Summary of Assessment of Public Comment

A Notice of Proposed Rulemaking was published in the State Register on July 13, 2022. During the public comment period the Office of the Medicaid Inspector General ("OMIG") received comments from the Association for Community Living Agencies in Mental Health; Basset Healthcare Network; Greater New York Hospital Association; Harris Beach, PLLC; Healthcare Association of New York State; Healthy Alliance; HHA Exchange; Hinman Straub, PC; LeadingAge New York; MVP Healthcare; the New York Health Plan Association; the New York State PACE Alliance; Rivkin Radler, LLP; VCS, Inc.; Choiceof NY; Loeb House; Mohawk Opportunities, Inc.; MHA of Columbia-Greene Counties; MHA of Ulster; MHA of Rockland; Rehabilitation Support Services, Inc.; MHA of Orange County, Inc.; CoveCareCenter, Inc.; Rockland Hospital Guild; Rise, Housing and Support Services Inc.; Unity House of Troy, Inc.; Search for Change, Inc.; and Warren Washington Association for Mental Health, Inc.

All comments received were reviewed and evaluated. OMIG has posted on its website (https://omig.ny.gov/information-resources/laws-and-regulations) a complete assessment of the public comments that OMIG received regarding the rule. No substantive changes have been made to the regulations in light of the comments received. Other clarifications and technical, non-substantive changes have been made:

Section 521-1.2(b)(3) was amended to clarify by providing examples of what would constitute a provider's "characteristics" as that term is used in the definition of "effective compliance program."

Section 521-1.3(c) was amended to clarify that contractors, agents, subcontractors, and independent contractors are only subject to the elements of a required provider's compliance program to the extent

that it is related to their contracted role and responsibilities within a provider's identified risk areas. The subdivision was also restructured, separating the provisions into separate paragraphs.

Sections 521-1.3(c), 521-1.4(b)(1)(vi), and 521-1.4(g)(3)(ii) were amended to refer to "contractors, agency, subcontractors, and independent contractors" as "contractors".

Section 521-1.4(a)(2)(viii)(a) was amended to clarify that the required provider shall establish in its written policies and procedures "standards for escalating disciplinary actions" instead of "the degrees of disciplinary actions that must be taken in response to non-compliance".

Section 521-1.4(a)(2)(ix) was amended to clarify where copies of 42 United States Code 1396a(a)(68) can be obtained and are available for copying and inspection.

Section 521-1.4(b) was amended to clarify that the compliance officer is responsible for the day-to-day oversight of the compliance program.

Section 521-1.4(c)(1)(iii) was amended to clarify the role of the compliance committee in advocating for the allocation of sufficient funding, resources and staff for the compliance officer.

Section 521-1.4(c)(1)(v) was amended to clarify the role of the compliance committee in "advocating" for, rather than "enacting", the adoption and implementation of required modifications to the compliance program.

Section 521-1.4(g)(1) was amended to clarify that the required provider shall perform “routine” audits rather than “ongoing” audits.

Section 521-1.4(g)(2)(i) was amended to clarify that for reviews carried out by other staff under the auditing and monitoring provisions of the compliance program, that such other staff have the necessary knowledge and expertise to evaluate the effectiveness of the compliance of the program that they are reviewing and are independent from the functions being reviewed.

Section 521-1.4(h)(4) was amended to clarify that required providers are only required to report violations of state or federal law, rules or regulations to the appropriate governmental entity “where such reporting is otherwise required by law, rule or regulation”.

Section 521-2.4(c)(1) was amended to clarify that the SIU is primarily responsible for performing “or collaborating with and monitoring individuals performing” the MMCOs audits, investigations and reviews.

Section 521-2.4(b)(4)(iii) to make a technical correction to cite the correct subdivision for the fraud, waste and abuse prevention plan (subdivision (i) of section 521-2.4).

Section 521-3.2(a) was amended to clarify that the definitions of parts 504 and 515 of Title 18 of the NYCRR apply, except as otherwise noted in SubPart 521-3. Thus, the definition of “person” under section 521-3.2(b) would control under SubPart 521-3, rather than the definition of “person” under 18 NYCRR Part 504.

Section 521-3.4(b)(1)(i) was amended to clarify that a person under audit, investigation or review by OMIG is eligible to participate in the Self-Disclosure Program with respect to the overpayment being disclosed if it does not relate to the existing audit, investigation or review.

Section 521-3.4(b)(1)(iv) was amended to correct a spelling mistake.

Several proposed revisions from commenters were not incorporated because they were determined to be duplicative of other sections of Title 18, inconsistent with the statutory authority underlying the proposed rulemaking, or did not align with the objectives of the proposed rulemaking.

Assessment of Public Comments

Comment: Several commenters raised concerns with the proposed revisions to Part 521 creating undue financial and administrative burdens on providers. Many comments addressed the current environment in health care due to the challenges associated with the COVID-19 pandemic, and the many new and substantial challenges it created for providers. Commenters were also concerned about implementation timing. A common concern raised was with respect to staffing shortages and the ability hire additional staff and fiscal constraints commenters foresee with implementation of the new regulation. Commenters requested that the proposed regulation allow providers a longer timeframe to hire the staff and make the changes needed to comply. A couple of commenters requested the enforcement be delayed for 12 months after the termination of the federal COVID-19 public health emergency. Another commenter suggested MMCOs should have 180 days to implement the new requirements. Another commenter also requested Audit Protocols to assist in the implementation. One commenter requested that the proposed regulation be revised to eliminate the provisions that are not explicitly required to implement the provisions of the 2020-2021 Executive Budget.

Response: OMIG acknowledges the concerns of these commenters and is committed to working collaboratively with the provider and MMCO communities to ensure that the requirements of this regulation are met in the least burdensome manner possible. Social Services Law ("SOS") § 363-d requires certain providers, to adopt and implement compliance programs, and SOS § 364-j requires MMCOs to adopt and implement fraud, waste and abuse prevention programs. While these requirements were enhanced under the State Fiscal Year 2020-2021 Enacted Budget (Chapter 56 of the Laws of 2020, Part QQ), they are not entirely or even substantially new requirements. Since 2007, providers pursuant to SOS § 363-d were required to adopt and implement compliance

programs, and MMCOs, with a minimum enrolled population, have long been required to adopt and implement fraud and abuse prevention plans under both Department of Health ("DOH") and Department of Financial Services (previously Department of Insurance) regulations. 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. This rulemaking is responsive to previously identified provider concerns and provides direction as to OMIG expectations regarding compliance programs to providers under SOS § 363-d, and MMCOs participating in the NYS Medicaid program. Therefore, in most cases providers and MMCOs should already have certain resources and employees in place in order to carry out the obligations under this regulation.

In enforcing the requirements of SubParts 521-1 and 521-2, OMIG expects providers and MMCOs to meet these requirements. OMIG will, however, take into consideration a provider's and MMCO's documented good faith efforts to hire and retain staff in any review or enforcement action.

With respect to the Self-Disclosure program, no additional time or resources should be necessary with respect to reporting overpayments. Since the Affordable Care Act was passed in 2010, Medicaid providers and MMCOs have had the obligation to report, return and explain identified overpayments. This rulemaking clarifies the procedure by which an individual or entity may report such overpayments. Moreover, with respect to identifying overpayments, the provider's or MMCO's compliance program, if successful, should identify and correct these potential compliance issues.

Comment: One commenter was concerned that PACE Organizations are, pursuant to Federal law and regulation, a single entity that, operate in New York, with licenses authorized by Article 44, Article 28 and Article 36 of the Public Health Law. As such they should be considered as a single entity for purposes of meeting the definition of a "required provider" under SubPart 521-1.

Response: OMIG agrees with the commenter to the extent that OMIG will review and assess a required provider's obligation to adopt and implement an effective compliance program at an organizational level. While each individual provider may meet the definition of a "required provider", OMIG expects that such providers would operate one, cohesive compliance program. However, we do not feel a revision to the regulation is required to effectuate this interpretation.

Comment: One commenter requested clarification regarding the application of SubPart 521-2 (Managed Care) to PACE organizations and requested that PACE organizations be exempt from such requirements, or at a minimum from the SIU requirements.

Response: PACE organizations are subject to the requirements of Part 521 to the extent they meet the definition of a required provider or are an MMCO (which includes managed long term care plans). PACE organizations with an enrolled population of 1,000 are also expected to establish a special investigation unit, in accordance with SubPart 521-2.

SubPart 521-1 Compliance Programs

Comment: One commenter requested that OMIG revise the meaning of "required provider" from including "any person" to only include "provider" based upon a concern about individual personal liability.

