**Compliance Program Requirements**
**Frequently Asked Questions**
Issued September 21, 2023

## Table of Contents



## General Information

Each required provider shall adopt, implement, and maintain an effective compliance program that is tailored to its specific organizational needs, depending upon its size, complexity, resources, and culture. The Office of the Medicaid Inspector General (OMIG) takes into consideration each provider's unique circumstances and characteristics when conducting its reviews.

**Q. What is the purpose of a compliance program?**

**A**. The purpose of a compliance program is 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.

## Required Providers

**Q. How do I determine if I am a required provider?**

**A**. 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.

NYS Social Services Law (SOS) § 363-d and Title 18 of the New York Codes, Rules and Regulations (18 NYCRR) SubPart 521-1 defines those factors that require providers to have a compliance program.

If you answer YES to any of the following questions, you are a required provider who must have a compliance program in New York State.

a. Is your organization subject to Article 28 or Article 36 of the NYS Public Health Law (PBH)?

b. Is your organization subject to Article 16 or Article 31 of the NYS Mental Hygiene Law?
c. Notwithstanding the provisions of § 4414 of the NYS PBH, is your organization a managed care provider, as defined in SOS § 364-j, which includes managed long-term care plans?
d. Does your organization claim —and/or can be reasonably expected to claim— Medicaid services or supplies of at least $1,000,000 in any consecutive 12-month period?
e. Does your organization receive Medicaid payments—and/or can be reasonably expected to receive payments—either directly or indirectly, of at least $1,000,000 in any consecutive 12-month period? Indirect Medicaid reimbursement is any payment that you receive for the delivery of Medicaid care, services, or supplies that comes from a source other than the State of New York. For example, if you provide covered services to a Medicaid beneficiary who is enrolled in a Medicaid Managed Care Plan, the payment you receive from the Managed Care Organization is considered an indirect payment.

**Q. How do I certify to the department that I have met the requirements of Social Services Law 363-d and 18 NYCRR Part 521?**

**A.** Providers adopting and maintaining an effective compliance program record (attest to) this as part of their annual completion of the Certification Statement for Provider Billing Medicaid/Electronic Transmitter Identification Number (ETIN) form. This annual certification occurs on the anniversary date of the provider's enrollment in Medicaid and includes a certification to the effectiveness of their compliance program. Providers can find their anniversary dates on their initial Medicaid enrollment welcome letters.

The ETIN form is completed annually for each Provider ID. Each year, approximately 45-60 days before the anniversary of a provider's enrollment, the NYS Department of Health mails a package of information and materials to the provider, which includes the ETIN Form. This Form must be completed and returned to the NYS Department of Health by the enrollment anniversary date for each Provider ID.

**Q. If I am required to have an effective compliance program, do I have to provide a copy of my ETIN form to each managed care provider or managed long term care plan (collectively, MMCO) I contract with?**

**A.** Yes, required providers should submit a copy of their annual ETIN form to each MMCO they contract with. MMCOs are responsible for maintaining a method for submitting such certification on their website, which may include a dedicated email address.

## Compliance Program Requirements

**Q. Are the requirements of 42 U.S.C. § 1396a(a)(68), also known as the Deficit Reduction Act (DRA), applicable to all required providers, regardless of the $5 million threshold?**

**A.** While federal law only applies these requirements to individuals or entities that bill or receive $5 million annually, OMIG has extended these requirements to all required

providers. Title 18 NYCRR § 521-1.4(a)(2)(ix) applies each of the provisions of 42 U.S.C. § 1396a(a)(68) to all required providers, notwithstanding the threshold required by 42 U.S.C § 1396a(a)(68) for such entities to also receive or make annual payments of at least $5 million annually.

The rule exceeds this federal requirement because Social Services Law § 363-d broadly requires providers to have written policies and procedures, as well as training programs, which address the provider's compliance with state and federal standards. OMIG believes that having policies and procedures, as well as education, regarding the State and Federal False Claims Act as part of a provider's compliance program, which includes the rights of employees to be protected as whistleblowers, is an important safeguard in the prevention and detection of fraud and abuse in the Medicaid program. Moreover, unlike New York State, federal law, with some exceptions, does not mandate that Medicaid providers adopt and implement an effective compliance program. OMIG believes the substantive requirements outlined in 42 U.S.C. § 1396a(a)(68) are appropriate for inclusion in an effective compliance program.

Please see Addendum B of the Compliance Program Guidance for more information on the DRA requirements.

