



Garfunkel Wild

Prepare Now: New York's Compliance Program Proposed Regulations

Presenters

Robert A. Del Giorno, Partner/Director
Peter M. Hoffman, Partner/Director

Status of the OMIG's Proposed Regulations

- On July 13, 2022 OMIG published proposed changes to NY's Compliance Program regulations
- The proposed regulations are substantially more detailed than the existing ones
- If and when finalized, the new regulations will replace the existing regulations
- **Enforcement will not occur until 90 days after the effective date**
- “Winter is a season of recovery and preparation”
- Preparation is the key to success

OMIG's Proposed Regulations – THE HIGHLIGHTS

- Significant New Definitions and Additions:
 - “Required Providers”
 - “Substantial Portion of Business Operations”
 - “Affected Individuals”
 - Risk Areas – expanded!
 - “Effective Compliance Program”
 - “Organizational Experience”
 - Compliance Officer Responsibilities
 - Compliance Committee Responsibilities
- New Policy and Procedure Requirements
- New Contract Requirements
- Record Retention Requirements
- New Self-Disclosure Regulations

Definitions: Changes to the Definition of “Required Providers”

“Required Providers” under New York law must have an effective compliance program that meets the regulatory requirements. Required providers are:

- any person subject to the provisions of Articles 28 or 36 of the Public Health Law;
- any person subject to the provisions of Articles 16 and 31 of the Mental Hygiene Law;
- any managed care provider or managed long term care plan (i.e., collectively, “Medicaid managed care organizations” or “MMCOs”); and
- any other person for whom the Medicaid program is, or is reasonably expected by the person to be, a substantial portion of their business operations

Definitions: “Substantial Portion of Business Operations” – Increased Threshold

If and when the OMIG’s proposed regulations are adopted, the threshold for a “substantial portion of business operations” **will increase from \$500,000 to \$1 million:**

Substantial Portion of Business Operations:

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

Definitions: “Affected Individuals” – New

The definition of “Affected Individuals” helps define to whom a compliance program must apply:

“Affected Individuals”: Under the proposed rules is defined to include ***“all persons who are affected by the required provider’s risk areas including ... employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.”***

- OMIG sending clear guidance on the breadth of the application of your compliance program.
- You will have to evaluate this for vendors/1099/service organizations, etc.

Definitions: Risk Areas – Expanded

The OMIG’s proposed rules expand the “risk areas” to which compliance programs must apply.

Risk areas are defined in the proposed regulations as “those areas of operation affected by the compliance program and shall apply to:

- billings;
- payments;
- ordered services;
- medical necessity;
- quality of care;
- governance;
- mandatory reporting;
- credentialing;
- contractor, subcontractor, agent or independent contract oversight; (Will Need Clarity!!);
- other risk areas that are or should reasonably be identified by the provider through its organizational experience; and
- Additional risk areas specified for MMCOs

Definitions: Organizational Experience – New

Under the proposed regulations, OMIG has defined “organizational experience” to mean the required provider’s:

- knowledge, skill, practice and understanding in operating its compliance program;
- identification of any issues or risk areas in the course of its internal monitoring and auditing activities;
- experience, knowledge, skill, practice and understanding of its participation in the Medicaid program and the results of any audits, investigations, or reviews it has been the subject of; or
- awareness of any issues it should have reasonably become aware of for its category or categories of service.

Definitions: “Effective Compliance Program” – New

- The proposed regulations define what comprises an “effective compliance program”:
- Means a compliance program “adopted and implemented by the required provider that, at a minimum, satisfies the requirements of [the proposed regulations] and that is designed to be compatible with the provider’s characteristics, which shall mean that it:
 - is well-integrated into the company’s operations and supported by the highest levels of the organization, including the chief executive, senior management, and the governing body;
 - promotes adherence to the required provider’s legal and ethical obligations; and
 - is reasonably designed and implemented to prevent, detect, and correct noncompliance with Medicaid program requirements, including fraud, waste, and abuse [FWA] most likely to occur for the required provider’s risk areas and organizational experience.”

