetings or receiving reports that could be viewed as having a compliance program focus.
 - f. Multiple insufficiencies in other elements (specifically 3, 6, and 7) are an indication that compliance responsibilities are not being satisfactorily carried out.
 - g. If compliance duties are not being satisfactorily carried out due to insufficient resources provided for the compliance function, an Insufficiency will result.
2. The compliance function must have access to and interaction with documentation relative to the Seven Areas in order to fully evaluate these risk areas. The compliance function must be able to provide evidence of such access and interaction.
 3. Some examples of day-to-day compliance responsibilities may include but are not limited to:
 - a. Develop, revise, maintain, implement, and distribute compliance-related policies, procedures, systems, and other materials for all Affected Individuals.
 - b. Work with the certifying official (e.g., chief executive) identified on the annual SSL certification(s) to ensure accurate completion of the certification on OMIG's website.
 - c. Foster appropriate environment within the organization to promote participation in the compliance program by all Affected Individuals.
 - d. Establish and maintain open lines of communication within the organization so potential compliance problems may be reported promptly.
 - e. Monitor all methods of communication, including anonymous and confidential methods.
 - f. Create and maintain appropriate documentation (e.g., logs, spreadsheets, and records) of compliance activities.
 - g. Chair management compliance committee (if any) that oversees operation of the compliance program.
 - h. If applicable, supervise assigned staff to ensure compliance-related duties are satisfactorily carried out.
 - i. Report Periodically on compliance activities to the chief executive or other senior administrator, and the Governing Body.
 - j. Develop, provide, coordinate, and/or track compliance training and education for orientation and Periodic training for all Affected Individuals
 - k. Monitor results of compliance-related disciplinary actions to confirm fair and firm enforcement.
 - l. Develop, manage, and report on the annual compliance work plan, including routine identification of compliance risk areas and trends.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- m. Monitor credentialing and conduct monthly checks of the federal and state exclusion lists.
- n. Conduct and/or oversee and review results of internal and external audits and self-evaluations of compliance risk areas, as well as the resulting evaluations of potential or actual non-compliance.
- o. Investigate potential and actual compliance issues, including root cause analyses.
- p. Ensure prompt and thorough resolution of compliance issues, including implementation of policies, procedures, systems and necessary training of all Affected Individuals to reduce the potential for recurrence.
- q. Monitor plans of correction to confirm problems have been resolved or new plans of correction are required.
- r. Report compliance issues to DOH and/or OMIG.
- s. Oversee self-disclosures and refunding of overpayments.

2.4 Does the designated employee (referred to in 2.1) report directly to the entity's chief executive or other senior administrator?

1. Reporting must include not only compliance issues but also how the CO's personnel performance issues are addressed.
2. BOC reviews organization charts, job descriptions, performance appraisals, etc. to confirm the direct reporting structure from the designated employee to the entity's chief executive or appropriately-designated senior administrator.
 - a. If the direct reporting structure from the designated employee is to another senior administrator, evidence of the designation by the chief executive to the senior administrator must exist.
A senior administrator should include someone with senior management responsibilities (e.g., Chief Operating Officer, President, Administrator, Vice President, etc.).
 - b. Evidence of designation may include but is not limited to:
 - i. memo or email from the entity's chief executive;
 - ii. letter of appointment from the entity's chief executive;
 - iii. offer letter issued by or job description approved by the chief executive;
 - iv. designation in the supporting policies and procedures that are approved by the entity's chief executive; or
 - v. designation in an organization chart that is approved by the entity's chief executive.
3. BOC looks for evidence of reporting on compliance issues from the designated employee to the entity's chief executive or designee; this may include results of audits and investigations; work plans; plans of action; plans of correction; and/or results of annual self-assessment of the compliance program, related policies and procedures, and risk analyses.
4. BOC determines that a direct reporting structure to the governing board also meets this requirement.
5. BOC looks for possible conflicts of interest that may arise from the reporting structure used when the designated employee is reporting for personnel performance evaluations to a senior administrator whose functional responsibilities could be reasonably expected to be the focus of a compliance audit or investigation (e.g., reporting to a CFO typically is a conflict in reference to compliance audits associated with billing and payment issues).

2.5 Does the designated employee (referred to in 2.1) Periodically report directly to the Governing Body on the activities of the compliance program?