Response: The term “person” as well as “provider” are defined in Part 504 and the suggested language change is therefore unnecessary. The definition of “person” under Part 504 includes “natural persons, corporations, partnerships, associations, clinics, groups and other entities.” However, in order for a person to be subject to SubPart 521-1, that person must be (1) subject to articles 28 or 36 of the Public Health Law, (2) subject to articles 16 or 31 of the mental hygiene law, (3) be an MMCO, or (4) claim or receive at least $1,000,000 dollars per year. While this will generally only apply to providers under the Medicaid program, the term is written broadly to ensure that all required providers are captured.

Comment: Several commenters stated that 18 NYCRR § 521-1.2 (b)(3) - “Effective compliance program” needs to be better defined with more objective and quantitative standards. Commenters felt that, as written, the definition of an effective compliance program appears vague and could result in disparate application as to what is considered effective among required providers. Commenters noted that it is not clear, what will be deemed “effective” and what is “reasonably designed” and that there is no guidance. Commenters requested that the term be more specific, with clearly delineated boundaries, as OMIG may rely upon this definition to enforce the requirements of SubPart 521-1. It was suggested that OMIG should consider the federal criteria as a baseline. Another commenter noted that the definition of “Effective compliance program” does not include any expectation that there will be outputs from the operation of the compliance program. Another commenter asked if at 18 NYCRR § 521-1.3(a), should the term be capitalized?

Response: The definition of effective compliance program is deliberately broad to give providers flexibility based on their size, complexity, resources, culture, and organizational experience. OMIG

will consider provider size, complexity, resources, culture, and organizational experience to determine effectiveness. The necessary specificity can be found in the subsequent sections and subdivisions to allow for differences in organizational experience.

OMIG applies reasonableness in reviews, however, there is no one-size-fits-all reasonableness standard. OMIG will consider provider size, complexity, resources, culture, and organizational experience when assessing providers' compliance programs. It is a reasonable expectation for compliance programs that are implemented to have outcomes, which demonstrate their effectiveness. Consequently, it is not necessary to include outcomes in the definition.

As is the case in other Parts of 18 NYCRR governing OMIG's authority, none of the defined terms are capitalized throughout the regulation.

Comment: One commenter recommended including definitions of the terms "fraud" and "abuse" in SubPart 521-1.

Response: Section § 521-1.2(a) incorporates the definitions from 18 NYCRR Part 515, which includes definitions for the terms "fraud" and "abuse". 18 NYCRR § 515.1(b)(1) defines "abuse" as: "…practices that are inconsistent with sound fiscal, business, medical or professional practices and which result in unnecessary costs to the medical assistance program, payments for services which were not medically necessary, or payments for services which fail to meet recognized standards for health care." 18 NYCRR 515.1(b)(7) defines "fraud" as: "…an intentional deception or misrepresentation made with the knowledge that the deception could result in an unauthorized benefit

to the provider or another person and includes the acts prohibited by section 366-b of the Social Services Law."

Comment: One commenter recommended including a definition of "waste" in SubParts 521-1 and 521-2.

Response: Unlike the terms "fraud" and "abuse", the term "waste" is not currently defined elsewhere in Title 18, or in federal regulations governing the Medicaid program. OMIG has already begun to incorporate a definition of "waste" in the model contracts between the Medicaid Managed Care Organizations ("MMCO") and the department to participate as MMCOs. In such contracts, OMIG has defined "waste" as meaning: "the overutilization of services, or other practices that directly or indirectly, result in unnecessary cost to the Medicaid program." OMIG will continue to provide guidance to providers and MMCOs regarding the use and interpretation of the term "waste" through sub-regulatory guidance.

Comment: One commenter requested a definition be included in the proposed regulations for the following phrase which is used in SOS § 363-d(2)(d): "organizations first tier downstream and related entities".

Response: The term "organizations first tier downstream and related entities", as it is employed by SOS § 363-d(2), does not require a specialized definition in the proposed regulations as it uses words with a common and everyday meaning that is already used in related context by the Centers for Medicare & Medicaid Services.

Comment: One commenter recommended a $5,000,000 threshold instead of a $1,000,000 threshold should be used to determine whether a person is receiving a "substantial portion of business operations" from the MA program. The commenter noted that 42 U.S.C. § 1396a(a)(68) uses a $5,000,000 threshold, and the change would make the definition of "substantial portion of business operations" consistent with this requirement. The commenter also noted that the auditing and monitoring obligation "…are substantial and could easily require a six figure expense…".

Response: OMIG declines to make this change. As part of this rulemaking, OMIG is increasing the threshold from $500,000 to $1,000,000 to reduce the burden on smaller providers. However, increasing the $1,000,000 threshold to $5,000,000 will make the MA program vulnerable to additional fraud, waste, and abuse. Furthermore, as noted elsewhere, OMIG has determined to extend the requirements of 42 U.S.C. § 1396a(a)(68) to all required providers. Unlike New York State, federal law, with some exceptions, does not mandate that Medicaid providers adopt and implement an effective compliance program. OMIG believes the substantive requirements outlined in 42 U.S.C. § 1396a(a)(68) are appropriate for inclusion in an effective compliance program.

Comment: One commenter recommended a definition of the term "category of service", which is referenced in 521-1.2(b)(9), be added to 18 NYCRR SubPart 521-1.

Response: The term "categories of service" as applied by 18 NYCRR Part 521 does not require a specialized definition in that the term uses words with a common and everyday meaning which are applied in the same manner by other MA program requirements. This term refers to the category or categories of service the provider enrolled as in the Medicaid program.

Comment: One commenter requested a stand-alone definition of “provider characteristics” as used in 521-1.2(b)(3).

Response: OMIG declines to define this term in the regulation but has amended 521-1.2(b)(3) to include examples of a provider’s characteristics to clarify the meaning of the term.

Comment: One commenter raised a question with respect to record retention requirements under 521-1.3. Specifically, the commenter asked if a compliance plan was adopted ten years ago and there were annual amendments and changes, would the original documentation associated with the approval of the underlying compliance plan ten years ago be required to be maintained for only six years?

Response: Records shall be retained for six (6) years from the date such program was implemented. If for illustrative purposes, a Provider’s compliance program is adopted, implemented and begins operating in 2022, records for such compliance program are required to be retained through and including 2028. If, in 2023, an amendment to the program is made, the records with respect to that amendment shall be retained until 2029, but the documents from the pre-amendment section will continue to have a retention year through 2028. providers are reminded that pursuant to SOS § 363-d(2), adopting and implementing an effective compliance program is a condition of receiving payment under the Medicaid program. Providers are also required, pursuant to 18 NYCRR § 504.3(a), to maintain records demonstrating the right to receive payment under the program for a period of six (6) years from the date the care, services or supplies were furnished.

Comment: Several commenters raised concerns regarding the different regulatory obligations that required providers would have in relation to "contractors, agents, subcontractors, and independent contractors". The comments included specific concerns about: how the definition of affected individuals intermingles different categories for which the required provider may not have the authority to manage equally in all instances; how required providers are responsible for the performance of "contractors, agents, subcontractors, and independent contractors" with the required provider's compliance program; a recommendation to revise 18 NYCRR Part 521 to include authority that would allow required providers to terminate contracts with "contractors, agents, subcontractors, and independent contractors"; how "contractors, agents, subcontractors, and independent contractors" will be trained regarding the required provider's compliance program; "contractors, agents, subcontractors, and independent contractors" being subject to both their own compliance programs and the required provider's compliance program; and existing contracts between required providers and "contractors, agents, subcontractors, and independent contractors" do not permit the enforcement of disciplinary standards required by 18 NYCRR Part 521.

Response: OMIG appreciates the perspective of these commenters. As a general matter, as the party to which payment is made by the MA program, required providers are responsible for ensuring services provided to Medicaid recipients comply with the laws and official directives of the MA program which govern the performance of those services. As such, required providers are responsible for ensuring the services to Medicaid recipients that it provides by using "contractors, agents, subcontractors, and independent contractors" (hereinafter collectively referred to as "Contractors") also comply with applicable laws and official directives of the MA program. This includes the adherence of Contractors with the compliance program of the required provider.

To enforce compliance by Contractors, required providers may need to modify the existing contracts it has with Contractors. To assist required providers in meeting these requirements, OMIG will only enforce the requirements of section 521-1.3(c) for contracts executed or renewed starting 90-days and no later than 2-years from the effective date of SubPart 521-1, which shall also be confirmed in guidance.

OMIG will also make technical revisions to section 521-1.3(c), restructuring the subdivision into paragraphs, and clarifying that Contractors are only subject to the required provider's compliance program to the extent it is related to their contracted role and responsibilities within the provider's identified risk area. For example, an entity contracted to provide "credentialing services" would be required to comply with written policies and procedures, training, etc., as it related to the provision of "credentialing services." Supplemental guidance will be issued about how OMIG intends to interpret 18 NYCRR § 521-1.3(c) in the context of when Contractors are subject to both its own compliance program and the compliance program of the required provider. However, we believe the technical corrections above should clarify and narrow the scope of this requirement to better reflect OMIG's intent. In addition, OMIG will explore with DOH amending the standard clauses for MMCO network providers to incorporate the requirements of this SubPart.