**Q. Why is a compliance work plan needed?**

**A.** An annual compliance work plan is an organizational tool and a working document, which assists providers in documenting and tracking their strategy for identifying and addressing risk areas specific to their operations. A work plan is a valuable tool in evaluating the degree to which a provider is engaged in enhancing its compliance program based on its "organizational experience," a risk area identified in 18 NYCRR § 521-1.3(d). As such, the compliance work plan is a key component in demonstrating that a provider has an effective compliance program. Providers have the flexibility to develop a work plan that best meets their unique characteristics and risk environment.

While drafting, implementing, and updating a compliance work plan is a primary responsibility for the compliance officer, it is a reasonable expectation that the compliance officer should be the person coordinating the implementation of the work plan, and there will be other individuals involved in completing auditing and monitoring activities identified in such a work plan.

**Q. Can the compliance officer's quarterly reports to the governing body be in written format or does the compliance officer have to do an in-person presentation?**

**A.** Evidence of the compliance officer's reports to the governing body may be in the form of written reports or governing body meeting agendas, minutes, and excerpts that set out reports by the compliance officer. There should be evidence the compliance officer made such reports directly to the governing body members, and there was an established method for governing body members to directly ask questions of the compliance officer related to such reporting.

A best practice is for the compliance officer to provide such reports during an in-person presentation. OMIG recommends there be an executive session that includes the governing body and the compliance officer only. This need not be for the whole report,

but for a portion of the report. This is similar to the executive session that accountants have with the governing body for year-end audits.

For required providers without a governing body, the compliance officer should provide reports to the owner(s), member(s), partner(s), or person(s) with responsibility for oversight of senior management.

**Q. How do I make disciplinary standards applicable to the board of directors or governing body?**

**A.** The term "affected individuals" expressly includes "the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers." This means that disciplinary standards apply to these individuals. Disciplinary standards may be defined in documents other than written policies for governing body members such as in bylaws and for Contractors, in contract provisions.

**Q. Is our compliance program not effective if it fails to prevent a compliance issue?**

**A.** 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 ineffective. When reviewing compliance programs, OMIG will take into consideration all factors related to the provider's compliance program to identify the severity of an individual instance or if a trend is identified.

**Q. Should I send my Compliance Plan to OMIG for approval?**

**A.** No, providers are not required to submit their compliance plan to OMIG for approval. Providers should only send their Compliance Plan and supporting documentation if OMIG engages them in a review and requests they do so. Providers will receive a notification letter at the commencement of a review.

## Compliance Program Reviews

**Q. If I am notified my compliance program will be reviewed, how long do I have to send in my documents?**

**A.** Upon notification, the provider needs to download a Review Module from OMIG's website and submit the completed Module and supporting documentation to OMIG within thirty calendar (30) days from the date of the notification. Providers should not submit the Module to OMIG unless they receive a notification letter from OMIG instructing them to do so.

Refer to the Compliance Program Guidance for more information on the compliance program review process.

**Q. How will OMIG calculate the average score percentage for a compliance program review?**

**A.** The importance and value of effective compliance programs is widely understood across the health care system. As such, a variety of equally effective compliance strategies are on display among health care providers to respond to their unique business profile, size, and level of assumed risk. Consequently, the OMIG compliance program review process recognizes this diversity in the evaluation of program effectiveness, rather than employing a one-size-fits all process.

The Compliance Program Review Module, which providers will complete upon notice of a review, outlines all the necessary elements and requirements of an effective compliance program. The associated scoring system allows OMIG to review provider documentation received in response to the Module and evaluate whether the requirements were identified or observable in the documentation shared or upon subsequent interview.

OMIG will calculate the average score percentage as follows:

- An average score is calculated for each month of the review period by counting the number of requirements that are met and then dividing that number by the number of assessable requirements.
  - For example, if there are 90 requirements that were met and there were 100 assessable requirements, the average score is 90% (i.e., 90/100 = 90%).
- The monthly scores are averaged to calculate the overall average score.
  - For example, for a three-month review period, all monthly scores (e.g., 80%, 85%, 90%) are added together to equal 255, and then divided by three (the number of months reviewed) for an overall average score of 85%. This average score is used to determine whether the provider's compliance program satisfactorily met the requirements (i.e., $\geq$ 60% = satisfactory, or < 60% = not satisfactory).
- Most, but not all, requirements receive a monthly score.
  - For example, the provider is required to confirm the identity and determine the exclusion status of affected individuals at least every thirty (30) days.
    - This requirement is scored for each month in the review period.
- Quarterly requirements are scored accordingly.
  - For example, the compliance officer is required to give a quarterly report to the governing body.
    - This requirement is scored once in each quarter of the review period.
    - The other two months in each quarter are marked not assessable and do not affect the score for those months.
- Annual requirements are scored accordingly.
  - For example, the provider is required to review, at least annually, whether the requirements of 18 NYCRR SubPart 521-1 have been met.
    - This requirement is assessed once in a twelve-month period and is scored only for the month in which the provider performed, or was expected to perform, such review.
    - The other months in the review period are marked not assessable and do not affect the overall average score.

