Medicaid and CHIP Managed Care

Program Integrity Toolkit

42 CFR 438 Subpart H

Compliance Program Requirements

§438.608(a)(1)

Last Updated: 11/01/2023

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Content Summary

Through the Medicaid and Children's Health Insurance Program (CHIP) Managed Care Program Integrity Toolkits, CMS features key topics that will help state Medicaid agencies, as well as managed care plans (MCPs) [Endnote 1], improve program integrity through greater oversight, accountability, and transparency.

This Compliance Program Requirements Toolkit discusses the compliance program requirements that states must follow when entering into contracts with MCPs. Specifically, CMS regulations at 42 CFR 438.608(a)(1) require that states, through contracts with MCPs, must require MCPs to implement and maintain arrangements or procedures designed to detect and prevent fraud, waste, and abuse. These arrangements or procedures must include a compliance program that meets several minimum elements.

Introduction

Medicaid and CHIP are federal-state partnerships, and those partnerships are central to the programs' success. Given the extensive and expanding use of managed care in Medicaid and CHIP, it is critical that the Centers for Medicare & Medicaid Services (CMS) and state Medicaid agencies (SMAs) ensure accountability and strengthen program integrity safeguards in states' managed care programs.

This toolkit summarizes and clarifies certain program integrity provisions in 42 CFR 438 Subpart H, as finalized in the "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability" rule (referred to as the 2016 Managed Care Final Rule). [Reference 1] This toolkit provides information and examples regarding oversight practices SMAs should consider to ensure that effective program integrity measures are in place. [Endnote 2, Reference 2]

Note: This toolkit does not contain an exhaustive list of all federal requirements and is only intended to be a tool to aid SMAs in the development of contracts with, and oversight of, its Medicaid and CHIP MCPs. The contents of this toolkit do not have the force and effect of law and are not meant to bind the public or any parties in any way, unless specifically incorporated into a contract. This toolkit is intended only to provide clarity to existing requirements under the law and may be revised and updated periodically to reflect statutory, regulatory, and other policy changes. The "Last Updated" date is the date this toolkit was most recently updated.

Background

On May 6, 2016, CMS published the 2016 Managed Care Final Rule that included important program integrity safeguards in Part 438, Subpart H [adopted in CHIP via cross-reference at §457.1285 with the exception of §§438.604(a)(2) and 438.608(d)(4)]. Specifically, these regulations outlined requirements to help address fraud and other improper payments caused by MCPs and related network providers. The final rule also tightened standards for MCPs' submission of certified data, information, and documentation that are critical to program integrity oversight by state and federal agencies.

States and MCPs are required to comply, as applicable, with the program integrity requirements in §§438.600 (statutory basis and applicability), 438.602 (state responsibilities), 438.604 (data, information, and documentation that must be submitted), 438.606 (source, content, and timing of certification), 438.608 (program integrity requirements under managed care contracts), and 438.610 (prohibited affiliations). States have been required to comply with §§438.602(a), 438.602(c) - (h), 438.604,438.606, 438.608(a), and 438.608(c) and (d), since no later than the rating period for contracts starting on or after July 1, 2017. States have been required to comply with §§438.602(b) and 438.608(b) since no later than the rating period for contracts beginning on or after July 1, 2018.

A. Applicability to Medicaid

Federal statute and regulations specify the authorities and requirements under which states can offer services via contracts with Medicaid MCPs [see generally, sections 1902 through 1905 and 1932 of the Social Security Act (the Act)]. These statutory provisions provide the basis of the federal regulatory structure found in Part 438 Subpart H. The SMA must have a monitoring process for compliance with requirements of the state's managed care program and the MCP contract with the state. SMAs are responsible for ensuring that MCPs comply with federal regulations. MCPs must provide the safeguards necessary to ensure that eligibility is determined, and that services are provided, in a manner consistent with simplicity of administration and the best interests of the recipients (see section 1902(a)(19) of the Act).

There are basic requirements listed in Part 438 Subpart H for MCPs to receive payment under a Medicaid managed care program. In general, most of the requirements apply to most MCPs, but there is variation with respect to primary care case managers (PCCMs) and primary care case management entities (PCCM entities). For example, §§438.600(b) and (c) apply to PCCMs and PCCM entities but §§438.608(a) and (d) do not. PCCMs and PCCM entities must comply with the requirements in §§438.604, 438.606, 438.608, and 438.610, as applicable.

