Implementing Compliant Managed Care Program Integrity Requirements Across Medicaid, Medicare, and Dual Eligible Lines of Business

Health Care Compliance Association
Managed Care Compliance Conference
February 3, 2016

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Agenda

- Scope of programs and reliance on Medicare Advantage (MA) compliance scheme
- Comparison of subcontractor requirements
- MA exclusion checks and certifications
- “Program Integrity” (PI) defined
- Medicaid managed care (MC) trends and oversight focus
- In-depth look at current and proposed CMS Medicaid MC PI requirements
  - Statutory and regulatory requirements
  - CMS sub-regulatory guidance and other issuances (e.g., state audits)
  - State Medicaid contract provisions

Scope of Medicaid and Medicare Programs

Medicaid

- Over **71 million** Medicaid/CHIP enrollees
  - **24% increase** since ACA
- **39 states** (including DC) contracted with Managed Care Organizations (MCOs) in 2015
- **44.5 million** Medicaid enrollees in **managed care plans** as of 2013

Medicare

- **55 million** Medicare enrollees
- Over **30% (17+million)** enrolled in Medicare Advantage (MA)
  - **50% increase** since ACA
- **24 million** enrolled in stand-alone Part D

Medicare Advantage and Part D: The Compliance Blueprint

- Medicare Advantage and Part D – well-developed compliance requirements
- CMS experienced with Medicare oversight model
- Used as foundation for Medicaid (and QHP) compliance requirements
- Opportunity for plans to utilize internal and external Medicare and Medicaid managed care expertise efficiently

Subcontractor Requirements

Subject Matter	Medicare Advantage	Medicaid Managed Care (Proposed Rule 5/28/15)
Subcontractors defined	First tier, downstream, and related entities defined (administrative or health care services to Medicare eligibles) 42 CFR 422.500, Ch 21 MMCM, Sec 40	All contracts relating directly or indirectly to performance of MCO's obligations under the contract 42 CFR 438.230(a)
Ultimate accountability	MA Organization (MAO) has ultimate responsibility for compliance with government contract 42 CFR 422.504(i)(2)(i)	Same 42 CFR 438.230(b)(1)

Subcontract Content Requirements

Subject Matter	Medicare Advantage	Medicaid Managed Care (Proposed Rule 5/28/15)
Government audit rights	Grant CMS, HHS, OIG right to directly audit, collect and inspect any records or systems relating to contract 42 CFR 422.504(i)(2)(ii)	Same, with addition of the state, plus subcontractor must make available its premises, physical facilities, equipment and records relating to Medicaid enrollees 42 CFR 438.230(c)(3)(i) and (ii)
Audit rights	Current contract year (or audit completion) +10 years 42 CFR 422.504(i)(2)(iii)	Same with addition that there is no time limit for audits with reasonable possibility of fraud or similar risk 42 CFR 438.230(c)(3)(iii) and (iv)

Subcontract Content Requirements (continued)

Subject Matter	Medicare Advantage	Medicaid Managed Care (Proposed Rule 5/28/15)
Delegated Activities	Specify delegated activities government contract and reporting responsibilities 42 CFR 422.504(i)(4)(i)	Same 42 CFR 438.230(c)(1)(i)
Revocation	Revocation of delegation or other remedies) if CMS or MAO determines subcontractor has not performed satisfactorily 42 CFR 422.504(i)(4)(ii)	Same, with reference to State regulator 42 CFR 438.230(c)(1)(iii)

Subcontract Content Requirements (continued)

Subject Matter	Medicare Advantage	Medicaid Managed Care (Proposed Rule 5/28/15)
Compliance with Contract Obligations	Services must be consistent and comply with MAOs contractual obligations 42 CFR 422.504(i)(3)(iii)	Same 42 CFR 438.230(c)(1)(ii)
Compliance with Laws	Subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions 42 CFR 422.504(i)(4)(v)	Same, with reference applicable Medicaid laws, regulations, and subregulatory guidance 42 CFR 438.230(c)(2)

MA Subcontract (FDR) Content Requirements without Proposed Medicaid Equivalent

- Enrollees held harmless for fees that are obligation of MAO
- Ongoing monitoring of performance by MAO
- Credentials or credentialing process will be reviewed by MAO
- MAO retains right to approve, suspend, or terminate any provider or subcontractor selected by subcontractor

