



# Compliance Program Guidance

**January 2023**

This guidance does not constitute rulemaking by OMIG and does not have the force of law or regulation. Nothing in this guidance alters any statutory or regulatory requirement. In the event of a conflict between statements in this guidance and either statutory or regulatory requirements, the requirements of the statutes and regulations shall govern.

A Medicaid provider's legal obligations are determined by the applicable federal and state statutory and regulatory law. This guidance does not encompass all the current compliance program requirements and, therefore, is not a substitute for a review of the statutory and regulatory law. OMIG cannot provide individual advice or counseling, whether medical, legal, or otherwise. If you are seeking specific advice or counseling, you should contact an attorney or a compliance consultant.

This guidance supersedes any prior guidance issued by OMIG addressing, or relating to, the compliance program requirements of New York State Social Services Law (SOS) § 363-d and 18 NYCRR SubPart 521-1 (SubPart 521-1). OMIG may amend this guidance as necessary.

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# INTRODUCTION

## Purpose

Although all New York State Medicaid providers should prioritize compliance, certain providers, defined further below, are required to establish, integrate, and demonstrate the effectiveness of their compliance programs to OMIG. It is the purpose of such compliance programs to detect and prevent fraud, waste, and abuse in the Medicaid program as well as organize provider resources to address compliance issues as quickly and efficiently as possible, and to impose systemic checks and balances to prevent future recurrence of such issues.

This document gives general guidance to assist providers in meeting these compliance program requirements. Variation among provider compliance programs is expected for reasons, including but not limited to, providers size, scope, structure, or service delivery method. OMIG recognizes this variation. Hence the goal of this guidance document is to share recommendations and principles that are key components and must be included in every compliance program for providers to be effective partners in preventing fraud, waste, and abuse within the Medicaid program.

## Definitions

Section § 521-1.2(a) incorporates the definitions from 18 NYCRR Part 515, which includes definitions for the terms “fraud” and “abuse.” “Abuse” is defined in 18 NYCRR § 515.1(b)(3), and “fraud” is defined in 18 NYCRR 515.1(b)(7).

Although not defined in regulation, waste generally is defined as “the overutilization of services, or other practices that directly or indirectly, result in unnecessary cost to the Medicaid program.”

Category or categories of service related to the definition of “organizational experience” refers to the category(ies) of service in which the provider is enrolled in the Medicaid program.

## Background

Recognizing that Medicaid program providers play a vital role in detecting and correcting payment and billing errors and identifying potential fraud, New York State implemented the compliance program requirement in 2009. These requirements were most recently amended (SOS § 363-d), effective April 1, 2020, to clarify and update program participation requirements, better align with federal standards for effective compliance programs, and to broaden enforcement options.

Providers subject to these requirements consist of enrolled New York State Medicaid program providers who are categorized as hospitals, residential health care facilities, home care services agencies, providers of developmental disability services, providers of mental disability services, managed care plans, and managed long-term care plans, regardless of the amount claimed or received from the Medicaid program. Beyond these service categories, the definition also includes any enrolled provider that claims or receives \$1 million or more directly or indirectly (such as managed care network participating providers) from the Medicaid program.

Each provider shall adopt, implement, and maintain an effective compliance program, which is tailored to fit its specific organizational needs, depending upon its size, complexity, resources, and culture.

OMIG's assessment of compliance programs will take into consideration each provider's unique characteristics. Federal and state statutes, rules, regulations, and Medicaid program requirements should be integrated into every compliance program.

Compliance programs should be reasonably designed, implemented, and enforced so that the program is generally effective in preventing, detecting, and correcting fraud, waste, abuse, and non-compliance with Medicaid program requirements. The failure to prevent or detect an individual or unique compliance issue does not necessarily mean that the program is not generally effective.

SubPart 521-1 implements the statutory changes. Providers have ninety (90) days from the effective date of SubPart 521-1 to adopt and implement changes to their compliance programs to ensure they satisfactorily meet the requirements of SubPart 521-1. Addendum A to this guidance document identifies the changes in compliance program requirements between 18 NYCRR Part 521 (effective July 1, 2009) and SubPart 521-1 (effective December 28, 2022).

## **Contractors**

Contractors are only subject to the provider's compliance program to the extent it is related to their contracted role and responsibilities within the provider's identified risk area. For example, an entity contracted to provide "credentialing services" would be required to comply with written policies and procedures, training, and so forth, as it related to the provision of "credentialing services."

To enforce compliance by Contractors, providers may need to modify the existing contracts it has with Contractors. To assist providers in meeting these requirements, OMIG will only enforce the requirements of section 521-1.3(c) for contracts executed or renewed starting 90 days and no later than two years from the effective date of SubPart 521-1.

A Contractor, who is also a required provider, can and should work with the providers it contracts with to determine how to implement the requirements of SubPart 521-1 in the most efficient manner possible. OMIG will take into consideration each provider's unique circumstances and characteristics when conducting its reviews.

## **Managed Care Providers and Managed Long Term Care Plans**

Managed care providers and managed long term care plans (collectively, "MMCO") are responsible for ensuring that the requirements of their fraud, waste, and abuse prevention programs are incorporated into their compliance programs. OMIG's Medicaid Managed Care Fraud, Waste and Abuse Prevention Programs Guidance relative to SubPart 521-2 will serve as the primary guidance for these fraud, waste, and abuse prevention program requirements.

Participating providers that are also required providers shall provide a copy of their Certification Statement for Provider Billing Medicaid (ETIN) form to each MMCO for which they are a participating provider upon signing the provider agreement with the MMCO, and annually thereafter, that includes the following language:

I (or the entity) have adopted and implemented, where applicable, an effective compliance program pursuant to New York State Social Services Law section 363-d, and have satisfied the requirements of Title 18 of the New York State Codes, Rules and Regulations Part 521

MMCOs shall maintain a method for submitting such certification on the MMCO's website and shall retain such certification in accordance with the record retention requirements of its contract with the department to participate as an MMCO.

The MMCO shall develop a fraud, waste, and abuse public awareness program focused on the cost and frequency of MA program fraud, and the methods by which the MMCO's enrollees, providers, and other contractors, agents, subcontractors, or independent contractors can prevent it. The MMCO shall make information regarding the public awareness program available on its website, including but not limited to, information on how and where to report, return, and explain overpayments to the MMCO.

## **What is an effective compliance program?**

OMIG considers an "effective compliance program" to be a compliance program that is adopted and implemented by the provider that, at a minimum, satisfies the compliance program requirements, and that is designed to be compatible with the provider's characteristics. Being compatible with the provider's characteristics means that the compliance program:

1. 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;
2. promotes adherence to the provider's legal and ethical obligations; and
3. is reasonably designed and implemented to prevent, detect, and correct non-compliance with Medicaid program requirements, including fraud, waste, and abuse most likely to occur for the provider's risk areas and organizational experience.

