

Compliance Program Regulations Overview

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Amendments to New York State Social Service Law Section 363-d

- Part of Laws of 2020
- Approved 4/1/2020
- Effective 4/1/2020
- Fines and penalties effective 1/1/2021

18 NYCRR Part 521

- Key dates:
 - First implemented: 2009
 - Updated and out for public comment: 7/13/2022
 - Public comment period ended: 9/13/2022
 - Finalized and Effective: **12/28/2022**
 - Enforcement: **3/28/2023**

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Required Elements

1. Written Policies and Procedures and Standards of Conduct
2. Compliance Officer
3. Compliance Committee
4. Training and Education
5. Lines of Communication
6. Discipline
7. Auditing and Monitoring

Significant Changes

1. Required Providers – Increased Medicaid revenue threshold for “Substantial portion of business operations” to \$1,000,000 (from \$500,000)
2. Compliance Program documentation retention period
3. Defined “Affected Individuals”
4. Increased Compliance Program applicability to specific risk areas to be addressed
5. Addressed Compliance Officer reporting requirements; requires Compliance Committee and Charter
6. Risk Assessment and Annual Work Plan
7. Training requirements (Topics, Training Plan, Deficit Reduction Act training: fraud, abuse, waste, and Whistleblower statutes)
8. Compliance Program, Policies & Procedures, and Standards of Conduct to be reviewed annually
9. Includes detailed Self-Disclosure Program
10. Extensive requirements for Managed Care Organizations

Part 521 Regulations: Required Providers

- Article 16 Clinic
- Article 28 Clinic
- Article 31 Clinic
- Article 36 (Home Care)
- Medicaid Managed Care Organizations
- \$1,000,000+ of Medicaid revenue in 12 month period

Part 521 Regulations: Affected Individuals

- All persons affected by the required provider's risk areas
 - Employees
 - Chief Executive
 - Senior Administrators and Managers
 - Contractors
 - Agents
 - Subcontractors
 - Independent Contractors
 - Governing Body and Corporate Officers

Part 521 Regulations: Record Retention

- Retain all records demonstrating that required provider has adopted, implemented and operated an **EFFECTIVE COMPLIANCE PROGRAM**
- Retained for a period not less than six years

Part 521 Regulations: Contracts

- Contracts with contractors, agents, subcontractors, and independent contractors specify that the contractors, agents, subcontractors, and independent contractors are subject to the required provider's Compliance Program to the extent that such contractors are affected by the required provider's risk areas and only within the scope of the contracted authority and affected risk areas.
- All contracts shall include termination provisions for failure to adhere to the required provider's Compliance Program requirements.

Part 521 Regulations: Policies and Procedures

- Need to establish a policy and procedure development policy and procedure.
 - Establishes a process for:
 - Drafting
 - Revising
 - Approving
- Must establish the expectation that all Affected Individuals will act in accordance with the standards of conduct, that they must refuse to participate in unethical or illegal conduct, and that they must report any unethical or illegal conduct to the Compliance Officer.
- P&Ps must be available, accessible, and applicable to all “Affected Individuals”.
- P&Ps and Standards of Conduct to be reviewed annually for effectiveness and need to revise.

Part 521 Regulations: Policies and Procedures

P&Ps to address:

- Structure of the Compliance Program
- Responsibilities of all Affected Individuals in carrying out the functions of the Compliance Program
- Guidance to Affected Individuals on dealing with potential compliance issues
- Methods and procedures for communicating compliance issues to the appropriate compliance personnel
- How potential compliance issues are investigated and resolved; documentation of investigation
- Non-intimidation and non-retaliation for good faith participation (reporting, participating in investigation, reporting retaliation, reporting fraud to authorities)

Part 521 Regulations: Exclusion Screening

- Required monthly checks –“at least every 30 days”
 - New York State Office of the Medicaid Inspector General Exclusion List
 - Health and Human Services Office of Inspector General’s List of Excluded Individuals and Entities
- Contractors, agents, subcontractors, and independent contractors should be checked
- “Required providers shall require contractors to comply”

Part 521 Regulations: Compliance Officer

- Designate an “individual” to serve as Compliance Officer
- Oversee Compliance Program
- Evaluate effectiveness
- Draft, oversee, and update a Compliance Work Plan at least annually
- Review and revise Compliance Program
- Report directly no less frequently than quarterly to the Governing Body, Chief Executive, and Compliance Committee
- Provider to “ensure that the Compliance Officer is allocated sufficient staff and resources to satisfactorily perform their responsibilities”

Part 521 Regulations: Compliance Committee

- Compliance Committee is required
- Comprised of Senior Management
- Reports directly and is accountable to the Chief Executive and governing body
- Compliance Committee Charter is required, to outline:
 - Duties and responsibilities
 - Membership
 - Designation of a chair
 - Frequency of meetings
- Meet at least quarterly; review Charter at least annually

Part 521 Regulations: Compliance Committee

Duties include:

- Coordinating with the Compliance Officer to ensure that the written policies and procedures and required standards of conduct are current, accurate, and complete, and that the required training topics are completed timely;
- Coordinating with the Compliance Officer to ensure communication and cooperation by affected individuals on compliance-related issues, internal or external audits, or any other function or activity required in the regulations;
- Ensuring that the Compliance Officer is allocated sufficient funding, resources, and staff to fully perform their responsibilities;
- Ensuring that effective systems and processes are in place to identify Compliance Program risks, overpayments, and other issues, and effective policies and procedures for correcting and reporting such issues; and
- Enacting required modifications to the Compliance Program.