MAO Exclusion and Debarment Checks

- Review DHHS OIG List of Excluded Individuals and Entities and GSA Excluded Parties List System
  - Before hiring or contracting with any new employee, temporary employee, volunteer, consultant, board member, or FDR (subcontractor and provider)
  - Monthly thereafter
  - Chapter 21 MMCM, Section 50.6.8
- Guidance is unclear as to which persons within FDRs (employees, board members, owners) must be screened individually
  - Plan approaches vary
  - Consider function performed by FDR

MAO Payment Data Certifications

- CEO, CFO, or an individual delegated to sign on their behalf and who reports directly to such officer must certify monthly with payment request:
  - Based on best knowledge, information, and belief
  - Accuracy, completeness, and truthfulness of data
    - Enrollment information and encounter data
    - Risk adjustment data
    - Bid data
- FDR must provide additional certification if it generates data
- Additional certification by CEO, CFO, or COO of accuracy of data for reporting and return of overpayments
- 42 CFR 422.504(l)

D-SNPs and Dual Demonstrations

- Dual Eligible Special Needs Plans (D-SNPs)
  - MA-PD Contract with CMS
  - Have a separate State Medicaid contract (limited exceptions) – See Chapter 16b, MMCM
  - Comply with MA and Part D compliance requirements as well as those of State Medicaid

- Dual Demonstration Plans
  - Vary state to state
  - 3-way agreement with CMS and State
  - Ex. NY Fully Integrated Duals Advantage
    - Contract requires compliance with
      - MA and Part D requirements except if specifically waived
      - Medicaid program integrity regulations at 42 CFR 438.600, et seq, and other Medicaid requirements

Program Integrity (PI) Defined

- Broadly defined term:
  - Activities/requirements that promote “integrity” of the Medicare and Medicaid programs
- Social Security Act (SSA), §1936 (defines required CMS Medicaid integrity PI activities):
  - Review of individuals/entities furnishing items or services to determine whether fraud, waste, or abuse or expenditure of funds in manner not intended
  - Audits of claims for payment for items or services furnished, or administrative services rendered, under a State plan, including contracts with managed care organizations (MCOs)
  - Identification of overpayments to individuals/entities receiving Federal funds
  - Education/training of individuals/entities re: payment integrity and quality of care
- Goal of PI is to reduce or eliminate fraud, waste, and abuse

Medicaid Program Trends and Oversight Focus

- Sharp growth in enrollments and overall expenditures
- States increasing use of Medicaid MC solutions
- CMS Medicaid improper payment rates nearly doubled in 2 years
- CMS proposed Medicaid MC rule:
  - first regulatory changes in over 12 years
  - significant changes to program
  - Increased State oversight responsibilities including for program integrity requirements

Medicaid Program Integrity Statutory Provisions

Social Security Act §	Program Integrity Provision (*provision applies to Medicaid and Medicare)
1124*	Disclosure of ownership, control interests and related information
1126*	Disclosure of owners and other individuals convicted of certain offenses
1128*	Exclusion of certain individuals and entities from Medicare and Medicaid
1128J(d)*	Obligation to report/return any identified overpayments within 60 days
1902(a)(4)	State plan must provide for methods of administration for the proper and efficient operation of the plan
1902(a)(19)	State plan must provide safeguards to ensure eligibility is determined and services are provided in a manner consistent with simplicity of administration and best interests of beneficiaries
1902(a)(27)	Requires States to enroll persons/institutions that provide services under the State plan
1902(a)(68)	Requires entities receiving annual payments of $5M or more must establish certain minimum written policies relating to the Federal False Claims Act

Medicaid Program Integrity Statutory Provisions

Social Security Act §	Program Integrity Provision
1902(a)(77)	Requires States to comply with provider and supplier screening, oversight, and reporting requirements described in section 1902(kk)(1)
1902(a)(80)	Prohibits payments for items/services provided under the State plan or waiver to any financial institution/entity located outside US
1902(kk)(7)	Requires States to enroll physicians or other professionals that order or refer services under the State plan
1903(i)	Prohibits federal payments (FFP) for MCO amounts expended for providers excluded by Medicare, Medicaid, or CHIP, except for emergency services
1903(m)	Establishes conditions for payments to States for contracts with MCOs
1909	Provides for increased State Share of Federal False Claims Act Recoveries for States with FCA Laws
1932(d)(1) (provisions related to MC)	Prohibits MCOs from knowingly having certain types of relationships with individuals and entities debarred under Federal regulations or with affiliates of those individuals

