

SUMMARY OF REGULATION

The proposed rulemaking would repeal and add a new 18 NYCRR Part 521 to implement statutory changes resulting from the recommendations of the Medicaid Redesign Team II as adopted in the State Fiscal Year 2020-2021 Enacted Budget (Chapter 56 of the Laws of 2020, Part QQ) and to make other conforming changes related to (1) provider compliance programs, (2) Medicaid managed care plan fraud, waste and abuse prevention programs under the Medical Assistance (Medicaid) program, and (3) the obligation to report, return and explain Medicaid overpayments through OMIG's Self-Disclosure Program.

SubPart 521-1 is added to replace what was formerly Part 521, Provider Compliance Programs, to conform to changes made to Social Services Law (SOS) § 363-d to align State and Federal provisions related to compliance programs.

Section 521-1.1 is added to establish the scope of the regulation setting forth the requirements for the adoption and implementation of effective compliance programs. Consistent with statutory requirements, the regulation applies to any person (referred to as a "Required Provider") subject to Articles 28 or 36 of the Public Health Law, Articles 16 or 31 of the Mental Hygiene Law, Medicaid managed care organizations, including managed long term care plans, referred to collectively as "MMCO," and any other person for whom the Medicaid program is a substantial portion of their business operations.

Section 521-1.2 is added to define certain terms.

Section 521-1.3 is added to specify the duties of a Required Provider.

Section 521-1.3(a) sets forth the general obligation of Required Providers to adopt, implement and maintain an effective compliance program.

Section 521-1.3(b) is added to establish the obligation of Required Providers to retain records relevant to their adoption, implementation and maintenance of a compliance program under the regulation, and to make such records available to OMIG, DOH or the New York State Medicaid Fraud

Control Unit (MFCU). It also establishes the record retention period which is consistent with the requirements of 18 NYCRR § 504.3(a) and § 517.3, except that MMCOs shall retain records for a period of 10 years, consistent with the terms of the contracts between the MMCOs and DOH.

Section 521-1.3(c) is added to specify compliance program requirements relevant to any Required Provider's contractor, agent, subcontractor or independent contractor.

Section 521-1.3(d) is added to specify the "Risk Areas" that shall be applicable to the Required Provider and specify additional risk areas applicable to MMCOs.

Section 521-1.3(e) is added to require that Required Providers comply with the directives of DOH and OMIG with respect to compliance programs required by the regulation.

Section 521-1.3(f) is added to specify, consistent with statutory requirements, that Required Providers certify to DOH that they have adopted and implemented an effective compliance program upon enrollment and annually thereafter, and to clarify certification requirements for MMCO Participating Providers.

Section 521-1.3(g) is added to specify that Required Providers must comply with SubPart 521-3 of this Part to report, return and explain overpayments.

Section 521-1.4 is added to clarify, consistent with statutory requirements, the seven (7) elements of an effective compliance program, and to provide direction to Required Providers in the adoption and implementation of such programs.

Section 521-1.4(a) is added to clarify the requirements for the development of written policies and procedures, and the types of written policies and procedures that the Required Provider is required to develop and maintain.

Section 521-1.4(b) is added to clarify the requirements for the designation of a compliance officer, their primary responsibilities, the reporting structure, and other provisions related to the compliance officer being able to effectively carry out their responsibilities.

Section 521-1.4(c) is added to clarify the requirements for the establishment of a compliance committee, its primary responsibilities, the requirement for a compliance committee charter, and reporting structure.

Section 521-1.4(d) is added to clarify the requirements for establishing and implementing an effective training program for the Required Provider's compliance officer and all Affected Individuals.

Section 521-1.4(e) is added to clarify the requirements for establishing and implementing effective lines of communication, including accessibility, publication, a method for anonymous reporting, and confidentiality.

Section 521-1.4(f) is added to clarify the requirements for the publication and enforcement of the Required Provider's disciplinary procedures, and the requirement that such procedures be enforced fairly and consistently.

Section 521-1.4(g) is added to clarify the requirements for the Required Provider's auditing and monitoring, including the types of audits the Required Provider must undertake, the frequency of such audits, and other requirements related to internal and external auditing. It also includes a requirement that the Required Provider actively monitor its Affected Individuals to identify persons who have been excluded from participation in the Medicaid program.

Section 521-1.4(h) is added to clarify the requirements for responding to compliance issues, including procedures for the detection of compliance issues, documentation of such issues, and reporting, where such reporting is required, of any violations of State or Federal law.

Section 521-1.5 is added to specify the procedures for OMIG compliance program reviews. Sections 521-1.5(a)-(d) outlines the scope of the review, notifications to the Required Provider, and how OMIG or DOH will communicate its determination.

SubPart 521-2 is added to establish the requirements, consistent with SOS § 364-j(39), for Medicaid Managed Care Fraud, Waste and Abuse Prevention Programs.

Section 521-2.1(a) – (c) is added to set forth the scope of the SubPart, that it shall apply to MMCOs, and to acknowledge related regulations in 10 NYCRR § 98-1.21 and 11 NYCRR § 86.6.

Section 521-2.2(a) is added to define certain terms.

Section 521-2.3(a) is added to establish the general requirement that MMCOs adopt and implement policies and procedures designed to detect and prevent fraud, waste and abuse.

Section 521-2.3(b) is added to specify the MMCO's record retention and cooperation obligations relevant to the adoption and implementation of its fraud, waste and abuse prevention program under this SubPart.

Section 521-2.3(c) is added to specify requirements relative to an MMCO's contractors, agents, subcontractors, and independent contractors with respect to its fraud, waste and abuse prevention program.

Section 521-2.4(a) is added to specify, consistent with statutory requirements, that MMCOs, as part of their fraud, waste and abuse prevention programs, adopt, implement, and maintain an effective compliance program pursuant to SubPart 521-1, and to specify the requirements for incorporating elements of the prevention program into the compliance program.

Section 521-2.4(b) is added to specify requirements for the establishment of special investigation units (SIU), including staffing requirements, investigator qualifications, lead investigator obligations, the obligation to prepare an SIU work plan, and requirements for delegating the MMCO's SIU function to a management contractor.

Section 521-2.4(c) is added to specify audit and investigation requirements including the scope of audits to be undertaken and the general requirements for conducting such audits and investigations.

Section 521-2.4(d) is added to require MMCOs to report cases of fraud, waste and abuse to OMIG in accordance with the provisions of the MMCO's contract with DOH.

Section 521-2.4 (e) is added to clarify that MMCOs and their subcontractors shall refer reasonably suspected criminal activity to OMIG and MFCU in accordance with contractual obligations.

Section 521-2.4(f) is added to clarify that MMCOs, consistent with Federal and contractual requirements, shall have policies and procedures for providers to report, return and explain overpayments to the MMCO within sixty (60) days of identification, and that the MMCO shall report such recoveries to OMIG and DOH in accordance with the terms of the MMCO's contract with the department.

Section 521-2.4(g) is added to require the MMCO to develop a fraud, waste and abuse procedures manual for the use of its employees.

Section 521-2.4(h) is added to specify additional program integrity obligations, including the development and publication of a fraud, waste and abuse public awareness program and the publication of the policies and procedures for providers to report, return and explain overpayments to the MMCO.

Section 521-2.4(i) is added to clarify the MMCO's obligation to prepare and file with OMIG a fraud, waste and abuse prevention plan. Section 521-2.4(j)(4) specifies that OMIG will accept a fraud and abuse prevention plan that has been prepared in accordance with the provisions of 10 NYCRR § 98-1.21 or 11 NYCRR § 86.6, provided that any additional requirements under SubPart 521-2 are included with the submission.

Section 521-2.4(j) is added to specify the deadline for submitting and the elements to include in the annual report the MMCO is required to submit to OMIG on its performance under the fraud, waste and abuse prevention program.

Section 521-2.4(k) is added to clarify an MMCO's obligation to report information required by the regulation and contract.

SubPart 521-3 is added to establish the requirements, consistent with the statutory requirements, that persons shall report, return and explain overpayments consistent with SOS § 363-d (6), and to explain the requirements of the self-disclosure program administered by OMIG consistent with SOS § 363-d (7).

Section 521-3.1(a) – (c) is added to set forth the scope and applicability of the SubPart.

Section 521-3.2 is added to define certain terms.

Section 521-3.3(a) is added to clarify the requirements for reporting and returning overpayments received from the Medicaid program.

Section 521-3.3(b) is added to clarify the timeframes for reporting, returning and explaining overpayments received from the Medicaid program.

Section 521-3.4(a) is added to identify OMIG's Self-Disclosure Program as the mechanism by which a person reports, returns and explains an overpayment received from the Medicaid program.

Section 521-3.4(b) is added to set forth the general requirements for OMIG's Self-Disclosure Program, including eligibility of a person to participate in the program.

Section 521-3.4(c) is added to specify the information required to be submitted by the person seeking to report, return and explain an overpayment through OMIG's Self-Disclosure Program.

Section 521-3.4(d) is added to outline OMIG's process for receiving and reviewing self-disclosure submissions.

Section 521-3.4(e) is added to clarify the requirements for Self-Disclosure and Compliance Agreements and the requirements for executing such agreements.

Section 521-3.4(f) is added to clarify the circumstances under which and the process by which OMIG may terminate a person's participation in the Self-Disclosure Program.

Section 521-3.5 is added to specify the requirements, following the completion of OMIG's review of the person's self-disclosure, for the person to remit the overpayment, including interest, if applicable, to the department.

Section 521-3.6 is added to specify the requirements applicable to all notifications OMIG issues to the person under SubPart 521-3.

Section 521-3.7 is added to clarify how the requirements of SubPart 521-3 will be enforced where a person fails to report, return and explain an overpayment by the deadline specified in law and regulation.

18 NYCRR PART 521 FRAUD, WASTE AND ABUSE PREVENTION

Pursuant to the authority vested in the Medicaid Inspector General by Section 32(20) of the Public Health Law, Part 521 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is repealed and a new Part 521 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 521 is repealed and a new Part 521 is adopted to read as follows:

PART 521 FRAUD, WASTE AND ABUSE PREVENTION

SUBPART 521-1 COMPLIANCE PROGRAMS

SUBPART 521-2 MEDICAID MANAGED CARE FRAUD, WASTE AND ABUSE PREVENTION

SUBPART 521-3 SELF-DISCLOSURE PROGRAM

SUBPART 521-1 COMPLIANCE PROGRAMS

521-1.1 Scope and applicability

521-1.2 Definitions

521-1.3 Required provider duties

521-1.4 Compliance program requirements

521-1.5 Compliance program reviews

521-1.1 Scope and applicability.

(a) Scope. Social Services Law requires certain persons participating in the Medical Assistance (MA) program to adopt and implement programs designed to detect and prevent fraud, waste and abuse in the MA program. Required providers may be able to detect and correct payment and billing mistakes and fraud if required to develop and implement a compliance program. This SubPart sets forth the requirements for establishing and operating effective compliance programs pursuant to section 363-d of the Social Services Law, the obligation to self-disclose overpayments, and the procedures for reviewing compliance programs.

(b) Applicability. The following persons shall be subject to the provisions of this SubPart, and shall hereinafter be referred to as “*required providers*”:

- (1) any person subject to the provisions of articles 28 or 36 of the Public Health Law;
- (2) any person subject to the provisions of articles 16 and 31 of the Mental Hygiene Law;
- (3) any managed care provider or managed long term care plan, which shall hereinafter be collectively, unless otherwise noted, referred to as “*Medicaid managed care organization*” or “*MMCO*,” and
- (4) any other person for whom the MA program is, or is reasonably expected by the person to be, a substantial portion of their business operations.

521-1.2 Definitions.

(a) For purposes of this SubPart, the terms defined in Parts 504 and 515 of this Title, except as otherwise noted, shall apply.

(b) In addition, for the purposes of this SubPart, the following terms have the following meanings:

- (1) “*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.
- (2) “*Days*” means, unless otherwise noted, calendar days.
- (3) “*Effective compliance program*” means a compliance program adopted and implemented by the required provider that, at a minimum, satisfies the requirements of this SubPart and that is designed to be compatible with the provider’s characteristics (i.e., size, complexity, resources, and culture), which shall mean that it:
 - (i) 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;

(ii) promotes adherence to the required provider's legal and ethical obligations; and
(iii) is reasonably designed and implemented to prevent, detect, and correct non-compliance with MA program requirements, including fraud, waste, and abuse most likely to occur for the required provider's risk areas and organizational experience.

(4) "*MA*" means medical assistance for needy persons provided under Title 11 of Article 5 of the Social Services Law.