Part 521 Regulations: Training and Education

- Establish an effective Compliance Training program for the Compliance Officer and all Affected Individuals
- Compliance training no less than annually
- Part of orientation of new Compliance Officers and Affected Individuals
- Occur promptly upon hire
- **Develop and maintain a training plan** that includes:
 - Subjects or topics for training and education,
 - The timing and frequency of the training,
 - Which affected individuals are required to attend,
 - How attendance will be tracked, and
 - How the effectiveness of the training will be periodically evaluated.

Part 521 Regulations: Training and Education

Must address:

- Risk areas and organizational experience
- Written P&Ps (Standards of Conduct, reporting/resolution/investigation, non-retaliation, etc.)
- Role of Compliance Officer and Compliance Committee
- How to report; confidentiality, anonymous means
- Disciplinary standards
- Deficit Reduction Act, False Claims Act, Whistleblower protections (if >\$5 million annually)
- Requirements specific to the Medicaid program and the provider's category or categories of service
- Coding and billing requirements and best practices, if applicable
- Claim development and the submission process, if applicable

Part 521 Regulations: Lines of Communication

- Required provider shall publicize the lines of communication to the Compliance Officer
 - Must be made available to all “Affected Individuals” **and Medicaid recipients of service**
- Make information about Compliance Program, including the Standards of Conduct, available on website

Governance and Compliance: The Interface

Regular communication with Compliance Officer regarding:

- Status of Compliance Work Plan
- Compliance issues, investigations and results
- Audit findings (internal and external) and corrective actions
- Training status
- Risk areas (quality, regulatory, billing, etc.)
- Overpayments, Self-Disclosures
- Regulatory environment, changes

Part 521 Regulations: Discipline

- Written P&P
- Address disciplinary standards and the procedures for taking such actions shall be published and disseminated to all Affected Individuals and be incorporated into the training plan

Part 521 Regulations: Risk Areas

“The compliance program shall apply to the required provider’s risk areas, which are those areas of operation affected by the compliance program and shall apply to:

- (1) billings;
- (2) payments;
- (3) ordered services;
- (4) medical necessity;
- (5) quality of care;
- (6) governance;
- (7) mandatory reporting;
- (8) credentialing;
- (9) contractor, subcontractor, agent or independent contract oversight;
- (10) other risk areas that are or should reasonably be identified by the provider through its organizational experience; and..... “ (*MCO risks follow*)

Part 521 Regulations: Risk Areas

- Compliance Officer and Committee oversee this area
- Assess risk areas – start with billing and documentation audits, progress to other areas of compliance with laws and regulations (those not addressed by QA activities)
- Include any external audits for risks
- Require corrective action plans to address findings
- Implement systemic corrective actions
- Conduct follow-up audit/monitoring to determine effectiveness of corrective action
- Results of audits and monitoring activities to Chief Executive, Compliance Committee and Governing Body

Part 521 Regulations: Auditing

“The required provider shall establish and implement an effective system for the **routine monitoring and identification of compliance risks**. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the organization’s compliance with the requirements of the MA program and the overall effectiveness of the required provider’s compliance program.”

Part 521 Regulations: Auditing

- “Routine audits by internal or external auditors who have expertise in state and federal MA program requirements and applicable laws, rules and regulations, or have expertise in the subject area of the audit” *Government audits do not apply.*
- Focused on risk areas identified within the regulations
- The design, implementation, and results of any internal or external audits shall be documented, and the results shared with the compliance committee and the governing body
- Results of audits (internal, external, or by government) reviewed for risk areas to be included in Compliance Program and Work Plan

Part 521 Regulations: Self Disclosures/Overpayments

- SubPart 521-3
- For any receipt of overpayment under the Medicaid program, directly or indirectly:
 - Report
 - Return
 - Explain
 - Self-disclosure statement to OMIG's self-disclosure program
- Payment to be made within 60 days of overpayment being "identified"
 - Define as to when overpayment has been "quantified"

Part 521 Regulations: Annual Compliance Work Plan

It is now a required element of Compliance Program.

What Is It?

