We are proud to dedicate the Arc New York Compliance Manual to the memory of Suzanne Williams.

Suzanne began her career at The Arc Oneida-Lewis in 2003 as a Program Manager in Residential Services. In 2012, she was promoted to Corporate Compliance/Quality Assurance Manager, before ascending to the role of Corporate Compliance/HIPPA Privacy Officer in 2016. Suzanne was a dedicated, valued employee, whose ethics and principles guided her throughout her career. She always put the needs of the people we support before her own.

Suzanne consistently contributed to The Arc New York State Office quality improvement and corporate compliance initiatives. She was always ready to lend her knowledge and experience to support her colleagues. Her investment in our initiatives, and her efforts as a member of the Compliance Standards Professional Work Group, helped make this manual possible.

Suzanne was much more than an exemplary employee. She was an outstanding person. Suzanne was an animal lover, raising boxers and providing caring homes for cats and other pets. She also served as an Emergency Medical Technician for her local volunteer fire company. She was an avid hockey fan, and she loved going to games to cheer in person whenever she was able.

Most of all, Suzanne loved her family. She relished her role as a stepmother and grandmother. The holidays were a favorite time for Suzanne, and she would spend time decorating and celebrating with loved ones.

Suzanne is missed daily by the people we support, her coworkers, and The Arc New York family.
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About The Arc New York Compliance Standards Manual

In September 2017, Executive Directors from the Central South Region agreed to formalize a Compliance Standards Professional Workgroup (CSPW) that would develop standardized processes and procedures for auditing as well as the establishment of corporate compliance best practices. A key focus included mitigating organizational spillover liability risk through standardized corporate compliance practices.

Compliance leadership from Broome Chenango Tioga (ACHIEVE), Delaware, Herkimer, Jefferson, Madison Cortland, Oneida Lewis, Onondaga, Oswego, and Otsego committed to leverage their combined knowledge and materials to aid other Chapters in developing premier compliance programs.

The CSPW has worked on several initiatives, such as the standardization of corporate compliance practices throughout the Arc Chapters, the development of standard audit tools for use by Chapter corporate compliance programs, and the creation of a Compliance Standards Manual that would provide guidance, best practices and knowledge sharing for the whole organization.

The Compliance Standards Manual serves as a resource that will allow the user to access a myriad of resources applicable to each Compliance Program element. Each element features OMIG regulatory language, applicable OMIG Minimum Standards, OMIG Compliance Program Review Guidance, OMIG Opportunities for Compliance Program Enhancement, Arc New York Best Practices, Bureau of Compliance Identified Compliance Program Best Practices, and Arc New York template policies, assessments, and tools in a centralized location.

We would like to thank Caitlin Doran-Prior, Donna Loveland, Jennifer Draper, Josie Clary, Karen Stace, Richella Abell-Hawes, Suzanne Williams, and Winn Wolfe for sharing their resources, time, and knowledge in developing this manual. Their many contributions made it possible to complete such a large body of work for the benefit of all Chapters.
Using The Arc New York Compliance Standards Manual

Each Chapter in this manual follows a standard format:

**OMIG Regulatory Cite**
This highlights what part of NYCRR 521.3 – compliance program assigned duties – governs the specific compliance element.

**Minimum OMIG Requirements**
These represent the minimum requirements that OMIG looks for when it assesses compliance programs required under SSL 363d and Part 521. These minimum requirements can be found in Elements 1, 3, 5, and 7.

**OMIG Compliance Program Effectiveness Questions and Guidance**
The guidance found in this section ventures beyond OMIG’s minimum requirements and provides examples of OMIG’s suggestions on how Required Providers can best meet the statutory and regulatory requirements. Additional guidance can be found in this section in the form of OMIG Opportunities for Compliance Program Enhancement, Bureau of Compliance Identified Compliance Best Practices, and The Arc New York Best Practices:

- **OMIG Opportunity for Compliance Program Enhancement**
  These allow the user to identify ways a provider can enhance a compliance program beyond both minimum acceptable OMIG standards & standards found in the OMIG Compliance Program Guidance.

- **Bureau of Compliance Identified Compliance Program Best Practices**
  OMIG identified these best practices during the Bureau of Compliance’s reviews of various provider compliance programs.

- **The Arc New York Best Practice**
  These best practices have been identified through CSPW collaboration and consensus following reviews of participating Chapter practices.

**Template Policies**
Template policies have been authored and complied by the Chapters represented in the CSPW and by The Arc New York. These templates should be utilized as a reference for the development of Chapter-specific policies, tools, and assessments. All template policies are hyperlinked within the manual in PDF format. The Arc New York policies can also be downloaded in editable word format by clicking the [.doc] links. The full compliance manual and all template documents can be found online [here](#).

**References**
Links to various OMIG source material used in the development of this manual can be found here.
ELEMENT 1: Written Policies and Procedures

• OMIG Regulatory Cite
• Minimum OMIG Requirements
• OMIG Compliance Program Effectiveness Questions and Guidance
  ▪ Arc New York Best Practices
  ▪ OMIG Opportunities for Enhancement
  ▪ OMIG Best Practices
• Template Policies
• References
Element 1: OMIG Regulatory Cite

• 18 NYCRR 521.3

(c) A required provider's compliance program shall include the following elements:

(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.

Element 1: Minimum OMIG Requirements

The following must be present for each requirement in Element 1:

1) For Element 1, policies and procedures must be in writing.
   It is important to note that, after implementation, these policies need to be reviewed and revised as changes occur to regulations and statutes.

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) The Bureau of Compliance (BOC) considers who would normally approve or adopt similar enterprise-level policies and procedures within the organization.
      ii) BOC reviews if the corporate compliance plan and related policies and procedure 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.
Use standardized language in all documentation when specifying to whom the document is applicable.

Identify the provider’s approving authority and the adoption and revision dates on written policies and procedures that describe compliance expectations.

Chapters should refer to the model policies made available by the State Office. These policies include:

- Compliance Plan
- Corporate Compliance Structure
- Code of Conduct
- Conflict of Interest
- Reporting Compliance Concerns with Whistleblower
- Policy Development
- Client Inducement/Co-payments
- Contractual Financial Arrangements with Physicians/Stark
- Detecting and Responding to Compliance Violations; Voluntary Disclosures
- Employee Discipline
- Documentation of Services
- Documentation of Compliance Activities
- Compliance Program Education and Training of Employees and Others
- Exclusion Checks
- Exit Interview and Separation from Service Procedures
- Gifts and Entertainment
- Internal Investigations
- Political Contributions/Lobbying
- Responding to Government Investigations
- False Claims
- Billing Third Party Payors

It is important to note that, after implementation, these policies need to be reviewed and revised as changes occur to regulations and statutes.

The following documents should be reviewed and revised at least annually, as compliance activity necessitate review and revision, and as changes occur to regulations and statutes:

- Corporate Compliance Plan
- Corporate Compliance Work Plan
- Code of Ethics/Code of Conduct
✓ All other Corporate Compliance policies & procedures should be reviewed at a minimum of every 5 years and the review date should be documented somewhere (i.e. on the policy itself, within the Corporate Compliance Committee (CCC) Meeting Minutes, as mandated by Chapter policy, etc.). To ensure compliance with regulations, statutes, and organizational policies, Corporate Compliance policies/procedures are to be authored by the Compliance Officer (CO) or designated person within the Compliance Department and must be approved by the CCC or the Chapter Board. The formatting of policies and procedures is at the discretion of each Chapter but should be user friendly for staff.

✓ Chapter websites should also include a link to the Corporate Compliance Plan and contact information for the CO as well as the anonymous contact option.

- 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).

✓ Identify the provider’s approving authority and the adoption and revision dates on written policies and procedures that describe compliance expectations.

✓ Maintain a historical record of approval, implementation, and revision dates of the Code of Conduct and all related policies and procedures. Identify the provider’s approving authority and the adoption and revision dates on written policies and procedures that describe compliance expectations.
Element 1: OMIG Compliance Program Effectiveness Questions and Guidance

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

- 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 support integrity in operations.

- Develop a more specific list of compliance expectations. This may include a statement that refers to the existence of the compliance program and that the provider will operate at all times under the highest standards for integrity in its dealings with its Medicaid business.

- 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.

- A code of conduct or code of ethics is preferred, but if policies and procedures are complete, that will suffice.