## **Benefits of an Effective Compliance Program**

OMIG recognizes that the implementation of a compliance program may not entirely eliminate fraud, waste, and abuse in the Medicaid program. However, a sincere effort by providers to establish an effective compliance program meeting the requirements may serve to mitigate risks associated with unlawful or improper conduct, enhance program effectiveness and efficiency, and allow providers to demonstrate a positive track-record of performance. Early detection and reporting minimize loss to the Medicaid program from false claims, and may help providers avoid exposure to recoveries, civil damages and penalties, criminal sanctions, administrative remedies such as program exclusion, reputational issues, and litigation.

## **Consequences of not having an Effective Compliance Program**

A provider that is not effectively monitoring its compliance with state and federal Medicaid requirements is potentially exposed to increased operational, reputational, service, and audit risks, as well as sanctions and the repayment of identified Medicaid overpayments. These consequences may include:

1. Monetary penalties up to \$5,000 for each month that a provider fails to adopt, implement, and maintain an effective compliance program. For a second violation, this amount may increase to \$10,000 per month.<sup>1</sup>
2. Recoupment of monies paid to the provider during the period in which it did not have a compliance program.
3. Termination of the provider's enrollment in the Medicaid program.
4. Sanctions, up to and including exclusion from participation in the Medicaid program.

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<sup>1</sup> See 18 NYCRR Part 516 and SOS § 363-d for more information.

## COMPLIANCE PROGRAM REVIEW PROCESS

OMIG conducts ongoing compliance program reviews (Reviews) to determine if providers are meeting their compliance program obligations. OMIG's Reviews encompass a specific time period (Review Period) not to exceed 12 months.

The focus of these Reviews is to determine if the provider adopted, implemented, and maintained an effective compliance program during the Review Period that satisfied the Medicaid program requirements.

The process OMIG will follow in conducting these Reviews is outlined below:

1. OMIG initiates a Review by issuing a written notification to the provider<sup>2</sup> identifying the Review Period, specific Provider IDs included in the Review, and procedures for completing the Review.
2. Upon notification, the provider will download the Review Module from OMIG's website and submit the completed Module and supporting documentation to OMIG within thirty days. Providers should not submit the Module to OMIG unless they receive a notification letter from OMIG instructing them to do so.

If documentation includes multiple versions of documents that were in effect during the Review Period, the provider should submit all such versions for review. All documentation should include effective dates evidencing that the provider met the requirement during the Review Period. Examples of how providers can demonstrate their compliance program met the requirements are included below.

3. OMIG reviews the completed Module and supporting documentation submitted by the provider and may reach out with questions or to request additional documentation as necessary.

Upon completion of the compliance program review, OMIG will notify the provider of the results of its review in a written compliance program assessment. OMIG's compliance program assessment will advise the provider whether its compliance program satisfactorily met the requirements and of any recommendations for improvement.

OMIG will evaluate provider performance for each requirement and assess a score per month for each question, and then calculate an average score for each month of the Review Period. The score will be used to determine whether the provider's compliance program satisfactorily met the requirements for all months of the Review Period.

Average Score Percentages:

≥ 60% is satisfactory

< 60% is unsatisfactory and may result in a monetary penalty.

Refer to the "Consequences of not having an Effective Compliance Program" section above for more details on monetary penalties.

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<sup>2</sup> The requirement to establish a compliance program is tied to the individual Medicaid Provider ID. However, OMIG will review providers at the enterprise level, where appropriate.

4. The provider should identify and implement corrective actions in all areas identified by OMIG as needing improvement. Implementation of these corrective actions may not be immediately reviewed again, but failure to implement requested corrective action could subject the provider to sanctions associated with a future review.

## **ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM**

The sections below identify the seven elements of an effective compliance program. Included with these elements are general recommendations regarding their implementation.

It is a provider's obligation to maintain documentation demonstrating that it has adopted and implemented an effective compliance program. Included with the elements below are examples of documentation providers may produce for compliance program reviews as evidence they met the specified requirements during a Review Period. The identified types of documentation are not meant to be all inclusive. OMIG recognizes that providers may have other types of documentation to evidence meeting the requirements. So long as the documentation demonstrates that the Medicaid compliance program requirements were met, that documentation will be accepted.

### **ELEMENT 1: Written Policies, Procedures, and Standards of Conduct**

The provider's obligations related to compliance program requirements should be incorporated into the provider's written policies, procedures, and standards of conduct (Policies). The written Policies should outline the operation of the compliance program and be reviewed at least annually and modified, as necessary. The provider's written Policies regarding confidentiality, non-intimidation, and non-retaliation should extend to all persons who report compliance issues, including Medicaid recipients of service. Referencing the governing laws, regulations, and Medicaid program policies and procedures applicable to the provider's risk areas and/or categories of service, by citation in the written Policies, would be appropriate and sufficient to meet the requirements of this element. The only exception is written policies and procedures related to 42 U.S.C. 1396a(a)(68), which require detailed information.

Evidence that written Policies were in effect includes, but is not limited to, the following:

1. A detailed set of compliance written Policies that included a record of implementation and revision dates for individual Policies.
2. Evidence that the written Policies were applicable to all affected individuals. "Affected Individuals" is defined as all persons who are affected by the provider's risk areas, including employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.
3. Documentation of an annual review of written Policies and any identified updates.
4. Evidence that written Policies were distributed to all Affected Individuals.
5. There is work product that demonstrates the written Policies were in effect or operating. For example: training and work plans existed, evidence that investigations were commenced and completed, and actions were taken in response.
6. A demonstration that the provider met the Deficit Reduction Act (DRA) requirements by submitting written Policies and any employee handbook that specifically addressed all DRA requirements. If the provider did not have an employee handbook, they do not need to establish one. However, if the provider did have an employee handbook, it should meet the requirements.

See Addendum B for specific information related to DRA requirements.