- A master compliance to do list
- Helps keep Compliance Officer on task
- Helps keep track of accomplishments
- Helps keep Compliance Committee on task
- Helps keep Governing Body informed
- Helps keep Compliance Officer accountable
- Used to demonstrate effectiveness of Compliance Program and Compliance Officer performance

Part 521 Regulations: Annual Compliance Work Plan

- Compliance Officer and Compliance Committee develop Annual Work Plan and audit schedule based on:
 - Review of OIG and OMIG Work Plans
 - Organizational risk assessment
 - Internal and external audit results
 - Investigation of non-compliance
- Annual Work Plan includes milestones for action and staff responsibility assignments
- Annual Work Plan is approved by Governing Body; status reports are provided to Chief Executive and Governing Body
- Annual Work Plan is reviewed at each Compliance Committee meeting to address compliance activities and risk areas

Part 521 Regulations: Annual Compliance Program Review

- Annual review of Compliance Program
- Carried out by:

“the compliance officer, compliance committee, external auditors, or other staff designated by the required provider, provided however, that such staff have the necessary knowledge and expertise to evaluate the effectiveness of the components of the compliance program they are reviewing and are independent from the functions being reviewed.”

Part 521 Regulations: Annual Compliance Program Review

- Annual review of Compliance Program effectiveness, to include:
 - On-site visits;
 - Interviews;
 - Record reviews;
 - Surveys;
 - Or other comparable methods
- Document the design, implementation, and results of effectiveness review
- Document any corrective actions implemented
- Results shared with Chief Executive, Senior Management, Compliance Committee, and Board

Effectiveness of Compliance Program

Part 521: “Effective compliance program” ... “shall mean that it:

- Is well-integrated into the company’s operations and supported by the highest levels of the organization, including the chief executive, senior management, and the governing body;
- Promotes adherence to the required provider’s legal and ethical obligations; and
- Is reasonably designed and implemented to prevent, detect, and correct noncompliance with Medicaid program requirements, including fraud, waste, and abuse most likely to occur for the required provider’s risk areas and organizational experience.”

Determining Effectiveness

To determine the effectiveness of the Compliance Program, the provider must:

- Continuously evaluate its program by updating its risk assessment on a periodic basis
- Review and update policies and procedures
- Survey the culture of compliance
- Conduct testing to confirm that established controls are working

Actions to Date

- ✓ Educated Governing Body and senior leadership on SSL 363-d and Part 521 revisions
- ✓ Performed gap analysis – 2022 Compliance Program vs. Part 521 revisions
- ✓ Developed 2023 Compliance Work Plan
- ✓ Defined “Affected Individuals”
- ✓ Adopted or revised Compliance Plan and Policies & Procedures
- ✓ Adopted or revised Standards of Conduct (formerly Code of Conduct)

Actions to Date

- ✓ Disseminated Compliance Plan, Standards of Conduct, Policies & Procedures to Affected Individuals
- ✓ Established Compliance Committee membership and responsibilities
- ✓ Adopted Compliance Committee Charter and set meeting schedule for 2023 (at least quarterly)
- ✓ Established reporting mechanism to the Governing Body
- ✓ Updated compliance training/education; developed Training Plan
- ✓ Established and communicated lines of communication to Compliance Officer
- ✓ Implemented/revised Exclusion Screening procedures

Actions to Date

- ✓ Conducted a risk assessment
- ✓ Established internal audit plan
- ✓ Adopted/revised return of overpayments (Self-Disclosure) Policy and Procedures
- ✓ Prepared for annual review of Compliance Program effectiveness

Part 521 Regulations: What's Next?

- Now is the time.....
 - Review the OMIG Review Module
 - Released 03/2023
 - Review OMIG Guidance Document
 - Review Compliance Program Regulations
 - Again and Again and Again

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Excerpt from NYS OMIG Compliance Program Review Module

3-1	<p>18 NYCRR § 521-1.4(d)(1), (3), and (4)</p> <p>Did the provider have an effective compliance training and education program for all Affected Individuals which met all the requirements of 18 NYCRR § 521-1.4(d)(1), (3), and (4) during the Review Period?</p> <p>Yes _____ No _____</p>	<p>If yes, provide a copy, as "Attachment 3-1" of:</p> <ul style="list-style-type: none">a. a dated compliance program training and education plan(s), andb. documentation evidencing what steps the provider took to ensure its compliance program training and education was provided in a form and format accessible and understandable to all Affected Individuals.																										
<p>Please mark which months during the Review Period that the provider had an effective compliance training and education plan that met the requirements of 18 NYCRR § 521-1.4(d)(1), (3), and (4) for all Affected Individuals:</p> <table border="1" data-bbox="630 948 1711 1028"><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr><tr><td>None</td><td>Jan</td><td>Feb</td><td>Mar</td><td>Apr</td><td>May</td><td>Jun</td><td>Jul</td><td>Aug</td><td>Sep</td><td>Oct</td><td>Nov</td><td>Dec</td></tr></table>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	None	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
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Part 521 Regulations: What's Next?

- Now is the time.....
 - To determine how these changes affect you and your agency.
 - What additional resources, if any, will you need.
 - Educate senior leaders and board.
 - Compare your current Compliance Program to the requirements.

Remember.....Compliance Programs must be **EFFECTIVE!!!**
How will you demonstrate this?

Questions and Discussion



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