Comment: Several commenters sought general clarification of the terms "affected individuals" and "contractors, agents, subcontractors, and independent contractors," including whether all policies and procedures would be applicable to affected individuals. One commenter recommended the term "first tier, downstream or related entities" be used instead of the term "affected individuals".

Response: As noted above, OMIG is making technical corrections to section 521-1.3(c), which we believe should clarify and narrow the scope of this requirement. As we interpret the requirement, only those policies and procedures relating to the scope of the contracted authority and affected risk areas would need to be shared with the Contractor. The terms “affected individuals” is defined in the regulation and we decline to make adjustments to its definition.

In addition, 18 NYCRR Part 521 permits required providers to implement compliance programs that are subject to each entity’s characteristics provided those compliance programs also comply with regulatory requirements.

Comment: Multiple commenters were concerned that the requirement for Contractors to be subject to both their own compliance program and the required provider’s compliance program is burdensome.

Response: Not all Contractors are required providers. However, to the extent that Contractors qualify as a required provider, the Contractors are responsible for implementing its own compliance program pursuant to the requirements of 18 NYCRR SubPart 521-1. Contractors are also subject to the compliance program of the required provider with which it contracts. However, as noted in section 521-1.3(a), 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 SubPart 521-1 are met. Therefore, a Contractor who is also a required provider, can and should work with the required providers it contracts with to determine how to implement the requirements of SubPart 521-1 in the most efficient manner possible. OMIG will issue supplemental guidance on this topic and will take into consideration each required provider’s circumstances and characteristics when conducting its reviews.

Comment: A commenter was concerned about the application of the term “contractors, agents, subcontractors, and independent contractors” to entities who do not provide direct Medicaid services to recipients, but who, instead, furnish goods to required providers.

Response: To the extent that “contractors, agents, subcontractors, and independent contractors” are affected by the required provider’s risk areas related to the provision of care, services, and supplies under the MA program, it is subject to the required provider’s compliance program.

Comment: One commenter stated that Contractors who provide critical services or supplies cannot be easily replaced if the contract is terminated. Therefore, such Contractors cannot be terminated by required providers.

Response: 18 NYCRR § 521-1.4(a)(viii) includes sanctions other than termination. Further, while contracts between required providers and Contractors are required to include termination provisions, they can also be drafted to include progressive remedies.

Comment: A commenter was concerned that 18 NYCRR Part 521 will be burdensome on smaller required providers to ensure that their contractors and vendors are compliant with the regulations.

Response: This concern is addressed by 18 NYCRR § 521-1.1(b)(4) and 18 NYCRR § 521-1.2(b)(11). Specifically, notwithstanding 18 NYCRR § 521-1.1(b)(1-3), a required provider does not include an entity which does not claim or should be reasonably expected to claim at least one million dollars annually from the MA program. Only required providers are obligated to ensure Contractors adhere to the required provider’s compliance program. The burdens placed on smaller providers was

one of the factors OMIG considered in raising the billing threshold from $500,000 to $1,000,000 in this rulemaking.

Comment: One commenter asserted that disciplinary standards are not generally applicable to the board or governing body of some affected individuals. The commenter also asserted disciplinary standards are not applicable to all affected individuals.

Response: The term “affected individuals” expressly includes “the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.” See, 18 NYCRR § 521-1.2(b)(1). Disciplinary standards may be defined in different documents other than written policies for governing body members such as in bylaws and for Contractors, in contract provisions.

Comment: A couple of commenters raised questions about the risk areas in 18 NYCRR § 521-1.3(d). One commenter requested the addition of a definition for “statistically valid service verification” found in 18 NYCRR § 521-1.3(d)(11)(x). Another commenter suggested adding “government audits and investigations” to the list of Risk Areas.

Response: ”Statistically valid service verification” is a requirement imposed on MMCOs and is specified in the MMCO’s contract with DOH to participate as an MMCO. Per the March 1, 2019 Medicaid Managed Care model contract, MMCOs are required “[p]ursuant to 42 CFR 438.608(a)(5), the [MMCO] will implement a service verification process that accurately evaluates the delivery of billed services to the recipient population by using statistically valid sample sizes and timeframes that determine whether Enrollees received services billed by Providers.” As this

requirement is specified in the model contracts, it is unnecessary to further define the requirement in this regulation.

Comment: One commenter recommended that 18 NYCRR § 521-1.3(e) should include a list of the relevant directives the department and OMIG expect providers and payors to incorporate and/or comply with.

Response: Section 521-1.3(e) requires providers to comply with all directives of the department or OMIG with respect to compliance programs. OMIG will communicate its directives to providers through the issuance of guidance documents, compliance alerts and through the Medicaid Updates.

Comment: Multiple commenters were concerned that 18 NYCRR § 521-1.3(f)(2) requires participating providers, who are required providers, to provide MMCOs with a copy of the Certification Statement for Provider Billing Medicaid (ETIN) with the execution of the participating provider agreement and annually thereafter.

Response: The submission of the Certification Statement for Provider Billing Medicaid (ETIN) to each MMCO with which the provider participates is appropriate, as a compliance program is a condition of payment by the MA program. To satisfy this requirement, the participating provider is required to submit a copy of the annual Certification Statement for Provider Billing Medicaid (ETIN) form to the MMCO.

Comment: Several commenters raised concerns with the requirements under SubPart 521-1 relating to written policies and procedures. Two commenters were concerned with the requirement that a

required provider identify "…governing laws, and regulations that are applicable to the provider's risk areas, including any MA program policies and procedures…" One commenter suggested the requirement be omitted, or, as an alternative, that the language of this provision be amended to require that providers' written policies and procedures reference only those statutes and regulations that are the most directly relevant to, or materially impact, providers' risk areas, in the judgment of the provider. One commenter was also concerned with the requirement to review written policies and procedures on an annual basis and suggested the requirement either be omitted or changed to once every three years. One commenter was also concerned that the scope of the requirements under §521-1.4(a) would be unduly burdensome on required providers and result in written policies and procedures that are so large and complex, as to be meaningless to affected individuals. One commenter was also concerned with the requirement to make written policies and procedures available to all affected individuals, which would also include contractors, subcontractors, agents, and independent contractors, and that such policies and procedures may contain proprietary information that would not be appropriate to share with such entities.

Response: OMIG appreciates these perspectives, and agrees that requiring "… governing laws, and regulations that are applicable to the provider's risk areas, including any MA program policies and procedures …" to be in the required provider's policies and procedures can be voluminous. With the exception of written policies and procedures related to 42 U.S.C. 1396a(a)(68), referencing the governing laws, regulations, and Medicaid program policies and procedures by citation would be appropriate and sufficient to meet the requirements of this regulation. Moreover, focusing on those governing laws and regulations that are significant to the provider's participation in the Medicaid program and risk areas, would not be inconsistent with our regulatory intent.

We also understand the concern with conducting the annual review of the written policies and procedures. A best practice is for the provider to update the policies and procedures on an ongoing, as-needed basis due to changes in statutes, regulations, directives, and internal procedures. An annual review of both the compliance program and compliance-related policies and procedures is a good method to confirm the effectiveness of the provider's compliance program. Therefore, we decline to revise the regulation to require a review of written policies and procedures every three years.

Providers have the flexibility to create compliance-related written policies and procedures that are brief and to the point, so long as they include all the requirements. Moreover, the regulation already limits the inclusion of governing laws, regulations, and Medicaid program policies and procedures to those that are applicable to the provider's risk areas.

Finally, in terms of the requirement to share written policies and procedures with contractors, subcontractors, independent contractors, and agents, OMIG recognizes the concern about sharing proprietary information, and the larger concerns expressed elsewhere in the comments with the application of the term "affected individuals" to such entities and the wider implications thereof. Therefore, OMIG will make non-substantive revisions to 521-1.3(c) designed to clarify OMIG's intent that Contractors are only subject to the required provider's compliance program to the extent it is related to their contracted role and responsibilities within the provider's identified risk area.

Comment: One commenter requested that guidance should be provided on how a provider should determine if policies and procedures are being followed.

Response: Since the written policies, procedures, and standards of conduct required by SubPart 521-1.4(a) encompass many business practices, they may need to be audited for compliance via different methods. The regulation is so as to not be overly proscriptive, so providers have flexibility to determine the best way to validate that their policies are being followed. OMIG will continue to monitor to
determine if additional guidance is needed.

Comment: Multiple commenters expressed concern with how the application of disciplinary procedures would interact with the terms of collective bargaining agreements, when applicable; whether they need to include a specific description of "degrees of disciplinary actions" for potential instances of non-compliance in disciplinary procedures; whether disciplinary standards are applicable to the governing body, contractors, and agents; and requested detailed guidance as to what these disciplinary standards should look like and what will be deemed acceptable.