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

1. The CO must Periodically report to the Governing Body.
2. Organizational chart should have a dotted line reporting structure from the designated employee to the Governing Body.
3. **BOC looks for evidence of reporting on compliance functions to the Governing Body.**
 - a. Evidence of the designated employee's reports to the Governing Body may be in the form of a written report or Governing Body meeting agendas, minutes, and excerpts that set out reports by the designated employee. There must be an established method for the Governing Body to directly ask questions of the CO related to the Periodic reporting.
 - b. Evidence that the designated employee is reporting directly to the Governing Body without going through others.
 - c. It is acceptable for the Required Provider to have established a sub-committee of the Governing Body ("Compliance Committee") that the designated employee is part of or reports to.
 - d. For Required Providers without governing boards, the report should be to the owner(s), partner(s), or person(s) with responsibility for oversight of senior management.
4. **BOC recommends that there be an executive session** that includes the Governing Body and the CO only. This need not be for the whole report, but for a portion of the report. This is similar to the executive session that accountants have with the Governing Body for year-end audits.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

GUIDANCE: ELEMENT 3

Element 3 - Training and education

18 NYCRR 521.3 (c):

... (3) training and education of all affected employees and persons associated with the provider, including executives and governing body members, on compliance issues, expectations and the compliance program operation; such training shall occur periodically and shall be made a part of the orientation for a new employee, appointee or associate, executive and governing body member;

Assessment form questions:

- 3.1 Periodic training and education on compliance issues, expectations, and the compliance program operation.
- 3.2 Compliance training as part of orientation.

Minimum Requirements—the following must be present for each requirement in Element 3:

1. Compliance training for all Affected Individuals must include compliance issues, expectations and the compliance program operation as defined herein. Subject matter of the compliance training must be consistent with the terms of the compliance plan and applicable policies and procedures. Compliance-related training may be customized for different categories of Affected Individuals based upon specific issues for each category so long as the minimum requirements are included for all.
2. **Compliance training content/materials must include the following minimum requirements:**
 - a. Compliance issues:

Training and education must include requirements identified in Element 1:

 - i. guidance on dealing with compliance issues;
 - ii. how to communicate compliance issues to appropriate compliance personnel; and
 - iii. guidance on how potential compliance problems are investigated and resolved.
 - b. Compliance expectations:
 - i. Training and education must include requirements identified in Element 1:
 1. expectations related to acting in ways that support integrity in operations;
 2. written policies and procedures that describe compliance expectations; and
 3. written policies and procedures that implement the operation of the compliance program.
 - ii. Training and education must include requirements identified in Element 3:
 1. compliance training at orientation; and
 2. Periodic compliance training.
 - iii. Training and education must include reporting requirements identified in Element 4:
 1. training materials must identify who the designated employee is; and
 2. methods for anonymous and confidential good faith reporting of potential compliance issues as they are identified must be included.
 - iv. Training and education must include disciplinary policies related to the compliance program identified in Element 5:

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

1. expectations for reporting compliance issues;
 2. expectations for assisting in the resolution of compliance issues;
 3. sanctions for failing to report suspected problems;
 4. sanctions for participating in non-compliant behavior;
 5. sanctions for encouraging, directing, facilitating, or permitting non-compliant behavior; and
 6. expectations that compliance-related disciplinary policies are fairly and firmly enforced.
- v. Training and education must include information about the non-intimidation and non-retaliation requirements identified in Element 8.
 - vi. BOC recommends that training and education be given using a method that is reasonably expected to be understood by the individuals required to receive training. Examples of such a method include but are not limited to:
 1. Training and education offered in a language understandable to Affected Individuals.
 2. Training and education should be sensitive to any reasonable accommodations of the Affected Individuals.
 3. Applicable training and education materials should be legible.

c. Compliance program operation:

- i. Training and education must identify the employee vested with responsibility for the day-to-day operation of the compliance program as identified in Element 2 and include how the compliance function interacts with management and the Governing Body.
 - ii. Training and education must include information about the system for identifying compliance risk areas as identified in Element 6.
 - iii. Training and education must include information about the system for self-evaluation of the risk areas identified in Element 6, including internal audits and, as appropriate, external audits.
 - iv. Training and education must include information about the system for responding to compliance issues as identified in Elements 1 and 7, as follows:
 1. Written policies and procedures that provide guidance on how potential compliance problems are investigated and resolved.
 2. A system in effect for responding to compliance issues as they are raised.
 3. A system in effect for responding to compliance issues as identified in the course of audits and self-evaluations.
 4. A system in effect for correcting compliance problems promptly and thoroughly.
 5. A system in effect for implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.
 6. A system in effect for identifying and reporting compliance issues to DOH or OMIG.
 7. A system in effect for refunding Medicaid overpayments.
3. BOC recommends training material reflect current information about the compliance program.
 - a. Listing of the CO and his/her contact information should be accurate and up-to-date.
 - b. Policies and procedures reflected in the training should be accurate and up-to-date.
 4. Evidence of the subject matter and delivery of training must be readily available. Examples of documented evidence may include, but is not limited to:

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- a. written policies and procedures outlining the training requirements that:
 - i. orientation training for new Affected Individuals must occur;
 - ii. Periodic training must occur for all Affected Individuals; and
 - iii. document a follow-up process for the Affected Individuals that miss trainings.
 - b. documented training materials evidencing that all training subjects are covered (e.g., PowerPoint, audio/video program, course book, course syllabus, etc.);
 - c. sign-in sheets and/or signed acknowledgements that individuals attended training;
 - d. copies of pre- and post-training tests;
 - e. demonstration of training program;
 - f. employee confirmations that training occurred (during on-site reviews); or
 - g. disciplinary action for compliance orientation/training absences that is consistent with discipline for failures to attend orientation or other work-related trainings.
5. **Only distributing the compliance-related policies and procedures does not qualify as compliance training and education.** BOC determines that self-study programs are acceptable where compliance-related policies and procedures and/or compliance training materials are distributed so long as the Required Provider can produce evidence that individuals being trained have received, read, and understood the materials. **Those required to receive training must be afforded an opportunity to ask questions and receive responses to any questions they have in order for training to be considered complete.**

Additional Considerations:

The following are examples of additional training content beyond the minimum requirements:

1. Compliance training content/materials may also include the following compliance issues:
 - a. Compliance training may focus in part on what compliance issues the Required Provider previously experienced and how the issues were investigated and resolved.
 - b. Compliance training may use definitions and examples to help employees understand what a compliance issue is. This may include:
 - i. definitions of fraud, waste, and abuse; and/or
 - ii. examples of compliance issues in each of the Seven Areas. Different categories of Affected Individuals may receive additional training on specific risk areas related to their job function.
2. If compliance training includes a self-study component, BOC recommends that all compliance-related policies and procedures are distributed, individuals being trained are given an opportunity to read the materials, and those trained have an opportunity to ask questions and receive responses to those questions.
3. The CO should be provided an opportunity for continuing education on general health care compliance issues, as well as health care compliance issues specific to the Required Provider type.

Guidance:

3.1 Periodic training and education on compliance issues, expectations, and the compliance program operation.

1. Periodic compliance training can take place at the same time as other mandatory trainings, or more frequently if required.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

2. Periodic compliance training and education must be provided to all categories of Affected Individuals in order to meet the requirement.

3.2 Compliance training as part of orientation.

Orientation should occur within a short period of start date. The policies and procedures should define the period in which orientation must occur.

1. BOC suggests that compliance training as part of orientation to occur within 30 days of start date.
2. Compliance training as part of orientation must be provided to all Affected Individuals, even if some categories of Affected Individuals do not receive general orientation.

GUIDANCE: ELEMENT 4

Element 4 - Lines of communication to the responsible compliance position

18 NYCRR 521.3 (c):

... (4) communication lines to the responsible compliance position, as described in paragraph (2) of this subdivision, that are accessible to all employees, persons associated with the provider, executives and governing body members, to allow compliance issues to be reported; such communication lines shall include a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified;

Assessment form questions:

- 4.1 Written policies and procedures in effect that identify how to communicate compliance issues to appropriate compliance personnel.
- 4.2 Accessible lines of communication to the designated employee referred to in requirement 2.1.
- 4.3 Methods for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

Guidance:

4.1 Written policies and procedures in effect that identify how to communicate compliance issues to appropriate compliance personnel.

See Element 1 Guidance.

4.2 Accessible lines of communication to the designated employee referred to in requirement 2.1.

1. "Lines of communication" is interpreted very broadly to include: telephone, email, website-based correspondence, interoffice mail, regular mail, face-to-face interaction, drop box, and any other reasonable means to communicate.
2. There must be **at least one method of communication to the compliance function available to each of the categories of Affected Individuals to allow reporting on compliance issues.**
3. Lines of communication should encourage submission and receipt of information on compliance issues.