- Develop the Code of Conduct to more specifically address the issues surrounding compliance under NYS Social Services Law §363-d and 18 NYCRR Part 521.
1.2 Written policies and procedures in effect that implement the operation of the compliance program

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider's Evidence of Compliance or Action Required</th>
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</thead>
<tbody>
<tr>
<td>1.2 Do you have written policies and procedures in effect that implement the operation of the compliance program?</td>
<td></td>
<td>For each response - include specific citations to the documents and text that meets the requirement</td>
</tr>
</tbody>
</table>

- BOC looks for the Required Provider to identify written policies and procedures that support the operation of their compliance program.

- 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.

  ✓ Develop a compliance plan document and policies and procedures that address the eight elements of NYS Social Services Law §363-d and 18 NYCRR Part 521, as well as the Deficit Reduction Act (DRA). The DRA establishes certain requirements for providers who are paid $5 million or more by Medicaid. Please visit OMIG’s website at [www.omig.ny.gov](http://www.omig.ny.gov) under the Compliance Tab for more information.

  b) The written policies and procedures have been distributed to all Affected Individuals. Distribution may consist of:
     o handing out a hard copy;
     o a hard copy being made available in a public area; or
     o 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:
     o Work plans exist.
     o Evidence that investigations have commenced and been completed, and action has been taken in response.
     o 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.

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<tbody>
<tr>
<td>1.3</td>
<td></td>
<td>&quot;Others&quot; for purposes of this requirement should be defined to include all those individuals that are not employees that are subject to the Compliance Program. This includes, but may not be limited to: executives, governing body members, appointees, and persons associated with the provider.</td>
</tr>
</tbody>
</table>

NOTE: 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.

✔ Develop and document a process to address appropriate vendors as being within the scope of the provider’s Compliance Program and address compliance expectations and consequences for vendors and vendors’ employees in the provider’s contract with its vendors.

- 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.

✔ Develop definitions for constituencies covered by the Compliance Program (e.g. employees and others) so that it is clear who is subject to the requirements of the Compliance Program, the Code of Conduct Code of Ethics and the compliance plan.
4.1 Written policies and procedures in effect that identify how to communicate compliance issue to appropriate compliance personnel.

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</tr>
</thead>
<tbody>
<tr>
<td>Are there written policies and procedures that identify how to communicate compliance issues to appropriate compliance personnel?</td>
<td></td>
<td>For each response - include specific citations to the documents and text that meets the requirement</td>
</tr>
</tbody>
</table>

- 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.
- 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.
  a) Reporters must also have a clear reporting path to appropriate compliance personnel.
  b) It is acceptable for the Required Provider to use a hotline service (vendor) as long as reports from the hotline service are not filtered and are provided directly to appropriate compliance personnel.
  c) 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.

- Develop, document, and implement a grievance policy that includes references to the compliance plan and Code of Conduct policies and procedures dealing with guidance on how potential compliance problems are investigated and resolved.

- 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.

- Update all references in compliance plan and applicable policies to contact information for compliance function (e.g. changes in telephone numbers, e-mail contact and identity of compliance officer, as may be necessary).
7.1 Written policies and procedures in effect that provide guidance on how potential compliance problems are investigated and resolved.

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<th>Provider’s Evidence of Compliance or Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have written policies and procedures that provide guidance on how potential compliance problems are investigated and resolved?</td>
<td>Yes/No</td>
<td>For each response - Include specific citations to the documents and text that meets the requirement</td>
</tr>
</tbody>
</table>

- 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.
     - It is permissible for investigations to be conducted by people outside of the compliance function.
     - To the extent that someone outside the compliance function is investigating, the results of the investigation will be shared with appropriate compliance personnel.
     - Results from investigations should not be filtered by someone outside of the compliance function.

    ✓ Amend the Handbook to include references to the compliance plan and Code of Conduct policies and procedures dealing with guidance on how potential compliance problems are investigated and resolved.

  b) How the investigation will be conducted (e.g., interviews, documentation reviews, and root cause analyses).
     - Identification of investigative steps from start to finish.
     - 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.

    ✓ Develop written policies and procedures that centralize the process used by the compliance officer when conducting investigations.

  c) Documentation of results.
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.

**Element 1: Template Policies**

1. **Code of Conduct Policy** (Arc of Jefferson St. Lawrence)
2. **Corporate Compliance Plan** (Madison Cortland Chapter, NYSARC, Inc.)
3. **Appendix, Corporate Compliance Plan** (Madison Cortland Chapter, NYSARC, Inc.)
4. **Arc New York Template Policies:**
   - Compliance Plan [.doc]
   - Corporate Compliance Structure [.doc]
   - Code of Conduct [.doc]
   - Conflict of Interest [.doc]
   - Reporting Compliance Concerns with Whistleblower [.doc]
   - Policy Development [.doc]
   - Client Inducement/Co-payments [.doc]
   - Contractual Financial Arrangements with Physicians/Stark [.doc]
   - Detecting and Responding to Compliance Violations; Voluntary Disclosures [.doc]
   - Employee Discipline [.doc]
   - Documentation of Services [.doc]
   - Documentation of Compliance Activities [.doc]
   - Compliance Program Education and Training of Employees and Others [.doc]
   - Exclusion Checks [.doc]
   - Exit Interview and Separation from Service Procedures [.doc]
   - Gifts and Entertainment [.doc]
   - Internal Investigations [.doc]
   - Political Contributions/Lobbying [.doc]
   - Responding to Government Investigations [.doc]
   - False Claims [.doc]
   - Billing Third Party Payors [.doc]

**Element 1: References**

1. OMIG Compliance Program Review Guidance dated 10/26/16
   [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
2. Element 1, page 9-13 of the OMIG Program Self-Assessment document
   [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
3. Element 1, page 2 of the OMIG Best Practices dated 3/31/14
4. Element 1, page 2-3 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 2: Designate an Employee Vested with Responsibility

- OMIG Regulatory Cite
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Policies
- References
Element 2: Designate an Employee Vested with Responsibility

Element 2: OMIG Regulatory Cite

- 18 NYCRR 521.3

(c) A required provider’s compliance program shall include the following elements:
(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.

Element 2: OMIG Compliance Program Effectiveness Questions and Guidance

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

<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td>2.1 Has a designated employee been vested with responsibility for the day-to-day operation of the compliance program?</td>
<td></td>
<td>Identify the designated employee, and include evidence to support that the person has been vested with responsibility.</td>
</tr>
</tbody>
</table>

- Bureau of Compliance (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.
- Tests to determine whether a Compliance Officer (CO) is an employee of a Required Provider may include but are not limited to:
  a. The CO is a “W-2 employee”.
  b. The objective, non-contractual obligations that determine employment status.
- BOC refers to “Compliance Guidance 2015-02: Mandatory Compliance Program Requirement: Holding Company and Joint Venture Structures, Employee Vested with Responsibility for Day-to-Day Operations of the Compliance Program.” This also applies in the context of non-profit corporations where there is a sole corporate member.
- There must be consistency across documented evidence.
The organization chart, compliance plan, compliance-related policies and procedures and CO’s job description should be consistent in the reporting relationships and the duties and responsibilities.

Ensure that the compliance function is supported in the organizational structure: Organizational chart includes appropriate reporting structure between the compliance function, the governing board, and senior management.

- 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;

- Develop the CO’s job description so that compliance functions are specific and match the compliance plan’s references to the CO’s duties.
  d. management organization charts;
  e. communication to those covered by the compliance program; or

- Develop Ensure that the identity and contact information of the CO and compliance function are publicized in appropriate, highly visible locations and settings and is current.
  f. compliance plan document or other policies and procedures that describe compliance related duties and responsibilities.

- BOC recommends that the designated employee vested with responsibility for 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.
- 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?

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<tbody>
<tr>
<td>2.2 Are the designated employee’s (referred to in 2.1) duties related solely to compliance?</td>
<td>Yes/No</td>
<td>Include job description for all duties of the designated employee.</td>
</tr>
</tbody>
</table>

- 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 if it is in writing.
- BOC reviews organizational charts to identify areas of responsibility for the designated employee.

- 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, such as:
  a. billing and payment obligations; or
  b. quality management.

- The CO should not provide oversight of programming.
Element 2: Designate an Employee Vested with Responsibility

✓ Develop a cost center and reasonable budget for compliance to ensure that proper resources are devoted to compliance.

✓ Include the CO in quality assurance meetings, as opposed to merely receiving reports/memoranda.