## **ELEMENT 2: Compliance Officer and Compliance Committee**

### **Compliance Officer:**

Providers should demonstrate their compliance program is well-integrated into the company's operations and supported by the highest levels of the organization by ensuring there is a designated compliance officer who is vested with responsibility for the day-to-day activities of the compliance program. This includes:

1. The compliance officer is accountable to the chief executive, or other senior manager designated by the chief executive, and has access to the governing body.
2. The governing body, chief executive, and compliance committee receive quarterly reports from the compliance officer on the progress of adopting, implementing, and maintaining the compliance program.
3. Although the compliance officer is not required to be an employee of the provider, the designee must carry out the primary responsibilities for the compliance officer, including development of an annual compliance work plan. It is a reasonable expectation that the Compliance Officer should be the person coordinating the implementation of the work plan, and there may be other individuals involved in completing auditing and monitoring activities identified in such a work plan.
4. If the compliance officer has other duties, the provider must demonstrate that they have assessed whether the other duties hinder the compliance officer in carrying out their primary responsibilities, and whether the compliance officer is able to satisfactorily perform their responsibilities. Such assessment should be completed during the annual compliance program effectiveness review (as required in element 6), or whenever the compliance officer's duties change.
5. The provider must demonstrate that they have assessed whether the compliance officer is allocated sufficient staff and resources to satisfactorily perform their responsibilities for the day-to-day operation of the compliance program. Such assessment should be completed during the annual compliance program effectiveness review (as required in element 6).
6. There is risk in establishing an effective compliance program if the compliance officer and/or the compliance department is subordinate to the provider's general counsel or financial officer (e.g., comptroller). By separating the compliance function from these key management positions, a system of checks and balances is established. If it is not feasible for the provider to separate the compliance function, then a procedure for addressing conflicts of interest or potential risks is recommended to achieve an appropriate system of checks and balances.

OMIG's assessment of compliance programs will take into consideration each provider's documented good-faith efforts to hire and retain staff.

For MMCOs, the compliance officer is responsible for implementing the requirements of SubPart 521-2. However, if the MMCO is required to have a Special Investigation Unit (SIU), the SIU Director is responsible for implementing the MMCO's fraud, waste and abuse prevention program and the compliance officer is responsible for coordinating with the MMCO's SIU director, where applicable.

Examples of documentation the provider may use to demonstrate that it had a designated compliance officer include, but are not limited to, the following:

1. Compliance officer's performance plan and evaluation evidencing compliance responsibilities and other duties.
2. Governing body resolution/minutes evidencing appointment of the compliance officer with appropriate authorities.
3. Compliance officer's signed letter of appointment evidencing compliance responsibilities and other duties;
4. Compliance officer's executed contract evidencing compliance responsibilities and other duties, if applicable.
5. An organizational chart with designation from the chief executive that the compliance officer reported to another senior manager, if applicable.
6. Annual compliance work plan.
7. Quarterly written reports from the compliance officer to the governing body, chief executive, and compliance committee.
8. Meeting minutes documenting quarterly reports from the compliance officer to the governing body, chief executive, and compliance committee.
9. An analysis that demonstrates the provider determined the compliance officer's other duties did not hinder the compliance officer in carrying out their primary responsibilities, if applicable.
10. An analysis that demonstrates the provider determined the compliance officer was able to satisfactorily perform their responsibilities for the day-to-day operation of the compliance program.
11. For MMCOs, a description of how the compliance officer coordinated with the SIU director, if applicable.

### **Compliance Committee:**

Providers should demonstrate their compliance program is well-integrated into the company's operations and supported by the highest levels of the organization by ensuring there is an active compliance committee consisting of senior managers. This includes:

1. The compliance committee reports directly to the chief executive and governing body.
2. The compliance committee charter includes duties and responsibilities for coordinating with the compliance officer.
3. The compliance committee coordinates with the compliance officer to ensure that all Affected Individuals complete compliance training and education during orientation and annually.

The committee benefits from the perspectives of individuals with varying responsibilities in the organization, such as senior managers from operations, finance, audit, human resources, utilization review, social work, discharge planning, medicine, coding, and legal, as well as managers of key operating units.

In addition, MMCO's shall establish a regulatory compliance committee on the board of directors charged with overseeing its compliance program as required by their contract with the department to participate as an MMCO.

Examples of documentation the provider may use to demonstrate that it had a designated compliance committee include, but are not limited to:

1. Compliance committee charter that outlined the duties and responsibilities, membership, designation of a chair, and frequency of meetings.
2. List of compliance committee members and designated chair, including their names, titles, and from/to service dates.
3. Minutes from quarterly compliance committee meetings.

4. Evidence of annual compliance committee charter reviews, including date of review and a description of any updates.
5. Organizational chart showing the reporting structure between the compliance committee and the organization's chief executive and governing body.
6. Quarterly reports from the compliance committee to the organization's chief executive and governing body.

### **ELEMENT 3: Compliance Program Training and Education**

Providers should demonstrate they have established and implemented an effective compliance training and education program for all Affected Individuals. Compliance training and education must be documented in an annual training plan that is maintained and outlines:

1. required subjects or topics,
2. timing and frequency of training,
3. which affected individuals are required to attend<sup>3</sup>,
4. how attendance is tracked, and
5. how the effectiveness of the training is periodically evaluated.

Compliance program training may be customized for different types of Affected Individuals, including contractors, agents, subcontractors, and independent contractors (Contractors), based upon specific issues for each type, as long as all Affected Individuals meet the core training requirements of the Medicaid compliance program. Compliance training should be provided in a manner that is understandable and accessible to all Affected Individuals. For example, if Affected Individuals include people whose primary language is not English, the training should also be made available in appropriate languages.

Only distributing the written Policies does not qualify as effective compliance training and education. OMIG may determine that self-study programs are acceptable where written Policies and/or compliance training materials are distributed, so long as the provider can produce evidence that individuals being trained have received and appropriately applied the subject matter.

Contractors can be treated the same as other types of Affected Individuals for self-study compliance training programs. It is a best practice to include a dated distribution letter or have Contractors complete an acknowledgement to evidence that compliance training occurred.

It is a best practice that compliance training and education as part of orientation for new Affected Individuals occur within thirty days of their start date.

Providers may use, among other things, pre- and post-tests, and surveys to periodically evaluate the effectiveness of compliance training.

For MMCOs, compliance program training and education includes the fraud, waste, and abuse prevention program as specified in SubPart 521-2 and any applicable terms of the MMCO's contract with the department to participate as an MMCO.

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<sup>3</sup> All affected individuals are required to receive compliance training and education that includes all required topics; however, some affected individuals require additional training related to their job functions.

Examples of documentation the provider may use to demonstrate that it had a compliance training and education program that met all the requirements of 18 NYCRR § 521-1.4(d) during the entire Review Period include, but are not limited to:

1. A detailed compliance training plan for all Affected Individuals:
  - a. a list of all Affected Individuals that received, and did not receive, such compliance program training during the Review Period, including:
    - i. name of Affected Individual;
    - ii. type of Affected Individual (i.e., employee, chief executive, senior administrator, manager, contractor, agent, subcontractor, independent contractor, governing body member, and/or corporate officer);
  - b. type of compliance training(s) received (i.e., annual, orientation, or both);
  - c. how such training was provided;
  - d. date(s) of completion; and
  - e. date of hire for those who received orientation training.
2. Dated governing body meeting minutes and agendas that included such training and who attended, if applicable.
3. Dated attendance logs showing when such training occurred and who attended, if applicable.
4. Dated attestations signed by Affected Individuals that they received and understood such training, if applicable.
5. Dated compliance training distribution letters to Contractors.
6. Evidence that all Affected Individuals received compliance program training in a form and format that they understood, consistent with federal and state language and other access laws, rules, or policies.