4.3 Methods for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

1. Methods of communication:
 - a. At least one method must be anonymous.
 - i. There must be at least one anonymous method of communication available to each of the categories of Affected Individuals to allow reporting on compliance issues.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- ii. Anonymous methods of communication identified by Required Providers must be truly anonymous so reporting persons have assurance that there is no way the compliance function can discover who is reporting a matter.
- iii. Typically, the following are not considered anonymous methods of communication:
 1. telephone lines or hotlines with caller ID;
 2. email which can be reverse engineered to retrieve the sender's address;
 3. suggestion box not controlled by the CO that also serves as a drop box for compliance issues; and
 4. any method that may be located in an area where there is camera surveillance activity.
- b. At least one method must be confidential.
 - i. There is no requirement for all methods of communication to be confidential.
 - ii. There must be at least one confidential method of communication available to each of the categories of Affected Individuals to allow reporting on compliance issues.
 - iii. Those that report via a confidential method of communication and/or request confidentiality must have a reasonable expectation that their communication will be kept confidential.
 1. All reports via the confidential method must be kept confidential, whether requested or not.
 2. A statement indicating that a person's identity will be kept confidential unless the matter is turned over to law enforcement is acceptable.
 3. A statement indicating that a person's identity will be kept confidential unless necessary to complete an investigation is not acceptable. There must be a commitment that the investigation will not specifically identify the reporter.
 4. A statement indicating that a person's identity will be kept confidential to the extent possible is not acceptable because there may be too many undefined exceptions.
 5. An outside contractor, with a confidentiality agreement, that manages the communication methods and reports directly to the CO is an acceptable confidential communication method.
 6. A hotline telephone that may be answered by someone with no compliance responsibilities is not confidential.
 7. A compliance email inbox that may be accessed by someone with no compliance responsibilities is not confidential.
- c. It is acceptable that one method of communication can be both anonymous and confidential.
 2. There may be a confidential reporting structure, but if the reports are not secured (protected or guarded to retain confidentiality), this requirement is not being met.
 3. The written policies and procedures must identify the appropriate compliance personnel to receive the communication. It need not be the CO, but it must be compliance personnel who have a responsibility to keep communication confidential.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

GUIDANCE: ELEMENT 5

Element 5 - Disciplinary policies to encourage good faith participation

18 NYCRR 521.3 (c):

... (5) discipline policies to encourage good faith participation in the compliance program by all affected individuals, including policies that articulate expectations for reporting compliance issues and assist in their resolution and outline sanctions for: (i) failing to report suspected problems; (ii) participating in non-compliant behavior; or (iii) encouraging, directing, facilitating or permitting either actively or passively non-compliance behavior; such disciplinary policies shall be fairly and firmly enforced;

Assessment form questions:

- 5.1 Disciplinary policies in effect to encourage good faith participation in the compliance program by all Affected Individuals.
- 5.2 Policies in effect that articulate expectations for reporting compliance issues.
- 5.3 Policies in effect that articulate expectations for assisting in the resolution of compliance issues.
- 5.4 Policies in effect that outline sanctions for failing to report suspected problems.
- 5.5 Policies in effect that outline sanctions for participating in non-compliant behavior.
- 5.6 Policies in effect that outline sanctions for encouraging, directing, facilitating, or permitting non-compliant behavior.
- 5.7 Are all compliance-related disciplinary policies fairly and firmly enforced?

Minimum Requirements—the following must be present for each requirement in Element 5:

1. The best evidence of disciplinary policies is written disciplinary policies that address this Element. If disciplinary policies are said to exist but are not in writing, further inquiry is necessary. BOC looks for the following:
 - a. Consistent statements by management and staff about the policies, what they say, how they are communicated, etc.
 - b. Evidence of discipline being taken based upon the policies. BOC checks personnel files for such documentation.
 - c. Description of disciplinary policies in the training materials, employee handbook, compliance program, code of conduct, or other written policies.
 - d. Failure to identify evidence of disciplinary policies will result in an Insufficiency.
2. Progressive discipline policies are acceptable, but not required.

Guidance:

5.1 Disciplinary policies in effect to encourage good faith participation in the compliance program by all Affected Individuals.

1. Disciplinary policies that encourage Good Faith participation in the compliance program are covered in other areas (e.g., requirements 5.2, 5.3, 5.4, 5.5, 5.6, and 5.7). As a result, the main topic of this question is the applicability of the disciplinary policies identified in requirements 5.2,

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

5.3, 5.4, 5.5, 5.6, and 5.7 to all Affected Individuals. Assessment of the disciplinary policies will be done in requirements 5.2, 5.3, 5.4, 5.5, 5.6, and 5.7.

2. The disciplinary policies identified in requirements 5.2, 5.3, 5.4, 5.5, 5.6, and 5.7 must be applicable to all categories of Affected Individuals as defined in the table.

5.2 Policies in effect that articulate expectations for reporting compliance issues.

There must be policies that set out expectations for reporting compliance issues to the compliance function.

5.3 Policies in effect that articulate expectations for assisting in the resolution of compliance issues.

1. There must be policies that set out expectations for assisting in the resolution of compliance issues.
2. Assisting in resolution must include assisting in investigations of compliance issues by all Affected Individuals.

5.4 Policies in effect that outline sanctions for failing to report suspected problems.

There must be policies that set out a requirement for disciplinary action for failure to report suspected compliance issues.

5.5 Policies in effect that outline sanctions for participating in non-compliant behavior.

1. There must be policies that outline sanctions (e.g., discipline) for participating in non-compliant behavior.
2. Sanctions should include non-employees (e.g., vendors, contractors, governing body members, volunteers, etc.) that may be involved in the non-compliant behavior.