Medicaid MC Program Integrity: CMS Regulatory Requirements and Guidance

- 42 CFR Part 455 (Program Integrity: Medicaid)
  - Applies to Medicaid program as a whole – both FFS and Medicaid MC (where applicable)
- 42 CFR Part 438 (Medicaid MC regulations)
  - §§438.600-610 (Additional Program Integrity Safeguards)
- CMS Medicaid Program Integrity Manual
  - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mpi115c01.pdf
  - CMS conducts State PI reviews every 3 years, including reviews of State MC programs

Medicaid MC Program Integrity: CMS Regulatory Requirements and Guidance

- CMS Guidance to States (Program Integrity Support and Assistance)
  - State PI Review Reports and Summaries
  - Medicaid Guidance Fraud Prevention
  - Frequent Finding Toolkits for PI Reviews
  - https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/StateProgramIntegrityReviews.html

- CMS Federal Policy Guidance (State Medicaid Director's Letters (SMDL), Informational Bulletins, FAQs):
  - https://www.medicaid.gov/federal-policy-guidance/federal-policy-guidance.html
  - SMDL #07-003 (3/22/07): Deficit Reduction Act (DRA) employee FCA education requirements FAQs
  - SMDL #06-024 (12/13/06): Deficit Reduction Act (DRA) employee FCA education requirements guidance
  - SMDL #09-001 (1/16/09): Excluded providers
  - SMDL #08-003 (6/12/08): Excluded providers

Medicaid Program Integrity Regulations – 42 CFR 455

- 42 CFR Part 455 (Program Integrity: Medicaid)
- Applies to FFS Medicaid and and MC (depending on the regulation)
  - Subpart A: provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases
  - Subpart B: certain entities must agree to disclose ownership and control information to the Medicaid State agency
  - Subpart C: establishes the HHS/CMS Medicaid Integrity Program
  - Subpart E: Provider Screening and Enrollment (FFS Medicaid only – CMS proposed MC regulations would expand these requirements to MC)
  - Subpart F: Medicaid Recovery Audit Contractors (States may exclude MC claims from review by RACs)

Medicaid Program Integrity Regulations – 42 CFR 455

- 42 CFR Subpart B: §§455.100-106:
  - Disclosure of ownership and control information
  - Disclosure of information related to business transactions
  - Disclosure of information on owners and other convicted of criminal offenses against Medicare, Medicaid, CHIP

Medicaid Program Integrity Regulations – 42 CFR §455.104

- §104 (Disclosures on ownership and control):
  - State Medicaid agency must obtain disclosures from providers, fiscal agents and MC entities
  - Ownership or control disclosure interests that must be disclosed:
    - a person or entity that has at least a 5% or more direct, indirect or combined ownership interest
  - Federal financial participation (FFP) is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required

Medicaid Program Integrity Regulations – 42 CFR §455.104

- Must disclose the following information:
  - Name/address of all persons or entities with ownership or control interest (includes direct and indirect ownership)
  - DOB and SSN (individuals); Tax ID (entities)
  - Names, addresses, DOB, SSN of any "managing employees" of disclosing entity (officers, directors, etc.)
  - Includes information re: subcontractors in which the disclosing entity has a 5% or more interest
  - Includes information about familial relationships of owners
  - Includes names of other disclosing entities with same ownership
- MCEs required to disclose:
  - Upon submitting proposal in accordance with State's procurement process;
  - Upon MCE executing contract with State; and
  - With 35 days after any change in ownership of the MCE

Medicaid Program Integrity Regulations – 42 CFR §455.105

- §105 (Disclosures by providers: information related to business transactions):
  - Medicaid agency must enter into provider agreements that require providers to disclose upon request:
    - ownership of any subcontractor with whom the provider has had business transactions totaling more than $25K during the 12-month period ending on the date of the request; and
    - Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.
  - FFP not available in expenditures for services furnished by providers who fail to comply
  - State agencies and/or Medicaid health plans applying these requirements to MCE contracted health care providers and administrative contractors

Medicaid Program Integrity Regulations – 42 CFR §455.106

- §106 (Disclosures by providers: information on persons convicted of crimes):
  - Before Medicaid agency enters into or renews a provider agreement or upon request, providers must disclose :
    - Identity of any person with an ownership or control interest, agent, or managing employee who has been convicted of a crime related to that person's involvement with Medicare, Medicaid or CHIP programs
    - Medicaid agency must disclose information to HHS/OIG
    - State agency may deny provider application or non-renew provider agreement on this basis or where person did not fully and accurately make required disclosures
  - State agencies and/or Medicaid health plans applying these requirements to MCE contracted health care providers and administrative contractors