2.3 Are the compliance responsibilities satisfactorily carried out?

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<tr>
<td>Are the compliance responsibilities satisfactorily carried out?</td>
<td></td>
<td>Provide evidence of your assessment of whether the compliance duties are being satisfactorily carried out.</td>
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</table>

- 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:
     o Evidence that investigations have commenced and been completed, and action has been taken in response;
     o annual self-assessment of the compliance program and related policies Procedures, and risk analyses;
     o completion of the annual SSL and/or DRA certification(s) on OMIG’s web site;

✓ Ensure that the annual certifying person is a member of senior management who oversees the CO’s function. The certifying person and the CO listed on the certification should be different persons.

  o evidence of initial and Periodic compliance training for all Affected individuals; and
  o completion of investigations, including implementation and monitoring of plans of correction, for compliance issues.

- 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.
• BOC looks for evidence that the non-compliance duties allow for enough time and attention for the designated employee to satisfactorily carry out compliance responsibilities.

✓ Assess the non-compliance duties and reporting structure(s) of the CO regularly to ensure that conflicts do not exist between compliance and non-compliance duties.

• Establish and maintain open lines of communication within the organization so potential compliance problems may be reported promptly.
• Monitor all methods of communication, including anonymous and confidential methods.
• Create and maintain appropriate documentation (e.g., logs, spreadsheets, and records) of compliance activities.

✓ For compliance programs where there are multiple compliance personnel, develop and document the responsibilities at each compliance position and the reporting structures to ensure that compliance issues are reported within the compliance function for appropriate action.

• Chair management compliance committee (if any) that oversees operation of the compliance program.

✓ If developing a management compliance committee, include a variety of disciplines on the committee.

✓ The Corporate Compliance Committee (CCC) should include, among others: A Board Member, the CO, a member of the Finance Department, a Human Resources Department representative, a representative from IT and Program Operations departments.
*Note: Positions can be represented on the committee through other methods.

✓ The CCC should meet at least quarterly.
• If applicable, supervise assigned staff to ensure compliance-related duties are satisfactorily carried out.
• Report periodically on compliance activities to the chief executive or other senior administrator, and the Governing body.
• Develop, provide, coordinate, and/or track compliance training and education for orientation and periodic training for all Affected Individuals.
• Monitor results of compliance-related disciplinary actions to confirm fair and firm enforcement.
• Develop, manage, and report on the annual compliance work plan, including routine identification of compliance risk areas and trends.

✓ If Develop progress reports with due dates for assignments and responsible parties for delivery of milestones on the compliance work plan.

• Monitor credentialing and conduct monthly checks of the federal and state exclusion lists.
• 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.
• Investigate potential and actual compliance issues, including root cause analyses.
• 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.
• Monitor plans of correction to confirm problems have been resolved or new plans of correction are required.
• Report compliance issues to Department of Health (DOH) and/or OMIG.
• Oversee self-disclosures and refunding of overpayments.

✓ Offer additional compliance training to the CO as a way of changing the perception that the CO is a clerical position. The CO should be able to make decisions about compliance issues whether they are reported or discovered as a result of risk assessment.
2.4 Does the designated employee (referred to in 2.1) report directly to the entity’s chief executive or other senior administrator?

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<tbody>
<tr>
<td>2.4 Does the designated employee (referred to in 2.1) report directly to the entity’s chief executive or other senior administrator?</td>
<td></td>
<td>Specify the reporting relationship and provide a copy of an organizational chart. If the designated employee does not report to the chief executive, provide proof that the chief executive has designated the senior administrator to whom the employee reports.</td>
</tr>
</tbody>
</table>

✓ The CO should report directly to the Executive Director or COO.

- Reporting must include not only compliance issues but also how the CO’s personnel performance issues are addressed.
- 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.

✓ Ensure that there is an independent reporting structure for the compliance function to the governing body and senior management.

a. If the direct reporting structure for 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.).
   - Evidence of designation may include but is not limited to
     - memo or email from the entity’s chief executive;
     - letter of appointment from the entity’s chief executive;
     - offer letter issued by or job description approved by the chief executive;
     - designation in the supporting policies and procedures that are approved by the entity’s chief executive; or
     - designation in an organizational chart that is approved by the entity’s chief executive.
• 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.

**Bureau of Compliance**

**BEST PRACTICE**

✓ The Chief Executive Officer receives regular reports from the CO if the CO does not report directly to the CEO.

• BOC determines that a direct reporting structure to the governing board also meets this requirement.
• 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 the activities of the compliance program?

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider’s Evidence of Compliance or Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the designated employee (referred to in 2.1) periodically report directly to the governing body on the activities of the compliance program?</td>
<td></td>
<td>Specify the reporting relationship and the frequency of the reporting.</td>
</tr>
</tbody>
</table>

**OMIG Opportunity**

✓ Develop policies and procedures that ensure periodic reporting by the CO to the governing board.

✓ Make the CO’s reporting structure to the governing board clear so that the CO reports to the governing board on more than just specific instances of non-compliance and formalize the “periodic” reporting to the governing board in the compliance plan and other compliance related documents.
✓ Engage the governing board through training, regular reports from the compliance function, and progress reports on work plan issues. This will improve the compliance culture and ensure a “tone at the top” that supports compliance and becomes evident to management, employees, staff, and contractors.

- Organizational chart should have a dotted line reporting structure from the designated employee to the Governing Body as stated in Section 521.3 - Compliance Program Required Provider Duties and Social Services Law SOS § 363-d.

- 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.

✓ The CO should meet privately with the Board of Directors in executive session at least annually.

✓ Include compliance as a standing agenda item for governing board meeting appropriate board committee meetings. This can include attendance by the CO to explain current compliance issues and/or a report from the CO.

  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.

✓ Redefine the organizational chart to reflect a reporting relationship by the CO to the governing board, board committee, or governing board member who sits on the compliance committee.
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.

**Element 2: Template Policies**
1. Compliance Officer Job Description (Arc of Onondaga)
2. Compliance Officer Job Description (Oswego Industries/Arc of Oswego County)
3. Compliance Officer Job Description (The Arc of Schuyler)
4. Corporate Compliance Report/Meeting Structure (The Arc Onondaga)
5. Corporate Compliance Report Form (The Arc Onondaga)
6. Corporate Compliance Report Form (The Arc Oneida-Lewis)
7. Executive Session Guide (BoardSource)
8. Corporate Compliance Committee Meeting Agenda (The Arc New York)

**Element 2: References**
1. OMIG Compliance Program Review Guidance dated 10/26/16
   https://omig.ny.gov/compliance/compliance-library
2. Element 2, page 9-13 of the OMIG Program Self Assessment document
   https://omig.ny.gov/compliance/compliance-library
4. Element 2, page 2-3 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 3: Training & Education

- OMIG Regulatory Cite
- Minimum OMIG Requirements
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Policies
- References
Element 3: OMIG Regulatory Cite
• 18 NYCRR 521.3

(c) A required provider’s compliance program shall include the following elements:
(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;

Element 3: Minimum OMIG Requirements
The following must be present for each requirement in Element 3:

• 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.

✓ “Affected Individuals”, and what trainings they will receive, must be clearly identified. Additionally, the definition of vendors requiring training should include “those involved in the delivery of services,” as this will control the scope of vendors required to have the training (i.e., the single day vendor doing specific maintenance would not be required to have the training).

✓ Revise the compliance plan or appropriate policies and procedures to define who “affected persons” are in relation to training and education requirements.

✓ Maintain a distinction between compliance training and quality training. They should be related and connected, but do not sacrifice one for the other.
Issuance of a brochure to consumers, partners, and vendors that highlights the provider’s quality initiatives and commitment to performance and quality improvement. The brochure includes a “CONTACT US” section, which identifies contact names and numbers of the compliance staff.

- Compliance training content/materials must include the following minimum requirements:
  
  a. **Compliance Issues:**
     
     Training and education must include requirements identified in **Element 1:**
     
     - guidance on dealing with compliance issues;
     - how to communicate compliance issues to appropriate compliance personnel; &
     - guidance on how potential compliance problems are investigated and resolved.

  b. **Compliance Expectations:**
     
     Training and education must include requirements identified in **Element 1:**
     
     - expectations related to acting in ways that support integrity in operations;
     - written policies and procedures that describe compliance expectations; and
     - written policies and procedures that implement the operation of the compliance program.

   - Consider including the chief executive officer/administrator in the training so that he/she is well-versed in how the compliance program works. This provides a visible support for the Compliance Officer (CO) and the program. This can demonstrate a strong “tone from the top” support for compliance.

