Overview and Legal and Fiscal Impact

The regulations amend current regulations relating to the Maryland Medicaid Managed Care Program to comply with recently adopted federal regulations that alter the requirements for managed care organizations (MCOs) to participate in the program and the oversight of these organizations. The regulations address program eligibility and enrollment of individuals, MCO applications and conditions for participation, the needs of special education populations, data collection and reporting, subcontractual relationships, reimbursement of hospitals, access standards, enrollee benefits, program integrity, and procedures for dispute resolution.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Maryland Department of Health:
   Procedures: Fair Hearing Appeals Under the Maryland State Medical Assistance Program: COMAR 10.01.04.03, .04, and .08
   Medical Care Programs: Maryland Medicaid Managed Care Program:
   Definitions: COMAR 10.09.62.01
   Maryland Medicaid Managed Care Program: Eligibility and Enrollment:
   COMAR 10.09.63.02, .03, and .06
   Maryland Medicaid Managed Care Program: MCO Application:
   COMAR 10.09.64.03 and .11
   Maryland Medicaid Managed Care Program: Managed Care Organizations:
   COMAR 10.09.65.02, .04, .15, .17, .19, .20, and .28
   Maryland Medicaid Managed Care Program: Access: COMAR 10.09.66.01 and .02
   Maryland Medicaid Managed Care Program: Benefits: COMAR 10.09.67.01, .04, and .19
   Maryland Medicaid Managed Care Program: School-Based Health Centers:
   COMAR 10.09.68.01 – .03
   Maryland Medicaid Managed Care Program:
   MCO Dispute Resolution Procedures: COMAR 10.09.71.02, .04, and .05
   Maryland Medicaid Managed Care Program:
   Departmental Dispute Resolution Procedures: COMAR 10.09.72.01 and .06
Legal Analysis

Summary of Regulations

The regulations amend current regulations relating to the Maryland Medicaid Managed Care Program to comply with recently adopted federal regulations that alter the requirements for managed care organizations (MCOs) to participate in the program and the oversight of these organizations. The regulations address program eligibility and enrollment of individuals, MCO applications and conditions for participation in the program, the needs of special education populations, data collection and reporting, subcontractual relationships, reimbursement of hospitals, access standards, enrollee benefits, program integrity, and procedures for dispute resolution. A detailed overview of these regulations follows.

Fair Hearing Appeals

The regulations require that a request for a fair hearing to dispute a denial of service be postmarked, delivered in person, or sent by email or facsimile to the Office of Health Services with 120 days of the receipt of the notification right to request a fair hearing, if the appeal concerns services provided or denied by an MCO. When a decision is favorable to the appellant and the service provided is an MCO service, the MCO is required to authorize or provide the disputed services no later than 72 hours from the date it receives notice reversing the MCO’s determination.

Eligibility and Enrollment

The department is required to provide to eligible individuals the following information:

- how to access the provider directory and drug formulary, with instructions for how to request paper copies, if needed;
- which benefits, if any, are provided directly by the department;
- information about how to obtain services that an MCO does not provide, reimburse for, or provide coverage for because of moral or religious objections;
- requirements for each MCO to provide adequate access to covered services, including network adequacy standards
- quality and performance indicators for each MCO, including enrollee satisfaction; and
- managed care program materials, including the MCO enrollment and disenrollment process and the basic features of managed care.

On determination of program eligibility, the department is required to enroll eligible individuals into an MCO online. In addition, a newborn who is automatically assigned to its biological mother’s MCO is not eligible to change MCOs during the first 90 days of enrollment.
If the department does not transmit information relating to the health services needs of an enrollee to the MCO within 10 days of enrollment, the MCO must make at least two attempts to conduct an initial screening of the enrollee’s needs within 90 days of the effective date of enrollment. At least one of those attempts must be made during non–working hours.

The regulations increase, from 30 to 90 days, the number of successive days an enrollee must spend continuously institutionalized in a long term facility, subject to a determination by the department that an enrollee’s institutionalization in a long term facility has been medically necessary, before the department is required to disenroll the enrollee from an MCO.

**MCO Applications**

The regulations alter the requirements for an MCO application to include:

- a description of how the applicant plans to address the special access provisions in COMAR 10.09.66.01D; and
- a sample version of all material and communication the applicant plans to distribute to potential enrollees, including brochures, fact sheets, and posters.

The regulations specify additional application requirements for management information system and data reporting, including a description of the procedures for verifying the accuracy and timeliness of reported data.

**Conditions for MCO Participation**

Within 30 days before the intended effective date of a significant change in the nature or location of services provided, an MCO must provide enrollees with written notice of the change. All MCO publications, including provider directories, enrollee handbooks, and health education materials, must comply with COMAR 10.09.66.01A in order to address the individualized needs of enrollees, for example, individuals who do not speak English or who are hearing impaired.

**Special Needs Populations**

For enrollees in special populations, an MCO must:

- update the plan of care and treatment modalities at least annually, when an enrollee’s circumstances or needs change significantly, or at the enrollee’s request;
- be familiar with community and social support providers for special populations; and
- include email and text messaging as part of documented efforts to contact enrollees who fail to keep appointments or are noncompliant with a regimen of care.
Data Collection and Reporting

To report encounter data, an MCO may use alternative formats, including (1) ASC X12N837 and NCPDP formats and (2) ASC X12N835 format, as appropriate. An MCO must submit encounter data that identifies a provider who delivers any items or services to enrollees at a frequency and level of detail specified by the Centers for Medicare and Medicaid Services (CMS) and the department.

