Data-Driven Audits, Investigations, Litigation, and Program Integrity

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The Role of Technology and Data in Health Care Litigation

- Approach of prosecutors and regulators
- Impact on how providers and subcontractors maintain, monitor, and report data
- Impact of transition to managed care and technology

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Program Integrity

- Mission to protect enrollees in both governmental fee for service and managed care programs
- Imperative to prevent and detect fraud, waste and abuse that diverts dollars that should be spent to safeguard the health and welfare of enrollees
- Burden is on providers, including MCOs, & their providers & subcontractors, to document care is properly provided

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Program Integrity

- What does it really mean? Start with proof care has been provided
- 42 CFR § 438.3(u): Recordkeeping requirements – MCOs must retain and require subcontractors to retain documents for a period of no less than 10 years
- Superstorm Sandy, etc.

Overpayments v. False Claims: What is the difference?

- Any person receiving Medicaid money, even indirectly, must be able to show that the care, services and supplies has been properly provided for the money received and retain supporting documentation. If not, they can be subject to False Claims Act and other liability, including for acts of reckless disregard and for acts made in deliberate ignorance of the truth or falsity of the information
- Use of certifications and materiality of data errors – post *Escobar*

MFCU Authority- 42 U.S.C. §§ 1396b(q),1903(q)(3) of SSA

42 CFR § 1007.11 Duties and responsibilities of Unit.

(a) The Unit will conduct a statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws, including criminal statutes as well as civil false claims statutes or other civil authorities, pertaining to the following:

(1)Fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers.

(2) Fraud in any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)of the Act), if the Unit obtains the written approval of the Inspector General of the relevant agency and the suspected fraud or violation of law in such case or investigation is primarily related to the State Medicaid program.

(b) (1) The Unit will also review complaints alleging abuse or neglect of patients or residents in health care facilities receiving payments under Medicaid…

(2) At the option of the Unit, It may review complaints of abuse or neglect… of patients or residents of board and care facilities…

(3) If the initial review of the complaint indicates substantial potential for criminal prosecution, the Unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutorial authority…

(c) If the Unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider, the Unit will either recover such overpayment as part of its resolution of a fraud case or refer the matter to the appropriate State agency for collection.

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42 CFR § 438.604
Medicaid data, information, and documentation that must be submitted

"(a) ***Specified data, information, and documentation.*** The State must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit to the State the following data:

(1) Encounter data in the form and manner described in § 438.818.

(2) Data on the basis of which the State certifies the actuarial soundness of capitation rates to an MCO, PIHP or PAHP under § 438.4, including base data described in § 438.5(c) that is generated by the MCO, PIHP or PAHP.

(3) Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in § 438.8.

(4) Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under § 438.116.

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in § 438.206.

(6) Information on ownership and control described in § 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by § 438.230.

(7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

(b) ***Additional data, documentation, or information.*** In addition to the data, documentation, or information specified in paragraph (a) of this section, an MCO, PIHP, PAHP, PCCM or PCCM entity must submit any other data, documentation, or information relating to the performance of the entity's obligations under this part required by the State or the Secretary."

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42 CFR § 438.3: Inspection and Audit of Records and Access to Facilities

- (h) All contracts must provide that the State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.
- *See also* New York's 18 NYCRR § 504.3 – Duties of the provider

MFCU Data Mining - 42 CFR Part 1007

- The practice of electronically sorting Medicaid or other relevant data, including, but not limited to, the use of statistical models and intelligent technologies, to uncover patterns and relationships within that data to identify aberrant utilization, billing, or other practices that are potentially fraudulent.