   Training and education must include requirements identified in **Element 3:**
   
   - compliance training at orientation; and
   - periodic compliance training.

   - Consider adding language in the provider’s policies and procedures to reflect that training is given at the time of orientation for new relevant employees, appointees, and associates.

   Training and education must include reporting requirements identified in **Element 4:**
   
   - training materials must identify who the designated employee is; and
   - methods for anonymous and confidential good faith reporting of potential compliance issues as they are identified must be included.
Training and education must include disciplinary policies related to the compliance program identified in Element 5:

- expectations for reporting compliance issues;
- expectations for assisting in the resolution of compliance issues;
- sanctions for failing to report suspected problems;
- sanctions for participating in non-compliant behavior;
- sanctions for encouraging, directing, facilitating, or permitting non-compliant behavior; and
- expectations that compliance-related disciplinary policies are fairly and firmly enforced.

Include compliance training with education on disciplinary policies specifically addressing consequences for participating in noncompliant behavior; or encouraging, directing, facilitating, or actively or passively permitting noncompliant behavior, while emphasizing non-intimidation and non-retaliation for good faith participation in the compliance program.

Training and education must include information about the non-intimidation and non-retaliation requirements identified in Element 8.

Include information regarding non-intimidation and non-retaliation in training and education programs.

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:

- Training and education offered in a language understandable to Affected Individuals.
- Training and education should be sensitive to any reasonable accommodations of the Affected Individuals.
- Applicable training and education materials should be legible.
Element 3: Training and Education

✓ The compliance training and educational materials are tailored to the needs of differing organizational levels as well as the educational backgrounds of all employees.

c. Compliance Program operation:
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.

✓ Consider including the chief executive officer/administrator in the training so that he/she is well-versed in how the compliance program works. This provides a visible support for the compliance officer and the program. This can demonstrate a strong “tone from the top” support for compliance.

Training and education must include information about the system for identifying compliance risk areas as identified in Element 6.

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.

✓ Expand the training program to include more than just the billing and payment issues and document those changes in the compliance plan.

Training and education must include information about the system for responding to compliance issues as identified in Elements 1 and 7, as follows:
  o Written policies and procedures that provide guidance on how potential compliance problems are investigated and resolved.
  o A system in effect for responding to compliance issues as they are raised.
  o A system in effect for responding to compliance issues as identified in the course of audits and self-evaluations.
  o A system in effect for correcting compliance problems promptly and thoroughly.
  o A system in effect for implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.
  o A system in effect for identifying and reporting compliance issues to DOH or OMIG.
  o A system in effect for refunding Medicaid overpayments.
Align the training requirements in the corporate compliance program/plan with actual practice.

Provide training materials that refer to both the New York State-required compliance elements and the Federal Deficit Reduction Act of 2005’s compliance elements, where applicable.

BOC recommends training material reflect current information about the compliance program:

a) Listing of the CO and their contact information should be accurate and up-to-date.
b) Policies and procedures reflected in the training should be accurate and up-to-date.

The compliance manual/code of conduct is distributed annually and upon hire.

Evidence of the subject matter and delivery of training must be readily available. Examples of documented evidence may include, but is not limited to:

- Written policies and procedures outlining the training requirements that:
  - Orientation training for new Affected Individuals must occur;
  - Periodic training must occur for all Affected Individuals; and
  - Document a follow-up process for the Affected Individuals that miss trainings.

a) Documented training materials evidencing that all training subjects are covered (e.g., PowerPoint, audio/video program, course book, course syllabus, etc.);
   - Sign-in sheets and/or signed acknowledgements that individuals attended training;
   - Copies of pre- and post-training tests; Demonstration of training program;
   - Employee confirmations that training occurred (during on-site reviews); or
   - Disciplinary action for compliance orientation/training absences that is consistent with discipline for failures to attend orientation or other work-related trainings.

Develop a training syllabus for compliance.
✓ Establish an oversight and tracking system for education so that all constituencies required to undergo training are tracked for meeting the training obligation, as well as measurement of training testing.

✓ Use of an electronic training and education system that tracks mandatory compliance education of employees via an electronic system which:
  ▪ is customized to the organization;
  ▪ sends an individualized e-mail to employees to announce upcoming required and elective training; and
  ▪ tracks each employee’s required compliance training and educational needs.

✓ Relias could be a useful platform for conducting the training, particularly for Board members. This is especially useful for trainings after the formal (initial) training to allow affected parties to work the trainings into their own schedule. Relias can “white list” which means only certain IP addresses can be used to access the training. This can control when the affected party can do the training. This allows for the ability to limit employees to completing the training from a company workstation. This will help with controls on trainings being done during paid hours.

✓ A formal tracking system using either a sign-off sheet or other method should be implemented by the Chapter to track distribution of training to outside vendors.

- 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:
  
  a) 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.
    
    ✓ Ongoing training, such as news blasts and management “tidbits” can be a good option to keep Affected Individuals up to date on corporate compliance items. Some examples include monthly news blasts on hot topics such as not conducting personal business on agency time, social media risks, HIPAA, how to recall emails, etc. Actual stories of fraud and dollar amounts should be included as these make the information impactful.
    
    o Compliance training may use definitions and examples to help employees understand what a compliance issue is. This may include:
      
      ▪ definitions of fraud, waste, and abuse; and/or
      
      ▪ 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.
    
    ✓ Establish include definitions of fraud, waste, and abuse for individuals completing compliance training to identify suspicious and noncompliant behavior. This highlights differences for employees and makes identification of fraud, waste, and abuse more likely.

  b) If compliance training include 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.
    
    ✓ A mix of training options should be available to include at-home options and self studies. These trainings The CO or someone with knowledge of the compliance program should author or be involved in the development of the training materials.
c) 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.

Element 3: OMIG Compliance Program Effectiveness Questions and Guidance

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

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>3.1 Is periodic training and education on compliance issues, expectations</td>
<td>Yes</td>
<td>Also define the timing of the periodic training, and identify any categories of affected individuals that do not receive training and education, if any.</td>
</tr>
<tr>
<td>and the compliance program operation provided to all of the following</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>categories of affected individuals:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. employees;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. executives;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. governing body members; and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. persons associated with the provider?</td>
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<td></td>
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</table>

- Ongoing Training should be conducted in three phases – Pre orientation, Initial (Formal), and Periodic (Annual). Pre-orientation is defined in section 3.2.

- Training on compliance issues, expectations and the compliance program must be completed annually. Annual trainings that are completed in-person must be conducted by the CO or someone w/knowledge of the CC program (i.e., someone trained/identified by the CO). A system for consistent and annual training should be implemented to ensure predictability in training expectations.

- Periodic compliance training can take place at the same time as other mandatory trainings, or more frequently if required.
- Periodic compliance training and education must be provided to all categories of Affected Individuals in order to meet the requirement.
After compliance training, implement a testing tool that measures the effectiveness of the training and trainer to improve the content and presentation method on the compliance program.

Amend the corporate compliance plan to include how often the training is required for all groups required to receive compliance training (annual is recommended).

3.2 Compliance training as part of orientation.

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<tbody>
<tr>
<td>3.2 Is compliance training part of the orientation for all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td>Yes</td>
<td>Also define when orientation occurs, and any categories of affected individuals that do not receive orientation, if any.</td>
</tr>
</tbody>
</table>

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

Pre-Orientation Training
- A pre-orientation training should be presented in an in-person format.
- Compliance issues, expectations, and the compliance program operation should be included in the training packet.
- Pre-orientation training should be a summarized version of the full orientation training.
- The pre-orientation training should occur within the first 30 days of hire.
- The initial (formal) training should be completed within 90 days of hire.
- Initial (formal) training should be presented in an in-person format for all Affected Individuals.
- The CO or designee of the CC program must have a role in presenting the initial (formal) training.
- A post assessment test should be included in the formal (initial) training.
Element 3: Training and Education

- Establish employee pre-training benchmarks and compare with post-training to identify an individual’s future education opportunities.

- Consider utilizing the CO to conduct compliance education and training. This assists constituencies in identifying the CO.

- Results of online compliance education quiz scores are analyzed and tracked to identify areas of weakness for both the education program and for those being trained. Additional training and education is provided based on this analysis. Results of the online post-test quizzes are utilized to identify risk areas and assess the need for internal monitoring and auditing.

- 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.