(5) "*Managed care provider*" is as defined in subdivision 1 of section 364-j of the Social Services Law.

(6) "*Managed long term care plan*" or "*MLTCP*" means an entity that has received a certificate of authority pursuant to section 4403-f of the Public Health Law to provide or arrange for health and long term care services on a capitated basis for a population which the plan is authorized to enroll.

(7) "*Medicaid Fraud Control Unit*" or "*MFCU*" means the Attorney General of the State of New York operating the program required by 42 C.F.R. Part 1007 and the Social Security Act.

(8) "*Office of the Medicaid Inspector General*" or "*OMIG*" means the independent office within the department established pursuant to Title 3 of Article 1 of the New York State Public Health Law.

(9) "*Organizational experience*" means the required provider's:

- (i) knowledge, skill, practice and understanding in operating its compliance program;
- (ii) identification of any issues or risk areas in the course of its internal monitoring and auditing activities;
- (iii) experience, knowledge, skill, practice and understanding of its participation in the MA program and the results of any audits, investigations, or reviews it has been the subject of; or

(iv) awareness of any issues it should have reasonably become aware of for its category or categories of service.

(10) “*Participating provider*” means a provider of medical care and/or services that has a provider agreement with an MMCO.

(11) “*Substantial portion of business operations*” means:

(i) when a person claims or has claimed, or should be reasonably expected to claim, at least one million dollars (\$1,000,000), in the aggregate, in any consecutive twelve-month period, directly or indirectly, from the MA program; or

(ii) when a person receives or has received, or should be reasonably expected to receive, at least one million dollars (\$1,000,000), in the aggregate, in any consecutive twelve-month period, directly or indirectly, from the MA program.

521-1.3 Required provider duties.

(a) General. Required providers shall, as a condition of receiving payment under the MA program, adopt, implement, and maintain an effective compliance program which satisfies the requirements of this SubPart. The required provider’s compliance program may be a component of more comprehensive compliance activities by the required provider so long as the requirements of this SubPart are met. Required providers must implement and maintain a compliance program, adopted pursuant to this SubPart, for the entire period that the person meets the definition of being a required provider.

(b) Record retention. A required provider shall retain all records demonstrating that it has adopted, implemented and operated an effective compliance program and has satisfied the requirements of this SubPart. The required provider shall make available to the department, OMIG, or MFCU upon request, copies of such records. Records shall be retained:

(1) by required providers for a period not less than six (6) years from the date such program was implemented, or any amendments thereto, were made; or

(2) by MMCOs in accordance with the retention periods specified in their contract with the department to participate as MMCOs.

(c) Contractors, agents, subcontractors, and independent contractors.

(1) Contractors, agents, subcontractors, and independent contractors are hereinafter referred to collectively, unless otherwise noted, as “contractor” or “contractors”.

(2) The required provider shall ensure that contracts with contractors specify that the contractors are subject to the required provider’s compliance program, to the extent that such contractors are affected by the required provider’s risk areas and only within the scope of the contracted authority and affected risk areas.

(3) The required provider shall ensure that such contracts include termination provisions for failure to adhere to the required provider’s compliance program requirements.

(4) The required provider is ultimately responsible for the adoption, implementation, maintenance, enforcement, and effectiveness of its compliance program.

(d) Risk areas. The compliance program shall apply to the required provider’s risk areas, which are those areas of operation affected by the compliance program and shall apply to:

(1) billings;

(2) payments;

(3) ordered services;

(4) medical necessity;

(5) quality of care;

(6) governance;

(7) mandatory reporting;

(8) credentialing;

(9) contractor, subcontractor, agent or independent contract oversight;

(10) other risk areas that are or should reasonably be identified by the provider through its organizational experience; and

(11) for MMCOs, in addition to paragraphs (1) – (10) of this subdivision, the following risk areas:

- (i) compliance with terms of the MMCO's contract with the department to participate as an MMCO;
- (ii) cost reporting;
- (iii) submission of encounter data to the department;
- (iv) network adequacy and contracting;
- (v) provider and subcontractor oversight;
- (vi) underutilization;
- (vii) marketing;
- (viii) provision of medically necessary services;
- (ix) payments and claims processing; and
- (x) statistically valid service verification.

(e) The required provider shall comply with all directives of the department or OMIG with respect to the adoption, implementation and maintenance of compliance programs required by this SubPart.

(f) Certification.

(1) Required providers shall certify to the department upon enrollment and annually thereafter, using a form and manner required by OMIG and the department, that the required provider has met the requirements of section 363-d of the Social Services Law and this SubPart.

(2) Participating providers that are also required providers pursuant to this SubPart shall provide a copy of the certification, required under the preceding paragraph, to each MMCO for which they are a participating provider upon signing the provider agreement with the MMCO, and annually thereafter. MMCOs shall maintain a method for submitting such certification on

the MMCO's website, which may include a dedicated email address, and shall retain such certification in accordance with the requirements of subdivision (b) of this section.

(g) Report, return and explain. Required providers shall comply with the requirements of SubPart 521-3 of this Part to report, return and explain overpayments.

521-1.4 Compliance program requirements.

(a) Written policies and procedures.

(1) General. Required providers shall have written policies, procedures, and standards of conduct. The required provider shall establish a process for drafting, revising, and approving the written policies and procedures required by this subdivision. The written policies and procedures described in this subdivision must be available, accessible, and applicable to all affected individuals.

(2) The written policies and procedures shall:

(i) articulate the required provider's commitment and obligation to comply with all applicable federal and state standards. The required provider shall identify governing laws, and regulations that are applicable to the provider's risk areas, including any MA program policies and procedures, as specified in subdivision (d) of section 521-1.3 of this SubPart or category of service.

(ii) describe compliance expectations as embodied in standards of conduct. The standards of conduct shall serve as a foundational document which describes the required provider's fundamental principles and values, and commitment to conduct its business in an ethical manner.

(iii) document the implementation of each of the subdivisions under this section and outline the ongoing operation of the compliance program. Policies and procedures shall describe, at a minimum, the structure of the compliance program, including the

responsibilities of all affected individuals in carrying out the functions of the compliance program.

(iv) provide guidance to affected individuals on dealing with potential compliance issues.

Such guidance shall, at a minimum:

(a) assist affected individuals in identifying potential compliance issues, questions and concerns, set forth expectations for reporting compliance issues, and explain how to report such issues, questions, and concerns to the compliance officer; and

(b) establish the expectation that all affected individuals will act in accordance with the standards of conduct, that they must refuse to participate in unethical or illegal conduct, and that they must report any unethical or illegal conduct to the compliance officer.

(v) identify the methods and procedures for communicating compliance issues to the appropriate compliance personnel.

(vi) describe how potential compliance issues are investigated and resolved by the required provider and the procedures for documenting the investigation and the resolution or outcome.

(vii) include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to:

(a) reporting potential compliance issues to appropriate personnel;

(b) participating in investigation of potential compliance issues;

(c) self-evaluations;

(d) audits

(e) remedial actions

(f) reporting instances of intimidation or retaliation; and

(g) reporting potential fraud, waste or abuse to the appropriate State or Federal entities.

(viii) Disciplinary standards. Include a written statement setting forth the required provider's policy regarding affected individuals who fail to comply with the written policies and procedures, standards of conduct, or State and Federal laws, rules and regulations.

(a) Such statement shall establish standards for escalating disciplinary actions that must be taken in response to non-compliance, with intentional or reckless behavior being subject to more significant sanctions. Sanctions may include oral or written warnings, suspension, and/or termination.

(b) The written policies and procedures shall also outline the procedures for taking disciplinary action and sanctioning individuals. Disciplinary procedures shall conform with collective bargaining agreements when applicable.

(ix) Additionally, notwithstanding the requirement under 42 U.S.C. 1396a(a)(68), which applies to entities that receive or make annual payments of at least \$5,000,000 annually, all required providers shall comply with the provisions of 42 U.S.C.

1396a(a)(68) (United States Code, 2006 edition, Title 42, Chapter 7, SubChapter XIX, Government Printing Office, <https://www.govinfo.gov/content/pkg/USCODE-2006-title42/pdf/USCODE-2006-title42-chap7-subchapXIX-sec1396a.pdf>. A copy of which is available for copying and inspection at the Office of the Medicaid Inspector General, 800 North Pearl Street, 2nd Floor, Albany, NY 12204).

(x) for MMCOs, describe the MMCO's implementation, where applicable, of the requirements of SubPart 521-2 of this Part.

(3) The required provider shall review the written policies and procedures, and standards of conduct required by this subdivision at least annually to determine:

- (i) if such written policies, procedures, and standards of conduct have been implemented;
- (ii) whether affected individuals are following the policies, procedures, and standards of conduct;
- (iii) whether such policies, procedures, and standards of conduct are effective; and
- (iv) whether any updates are required.

(b) Compliance officer. The required provider shall designate an individual to serve as its compliance officer. The compliance officer is the focal point for the required provider's compliance program and is responsible for the day-to-day operation of the compliance program. The required provider's designation of a compliance officer shall meet the following requirements:

(1) The compliance officer's primary responsibilities shall include:

- (i) overseeing and monitoring the adoption, implementation and maintenance of the compliance program and evaluating its effectiveness;
- (ii) drafting, implementing, and updating no less frequently than annually or, as otherwise necessary, to conform to changes to Federal and State laws, rule, regulations, policies and standards, a compliance work plan which shall outline the required provider's proposed strategy for meeting the requirements of this section for the coming year, with a specific emphasis on subdivisions (a), (d), (g), (h) of this section and, if applicable, SubPart 521-2 of this Part;
- (iii) reviewing and revising the compliance program, and, in accordance with paragraph 3 of subdivision (a) of this section, the written policies and procedures and standards of conduct, to incorporate changes based on the required provider's organizational experience and promptly incorporate changes to Federal and State laws, rules, regulations, policies and standards;

(iv) reporting directly, on a regular basis, but no less frequently than quarterly, to the required provider's governing body, chief executive, and compliance committee on the progress of adopting, implementing, and maintaining the compliance program;

(v) assisting the required provider in establishing methods to improve the required provider's efficiency, quality of services, and reducing the required provider's vulnerability to fraud, waste and abuse;

(vi) investigating and independently acting on matters related to the compliance program, including designing and coordinating internal investigations and documenting, reporting, coordinating, and pursuing any resulting corrective action with all internal departments, contractors and the State; and

(vii) the compliance officer shall be responsible for coordinating the implementation of the fraud, waste, and abuse prevention program with the director and lead investigator of the MMCO's special investigation unit pursuant to SubPart 521-2 of this Part, if applicable.

(2) The compliance officer shall report directly and be accountable to the required provider's chief executive or another senior manager whom the chief executive may designate for reporting purposes provided, however, such designation does not hinder the compliance officer in carrying out their duties and having access to the chief executive and governing body.

(3) The responsibilities in paragraph (1) of this subdivision may be the compliance officer's sole duties or, depending on the size, complexity, resources, and culture of the required provider and the complexity of the tasks, 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 under this SubPart.

(4) The required provider shall ensure that the compliance officer is allocated sufficient staff and resources to satisfactorily perform their responsibilities for the day-to-day operation of the compliance program based on the required provider's risk areas and organizational experience.

(5) The required provider shall ensure that the compliance officer and appropriate compliance personnel have access to all records, documents, information, facilities and affected individuals that are relevant to carrying out their compliance program responsibilities.

(c) Compliance committee. The required provider shall designate a compliance committee which shall be responsible for coordinating with the compliance officer to ensure that the required provider is conducting its business in an ethical and responsible manner, consistent with its compliance program. The required provider shall outline the duties and responsibilities, membership, designation of a chair and frequency of meetings in a compliance committee charter. The required provider's designation of a compliance committee shall meet the following requirements:

(1) The compliance committee's responsibilities shall include:

(i) coordinating with the compliance officer to ensure that the written policies and procedures, and standards of conduct required by subdivision (a) of this section are current, accurate and complete, and that the training topics required by subdivision (d) of this section are timely completed;

(ii) coordinating with the compliance officer to ensure communication and cooperation by affected individuals on compliance related issues, internal or external audits, or any other function or activity required by this SubPart;

(iii) advocating for the allocation of sufficient funding, resources and staff for the compliance officer to fully perform their responsibilities;

- (iv) ensuring that the required provider has effective systems and processes in place to identify compliance program risks, overpayments and other issues, and effective policies and procedures for correcting and reporting such issues; and
- (v) advocating for adoption and implementation of required modifications to the compliance program.