Medicaid Managed Care Proposed Regulations (June 2015)

- 80 Fed. Reg. 31098 (June 1, 2015) (RIN: 0938-AS25)(CMS-2390-F)
- CMS final regulations expected April 2016
- Sweeping program changes (MLR, provider network adequacy standards, etc.) with multiple policy objectives:
  - Modernize MC regulatory structure to facilitate delivery reforms while managing costs and protecting beneficiaries
  - Align with requirements for other sources of coverage (Medicare, individual coverage, group coverage, etc.) to ease transitions among coverage and simplify administration
  - Account for growing reliance of States on managed care plans to administer covered benefits and increasing federal/state funds (PI objective)
    - protect expenditures through increased accountability and strengthening PI safeguards

Medicaid Managed Care Proposed Regulations (June 2015)

- Program integrity provisions (42 CFR §§438.600; 438.602; 438.604; 438.606; 438.608; 438.610)
- State/federal Medicaid funds increasingly vulnerable to fraud given States' growing reliance on managed care plans
- Rethinking Medicaid MC PI provisions (considered broader set of information from sources such as CMS PI reviews, OIG reports)
- Focused on 2 primary risks:
  - (1) fraud by health plans and;
  - (2) fraud by network providers
- Adding/amending existing provisions to address managed care PI risks

Medicaid MC Program Integrity Regulatory Provisions – Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
1. §600 (Statutory basis)	Cites 4 statutory bases for Medicaid managed care program integrity provisions	**Adds 8 statutory bases to account for new legislative requirements since issuance of 2002 regulations (e.g., Deficit Reduction Act, Affordable Care Act).**
2. §602 (State responsibilities)	As a condition for receiving payment under the Medicaid managed care program, a managed care entity must comply with the applicable certification, program integrity and prohibited affiliation requirements of this subpart.	**Replaces §602 in its entirety and specifically outlines all specific State managed care PI responsibilities. Includes:** (b) **States must enroll and screen all network providers not otherwise enrolled in FFS Medicaid**; includes all applicable screening and disclosure standards under Part 455, Subparts B and E; States may incorporate additional provider screening; (c) **States must review the ownership and control disclosure forms submitted by MCEs and any subcontractors** in accordance with Part 455, subpart B; (d**) States must conduct federal database checks** (consistent with 42 CFR §455.436) to confirm the identity and determine exclusion status of MCE, any subcontractor, any person with an ownershiop or control interest, or any agent or managing employee at the time of entering into the contract and no less frequently than monthly thereafter. Checks include the SSA's Death Master File, the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the State or Secretary may prescribe. If the state determines a match, it must promptly notify the MCE and take action consistent with § 438.610(c);

Medicaid MC Program Integrity Regulatory Provisions – Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
2. §602 (State responsibilities) (cont'd.)		(e) States must periodically (no less frequently than once every 3 years), conduct, or contract for the conduct of, **an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data** submitted by each MCE; (f) States must receive and investigate information from whistleblowers relating to the integrity of the MCE, subcontractors, or network providers receiving Federal funds under this part; (g) **States must post on its Web site** or make available upon request the following documents and reports: (1) The MCE contract; (2) The data submitted under §438.604; (3) The results of any audits under paragraph (e) of this section; (h) **States must have in place conflict of interest safeguards** described in § 438.58 and must comply with the requirement described in SSA, 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors; and (i) The State must ensure that the **MCE** with which the State contracts under this part is **not located outside of the US and that no claims paid by a MCE to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S.** are considered in the development of actuarially sound capitation rates.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
3. §604 (Data, information and documentation that must be submitted)	(a) *Data certifications.* When State payments to a MCE is based on data submitted by the MCE, the State must require certification of the data as provided in §438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents. (b) *Additional certifications.* Certification is required, as provided in §438.606, for all documents specified by the State.	The **State must require a MCE to submit the following data, information or documentation**: (1) Encounter data; (2) Data on the basis of which the State certifies the actuarial soundness of the capitation rates; (3) Data upon which the State determines the MCE's compliance with medical loss ratio requirements; (4) Data upon which the State determines the MCE has made adequate provision against risk of insolvency; (5) Documentation upon which the State bases its certification that the MCE has complied with requirements for availability and accessibility of services, including network adequacy; (6) Information on ownership and control from MCEs and subcontractors as governed by §438.230; and (7) Annual report of overpayment recoveries as required by §438.608(d)(3); (8) Any other data, documentation or information relating to the performance of the MCE's obligations required by the State or CMS.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
4. §606 (Source, content and timing of certification)	The data the MCE submits to the State under §438.604 must be certified by one of the following: (1) The CEO, CFO or any individual who has delegated authority and reports directly to, the MCE's CEO or CFO. (b) The certification must attest, based on best knowledge, information, and belief, as follows: (1) To the accuracy, completeness and truthfulness of the data. (2) To the accuracy, completeness and truthfulness of the documents specified by the State. (c) The MCE must submit the certification concurrently with the certified data.	(a) The **State must require that the data, documentation or information the MCE submits to the State be certified by either the MCO's CEO or CFO**. (b) The certification must attest that the MCE has **conducted a reasonably diligent review of the data**, documentation, and information specified in §438.604(a) and (b), and that the data documentation, and information is accurate, complete, and truthful. (c) The State must require the MCE to submit the certification concurrently with the submission of the data, documentation, or information required in §438.604(a) and (b).