- The initial (formal) training for Board members should be completed within 90 days of hire. Consider asking the Board member to meet with the CO to do a general overview of Corporate Compliance a day or so before the next Board meeting.

- Implement some level of training for the governing board, contracted staff, and non-employed medical staff.

Element 3: Template Policies

1. New Employee Compliance Training Policy (The Arc Otsego)
2. Pre-Orientation Training Policy and Pre-Orientation Training Checklist (The Arc of Onondaga)
3. Vendor Compliance Program Letter (The Arc of Onondaga)
4. Vendor Code of Conduct (The Arc of Onondaga)
5. Initial (Formal) Training and Training Policies (The Arc of Onondaga)
6. Initial (Formal) Training Checklist/Outline (The Arc Onondaga)
7. Periodic (Annual) Training (The Arc Herkimer)
8. Compliance Training Test (The Arc Onondaga)
9. Compliance Training Test (The Arc of Madison Cortland – pre- and post-tests)
10. **Compliance Program Board Training** (The Arc Oswego)
11. **Ongoing Training/Brief News Blast Example** (ACHIEVE)
12. **Training Acknowledgment** (The Arc of Madison Cortland)
13. **Compliance Handbook** (The Arc Otsego)
14. **Compliance Handbook Acknowledgment** (The Arc Otsego)

**Element 3: References**

1. OMIG Compliance Program Review Guidance dated 10/26/16
   [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
2. Element 3, page 14-17 of the OMIG Program Self Assessment document
   [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
4. Element 3, page 3-4 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 4: Lines of Communication to the Responsible Compliance Position

- OMIG Regulatory Cite
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Policies
- References
Element 4: OMIG Regulatory Cite

- 18 NYCRR 521.3

(c) A required provider’s compliance program shall include the following elements:

(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;

Element 4: OMIG Compliance Program Effectiveness Questions and Guidance

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

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider’s Evidence of Compliance or Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Are there written policies and procedures that identify how to communicate compliance issues to appropriate compliance personnel?</td>
<td></td>
<td>For each response - Include specific citations to the documents and text that meets the requirement</td>
</tr>
</tbody>
</table>

- The written policies and procedures must identify the appropriate compliance personnel to receive the communication. It need not be the Compliance Officer (CO), but it must be compliance personnel.
  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.

- Implement Ensure that the compliance function is supported in the organizational structure:
  - Consider that various organizational constituencies interact with the provider in different ways and that not every communication method is effective for all constituencies. This includes ensuring that appropriate anonymous methods are readily available.

- Develop, document, and implement a grievance policy that includes references to the compliance plan and Code of Conduct policies and procedures dealing with guidance on how potential compliance problems are investigated and resolved.
✓ Include specific language in the compliance plan and applicable policies and procedures that supervisors or senior staff must report to the compliance function all compliance-related issues they receive and that they will respect requests for confidentiality or anonymity.

✓ The compliance program operates in an environment of transparency throughout the organization and includes communication lines among the president/director, senior management, and employees.

✓ Expand the publication of the CO’s contact information. This could include using a photograph of the CO to assist in identification, publicizing the lines of communication in provider publications, and providing examples of the types of issues to be reported to the compliance function.

✓ Revise language used to report compliance matters so that it is positive in approach rather than negative.

✓ Utilize the provider’s Internet Web site to publish compliance expectations and reporting information.

✓ Provider issues laminated cards to all employees to wear with their ID badges. The cards include the CO’s contact information; a list of compliance risk areas; and a summary of the provider’s policies addressing the risk areas items. The cards are printed in five different languages.

c) It is acceptable for the Required Provider to use a hotline service if 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.

✓ Emphasize in the training that reports of potential compliance issues go directly to the CO.
d) It is acceptable for the Required Provider to use a drop box for communication if the drop box is used to report compliance issues and is monitored and controlled exclusively by appropriate compliance personnel.

- If a compliance drop box is used as a communication method, it should be controlled by the compliance function with the ability to ensure that there is a process to check that all insertions are seen by the CO and not screened by a non-compliance functionary.

- 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.

- Update all references in compliance plan and applicable policies to contact information for compliance function (e.g., changes in telephone numbers, e-mail contact and identity of compliance officer, as may be necessary).

- Clients/patients receive information on how to identify Medicaid fraud and how any concerns can be reported to management. They also are given examples of Medicaid fraud, and compliance-related issues.

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

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider’s Evidence of Compliance or Action Required</th>
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</thead>
<tbody>
<tr>
<td>4.2 Are there lines of communication to the designated employee referred to in item 2.1 that allow compliance issues to be reported and which are accessible to all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td>Yes</td>
<td>Also identify any categories of affected individuals that do not have access to the lines of communication identified.</td>
</tr>
</tbody>
</table>
“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.

- Add language in provider’s policies and procedures to itemize all of the methods for reporting compliance issues.
- Dedicate a specific telephone number as a hotline for compliance issues, rather than using an all-issues hotline.
- Use of drop boxes to enhance access for anonymous reporters.

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.

- Training A member of the Board or the compliance committee should regularly test the methods of communication to gauge responsiveness.
- Implement a back-up plan to allow for compliance issues to be communicated when the CO is not available.
- Include compliance function contact information in patient registration materials.
- Implement a system to periodically test the functionality and operation of all identified lines of communication to the compliance function.
An electronic information board is used for communication as part of compliance education for staff and patients.

- Lines of communication should encourage submission and receipt of information on compliance issues.

Include various communication methods on the provider's front page of their web site to maximize compliance program visibility.

For the voice mail announcement on a phone line used for reporting compliance issues, confirm that the telephone number called is a compliance function number, as well as the number for the CO.

Publicize and include in the compliance education materials, all of the CO’s contact information (i.e., address, telephone number, e-mail, and other methods of contact, if any).

Improve access to contact information by hanging posters; making the information more obvious on both the provider’s web site and the intranet; publicize the hot line more prominently; and expand access to contact information to public areas, break rooms, and administrative offices.

Human resource department’s exit interviews of employees include specific compliance-related questions that are fed back to the compliance function.
4.3 Methods for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>4.3</td>
<td></td>
<td>For each response - Include specific citations to the documents and text that meets the requirement. Also identify any categories of affected individuals that do not have access to the lines of communication identified.</td>
</tr>
</tbody>
</table>

- Methods of communication:
  a) At least one method must be anonymous.
     o 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.

  ✓ Include the governing board in the list of individuals entitled to anonymity.

  ✓ Publicize how to anonymously report compliance issues.

- 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.

  a) Typically, the following are not considered anonymous methods of communication:
     o telephone lines or hotlines with caller ID;
     o email which can be reverse engineered to retrieve the sender’s address;
     o suggestion box not controlled by the CO that also serves as a drop box for compliance issues; and
     o any method that may be located in an area where there is camera surveillance activity.
b) At least one method must be confidential.
   - There is no requirement for all methods of communication to be confidential.
   - 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.
   - 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.
     - All reports via the confidential method must be kept confidential, whether requested or not.
     - A statement indicating that a person’s identity will be kept confidential unless the matter is turned over to law enforcement is acceptable.
     - 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.
     - 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.

✓ Clarify language regarding “confidential and anonymous” reporting of potential compliance issues.

✓ To encourage reporting, confirm in the compliance plan and supporting policies and procedures that the compliance function respects request for confidentiality and anonymity in any good-faith reporting of potential compliance issues.

   - An outside contractor, with a confidentiality agreement, that manages the communication methods and reports directly to the CO is an acceptable confidential communication method.
   - A hotline telephone that may be answered by someone with no compliance responsibilities is not confidential.
   - 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.
Use a compliance-dedicated and secure method for use in confidential and anonymous communication to the compliance function.

- 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.
- 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.

**Element 4: Template Policies**

1. [Confidentiality Policy](#) (The Arc Otsego)
2. [Compliance Hotline Policy](#) (The Arc Otsego)
3. [Compliance Hotline Policy](#) (The Arc of Madison-Cortland)
4. [Other Forms of Communication](#) (The Arc Otsego)
5. [Ethics Helpline Policy](#) (The Arc Jefferson-St. Lawrence)
6. [Compliance Line Poster](#) (The Arc Otsego)

**Element 4: References**

1. OMIG Compliance Program Review Guidance dated 10/26/16
   - [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
2. Element 4, page 18-19 of the OMIG Program Self Assessment document
   - [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
3. Element 4, page 2-3 of the OMIG Best Practices dated 3/31/14
4. Element 4, page 5-6 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 5: Disciplinary Policies to Encourage Good Faith Participation

- OMIG Regulatory Cite
- Minimum OMIG Requirements
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Policies
- References
Element 5: Disciplinary Policies to Encourage Good Faith Participation

Element 5: OMIG Regulatory Cite

• 18 NYCRR 521.3

(c) A required provider’s compliance program shall include the following elements:
(5) disciplinary 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-compliant behavior; such disciplinary policies shall be fairly and firmly enforced.