(2) Membership in the committee shall, at a minimum, be comprised of senior managers. The compliance committee shall meet no less frequently than quarterly and shall, no less frequently than annually, review and update the compliance committee charter.

(3) The compliance committee shall report directly and be accountable to the required provider's chief executive and governing body.

(d) Training and education. The required provider shall establish and implement an effective compliance training and education program for its compliance officer and all affected individuals. The required provider's compliance training and education program shall meet the following requirements:

- (1) The training and education shall include, at a minimum, the following topics:
 - (i) the required provider's risk areas and organizational experience;
 - (ii) the required provider's written policies and procedures identified in subdivision (a) of this section;
 - (iii) the role of the compliance officer and the compliance committee;
 - (iv) how affected individuals can ask questions and report potential compliance-related issues to the 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 the protection from intimidation and retaliation for good faith participation in the compliance program;
 - (v) disciplinary standards, with an emphasis on those standards related to the required provider's compliance program and prevention of fraud, waste and abuse;

- (vi) how the required provider responds to compliance issues and implements corrective action plans;
- (vii) requirements specific to the MA program and the required provider's category or categories of service;
- (viii) coding and billing requirements and best practices, if applicable;
- (ix) claim development and the submission process, if applicable; and
- (x) for MMCOs only, the fraud, waste and abuse prevention program, as specified in SubPart 521-2 of this Part, and any applicable terms of the MMCO's contract with the department to participate as an MMCO.

(2) The compliance officer and all affected individuals shall complete the compliance training program required by this subdivision no less frequently than annually. The training and education required by this subdivision shall be made a part of the orientation of new compliance officers and affected individuals and shall occur promptly upon hiring.

(3) Training and education shall be provided in a form and format accessible and understandable to all affected individuals, consistent with Federal and State language and other access laws, rules or policies.

(4) The required provider shall develop and maintain a training plan. The training plan shall, at a minimum, outline the subjects or topics for training and education, the timing and frequency of the training, which affected individuals are required to attend, how attendance will be tracked, and how the effectiveness of the training will be periodically evaluated.

(e) Lines of communication. The required provider shall establish and implement effective lines of communication which ensure confidentiality for the required provider's affected individuals. In designing its lines of communication, the required provider shall meet the following requirements:

(1) The lines of communication shall be accessible to all affected individuals and allow for questions regarding compliance issues to be asked and for compliance issues to be reported.

(2) The required provider shall publicize the lines of communication to the compliance officer and such lines of communication must be made available to all affected individuals and all MA recipients of service from the required provider.

(3) The required provider shall have a method for anonymous reporting of potential fraud, waste and abuse, and compliance issues directly to the compliance officer.

(4) The required provider must ensure that 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 the required provider's policy for non-intimidation and non-retaliation.

(5) If applicable, the required provider shall make available on its website, information concerning its compliance program, including its standards of conduct.

(f) Disciplinary standards. The required provider shall establish disciplinary standards and shall implement procedures for the enforcement of such standards to address potential violations and encourage good faith participation in the compliance program by all affected individuals. In developing and enforcing its disciplinary standards, the required provider shall meet the following requirements:

(1) The written policies and procedures establishing, pursuant to subdivision (a) of this section, the required provider's disciplinary standards and the procedures for taking such actions shall be published and disseminated to all affected individuals and shall be incorporated into the required provider's training plan as set forth in subdivision (d) of this section.

(2) The required provider shall enforce its disciplinary standards fairly and consistently, and the same disciplinary action should apply to all levels of personnel.

(g) Auditing and monitoring. The required provider shall establish and implement an effective system for the routine monitoring and identification of compliance risks. The system should include internal

monitoring and audits and, as appropriate, external audits, to evaluate the organization's compliance with the requirements of the MA program and the overall effectiveness of the required provider's compliance program. In developing its auditing and monitoring program the required provider shall meet the following requirements:

(1) Auditing. Required providers shall perform routine audits by internal or external auditors who have expertise in state and federal MA program requirements and applicable laws, rules and regulations, or have expertise in the subject area of the audit. Audits or investigations conducted by state or federal governmental entities are not considered external audits for purposes of this paragraph. The audits required by this paragraph shall meet the following requirements:

(i) Internal and external compliance audits shall focus on the risk areas identified in section 521-1.3 of this SubPart.

(ii) The results of all internal or external audits, or audits conducted by the State or Federal government of the required provider, shall be reviewed for risk areas that can be included in updates to the required provider's compliance program and compliance work plan.

(iii) The design, implementation, and results of any internal or external audits shall be documented, and the results shared with the compliance committee and the governing body.

(iv) Any MA program overpayments identified shall be reported, returned and explained in accordance with the provisions of SubPart 521-3 of this Part and the required provider shall promptly take corrective action to prevent recurrence.

(2) Annual compliance program review. The required provider shall develop and undertake a process for reviewing, at least annually, whether the requirements of this SubPart have been

met. The purpose of such reviews shall be to determine the effectiveness of its compliance program, and whether any revision or corrective action is required.

(i) The reviews may be carried out by the compliance officer, compliance committee, external auditors, or other staff designated by the required provider, provided however, that such 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.

(ii) The reviews should include on-site visits, interviews with affected individuals, review of records, surveys, or any other comparable method the required provider deems appropriate, provided that such method does not compromise the independence or integrity of the review.

(iii) The required provider shall document the design, implementation and results of its effectiveness review, and any corrective action implemented.

(iv) The results of annual compliance program reviews shall be shared with the chief executive, senior management, compliance committee and the governing body.

(3) Excluded providers. In accordance with the requirements of section 515.5 of this Title, required providers shall 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 to participate as an MMCO, including its participating providers and its subcontractors.

(i) In determining the exclusion status of a person required providers shall review the following State and Federal databases at least every thirty (30) days:

(a) New York State Office of the Medicaid Inspector General Exclusion List;

(b) Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities; and

(c) for MMCOs only, any other list or database required by the contract between the MMCO and the department to participate as an MMCO.

(ii) Required providers shall require contractors to comply with the provisions of this paragraph. In addition, MMCOs shall require their participating providers and subcontractors to comply, where applicable, with the provisions of this paragraph.

(4) The required provider shall promptly share the results of the activities required by this subdivision with the compliance officer and appropriate compliance personnel.

(h) Responding to compliance issues. The required provider shall establish and implement procedures and systems for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of the internal auditing and monitoring conducted pursuant to subdivision (g) of this section, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with State and Federal laws, rules and regulations, and requirements of the MA program. In developing its system for responding to compliance program issues, the required provider shall meet the following requirements:

(1) Upon the detection of potential compliance risks and compliance issues, whether through reports received, or as a result of the auditing and monitoring conducted pursuant to subdivision (g) of this section, the required provider shall take prompt action to investigate the conduct in question and determine what, if any, corrective action is required, and likewise promptly implement such corrective action.

(2) The required provider shall document its investigation of the compliance issue which shall include any alleged violations, a description of the investigative process, copies of interview notes and other documents essential for demonstrating that the required provider completed a thorough investigation of the issue. Where appropriate, the required provider may retain outside experts, auditors, or counsel to assist with the investigation.

(3) The required provider shall document any disciplinary action taken and the corrective action implemented.

(4) If the required provider identifies credible evidence or credibly believes that a State or Federal law, rule or regulation has been violated, the required provider shall promptly report such violation to the appropriate governmental entity, where such reporting is otherwise required by law, rule or regulation. The compliance officer shall receive copies of any reports submitted to governmental entities.

521-1.5 Compliance program reviews.

(a) Nothing in this SubPart shall preclude or limit the department's ability to determine if a required provider has an effective compliance program.

(b) OMIG may, at any time, review to determine if a required provider has adopted, implemented and maintained a compliance program as required by this SubPart, and to confirm that:

(1) the adopted compliance program satisfies the requirements of this SubPart;

(2) the adopted compliance program has been implemented and that the required provider has continuously operated such program for the entire period under review;

(3) that the required provider met the criteria requiring the adoption, implementation and maintenance of such programs; and

(4) the adopted, implemented and maintained compliance program is effective.

(c) Notification.

(1) OMIG shall notify a required provider of its intent to commence a review of its compliance program by sending the required provider written notification of the review period and procedures for completing the review. The notification shall be sent to the required provider's correspondence or pay-to address on file with the department, or last known address. The notification shall include the legal authority for the review, outline the process and timeframes for completing the review, and list any documentation the required provider must provide.

(2) The required provider shall provide its responses in the form and manner prescribed by OMIG, including any requested records, within thirty (30) days of the date on OMIG's notification of its intent to commence a compliance program review. For good cause shown, OMIG may extend the thirty (30) day period to respond.

(3) The provisions of this section notwithstanding, OMIG may separately review an MMCO's compliance program as part of a Medicaid program integrity review pursuant to subdivision 36 of section 364-j of the Social Services Law.

(d) Determination. After completing its review OMIG shall notify the required provider of the results of its review. The notice shall:

(1) advise the required provider whether its compliance program satisfactorily met the requirements of this SubPart;

(2) advise the required provider of any recommendations for improving its compliance program or correcting deficiencies; or

(3) where OMIG has determined that a required provider has not satisfactorily met the requirements of Social Services Law section 363-d and the requirements of this SubPart, OMIG will advise the required provider that, in addition to any other action authorized by law, it may be subject to monetary penalties pursuant to Part 516 of this Title, and that its participation in the Medicaid program may be revoked (terminated) pursuant to Part 504 of this Title.

SUBPART 521-2 MEDICAID MANAGED CARE FRAUD, WASTE AND ABUSE PREVENTION

521-2.1 Scope and applicability

521-2.2 Definitions

521-2.3 MMCO duties

521-2.4 Fraud, waste and abuse prevention program requirements

521-2.1 Scope and applicability.

(a) Scope. Social Services Law requires managed care providers, including managed long term care plans, to adopt and implement programs designed to detect and prevent fraud, waste and abuse in the MA program. This SubPart sets forth the standards for managed care fraud, waste and abuse prevention programs pursuant to subdivision 39 of section 364-j of the Social Services Law.

(b) Applicability. This SubPart applies to managed care providers and includes managed care long term care plans, which shall hereinafter be collectively, unless otherwise noted, referred to as “Medicaid managed care organizations” or “MMCO.”

(c) Related regulations. Section 98-1.21 of Title 10 and section 86.6 of Title 11 set forth requirements related to the establishment and operation, for certain managed care plans, of fraud and abuse prevention plans and programs. MMCOs subject to those sections shall continue to comply with such requirements, provided that, as it pertains to the MMCO’s participation in the MA program, the requirements of this SubPart are met. To the extent that any requirements of this SubPart conflict with or are greater than the requirements of those sections, the requirements of this SubPart shall apply to the MMCO.

521-2.2 Definitions.

(a) For purposes of this SubPart, the terms defined in Parts 504 and 515 of this Title, and SubPart 521-1 of this Part, unless noted otherwise, shall apply.

(b) In addition, for the purposes of this SubPart, the following terms have the following meanings:

(1) “*Abuse*” means practices that are inconsistent with sound fiscal, business, medical or professional practices, and which result in unnecessary costs to the Medicaid program, payments for services that were not medically necessary, or payments for services which fail to meet recognized standards for health care. It also includes enrollee practices that result in unnecessary costs to the Medicaid program.

(2) “*Fraud*” means an intentional deception or misrepresentation made with the knowledge that the deception could result in some unauthorized benefit to the provider, Contractor, Subcontractor, or another person and includes the acts prohibited by section 366-b of the Social Services Law. It also includes any other act that constitutes fraud under applicable Federal or State law.

521-2.3 MMCO duties.

(a) General. MMCOs shall adopt and implement policies and procedures designed to detect and prevent fraud, waste and abuse. Such policies and procedures shall satisfy the requirements of this SubPart. The MMCO’s fraud, waste, and abuse prevention program may be a component of more comprehensive fraud, waste and abuse prevention activities by the MMCO, so long as the requirements of this SubPart are met.

(b) Record retention, access to records and facilities, and cooperation with OMIG, Department and MFCU requests. In addition to the MMCO’s record retention obligations under the MMCO’s contract with the department to participate as an MMCO, an MMCO shall retain all records demonstrating that it has adopted, implemented and operated a fraud, waste and abuse prevention program which has satisfied the requirements of this SubPart.

(1) The MMCO and its subcontractors shall retain records in accordance with the requirements of its contract with the department to participate as an MMCO.