5.6 Policies in effect that outline sanctions for encouraging, directing, facilitating, or permitting non-compliant behavior.

There must be policies that outline sanctions (e.g., discipline) for encouraging, directing, facilitating, or permitting non-compliant behavior.

5.7 Are all compliance-related disciplinary policies fairly and firmly enforced?

1. There must be policies in effect that set out expectations that compliance-related discipline will be fairly and firmly enforced.
 - a. Disciplinary policies must be in effect (e.g., operating) in order for them to be enforced.
 - b. Sanctions for co-participants in non-compliant behavior must be commensurate with their participation and involvement.
 - c. Application of discipline and the language in the disciplinary policies must be the same across management and line staff.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- d. In the search for firm enforcement, BOC looks for sanctions/discipline cited in the policies that are consistent with what is carried out. BOC assesses if the sanction/discipline fits the violation (e.g., whether someone was discharged when appropriate).
2. It is acceptable that **the expectation for fair and firm enforcement** of compliance-related disciplinary actions **may be included in training and education materials**.
3. Typical language that has been found acceptable includes:
 - a. "Violations of the compliance program may result in discipline being taken up to and including termination of employment."
 - b. "Disciplinary policies will be fairly and firmly enforced."
4. BOC looks for whether there has been any enforcement of compliance-related disciplinary policies.
 - a. If yes, BOC assesses whether disciplinary actions were fairly and firmly enforced.
 - b. If no, BOC assesses why no discipline has been identified.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

GUIDANCE: ELEMENT 6

Element 6 - A system for routine identification of compliance risk areas

18 NYCRR 521.3 (c):

... (6) a system for routine identification of compliance risk areas specific to the provider type, for self-evaluation of such risk areas, including but not limited to internal audits and as appropriate external audits, and for evaluation of potential or actual non-compliance as a result of such self-evaluations and audits, credentialing of providers and persons associated with providers, mandatory reporting, governance, and quality of care of medical assistance program beneficiaries;

Assessment form questions:

- 6.1 A system in effect for routine identification of compliance risk areas specific to your provider type.
- 6.2 A system in effect for self-evaluation of the risk areas identified in 6.1, including internal audits and, as appropriate, external audits.
- 6.3 A system in effect for evaluation of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2.

Additional Considerations:

The following are examples of additional methods of identifying risk areas beyond the minimum requirements:

The best evidence of a system is a written description. In the absence of a written description, evidence of a system may include but is not limited to:

- 1. A sufficient description of the system (e.g., verbal description, demonstration of a system, or description included in training materials) and evidence of the outcome of the system's operation. **Evidence of the outcome of the system's operation may include but is not limited to:**
 - a. call/report logs that track activity;
 - b. work plans;
 - c. documentation and reports of audits and/or investigations;
 - d. plans of correction; or
 - e. documentation of refunded overpayments and/or self-disclosures.
- 2. **Evidence of appropriate responses to reports of compliance issues, appropriate resolutions of compliance issues, and evidence of preparation and distribution of reports of compliance issues.**

Guidance:

6.1 A system in effect for routine identification of compliance risk areas specific to your provider type.

- 1. There must be a system for routine identification of compliance risk areas. Evidence of a system may include but is not limited to:

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- a. a description of a system or method for routine identification of compliance risk areas and evidence that the described system is working;
 - b. using a self-assessment tool to identify compliance risk areas;
 - c. a compliance work plan that addresses compliance risk areas;
 - d. an existing list of identified compliance risk areas. Compliance risk areas that must be included are those identified in 18 NYCRR 521.3 (a):
 - i. Medicaid billings;
 - ii. Medicaid payments;
 - iii. the medical necessity and quality of care of the services provided to Medicaid program enrollees;
 - iv. governance of the Required Provider, particularly as related to the Medicaid program;
 - v. mandatory reporting requirements as related to the Medicaid program;
 - vi. credentialing for those who are providing covered services under the Medicaid program; and
 - vii. other risk areas that are or should with due diligence be identified by the Required Provider.
 - e. Operation of the system must be routine meaning it must be operating on a regular basis.
2. Risk identification must focus on the specific issues associated with the delivery and payment of services for the type of provider under the compliance program. Examples may include but are not limited to:
- a. performing services that are within the scope of a Required Provider's certificate, license, or recognized scope of practice;
 - b. reviewing OMIG, OIG, or CMS audit Guidance for provider types to identify risk areas; and
 - c. reviewing NYS Medicaid provider manuals and program requirements to establish parameters of operation by provider type.

6.2 A system in effect for self-evaluation of the risk areas identified in 6.1, including internal audits and, as appropriate, external audits.