Element 5: Minimum OMIG Requirements

The following must be present for each requirement in Element 5:
• 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. The Bureau of Compliance (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.

✓ Ensure the existence of disciplinary policies that support and encourage good-faith reporting and participation in the compliance program, and that these are included in the employee handbook or other appropriate publication(s).

✓ Policies and procedures can be detailed but code of conduct and Employee Handbook should be easy to comprehend and follow.

d. Failure to identify evidence of disciplinary policies will result in an Insufficiency.

✓ Ensure consistent representations in the compliance plan and the policies and procedures that address the specific disciplinary requirements for Element 5.
Element 5: Disciplinary Policies to Encourage Good Faith Participation

There should be a standalone compliance disciplinary policy for compliance plan related issues:
- The HR disciplinary policies will reference the applicable, separate policy for corporate compliance related issues.
- The Compliance Officer (CO) should maintain an updated tracking log or other system of compliance reports. This tracking/logging system should include:
  - A summary of the actions taken, CO recommendations, and final outcome.
  - Justification from HR of actions taken (when applicable). This is imperative to be able to verify that the CO is involved in ensuring fair and firm response.

Element 5: OMIG Compliance Program Effectiveness Questions and Guidance

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

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider’s Evidence of Compliance or Action Required</th>
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<tbody>
<tr>
<td>6.1 Do disciplinary policies exist to encourage good faith participation in the compliance program by all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td>Yes/No</td>
<td>For each response - Include specific citations to the documents and text that meets the requirement. Also identify any categories of affected individuals not covered by the disciplinary policies.</td>
</tr>
</tbody>
</table>

- 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, 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.

Include in the compliance plan specific language addressing disciplinary policies that support good-faith participation in the compliance program.
Organization must identify “key employees” in policy to determine who needs to complete applicable Conflict of Interest forms.

The Code of conduct and/or Employee Handbook should include both non retaliation and non-intimidation language.

Employee performance evaluations incorporate compliance as one indicator of performance, as well as an employee’s adherence to applicable laws, regulations, and policies.

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.

The Code of Conduct should be provided to all “key employees”, consultants, contractors and board members. The notice to contracted vendors should be done annually.

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<th>Requirement</th>
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</table>
| 5.2        |                    | For each response - include specific citations to the documents and text that meets the requirement | Also identify any categories of affected individuals not covered by the policies.

Are there policies in effect that articulate expectations for reporting compliance issues for all of the following categories of affected individuals:

a. employees;

b. executives;

c. governing body members; and

d. persons associated with the provider?
• There must be policies that set out expectations for reporting compliance issues to the compliance function.

✓ Include in disciplinary policies and procedures language that administration, staff, governing body members, and all affected individuals have an obligation to report compliance failures.

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

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<tbody>
<tr>
<td>5.3 Are there policies in effect that articulate expectations for assisting in the resolution of compliance issues for all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td></td>
<td>For each response - Include specific citations to the documents and text that meets the requirement Also identify any categories of affected individuals not covered by the policies.</td>
</tr>
</tbody>
</table>

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

✓ Implement disciplinary policies that articulate expectations for assisting in the resolution of compliance issues for affected individuals.

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

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<th>Requirement</th>
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<tbody>
<tr>
<td>5.4 Is there a policy in effect that outlines sanctions for failing to report suspected problems for all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td></td>
<td>For each response - Include specific citations to the documents and text that meets the requirement Also identify any categories of affected individuals not covered by the policy.</td>
</tr>
</tbody>
</table>
• 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.

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<th>Requirement</th>
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<tr>
<td>5.5 Is there a policy in effect that outlines sanctions for participating in non-compliant behavior for all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td>Yes No</td>
<td>For each response - Include specific citations to the documents and text that meets the requirement. Also identify any categories of affected individuals not covered by the policy.</td>
</tr>
</tbody>
</table>

• There must be policies that outline sanctions (e.g., discipline) for participating in non-compliant behavior.

• 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.

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<tbody>
<tr>
<td>5.8 Is there a policy in effect that outlines sanctions for encouraging, directing, facilitating or permitting non-compliant behavior for all of the following categories of affected individuals: a. employees; b. executives; c. governing body members; and d. persons associated with the provider?</td>
<td>Yes No</td>
<td>For each response - Include specific citations to the documents and text that meets the requirement. Also identify any categories of affected individuals not covered by the policy.</td>
</tr>
</tbody>
</table>

✓ Ensure that policies reflect appropriate disciplinary consequences (potentially up to and including dismissal) for participating in noncompliant behavior, or encouraging directing, facilitating, or actively or passively permitting noncompliant behavior.
Disciplinary policies and procedures must include both non-retaliation and non-intimidation language.

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

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<th>Requirement</th>
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<tbody>
<tr>
<td>5.7 Are all compliance-related disciplinary policies fairly and firmly enforced?</td>
<td></td>
<td>Also list all policies in effect that support your answer and identify circumstances where compliance-related discipline was enforced.</td>
</tr>
</tbody>
</table>

- 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.
  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).

- It is acceptable that the expectation for fair and firm enforcement of compliance-related disciplinary actions may be included in training and education materials.

- 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.”

- 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.

Ensure consistent representations in the compliance plan and the policies and procedures that address the specific disciplinary requirements for Element 5.
Element 5: Template Policies

1. Detecting and Responding to Violations; Voluntary Disclosures (The Arc of Madison-Cortland)
2. Discipline and Incentive Program Policy (The Arc of Madison-Cortland)
3. Enforcement and Discipline Procedure (The Arc of Madison-Cortland)
4. Responding to Detected Offenses (The Arc of Madison-Cortland)*
   *A “Response to Reported Compliance Issue” Template is included with this policy
5. Compliance Event Tracking Log (The Arc New York) [.xls]

Element 5: References

1. OMIG Compliance Program Review Guidance dated 10/26/16
   https://omig.ny.gov/compliance/compliance-library
2. Element 5, page 20-22 of the OMIG Program Self Assessment document
   https://omig.ny.gov/compliance/compliance-library
3. Element 5, page 3 of the OMIG Best Practices dated 3/31/14
4. Element 5, page 6 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 6: Risk Assessment

- OMIG Regulatory Cite
- OMIG Additional Considerations
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Risk Assessment and Instructions
- Template Interview Questionnaire
- Template Risk Assessment Write Up
- References
Element 6: OMIG Regulatory Cite

- **18 NYCRR 521.3**

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; (7) other risk areas that are or could be identified.

(c) A required provider’s compliance program shall include the following elements:

- (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 5 of care of medical assistance program beneficiaries

**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:

a. 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:

- call/report logs that track activity;
- work plans;
- documentation and reports of audits and/or investigations;
- plans of correction; or
- documentation of refunded overpayments and/or self-disclosures.

**BEST PRACTICE**

- Risk Assessment should be a formal, documented process.
- The Arc New York has developed a template risk assessment that should be used.
- The Risk Assessment should be completed in the following fashion:
  - Ask department leads/heads to complete their respective section of the risk assessment form.
Element 6: Risk Assessment

- Departments should complete and submit to the designated risk assessment lead.
- Risk Assessment lead should conduct interview with the department lead to review responses and explore risks together.
- Arc New York has developed a template interview questionnaire to assist. This template is contained further down in this Chapter.
- Interviews should be documented and incorporated into the final risk assessment write up.

b. 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.

- A formal write up of the outcome of the risk assessment form and the subsequent interviews should be completed, provided to the senior leadership and the Compliance Committee at a minimum. (sample provided).
- The formal risk assessment should occur no less than once every three years, with less formal risk assessments being done annually. The compliance officer generally identifies the risk areas to focus on, with Executive Director input, but the compliance committee or workgroup should make the determination of the risk areas to focus on.