(2) The MMCO and its subcontractors shall provide to OMIG, the department or their authorized representatives, and MFCU, all records and information requested, in the form

requested, and allow access to their facilities at any time. All copies of records must be provided free of charge. The MMCO and its subcontractors shall comply with any additional terms regarding access to records in accordance with the terms of its contract with the department to participate as an MMCO.

(3) The MMCO and its subcontractor shall permit OMIG, the department and MFCU to conduct private interviews of MMCO personnel, its subcontractors and their personnel, witnesses, and enrollees. MMCO personnel, and subcontractors and their personnel must cooperate fully in making MMCO personnel, subcontractors and their personnel available in person for interviews, consultation, grand jury proceedings, pre-trial conferences, hearings, trial and in any other process, including investigation, at the MMCO's and subcontractor's own expense.

(c) Contractors, agents, subcontractors, and independent contractors. MMCOs shall ensure that contracts with contractors, agents, subcontractors, independent contractors, and participating providers specify that the contractors, agents, subcontractors, independent contractors, and participating providers are subject to audit, investigation, or review under the MMCO's fraud, waste and abuse prevention program, to the extent that such contractors, agents, subcontractors, independent contractors, and participating providers relate to the MMCO's participation in the MA program.

521-2.4 Fraud, waste and abuse prevention program requirements.

(a) Compliance program. The MMCO shall adopt, implement and maintain a compliance program that satisfies the requirements of SubPart 521-1 of this Part. The MMCO shall be responsible for ensuring that the requirements of its fraud, waste and abuse prevention program are incorporated into its compliance program. Specifically, the MMCO shall:

(1) incorporate into the written policies and procedures required by subdivision (a) of section 521-1.4 of this Part, the MMCO's policies and procedures for preventing, detecting and investigating fraudulent, wasteful or abusive activities by its participating providers, non-

participating providers, contractors, agents, subcontractors, independent contractors, and any other person the MMCO or its subcontractors pay for ordering, providing, furnishing or arranging for a service to a MA program recipient. The MMCO shall also incorporate any other policies and procedures related to its obligations under this SubPart;

(2) require its designated compliance officer, as required by subdivision (b) of section 521-1.4 of this Part, to be responsible, except where noted, for implementing the requirements of this SubPart, and shall be responsible for coordinating with the MMCO's SIU director, where applicable;

(3) include, as part of the training required by subdivision (d) of section 521-1.4 of this Part, training of all personnel involved in identifying and evaluating instances of potential fraud, waste and abuse; and

(4) include, as part of its auditing and monitoring activities as required by subdivision (g) of section 521-1.4 of this Part, the requirements of subdivision (c) of this section.

(b) Special investigation unit (SIU). If the MMCO has an enrolled population of one thousand (1,000) or more persons in the aggregate in any given year, the MMCO shall establish a full-time SIU to identify risk and to detect and investigate cases of potential fraud, waste and abuse, report such cases to OMIG, and electively report potential fraud to MFCU, in accordance with the provisions of this SubPart and the terms of the MMCO's contract with the department to participate as an MMCO. The SIU must be separate and distinct from any other unit or function of the MMCO. In establishing its SIU, the MMCO shall meet the following requirements:

(1) Staffing requirements. The MMCO shall dedicate sufficient staff and resources to the SIU to effectively detect and prevent fraud, waste and abuse in the New York State MA program.

(i) The MMCO shall employ at least one full-time lead investigator and one SIU director who shall be based in the State of New York and be responsible for communicating and coordinating with OMIG or MFCU with respect to:

- (a) conducting fraud, waste and abuse investigations;
- (b) making fraud, waste and abuse referrals;
- (c) preparing investigatory reports;
- (d) investigating and remediating conflicts of interest;
- (e) identifying and recovering overpayments;
- (f) conducting provider terminations, education or re-education, and other related actions;
- (g) implementing the fraud, waste and abuse prevention program required by this SubPart;
- (h) participating in any meetings required by OMIG; and
- (i) participating in any meetings required by MFCU

(ii) The MMCO shall employ at least one (1) full-time investigator per sixty thousand (60,000) enrollees, except in the case of an MLTCP, which shall employ at least one (1) full-time investigator per six thousand (6,000) enrollees. The MMCO shall employ investigators dedicated to servicing a particular county when that county on its own meets the designated investigator-to-enrollee ratio required by this paragraph. An MMCO may propose for OMIG's consideration alternative minimum staffing levels, provided the MMCO demonstrates to OMIG's satisfaction that its proposal would be no less effective than those required by this subparagraph and that the requirements of this SubPart can be fully met. The MMCO must apply for and receive written approval from OMIG of any alternative staffing levels prior to the implementation of any alternative minimum staffing levels. The approval or denial of any alternative staffing level proposal is at the discretion of the Medicaid Inspector General or their designee, and such approval may be rescinded by the Medicaid Inspector General or their designee with ninety 90 days' notice.

(iii) In addition to investigators, the MMCO shall also employ or utilize existing employees who are certified coders, clinicians, data analysts, or pharmacists to support the work of the SIU.

(2) SIU investigator qualifications. Persons employed by the SIU as investigators shall be qualified by education or experience, which shall include:

- (i) a minimum of five years in the healthcare field working in fraud, waste, and abuse investigations and audits, or five years of insurance claims investigation experience or professional investigation experience with law enforcement agencies, or seven years of professional investigation experience involving economic or insurance related matters;
- (ii) an associate's or bachelor's degree in criminal justice or a related field; or
- (iii) employment as an investigator in the MMCO's SIU on or before the effective date of this SubPart.

(3) SIU work plan. No less frequently than annually, the SIU shall prepare a work plan outlining the activities that it plans to complete in the coming year. The SIU shall consider the MMCO's risk areas, as specified in SubPart 521-1 of this Part, and organizational experience in developing the work plan. The SIU work plan may be a standalone document, or a component of its larger compliance work plan required by SubPart 521-1 of this Part.

(4) Delegation. The MMCO may delegate all or part of the functions of the SIU under this subdivision, provided, however, that it shall be no defense to enforcement of this SubPart that a subcontractor failed to provide effective service enabling the MMCO to comply with its obligations. The MMCO is ultimately responsible for meeting the requirements of this SubPart.

- (i) The MMCO shall require that the subcontractor to whom it delegates the SIU function comply with all the requirements of this subdivision, and any other relevant requirements under this SubPart. The MMCO shall also require that the subcontractor cooperate fully with OMIG in any examination of the implementation of the fraud, waste

and abuse prevention program required by this SubPart and provide any and all assistance requested by OMIG, the department, MFCU and any other law enforcement agency or any prosecutorial agency in the investigation of fraud, waste and abuse, and the prosecution of fraud and abuse and related crimes.

(ii) The MMCO shall review any contract for SIU functions to determine if it delegates any management authority. An MMCO shall not enter into any agreement delegating management authority except pursuant to a management contract which complies with the requirements of subdivisions (h) through (s) of section 98-1.11 of Title 10 and section 98-1.18 of Title 10.

(iii) If the MMCO enters into a management contract for all or part of its SIU function, the management contract shall be submitted to the department and OMIG, and included as part of the fraud, waste and abuse prevention plan required by subdivision (i) of this section.

(c) MMCO audits and investigations. In addition to the auditing and monitoring requirements of subdivision (g) of section 521-1.4 of this Part, the MMCO shall audit, investigate, or review cases of fraud, waste or abuse specific to its participation in the MA program, and the MMCO's risk areas as specified in SubPart 521-1 of this Part. The MMCO shall conduct such audits, investigations or reviews in accordance with the following requirements and as specified in the contract between the MMCO and the department to participate as an MMCO:

(1) The MMCO's SIU, if applicable, shall be primarily responsible for performing, or collaborating with and monitoring those individuals performing, such audits, investigations and reviews, and shall coordinate with the MMCO's designated compliance officer.

(2) Such audits, investigations and reviews must involve at least one percent (1%) or more of the aggregate of MA program claims it pays to providers and subcontractors, based on the total prior year's claims paid by the MMCO. Such audits, investigations and reviews may

review claims consistent with any lookback period established in the MMCO's contract with the Department to participate as an MMCO.

(3) Such audits, investigations and reviews must be of clinical and billing records to verify that no duplicate payments were made, appropriate services were rendered and billed, appropriate procedure codes were utilized, and accurate encounter data was reported to the department.

(d) Reporting cases of fraud, waste and abuse. The MMCO and its subcontractors shall report all cases of potential fraud, waste and abuse to OMIG. The MMCO may also report cases of potential fraud to the MFCU. In reporting such cases, the MMCO shall comply with the terms of its contract with the department to participate as an MMCO. The reports shall be reviewed and signed by an executive officer of the MMCO responsible for the operations of the SIU. In addition, the MMCO shall include the following information when reporting potential fraud, waste and abuse to OMIG:

(1) Information about the subject of the report, including:

- (i) the name of the person or provider;
- (ii) the provider's Medicaid provider ID, if applicable;
- (iii) the person's or provider's national provider ID, if applicable;
- (iv) the person's or provider's address;
- (v) the type of provider; and
- (vi) any other information requested by OMIG.

(2) The source and origin of the allegation;

(3) The date the allegation was first reported to the MMCO, or the MMCO first became aware of the allegation;

(4) A summary of the investigation, which shall be in a form and format approved by OMIG;

(5) A description of the suspected misconduct, with specific details including:

- (i) the category of service;
- (ii) a factual explanation of the allegation;

(iii) the specific MA program statutes, rules, regulations, and/or policies violated; and

(iv) the date(s) of the conduct.

(6) The amount the MMCO paid to the person or provider during the past three (3) years or during the period of the alleged misconduct, whichever is greater;

(7) All communications between the MMCO and the provider or person concerning the conduct at issue;

(8) The contact information for the MMCO SIU director, lead investigator, investigator(s) and staff with knowledge of the case;

(9) An estimate of the overpayment, when available; and

(10) Copies of the investigation file and related material.

(e) The MMCO and its subcontractors shall immediately refer reasonably suspected criminal activity to OMIG and MFCU in accordance with the requirements specified in the MMCO's contract with the department to participate as an MMCO.

(f) Report, return and explain. The MMCO shall establish policies and procedures in accordance with the requirements of section 363-d of the Social Services Law for its participating providers and other subcontractors to report, return and explain overpayments to the MMCO within sixty (60) days of identification. The MMCO shall promptly report all recoveries, including recoveries which result from a provider or subcontractor reporting, returning and explaining an overpayment under this subdivision:

(1) in its cost reports to the department, and in accordance with the instructions and directives of the department; and

(2) in a monthly report to OMIG in a form and format to be determined by OMIG, or as otherwise specified in its contract with the department to participate as an MMCO.

(g) The MMCO shall develop a fraud, waste and abuse detection procedures manual for use by officers, directors, managers, personnel, and subcontractors performing claims underwriting, member services, utilization management, complaint, investigative and/or SIU services.

(h) Other program integrity requirements.

(1) 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.

(2) The MMCO shall make available on its website information on how and where to report, return and explain overpayments to the MMCO, in accordance with the requirements of subdivision (f) of this section.

(i) Fraud, waste and abuse prevention plan.

(1) Within ninety (90) calendar days of the effective date of this SubPart or of signing a new contract with the department to begin participation as an MMCO, the MMCO shall develop a fraud, waste and abuse prevention plan and shall submit such plan to OMIG.

(2) The MMCO shall review and update such plan no less frequently than annually.

(3) The plan shall include:

(i) a description of the MMCO's program for preventing and detecting fraud, waste and abuse;

(ii) a description, if applicable, of the organization of the SIU, including:

(a) titles and job descriptions of the investigators, investigative supervisors and other staff;

(b) the minimum qualifications for employment in these positions in addition to those qualifications required by this section;

- (c) the geographical location and assigned territory of each investigator and investigative supervisor;
- (d) the support staff and other physical resources, including database access available to the SIU; and
- (e) the supervisory and reporting structure within the SIU and between the SIU and senior management of the MMCO.