Response: It is not the intent of the regulation to require providers to pre-determine specific scenarios and related disciplinary actions. We agree that disciplinary actions should be progressive. A technical revision will be made in 521-1.4(a)(2)(viii)(a) to clarify that providers are required to have standards for escalating disciplinary actions in response to non-compliance. Such standards should be documented and maintained in accordance with the document retention requirements of 18 NYCRR § 521-1.3(b).

The proposed rule does account for collective bargaining agreements. Section 521-1.4(a)(2)(viii)(b) states, "Disciplinary procedures shall conform with collective bargaining agreements when applicable."

Comment: Two commenters asserted that 18 NYCRR § 521-1.4(2)(ix) should apply the $5,000,000 threshold required by 42 U.S.C. § 1396-a(a)(68), and not extend the requirement to all required providers. One commenter stated that the regulation did not align with SOS § 363-d and with federal requirements.

Response: SOS § 363-d(2)(a)(8) applies each of the provisions of 42 U.S.C. § 1396a(a)(68) to all providers, notwithstanding the threshold required by 42 U.S.C § 1396a(a)(68) for such entities to also receive or make annual payments of at least $5,000,000 annually. 18 NYCRR § 521-1.4(a)(2)(ix) reiterates and clarifies how the provisions of 42 U.S.C. § 1396a(a)(68) are applied by SOS § 363-d(2)(a)(8). While federal law only applies these requirements to individuals or entities that bill or receive $5 million annually, OMIG has determined to extend this requirement to all required providers. 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. OMIG believes that having policies and procedures, as well as education, regarding the State and Federal false claims act as part of a provider's compliance program, which includes the rights of employees to be protected as whistleblowers, is an important safeguard in the prevention and detection of fraud, waste and abuse in the Medicaid program. Moreover, unlike New York State, federal law, with some exceptions, does not mandate that Medicaid providers adopt and implement an effective compliance program. OMIG believes the substantive requirements outlined in 42 U.S.C. § 1396a(a)(68) are appropriate for inclusion in an effective compliance program.

Comment: Several commenters raised concerns with the use of the term “compliance officer” and with the scope of the responsibilities of the compliance officer. One commenter was concerned that section 521-1.4(b)(1)(iii) creates an obligation for the compliance officer to revise the compliance program without input or approval from the CEO, senior administration or the governing body. The commenter was also concerned about creating a conflict of interest with the requirement that the compliance officer assist with establishing methods to improve the required provider’s efficiency and quality of services under section 521-1.4(b)(1)(v). Several commenters disagreed with the regulation identifying the compliance officer as the “focal point” for the required provider’s compliance program and suggest that it transforms the compliance officer’s role from oversight to operations and makes the compliance officer “personally” responsible for carrying out the day-to-day activities of the program. Several commenters suggested revisions to address their concerns with the scope of the compliance officer’s role. Another commenter was concerned that using the term “compliance officer” conferred on the individual fiduciary responsibilities and recommended that the regulation use alternative terms, or switch to a tiered system based on the size of the provider.

Response: OMIG appreciates the concerns of these commenters and the perspectives they bring. From OMIG’s perspective in drafting this regulation, the Compliance Officer is meant to be the one central person designated as having the compliance oversight responsibility. The term “compliance officer” is the title used and is not intended to require that the individual be an officer of the provider, nor is it intended to confer a “fiduciary responsibility” on the individual, nor, standing alone without any other legal violation, to impose personal responsibility for the actions of the provider. OMIG will make technical revisions to 521-1.4(b) to clarify the role of the compliance officer as providing day-to-day oversight of the compliance program.

Comment: One commenter recommended that OMIG adopt the requirement, found in federal corporate integrity agreements, that a compliance officer cannot be the general counsel or chief financial officer, that the compliance officer cannot report to these positions, and the compliance officer cannot be involved in any non-compliance activities that conflict with compliance responsibilities (i.e., billing, coding, etc.). The commenter also notes that increasing the threshold for "substantial portion of business operations" to $5,000,000 would make imposing this requirement possible.

Response: OMIG agrees, in principle, that the compliance officer should not be the general counsel or chief financial officer, or report to those positions, or be involved in activities that conflict with compliance activities. However, OMIG believes the threshold of $1,000,000 for "substantial portion of business operations" is reasonable and should not be increased as the commenter suggests. As such, we believe it is reasonable to maintain flexibility for providers who may not be able to separate the compliance officer from these functions. If it is not feasible for the provider to separate the compliance function, then a procedure for addressing conflicts of interest or potential risks to achieve an appropriate system of checks and balances is recommended. Therefore, OMIG declines to make the requested change, but will provide additional clarification and direction through its sub-regulatory guidance.

Comment: One commenter had concerns with the provision in 18 NYCRR §521-1.4(b) that requires a compliance officer to develop and implement a compliance work plan and recommended requiring such a plan only in the event a deficiency is found during an audit of the entity's compliance with the regulation.

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

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

Comment: Several commenters had concerns with the membership and responsibilities of the compliance committee. Specifically: One commenter had a concern about 521-1.4(c)(1)(v) creating an obligation for the compliance committee to modify the compliance program; one commenter stated that the requirements that the compliance committee meet no less than quarterly, update the committee charter annually, and report directly to the CEO and board were unnecessarily inflexible; one commenter recommended that 18 NYCRR §521.1.4(c) be clarified to allow for a minimum of at least one senior manager from each department implicated by the articulated risk area; one commenter recommended that OMIG require the Chair of the Compliance Committee be someone other than the Compliance Officer and instead be a senior manager designated by the chief executive; and one commenter felt it is impractical to expect the Compliance Committee to ensure the

Compliance Officer is allocated sufficient funding, resources, and staff as this is the function of the chief executive and the governing body.

Response: Compliance committee responsibilities are meant to be coordinated with, and in support of, the compliance officer's responsibility for the oversight of the day-to-day activities of the required provider's compliance program. This cannot be accomplished unless the compliance committee is meeting regularly. Therefore, OMIG disagrees that meeting at least quarterly, at a minimum, is an excessive burden. OMIG believes that meeting less frequently could limit the ability of the provider to adapt to changes and fulfill requirements for its annual review of the compliance program. The information included in the compliance committee charter may change over time. Therefore, it is a reasonable expectation that such charter be reviewed and, if needed, updated annually. However, it is possible that the annual review of the compliance committee charter may produce no updates. If the provider can produce evidence of an annual review of the compliance committee charter, and no updates were necessary, the requirement is met.

Since the compliance committee is comprised of senior managers, it is reasonable that it is accountable to the chief executive and governing body. Reporting on its activities and progress allows the compliance committee to: (a) show that it is meeting its mission and (b) receive guidance from the top of the organization. A non-substantial change was made to 18 NYCRR §521-1.2(b)(3) for clarity. Section 521-1.4(c)(2) states, "Membership in the committee shall, at a minimum, be comprised of senior managers." This allows flexibility for providers to determine how many senior managers, and other personnel, they include on the committee. Also, Section 521-1.4(c) states, "The required provider shall outline the … designation of a chair … in a compliance committee charter." The language allows flexibility for providers to determine who should be the chair of the committee.

Ensuring that the provider allocates sufficient funding, resources, and staff means that the committee is meant to advocate for the compliance function with whomever is responsible for such allocation. To do so, the committee should work with the compliance officer to identify what sufficient funding, resources, and staff are needed. OMIG will make technical, non-substantive revisions to Sections 521-1.4(c)(1)(iii) and 521-1.4(c)(1)(v) to clarify the role and responsibilities of the compliance committee to advocate for the compliance officer to be allocated sufficient resources and for the adoption and implementation of required modifications to the compliance program.

Comment: Two commenters expressed concerns regarding the training and education requirements. Specifically, one commenter recommended the state develop more frequent trainings for compliance officers that are available for free or at a nominal cost. We find that the trainings OMIG and other agencies do provide are quite helpful. Another commenter recommended OMIG revise its training and education requirements to better align with the goal of preventing and detecting waste, fraud, and abuse in the Medicaid program. Employees, board members and contractors, for example, all have different training and education needs, depending upon their roles and responsibilities. Providers should have discretion to determine when, how, and under what circumstances it may be appropriate to train and educate these individuals.

Response: Compliance training and education are important requirements and should be complied with. Additionally, OMIG plans on issuing provider guidance, developing templates to support collection of information and offering necessary trainings on the new regulations after they go into effect. OMIG intends to work with the provider community to identify the need for training and how to best address those identified needs. Providers and/or associations will have the opportunity to

request presentations or trainings from OMIG. Providers can also find no-cost training opportunities on the web, as well.

The requirement for training at orientation and annually thereafter is not a new requirement. Under the prior version of Part 521, Contractors were included as affected individuals within the category of "persons associated with the provider."