#### **ELEMENT 4: Lines of Communication**

Providers should demonstrate that they have established and implemented effective lines of communication for all Affected Individuals. These lines of communication must guarantee the confidentiality of reporting persons.

“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.

Anonymous methods of communication should be truly anonymous so reporting persons have assurance that there is no way the compliance function can discover who is reporting a matter. Examples include, but are not limited to, compliance hotline, online compliance portal, mailing address, and drop box. Typically, the following are not considered anonymous methods of communication:

1. telephone lines or hotlines with caller ID,
2. email that can be reverse engineered to retrieve the sender’s address,
3. drop/suggestion box not controlled by appropriate compliance personnel, or
4. any method that may be located in an area where there is camera surveillance.

Persons, including Medicaid recipients of service, who report compliance issues should have a reasonable expectation that their communication will be kept confidential, whether requested or not. Such persons are protected under the provider’s non-intimidation and non-retaliation Policies.

Examples of documentation the provider may use to demonstrate that it had lines of communication include, but are not limited to:

1. A list of lines of communication including, but not limited to:
  - a. description or identification of lines of communication;
  - b. anonymous reporting methods to the compliance officer;
  - c. effective dates for the lines of communication;
  - d. to whom the lines of communication went or who had access to reports coming through the lines of communication; and
  - e. categories of individuals (i.e., Affected Individuals or Medicaid recipients of services) who had access to utilize such lines of communication.
2. Documentation identifying how the various lines of communication to the compliance officer were publicized may include, but are not limited to:
  - a. dated distribution letter to all Affected Individuals and/or their Medicaid recipients of service,
  - b. screenshot of notification on an intranet and affirmation that such information was published on the intranet during the entire Review Period,
  - c. screenshot of notification on a public website and affirmation that such information was published on the public website during the entire Review Period,
  - d. compliance posters that identified communication methods and an affirmation of where and when they were posted that made them accessible to all Affected Individuals and Medicaid recipients of service, and
  - e. copy of dated notifications to Contractors.
3. Documentation for how the provider ensured the confidentiality of persons reporting compliance issues and that such persons were protected under the provider's policy for non-intimidation and non-retaliation may include, but is not limited to:
  - a. a summary of compliance issues reported during the Review Period, including a description of how such reports were documented, stored, and shared within the organization; a list of persons with whom they were shared and their titles; and a description of how the provider ensured persons reporting compliance issues were protected under the provider's policy for non-intimidation and non-retaliation; or
  - b. if there were no reports of compliance issues during the Review Period, provide a copy of written Policies that included an expectation to maintain the confidentiality of persons reporting compliance issues, and a copy of the provider's written Policy for non-intimidation and non-retaliation.

Documentation evidencing the provider made information about its compliance program, including its standards of conduct, available on its website.

## **ELEMENT 5: Disciplinary Standards**

Providers should demonstrate they have established disciplinary standards and have implemented procedures for the enforcement of such standards to address potential violations and encourage good-faith participation in the compliance program by all Affected Individuals.

Disciplinary standards that encourage good-faith participation in the compliance program for all Affected Individuals should be documented in written Policies and may include, but are not limited to, the following:

1. Expectations for reporting compliance issues.
2. Expectations for assisting in the investigation and resolution of compliance issues.
3. Sanctions for failing to report suspected problems.
4. Sanctions for participating in non-compliant behavior.

5. Sanctions for encouraging, directing, facilitating, or permitting non-compliance behavior.

Typically, disciplinary action for governing body members is found in the by-laws/operating agreements.

Examples of documentation the provider may use to demonstrate that it had appropriate disciplinary standards include, but are not limited to:

1. Evidence the written Policies, which established the provider's disciplinary standards and the procedures for taking such actions, were published and disseminated to all Affected Individuals.
2. Evidence the provider enforced its disciplinary standards fairly and consistently with the same disciplinary action applied to all levels of personnel.
3. Dated governing body bylaws/operating agreements that identified disciplinary standards and related procedures for governing body members, if applicable.
4. Dated memos documenting such written Policies were distributed to all Affected Individuals.
5. Contracts for Contractors that included disciplinary standards and related procedures, if applicable.

## **ELEMENT 6: Auditing and Monitoring**

Providers should demonstrate that their compliance program includes routine auditing and monitoring of compliance risks. This may include, but is not limited to, the following:

1. Internal and external audits are documented and shared with the compliance committee and governing body.
2. The annual compliance program reviews are shared with the chief executive, senior management, compliance committee, and governing body.
3. Monthly exclusion checks are shared with the compliance officer and appropriate compliance personnel.

The provider's compliance program should be designed and implemented to prevent, detect, and correct non-compliance with Medicaid program requirements, including fraud, waste, and abuse most likely to occur for the provider's risk areas and organizational experience. The provider can do this by ensuring it has established and implemented an effective system for routine identification and monitoring of compliance risks. Examples include, but are not limited to:

1. Internal and external compliance audits focus on required risk areas.
2. Any identified Medicaid program overpayments are reported, returned, and explained in accordance with Medicaid self-disclosure program requirements.
3. Conducting annual reviews of the compliance program to determine its effectiveness, and whether any revision or corrective action is required.
4. Checking the exclusion status of all affected individuals.
5. MMCOs shall confirm the identity and determine the exclusion status of any other persons identified in its contract with the department to participate as an MMCO, including its participating providers and its subcontractors. In addition, MMCOs shall require their participating providers and subcontractors, where applicable, to confirm the identity and determine the exclusion status of all affected individuals.

Providers shall complete an annual review of whether the Medicaid compliance program requirements have been met, to determine the effectiveness of its compliance program, and whether any revision or corrective action is required. Completing an annual review is an essential component of an effective compliance program and helps providers prepare for their annual certification and an OMIG compliance program review.