There must be a system for self-evaluation of the risk areas identified in 6.1. Evidence of a system may include but is not limited to:

- 1. a written expectation for routine self-evaluation of identified risk areas;
- 2. documented results of self-evaluations;
- 3. a written expectation for internal and/or external audits of the identified risk areas;
- 4. documented results of internal and/or external audits;
- 5. a compliance work plan that identifies self-evaluation or auditing of identified risk areas; or
- 6. documented results of work plan activities.

6.3 A system in effect for evaluation of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2.

There must be a system for evaluation of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2. Evidence of a system may include but is not limited to:

- 1. written expectations for evaluation of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

2. documented results of evaluations. When self-evaluations and audits of compliance risk areas identified in 6.1 are conducted by individuals outside of the compliance function, the results of self-evaluations and audits should be shared with the compliance function.
3. evidence that risks are prioritized. This may include but is not limited to:
 - a. identifying frequency of each risk;
 - b. likelihood that the negative outcome will result;
 - c. impact on the delivery of services;
 - d. impact on other contracts and operations; or
 - e. financial impact.
4. a compliance work plan that identifies evaluation of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2;
5. documented results of work plan activities; or
6. documented results of a root cause analysis of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

GUIDANCE: ELEMENT 7

Element 7 - A system for responding to compliance issues

18 NYCRR 521.3 (c):

... (7) a system for responding to compliance issues as they are raised; for investigating potential compliance problems; responding to compliance problems as identified in the course of self-evaluations and audits; correcting such problems promptly and thoroughly and implementing procedures, policies and systems as necessary to reduce the potential for recurrence; identifying and reporting compliance issues to the department or the office of Medicaid inspector general; and refunding overpayments;

Assessment form questions:

- 7.1 Written policies and procedures in effect that provide guidance on how potential compliance problems are investigated and resolved.
- 7.2 A system in effect for responding to all of the following:
 - a. compliance issues as they are raised; and
 - b. as identified in the course of audits and self-evaluations.
- 7.3 A system in effect for correcting compliance problems promptly and thoroughly.
- 7.4 A system in effect for implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.
- 7.5 A system in effect for identifying and reporting compliance issues to the NYS Department of Health or the NYS Office of Medicaid Inspector General.
- 7.6 A system in effect for refunding Medicaid overpayments.

Minimum Requirements—the following must be present for each requirement in Element 7:

For requirements 7.2, 7.3, 7.4, 7.5, and 7.6, the best evidence of a system is a written description for each requirement. In the absence of a written description, evidence of a system for each requirement must be provided.

Additional Considerations:

The following are examples of additional systems for responding to compliance issues beyond the minimum requirements:

Evidence of a system may include but is not limited to:

1. A sufficient description of the system (e.g., verbal description, demonstration of a system, or description included in training materials) and evidence of the outcome of the system's operation. Evidence of the outcome of the system's operation may include but is not limited to:
 - a. logs that track activity (e.g., call logs);
 - b. work plans;
 - c. documentation and reports of audits and/or investigations;
 - d. plans of correction; or
 - e. documentation of refunded overpayments and/or self-disclosures.
2. Evidence of appropriate responses to reports of compliance issues, appropriate resolutions of compliance issues, and evidence of preparation and distribution of reports of compliance issues.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

Guidance:

7.1 **Written policies and procedures in effect that provide guidance on how potential compliance problems are investigated and resolved.**

See Element 1 Guidance.

7.2 **A system in effect for responding to all of the following: a. compliance issues as they are raised; and b. as identified in the course of audits and self-evaluations.**

1. There must be evidence identifying the issues being addressed in a reasonably diligent manner.
2. **There must be a system to investigate potential compliance problems.** Activities for the investigation of potential compliance problems must include but are not limited to:
 - a. A process to identify an appropriate investigator.
 - b. How the investigation will be conducted (e.g., interviews, documentation reviews, and root cause analyses).
 - c. Documentation of results.

7.3 **A system in effect for correcting compliance problems promptly and thoroughly.**

1. There must be an **expectation in the compliance program for correcting compliance problems promptly.**
 - a. BOC looks for whether there is evidence the problems are being promptly addressed.
 - b. If corrections proceed ineffectually, that is an indication of not being prompt.
2. There must be an **expectation in the compliance program for correcting compliance problems thoroughly.**
 - a. BOC looks for whether there is evidence the problems are being thoroughly addressed.
 - b. There must be an expectation that the matter will be effectively addressed as evidenced by plans of correction being completed or appropriately revised before the matter is considered closed.
3. Examples of a system, that is in effect, include but are not limited to:
 - a. Corrective action being implemented within a reasonable time following the completion of an investigation substantiating that a compliance problem exists.
 - b. Compliance reports to the Executive or Governing Body on what corrective actions have been implemented and if the compliance problem was corrected in a reasonable time. Also, determine whether there was a follow up to see if the correction thoroughly addressed the specific issue.
 - c. Plans of correction, action plans, strategic initiatives, or work plans following root cause analysis activities associated with compliance problems and the length of time it took to put the action in place, as well as evidence of any follow up to confirm the corrective action was effective.
 - d. Meeting minutes for the compliance committee or another group that handles correcting compliance problems.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