B. Applicability to CHIP

Most of the program integrity requirements of Part 438 Subpart H apply to CHIP via a cross reference in §457.1285. Specifically, §457.1280 governs contracting standards and §457.1285 applies the Medicaid program integrity safeguards of Part 438 Subpart H to CHIP. [Endnote 3]

Compliance Program Requirements

States must include a requirement in all MCP contracts that MCPs implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include a compliance program that meets several elements of corporate integrity. The MCPs' compliance programs must, at a minimum, include the following elements:

A. Written Policies, Procedures, and Standards of Conduct (§438.608(a)(1)(i))

Under §438.608(a)(1)(i), MCPs must have 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. The term "compliance plan" is used throughout this section to refer to a document that includes all of the required elements of corporate integrity under §438.608(a)(1)(i-vii), and promotes the prevention, detection, and resolution of noncompliance with requirements under the contract with the SMA.

The MCPs' written Standards of Conduct should reflect and affirm the MCP's governing and ethical principles and include a Resolution of the Governing Body that affirms the MCP's commitment to compliant, lawful, and ethical conduct. The MCP's governing body should be knowledgeable about the content and operation of the compliance program and exercise reasonable and effective oversight with respect to the program's implementation. The Standards of Conduct must also include disciplinary guidelines, as described in §438.608(a)(1)(vi).

Written policies should describe specific procedures that employees and contractors should follow when performing their duties. These policies should be detailed and specific to the administrative arrangements and procedures that govern the operation of the compliance program. MCPs must include written policies and procedures that, at a minimum, describe:

- The establishment of a Compliance Officer and Regulatory Compliance Committee, as required under §438.608(a)(1)(ii) and (iii), respectively.
- Systems for training and educating MCP Compliance Officer, senior management, and employees, as required under §438.608(a)(1)(iv).
- Effective lines of communication between the compliance officer and organization's employees and the enforcement of well-publicized disciplinary guidelines as required under §§438.608(a)(1)(v) and (vi), respectively.
- Processes for conducting routine internal monitoring and auditing of compliance risks, as required in §438.608(a)(1)(vii).

B. Compliance Officer and Communication with Employees (§438.608(a)(1)(ii), (v))

Under §438.608(a)(1)(ii), MCPs must designate a Compliance Officer (CO) who reports directly to the Chief Executive Officer and the Board of Directors. The CO is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and all applicable federal and state requirements. Under §438.608(a)(1)(v), MCPs must establish effective lines of communication between the CO and the organization's employees.

The CO should be responsible for the following activities:

- Operating the MCP's compliance program and overseeing MCP and employee compliance with all provisions.
- Assessing the MCP's operations, policies, and reporting and oversight systems to mitigate risk and ensure that the MCP and network providers are performing their respective duties in a manner that is safe, legal, transparent, and in compliance with its contracts with the SMA and network providers.
- Developing a risk profile that evaluates current risks facing the MCP.
- Working with the organization's employees to develop appropriate internal controls to mitigate identified risks.
- Undertaking and coordinating investigations and audits with appropriate organization employees.

The CO should protect the integrity and confidentiality of any inquiry and take appropriate steps to ensure confidentiality whenever possible.

C. Regulatory Compliance Committee (§438.608(a)(1)(iii))

Under §438.608(a)(1)(iii), MCPs must establish a Regulatory Compliance Committee (RCC) on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract with the SMA. The RCC should include governing board members and other senior management (such as the Chief Financial Officer and/or the Chief Operating Officer), and include individuals with a variety of backgrounds, including auditing, clinical, legal, and statistical experience. While the MCPs have discretion to determine the composition of the RCC, including the number of meetings and frequency of meetings, the size of the RCC should reflect the size and scope of the MCP's responsibilities under its contract with the state. States may also add additional requirements through the contract with the MCP.