Examples of documentation the provider may use to demonstrate that it had a system for the routine monitoring and identification of compliance risks include, but are not limited to:

1. Auditing and monitoring results, including dates completed and any compliance issues identified.
2. Risk analysis performed to identify any other risk areas.
3. Exclusion check reports, including databases checked and dates performed.
4. Dated meeting minutes that documented discussion of auditing and monitoring activities, and exclusion check reports, including who was in attendance.
5. Documentation evidencing review of the results of internal and external audits for new risk areas may include, but is not limited to, a list of internal and external audit results, dates completed, and any risk areas identified.
6. Updates to compliance work plan(s).
7. Documentation of the design, implementation, results, and relevant corrective actions implemented for internal and external audits, and annual compliance program effectiveness reviews.
8. Dated audit reports that identified distribution to the compliance officer, appropriate compliance personnel, compliance committee, and governing body.
9. Dated annual compliance program review reports that identified distribution to the chief executive, senior management, compliance committee, and governing body.
10. Documentation evidencing how Medicaid program overpayments were reported, returned, and explained.
11. Documentation evidencing the provider took corrective action to prevent overpayments from recurring.
12. Report on the annual review of the compliance program, including date completed.
13. Dated compliance committee and governing body meeting minutes that showed discussion of internal and external audit results, and the compliance program review.
14. List of updates or modifications to the compliance program as a result of the annual review, including implementation dates.
15. Any documentation to evidence that other 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.

## **ELEMENT 7: Responding to Compliance Issues**

The provider's compliance program should be designed and implemented to prevent, detect, and correct non-compliance with Medicaid program requirements, including fraud, waste, and abuse most likely to occur for the provider's risk areas and organizational experience. The provider can do this by ensuring it has established and implemented procedures and systems for promptly responding to compliance issues, including any issues identified in the course of an internal or external audit. Examples include, but are not limited to:

1. Taking prompt action to investigate the conduct in question and determining if any corrective action is required.
2. Correcting compliance problems promptly and thoroughly to reduce the potential for recurrence.
3. Monitoring plans of correction to ensure compliance issues do not recur.
4. Ensuring ongoing compliance with state and federal laws, rules, and regulations of the Medicaid program.
5. Promptly reporting credible evidence that a state or federal law, rule, or regulation has been violated to the appropriate governmental entity.

6. Reporting and returning overpayments in accordance with Medicaid self-disclosure program requirements.

Examples of documentation the provider may use to demonstrate it had a system for promptly responding to Medicaid compliance issues include, but are not limited to:

1. List of all potential compliance issues during the Review Period, including date(s) and description.
2. Reports of all investigations of potential compliance issues, including date(s), description, interview notes, the investigative process, and results of such investigations.
3. Documentation of all plans of correction that were promptly implemented to resolve identified compliance issues, including implementation date(s), disciplinary actions, and description of plan(s) of correction.
4. Dated reports containing credible evidence of violations of state or federal law, rule, or regulation, including:
  - a. dated transmittals of such reports to the appropriate government entity, and
  - b. dated transmittals of such reports to the compliance officer.

Following any internal or external audits or investigations that identified overpayments, providers should:

1. Conduct internal audits or investigations to identify the root cause of the identified findings and any additional overpayments. Such audits or investigations should include a:
  - a. look-back period (up to the six-year records retention period) prior to the audit period, and
  - b. look-ahead period beyond the audit period up to the time of implementation of a plan(s) of correction to resolve the identified issue(s).
2. Report, return, and explain any identified additional overpayments to the Medicaid program through the OMIG Self-Disclosure Program.
3. Implement corrective actions related to the identified findings and follow-up activities to confirm effectiveness of such corrective actions.

## **SUMMARY/CONCLUSION**

It is the purpose of compliance programs to detect and prevent fraud, waste, and abuse in the Medicaid program as well as organize provider resources to address compliance issues as quickly and efficiently as possible, and to impose systemic checks and balances to prevent future recurrence of such issues. OMIG is committed to working with providers to improve the quality of the Medicaid program.

Each provider shall adopt, implement, and maintain an effective compliance program, which is tailored to fit the needs and resources of the provider, depending upon its size, complexity, resources, and culture. Federal and state statutes, rules, regulations, and Medicaid program requirements should be integrated into every provider's compliance program.

Questions regarding this guidance should be directed to OMIG's Bureau of Compliance at [compliance@omig.ny.gov](mailto:compliance@omig.ny.gov) or (518) 408-0401.

## SELECTED REFERENCES AND AUTHORITIES

The following are some references and authorities that were considered in the preparation of this guidance document.

NYS Social Services Law § 363-d

NYS Social Services Law § 145-b

18 NYCRR SubPart 521-1, Scope and applicability

18 NYCRR SubPart 521-2, Definitions

18 NYCRR SubPart 521-3, Required provider duties

18 NYCRR Part 504, Medical Care – Enrollment of Providers

18 NYCRR Part 515, Provider Sanctions

18 NYCRR Part 516, Monetary Penalties

18 NYCRR Part 519, Provider Hearings

42 United States Code 1396a(a)(68), State plans for medical assistance

2007 DRA 6032 - Employee Education About False Claims Recovery - Frequently Asked Questions

1998 OIG Compliance Program Guidance for Hospitals

2005 OIG Supplemental Compliance Program Guidance for Hospitals

2012 OMIG Compliance Program Guidance for General Hospitals

2016 OMIG Compliance Program Guidance

2017 HCCA-OIG Measuring Compliance Program Effectiveness: A Resource Guide

# ADDENDUM A

SubPart 521-1 implements statutory and conforming changes to provider compliance programs identified in SOS § 363-d. Providers have ninety (90) days from the effective date of SubPart 521-1 to adopt and implement changes to their compliance programs to ensure their compliance program satisfactorily meets the requirements of SubPart 521-1. The following table identifies changes in compliance program requirements between 18 NYCRR Part 521 (effective July 1, 2009) and SubPart 521-1 (effective December 28, 2022). A Medicaid provider's legal obligations are determined by the applicable federal and state statutory and regulatory law. This guidance does not encompass all the current compliance program requirements and, therefore, is not a substitute for a review of the statutory and regulatory law

<b>18 NYCRR Part 521 (effective 7/1/2009)</b>	<b>SubPart 521-1 (effective 12/28/2022)</b>
<b>SCOPE AND APPLICABILITY</b>	
<p><b>Section 521.1</b> The following persons shall adopt and implement effective compliance programs: (a) persons subject to the provisions of articles twenty-eight or thirty-six of the public health law; (b) persons subject to the provisions of articles sixteen or thirty-one of the mental hygiene law; or (c) other persons, providers or affiliates who provide care, services, or supplies under the medical assistance program or persons who submit claims for care, services, or supplies for or on behalf of another person for which the medical assistance program is or should be reasonably expected by a provider to be a substantial portion of their business operations.</p>	<p><b>Section 521-1.1(b)</b> Providers required to implement an effective compliance program has been expanded to also include managed care provider or managed long term care plan (collectively, MMCO).</p>
<b>DEFINITIONS</b>	
	<p><b>Section 521-1.2(b)(1)</b> Several definitions have been added to clarify terms used in the regulation. Particular terms providers should pay attention to are:</p> <ul style="list-style-type: none"> <li>• Affected Individuals,</li> <li>• Effective Compliance Program, and</li> <li>• Organizational Experience.</li> </ul>
<p><b>Section 521.2(b)</b> “Substantial portion” of business operations means five hundred thousand dollars (\$500,000) claimed, ordered, or received in any consecutive twelve-month period, directly or indirectly, from the Medicaid program.</p>	<p><b>Section 521-1.2(b)(11)</b> The substantial portion of business operations has increased to one million dollars (\$1,000,000) claimed or received in any consecutive twelve-month period, directly or indirectly, from the Medicaid program.</p>