7.4 A system in effect for implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.

1. There must be an expectation in the compliance program document for implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.
2. If a system is said to exist but is not in writing, further inquiry is necessary. BOC looks for how the potential for recurrence is reduced.
3. BOC looks for the following:
 - a. Evidence of root cause analyses associated with compliance problems are followed by the implementation of new compliance policies and procedures or control systems that attempt to prevent the recurrence of compliance problems.
 - b. Work plan activities or evidence of internal/external audits that test to see if compliance problems have recurred.
 - c. Meeting minutes for the compliance committee or another group that handles implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.
 - d. Changes to reporting relationships.

7.5 A system in effect for identifying and reporting compliance issues to the NYS Department of Health or the NYS Office of Medicaid Inspector General.

1. There must be an expectation in the compliance program document for identifying and reporting compliance issues specifically to DOH or OMIG.
2. If a system is said to exist but is not in writing, further inquiry is necessary. BOC looks for whether there have been any reports of compliance issues to DOH or OMIG.
3. Examples of reports of compliance issues include but are not limited to the following:
 - a. evidence of reports of fraud, waste, and abuse;
 - b. evidence of self-disclosures to DOH, OMIG, or MCOs;
 - c. plans of correction that identify disclosure to DOH or OMIG as a step in the process; and
 - d. a system that identifies what compliance issues should be reported.

7.6 A system in effect for refunding Medicaid overpayments.

1. There must be an expectation in the compliance program document for refunding Medicaid overpayments.
2. If a system is said to exist but is not in writing, further inquiry is necessary. BOC looks for whether there have been any self-disclosures of overpayments.
3. BOC looks for the following:
 - a. Evidence of refunding overpayments through self-disclosure history, claim adjustments, or claim voids. Refunding of overpayments through self-disclosures may be made to OMIG as well as the NYS Attorney General, CMS, OIG, or MCOs.
 - b. Evidence of the ACA process to address refunding of overpayments².

² 42 USC § 1320a-7k (d).

GUIDANCE: ELEMENT 8

Element 8 - A policy of non-intimidation and non-retaliation

18 NYCRR 521.3 (c):

... (8) a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, self-evaluations, audits and remedial actions, and reporting to appropriate officials as provided in sections 740 and 741 of the Labor Law.

Assessment form questions:

- 8.1 A policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to:
- reporting potential issues,
 - investigating issues,
 - self-evaluations,
 - audits,
 - remedial actions, and
 - reporting to appropriate officials as provided in sections 740 and 741 of the NYS Labor Law.

Guidance:

- 8.1 There must be a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to:**
- reporting potential issues,**
 - investigating issues,**
 - self-evaluations,**
 - audits,**
 - remedial actions, and**
 - reporting to appropriate officials as provided in sections 740 and 741 of the NYS Labor Law.**
- Policies of non-intimidation and non-retaliation must be present.**
 - Reference to reporting to appropriate officials as provided in sections 740 and 741 of the NYS Labor Law must be present.**
 - The non-intimidation and non-retaliation policies may be a single policy or separate policies.
 - At **minimum, there must be reference in the compliance plan document, or other policies or employee handbooks, to NYS Labor Law sections 740 and 741 in connection with non-intimidation and non-retaliation expectations.**
 - If a **policy is said to exist but is not in writing, further inquiry is necessary.** The Required Provider must be able to describe the details of the policy of non-intimidation and non-retaliation. BOC looks for the following evidence of:
 - allegations or cases of intimidation and/or retaliation and appropriate discipline in response to the allegations.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

- b. discussions with the CO or HR Director related to allegations of intimidation and/or retaliation resulting from a good faith report or support for the compliance program.
- c. any complaints of intimidation and/or retaliation by those that participate in the compliance program.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

GUIDANCE: SEVEN AREAS

18 NYCRR 521.3 (a):

Every required provider shall adopt and implement an effective compliance program. The compliance program may be a component of more comprehensive compliance activities by the required provider so long as the requirements of this Part are met. Required providers' compliance programs shall be applicable to:

1. billings;
2. payments;
3. medical necessity and quality of care;
4. governance;
5. mandatory reporting;
6. credentialing; and
7. other risk areas that are or should with due diligence be identified by the provider.

Assessment form questions:

BOC does not include specific questions related to the Seven Areas in its Assessment form. However, the Seven Areas must be considered by Required Providers when evaluating and responding to risk areas in Elements 6 and 7. BOC assesses whether Required Providers are addressing all of the Seven Areas appropriately in questions for Elements 6 and 7.