Since compliance program requirements extend to many provider types with different characteristics, the compliance program training and education requirement may be implemented in various ways. As a result, evaluating whether a compliance training and education program is effective may be accomplished via different methods. The regulation is purposely vague on this point to allow providers flexibility when determining the best way to evaluate that their compliance program training and education is effective.

OMIG agrees that employees, board members, and contractors all have different training and education needs, depending upon their roles and responsibilities. However, all Affected Individuals must receive compliance program training and education that includes all of the required topics outlined in Section 521-1.4(d)(1). The regulation is purposely vague on the need for additional role-specific training, so providers have flexibility when determining how to accomplish such training.

Comment: One commenter requested clarification on the requirement under section 521-1.4(d)(1)(viii) that training include coding and billing "best practices." Specifically, the commenter requested where the "best practices" are published and what source OMIG will use to determine "best practices."

Response: In determining whether a required provider met the requirement to include "coding and billing requirements and best practices" in its training program for affected individuals, OMIG will rely on the rules and regulations, and policy directives of the Medicaid program. There is also guidance issued by HHS and DOH regarding best practices, topically, and based on provider type, as well as likely best practices identified within a given industry. Ultimately, it is the provider's responsibility to identify their unique coding and billing requirements and develop and implement best practices, if applicable.

Comment: One commentor inquired about how "an effective system for the routine monitoring and identification of compliance risks" is defined under section 521-1.4(g). The commenter specifically asked if the next sentence in section 521-1.4(g) defines it?

Response: The entirety of sections 521-1.4(g) and (h) describe what comprises an effective system for the routine monitoring and identification of compliance risks, and how to respond to such risks.

Comment: One commenter sought clarification on the use of the term "ongoing" in Section 521-1.4(g)(1). The commenter stated that the term was very general and should be more clearly defined to establish a clear expectation. The commenter suggested a tiered system to determine how often and to what extent audits should be conducted. The commenter requested clarity in the regulation, OMIG protocols, or through guidance.

Response: OMIG agrees with the commenter's concern regarding the use of the term "ongoing". The regulation addresses all provider types and sizes so as to not be overly proscriptive and burden

smaller providers. This gives providers flexibility to implement compliance program requirements based on their size, complexity, resources, and culture. However, the term “ongoing” means continual or in progress. We recognize that this could be taken to require providers to conduct audits on a continuous basis, which depending on the size the provider, may not be reasonable or clearly set our expectation. Therefore, we will make a technical revision to replace the word “ongoing” with “routine” to better reflect the intent of the provision and will provide additional clarity through our sub-regulatory guidance.

Comment: Several commenters were concerned with the requirement to conduct compliance program reviews on an annual basis, and felt the requirement was neither necessary nor advisable. Commenters requested OMIG modify this proposal and require that compliance program reviews be undertaken no less frequently than every three years. One commenter also requested that OMIG consider a federal requirement that allows Medicare Advantage Plans to conduct an annual assessment and requested that MMCOs be allowed to conduct one assessment for both agencies to reduce administrative redundancies.

One commenter also requested that the requirement at 18 NYCRR § 521-1.4(g) be clarified, that the word “other” be added when referring to the qualifications of staff, to make it clear that these requirements do not apply to the compliance officer or compliance committee.

Response: An annual review of the compliance program is a good method to confirm its effectiveness. Required providers must conduct an annual compliance program review to accurately attest in the annual Certification Statement for Provider Billing Medicaid (ETIN) form that, “I (or the entity) have adopted and implemented, where applicable, an effective compliance program pursuant to New York State SOS § 363-d and have satisfied the requirements of Title 18 of the New York

Codes, Rules and Regulations Part 521." Therefore, OMIG believes that an annual review supports this certification requirement. It should be noted that this certification requirement took the place of an annual reporting requirement to OMIG that many providers saw as duplicative.

18 NYCRR § 521-1.3(a) states "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." To the extent the assessments overlap, they can certainly be done in conjunction. However, the OMIG requirements, to the extent they differ or supplement the federal requirements, must be met.

OMIG agrees that in 18 NYCRR § 521-1.4(g), a non-substantive revision to add word "other" between the words "such" and "staff," will be made for clarity.

Comment: One commenter suggested that the introductory sentence of §521-1.4(g)(3) "In accordance with section 515.5 of this Title" makes it appear as if 18 NYCRR 515.5 requires Medicaid providers to conduct the portion of exclusion check that is created by 521-1.4(g)(3). The commenter suggested that the "In accordance with section 515.5 of this Title" be removed.

Response: 18 NYCRR § 515.5 establishes the effect of an exclusion or condition or limitation on a person's participation in the Medicaid program. 18 NYCRR § 515.5(d) and (e) requires the provider to know the identity of excluded individuals in order to not seek reimbursement for costs or for medical care services or supplies furnished by an excluded person. A provider would not be able to claim as allowable any amounts paid or credited to a person who is excluded from the program. Therefore, while it may not explicitly require a provider to check specific exclusion lists, a deeper

reading of 515.5 does require the provider to identify and determine the exclusion status of an affected person so that they do not submit claims or claim costs that are not payable under the Medicaid program.

Comment: One commenter requested clarification under section 521-1.4(g)(3) as to which individuals or entities, in addition to participating providers and subcontractors, an MMCO is required to identify and determine the exclusion status.

Response: Section 521-1.4(g)(3) requires MMCOs to identify and determine the exclusion status of persons, in addition to participating providers and subcontractors, identified in the contract an MMCO has with the DOH to participate as an MMCO. Under the contracts, an MMCO may have additional obligations to check the exclusion status of employees, who may also meet the definition of affected individual (i.e., managing employees and owners). In addition, they may also be required to review and determine the exclusion status of non-participating providers.

Comment: One commenter suggested that OMIG include the Federal General Services Administration's System for Award Management ("SAM") as an exclusion database required providers must check under section 521-1.4(g)(3)(i).

Response: The SAM list is a database of individuals and entities who the federal government has debarred from federal contracting. 42 C.F.R. § 455.436 requires the state to check the Excluded Parties List System (EPLS) (aka SAM) list no less frequently than monthly. Likewise, the model contract has imposed a similar requirement on the MMCOs. As the SAM is a federal list, and the federal government has only required the State to check the list and not imposed a requirement that

providers check the SAM list, the proposal from the commenter is unnecessary. Moreover, as the State is checking the SAM list for providers, and any person with an ownership or control interest or who is an agent or managing employee of the provider, imposing this requirement on the providers would be redundant.

Comment: Several commenters raised concerns with the requirement to report credible violations of State or Federal laws, rules or regulations to the appropriate government entity under section 521-1.4(h)(4). The commenters were concerned that the reporting requirement was too broad and would burden the provider and the appropriate governmental entity. Commenters requested that OMIG either delete the requirement, provide a threshold for reporting and/or narrow the scope.

Response: OMIG will make a technical revision to 18 NYCRR § 521-1.4(h)(4) to clarify that such reports are only necessary when they are otherwise required by law, rule or regulation.

Comment: OMIG received several comments regarding the compliance program review provisions of section 521-1.5, and the definition of “effective compliance program”. Several commenters stated that, as written, the definition of an effective compliance program is vague and could result in disparate application as to what is considered effective among required providers. Commenters recommended including at 18 NYCRR § 521-1.5(d)(3) a definition of what constitutes not satisfactorily meeting the requirements of SOS §363-d and 18 NYCRR Subpart 521-1 since this may be the basis of possible monetary penalties and/or revocation of participation in the Medicaid program. A commenter fears that the statement in 18 NYCRR § 521-1.5(a), that “[n]othing in this SubPart shall preclude or limit the department’s ability to determine if a required provider has an effective compliance program”, gives carte blanche to OMIG to determine what is considered an

"Effective Compliance Program." The commenter strongly encouraged OMIG to provide more clarification to address this concern, and at a minimum, adopt a "reasonableness" standard for evaluating compliance program efficiency. Commenters also believe it is critical that OMIG provide a process and related details for providers and MMCOs to appeal an OMIG determination that an adopted compliance program is not satisfactory. Commenters noted that the proposed regulations do not allow providers the opportunity to correct any deficiencies in their compliance program prior to a finding, including deficiencies that are simply administrative in nature and can be easily corrected. One commenter requested that OMIG include objective criteria for when a provider passes or fails a compliance program review and stated that prior reviews required a provider to get a 100% score to obtain a satisfactory review.

Response: OMIG appreciates the perspective of these commenters. In drafting SubPart 521-1, OMIG left the terms "satisfactory" or "effective" deliberately broad, because the section applies to different organizations, each with varying organizational experiences and risk areas. 18 NYCRR § 521-1.2(b)(3) includes a definition for "effective compliance program," which is broad enough to encompass all provider types and the unique characteristics of the providers. OMIG believes the "not satisfactorily meeting the requirements of SOS § 363-d and 18 NYCRR Subpart 521-1" uses words with a common and everyday meaning and therefore, OMIG declines to include a specific definition. OMIG does not expect providers to achieve a 100% score in order to obtain a satisfactory review. When OMIG conducts a compliance program review, it will apply a reasonable standard based on the provider's size, complexity, resources, and culture. OMIG will issue guidance outlining in more detail the process it will use for conducting its compliance program reviews.