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
<b>PROVIDER DUTIES</b>	
<p><b>Section 521.1</b> To be eligible to receive medical assistance payments for care, services, or supplies, or to be eligible to submit claims for care, services, or supplies for or on behalf of another person, Providers shall adopt and implement effective compliance programs.</p>	<p><b>Section 521-1.3(a)</b> Having an effective compliance program as a condition of receiving payments from the Medicaid program remains in regulation and has now been codified in SOS § 363-d.</p>
	<p><b>Section 521-1.3(c)</b> This section includes new requirements for contracts with contractors, agents, subcontractors, and independent contractors (Contractors).</p>
<p><b>Section 521.3(a)</b> Providers' compliance programs shall be applicable to: (1) billings, (2) payments, (3) medical necessity and quality of care, (4) governance, (5) mandatory reporting, (6) credentialing, and (7) other risk areas that are or should with due diligence be identified by the provider.</p>	<p><b>Section 521-1.3(d)</b> The compliance program risk areas have been expanded to also include:</p> <ul style="list-style-type: none"> <li>• ordered services;</li> <li>• contractor, subcontractor, agent, or independent contract oversight; and</li> <li>• additional risk areas specific for MMCOs.</li> </ul>
<p><b>Section 521.3(b)</b> A Provider shall certify upon enrollment in the Medicaid program, and annually thereafter, using a form provided by OMIG on its website, that a compliance program meeting the requirements is in place.</p>	<p><b>Section 521-1.3(f)</b> Providers no longer need to use a form on OMIG's website to certify.</p> <ul style="list-style-type: none"> <li>• Certification is now completed by Providers using the annual Certification Statement for Provider Billing Medicaid (ETIN) form that is submitted to the department.</li> <li>• This section also includes certification requirements for MMCOs and their network participating providers.</li> </ul>
<p><b>Section 521.3(c)(7)</b> A system for refunding overpayments.</p>	<p><b>Section 521-1.3(g)</b> Providers shall report, return, and explain overpayments as required in 18 NYCRR SubPart 521-3.</p>
<b>ELEMENT 1</b>	
	<p><b>Section 521-1.4(a)(1)</b> Providers shall have a process for drafting, revising, and approving written Policies. Such Policies must be accessible and applicable to all Affected Individuals.</p>
	<p><b>Section 521-1.4(a)(2)(i)</b> Providers shall have written Policies that articulate their commitment to comply with</p>

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
	applicable federal and state standards. The Provider shall identify governing laws and regulations applicable to their risk areas, including any relevant Medicaid program policies and procedures.
<p><b>Section 521.3(c)(1)</b> Written Policies that describe compliance expectations as embodied in a code of conduct or code of ethics.</p>	<p><b>Section 521-1.4(a)(2)(ii)</b> In addition to compliance expectations, written Policies shall also describe the Provider’s fundamental principles and values, and commitment to conduct its business in an ethical manner.</p>
<p><b>Section 521.3(c)(1)</b> Written Policies that implement the operation of the compliance program.</p>	<p><b>Section 521-1.4(a)(2)(iii)</b> In addition to the operation of the compliance program, written Policies shall describe the structure of the compliance program, including the responsibilities of all Affected Individuals in carrying out the functions of the compliance program.</p>
<p><b>Section 521.3(c)(1)</b> Written Policies that provide guidance to employees and others on dealing with potential compliance issues.</p>	<p><b>Section 521-1.4(a)(2)(iv)</b> This section expands the written Policies requirement to include specific guidance on dealing with potential compliance issues.</p>
<p><b>Section 521.3(c)(1)</b> Written Policies that identify how to communicate compliance issues to appropriate compliance personnel.</p>	<p><b>Section 521-1.4(a)(2)(v)</b> Written Policies shall identify methods and procedures for communicating compliance issues to the appropriate compliance personnel.</p>
<p><b>Section 521.3(c)(1)</b> Written Policies that describe how potential compliance problems are investigated and resolved.</p>	<p><b>Section 521-1.4(a)(2)(vi)</b> This section expands the written Policies requirement to include a description of the procedures for documenting the investigation and the resolution or outcome.</p>
<p><b>Section 521.3(c)(8)</b> A policy of non-intimidation and non-retaliation for good-faith participation in the compliance program, including but not limited to:</p> <ul style="list-style-type: none"> <li>• reporting potential issues,</li> <li>• investigating issues,</li> <li>• self-evaluations,</li> <li>• audits and remedial actions, and</li> <li>• reporting to appropriate officials as provided in sections seven hundred forty and seven hundred forty-one of the labor law.</li> </ul>	<p><b>Section 521-1.4(a)(2)(vii)</b> The non-intimidation and non-retaliation requirements were moved from Element 8 to Element 1 under written Policies. Additionally, such protections were expanded to include reporting instances of intimidation or retaliation.</p>
	<p><b>Section 521-1.4(a)(2)(viii)</b> This section expands the written Policies requirement to include a policy regarding Affected Individuals who fail to comply with the</p>