The role and responsibilities of the RCC should be clearly articulated in the compliance plan described in §438.608(a)(1)(i). The objectives, oversight, and functions of the RCC should be consistent with the MCP's overall compliance and program integrity activities. Duties of the RCC may include, but are not limited to, the following:

- Meeting at least on a quarterly basis, or more frequently as necessary, to ensure reasonable oversight of the compliance program.
- Developing strategies to promote compliance and the detection of any violations.
- Reviewing and approving compliance and training on fraud, waste, and abuse, and ensuring that training and education are effective and appropriately completed.
- Assisting with the creation and implementation of a compliance risk assessment, and compliance monitoring and auditing work plan.
- Reviewing the effectiveness of the system of internal controls designed to ensure compliance with federal and state requirements in daily operations.
- Supporting the CO's need for sufficient staff and resources to carry out duties.
- Ensuring that the MCP has up-to-date compliance policies and procedures.
- Ensuring that the MCP has a method for enrollees to report potential fraud, waste, and abuse.
- Ensuring that the MCP has a system for employees and contractors to seek assistance with compliance issues and report noncompliance or potential fraud, waste, and abuse confidentially without fear of retaliation.
- Reviewing and addressing reported issues and focusing audits on areas in which the MCP is at risk for noncompliance or potential fraud, waste, and abuse, and ensuring that associated corrective action plans are implemented and monitored for effectiveness.
- Providing the MCP's governing body with regular and ad hoc reports on the status of compliance, including recommendations for improvement.

D. Training and Education (§438.608(a)(1)(iv))

Comprehensive and effective training is critical to ensuring the success of a compliance program. Under §438.608(a)(1)(iv), MCPs are responsible for developing a system for training and educating the CO, the organization's senior management, and its employees about the federal and state standards and requirements under the contract with the SMA. Training and education should be mandatory for all employees. MCPs should conduct training upon initial hire or appointment and at regular intervals (at least annually) to ensure that the RCC, Governing Board, senior management, employees, and contractors are aware of current compliance standards.

MCPs should also incorporate into their compliance training and education program any recent changes in compliance standards, compliance activities for the past period, current and future compliance priorities, and performance outcomes related to compliance activities.

The prime objective of compliance training and education is that individuals will have the knowledge and skills necessary to conduct the compliance program's activities and meet its standards. A general compliance training and education program should prepare participants to:

- Articulate the relationships between the MCP and the federal and state governments, subcontractor, and other external partners.
- Identify the compliance policies/procedures and Standards of Conduct.
- Affirm the MCP's commitment to business ethics and compliance with all Medicaid and CHIP requirements and understand where to locate resources and more information.
- Report noncompliance or potential fraud, waste, and abuse.
- Understand the protection of an individual's confidentiality and freedom from retaliation for making reports of noncompliance or potential fraud, waste, and abuse.
- Understand the rights of employees, contractors, and agents to be protected as whistleblowers and information about how to make whistleblower complaints related to the integrity of the MCP, subcontractors, or network providers receiving Federal funds.
- Describe examples of reportable noncompliance.
- Describe disciplinary guidelines that govern non-compliance and behavior that may indicate fraud, waste, and abuse, and understand that such behavior can result in disciplinary action, including possible termination.
- Describe policies related to contracting with the government, such as the laws addressing gifts and gratuities for government and contractor employees.
- Recognize conflicts of interest and articulate the procedures for disclosure.
- State the essential purpose of the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health (HITECH) Act and affirm the importance of maintaining the confidentiality of personal health information.
- Understand the basics of the False Claims Act, Anti-kickback statute, and civil monetary penalty authorities.
- Understand an MCP's internal monitoring and auditing processes.

E. Distributing Written Disciplinary Guidelines and Standards of Conduct (§438.608(a)(1)(vi)

MCPs are required to establish written standards of conduct that must include disciplinary guidelines. Under §438.608(a)(1)(vi), MCPs are required to distribute disciplinary guidelines to all employees, agents, and contractors in a well-publicized manner. MCPs should distribute compliance materials to employees, agents, and subcontractors shortly after (e.g., within 30 calendar days) a contract's effective date or an individual's hire date, and redistribution should occur when there are material updates to the policies or requirements. Distribution should occur annually thereafter.

MCPs may choose the method, unless the state specifies by law or in contract, by which materials will be distributed. If the state does not specify a method, an MCP may furnish a hard copy of the material upon hiring an employee or furnish electronic copies. Standards of Conduct should be written in plain language and organized in a format that is easy to read and comprehend. Further, MCPs should document that Standards of Conduct were distributed to all employees, agents, and contractors.

F. Internal Monitoring and Auditing (§438.608(a)(1)(vii))

Under §438.608(a)(1)(vii), MCPs must establish and implement procedures and a system that support internal controls and auditing of compliance risks within the MCP. Compliance risks include program integrity vulnerabilities that may exist within the MCP's operations and systems.