Expands and Details Compliance Officer Responsibilities

The proposed regulations lay out, with specificity, the primary responsibilities of the Compliance Officer. These include:

- Oversight. **Overseeing and monitoring** the adoption, implementation and maintenance of the compliance program and **evaluating** its effectiveness;
- Creating and Using Annual Compliance Work Plan. Drafting, implementing, and updating no less frequently than annually or, as otherwise necessary, to conform to changes in laws/rules, etc., **a compliance work plan** which shall outline the required provider's proposed strategy for meeting the requirements of the [proposed rules] for the coming year (with certain areas emphasized).
- Improving the Program. **Reviewing and revising the compliance program**, and the written policies and procedures and standards of conduct, to incorporate changes based on the **provider's organizational experience** and promptly incorporate changes to laws/rules;

Expands and Details Compliance Officer Responsibilities - Cont'd

- Regular Reporting. **Reporting directly**, on a regular basis, but **no less frequently than quarterly**, to the governing body (e.g., a board of directors), CEO, and compliance committee on the progress of adopting, implementing, and maintaining the compliance program;
- Make Improvements. Assisting the required provider in establishing methods to **improve the required provider's efficiency, quality of services, and reducing the required provider's vulnerability to FWA**;
- Investigate & Implement Corrective Action. **Investigate and independently act** on matters related to the compliance program, including designing and coordinating internal investigations, documenting, reporting, coordinating, and pursuing any resulting corrective action
- MMCO Coordination. **Coordinate implementation of FWA Prevention with MMCO SIU (if applicable)**.

Details the Role for the Compliance Committee

The proposed regulations require a Compliance Committee to “coordinate” with the CO and “ensure that the ... provider is conducting its business in an ethical and responsible manner, consistent with its compliance program.”

- **New: Compliance Committee Charter**. You must create a **Compliance Committee Charter**, which outlines the Committee’s duties and responsibilities, membership, designation of a chair and frequency of meetings. The Committee must review and update the charter no less frequently than annually.
- **New: Membership and Meetings**. The membership of the Compliance Committee must be comprised of, at a minimum, **senior managers**. The Committee must meet **no less frequently than quarterly**.
- **New: Accountability and Reporting Lines**. The Committee “shall **report directly and be accountable to the required provider’s chief executive and governing body**.”

Details the Role for the Compliance Committee - Cont'd

- ***New: The Committee's Responsibilities.***

- coordinating with the compliance officer to **ensure that the written policies and procedures, and standards of conduct are current, accurate and complete, and that the required training topics are timely completed;**
- coordinating with the compliance officer to **ensure communication and cooperation by affected individuals on compliance related issues, internal or external audits, or any other function or activity required;**
- ***ensure that the compliance officer is allocated sufficient funding, resources, and staff to fully perform their responsibilities;***
- **ensure there are effective systems and processes in place** to identify compliance program risks, overpayments and other issues, and **effective policies and procedures** for correcting and reporting such issues; and
- **enacting** required modifications to the compliance program.

Written Policies and Procedures: More Specificity

- Include a Process: Under the proposed rules, you must have **a process for drafting, revising, and approving the required written policies and procedures.**
- Accessible/Available: Policies/procedures must be available, accessible, and applicable **to all affected individuals.**
- Policy Requirements Include:
 - Articulate commitment and obligation to comply with all applicable federal and state standards;
 - **Identify governing laws/regs applicable to your risk areas, including Medicaid program policies/procedures;**
 - Formal standards of conduct – describe fundamental principles/values and commitment to conduct business in an ethical manner;
 - Document the implementation of compliance program requirements and outline ongoing operation; and
 - Describe the structure of the program, responsibilities of affected persons to carry out compliance functions.

Written Policies and Procedures - Continued

- **Provide guidance to affected individuals:**
 - Assist in identifying compliance issues/questions/concerns, set reporting expectations, how to report to compliance officer;
 - Establish expectation that all affected individuals will follow standards of conduct, refuse to participate in unethical or illegal conduct, and must report unethical or illegal conduct to compliance officer;
 - Identify methods and procedures for communicating compliance issues to appropriate compliance personnel; and
 - Describe how potential compliance issues are investigated and resolved and procedures for documenting the investigation and the resolution/outcome.
- Policy of non-intimidation and non-retaliation for good faith participation in the compliance program

Written Policies and Procedures – Continued

- Disciplinary Standards: Include a written statement setting forth the required provider's policy regarding affected individuals who fail to comply with the policies and procedures, standards of conduct, or State and Federal laws, rules and regulations.
 - **Such statement shall establish the degrees of disciplinary actions the required provider must take, with intentional or reckless behavior being subject to more significant sanctions. Sanctions may include oral or written warnings, suspension, and/or termination.**
 - **The written policies and procedures shall also outline the procedures for taking disciplinary action and sanctioning individuals. Disciplinary procedures shall conform with collective bargaining agreements when applicable.**
- Must comply with DRA (**whether or not you hit \$5M requirements**)
- Certain other requirements for MMCO's
- **Mandatory Review, At Least Annually**: For implementation; whether they are being followed; whether they are effective; and whether updates are required.