(iii) If investigators employed by the unit will be responsible for investigating cases in more than one state, the plan must apportion that percentage of the investigators' efforts that will be devoted to New York cases;

(iv) the rationale, if applicable and different from the minimum staffing levels required by subdivision (b) of this section, for the level of staffing and resources of the SIU which may include, but is not limited to, objective criteria such as the number of claims received with respect to the MMCO's participation in the New York State MA program on an annual basis, volume of potential fraud, waste and abuse for the MMCO's New York MA claims currently being detected, other factors relating to the vulnerability of the MMCO to fraud, waste and abuse, and an assessment of optimal caseload which can be handled by an investigator on an annual basis;

(v) a description of the roles, responsibilities and interaction between the MMCO's:

- (a) designated compliance officer responsible for carrying out the provisions of the fraud, waste and abuse prevention program and the SIU;

- (b) SIU and the claims, quality, member services, utilization review, complaint procedures and underwriting functions of the MMCO for the purpose of enhancing the ability of the MMCO to detect fraud, waste and abuse and to increase the likelihood of its successful prosecution, and for the initiation of civil action when appropriate;

(c) SIU and the MMCO's legal department; and

(d) SIU and OMIG, the department, MFCU, or other law enforcement agencies and prosecutors;

(vi) the MMCO's policies and procedures required by paragraph (1) of subdivision (a) of this section;

(vii) the criteria the MMCO uses for the internal referral of a case to the SIU for evaluation, and the criteria the SIU utilizes for reporting cases of potential fraud, waste and abuse to the department and OMIG in accordance with subdivision (d) of this section;

(viii) a description of the specific controls in place for the prevention and detection of potential fraud, waste and abuse, including a list of any automated pre-payment claims edits and a list of any automated post-payment review of claims;

(ix) a description of the training required by paragraph (3) of subdivision (a) of this section;

(x) the timetable for the implementation of the fraud, waste and abuse prevention plan, provided however, that the period preceding implementation shall not exceed one hundred and eighty (180) calendar days from the date the MMCO executes its contract with the department to participate as an MMCO and develops its fraud, waste and abuse prevention plan pursuant to paragraph (1) of this subdivision.

(4) A fraud and abuse prevention plan developed in accordance with the provisions of section 98-1.21 of Title 10 or section 86.6 of Title 11 will satisfy the requirements of this subdivision, provided that the MMCO includes any additional information required by this subdivision.

(j) Annual report. The MMCO shall on or before a date specified by OMIG, which shall be no sooner than January 31 of each calendar year, file with OMIG, in a form and format approved by OMIG, an

annual report for the preceding calendar year, demonstrating that it has satisfied the requirements of this SubPart. Such report shall, at a minimum, include:

- (1) a description of the MMCO's experience, performance and cost effectiveness in implementing the fraud, waste and abuse prevention program;
- (2) the MMCO's proposals for modifications to its fraud, waste and abuse prevention program and plan, to amend its operations, to improve performance or to remedy observed deficiencies;
- (3) a summary of the MMCO's SIU staffing;
- (4) a summary of the activities of the MMCO's subcontractors or vendors who perform audit, investigation or review functions for the MMCO;
- (5) the total number of reported cases of potential fraud, waste or abuse identified by the MMCO, its subcontractor(s) or vendor(s);
- (6) the MMCO's SIU work plan for the next calendar year;
- (7) results of service verification reviews as specified in the MMCO's contract with the department to participate as an MMCO; and
- (8) any other information or data that OMIG may require relevant to the requirements of this SubPart or related requirements under the MMCO's contract with the department to participate as an MMCO.

(k) Notwithstanding any requirement to report using forms or formats approved by OMIG under this SubPart or under the MMCO's contract with the department to participate as an MMCO, in the event that such form or format has not been promulgated, the MMCO shall report the substantive information required by this SubPart or the contract.

18 NYCRR SUBPART 521-3 SELF-DISCLOSURE PROGRAM

521-3.1 Scope and applicability

521-3.2 Definitions

521-3.3 Reporting and returning overpayments

521-3.4 Self-Disclosure Program

521-3.5 Returning the overpayment

521-3.6 Notification

521-3.7 Enforcement

521-3.1 Scope and applicability.

(a) Scope.

(1) Subdivision 6 of the section 363-d of the Social Services Law requires persons who have received an overpayment under the MA program to report, return and explain the overpayment to the department and the Office of Medicaid Inspector General (“OMIG”).

(2) A person satisfies their obligation to report, return and explain by making a disclosure through OMIG’s Self-Disclosure Program, complying with the requirements as specified in section 521-3.4 of this SubPart, and returning the overpayment and interest to the department in accordance with the provisions of section 521-3.5 of this SubPart.

(b) Applicability. This SubPart applies to persons who have received an overpayment under the MA program.

(c) Related requirements. 42 U.S.C. § 1320a-7k(d) requires persons who have received an overpayment from the MA program to report, return and explain the overpayment to the Federal Department of Health and Human Services, the State, or appropriate fiscal intermediary.

521-3.2 Definitions.

(a) For purposes of this SubPart, the terms defined in Parts 504 and 515 of this Title, and SubPart 521-1 of this Part, except as otherwise noted in this SubPart, shall apply.

(b) In addition, for the purposes of this SubPart, the following terms have the following meanings:

(1) “*Managed long term care plan*” means an entity that has received a certificate of authority pursuant to section 4403-f of the Public Health Law to provide or arrange for health and long term care services on a capitated basis for a population which the plan is authorized to enroll.

(2) “*MMCO*” means:

(i) a managed care provider as defined in in subdivision 1 of section 364-j of the Social Services Law; and

(ii) a managed long term care plan.

(3) “*Overpayment*” has the same meaning as used in subdivision (c) of section 518.1 of this Title.

(4) “*Person*” means:

(i) a provider as defined in section 504.1 of this Title;

(ii) an MMCO, and any subcontractors or network providers of an MMCO; and

(iii) does not include MA program recipients.

(5) “*Self-Disclosure and Compliance Agreement*” or “*SDCA*” means the stipulation of settlement between OMIG and a person who agrees to repay the MA program the amount of the overpayment and interest in accordance with the provisions of section 518.4 of this Title through installment payments and/or agrees to implement corrective action to prevent recurrence of the conduct giving rise to the overpayment.

521-3.3 Reporting and returning overpayments.

(a) General. Any person who has received an overpayment under the MA program, directly or indirectly, shall report, return and explain the overpayment by submission of a Self-Disclosure Statement to OMIG’s Self-Disclosure Program pursuant to section 521-3.4 of this SubPart.

(b) Deadline for reporting and returning overpayments.

(1) If a person has received an overpayment under the MA program, the person shall report and return the overpayment and interest if applicable to the department, and explain the reasons for the overpayment to OMIG by the later of:

(i) the date which is sixty (60) days after the date on which the overpayment was identified; or

(ii) the date any corresponding cost report is due, if applicable.

(2) Pursuant to paragraph (b) of subdivision 6 of section 363-d of the Social Services Law, a person has identified an overpayment when that person has or should have through the exercise of reasonable diligence, determined that they have received an overpayment and quantified the amount of the overpayment.

(3) Where a person fails to exercise reasonable diligence, and the person in fact received an overpayment, they shall be subject to any enforcement action authorized by section 521-3.7 of this SubPart and any applicable provisions of federal and state law, including but not limited to Article XIII of the New York State Finance Law.

(4) Pursuant to paragraph (c) of subdivision 6 of section 363-d of the Social Services Law, the deadline for reporting, returning and explaining an overpayment shall be tolled when OMIG acknowledges receipt of a submission of a Self-Disclosure Statement to its Self-Disclosure Program pursuant to section 521-3.4 of this SubPart, and shall remain tolled until such time:

(i) that an SDCA, in accordance with subdivision (e) of section 521-3.4 of this SubPart, is executed by both the person reporting, returning and explaining the overpayment and OMIG, if applicable;

(ii) the person withdraws from the Self-Disclosure Program;

(iii) the person repays the full amount of the overpayment along with any interest due, as determined by OMIG after review of a person's disclosure, in accordance with the provisions of section 521-3.5 of this SubPart; or

(iv) OMIG terminates, pursuant to subdivision (f) of section 521-3.4 of this SubPart, the person's participation in the Self-Disclosure Program.

(5) For an overpayment made by an MMCO to the person under the MA program. A person who reports, returns and explains an overpayment to an MMCO, in accordance with the provisions of subdivision (f) of section 521-2.4 of this Part shall be considered to have satisfied the requirements of subdivision 6 of section 363-d of the Social Services Law, provided that the overpayment is reported and returned to the MMCO by the deadline specified in paragraph (1) of this subdivision.

521-3.4 Self-Disclosure Program.

(a) General. Pursuant to subdivision 7 of section 363-d of the Social Services Law, the OMIG's Self-Disclosure Program is the process by which persons who have identified an overpayment under the MA program report, return and explain overpayments to the MA program. Persons required to report, return and explain overpayments pursuant to section 521-3.3 of this SubPart shall submit information regarding the overpayment to OMIG and make repayment in the form and manner set forth in this section.

(b) Self-Disclosure Program - General Provisions.

(1) Eligibility. A person is eligible to participate in the Self-Disclosure Program if:

- (i) the person is not currently under audit, investigation, or review by OMIG. If the person is under audit, investigation, or review, but the overpayment being disclosed does not relate to the existing audit, investigation, or review the person shall be eligible to participate, with respect to the overpayment being disclosed. For purposes of this paragraph, an audit, investigation, or review includes, but is not limited to, Parts 515, 516, 517, 518 and 521 of this Title;
- (ii) the person is disclosing an overpayment and related conduct that OMIG has not identified at the time of the disclosure;

(iii) the overpayment and related conduct are reported by the deadline specified in

paragraph (1) of subdivision (b) of section 521-3.3 of this SubPart; and

(iv) the person is not currently a party to or the subject of any criminal investigation, related to their participation in the MA program, being conducted by the MFCU or an agency of the United States Government or any political subdivision thereof.

(2) For persons eligible to participate in the Self-Disclosure Program, pursuant to paragraph (1) of this subdivision, OMIG, in its sole discretion, after a written request from an eligible person participating in the Self-Disclosure Program, may:

(i) waive the imposition of interest on the amount of the overpayment, in whole or in part;

(ii) permit repayment through installments pursuant to an SDCA;

(iii) in accordance with the provisions of subdivision 18 of section 32 of the Public Health Law, consider the person's reporting and returning overpayments as a mitigating factor in the determination of an administrative enforcement action; and

(iv) for persons subject to the provisions of SubPart 521-1 of this Part and in accordance with section 363-d of the Social Services Law, consider the person's reporting and returning overpayments as a factor in determining whether the person has adopted and implemented an effective compliance program.

(3) Regardless of eligibility, if the person has determined that they have received an overpayment pursuant to section 521-3.3 of this SubPart, the person shall submit a Self-Disclosure Statement pursuant to subdivision (c) of this section.

(4) If OMIG determines that a person is ineligible, it shall notify the person of this determination in writing, in accordance with the requirements of subdivision (a) of section 521-3.6 of this SubPart.

(c) Self-Disclosure Statement.

(1) As a condition of participation in the Self-Disclosure Program, the person shall apply by the submission of a self-disclosure statement, cooperate and furnish any information requested, including any additional data, documentation, or information requested by the OMIG needed to confirm the overpayment.

(2) To participate in the Self-Disclosure Program, a person shall submit a statement which shall contain the following information:

(i) An estimate of the amount of the overpayment. The person shall calculate the estimated overpayment and provide information to OMIG which supports the calculated overpayment amount. OMIG has the sole discretion to approve the methodology used for the calculation and to determine the overpayment amount and interest if applicable;

(ii) A detailed explanation of the reason the person received the overpayment, which shall, at a minimum include:

(a) a description and explanation of the circumstances that gave rise to the overpayment;

(b) how the circumstances giving rise to the overpayment were discovered;

(c) the date the overpayment was identified;

(d) how the person calculated the amount of the overpayment;

(e) the date(s) the overpayment(s) were received; and

(f) the action taken to correct the error which caused the overpayment.

(iii) the person's contact information;

(iv) data file, in the form and format specified by OMIG;

(v) whether the person is requesting to repay through installment payments;

(vi) whether the person is requesting the waiver of any applicable interest;

(vii) the person's agreement to return the full amount of the overpayment and interest if applicable, as determined by OMIG; and

(viii) any other data, documentation, or information OMIG shall require through the issuance of guidance or in response to its review of the submission.

(3) The Self-Disclosure Statement shall be signed by the person's compliance officer, where the person is a required provider pursuant to SubPart 521-1 of this Part. Where the person is not a required provider pursuant to SubPart 521-1 of this Part, the Self-Disclosure Statement may be signed by one of the following, the person's chief executive officer, chief operating officer, a senior manager of the person, or the person, where the person is a sole practitioner.

(4) A person requesting to repay through installment payments may be required to furnish OMIG with financial records and other documentation in support of the request. OMIG shall approve or reject a person's request based on a review of the person's financial documentation, participation in the MA program, and any other factors OMIG identifies.

(5) If OMIG determines that no overpayment was made, it shall notify the person in writing of the determination.