18 NYCRR § 521-1.5(a), does not relate to OMIG compliance reviews. Under SOS § 363-d DOH is also authorized to conduct compliance program review and are not bound to the procedures of this SubPart.

Since compliance program reviews will be for a specified time in the past, there is no opportunity for providers to correct deficiencies in past practices. OMIG will include recommendations for improvement in its assessment along with an expectation that providers take immediate action to implement corrective actions to remedy any identified deficiencies going forward, and which may be ongoing. There is no appeal process attached to compliance program reviews. However, OMIG will afford providers an opportunity to respond prior to issuing a final assessment. Moreover, if OMIG seeks to take an enforcement action, the required provider will have the opportunity to appeal that action. For example, if OMIG seeks to impose a monetary penalty under 18 NYCRR Part 516, the provider would have an opportunity to respond to a notice of proposed agency action, and, following issuance of a notice of agency action, the opportunity to request an administrative hearing under 18 NYCRR Part 519.

Comment: One commenter requested clarification on the “period” OMIG will use for its review of compliance program and noted that evidence of “continuous operation” may be difficult to prove in the phase-in period of the regulation. The commenter also requested to know if OMIG will take into consideration mergers, acquisitions, ownership changes, etc. when reviewing a provider’s historical operation of their compliance program.

Response: OMIG will notify required providers of the period that is under review through its notification required by section 521-1.5(c). The review period will be within the six (6) year lookback

period for which the required provider is required to retain records demonstrating the adoption, implementation, and continuous operation of their compliance program. Please note, that any review by OMIG and any enforcement action would not occur for at least 90-days following the adoption and effective date of this rule, in accordance with the requirements of SOS § 363-d(c). Moreover, SOS § 363-d(1) & (2) authorizes the imposition of a monetary penalty on a per calendar month basis, for up to 12 months. That also establishes a constraint on the scope and length of any review period. OMIG will review and consider, in the course of its review of a required provider's compliance program, any written arguments or documentation submitted by a provider regarding mergers, acquisitions, ownership changes, or any other factor not listed but raised by the provider, which impacted the historical operation of its compliance program.

Comment: OMIG received comments concerning the application of the compliance program requirement to regional social determinants of health networks (SDHN) who oversee a regional network of social care community based organization ("CBO") providers under an 1115 waiver currently pending approval with CMS. The commenter stated that value based payments ("VBP") and fee-for-service payments to CBOs are not predictable, and MMCOs are likely to apply the requirement across all service organizations. The commenter was concerned that the cost of establishing a compliance program for most CBOs would be prohibitive. The commenter indicated that CBOs have existing compliance program requirements, including annual audits by the NYS Charities Bureau. The commenter recommended that the requirements for maintaining a compliance program should be on the SDHN, who would be responsible for oversight and risk assessment for their network. The commenter also asked that an annual attestation from each CBO participating in an SDHN Independent Practice Association ("IPA") should be the only requirement for CBOs to submit to OMIG, their regional HERO, and the contracting lead entity in which the CBO participates.

The commenter also requested that OMIG issue guidance to SDHNs similar to what was issued in 2015 to the DSRIP Performing Providers Systems regarding their obligation to implement effective compliance programs. The commenter requested that the guidance outline the SDHN and MMCO compliance requirements for social needs services under the 1115 waiver, if approved by CMS. The commenter also requested that if there is the recovery of an overpayment because of erroneous or falsified reporting on the part of an SDHN participant, where such reporting was rolled up by the SDHN to determine a waiver related payment or MMCO, the CBO would be responsible.

Response: OMIG expects that any provider who meets the definition of a "required provider" should meet the requirements of SubPart 521-1. Required providers are required to certify, in accordance with the requirements of subdivision (f) of section 521-1.3, that they have met the requirements of SOS § 363-d and SubPart 521-1. OMIG declines to create an alternative certification or attestation requirement at this time. Pursuant to 18 NYCRR Part 518, OMIG may pursue recovery of an overpayment from the person who submitted an improper or incorrect claim, the person who caused such claim to be submitted, or the person receiving payment for the claim.

Comment: A commenter asked if the proposed regulations have any impact on the Verification Organization ("VO") Audits that are conducted on behalf of OMIG?

Response: This rulemaking does not impact the activities of VOs conducted on behalf of certified home health agencies, long term home health agencies, and personal care providers pursuant to SOS § 363-e. In addition, any VO that is a "required provider" will be subject to the requirements of SubPart 521-1. Moreover, any contract that a required provider has with a VO will be subject to that provider's compliance program pursuant to 521-1.3(1)(c) (if the contractor falls under the "Affected

Individual" definition of 521-1.2 (b)(1)). The Affected Individual will include such contractors who are affected by the required provider's risk areas as defined by 521-1.3(d).

SubPart 521-2 Medicaid Managed Care Fraud, Waste and Abuse Prevention Programs

Comment: One commenter indicated that the breadth and scope of the regulation would lead to increased administrative burden and increased costs for MMCOs and the State, and abrasion with providers. The commenter also recommended that the OMIG withdraw the proposal until the impact of the pending legislation, S.4486-B/A.7889, is determined.

Response: The standards being implemented are reasonable, attainable, and comparable to the standards imposed by other state's Medicaid programs or found in other regulatory requirements. In many instances, the Plans already meet the thresholds imposed in the regulation. Moreover, the regulation allows for flexibility in the types of activities a Plan can take in meeting the 1% Medicaid claims review requirement as well as allow for the use of alternative minimum staffing in certain instances.

OMIG does not need to delay moving forward with the proposal due to S.4486-B/A.7889 as it does not amend SOS § 364-j(39) which requires MMCOs to adopt and implement fraud, waste and abuse prevention programs and for OMIG to promulgate regulations establishing the standards for such programs. Nor does it preclude OMIG from requiring Plans to comply with regulatory requirements and/or inhibit OMIG's ability to amend/create requirements related to SIU staffing or claims review.

Comment: One commenter requested that OMIG clarify the scope of SubPart 521-2 as to the inclusion of "waste" and to provide a definition of "waste." The same commenter also requested that OMIG define "all personnel", as that term is used in section 521-2.4(a)(3), to mean SIU staff.

Response: SubPart 521-2 includes, within its scope, waste, in addition to fraud and abuse. Under Federal regulations (42 CFR § 438.608) MMCOs are required to refer to OMIG all cases of potential fraud, waste and abuse. Therefore, the term "waste" has been incorporated into this SubPart, as it was in the model contracts, in compliance with federal requirements. Under the March 1, 2019, Mainstream Model Contract, OMIG provided the following definition of "waste": "the overutilization of services, or other practices that directly or indirectly, result in unnecessary cost to the Medicaid program."

We also decline to define "all personnel" under 521-2.4(a)(3) as only applying to SIU staff. The term is already narrowed by the inclusion of language specifying "all personnel involved in identifying and evaluating instances of potential fraud, waste and abuse." While in most instances this will encompass SIU staff, we decline to be so proscriptive that other staff of an MMCO involved in such activities would be excluded from the training requirement.

Comment: One commenter requested clarification regarding the meaning of "private interviews" under section 521-2.3 and expressed concerns regarding the MMCO's ability to make subcontractor personnel or enrollee's available for such interviews. The commenter also expressed concern that the term may be meant to prevent counsel from being present during such interviews.

Response: This requirement already exists for MMCOs subject to 10 NYCRR 98-1.21(b)(8), and the provision has been included in Part 521 to ensure consistency. Moreover, the requirement is that an MMCO "permit" OMIG and MFCU to conduct private interviews with its personnel, and the personnel of its subcontractors, and enrollees. OMIG's expectation, therefore, is that even if an MMCO cannot compel a witness to appear, that the MMCO will not interfere or prevent OMIG or MFCU from conducting an interview; inter alia, to "permit" the interview. To be clear, the regulation does not prevent an individual or entity from having their own counsel present during the "private interview".

Comment: Several comments were received in connection with the staffing requirements outlined in Section 521-2.4. One commenter sought clarification of the staffing requirements in Section 521-2.4(b)(1) asking if there are interim requirements when the number of enrollees fall between the staffing thresholds. One commenter sought clarification on the requirement to "employ investigators dedicated to servicing a particular county when that county on its own meets the designated investigator-to-enrollee ratio." Several commenters indicate the staffing requirements in 521-2.4 are unnecessary, costly, and difficult to implement due to limitations in finding qualified investigators. It was recommended that MMCOs be able to demonstrate that their FWA prevention programs have sufficient staff and resources to be effective without referring to a specific number of investigators or requiring SIU investigator qualifications. One commenter asked for a definition of "full time" and recommended that it be defined as a "full-time equivalent (FTE)" under which more than one individual can meet the requirement. Another commenter was concerned that the regulation imposed more rigorous staffing requirements on MLTCs then on MCOs.