1007.20 – Circumstances of permissible data mining

"(a) Notwithstanding § 1007.19(e)(2), a Unit may engage in data mining as defined in this part and receive [Federal Financial Participation] only under the following conditions:

(1) The Unit identifies the methods of coordination between the Unit and the Medicaid agency, the individuals serving as primary points of contact for data mining, as well as the contact information, title, and office of such individuals;

(2) Unit employees engaged in data mining receive specialized training in data mining techniques…"

MCO/Provider/Subcontractor Responsibilities re: Data

- Duties to collect and monitor data
- Data as mitigating or confounding factor

- Under recent NY budget related statutory amendments, OMIG can obtain penalties from MCOs for inaccurate or incomplete encounter data

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42 CFR § 438.608: Program integrity requirements under the contract

Some of the many contract requirements between the State and the MCO must include:

- Compliance program with written policies and procedures
- Designated Compliance officer must report directly to CEO and Board
- Effective training program for CO, Sr. management, and employees
- Dedicated staff for routine internal monitoring, auditing, investigation, and coordination with law enforcement
- Staff review of compliance programs
- Provision for prompt reporting of overpayments
- Methods to regularly verify that appropriate and quality services provided
- Provide information to employees about False Claims Act and whistleblower protection
- Prompt referral of any potential fraud, waste, or abuse to state program integrity unit or potential fraud to MFCU (each state determines procedure)

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Certification Requirements

- Certifications are executed by providers and Medicaid MCOs & their providers & subcontractors

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eMedNY/Medicaid Certification Statement (link on next slide)

(1) ETIN _____ (2) BILLING SERVICE NAME (IF APPLICABLE) _____

eMedNY/MEDICAID MANAGEMENT INFORMATION SYSTEM

CERTIFICATION STATEMENT FOR PROVIDER BILLING MEDICAID

(3) As of (date) _____, all claims submitted electronically or on paper to the State's Medicaid fiscal agent, for services or supplies furnished

(4) by (provider name) _____

(5) (10-digit National Provider ID (NPI) -- REQUIRED unless exempted from NPI)

(6) (8-digit Medicaid Provider Number -- If NPI exempt)

will be subject to the following certification.

I am (or the business entity named in this form of which I am a partner, officer, or director is) a qualified provider enrolled with and authorized to participate in the New York State Medical Assistance Program and in the profession or specialties, if any, required in connection with this claim; the persons providing services, care and supplies have the necessary licensing, certification, training and experience to perform the claimed services; I have reviewed these claims; I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations; I have read the eMedNY Provider Manual and all revisions thereto; all claims are made in full compliance with the pertinent provisions of the Manual and revisions; all claims for care, services and supplies provided at the order of another professional have to the best of my knowledge been ordered by that professional in bona fide compliance with the procedures set forth in the manual and revisions. All care, services and supplies for which claim is made are medically necessary for the treatment of the named recipient, the amounts listed are due and, except as noted, no part thereof has been paid by, or to the best of my knowledge is payable from any other source other than the Medical Assistance Program; payment of fees made in accordance with established schedules is accepted as payment in full; other than a claim rejected or denied or one for adjustment, no previous claim for the care, services and supplies itemized has been submitted or paid; ALL STATEMENTS, DATA AND INFORMATION TRANSMITTED ARE TRUE, ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE; NO MATERIAL FACT HAS BEEN OMITTED; I UNDERSTAND THAT PAYMENT AND SATISFACTION OF THIS CLAIM WILL BE FROM FEDERAL, STATE AND LOCAL PUBLIC FUNDS AND THAT I MAY BE FINED AND/OR PROSECUTED UNDER APPLICABLE FEDERAL AND STATE LAWS FOR ANY VIOLATION OF THE TERMS OF THIS CERTIFICATION, INCLUDING BUT NOT LIMITED TO FALSE CLAIMS, STATEMENTS OR DOCUMENTS, OR CONCEALMENT OF A MATERIAL FACT; taxes from which the State is exempt are excluded; all records pertaining to the care, services and supplies provided including all records which are necessary to disclose fully the extent of care, services and supplies provided to individuals under the New York State Medical Assistance Program will be kept for a period of six years from the date of payment, and such records and information regarding these claims and payment therefor shall be promptly furnished upon request to the local Department of Social Services, the State Department of Health, the Office of the Medicaid Inspector General, the State Medicaid Fraud Control Unit or the Secretary of the Department of Health and Human Services; there has been compliance with the Federal Civil Rights Act of 1964 and with section 504 of the Federal Rehabilitation Act of 1973, as amended, which forbid discrimination on the basis of race, color, national origin, handicap, age, sex and religion; I agree (or the entity agrees) to comply with the requirement of 42 CFR Part 455 relating to disclosures by providers; the State of New York through its fiscal agent or otherwise is hereby authorized to (1) make administrative corrections to claims submitted under this agreement to enable its automated processing, subject to reversal by the provider, and (2) accept the claim under this agreement as original evidence of care, services and supplies furnished.