(6) A person who has received and disclosed an overpayment or has received notice of the overpayment amount due, and interest if applicable, pursuant to section 521-3.5 of this SubPart is required to return the overpayment and interest if applicable, in accordance with section 521-3.3 of this SubPart.

(d) Review of Accepted Self-Disclosures.

(1) OMIG shall acknowledge receipt and review the Self-Disclosure Statement and consider any written requests made pursuant to paragraph (2) of subdivision (b) of this section and shall complete a preliminary review within twenty (20) days of the submission. The deadline to report, return and explain shall be tolled, in accordance with the provisions of subdivision (b) of section 521-3.3 of this SubPart, from the date the submission was acknowledged by OMIG until completion of OMIG's preliminary review. Upon completion of its preliminary review, OMIG shall notify the person, in accordance with the notice provisions of subdivision (a) of

section 521-3.6 of this SubPart, and either accept the submission or return the submission as incomplete and identify the information and data needed to complete the submission. Only a submission that is acknowledged and accepted shall continue to toll the deadline to report, return and explain, in accordance with the provisions of subdivision (b) of section 521-3.3 of this SubPart, from the date the submission was acknowledged by OMIG. OMIG's acceptance of the person's submission of a Self-Disclosure Statement is conditioned upon the person's cooperation with OMIG under the Self-Disclosure Program, including any request for additional information or data under paragraph (2) of this subdivision.

(2) OMIG may, at any time, request additional information or data from the person who submitted the Self-Disclosure Statement. Such requests will be made in writing in accordance with subdivision (a) of section 521-3.6 of this SubPart. The person shall respond with such information and data within fifteen (15) days of the date of OMIG's notice.

(i) OMIG may extend the period to respond for good cause. Any request by the person to extend the period to respond shall be made in writing to OMIG and any approval or denial of the extension request shall be made by OMIG, in writing, in accordance with the provisions of subdivision (a) of section 521-3.6 of this SubPart.

(ii) Failure by the person to respond within fifteen (15) days or by any extended deadline will result in the submission being deemed not accepted and returned to the person as incomplete, and any tolling of the deadline to report, return and explain shall be terminated. OMIG will notify the person in writing, in accordance with the provisions of subdivision (a) of section 521-3.6 of this SubPart, that the submission has not been accepted, and the notice shall include the date on which the submission was deemed not accepted and the tolling of the deadline to report, return and explain was terminated.

(3) Once OMIG has accepted the submission of a self-disclosure statement and determined that the submission is complete, OMIG will review and verify the amount of the overpayment

and issue a notification, in accordance with subdivision (a) of section 521-3.6 of this SubPart, to the person of the overpayment amount due, including interest if applicable, and instructions for repayment.

(e) Self-Disclosure and Compliance Agreement.

(1) The SDCA is a binding contract between the person and OMIG. A person may be eligible for an SDCA based on the conduct being disclosed and/or where the person has requested to repay the determined overpayment amount through installments. The overpayment amount shall include interest unless interest is waived, in the sole discretion of OMIG.

(2) The SDCA shall include, at a minimum, the following terms and conditions:

(i) Agreement by the person to repay the amount of the overpayment and interest if applicable, as determined by OMIG, which is the subject of the disclosure.

(ii) If approved by OMIG for installment payments, agreement to make all installment payments on time, and in accordance with the repayment schedule.

(iii) Identification of, and agreement by the person to implement any corrective actions to prevent the issues which caused the person to receive an overpayment from the MA program from recurring.

(3) The person shall execute and return the SDCA, which must be received by OMIG within fifteen (15) days of the person receiving said agreement from OMIG, or such other timeframe as OMIG may permit, provided that such period shall not be less than fifteen (15) days.

(4) If the person fails to execute and return the SDCA to OMIG within the timeframe specified in paragraph (3) of this subdivision the person's participation in the Self-Disclosure Program shall be terminated. Notice of such termination shall be provided in accordance with paragraph (2) of subdivision (f) of this section.

(5) OMIG shall have the authority to enter into an SDCA with a person making a Self-Disclosure, in its sole discretion.

(f) Termination of participation.

(1) In accordance with subparagraph (4) of paragraph (f) of subdivision 7 of section 363-d of the Social Services Law a person's participation in the Self-Disclosure Program shall be immediately terminated if:

- (i) the person provides false material information or omits material information in their Self-Disclosure Statement or other communications with OMIG;
- (ii) the person attempts to defeat or evade an overpayment due pursuant to the SDCA or notification of an overpayment due, and interest if applicable, pursuant to section 521-3.5 of this SubPart; or
- (iii) the person fails to execute and return the SDCA in accordance with the timeframes specified in subdivision (e) of this section.

(2) If OMIG terminates a person's participation in the Self-Disclosure Program it shall issue a notice to the person within five (5) business days of its determination. The notice shall be mailed to the person's designated payment address or correspondence address or address provided on the Self-Disclosure Statement submitted pursuant to subdivision (c) of this section.

The notice shall contain:

- (i) the reason for the termination and the legal authority for the action taken;
- (ii) the effective date of the termination;
- (iii) the overpayment amount and interest due;
- (iv) the due date of the overpayment amount and interest;
- (v) the date on which the tolling of the return of the overpayment amount ends;
- (vi) notification that the overpayment and interest amount may be recovered in accordance with Part 518 of this Title; and
- (vii) notification that failure to return the overpayment and interest amount by the due date may result in monetary penalties pursuant to section 145-b(4) of the Social

Services Law and Part 516 of this Title, and any other sanction or penalty authorized by law.

521-3.5 Returning the overpayment.

(a) Once OMIG has completed its review and verified the amount of the overpayment OMIG shall notify the person of the amount of the overpayment and interest if applicable, and such notification shall contain instructions for remitting payment to the department. Interest may be waived in the sole discretion of OMIG.

(1) The notification will be issued in accordance with the provisions of subdivision (a) of section 521-3.6 of this SubPart.

(2) The person shall remit the full amount of the overpayment and interest within fifteen (15) days of the date of OMIG's notification of the determination of the amount of the overpayment, and interest, unless the person has been approved by OMIG to repay the overpayment through installments.

(3) Where a person has been approved to repay the overpayment and interest through installment payments, OMIG's notification of the amount of the overpayment shall also include an SDCA which the person shall execute and return to OMIG within the timeframe specified in paragraph (3) of subdivision (e) of section 521-3.4 of this SubPart.

(i) In order to remain eligible to participate in OMIG's Self-Disclosure Program the person must comply with all the terms of the SDCA, including the schedule of repayments.

(4) Notwithstanding any provision tolling the deadline to report, return and explain, in no event shall the person be required to repay the full amount of the overpayment and interest prior to the expiration of the deadline to report, return and explain, as set forth in paragraph (1) of subdivision (b) of section 521-3.3 of this SubPart.

(b) The full amount of any overpayment shall become immediately due and payable, with interest, if:

(1) the person fails to remit payment, either for the full amount of the overpayment or any scheduled installment payment pursuant to the terms of an SDCA, or

(2) participation in the Self-Disclosure Program is terminated in accordance with the provisions of subdivision (f) of section 521-3.4 of this SubPart.

(c) Where the person is required to pay interest, interest shall accrue on the amount of the overpayment as determined by OMIG, in whole or in part, in accordance with the provisions of section 518.4 of this Title.

(d) OMIG may recover the overpayment in accordance with Part 518 of this Title or by any other mechanism authorized by law.

521-3.6 Notification.

(a) Any notification issued by OMIG to the person under this SubPart shall meet the following requirements:

(1) Notification shall be made by sending written notification to the person at:

(i) the person's designated payment address or correspondence address or address provided on the Self-Disclosure Statement submitted pursuant to subdivision (c) of section 521-3.4 of this SubPart; or

(ii) an email address designated on the Self-Disclosure Statement if the person so designates that email address for receipt of electronic communication. It shall be the obligation of the person electing to receive notification electronically to provide and maintain a valid email address with OMIG. Proof of such email, containing a time and date stamp, shall constitute sufficient notification that the electronic communication was received by the person making such Self-Disclosure.

(2) Notwithstanding the option of a person making a Self-Disclosure under this SubPart to select electronic notification, any notice pursuant to paragraph (2) of subdivision (f) of section 521-3.4 of this SubPart shall be mailed to the person's designated payment address or

correspondence address or address provided on the Self-Disclosure Statement submitted pursuant to subdivision (c) of section 521-3.4 of this SubPart.

(3) Notification mailed to the person's designated payment address or correspondence address or address provided on the Self-Disclosure Statement submitted pursuant to subdivision (c) of section 521-3.4 of this SubPart shall be assumed to be received five (5) business days from the date on the notification.

(b) OMIG shall provide the department with information and notices upon request and in periodic reporting at least monthly concerning providers who have received notification:

(1) that they are ineligible to participate in the Self-Disclosure program pursuant to paragraph (4) of subdivision (b) of section 521-3.4 of this SubPart;

(2) that their Self-Disclosure is not accepted pursuant to subparagraph (ii) of paragraph (2) of subdivision (d) of section 521-3.4 of this SubPart; and

(3) of the amount of the overpayment and interest due pursuant to subdivision (a) of section 521-3.5 of this SubPart.

521-3.7 Enforcement.

(a) A person who fails to report, return and explain an overpayment by the deadline specified in subdivision (b) of section 521-3.3 of this SubPart may be subject to monetary penalties pursuant to section 145-b(4) of the Social Services Law and Part 516 of this Title, and any other sanction or penalty authorized by law.

REGULATORY IMPACT STATEMENT

Statutory Authority

The Office of the Medicaid Inspector General (OMIG) is an independent office within the Department of Health (“Department”) responsible for the prevention, detection, and investigation of fraud and abuse in New York State’s Medical Assistance (Medicaid) program pursuant to New York State Public Health Law (“PBH”) § 31. PBH § 32(20) sets forth the functions, duties and responsibilities of OMIG, and specifically authorizes OMIG to “implement and amend, as needed, rules and regulations related to the prevention, detection, investigation and referral of fraud and abuse within the medical assistance program and the recovery of improperly expended medical assistance program funds.” New York State Social Services Law (“SOS”) § 363-d requires that certain Medicaid providers (including managed care plans) adopt and implement a compliance program and establishes the State requirement that persons shall report, return and explain overpayments within sixty (60) days of identification, and codifies the requirements of the self-disclosure program administered by OMIG and authorizes OMIG, in consultation with the Department, to promulgate regulations. SOS § 364-j(39) requires managed care plans, including managed long term care plans (collectively “MMCO”) to adopt and implement policies and procedures designed to detect and prevent fraud, waste and abuse, and authorizes OMIG, in consultation with the department, to promulgate regulations.

Legislative Objectives

The legislative objective is to protect the fiscal integrity of the Medicaid program and promote provider and MMCO compliance with Medicaid program laws, rules and requirements.

Subdivisions 1 – 7 of SOS § 363-d were amended to better align the elements of New York State’s mandatory compliance program with the elements found in Federal regulations and guidance, to codify the federal requirement that a person report, return and explain Medicaid overpayments in State law, and to codify the requirements of OMIG’s self-disclosure program. In addition, the statute

was updated to include a monetary penalty for any provider who fails to adopt and implement an effective compliance program and for any person who fails to report return and explain an identified overpayment received from the Medicaid program. The provisions relating to the monetary penalty were promulgated in OMIG's October 2020 rulemaking amending 18 NYCRR Part 516.

Subdivision 39 of SOS § 364-j was added to require MMCOs to adopt and implement policies and procedures designed to detect and prevent fraud, waste and abuse under the Medicaid program. These policies and procedures include a compliance program, consistent with the requirements of SOS § 363-d, and the establishment of a special investigation unit (SIU) if the MMCO meets certain enrolled population thresholds.

Needs and Benefits

This rulemaking is necessary for the State to implement provisions of the State Fiscal Year 2020-2021 Enacted Budget (Chapter 56 of the Laws of 2020, Part QQ) and Medicaid program integrity reform initiatives of the MRT II. SOS § 363-d sets forth the general requirements for providers to adopt and implement a compliance program, requires providers to report, return and explain overpayments from the Medicaid program, and codifies OMIG's self-disclosure program. SOS § 364-j(39) requires MMCOs to adopt and implement fraud, waste and abuse prevention programs. This rulemaking repeals and replaces Part 521 and creates three (3) new SubParts to address these requirements.

SubPart 521-1 further defines and clarifies the standards and requirements for the adoption and implementation of an effective compliance program. The prior version of Part 521 largely mirrored the language in the statute and relied on guidance documents to further define compliance program requirements. This rulemaking will provide clarity and direction to providers and set expectations prior to a compliance program review by OMIG.