Response: It is expected that additional staffing will only be prompted when the thresholds outlined in 521-2.4(1) are met and not at intermediate points. The intent of the county-based staffing

requirement is to ensure sufficient local staffing to facilitate fieldwork that would support the efficiency of investigations, not to dictate how those resources are utilized in specific situations thereby giving the MMCOs flexibility. The definition of full time will be defined in guidance and OMIG will consider the suggestion of FTE in issuing its guidance.

Prior federal audits of the State Medicaid Program have recommended minimum staffing requirements be implemented. The investigator qualification requirements for SIUs already exist in NYIL §409(b)(3) and §86.6(c) of Regulation 95, and in 10 NYCRR 98-1.21. The proposed regulations allow for plan flexibility through the option of proposing alternative staffing arrangements. In enforcing the requirements of SubPart 521-2, OMIG will take into consideration an MMCO's documented good faith efforts to hire and retain staff in any review or enforcement action.

We disagree that the staffing ratios for SIUs are more rigorous for MLTCs than for other Plan types. In developing the lower staffing ratio (6,000 enrollees) OMIG considered not only enrollment thresholds but payments to plans, with the rate of per member reimbursement for MLTCs is higher than other plan types. Taking these factors into consideration, OMIG developed a standard for MLTCs consistent with the requirements for MCOs, who have higher enrollment, but lower reimbursement per member, without overburdening the MLTCs. As noted by the commenter, MTLCs typically have fewer enrollees than other Plan types.

Comment: One commenter requested guidance as to what criteria and standard OMIG would be utilizing to determine that proposed alternative staffing levels by the MMCO are "no less effective" than the imposed minimum.

Response: OMIG intends to afford MMCOs latitude in proposing alternatives, and therefore will not be defining exception criteria nor establishing a standard. OMIG wishes to encourage innovation, including the application of technologies in demonstrating performance, and it is the MMCO's sole responsibility to establish that their proposed alternate staffing levels are as effective as the regulatorily-defined staffing requirements. The guidance will provide examples of the types of information that can be submitted.

Comment: Several commenters sought clarification, under § 521-2.4, on the expectations of SIUs and expressing concern with the 1% claims audit requirement. One commenter also sought clarification on the requirement to address "waste." Another commenter indicated MMCOs should have discretion in how to design their SIUs, hire investigators, and develop audit processes.

Response: The proposed regulatory language acknowledges some program integrity activities are conducted outside of SIUs and intended to ensure coordination within the plans while allowing for flexibility of business operations. A clarifying revision to § 521-2.4(c)(1) regarding the SIU's role will be made, replacing "…primarily responsible for performing such audits, investigations and reviews, and shall coordinate with the MMCO's designated compliance officer," with "…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."

The Cures Act and resulting revisions to the Managed Care contract identify the requirement to address and report potential waste. The requirement to audit 1% of claims was determined to be reasonable and attainable following consideration of information received from the plans and knowledge of their business processes. Many plans appear to be reaching this threshold today.

There will be guidance to the plans as to what activities shall be considered in determining whether the plans have met the requirement.

OMIG supports plan flexibility in implementing SIU requirements. Subpart 521-2 staffing requirements mirror certain existing staffing requirements in 10 NYCRR SubPart 98-1. Subpart 521-2 allows for MMCO flexibility through alternate staffing arrangements.

Comment: One commenter requested that section 521-2.4(b)(4)(iii) only apply to new contracts entered into by an MMCO.

Response: Section 521-2.4(b)(4)(iii) requires an MMCO, if it enters into a management contract for all or part of its SIU function, to submit such contract to DOH and OMIG, and to include the contract as part of its fraud, waste and abuse prevention plan. There is no need to resubmit any contracts that have already been entered prior to the effective date of this rulemaking. Pursuant to 521-2.4(i)(1), the MMCO is required to submit a fraud, waste and abuse prevention plan to OMIG within 90 days of the effective date of this rulemaking. Any existing management contracts for all or part of the MMCO's SIU function should be included with that submission. A technical revision is being made to 521-2.4(b)(4)(iii), correcting the reference to the fraud, waste and abuse prevention plan from subdivision (g) to subdivision (i).

Comment: One commentor requested that fraud, waste and abuse cases be reported quarterly and to have the fraud, waste and abuse prevention plan and the required DFS report be aligned to reduce administrative duplication. The commenter also requested clarification on whether "waste" was also required to be reported.

Response: The contract, in accordance with federal requirements, requires that MCO's promptly report potential fraud, waste and abuse to OMIG, and also electively, potential fraud, to MFCU. MMCOs must also immediately report suspected criminal activity to OMIG and MFCU. This rulemaking is consistent with those existing requirements. To confirm, the MMCOs are required to report waste. In order to minimize the administrative burden, OMIG will work with the MMCOs to conform similar reporting requirements wherever possible.

Comment: One Commenter requested that section 521-2.4(i)(3)(ii) be revised to acknowledge that an SIU organization description would only address staffing for suspected fraud investigations.

Response: Section 521-2.4(i)(3)(ii) requires an MMCO, as part of its fraud, waste and abuse prevention plan, to include a description of the organization of its SIU. Pursuant to 521-2.4(b), the SIU is required to detect and investigate potential fraud, waste and abuse, and is required to coordinate the same with OMIG and MFCU. Therefore, the MMCO is required to submit a description of the organization of its SIU, as it is organized to the meet the requirements of SubPart 521-2, and regardless of whether waste, under the oversight of the SIU, are being handled by other departments of the MMCO.

SubPart 521-3 Self-Disclosure Program

Comment: One commenter requested that OMIG expressly state that the lookback period for overpayments is six (6) years. The commenter noted that under Medicare rules, an overpayment must be reported and returned if the overpayment is identified within six years from the date the overpayment is received.

Response: A provider is obligated to report, return and explain any overpayment the provider discovers. 18 NYCRR 504.3(a) requires that providers keep, for a period of six (6) years from the date of care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider. Therefore, OMIG concurs that the lookback period for such obligation to report, return and explain a Medicaid overpayment for providers is six (6) years. Please note, that MMCOs are subject to different record retention and audit periods in their contracts with DOH to participate as an MMCO, and MMCOs should comply with those timeframes for purposes of meeting the requirements of SubPart 521-3.

Comment: One commenter expressed concerns with the extended time that negotiations take between OMIG and a self-disclosing provider using an extrapolation methodology. The commenter requested that OMIG adopt a more streamlined approach with providers that have used extrapolation in determining repayment amounts in a self-disclosure.

Response: OMIG agrees that there are times when there is considerable back-and-forth between OMIG and providers over the use of extrapolation in self-disclosures which may delay repayment. OMIG is committed to understanding a Provider's overpayment calculation which may take additional time and dialogue with the Provider. Standardization for the use of extrapolation within the Self-Disclosure Program will be beneficial for both OMIG and the provider community. OMIG will provide a standard process for the use of extrapolation in self-disclosures by providers in guidance and in documentation slated to replace the current documentation submitted by self-disclosing providers.

OMIG is committed to working with providers to ensure the timely repayment of overpayments through the Self-Disclosure Program.

Comment: One commenter suggested that self-disclosures involving extrapolation should be "settled" at the low-point, absent extenuating circumstances, similar to provider audits.

Response: Unlike an OMIG audit, a self-disclosure stems from a provider's legal obligation to report, return and explain overpayments. The individual or entity self-disclosing is required to identify and repay an amount that accurately represents the amount of the overpayments that they have received, in compliance with State and Federal law, and based on their own review of Medicaid claims. Compliance with these requirements is not impacted by the method the self-disclosing individual or entity uses to calculate the overpayment. OMIG is not "settling" with the provider, nor is the overpayment subject to a reduction or discount based on the method used to calculate the overpayment. If a provider elects to use extrapolation in connection with a self-disclosure because the provider is unable to review every single claim, it must be able to explain its calculation so that the provider and OMIG can reach an agreement on the overpayment amount. The Self-Disclosure Program will be providing, through forms and guidance, standardized methods for calculating overpayments which will assist providers in understanding the overpayment calculation and decrease the time to determine those overpayments.

Comment: Several commenters raised concerns regarding the obligation of individuals and entities, to submit a self-disclosure statement, regardless of eligibility to participate in the Self-Disclosure Program. Two commenters were concerned that the requirement violated due process protections, as it would require an individual or entity to self-disclose even if they are under audit or investigation

by OMIG or law enforcement. Another commenter stated it was unclear what impact or consequences there would be for a provider deemed ineligible to participate in the self-disclosure program.