Element 6: OMIG Compliance Program Effectiveness Questions and Guidance

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

<table>
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<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider’s Evidence of Compliance or Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1 Do you have a system in effect for routine identification of compliance risk areas specific to your provider type?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

- There must be a system for routine identification of compliance risk areas. Evidence of a system may include but is not limited to:
  a. a description of a system or method for routine identification of compliance risk areas and evidence that the described system is working.
Element 6: Risk Assessment

- Consider adding specific information to provider’s compliance program outlining how to identify risk areas.

b. using a self-assessment tool to identify compliance risk areas;

- Use a self-evaluation tool on an annual basis such as the Compliance Program Self-Assessment Form available on the OMIG web site that includes the requirements of NYS Social Services Law section 363-d and the seven areas that compliance programs should apply to that are set out in 18 NYCRR Section 521.3(a).

c. a compliance work plan that addresses compliance risk areas;

- Prepare an annual compliance work plan that identifies risk areas based upon self-identified weak areas, regulatory advisories, regulatory actions, and outside assessments, among others. Committee meetings, as appropriate. Members and contractors to assist in identification of 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):
  - Medicaid billings;
  - Medicaid payments;
  - the medical necessity and quality of care of the services provided to Medicaid program enrollees;
  - governance of the Required Provider, particularly as related to the Medicaid program;
  - mandatory reporting requirements as related to the Medicaid program;
  - credentialing for those who are providing covered services under the Medicaid program;
Element 6: Risk Assessment

✔ Ensure that policies and procedures are in place to address appropriate action against excluded parties, including checks with vendors to ensure that excluded parties are not involved in Medicaid services through the vendor.

  - and other risk areas that are or should with due diligence be identified by the Required Provider.

✔ Establish a list of the risk areas as part of the compliance program. This will focus efforts on the areas where weaknesses in the compliance program are most likely to exist and it will assist in the application of resources. committee meetings, as appropriate.

e. Operation of the system must be routine meaning it must be operating on a regular basis.

- 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.

✔ Include the compliance officer in quality assurance, risk management and utilization management committee meetings, as appropriate.

✔ Conduct compliance exit interviews for departing employees, staff, management, governing board members and contractors to assist in identification of risk areas.

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.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider’s Evidence of Compliance or Action Required</th>
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<tbody>
<tr>
<td>6.2</td>
<td></td>
<td>For each response - include specific citations to the documents and text that meets the requirement</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Do you have 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:

a. a written expectation for routine self-evaluation of identified risk areas;

b. documented results of self-evaluations;

c. a written expectation for internal and/or external audits of the identified risk areas;

d. documented results of internal and/or external audits;

e. a compliance work plan that identifies self-evaluation or auditing of identified risk areas; or

f. documented results of work plan activities.

✓ Document provider’s self-evaluation efforts to include all compliance risk areas specified under 18 NYCRR 521.3(a).

✓ Develop a process to test the provider’s employees, contractors, grantees and other organizations providing services or billings through the provider for potential violation of the federal False Claims Act or New York’s Fraud Enforcement and Recovery Act.

✓ Develop, document and implement a policy for consultants and contractors that includes requiring background checks prior to signing a contract, monthly exclusion list checks, and a process for approving/disapproving the contractual arrangement. The contract terms should have language that addresses the compliance program expectations, possible issues and the program operation.

✓ Incorporate routine documentation checks by someone outside of the compliance function for the compliance officer’s non-compliance program related data entry when the compliance officer has duties other than compliance.
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.

<table>
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<th>Provider’s Evidence of Compliance or Action Required</th>
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<tr>
<td>6.3</td>
<td></td>
<td>For each response - include specific citations to the documents and text that meets the requirement</td>
</tr>
<tr>
<td>Do you have a system in effect for evaluation of potential or actual non-compliance as a result of audits and self-evaluations identified in 6.2?</td>
<td>Also reference documents that outline your system for evaluating the cause of compliance problems.</td>
<td></td>
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</table>

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

  ✓ Document Add language to the compliance program that specifically addresses the evaluation of risk areas as identified in provider’s self-assessments.

  b. 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.

  ✓ Develop and implement a log of audit results, including identified compliance issues and corrective actions, if any.

  c. evidence that risks are prioritized. This may include but is not limited to:
     o identifying frequency of each risk;
     o likelihood that the negative outcome will result;
     o impact on the delivery of services;
     o impact on other contracts and operations; or financial impact.
d. 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;

e. documented results of work plan activities; or 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.

- Develop and implement a log of audit results, including identified compliance issues and corrective actions, if any.

- Check the appropriate exclusions lists at intervals recommended by OMIG and OIG/CMS.

- Utilize OMIG’s website for self-disclosure reporting process, checking the posted exclusion list, and other compliance tools.

Element 6: The Arc New York Template Risk Assessment, Policy and Instructions

- State Office does not prescribe a specific format for the risk assessment, but it must be documented. The Arc New York Model Risk Assessment, policy and instructions for use can be found on p. 62.

Element 6: Template Corporate Compliance Risk Assessment Interview Questionnaire

Regularly conducting a comprehensive risk assessment is recognized as one of the key elements of an effective compliance program. This risk assessment questionnaire has been developed to assist us in identifying, mitigating, and reducing risks.

The purpose of the interview questionnaire is to assist with conducting interviews with key employees and leaders in various departments to better understand the risks that exist within the department. Using the completed risk assessment form, conduct an interview with the department leadership to better understand the responses and to help identify med to high risk/med to high impact areas.
These questions are not intended to be limited, and the interview should be freeform and flowing. Try your best to keep it informal and to elicit thorough responses. Additional questions and follow may be needed depending on the responses.

1. **Reviewing the response to the risk assessment grid with the department leadership**
   - Review any topic with responses suggesting med/high likelihood with med/high impact.

   **Questions to ask department leadership:**
   - Why did you score this as med/high likelihood?
     - For each med/high likelihood & med/high impact responses, get more detailed information on why the likelihood exists. Why did they score the topic as med/high likelihood?
     - Review all topic responses and follow up on any areas that have identified as having occurred since the last risk assessment.

   ✓ New function/program? ✓ Significant turnover in department staff?
   ✓ Changes to regs/ADM? ✓ Changes in technology?
   ✓ Policies outdated or absent? ✓ Adverse internal audits?
   ✓ Changes in procedures? ✓ Adverse external audits?
   ✓ Changes in key staff? ✓ Why did you score this as med/high impact?

   - Upon identification of events that have occurred since last risk assessment:
     - Describe the change in detail.
     - How did you manage the change?
     - Have you noticed any impact to the performance of the work needed to be done? If so, what has been done to address the issue?
     - What challenges still exist?
     - Have you tested to see if the work is still be conducted properly? How so?
     - Do you have confidence that the change has been adequately managed?
     - What still concerns you about the change?
     - Do you need help determining whether the risk has been adequately addressed?

   **General Questions:**
   - Rank the top risks to achieving your goals with the department that you can control? (procedures, training, etc.)
   - Rank the three top risks to achieving your goals with the department but is outside of your control? (staffing, financial resources, changing regs/ADM, etc.)
   - Are there any low likelihood but high impact topics that concern you? Why?
   - What do you need to make your department or work more successful?
   - What about your department or work keeps you up at night?
Element 6: Template Risk Assessment

1. Risk Assessment Summary (The Arc St. Lawrence)
2. The Arc New York Assessment Interview Questionnaire (The Arc New York) [.doc]
3. Model Risk Assessment (The Arc New York) [.xls]
5. Model Risk Assessment – Instructions for Use (The Arc New York)
6. Compliance Issue Tracking Form (The Arc Onondaga)
7. Compliance Issue Chart (The Arc Onondaga)
8. Auditing and Monitoring Policy (The Arc of Onondaga)

Element 6: References

1. OMIG Compliance Program Review Guidance dated 10/26/16
3. Element 6, page 3 of the OMIG Best Practices dated 3/31/14
4. Element 6, page 6-7 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 7: A System for Responding to Compliance Issues

- OMIG Regulatory Cite
- Minimum OMIG Requirements
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Policies
- References
Element 7: OMIG Regulatory Cite

- 18 NYCRR 521.3

(c) A required provider's compliance program shall include the following elements:

(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.

Element 7: Minimum OMIG Requirements

- 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 methods of identifying risk areas beyond the minimum requirements. Evidence of a system may include but is not limited to:
  
  a. 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:

  • logs that track activity (e.g., call logs);
  • work plans;
  • documentation and reports of audits and/or investigations;
  • plans of correction; or
  • documentation of refunded overpayments and/or self-disclosures.

  b. 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.

