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

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
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.

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.”
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

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)
Certification Requirements

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

emNY/Medicaid Certification Statement (link on next slide)
eMedNY/Medicaid Certification Statement

[Form Image]

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

[Form Image]

Link to complete form available at:
https://omig.ny.gov/media/document/15886
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](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](https://apps.omig.ny.gov/ssl/ssl_certification.aspx)

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

Discussion of Recent Cases

New York State Right to Recovery of Overpayments

Upon identification of a medical assistance (MA) overpayment, the state has the right to collect a MA overpayment from the subcontractor, provider, managed care provider, or MLTC plan...

Soc. Serv. L. § 364-j(35)(a)

Where the state is unsuccessful in recovering such MA overpayment from the subcontractor, provider, managed care provider, or MLTC plan, however...

Soc. Serv. L. § 364-j(35)(b)

The state may require that the managed care provider or MLTC plan recover the MA overpayment from the subcontractor, provider, managed care provider, or MLTC plan on behalf of the state...

Soc. Serv. L. § 364-j(35)(b)

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)

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.
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.

HHS-OIG Guidance
Overpayments

- Flow of releases from different agencies
- Sometimes use extrapolation to calculate overpayments versus claim specific approach
- Risks of incomplete disclosure: Partial self-disclosure vs. reverse overpayments

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
New York OMIG Self-Disclosure Form

Damages and Penalties

Questions?

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