SubPart 521-2 establishes the standards and requirements for the adoption and implementation of policies and procedures to detect and prevent fraud, waste and abuse for MMCOs.

The statute requires MMCOs with a certain number of enrolled Medicaid recipients to establish an SIU. Existing DOH and DFS regulations require certain health plans to establish an SIU and have a fraud and abuse prevention plan. This new SubPart creates a standard for the Medicaid program that will be consistent across all plans participating in the Medicaid program.

SubPart 521-3 clarifies the requirement that persons shall report, return and explain overpayments within sixty (60) days of identification and codifies the requirements of the self-disclosure program administered by OMIG.

Costs

Generally, any costs that may be incurred by providers, MMCOs or other persons would be a direct result of the statutory authority and not this rulemaking. Furthermore, most, if not all, of the statutory authority were either modifications of existing statutory obligations, or codification of existing Federal requirements. The requirement that certain Medicaid providers adopt and implement a compliance program was established in SOS § 363-d in 2006. The current amendments did not change the pre-existing obligation to adopt and implement an effective compliance program or the scope of who was required to do so, nor the requirement to report, return and explain identified overpayments received from the Medicaid program. Rather, it aligned the State compliance program requirement more closely with the standard used at the Federal level and codified the Federal requirement that a person who has received and identified an overpayment from the Medicaid program, report, return and explain the overpayment to the Medicaid program. Likewise, many MMCOs are required to have a fraud and abuse prevention plan pursuant to existing DOH or DFS regulation. This rule will expand the requirement to establish an SIU to additional MMCOs. It is anticipated that this rulemaking will achieve savings for both providers and taxpayers as it provides direction and clarification of the statutory requirements, which will be subject to review by OMIG, and could result in the recovery of overpayments and/or the imposition of monetary penalties.

Costs to Regulated Parties

As a result of this rulemaking, regulated parties are not expected to incur additional costs for continuing compliance with SOS § 363-d. Under the statute, specific categories of providers are required to adopt, and implement effective compliance programs as well as the obligation to report, return and explain overpayments. Furthermore, this rulemaking amends the existing definition of “substantial portion of business operations,” to increase the value of claims submitted to the Medicaid program or payments received from the Medicaid program, from \$500,000 to \$1,000,000, and eliminates the category of “ordering.” The result is that fewer providers will be subject to the provisions of SubPart 521-1. Aligning the Federal and State standards for compliance programs should also reduce costs to Medicaid providers, such as MMCOs, who participate in other government programs with similar requirements.

Many MMCOs participating in the Medicaid program are currently required to have a fraud and abuse prevention plan and establish an SIU. The requirement that an MMCO with a certain enrolled Medicaid population must establish an SIU is set forth in statute, and therefore any costs associated with that requirement are the result of the statute, not this rulemaking. This rulemaking seeks to provide clarity and consistency in MMCO requirements within the Medicaid program. It is expected that MMCOs will incur additional costs associated with the staffing requirements for SIUs, particularly where an MMCO does not have an existing SIU. However, the rulemaking provides flexibility with regard to staffing and other provisions to allow for innovation on the part of MMCOs in meeting the SIU staffing requirement of SubPart 521-2.

Costs to State Government and the State Agency

State government and the Medicaid Inspector General are not expected to incur any additional costs as a result of this rulemaking. Agency personnel will continue to conduct compliance program reviews, audits, investigations, and reviews of individuals and entities participating in the Medicaid program.

Costs to Local Government

There will be no additional costs to local government as a result of this rulemaking.

Local Government Mandates

The proposed rulemaking does not impose any new program, services, duties, or responsibilities upon any county, city, town, village, school district, fire district, or other special district.

Paperwork

No additional paperwork requirements will be imposed upon regulated parties under the proposed regulation. Medicaid providers and MMCOs who are subject to the proposed regulations are already required to maintain documents associated with their compliance programs.

Duplication

The statute incorporates requirements under 42 U.S.C. 1396-a(a)(68), which requires providers who makes or receives payments from government programs (i.e., Medicaid) of more than \$5,000,000, to have policies, procedures, and education regarding Federal and State False Claims Act provisions and related Federal or State laws. Providers who are subject to this Federal statute are also required to adopt and implement an effective compliance program under SOS § 363-d. Its inclusion in the statute, and this rulemaking, does not create any overlapping or conflicting requirements. Rather it will ensure that OMIG reviews of compliance with the Federal requirement will be conducted in conjunction with its review of a provider's compliance program, which is more efficient for both the provider and the State.

The department is required, pursuant to 42 C.F.R. § 438.608, to require MMCOs, through the MMCO's contract with the department, to adopt and implement an effective compliance program. The amendments made to SOS § 363-d and this rulemaking align with the requirements of the Federal regulation and the MMCO's contract with the department and provides clarification on the general requirements outlined in the contract.

The statute also includes a provision that a provider whose compliance program is accepted by the Federal Office of Inspector General for the Department of Health and Human Services, or for MMCOs whose compliance program satisfies the requirements of the MMCO's contract with the department, that such programs may satisfy the requirements of the statute if it adequately addresses "medical assistance risk areas and compliance issues."

MMCO's subject to this rulemaking may already be required to adopt and implement policies and procedures designed to detect and prevent fraud and abuse pursuant to 10 NYCRR § 98-1.21 or 11 NYCRR § 86.6. To the extent it is appropriate for the Medicaid program, the requirements of SubPart 521-2 were drafted to be consistent with existing requirements.

Alternatives

There were no significant alternatives considered as the changes were made to align to the revised statutory obligations.

Federal Standards

There are no mandatory Federal standards or requirements for compliance programs for Medicaid providers. However, as noted previously, 42 U.S.C.1396-a(a)(68), requires providers who make or receive payments, directly or indirectly, from a government program (i.e., Medicaid) of more than \$5,000,000, to have policies, procedures and education regarding Federal and State False Claims Act provisions and other similar Federal or State laws. This rulemaking exceeds the Federal requirement by requiring all providers subject to the provisions of SOS § 363-d to have policies and procedures pursuant to 42 U.S.C.1396-a(a)(68), regardless of whether they meet the billing threshold. The rule exceeds this federal requirement because SOS § 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. The policies and procedures of 42 U.S.C.1396-a(a)(68) fall within this broad standard, and it is not expected that providers would incur any significant costs incorporating this requirement into their compliance programs. Finally, 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.

Further, the amendments to SOS §363-d and this rulemaking generally align with Federal requirements requiring overpayments from the Medicaid program be reported, returned and explained under 42 U.S.C. 1320-7k(d).

Compliance Schedule

SubParts 521-1, 521-2 and 521-3 will take effect upon publication of a Notice of Adoption in the State Register. As noted in SOS § 363-d(3)(c), enforcement of compliance program requirements under SubPart 521-1 will not begin until 90 days after the effective date of the regulation. Similarly, enforcement of the SubPart 521-2 requirements will not begin until 90 days after the effective date of the regulation.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES

AND LOCAL GOVERNMENTS

The proposed regulation applies to certain providers (defined by statute) participating in the Medicaid program, including some small businesses; modifies existing requirements for adopting and implementing required compliance programs; imposes an obligation for Medicaid managed care organizations and managed long term care plans (collectively “MMCO”) to establish a fraud, waste and abuse prevention program, and certain MMCOs to establish an SIU; establishes the requirement that persons shall report, return and explain overpayments to the Medicaid program; and codifies the requirements of the self-disclosure program administered by OMIG.

1. Effect of the rule:

The proposed regulations require that certain Medicaid providers, including small businesses adopt and implement a compliance program. In addition, all MMCOs participating in the Medicaid program are required to adopt and implement a fraud, waste and abuse prevention program under SubPart 521-2. The proposed regulations relating to compliance programs (SubPart 521-1) will apply to any businesses that fall under one or more of four general categories:

1. providers that are subject to the provisions of Articles 28 or 36 of the public health law;
2. providers that are subject to the provisions of Articles 16 or 31 of the mental hygiene law;
3. managed care providers; and
4. persons who submit Medicaid claims or receive Medicaid payments totaling \$1,000,000 or greater in a twelve-month period.

These categories of providers are required by SOS § 363-d to adopt, implement and maintain a compliance program. The proposed regulations are consistent with those statutory requirements. The fourth category of providers previously had a threshold of \$500,000 of Medicaid claims within a twelve-month period, and the amendment to this regulation increases the threshold to \$1,000,000. This change will enable OMIG to focus on providers with significant potential impact on the Medicaid

program, and it may result in cost savings for some small businesses and local governments which will no longer be required to maintain a compliance program which satisfies the requirements of SubPart 521-1. While OMIG is unable to estimate the number of small businesses impacted by this rulemaking, it is anticipated that with the changes fewer small businesses will be subject to and impacted by these requirements.

Small businesses that meet the criteria listed above will continue to be required to have a compliance program. The types of small business providers that may be subject to these regulations include, but are not limited to, MMCOs, pharmacies, physicians, dentists, durable medical equipment businesses, service bureaus, and transportation providers.

It is estimated, based on information available to OMIG, that approximately 276 local government providers, including some school districts, fall under one or more of the categories of providers that are required to establish compliance programs. These entities will be required to comply with the existing statute and proposed regulations. As with small businesses, with these changes OMIG estimates that at least 55 local government providers who were subject to the prior version of Part 521 will not be subject to this rulemaking.

The proposed regulation also requires MMCOs to establish a fraud, waste and abuse prevention program (SubPart 521-2). MMCOs subject to this SubPart include Medicaid managed care organization and managed long term care plans. Such plans vary in the size and complexity of operations, but in general, this SubPart should not adversely affect small business and local governments.

The proposed regulation also clarifies a person's obligation to report, return, and explain identified overpayments received from the MA program, consistent with statutory requirements.

2. Compliance requirements:

Any small business or local government that is subject to the proposed regulations will be required to adopt and implement a compliance program and to report, return and explain

overpayments received from the MA program in accordance with the requirements contained in SOS § 363-d and as further defined in the proposed regulations.

Many providers are already required to adopt and implement a compliance program under existing law, but depending on what policies, procedures and controls a provider has already instituted, additional action may be necessary. No additional affirmative acts will likely be required for a provider if that provider already has an effective compliance program that satisfies the elements contained in law and further defined in the proposed regulations.

3. Professional services:

Many providers are already required to adopt and implement a compliance program; however, they may require or continue to utilize the services of certain professionals, including medical professionals, auditors, attorneys, and compliance professionals, in order to update their policies, procedures, and controls in order to maintain an effective compliance program.

4. Compliance costs:

The requirement that certain Medicaid providers adopt and implement compliance programs is already a statutory requirement in SOS § 363-d. Providers and MMCOs may incur additional costs to comply with this rulemaking. These costs may result from additional reporting, recordkeeping and compliance costs. However, the costs incurred by these providers are a direct result of that statute and not this rulemaking. This rulemaking clarifies the types of providers that are subject to the compliance program requirement and must therefore incur costs, if any, associated with such a program.

The costs incurred by regulated parties in order to comply with the proposed rulemaking will vary depending upon existing control measures the provider has in place at the time the regulation takes effect. For those providers who already have an operating compliance program, potentially little or no costs may be incurred in order to modify a compliance program that satisfies the required elements in law and further defined in the proposed regulations. The extent of those costs will

depend on the level of effort that is necessary for the provider to establish a compliance program that satisfies each of the mandatory elements.

The costs will also vary depending upon the size and other specific attributes of the provider. SOS § 363-d states that a provider's compliance plan should reflect the provider's size, complexity, resources, and culture. Thus, a large, complex provider may incur more costs in establishing a compliance program than a smaller provider might incur.

The proposed rulemaking will not impose costs on local governments in general, but local government entities that fall within the definition of a "required provider," including school districts, will be required to implement a compliance program. The cost analysis would be the same as other similarly situated providers covered by the statute.

It is estimated that increasing the threshold to \$1,000,000 in Medicaid claims for the definition of "substantial portion of business operations" will reduce the number of providers subject to SubPart 521-1 by approximately 2,300, which may result in cost savings to small businesses and local governments no longer subject to the specific requirements of this regulation. In assessing the costs that may be incurred by a provider when it maintains a compliance program, pursuant to SOS § 363-d and the proposed regulations, OMIG also considered the cost savings that could result from the implementation of an effective compliance program due to risk mitigation and other factors. These cost savings should diminish, if not completely offset, any costs incurred by providers in the implementation and maintenance of an effective compliance program, or in the case of an MMCO, a fraud, waste and abuse prevention program.