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
5. §608 (Program integrity requirements under the contract) **(Compliance Program requirements)**	(a) The MCE must have administrative and management arrangements or procedures, including a mandatory compliance plan, designed to guard against fraud and abuse which must include the following: (1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal/State standards. (2) The designation of a compliance officer and compliance committee that are accountable to senior management. (3) Effective training and education for the compliance officer and employees. (4) Effective lines of communication between the compliance officer and employees. (5) Enforcement of standards through well-publicized disciplinary guidelines. (6) Provision for internal monitoring and auditing. (7) Provision for prompt response to detected offenses and corrective actions.	(a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.* The State, through its contract with the MCE, must require that the MCE or subcontractor to the extent that the subcontractor is delegated responsibility by the MCE for coverage of services and payment of claims under the contract between the State and the MCE implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following: (1) A compliance program that includes, at a minimum, all of the following elements: (i) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements. (ii) The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the CEO and the Board.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
5. §608 (Program integrity requirements under the contract) **(Compliance Program requirements)** (cont'd.)		(iii) The establishment of a Regulatory Compliance Committee at the Board and at the senior management level charged with overseeing the organization's compliance program and compliance with the contract. (iv) A system for training and education for the Compliance Officer, senior management, and employees for the Federal and State standards and requirements under the contract. (v) Effective lines of communication between the compliance officer and the organization's employees. (vi) Enforcement of standards through well-publicized disciplinary guidelines. (vii) Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
5. §608 (Program integrity requirements under the contract) **(Other Provisions)** (cont'd.)		(2) Provision for **prompt reporting all improper payments**, specifying improper payments due to potential fraud, to the State or law enforcement; (3) Provision for **prompt notification to the State when it receives information about changes in an enrollee's circumstances** that may affect eligibility including changes in the enrollee's residence; changes in the enrollee's income; the death of an enrollee; (4) Provision for **notification to the State when it receives information about a change in a provider's circumstances** that may affect eligibility to participate in the managed care program, including the termination of the provider agreement with the MCE; (5) Provision for a **method to verify, by sampling or other methods, whether services represented to have been delivered by network providers were received** by enrollees and the application of verification processes on a regular basis; (6) In the case of MCEs that receive annual payments under the contract of at least $5,000,000, written policies for all employees of the entity, and of any contractor or agent, providing detailed information about the False Claims Act and other Federal and State laws described in §1902(a)(68), including information about rights of employees to be protected as whistleblowers are in place (**Deficit Reduction Act provisions**);