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
	written Policies, or state and federal laws, rules, and regulations.
	<b>Section 521-1.4(a)(2)(ix)</b> All Providers shall comply with the provisions of 42 U.S.C. 1396a(a)(68), also known as the DRA. See Addendum B for DRA information.
	<b>Section 521-1.4(a)(2)(x)</b> Written Policies were expanded to include a description of MMCOs' implementation of the requirements of 18 NYCRR SubPart 521-2.
	<b>Section 521-1.4(a)(3)</b> Providers shall review their written Policies at least annually.
<b>ELEMENT 2</b>	
<b>Section 521.3(c)(2)</b> Designate an employee vested with responsibility for the day-to-day operation of the compliance program.	<b>Section 521-1.4(b)</b> The compliance officer is no longer required to be an employee of the provider.
<b>Section 521.3(c)(2)</b> [The compliance officer] shall periodically report directly to the governing body on the activities of the compliance program.	<b>Section 521-1.4(b)(1)</b> The regulation now includes specific primary responsibilities for the compliance officer.
<b>Section 521.3(c)(2)</b> [The compliance officer] 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.	<b>Section 521-1.4(b)(2)</b> The designation of the compliance officer reporting to another senior manager should not hinder the compliance officer in carrying out their duties, and accessing the chief executive and governing body.
<b>Section 521.3(c)(2)</b> [The compliance officer's] duties may solely relate to compliance or may be combined with other duties so long as compliance responsibilities are satisfactorily carried out.	<b>Section 521-1.4(b)(3)</b> The compliance officer may be assigned other duties, provided that such other duties do not hinder the compliance officer in carrying out their primary responsibilities.
	<b>Section 521-1.4(b)(4)</b> The compliance officer is allocated sufficient staff and resources to satisfactorily perform their responsibilities for the day-to-day operation of the compliance program.
	<b>Section 521-1.4(b)(5)</b> The compliance officer and appropriate compliance personnel have access to all records, documents, information, facilities, and Affected Individuals.
	<b>Section 521-1.4(c)</b> This section requires a designated compliance committee responsible for coordinating with the

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
	compliance officer and a compliance committee charter.
	<b>Section 521-1.4(c)(1)</b> This section requires specific compliance committee responsibilities.
	<b>Section 521-1.4(c)(2)</b> Membership in the committee consists of senior managers. The compliance committee meets quarterly, and reviews and updates the compliance committee charter annually.
	<b>Section 521-1.4(c)(3)</b> The compliance committee reports directly and is accountable to the chief executive and governing body.
<b>ELEMENT 3</b>	
<b>Section 521.3(c)(3)</b> Training and education of all affected employees and persons associated with the provider, including executives and governing body members, on: <ul style="list-style-type: none"> <li>• compliance issues,</li> <li>• expectations, and</li> <li>• the compliance program operation.</li> </ul>	<b>Section 521-1.4(d)</b> This section requires the implementation of an effective compliance training and education program for all Affected Individuals.
	<b>Section 521-1.4(d)(1)</b> This section requires compliance training and education include specific topics.
<b>Section 521.3(c)(3)</b> Training and education shall occur periodically and shall be made a part of the orientation for a new employee, appointee or associate, executive and governing body member.	<b>Section 521-1.4(d)(2)</b> All Affected Individuals complete the compliance training program annually. The compliance training and education are a part of orientation of new Affected Individuals occurring promptly upon hiring.
	<b>Section 521-1.4(d)(3)</b> Compliance training and education are accessible and understandable to all Affected Individuals.
	<b>Section 521-1.4(d)(4)</b> This section requires a compliance training plan outlining specific information.
<b>ELEMENT 4</b>	
<b>Section 521.3(c)(4)</b> Communication lines to the [compliance officer] that are accessible to all employees, persons associated with the provider, executives, and governing body members, to allow compliance issues to be reported.	<b>Section 521-1.4(e)</b> Effective lines of communication are established and implemented to ensure confidentiality for all Affected Individuals.

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
	<p><b>Section 521-1.4(e)(1)</b> Lines of communication are accessible to all Affected Individuals that allow for questions to be submitted and compliance issues to be reported.</p>
	<p><b>Section 521-1.4(e)(2)</b> Lines of communication to the compliance officer are publicized and available to all Affected Individuals and Medicaid recipients of service from the Provider.</p>
<p><b>Section 521.3(c)(4)</b> Communication lines shall include a method for anonymous good-faith reporting of potential compliance issues as they are identified.</p>	<p><b>Section 521-1.4(e)(3)</b> A method for anonymous reporting of potential fraud, waste, abuse, and compliance issues directly to the compliance officer.</p>
<p><b>Section 521.3(c)(4)</b> Communication lines shall include a method for confidential good-faith reporting of potential compliance issues as they are identified.</p>	<p><b>Section 521-1.4(e)(4)</b> The confidentiality of persons reporting compliance issues shall be maintained unless the matter is subject to a disciplinary proceeding; referred to, or under investigation by, MFCU, OMIG, or law enforcement; or disclosure is required during a legal proceeding; and such persons shall be protected under a policy for non-intimidation and non-retaliation.</p>
	<p><b>Section 521-1.4(e)(5)</b> If applicable, the Provider shall make information concerning its compliance program, including its standards of conduct, available on its website.</p>
<b>ELEMENT 5</b>	
<p><b>Section 521.3(c)(5)</b> 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:</p> <ul style="list-style-type: none"> <li>(i) failing to report suspected problems;</li> <li>(ii) participating in non-compliant behavior; or</li> <li>(iii) encouraging, directing, facilitating, or permitting either actively or passively non-compliant behavior.</li> </ul>	<p><b>Section 521-1.4(f)</b> Establishing disciplinary standards and implementing procedures for enforcing such standards to address potential violations and encourage good-faith participation in the compliance program by all Affected Individuals.</p>
	<p><b>Section 521-1.4(f)(1)</b> This section requires written Policies, establishing disciplinary standards and the procedures for taking such actions, be published and disseminated to all Affected Individuals, and incorporated into the training plan.</p>

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
<p><b>Section 521.3(c)(5)</b> Disciplinary policies shall be fairly and firmly enforced.</p>	<p><b>Section 521-1.4(f)(2)</b> Disciplinary standards are enforced fairly and consistently, and the same disciplinary action applies to all levels of personnel.</p>
<b>ELEMENT 6</b>	
<p><b>Section 521.3(c)(6)</b> A system for:</p> <ul style="list-style-type: none"> <li>• routine identification of compliance risk areas specific to the provider type;</li> <li>• self-evaluation of such risk areas including, but not limited to, internal audits and, as appropriate, external audits; and</li> <li>• evaluation of potential or actual non-compliance as a result of such self-evaluations and audits;</li> <li>• credentialing providers and persons associated with providers;</li> <li>• mandatory reporting;</li> <li>• governance; and</li> <li>• quality of care of medical assistance program beneficiaries.</li> </ul>	<p><b>Section 521-1.4(g)</b> An effective system for the routine monitoring and identification of compliance risks is established and implemented that includes internal monitoring and audits and, as appropriate, external audits, to evaluate compliance with the requirements of the Medicaid program and the overall effectiveness of the compliance program.</p>
	<p><b>Section 521-1.4(g)(1)</b> Ongoing audits are performed by internal or external auditors who have expertise in Medicaid program requirements or the subject area of the audit. Audits or investigations conducted by state or federal governmental entities are not considered external audits. This section identifies specific requirements for ongoing audits.</p>
	<p><b>Section 521-1.4(g)(2)</b> This section requires Providers to develop and implement a process for annually reviewing whether the requirements of SubPart 521-1 have been met. The purpose of such reviews is to determine the effectiveness of the compliance program, and whether any revision or corrective action is required.</p>
	<p><b>Section 521-1.4(g)(3)</b> This section requires Providers to:</p> <ul style="list-style-type: none"> <li>• confirm the identity and determine the exclusion status of Affected Individuals. In addition, MMCOs shall confirm the identity and determine the exclusion status of any other persons identified in its contract with the department, including its participating providers and subcontractors; and</li> </ul>