Details Training and Education Requirements

In the proposed regulations, OMIG has provided detail on what it expects for “effective” training and education, and imposes minimum requirements. Training and education must be **part of orientation, occur “promptly upon hiring” and at least annually. It must cover, at minimum:**

- Your risk areas and organizational experience;
- Your written policies and procedures;
- Role of Compliance Officer and Compliance Committee;
- How affected individuals can ask questions/report concerns;
- Duty of affected individuals to report suspected illegal/improper conduct and how to do so;
- Protection from retaliation or intimidation for good faith participation in the compliance program;
- Disciplinary standards, with focus on those related to compliance program and FWA prevention;
- How you respond to compliance issues/implement corrective action plans;
- Requirements specific to Medicaid program and provider’s category(ies) of service(s);
- Coding and billing requirements and claim development and submission; and
- MMCO specific items.

Must be in form and format accessible and understandable to all affected individuals!

Must have a training plan!

Lines of Communication: Details, Details, Details

Must establish and implement **effective** lines of communication which ensure **confidentiality** for affected individuals. Minimum requirements:

- lines of communication shall be **accessible to all affected individuals** and allow for questions regarding compliance issues to be asked and for compliance issues to be reported
- must **publicize** the lines of communication to the compliance officer and such lines of communication must be made **available to all affected individuals and all Medicaid recipients of service** from the required provider
- must have a **method for anonymous reporting** of potential FWA, and compliance issues, **directly** to the compliance officer
- must ensure that the **confidentiality** of persons reporting compliance issues shall be maintained unless the matter is subject to a disciplinary proceeding, referred to, or under investigation by, MFCU, OMIG or law enforcement, or disclosure is required during a legal proceeding, and such persons shall be protected under the required provider's policy for non-intimidation and non-retaliation
- If applicable, the required provider shall **make available on its website information** concerning its compliance program, including its standards of conduct

Disciplinary Standards and Enforcement

The proposed rules require disciplinary standards and procedures to enforce them.

This is to address potential violations and encourage good faith participation in the compliance program by all affected individuals.

Requirements include:

- written policies and procedures establishing disciplinary standards and the procedures for taking such actions **shall be published and disseminated to all affected individuals and shall be incorporated into the training plan**
- shall **enforce disciplinary standards fairly and consistently, and the same disciplinary action should apply to all levels of personnel**

Specifies Auditing and Monitoring Requirements

Under the proposed regulations, you are required to **establish and implement an effective system for the routine monitoring and identification** of compliance risks.

To include internal monitoring and audits and, as appropriate, external audits, to evaluate the organization's compliance with the requirements of the Medicaid program and the overall effectiveness of the compliance program.

Requirements include:

- Perform ongoing audits by internal or external auditors who have expertise in state and federal Medicaid program requirements and applicable laws, rules and regulations, or have expertise in the subject area of the audit – audits by state or feds do not count as external audits.
 - **Audits must include your risk areas**
 - **Must be reviewed to identify other risk areas for inclusion in work plan and compliance program**
 - **Design, implementation, and results of any internal or external audits shall be documented, and the results shared with the compliance committee and the governing body**
 - **Any Medicaid program overpayments identified shall be reported, returned and explained and corrective action promptly taken to prevent recurrence**

Auditing and Monitoring – Your Compliance Program

- You must (at least) annually audit/review your compliance program for effectiveness/need for revisions/corrective actions
- **Need to develop a process for doing this (we have a tool to help!)**
- May be carried out by compliance officer, compliance committee, external auditors, or other staff with necessary knowledge and expertise and independence
- **Should include:**
 - on-site visits
 - interviews with affected individuals
 - review of records and surveys
 - “or any other comparable method” that does not compromise the integrity or independence of the review
- Shall **document** the design, implementation and results of its effectiveness review, and any corrective action implemented.
- The results of annual compliance program reviews shall be **shared** with the chief executive, senior management, compliance committee and the governing body

Exclusion Checks – OMIG & OIG LEIE Checks

- Required to confirm the identity and determine the exclusion status **of affected individuals** (not just your employees!)
- Checks must be done **at least every 30 days**
- **Must check:**
 - OMIG's Exclusion List
 - OIG's List of Excluded Individuals and Entities
- Providers shall require contractors, agents, subcontractors, and independent contractors to comply
- Providers shall promptly share the results of the activities required by this subdivision with the compliance officer and appropriate compliance personnel
- (Additional MMCO requirements)

Details How to Respond to Compliance Issues

The proposed rules require the establishment and implementation of procedures and systems for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of the internal auditing and monitoring, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with State and Federal laws, rules and regulations, and requirements of the Medicaid program.