Specifically, the MCP must establish and implement procedures and a system for:

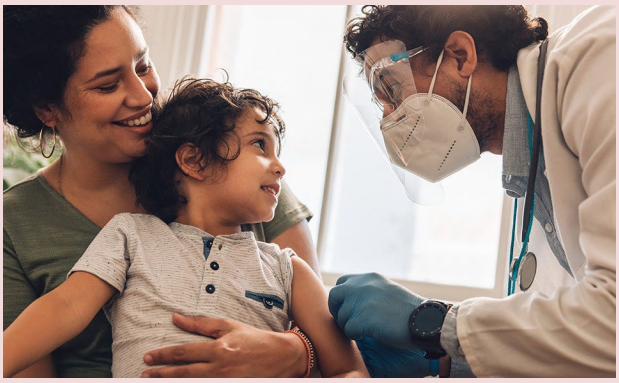
- Routine internal monitoring and auditing of compliance risks.
- Prompt response to compliance issues when raised.
- Investigation of potential compliance issues as identified in self-evaluations and audits.
- Correction of such problems promptly and thoroughly (or timely, effective coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence.
- Ongoing compliance with the requirements under the contract.

MCPs must have dedicated staff to execute procedures for routine internal monitoring and auditing of compliance risks. The dedicated staff's job descriptions should include the activities in §438.608. To continuously identify and address compliance risks, MCPs should implement an ongoing risk assessment, including ongoing review and data mining of encounter and claims data. Written policies should include operationally focused annual or bi-annual work plans to effectively target resources to address priority program integrity risks. Once the risk assessment has been completed by the MCPs, a monitoring and auditing work plan should be developed.

The internal monitoring system should also include an intake system for issues raised by employees and issues that emerge through the normal course of operations, such as enrollee complaints or reports of suspected fraud, waste, and abuse.

The CO, working with an MCP's claims data staff, audit staff, and/or other departments, should be involved in establishing and monitoring internal compliance audits and risks as issues are identified. The CO may coordinate with each department to develop a monitoring and auditing work plan based upon the results of the risk assessment. CMS encourages MCPs to include the following elements in the work plan:

- Audits to be performed
    - Encounter data - Accuracy and Completeness
    - Utilization Management
    - Access and Availability
    - Member Rights
    - Quality Improvement
    - Case Management and Coordination of Care
    - Regulatory
    - Training and Education
- Audit schedules, including start and end dates
- Announced and/or unannounced audits
- Audit methodology
- Necessary resources (e.g., staffing, funding)
- Types of audit: desk or onsite/virtual
- Person(s) responsible
- Final audit report due date to CO
- Follow up activities from findings



In particular, when conducting audits, CMS encourages MCPs to conduct an appropriate balance of announced and unannounced audits. CMS recommends that providers designated by the MCP as high-risk should undergo at least some unannounced audits. As the risk level decreases, the portion of unannounced audits may also decrease.

Once audit results are received, data should be analyzed to identify unusual patterns suggesting potential errors and/or potential fraud and abuse. The use of data analysis may include, but is not limited to, monitoring pharmacy and medical billing to detect unusual patterns.

Conclusion

Detecting risks and implementing mitigation activities are shared responsibilities among CMS, states, and MCPs. These shared activities are critical to protecting Medicaid and CHIP from fraud, waste, and abuse. This toolkit will help states and MCPs achieve their program integrity goals and remain in compliance with CMS requirements.

Endnotes

1. Managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), primary care case managers (PCCMs), and primary care case management entities (PCCM entities) are also referred to throughout as managed care plans (MCPs.). Contracts with Health Insuring Organizations (HIOs) that began operating on or after January 1, 1986, and are not explicitly exempt by statute from requirements in section 1903(m) of the Act, are subject to the requirements of Part 438 Subpart H to the same extent that the requirements apply to MCOs.

2. Medicaid managed care provider screening and enrollment requirements under §438.602(b)-(d) are referenced but not fully addressed in this toolkit. These requirements have been addressed separately in the Medicaid Provider Enrollment Compendium (MPEC).

3. Requirements at §§438.604(a)(2) and 438.608(d)(4) are not applicable to separate CHIP MCPs.

References

1. 81 FR 27497 (May 6, 2016), https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf.

2. The Medicaid Provider Enrollment Compendium (MPEC), https://www.medicaid.gov/affordable-care-act/program-integrity/index.html.

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