5. Economic and technological feasibility:

Although there may be some costs involved for some providers in modifying existing compliance programs to comply with the proposed regulations, OMIG anticipates those costs will be lessened or offset entirely by the cost savings that Medicaid providers could realize once the program is implemented.

There are no new technologically challenging aspects to the requirements of the proposed rulemaking that do not already exist as requirements in current statutes, such as HIPAA, as a compliance program would establish measures to ensure compliance with laws relevant to the Medicaid program.

For these reasons, OMIG concludes that the proposed regulations will be economically and technically feasible for any affected small businesses and local governments.

6. Minimizing adverse impact:

SOS § 363-d states in part: "The legislature. . . recognizes the wide variety of provider types in the medical assistance program and the need for compliance programs that reflect a provider's size, complexity, resources, and culture. For a compliance program to be effective, it must be designed to be compatible with the provider's characteristics."

While each required provider will need to develop a compliance program that adequately addresses each of the elements listed in SOS § 363-d and further defined in the proposed regulations, OMIG will give due consideration and attention to the concerns noted by the legislature and review compliance programs for appropriateness consistent with the provider's specific characteristics.

The benefits associated with implementation of a compliance program, and for MMCOs, a fraud, waste and abuse prevention program, far outweigh any adverse economic impact. An effective compliance program will assist providers in preventing inappropriate payments and avoiding costs, such as reimbursements, penalties, and other adverse consequences, that might otherwise be incurred due to violations. The compliance program requirement will also help to ensure that: Medicaid funds are used properly and that payments are made only for legitimate claims; providers systematically identify, report, and return overpayments; medical care, services, and supplies provided meet required standards of care; individuals can report unacceptable practices, such as fraud, directly and safely; and that providers establish accountability in governance structures.

Although there are no mandatory federal standards or requirements for compliance programs for Medicaid providers, the federal government has issued guidance for many types of providers interested in voluntary compliance programs. OMIG has issued guidance on compliance programs, and DOH also issues advisory opinions on appropriate standards of compliance. Local government entities required to comply with this regulation can utilize those no cost guidelines and advisory opinions when developing an effective compliance program pursuant to this regulation.

7. Small business and local government participation:

These proposed regulations arise from a change in State law pursuant to Chapter 56 of the Laws of 2020, Part QQ. The initiatives were recommended by the MRT II following a series of public meetings where stakeholders had the opportunity to comment and collaborate on ideas to aid in the development of these program integrity initiatives. In addition, the MRT II was comprised of representatives of providers and MMCOs, amongst others. OMIG will comply with SAPA section 202-b(6) by providing MMCO associations, provider associations, many of whom represent small businesses, and NY county and local government organizations and associations with a summary of the rule prior to the public comment period, publishing the proposed amendment in the State Register and posting the proposed amendment on its website. OMIG welcomes comments on the proposed regulations from local governments and businesses, and any other program stakeholders.

RURAL AREA FLEXIBILITY ANALYSIS

1. Types and estimated numbers of rural areas:

This rulemaking implements Social Services Law (SOS) § 363-d which requires certain Medicaid providers to adopt and implement required compliance programs and to report, return and explain overpayments received from the Medicaid program. In addition, it implements SOS § 364-j(39) which requires Medicaid managed care organizations and managed long term care plans (collectively “MMCO”) to adopt and implement procedures to detect and prevent fraud, waste and abuse in the Medicaid program. SOS §§ 363-d and 364-j(39), and these proposed regulations apply uniformly to Medicaid providers and MMCOs throughout all 62 counties of the State, including those operating in rural areas of the State.

2. Reporting, recordkeeping and other compliance requirements; and professional services:

Medicaid providers and MMCOs in rural areas may be subject to additional reporting, recordkeeping, or other compliance requirements as the implementation of a compliance program, or in the case of an MMCO, a fraud, waste and abuse prevention, program requires maintenance of records to demonstrate the adoption and implementation of such programs. These additional compliance requirements are expected to be minimal. All Medicaid providers, including MMCOs, are already subject to existing statutory and regulatory requirements for adopting and implementing compliance programs. Depending on what control measures a provider has already instituted, additional action may be necessary for a provider to meet the updated requirements of a Medicaid provider compliance program. Moreover, pursuant to SOS § 363-d the adoption and implementation of an effective compliance program is a condition, for those providers subject to the requirement, of being eligible to receive reimbursement under the Medicaid program, and Medicaid providers have existing requirements to maintain records demonstrating their right to receive payment. Furthermore, MMCOs have existing requirements in state and federal law and contract to maintain records and provide reporting to the state related to fraud, waste and abuse.

Many providers and MMCOs are already required to adopt and implement a compliance program or a fraud and abuse prevention plan; however, they may require or continue to utilize the services of certain professionals, including medical professionals, auditors, attorneys, and compliance professionals, in order to update their policies, procedures, and controls in order to maintain an effective compliance program.

3. Costs:

Providers and MMCOs may incur additional costs to comply with this rulemaking. These costs may result from additional reporting, recordkeeping and compliance costs. In the case of MMCOs, it may result from new requirements relating to the staffing of the MMCO's special investigation unit ("SIU"). There are also training requirements for the provider's or MMCO's "affected individuals." However, any costs should be minimal as most providers and MMCOs who are subject to this rulemaking, including those in rural areas, were required to have a compliance program under the prior iteration of the rule, and this rulemaking clarifies the types of providers that are subject to the compliance program requirement and likely to incur costs, if any, associated with such a program. It is anticipated that fewer providers will be subject to this regulation than under the prior version. Likewise, many MMCOs already have established fraud and abuse prevention programs, including the establishment of an SIU, and related requirements under contract.

In assessing the costs that may be incurred by a provider when it establishes a compliance program or an MMCO establishing a fraud, waste and abuse prevention program, OMIG also considered the cost savings that could result from the implementation such programs due to risk mitigation and other factors. These cost savings should diminish, if not completely offset, any costs incurred by providers and MMCOs in the development and implementation of the programs required under this regulation.

4. Minimizing adverse impact:

This rulemaking uniformly affects Medicaid providers and MMCOs located in both rural and non-rural areas in New York. It should not have an adverse impact on rural areas.

SOS § 363-d states in part: "The legislature. . . recognizes the wide variety of provider types in the medical assistance program and the need for compliance programs that reflect a provider's size, complexity, resources, and culture. For a compliance program to be effective, it must be designed to be compatible with the provider's characteristics."

While each required provider will need to develop a compliance program that adequately addresses each of the elements listed in SOS § 363-d and further defined in the proposed regulations, OMIG will give due consideration and attention to the concerns noted by the legislature and review compliance programs for appropriateness consistent with the provider's specific characteristics.

The benefits associated with implementation of a compliance program, and for MMCOs, a fraud, waste and abuse prevention program, far outweigh any adverse economic impact. An effective compliance program will assist providers in preventing inappropriate payments and avoiding costs, such as reimbursements, penalties, and other adverse consequences, that might otherwise be incurred due to violations. The compliance program requirement will also help to ensure that: Medicaid funds are used properly and that payments are made only for legitimate claims; providers systematically identify, report, and return overpayments; medical care, services, and supplies provided meet required standards of care; individuals can report unacceptable practices, such as fraud, directly and safely; and that providers establish accountability in governance structures.

Although there are no mandatory federal standards or requirements for compliance programs for Medicaid providers, the federal government has issued guidance for many types of providers interested in voluntary compliance programs. OMIG has also issued guidance on compliance programs. Providers and MMCOs in rural areas required to comply with this regulation can utilize

those no cost guidelines when developing an effective compliance program pursuant to this regulation.

5. Rural area participation:

These proposed regulations arise from a change in State law pursuant to Chapter 56 of the Laws of 2020, Part QQ. The initiatives were recommended by the MRT II following a series of public meetings where stakeholders had the opportunity to comment and collaborate on ideas to aid in the development of these program integrity initiatives. In addition, the MRT II was comprised of representatives of providers and MMCOs, amongst others. OMIG will comply with SAPA section 202-bb(7) by providing MMCO associations and provider associations, many of whom represent providers and MMCOs in rural areas, with a summary of the rule prior to the public comment period, publishing the proposed amendment in the State Register and posting the proposed amendment on its website. OMIG welcomes comments on the proposed regulations from providers and MMCOs operating in rural areas.

JOB IMPACT STATEMENT

The legislature has determined that Medicaid providers should be required to adopt and implement a compliance program in order to reduce errors and identify fraud in Medicaid billing and to report, return and explain overpayments. The legislature also determined that managed care plans and managed long term care plan (collectively “MMCO”) shall be required to adopt and implement policies and procedures designed to detect and prevent fraud, waste and abuse in the Medical Assistance (Medicaid) program. This rulemaking is necessary in order to implement the statutory mandate in Social Services Law (SOS) § 363-d and SOS § 364-j(39). This rulemaking will also ensure that the regulated community is given appropriate notice as to which providers must implement a compliance program.

This rulemaking is part of an overall effort by New York State to enhance the integrity of its Medicaid program. The compliance program requirement in existing law helps to ensure that Medicaid funds are used properly and that payments are made only for legitimate claims. Although this rulemaking will require providers that are subject to the statute to implement guidelines further defined in the regulation for employee training and education and designate an employee with the responsibility of overseeing the compliance program, those providers may also realize benefits associated with the implementation of a compliance program. An effective compliance program will assist a provider in preventing inappropriate payments and avoiding costs, reimbursements, penalties, and other adverse consequences that might otherwise be incurred due to violations.

Likewise, Subpart 521-2 of this rulemaking proposes staffing requirements for MMCOs related to the establishment of a special investigation unit. It is expected that MMCOs already have staffing in place that is consistent with the standards established in the regulation due to existing contractual obligations. In addition, the regulation allows the MMCO flexibility to propose alternative staffing levels, provided it can show the effectiveness of its proposal in achieving the objectives of this

rulemaking. Finally, it is expected that MMCOs will realize benefits, including increased recoveries or cost avoidance, through stepped up fraud, waste and abuse prevention and detection activities.

The costs incurred by regulated parties in order to comply with the proposed rulemaking will vary depending upon existing control measures the provider has in place at the time the regulation takes effect. Many providers are already required to adopt and implement a compliance program, all must report, return and explain overpayments, and many MMCO's are already required to have fraud and abuse prevention plans. However, they may require the services of certain professionals, including medical professionals, auditors, attorneys, and compliance professionals, to update their policies, procedures, and controls in order to maintain an effective compliance program. For those providers who already have an operating compliance program, potentially little or no costs may be incurred in order to meet the requirements in statute and in the proposed regulations. However, for those providers who do not have a program in place that meets the requirements set forth in this proposed rulemaking, some costs will be incurred in order to achieve compliance. The extent of those costs will depend on the level of effort that is necessary for the provider to establish a compliance program that satisfies each of the mandatory elements. Those elements are listed and described in both the proposed regulations and SOS § 363-d.

The requirement that certain Medicaid providers implement compliance programs and the requirement that all persons who have identified overpayments must report, return and explain overpayments is established by statute in SOS § 363-d. Likewise, the requirement that MMCOs adopt and implement a fraud, waste and abuse prevention program is established by statute in SOS § 364-j(39). Therefore, any adverse impact on jobs or employment opportunities that may be incurred by these providers would be a direct result of that statute and not this rulemaking. This rulemaking clarifies the types of providers that are subject to the compliance program requirement and must therefore incur costs, if any, associated with such a program.

In assessing the adverse impact on jobs or employment opportunities incurred by a provider when it establishes a compliance program, or the obligation to report, return and explain overpayments pursuant to SOS § 363-d or when an MMCO establishes a fraud, waste and abuse prevention program pursuant to SOS § 364-j(39) and the proposed regulations, due consideration should be given to the cost savings that may result from the implementation of such programs due to risk mitigation and other factors. These cost savings should diminish, if not completely offset, any costs incurred by providers or adverse impacts on jobs or employment opportunities in the implementation these requirements.

It is anticipated that the total impact on jobs and employment opportunities associated with establishing a provider compliance program, the obligation to report, return and explain overpayments, or MMCO fraud, waste and abuse prevention program will be relatively modest, particularly for providers or MMCOs who already have a full or partial program in place. For those providers and MMCOs who do not yet have an established program, the cost savings associated with such a program will help to offset the expense of implementing the program. Therefore, the statutorily required compliance program for certain Medicaid providers, the obligation to report, return and explain overpayments, and fraud, waste and abuse program for MMCOs, as implemented by this rulemaking, should not have a substantial adverse impact on jobs and employment opportunities.