**Q. What can providers do to position themselves better for future OMIG compliance program reviews?**

**A.** Conducting an internal annual compliance program review, as required in the regulations, serves as an effective mechanism for providers to assess their compliance programs and prepare for a future OMIG compliance program review. Additionally, providers are encouraged to consult the educational and support resources on the OMIG website, including the Compliance Program Self-Assessment Form, to identify requirements and best practices, and help determine the effectiveness of their compliance program and identify any revisions and/or corrective actions that may be necessary.

OMIG considers an "effective compliance program" to be one that, at a minimum, satisfies the compliance program requirements and is designed to be compatible with the provider's characteristics (i.e., size, complexity, resources, and culture). For example, the compliance program should:

- be well-integrated into the company's operations;
- be supported by the highest levels of the organization, including the chief executive, senior management, and the governing body;
- promote adherence to the provider's legal and ethical obligations; and
- be 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.

Providers should document they have implemented and maintain an effective compliance program which demonstrates Medicaid compliance program requirements were met. For example, such documentation may include written policies, procedures, and standards of conduct (collectively, Policies) along with evidence the compliance program activities, detailed in such written Policies, were completed. The Compliance Program Guidance on OMIG's website identifies types of documentation providers may produce for an OMIG compliance program review as evidence they met the specified requirements during a review period.

The types of documentation provided as examples are not meant to be all-inclusive. OMIG recognizes that providers may have other types of documentation meeting the requirements and encourages them to produce all documentation for consideration during an OMIG compliance program review.

## Affected Individuals/Contractors

### Q. Who is an affected individual?

**A.** "Affected individuals" means all persons who are affected by the required provider's risk areas including the required provider's employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.

### Q. Why are contractors, agents, subcontractors, and independent contractors subject to required providers' compliance programs?

**A.** Required providers are responsible for ensuring services provided to Medicaid recipients comply with the laws and official directives of the Medicaid program which govern the performance of those services. As such, required providers are responsible for ensuring the services contractors, agents, subcontractors, and independent

contractors (collectively, Contractors) provide to Medicaid recipients also comply with applicable laws and official directives of the Medicaid program. This includes Contractors' adherence to the compliance program of the required provider.

Required providers must evaluate and decide which Contractors are subject to their compliance program. It is important to note that Contractors are only subject to the provider's compliance program to the extent that it relates to their contracted role and responsibilities within the provider's identified risk area. For example:

a. an entity contracted to provide "credentialing services" is required to comply with written Policies, training, and so forth, as it relates to the provision of "credentialing services"; and
b. an entity contracted to provide landscaping services may or may not be considered an affected individual depending on the scope of services delivered and its impact on the risk areas contemplated by the provider's compliance plan (i.e., safety and security).

**Q. Which compliance program requirements must be included in contracts with Contractors?**

**A.** Providers should first determine if their Contractors are affected individuals subject to their compliance program.

If a Contractor is an affected individual, the contract should:

a. specify the Contractor is subject to the required provider's compliance program, and
b. include termination provisions for failure to adhere to the required provider's compliance program requirements.

It is acceptable for required providers to rely on termination language in existing contracts as long as it is clear that it includes failure to adhere to the required provider's compliance program.

Acceptable documentation that this requirement is met may include an amended contract with such language; or, if the underlying contract includes language that the contract is subject to changes in laws and regulations, providers may submit documentation showing the Contractor was provided notice of the requirements under 18 NYCRR § 521-1.4.

Required providers shall call for Contractors to demonstrate completion of monthly exclusion checks, as described in 18 NYCRR § 521-1.4(g)(3). In addition, MMCOs shall require their participating providers and subcontractors to comply, where applicable, with the provisions of 18 NYCRR § 521-1.4(g)(3).

As required in 18 NYCRR § 521-2.3(c), MMCOs shall ensure that contracts with Contractors and participating providers related to the MMCO's participation in the Medicaid program specify that the Contractors and participating providers are subject to audit, investigation, or review under the MMCO's fraud, waste, and abuse prevention program.

**Q. How can required providers accomplish compliance program training and education for Contractors?**

**A.** While all required providers must meet the same compliance program requirements, how they do so can vary greatly depending on the required provider's characteristics and operational experience. Contractors should be made aware of the required provider's specific compliance program requirements and methods for reporting issues to the required provider's compliance officer and have an opportunity to ask questions.