In submitting claims under this agreement I understand and agree that I (or the entity) shall be subject to and bound by all rules, regulations, policies, standards, fee codes and procedures of the New York State Department of Health and the Office of the Medicaid Inspector General as set forth in statute or title 18 of the Official Compilation of Codes, Rules and Regulation of New York State and other publications of the Department, including eMedNY Provider Manuals and other official bulletins of the Department. I understand and agree that I (or the entity) shall be subject to and shall accept, subject to due process of the law, any determinations pursuant to said rules, regulations, policies, standards, fee codes and procedures, including, but not limited to, any duly made determination affecting my (or my entity's) past, present or future status in the Medicaid program and/or imposing any duly considered sanction or penalty.

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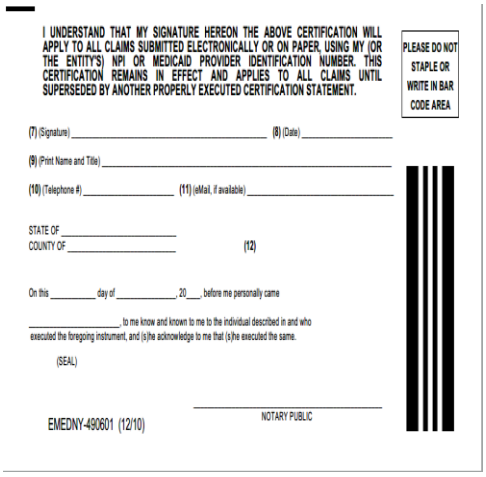
eMedNY/Medicaid Certification Statement



I UNDERSTAND THAT MY SIGNATURE HEREON THE ABOVE CERTIFICATION WILL APPLY TO ALL CLAIMS SUBMITTED ELECTRONICALLY OR ON PAPER, USING MY (OR THE ENTITY'S) NPI OR MEDICAID PROVIDER IDENTIFICATION NUMBER. THIS CERTIFICATION REMAINS IN EFFECT AND APPLIES TO ALL CLAIMS UNTIL SUPERSEDED BY ANOTHER PROPERLY EXECUTED CERTIFICATION STATEMENT.

PLEASE DO NOT STAPLE OR WRITE IN BAR CODE AREA

(7) (Signature) _____ (8) (Date) _____

(9) (Print Name and Title) _____

(10) (Telephone #) _____ (11) (eMail, if available) _____

STATE OF _____
COUNTY OF _____ (12)

On this _____ day of _____, 20___, before me personally came

_____, to me know and known to me to the individual described in and who executed the foregoing instrument, and (s)he acknowledge to me that (s)he executed the same.

(SEAL)

_____
NOTARY PUBLIC

EMEDNY-490601 (12/10)

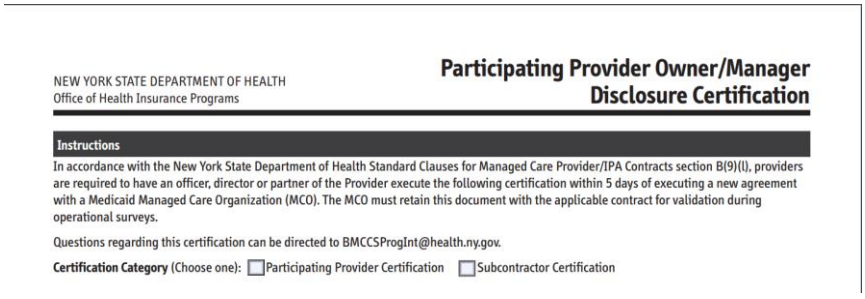
Link to complete form available at:

https://www.emedny.org/info/ProviderEnrollment/ProviderMaintForms/490501_ETIN_CERT_Certification_Statement_Cert_Instructions_for_Existing_ETINs.pdf

State of New York v. Medimmune, Inc., 342 F.Supp.3d 544 (SDNY 2018) (express certification)