Minimum Requirements—the following must be met:

1. Required Providers' compliance programs must have connectivity to all of the Seven Areas. BOC recognizes that some Required Providers may not have risks associated with all of the Seven Areas. However, BOC looks to see that Required Providers have considered each of the Seven Areas and made a determination of the applicability of the Seven Areas to their compliance program.
2. The items listed under each of the Seven Areas below are examples of how the risk area may apply to Required Providers' compliance functions. This is neither a required nor an exhaustive list.

Guidance:

18 NYCRR 521.3 (a)(1): Billings

1. Internal controls for documentation during data entry and billing.
2. Billing office internal audit results shared with compliance.
3. Conduct root cause analysis for persistent billing denials.
4. Conduct tracer audits for work being billed.
5. Self-assess if number and value of adjustments is accurate.
6. Separation of duties in billing and receipt functions.
7. Involvement of CO in analysis of strengths and weaknesses.

18 NYCRR 521.3 (a)(2): Payments

1. Track and analyze any overpayments, underpayments, and denials.
2. Results of accounts receivable internal audits are shared with CO.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

3. Conduct tracer audit for payments to assess accuracy of billing and resulting payments.
4. Determine if billing and payment system weaknesses are being identified and corrected as necessary.
5. Involvement of CO in analysis of strengths and weaknesses.

18 NYCRR 521.3 (a)(3): Medical necessity and quality of care

1. Develop compliance connectivity to quality oversight process as part of the reporting and control structures.
2. Conduct periodic tracers of care to assess if quality requirements are being met and provide reports to the compliance function.
3. Develop quality scorecards with resolution of outliers being reported to the compliance function.
4. Review documentation for completeness and appropriateness of entries.
5. Tracking and resolution of complaints from clients, patients, and family members.
6. Reporting of statistics and responses to aberrations of medical necessity and quality issues to the CO to be used for a control test for the effectiveness of the underlying control process.

18 NYCRR 521.3 (a)(4): Governance

1. Meaningful conflict of interest policy for Governing Body and management with reporting of unresolved conflicts.
2. Compliance function is connected to all management and Governing Body entities within the enterprise.
3. Include the Governing Body in compliance plan approval process and in setting compliance budget.
4. Include Governing Body in self-assessment and work plan process to include planning, tracking progress, and budgeting.
5. Governing Body oversight of the compliance program.
6. Frequency of compliance reports to the Governing Body.
7. Compliance training of the Governing Body and management.

18 NYCRR 521.3 (a)(5): Mandatory reporting

1. Report, repay, and explain all overpayments.
2. Required reporting of compliance issues for all Affected Individuals.
3. Required reporting of compliance issues to DOH and OMIG. Testing periodically on completeness of mandatory reporting of billing, payment, quality, and contractual issues.
4. Quality control of reporting to ensure accuracy and completeness of reports being made.
5. Ensure compliance with applicable mandatory reporting obligations:
 - a. annual SSL certification;
 - b. annual DRA certification;
 - c. SADC certification; and/or
 - d. other regulatory and program reporting.

18 NYCRR 521.3 (a)(6): Credentialing

1. Regularly check accuracy and comprehensiveness of credentialing process.
 - a. Identify Affected Individuals who must be credentialed.
 - b. Include normal credentialing considerations like primary source verification and licenses.
2. Regularly check the excluded party lists and take appropriate action if Affected Individuals are on those lists. CMS and BOC recommend checking the excluded party lists monthly.

This document is intended solely for guidance. No statutory or regulatory requirement(s) are in any way altered by any statement(s) contained herein. This Guidance does not constitute rulemaking by the OMIG and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person.

18 NYCRR 521.3 (a)(7): Other risk areas that are or should with due diligence be identified by the provider.

1. Determine if your compliance program is covering all risk areas specific to your provider type. BOC recommends Periodic and routine self-assessments and gap analyses because at any particular point in time, risks may change.
2. Assess affiliates' program integrity.
Commitments that affiliates (non-employees) are making to the Required Provider will require some level of audit and investigative expertise and activity.
3. Stratify risks within the compliance program. BOC recommends that Required Providers rank risk areas based upon frequency, severity, impact, etc. and address the ones that create the most exposure.
4. Expand risk areas based upon compliance program history and its operations.
As compliance issues are identified and resolved, they should be considered risks to be addressed in the future or the resolution tested to be sure that it resolved the problem needing attention. The analysis should include the other six areas discussed above.
5. For associates (non-employees) that provide Medicaid reimbursable services through the Required Provider, determine if they are independently required to have a compliance program and if they have met the annual certification obligation.
6. Monitor compliance with annual certification obligation for associates, if any.