Requirements include:

- upon the detection of potential compliance risks/issues, **take prompt action to investigate** the conduct in question **and determine** what, if any, **corrective action** is required, and **promptly implement** same
- **document the investigation**, including any alleged violations, a description of the investigative process, copies of interview notes and other documents essential for demonstrating that the required provider completed a thorough investigation of the issue. Where appropriate, can use outside experts, auditors, or counsel to assist
- **document any disciplinary action** taken and the **corrective action** implemented
- **If you identify credible evidence or credibly believe that a State or Federal law, rule or regulation has been violated, you are required to promptly report such violation to the appropriate governmental entity. The compliance officer shall receive copies of any reports submitted to governmental entities.**

Contracting Requirements / Record Retention

- **New – Contract Requirement**: required providers must ensure that contracts with contractors, agents, subcontractors, and independent contractors (who meet the definition of affected individual) specify that those persons/entities are subject to your compliance program, and the contract must include termination provisions for failure to adhere to the compliance program.
 - **Issues**: there are many ... contractor who has its own program; necessary contractor who refuses to be bound, etc.
- **New – Record Retention**: must retain all records demonstrating that you have adopted, implemented and operated an effective compliance program.
 - Must make available to OMIG, MFCU or DOH upon request
 - Must retain for period not less than 6 years from date of implementation or amendments

OMIG Compliance Reviews

- The proposed regulations outline OMIG's right to review whether a required provider has adopted, implemented and maintained an effective compliance program.
- OMIG must provide written notice of the review – and responses required within 30 days.
- Upon completion, OMIG must advise on the outcome (does the program meet the regulatory requirements), advise of recommendations for potential improvements or correcting deficiencies or, if the provider's is found not to be in compliance, OMIG must notify the provider that it may be subject to monetary penalties and its Medicaid Program enrollment may be terminated.

OMIG's Self-Disclosure Program

OMIG proposed a new set of regulations devoted to the formal establishment of its Self Disclosure Program, consistent with NY Social Services Law § 363-d and the Affordable Care Act.

- Duty to report remains the same – as does the deadline for reporting (within 60 days after the date on which the overpayment is “identified,” or the date any corresponding cost report is due, if applicable).
- The proposed regulations **mandate** the “submission of a self-disclosure statement” to the OMIG in order to satisfy this obligation.
- Eligibility: (i) not currently under audit, investigation or review by OMIG; (ii) disclosing an overpayment and related conduct that OMIG has not identified at the time of the disclosure; (iii) report overpayment and related conduct by the deadline; and (iv) not currently a party to, or the subject of, any criminal investigation related to their participation in the Medicaid program being conducted by the Medicaid Fraud Control Unit or a United States government agency -- **however, you still have to report if you are not eligible.**

OMIG Self-Disclosure Submission Requirements

Must submit a **self-disclosure statement** and it must include:

- An estimate of the amount of the overpayment
- A detailed explanation of the reason the person received the overpayment (specific requirements in the regulation for this)
- Contact information
- Data file per OMIG specifications
- Whether requesting installment payments and/or waiver of interest
- An agreement to return the full amount of the overpayment and interest as determined by OMIG
- Other information OMIG requires
- Must be signed by the compliance officer (if you are required to have a compliance program)

OMIG Self-Disclosure and Compliance Agreement (SDCA)

A SDCA is defined as a “stipulation of settlement” that constitutes “a binding contract between the [disclosing] person and OMIG” and includes, at minimum:

- an agreement to repay the overpayment and interest, if applicable, as determined by OMIG,
- an agreement to make all installment payments on time (if applicable), and
- identification of, and agreement to implement, any corrective actions to prevent recurrence of the issues that caused the overpayment.

OMIG has proposed certain time frames for completing this process. A SDCA must be executed, returned and received by OMIG within fifteen (15) days of receipt, unless OMIG permits otherwise. If the timeline is not met, participation in the SDP “shall be terminated.”

OMIG Self-Disclosure and Enforcement

The proposed rules reiterate that a failure to report, return and explain an overpayment by the deadline may result in significant monetary penalties pursuant under New York law – as well as other sanctions or penalties under applicable law.



Garfunkel Wild

QUESTIONS ?

Thank you for joining us.

Contact Information



Robert A. Del Giorno
Partner/Director

516.393.2505
rdelgiorno@garfunkelwild.com



Peter M. Hoffman
Partner/Director

516.393.2268
phoffman@garfunkelwild.com

Great Neck, New York
516.393.2200

Albany, New York
518.242.7582

New Jersey
201.883.1030

Connecticut
203.316.0483

Florida
754.228.3853

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