18 NYCRR Part 521 (effective 7/1/2009)	SubPart 521-1 (effective 12/28/2022)
	<ul style="list-style-type: none"> <li>obligate Contractors to comply with the exclusion status requirement.</li> </ul> <p>In addition, MMCOs shall require their participating providers and subcontractors to comply, where applicable, with the exclusion status requirement.</p>
	<p><b>Section 521-1.4(g)(4)</b> Results of the activities required by this subdivision are promptly shared with the compliance officer and appropriate compliance personnel.</p>
<b>ELEMENT 7</b>	
<p><b>Section 521.3(c)(7)</b> A system for:</p> <ul style="list-style-type: none"> <li>responding to compliance issues as they are raised;</li> <li>investigating potential compliance problems;</li> <li>responding to compliance problems as identified in the course of self-evaluations and audits;</li> <li>correcting such problems promptly and thoroughly;</li> <li>implementing procedures, policies, and systems as necessary to reduce the potential for recurrence;</li> <li>identifying and reporting compliance issues to the department or OMIG; and refunding overpayments.</li> </ul>	<p><b>Section 521-1.4(h)</b> Establish and implement procedures and systems for:</p> <ul style="list-style-type: none"> <li>promptly responding to compliance issues as they are raised;</li> <li>investigating potential compliance problems identified in the course of internal auditing and monitoring;</li> <li>correcting such problems promptly and thoroughly to reduce the potential for recurrence; and</li> <li>ensuring ongoing compliance with state and federal laws, rules, regulations, and requirements of the Medicaid program.</li> </ul>
	<p><b>Section 521-1.4(h)(1)</b> Upon the detection of potential compliance risks and compliance issues, the Provider shall take prompt action to investigate the conduct in question and determine what, if any, corrective action is required, and promptly implement such corrective action.</p>
	<p><b>Section 521-1.4(h)(2)</b> This section requires Providers to document their investigation of compliance issues, including specific details.</p>
	<p><b>Section 521-1.4(h)(3)</b> Any disciplinary action taken and the corrective action implemented are documented.</p>
	<p><b>Section 521-1.4(h)(4)</b> The Provider shall promptly report credible evidence that a state or federal law, rule, or regulation has been violated to the appropriate</p>

<b>18 NYCRR Part 521 (effective 7/1/2009)</b>	<b>SubPart 521-1 (effective 12/28/2022)</b>
	governmental entity, where such reporting is otherwise required by law. The compliance officer receives copies of any reports submitted to governmental entities.

# ADDENDUM B

Title 18 of the New York Codes, Rules and Regulations (18 NYCRR) § 521-1.4(a)(2)(ix) states all Required Providers shall comply with the provisions of 42 USC 1396a(a)(68). This addendum identifies the requirements of the DRA and the detailed information that OMIG looks for in a Required Provider's written Policies and any employee handbook when assessing if a compliance program meets statutory and regulatory requirements.

The Centers for Medicare and Medicaid Services issued the Deficit Reduction Act frequently asked questions that provides guidance on the DRA requirements and is available at [DRA 6032 - Employee Education About False Claims Recovery - Frequently Asked Questions 3-20-07](#).

## DEFICIT REDUCTION ACT (DRA) REQUIREMENTS

18 NYCRR § 521-1.4(a) requires inclusion of Title 42 United States Code § 1396-a(a)(68), also known as the DRA, which states:

Any entity ... as a condition of receiving [Medicaid] payments, shall:

- (A) establish written policies for all [affected individuals], that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31, administrative remedies for false claims and statements established under chapter 38 of title 31, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs (as defined in section 1320a–7b(f) of this title);
- (B) include as part of such written policies, detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and
- (C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

A. Written Policies should include detailed information about the topics listed below for each law:

1. **Federal False Claims Act, Title 31 United States Code §§ 3729 to 3733, excluding § 3730(h):**
  - a. liability,
  - b. damages and penalties,
  - c. the knowledge requirement, and
  - d. the qui tam provisions.
2. **Federal administrative remedies for false claims and statements, Title 31 United States Code §§ 3801 to 3812:**
  - a. liabilities,
  - b. civil penalties and damages, and
  - c. periodic adjustment to civil penalties by Congress.
3. **NYS False Claims Act, NYS Finance Law §§ 187 to 194, specifically §§ 187 to 190 and 192 to 194:**
  - a. liability,
  - b. damages and penalties,

- c. false claims and reverse false claims, and
    - d. the qui tam provisions.
  4. **NYS laws pertaining to civil liabilities, penalties, and administrative sanctions for false claims and statements:**
    - a. **Social Services Law § 145-b—False Statements; actions for treble damages, and**
    - b. **Social Services Law § 145-c—Sanctions.**
  5. **NYS laws pertaining to criminal liabilities and penalties for false claims and statements:**
    - a. **Social Services Law § 145—Penalties,**
    - b. **Social Services Law § 366-b—Penalties for Fraudulent Practices,**
    - c. **Penal Law Article 155—Larceny,**
    - d. **Penal Law Article 175—Offenses Involving False Written Statements,**
    - e. **Penal Law Article 176—Insurance Fraud, and**
    - f. **Penal Law Article 177—Health Care Fraud.**
  6. **federal and state whistleblower protections, including application, protections, prohibited actions, and available remedies:**
    - a. **Federal False Claims Act (31 U.S.C. § 3730(h)),**
    - b. **NYS False Claims Act (State Finance Law § 191—Remedies),**
    - c. **NYS Labor Law § 740, and**
    - d. **NYS Labor Law § 741.**
- B. OMIG considers the written policies and detailed provisions regarding an entity's policies and procedures for detecting and preventing fraud, waste, and abuse, that are required by Title 42 United States Code § 1396-a(a)(68), to be equivalent to the written Policies required by 18 NYCRR § 521-1.4(a).
- C. The Required Provider need not create an employee handbook if one does not already exist. The Required Provider's employee handbook, if applicable, should include a specific discussion of:
  1. the laws described above,
  2. the rights of employees to be protected as whistleblowers, and
  3. the entity's policies and procedures for detecting and preventing fraud, waste, and abuse (i.e., the Required Provider's compliance program).