NY DOH Medicaid Provider/Subcontractor Certification

Link to complete form available at:
https://omig.ny.gov/media/document/15886



NEW YORK STATE DEPARTMENT OF HEALTH
Office of Health Insurance Programs

Participating Provider Owner/Manager Disclosure Certification

Instructions

In accordance with the New York State Department of Health Standard Clauses for Managed Care Provider/IPA Contracts section B(9)(l), providers are required to have an officer, director or partner of the Provider execute the following certification within 5 days of executing a new agreement with a Medicaid Managed Care Organization (MCO). The MCO must retain this document with the applicable contract for validation during operational surveys.

Questions regarding this certification can be directed to BMCCSProgInt@health.ny.gov.

Certification Category (Choose one): ☐ Participating Provider Certification ☐ Subcontractor Certification

Federal Medicaid MCO Certification Requirement 42 CFR § 438.606

Source, content, and timing of certification.

- "(a) **Source of certification.** For the data, documentation, or information specified in § 438.604, the State must require that the data, documentation or information the MCO, PIHP, PAHP, PCCM or PCCM entity submits to the State be certified by either " their "Chief Executive Officer; Chief Financial Officer; or an individual who reports directly to" the CEO or CFO with delegated authority to sign …so that the CEO or CFO "is ultimately responsible for the certification".
- (b) **Content of certification.** The certification provided by the individual in paragraph (a) of this section must attest that, based on best information, knowledge, and belief, the data, documentation, and information specified in § 438.604 is accurate, complete, and truthful."

Other NY Medicaid Certification Requirements

There are two other compliance-related certification requirements on the OMIG website (see: https://omig.ny.gov/compliance/compliance-certification)

Medicaid providers who are required to have a compliance program must complete the SSL Certification. It requires them to certify that their compliance program has been adopted, implemented, and meets the requirements of SSL § 363-d and 18 NYCRR Part 521.

- **SSL Certification** https://apps.omig.ny.gov/ssl/ssl_certification.aspx

Some Medicaid providers may be subject to the federal Deficit Reduction Act of 2005 (DRA).

- **DRA Certification** (available at: https://apps.omig.ny.gov/dra/dra_certification.aspx)

Discussion of Recent Cases

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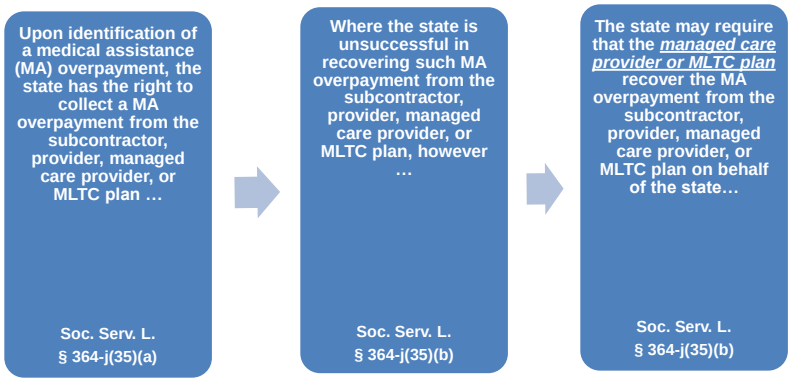
New York State Right to Recovery of Overpayments



See Soc. Serv. L. § 364-j(35) for full text

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Medicaid Managed Care Model Contracts

- Federal and additional State requirements are contained in contracts between State and MCO
- MCO representatives in New York participate in contract amendment process and review drafts before they are submitted to CMS. (Contracts also available on the DOH website)

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New York Medicaid Contract
Required Report: Pharmacy Benefit Manager Quarterly Report

- Mandatory MCO reporting
- "The Contractor shall submit to SDOH and OMIG a quarterly report of the amount paid to a PBM for pharmaceutical services by categories, including amounts for each prescription drug by NDC code, and also paid to a PBM for administrative services."
- Report provides important data window into drug costs & pricing…upcoming NY transition to carve drugs out of managed care.