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
5. §608 (Program integrity requirements under the contract) **(Other Provisions)** (cont'd.)		(7) Provision for the **prompt referral of any potential fraud, waste, or abuse** that the MCE identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit; and (8) Provision for the MCE's **suspension of payments to a network provider for which the State determines there is a credible allegation of fraud** in accordance with § 455.23 of this chapter. (b) ***Provider screening and enrollment requirements.*** **The State, through its contracts with a MCE must ensure that all network providers are enrolled with the State as Medicaid providers** consistent with the provider disclosure, screening and enrollment requirements of part 455, subparts B and E of this chapter. This provision does not require the network provider to render services to FFS beneficiaries. (c) *Disclosures.* **The State must ensure, through its contracts, that each MCE, and any subcontractors:** (1) Provides **written disclosure of any prohibited affiliation** under §438.610. (2) Provides **written disclosures of information on ownership and control** required under §455.104. (3) **Reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts** specified in the contract.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
5. §608 (Program integrity requirements under the contract) **(Other Provisions)** (cont'd.)		(d) ***Treatment of recoveries made by the MCE of overpayments to providers.*** (1) Contracts with a MCE must specify that the MCE retains the following: (i) Payments made to a network provider that was otherwise excluded from participation in the Medicaid program, and subsequently recovered from that network provider, by a MCE. (ii) Payments made to a network provider due to fraud, waste or abuse, and subsequently recovered from that network provider, by a MCE. (2) Each MCE requires and has a **mechanism for a network provider to report to the MCE when it has received an overpayment, to return the overpayment to the MCE within 60 calendar days after the date on which the overpayment was identified**, and to notify the MCE in writing of the reason for the overpayment. (3) Each MCE **must report annually to the State on their recoveries of overpayments.** (4) The State must use the results of the report in paragraph (d)(3) of this section for setting actuarially sound capitation rates for each MCE consistent with the requirements in § 438.4. (5) For purposes of paragraph (d) of this section, an overpayment is any payment made to a network provider by a MCE to which the network provider is not entitled to under title XIX of the Act.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
6. §610 (Prohibited affiliations)	(a) *General requirement.* An MCE may not knowingly have a relationship of the type described in paragraph (b) of this section with the following: (1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from non-procurement activities. (2) An individual who is an affiliate, as defined in the FAR, of a person described in paragraph (a)(1) of this section. (b) *Specific requirements.* The relationships described in this paragraph are as follow: (1) A director, officer, or partner of the MCE. (2) A person with beneficial ownership of five percent or more of the MCE's equity. (3) A person with an employment, consulting or other arrangement with the MCE for the provision of items and services that are significant and material to the MCE's obligations under its State contract.	(a) An MCE may not knowingly have a relationship of the type described in paragraph (c) of this section with the following: (1) An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from non-procurement activities. (2) An individual or entity who is an affiliate, as defined in the FAR, of a person described in paragraph (a)(1) of this section. (b) An MCE may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under §1128 or 1128A.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
6. §610 (Prohibited affiliations) (cont'd.)	(c) *Effect of Noncompliance.* If a State finds that a MCE is not in compliance with paragraphs (a) and (b), the State: (1) Must notify the Secretary of the noncompliance. (2) May continue an existing agreement with the MCE unless the Secretary directs otherwise. (3) May not renew or otherwise extend the duration of an existing agreement with the MCE unless the Secretary provides to the State/Congress a written statement describing compelling reasons that exist for renewing or extending the agreement. (d) *Consultation with the Inspector General.* Any action by the Secretary described in ¶(c)(2) or ¶(c)(3) is taken in consultation with the HHS/OIG.	(c) The relationships described in paragraph (a) of this section, are as follows: (1) A director, officer, or partner of the MCE. (2) **A subcontractor of the MCE, as governed by § 438.230.** (3) A person with beneficial ownership of 5% or more of the MCE's equity. (4) A network provider or persons with an employment, consulting or other arrangement with the MCE for the provision of items and services that are significant and material to the MCE's obligations under its State contract. (d) *Effect of noncompliance.* If a State finds that an MCE is not in compliance with paragraphs (a) and (b), the State: (1) Must notify the Secretary of the noncompliance. (2) May continue an existing agreement with the MCE unless the Secretary directs otherwise. (3) May not renew or otherwise extend the duration of an existing agreement with the MCE unless the Secretary provides to the State/Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

Medicaid MC Program Integrity Regulatory Provisions - Comparison of Current vs. Proposed Regulations

Regulation (42 CFR Part 438)	Current Requirement	Proposed Requirement
6. §610 (Prohibited affiliations)		(4) Nothing in this section must be construed to limit or otherwise affect any remedies available to the U.S. under §§ 1128, 1128A or 1128B. (e) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (d)(2) or (d)(3) of this section is taken in consultation with the HHS/OIG.

Medicaid Managed Care Proposed Regulations (June 2015)

- Other program integrity related proposals:
  - Subcontractual relationships and delegation (42 CFR §438.230)
  - Modeled on Medicare Advantage regulations ("MA framework for flow of responsibilities and accountability are effective program integrity safeguards")
  - Applies to all contracts or written arrangements with individuals/entities that relates directly or indirectly to performance of activities or obligations under the MCO's contract with the State
  - Subcontractors must contractually agree to:
    - Perform services in compliance with applicable law, regulations, subregulatory guidance and State MCO contract provisions
    - Right for CMS, HHS, OIG, Comp General to audit and inspect records/books for up to 10 years from completion of State contract (and at any time for fraud reasons)

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