If Contractors are not able to complete compliance program training and education in the same format as other categories of affected individuals, required providers may accomplish compliance program training by annually distributing a copy of their compliance manual or all compliance program written Policies that are applicable to such Contractors, along with a letter or memo including the following information:

a. identification of the required provider's risk areas and organizational experience (to the extent these relate to the Contractors' roles and responsibilities within the provider's identified risk areas);
b. the roles of the required provider's compliance officer and the compliance committee;
c. how affected individuals, or others, can ask questions and report potential compliance-related issues to the required provider's compliance officer and senior management, including the obligation of affected individuals to report suspected illegal or improper conduct and the procedures for submitting such reports; and protection from intimidation and retaliation for good-faith participation in the compliance program;
d. disciplinary standards, with an emphasis on those standards related to the required provider's compliance program and the prevention of fraud, waste, and abuse. For Contractors, this is contract provisions related to discipline and/or termination for failure to adhere to the required provider's compliance program requirements;
e. how the required provider responds to compliance issues and implements corrective action plans;
f. requirements specific to the Medicaid program and the required provider's category or categories of service;
g. if applicable, coding and billing requirements and best practices;
h. if applicable, claim development and the submission process; and
i. for MMCOs only, the fraud, waste, and abuse prevention program, and any applicable terms of the MMCO's contract with the department to participate as an MMCO.

It is a best practice to include a dated distribution letter or to request that Contractors complete an acknowledgement demonstrating that compliance training occurred.

**Q. How long do providers have to modify contract terms for Contractors?**

**A.** Providers should first determine if their Contractors are affected individuals subject to their compliance program. Contractors are only subject to the provider's compliance program to the extent it relates to their contracted role and responsibilities within the provider's identified risk area. For example:

a. an entity contracted to provide "credentialing services" is required to comply with written Policies, training, and so forth, as it relates to the provision of "credentialing services"; and
b. an entity contracted to provide landscaping services may or may not be considered an affected individual depending on the scope of services delivered and its impact

on the risk areas contemplated by the provider's compliance plan (i.e., safety and security).

OMIG recognizes that it may be difficult to amend certain contracts as well as the time needed to amend contracts to address these requirements. To assist providers in meeting these requirements, OMIG will only enforce the requirements of 18 NYCRR § 521-1.3(c) for contracts newly executed or renewed starting 90 days, and no later than two years, from December 28, 2022. Required providers must demonstrate they have made a good-faith effort to modify existing contracts they have with Contractors.

The required provider shall ensure that such contracts include termination provisions for failure to adhere to the required provider's compliance program requirements. It is acceptable for required providers to rely on termination language in existing contracts as long as it is clear that it includes failure to adhere to the required provider's compliance program.

A Contractor that is also a required provider can and should work with the providers it contracts with to determine how to implement its compliance program in the most efficient manner possible. OMIG will take into consideration each provider's unique circumstances and characteristics when conducting its reviews.

## Help and Support

Providers are encouraged to contact OMIG with any questions or concerns they may have. These communications are important to OMIG and help to inform updates to these Frequently Asked Questions (FAQs).

**Q. How do I contact OMIG if I have any questions or concerns on the Compliance Program Requirements?**

**A.** The quickest way to obtain an answer is to review the published regulations and guidance OMIG has posted to its website:

- Laws and Regulations
- Compliance Program Guidance
- Compliance Program Self-Assessment Form
- Compliance Program Review Module
- Compliance Program Requirements Webinar

Additionally, OMIG continuously updates these resources to ensure providers are informed. Providers that have questions or concerns not addressed in the resources posted are urged to contact OMIG's Bureau of Compliance via email at: compliance@omig.ny.gov or (518) 408-0401.

**Q. How do I stay informed of changes or updates to compliance program requirements and other OMIG programs? And how do I sign up for OMIG's Listserv to ensure I have up-to-date information?**

**A.** OMIG is committed to updating these FAQs regularly as new questions arise and are answered. Providers' questions and concerns are important to OMIG and help inform updates to these FAQs. Providers are encouraged to access the FAQs regularly, as OMIG will revise and update the information as necessary.

The Compliance Library on OMIG's website is updated regularly with compliance program resources and the most up-to-date information for required providers. Providers can sign up for OMIG's Listserv for information on upcoming events and announcements.

Please direct any questions regarding these FAQs or other compliance program-related matters to OMIG's Bureau of Compliance at: compliance@omig.ny.gov or (518) 408-0401.

Providers may obtain additional information by reviewing 18 NYCRR Part 521 and the Compliance Program Guidance.