Element 7: OMIG Compliance Program Effectiveness Questions and Guidance

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

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<th>Requirement</th>
<th>Meets Requirements</th>
<th>Provider's Evidence of Compliance or Action Required</th>
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<tbody>
<tr>
<td>7.1</td>
<td></td>
<td>For each response - include specific citations to the documents and text that meets the requirement</td>
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</table>
• 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.
     o It is permissible for investigations to be conducted by people outside of the compliance function.
     o To the extent that someone outside the compliance function is investigating, the results of the investigation will be shared with appropriate compliance personnel.
     o Results from investigations should not be filtered by someone outside of the compliance function.

  Investigation & Investigator Assignment
  ✓ Risk Assessment should be a formal, documented process.
     o Investigations into non-compliance should be assigned by the Compliance Officer (CO).
     o The CO may delegate minor issues to program administration. Program administration must report findings to the CO.
     o More substantial concerns should be delegated to someone within the compliance department.
     o Internal policies should indicate CO authority to delegate the investigation of potential concerns to personnel outside of the compliance department.
     o Regardless of the investigation assignment, compliance department staff must be involved throughout all steps of the investigation.
     o The scope, severity and complexity of the non-compliance should be considered when selecting an investigator.
     o The CO should be charged with this determination and should not be required to consult with executive leadership in assigning appropriate investigators to examine a compliance concern.

  Legal Counsel & Law Enforcement
  ✓ Risk Chapters utilize legal as needed for consultation, guidance and if or when they need an issue to be discussed under privilege.
Policies should address how the process will look if legal is involved and the situation/issue is under privilege (Example: If under privilege, legal counsel will generate a report).

Policies should also address how the process will look when law enforcement is involved, including influencing factors in selecting an investigator.

b. How the investigation will be conducted (e.g., interviews, documentation reviews, and root cause analyses).
   - Identification of investigative steps from start to finish.
   - 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/activities.

Develop written policies and procedures that centralize the process used by the compliance officer when conducting investigations

Investigator Training
- Risk Investigators should receive training specific to corporate compliance investigations before they can investigate compliance concerns and then periodically thereafter.
- Some of the investigative training can overlap with incident investigative training.
- Trainings should cover, at minimum:
  - Fraud, Retaliation, and Conflict of Interest
  - Creating an investigative plan prior to beginning the investigation to establish scope of interviews.

c. Documentation of results.

All supporting documentation from compliance investigations should be maintained by the compliance department in a locked and secure manner.
• 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.

✓ All requests for release of compliance investigations come through the CO.

✓ Amend the Handbook to include references to the compliance plan and Code of Conduct policies and procedures dealing with 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.

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<tr>
<td>7.2</td>
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<td>For each response - Include specific citations to the documents and text that meets the requirement Also reference documents that outline your system for responding to actual or potential compliance issues.</td>
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• There must be evidence identifying the issues being addressed in a reasonably diligent manner.
• 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.
Investigations

- An investigation should begin immediately upon receipt of a concern.
- Immediate corrections must include collaboration with the CO.
- Investigation determinations should be reached within 30 days of the beginning of an investigation. Policies should reflect this expectation but should also include direction in:
  - Establishing timelines that account for concerns that differ in severity and depth.
  - Addressing employees out on leave as a result of the concern/investigation.
  - CO authority to authorize extensions as needed.

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

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<td>7.3</td>
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- There must be an expectation in the compliance program for correcting compliance problems promptly.
  a. Bureau of Compliance (BOC) looks for whether there is evidence the problems are being promptly addressed. If corrections proceed ineffectually, that is an indication of not being prompt.
  b. There must be an expectation in the compliance program for correcting compliance problems thoroughly.
  c. BOC looks for whether there is evidence the problems are being thoroughly addressed.
  d. 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.
- 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.

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

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<td>7.4</td>
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<tr>
<td>Is there a system in effect for implementing procedures, policies and systems as necessary to reduce the potential for recurrence?</td>
<td>Yes</td>
<td>No</td>
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- There must be an expectation in the compliance program document (e.g., the Chapter Corporate Compliance Program Policy or the Corporate Compliance Plan) for implementing procedures, policies, and systems as necessary to reduce the potential for recurrence.
- 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.
- 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.

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<td>7.5 Is there a system in place for identifying and reporting compliance</td>
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<td>issues to the NYS Department of Health or the NYS Office of Medicaid</td>
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<td>the documents and text that meets the requirement.</td>
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<td>Inspector General?</td>
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- There must be an expectation in the compliance program document (e.g., the Chapter Corporate Compliance Program Policy or the Corporate Compliance Plan) for identifying and reporting compliance issues specifically to DOH or OMIG.
- 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.
- 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.

✓ All government inquiries must be brought to the compliance department.
✓ Concerning decisions to report to outside entity (OMIG) – Collaborate with legal counsel and consultation with The Arc New York should be considered when deciding to report compliance issues to outside entities.

7.6 A system in effect for refunding Medicaid overpayments.

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Also identify examples of prior refunds of Medicaid overpayments.
There must be an expectation in the compliance program document (e.g., the Chapter Corporate Compliance Program Policy or the Corporate Compliance Plan) for refunding Medicaid overpayments.

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.

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 Affordable Care Act (ACA) process to address refunding of overpayments.

**Element 7: Template Policies**

1. [Corporate Compliance Procedure](The Arc Jefferson-St. Lawrence)
2. [Internal Investigations Policy](The Arc Jefferson-St. Lawrence)
3. [Internal Investigations Policy](The Arc Onondaga)
4. [Detecting and Responding to Violations](The Arc Jefferson-St. Lawrence)

**Element 7: References**

1. OMIG Compliance Program Review Guidance dated 10/26/16
2. [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
3. Element 7, page 26-28 of the OMIG Program Self-Assessment document
4. [https://omig.ny.gov/compliance/compliance-library](https://omig.ny.gov/compliance/compliance-library)
5. Element 7, page 3 of the OMIG Best Practices dated 3/31/14
6. Element 7, page 7 of the OMIG Opportunities for Enhancement dated 3/31/14
ELEMENT 8: Policy of Non-Intimidation and Non-Retaliation

- OMIG Regulatory Cite
- OMIG Compliance Program Effectiveness Questions and Guidance
  - Arc New York Best Practices
  - OMIG Opportunities for Enhancement
  - OMIG Best Practices
- Template Policies
- References
Element 8: OMIG Regulatory Cite

- 18 NYCRR 521.3

(c) A required provider's compliance program shall include the following elements:

(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.

Element 8: OMIG Compliance Program Effectiveness Questions and Guidance

There must be a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to:

a. reporting potential issues,
b. investigating issues,
c. self-evaluations,
d. audits,
e. remedial actions, and
f. reporting to appropriate officials as provided in sections 740 & 741 of the NYS Labor Law

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<th>Provider’s Evidence of Completion or Action Required</th>
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<tr>
<td>Is there a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, self-evaluations, audits and remedial actions, and reporting to appropriate officials as provided in Sections 740 and 741 of the New York State Labor Law?</td>
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- 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.

Include in the Compliance Plan applicable policies and procedures, and training material references to reporting cases of intimidation and retaliation to officials as provided in New York State Labor Law Sections 740 and 741.

Include in all compliance literature language setting out non-intimidation and non-retaliation expectations.

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.

For multi-state providers, ensure that the appropriate references are made to New York law, for New York operations, rather than the law of the states where it has other operations.

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:

a. allegations or cases of intimidation and/or retaliation and appropriate discipline in response to the allegations.

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.

Policy Development

Chapter policies should incorporate the following items:

- Policies should ensure that non-intimidation as well as non-retaliation is included.

- Policies should identify that confidentiality will be maintained to the greatest extent possible. Policies should also clearly indicate the organization’s obligation to report to other governmental agencies as necessary.

Element 8: Template Policy

1. Reporting Compliance Concerns with Whistleblower (The Arc New York) [.doc]


Element 8: References

1. OMIG Compliance Program Review Guidance dated 10/26/16
   https://omig.ny.gov/compliance/compliance-library

2. Element 8, page 29-30 of the OMIG Program Self-Assessment document
   https://omig.ny.gov/compliance/compliance-library

3. Element 8, page 4 of the OMIG Best Practices dated 3/31/14

4. Element 8, page 8 of the OMIG Opportunities for Enhancement dated 3/31/14

5. What OMIG Looks for When it Assesses Element 8: OMIG Power Point, dated 11/2015
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