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New York Medicaid Mainstream Contract Required Reports

- **Comprehensive Provider Report**
- **Program Integrity Annual Assessment Report**
- **Provider Investigative Report**
- **Additional Reports**

Upon request by the SDOH, OMH or OASAS the Contractor shall prepare and submit other operational data reports. Such requests will be limited to situations in which the desired data is considered essential and cannot be obtained through existing Contractor reports.

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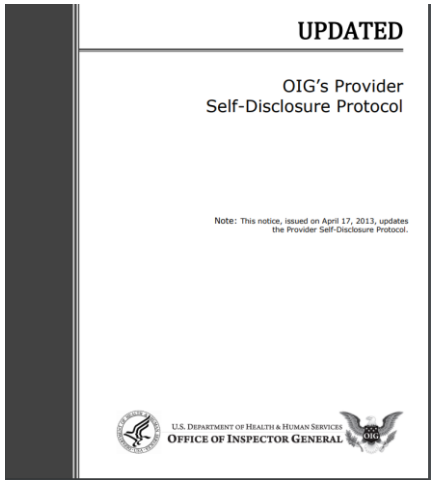
HHS-OIG Guidance



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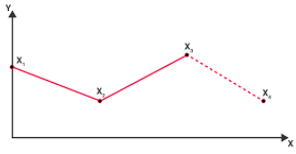
Overpayments

- Flow of releases from different agencies
- Sometimes use extrapolation to calculate overpayments versus claim specific approach
  - HHS-OIG guidance: https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf
- Risks of incomplete disclosure: Partial self-disclosure vs. reverse overpayments



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Overpayments must be identified and returned to the State

- Must report and return overpayments within 60 days of identification
- Treatment of Medicaid recoveries (42 CFR § 438.608(d))
- NY OMIG Medicaid self-disclosure program
- Do not minimize conduct - be truthful
- No release from criminal or civil liability for self-disclosing

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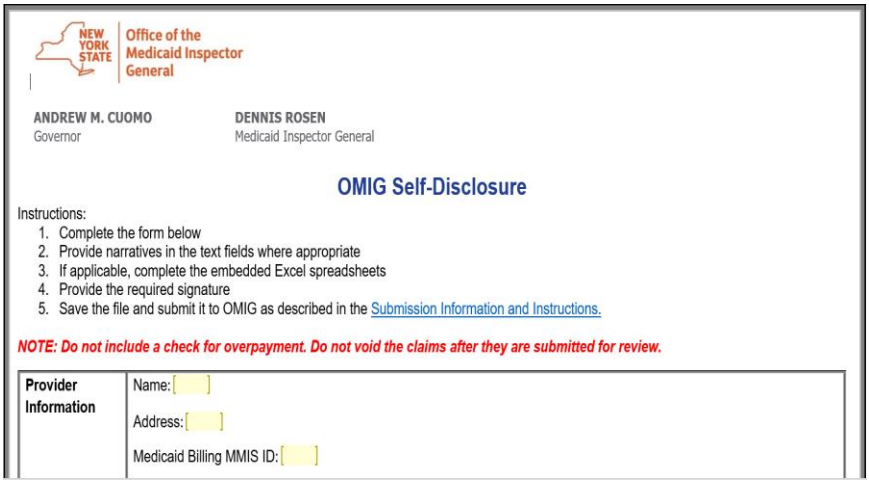
New York OMIG Self-Disclosure Form



NEW YORK STATE | Office of the Medicaid Inspector General

ANDREW M. CUOMO
Governor

DENNIS ROSEN
Medicaid Inspector General

OMIG Self-Disclosure

Instructions:

1. Complete the form below
2. Provide narratives in the text fields where appropriate
3. If applicable, complete the embedded Excel spreadsheets
4. Provide the required signature
5. Save the file and submit it to OMIG as described in the Submission Information and Instructions.

NOTE: Do not include a check for overpayment. Do not void the claims after they are submitted for review.

Provider Information	Name: [ ] Address: [ ] Medicaid Billing MMIS ID: [ ]

Damages and Penalties

- Under federal FCA and NY FCA, treble damages and penalties available (31 U.S.C. § 3730; *see* State Finance Law, Art. 13 §§ 187-194)

Questions?

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