Response: We appreciate and understand the concerns raised by the commenters. Providers have an obligation under both State and Federal law to report, return and explain overpayments they have identified. SOS § 363-d(7)(c) specifies the terms of eligibility to participate in the self-disclosure program, which are also codified under SubPart 521-3. Participation in the self-disclosure program is different than the requirement to report, return and explain identified overpayments. It is through participation in the Self-Disclosure Program that OMIG will consider waiver of interest and extended repayment terms. However, the obligation to report, return and explain is distinct from a person's eligibility to participate in the Self-Disclosure Program. Consistent with State and Federal law, a person is only required to report, return and explain an overpayment by the specified deadline if they have identified an overpayment. A provider is not obligated to submit a self-disclosure statement if they did not identify the overpayment. Therefore, a provider who is under audit or investigation by OMIG or law enforcement, and who did not independently identify the overpayment, is not obligated to, nor should they, report, return and explain, and they are not required to submit a self-disclosure statement under SubPart 521-3. However, if the provider independently identifies an overpayment, it must report, return and explain the overpayment by the deadline specified. This would not be a violation of the provider's due process protections, because it would be a report of an overpayment the provider has self-identified, independent of any OMIG or law enforcement audit or investigation.

Comment: Several commenters raised concerns with the requirement to enter into a Self-Disclosure and Compliance Agreement ("SDCA") pursuant to 521-3.4(e). One commenter sought clarification

that OMIG will only require an SDCA where the provider is requesting and is approved to repay in installments. Another commenter was concerned that the regulation requires all disclosing persons to enter into an SDCA, and that this requirement would have a chilling effect on self-disclosures. There was also a concern that the requirement that all SDCAs include a "compliance agreement" under § 521-3.4(e)(2)(iii) is unnecessary, as many disclosures arise from inadvertent mistakes.

Response: SOS § 363-d(7)(f)(3) authorizes OMIG to enter into a SDCA, with an eligible person. § 521-3.4(e) clarifies that a person would be eligible for a SDCA based on the conduct being disclosed and/or where the person has requested to repay the determined overpayment amount without appropriate interest or through installments. Therefore, not every self-disclosing entity will be required to execute a SDCA. A disclosure of an overpayment is not the end of a Provider's obligation. The provider is also required to address the reason for the overpayment and take corrective action to avoid a future overpayment for similar reasons. To the extent the SDCA requires a provider to implement corrective action, this requirement will be based on the conduct being disclosed and issues given rise to the overpayment. OMIG will provide guidance that will assist providers' understanding with respect to an SDCA based on conduct.

Comment: Several commenters raised concerns that the regulation does not address the option to void/adjust claims for the return of overpayments that are insignificant and the result of simple errors or mistakes. Commenters were concerned that if every instance must be disclosed, where in the past the payment could be simply voided or adjusted, this will add to provider's administrative burden. One commenter sought additional guidance as to when it was appropriate to void or adjust claims, and when a provider should submit a self-disclosure. The commenter suggested that in the past, the guidance was it was necessary to submit a self-disclosure in the case of a systemic failure. Another

commenter was concerned that OMIG expects providers to disclose every overpayment, without regard to the amount or extenuating circumstances. The commenter requested that the Self-Disclosure Program remain voluntary for providers, or if OMIG is unwilling to revise the requirement, that it revise the tolling trigger to ensure that providers are not penalized where OMIG fails to timely process submissions.

Response: OMIG appreciates the commenter's concerns. Voiding or adjusting claims remains an acceptable form of repayment to the Medicaid program following submission to the Self-Disclosure Program. OMIG will provide additional guidance regarding instances that may be more appropriate for resolution through normal billing process such as voiding or adjusting in a manner consistent with the requirements of SubPart 521-3. Additionally, it will provide clarification on the timing of OMIG's acceptance of a self-disclosure submission and the simultaneous tolling of the provider's 60 day time frame to report, return and explain the overpayment.

Comment: One commenter request that the timing to return an overpayment should be 30 days instead of the 15 days required by the regulation.

Response: SOS § 363-d(7)(f)(1) and § 521-3.5(a)(2) requires the person to repay within 15 days from the date of OMIG's notification of the amount of the overpayment, unless the person is approved to repay in installments through a SDCA. As the 15 days is a statutory requirement, OMIG is unable to modify this timeframe in the regulation. However, as noted in § 521-3.5(a)(4), a person will not be required to repay sooner than expiration of the deadline specified in § 521-3.3(b).

Comment: One commenter requested that any OMIG notification pursuant to § 521-3.6, be deemed made 10 days from the date of the notice rather than 5 days from the date of the notice. The commenter raised concerns with current issues with the U.S. Postal Service and delays with mailings.

Response: OMIG is sensitive to the current delays with respect to mail. However, 521-3.6(a)(1)(ii) includes sending written notification to an email address designated on the Self-Disclosure Statement if the person so designates that email address for receipt of electronic communication. Therefore, even with mail delays, the provider has an additional option of where to receive notification. Additionally, per 521-3.6(a)(3), the Self-Disclosure program will be mailing all Determination Notices to the address designated by the provider in their submission information in addition to emailing it. Finally, the provision presuming delivery 5-days from the date of the notice is consistent with similar provisions in 18 NYCRR Parts 515, 516 and 517.

Comment: Commenters felt that OMIG should incentivize providers to self-disclose and automatically confer benefits such as waiver of interest on those that do, rather than these determinations resting in OMIG's "sole discretion".

Response: Pursuant to 42 USC Section 3120a-7k and SOS § 363d the provider is required to report, return and explain Medicaid overpayments. If a provider does not meet that obligation, they could face fines and penalties under SOS § 145-b for failure to report, return and explain. OMIG's Self-Disclosure Program is the mechanism for providers to report and repay NYS Medicaid overpayments not already identified through investigation, audit, or existing reviews. For providers who participate in the self-disclosure program in good faith, and are cooperative, OMIG's preference, and historical practice, is to grant reasonable requests relating to the items listed under § 521-3.4(b)(2).

Comment: One commenter requested clarification on whether the regulation should be more consistent with SOS § 363-d(6) which requires a person to report and return to the department and explain the overpayment to OMIG.

Response: The regulation is consistent with the requirements of SOS § 363-d(6). OMIG is responsible for the department's duties with respect to the recovery of Medicaid overpayments. A person satisfies their obligation to report, return and explain under SOS § 363-d(6) by making a disclosure through OMIG's Self-Disclosure Program, which results in the overpayment and interest being returned to the NYS Medicaid program.

Comment: One commenter asked if a person opts to report, return and explain an overpayment to HHS or to the fiscal intermediary instead of the State as appears permitted under §1320a-7k(d), will OMIG consider there to be a violation of SubPart 521-3.

Response: 42 U.S.C. Section 1320a-7k(d) states that a person who has received an overpayment shall return the overpayment to "…the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate." If a person is disclosing an overpayment received from the NYS Medicaid program, then the State is where the payment should appropriately be returned. OMIG's Self-Disclosure Program is the mechanism to report and repay NYS Medicaid overpayments not already identified through an investigation, audit, or existing review.

Please note, however, that pursuant to § 521-3.3(b)(5), a person may report, return and explain to an MMCO where the overpayment was made by the MMCO to the person, as the MMCO is the

appropriate fiscal intermediary. Where a person reports to an MMCO in accordance with these provisions, they have satisfied their requirements under § 521-3.3(b)(5).

Comment: One commenter requested that provider's counsel be able to sign the self-disclosure statement on the provider's behalf.

Response: The provider needs to attest that everything they're reporting is accurate to the best of their knowledge. The statement should be signed by the person with first-hand knowledge of what is being disclosed and attested to.

Comment: One commenter stated that the regulation does not address the possibility of joint disclosures and joint resolutions where more than one provider is involved in the overpayment.

Response: SubPart 521-3 does not preclude circumstances where joint disclosures are necessary. This circumstance will be addressed in guidance and will also be streamlined by the updated Self-Disclosure Statement submission form OMIG will be releasing in conjunction with this regulation.

Comment: Two commenters requested clarification regarding the use of the term "person" in SubPart 521-3 and expressed concern that it's use in SubPart 521-3 could be used to confer personal liability on a provider's compliance officer or staff.

Response: 521-3.2(a) states that "[f]or 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, shall apply. NYS regulations at 18 NYCRR § 504.1(d)(17) defines "person" as including "…natural persons,

corporations, partnerships, associations, clinics, groups and other entities." While SubParts 521-1 and 521-2 incorporate by reference the definitions of 504.1, SubPart 521-3 "otherwise" notes a different definition of person, which aligns with the definitions of person under Social Services Law § 363-d(6)(e) and 363-d(7)(b). Section 521-3.2(b)(4) defines person as: "(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 recipients." Therefore, the use of the term person, in SubPart 521-3, does not confer personal liability on the compliance officer and other officers of a provider, as those individuals are not included in the definition of "person" under this SubPart. OMIG has further clarified that the "otherwise" noted language in 521-3.2(a) to in response to these concerns.