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New OMIG Regulation on Medicaid Fraud, Waste & Abuse:

This week, the Office of the Medicaid Inspector General (OMIG) published a Proposed Rule Making in the State Register related to Medicaid Program Fraud, Waste and Abuse Prevention with the stated purpose to establish requirements for providers to detect and prevent fraud, waste and abuse in the Medicaid Program.

The full text of the proposed rule can be found here: https://omig.ny.gov/information-resources/laws-and-regulations

Public comments are due within 60 days from when published on July 13, 2022.

In particular, the proposed rulemaking would repeal and add a new 18 NYCRR Part 521 to implement statutory changes resulting from the recommendations of the Medicaid Redesign Team II as adopted in the State Fiscal Year 2020-2021 Enacted Budget (Chapter 56 of the Laws of 2020, Part QQ) and to make other conforming changes related to:

(1) Provider Compliance Programs,

(2) Medicaid Managed Care Plan fraud, waste and abuse prevention programs under the Medical Assistance (Medicaid) program, and

(3) The Obligation to report, return and explain Medicaid overpayments through OMIG's Self-Disclosure Program.

Below are the new sections added to OMIG regulation through this rule making:

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

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

Section 521-1.2 is added to define certain terms.

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

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

Section 521-1.3(b) is added to establish the obligation of Required Providers to retain records relevant to their adoption, implementation and maintenance of a compliance program under the regulation, and to make such records available to OMIG, DOH or the New York State Medicaid Fraud Control Unit (MFCU). It also establishes the record retention period which is consistent with the requirements of 18 NYCRR § 504.3(a) and § 517.3, except that MMCOs shall retain records for a period of 10 years, consistent with the terms of the contracts between the MMCOs and DOH.

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

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

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

Section 521-1.3(f) is added to specify, consistent with statutory require- ments, that Required

Providers certify to DOH that they have adopted and implemented an effective compliance program upon enrollment and annually thereafter, and to clarify certification requirements for MMCO Participating Providers.

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

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

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

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

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

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

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

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

Section 521-1.4(g) is added to clarify the requirements for the Required Provider's auditing and monitoring, including the types of audits the Required Provider must undertake, the frequency of such audits, and other requirements related to internal and external auditing. It also includes a

requirement that the Required Provider actively monitor its Affected Individuals to identify persons who have been excluded from participation in the Medicaid program.

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

Section 521-1.5 is added to specify the procedures for OMIG compli- ance program reviews.

Sections 521-1.5(a)-(d) outlines the scope of the review, notifications to the Required Provider, and how OMIG or DOH will communicate its determination.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 521-2.4(i) is added to clarify the MMCO's obligation to prepare and file with OMIG a fraud, waste and abuse prevention plan.

Section 521-2.4(j)(4) specifies that OMIG will accept a fraud and abuse prevention plan that has been prepared in accordance with the provisions of 10 NYCRR § 98-1.21 or 11 NYCRR § 86.6, provided that any additional requirements under Subpart 521-2 are included with the submission.

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

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

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

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

Section 521-3.2 is added to define certain terms.

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

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

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

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

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

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

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

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

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

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

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