The regulations require an MCO to include additional information in the quarterly reports that are submitted to the department. No later than 45 days after the end of each quarterly rebate period, the MCO must report drug utilization data necessary for the department to bill manufacturers for rebates specified under the Social Security Act; the data must include, at a minimum, the following information by National Drug Code of each covered outpatient drug dispensed or covered by the MCO: (1) total number of units of each dosage form; (2) total number of units of each dosage strength; and (3) total number of units of each dosage package size. In addition, the data must distinguish utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program.

Subcontractual Relationships

The regulations clarify the content of a written agreement between an MCO and a subcontractor. The written agreement must include a provision:

- that the subcontractor complies with all State and federal requirements regarding audit, inspection, and evaluation;

- for a revocation of the delegation of activities or obligation, or specifying other remedies in instances when the department or an MCO determines that a subcontractor has not performed satisfactorily;

- stating that an MCO has the right to audit a subcontractor for a specified period of time; and

- that all providers and subcontractors are subject to a grievance and appeal system consistent with the requirements of COMAR 10.09.71.

When an MCO and a provider terminate their contract, current regulations require the MCO to provide the department with a written notice concerning the termination. In cases where the provider is terminating the contract, the regulations increase, from 10 to 15 days after the MCO receives notice from the provider, the amount of time to notify the department of the termination of the contract.

When an MCO terminates a subcontract impacting its operations, covered services, or enrollees, the MCO must provide the department with written notice regarding the termination that describes:
• the dollar amount of the subcontract;
• the effect of the termination on MCO operations;
• the effect of the termination on MCO covered services or enrollees; and
• the MCO’s plan to replace the subcontractor, if applicable.

If the termination of the subcontract impacts MCO operations, the notice to the department must be provided at least 90 days before the effective date of the termination.

**Payment for Hospital Services**

The regulations alter current regulations for MCO reimbursement of hospital providers. An MCO must reimburse Maryland hospital providers on the basis of rates approved by the Maryland Health Services Cost Review Commission (HSCRC). An MCO must reimburse hospital administrative days at the Medicaid fee–for–service rate. On the direction of the department, an MCO must reduce payments by 20 percent to a hospital located in a contiguous state or in the District of Columbia for services rendered to its enrollees, if the hospital has failed to supply appropriate discharge data to the HSCRC.

**Access Standards: Addressing Enrollees’ Individualized Needs**

An MCO must notify enrollees of the following services and make them available free of charge to the enrollee:

• written material in the prevalent non–English languages identified by the State;
• written materials in alternative formats;
• oral interpretation services in all non–English languages; and
• auxiliary aids and services, including Teletypewriter/Telecommunication Device for the Deaf and American Sign Language.

An MCO must include specified taglines with its written materials, including the availability of written translation or oral interpretation to understand the information provided. The written materials must be provided using language and a format that is easily understood in a specified font, in alternative formats, through the provision of auxiliary aids and services, and in a manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency. An MCO may provide enrollee information electronically, provided that specified requirements are met.

**Access Standards: Enrollee Handbook and Provider Directory**
The current regulations specify the information and education that an MCO must provide to enrollees. The regulations establish additional requirements for the information to be provided, including:

- definitions of managed care terminology in accordance with specified federal regulations;
- what constitutes an emergency medical condition and emergency services and that prior authorization is not required for these services, and the enrollee has a right to use any hospital or other setting for emergency care;
- the amount, duration, and scope of benefits available in sufficient detail to ensure that enrollees understand the benefits to which they are entitled;
- how enrollees may obtain benefits from out-of-network providers;
- requirements for service authorizations or referrals for specialty care and other benefits not furnished by the enrollee’s primary care provider; and
- how to report suspected fraud or abuse.

An MCO must:

- update its online provider directory no later than 30 days after the MCO receives updated provider information;
- update its paper directory on a monthly basis; and
- make provider directories available on its website in a specified machine-readable file and format.

**Benefits**

**Required Benefits Package**

The regulations require an MCO to ensure that the services provided are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished. An MCO may place appropriate limits on a service on the basis of criteria applied under the State plan, for example, medical necessity. An MCO may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of a diagnosis, type of illness, or condition of an enrollee.

**Pharmacy Services**

An MCO must provide outpatient drugs as defined under the Social Security Act. The regulations require that a drug formulary established and maintained by an MCO include at a
minimum covered generic and name brand medications and the tier each medication is on. In addition, an MCO must establish procedures to distinguish drug utilization data for covered outpatient drugs that are subject to discounts and provide the department with a detailed description of its drug utilization review program activities on an annual basis.

**Family Planning Services**

Current regulations require an MCO to provide its enrollees comprehensive family planning services. The regulations authorize an MCO to place appropriate limits on these services for the purpose of utilization control, if the services are provided in a manner that protects and enables the enrollee’s freedom to choose the method of family planning to be used consistent with federal regulations. The regulations prohibit an MCO from applying a copayment or coinsurance requirement for contraceptive drugs or devices. With a specified exception, an MCO must provide coverage for a single dispensing of a supply of prescription contraceptives for a 6–month period.

**Program Integrity**

**Requirements to Detect and Prevent Fraud, Waste, and Abuse**

The regulations establish additional requirements to detect and prevent fraud, waste, and abuse. An MCO or its responsible subcontractor must implement and maintain procedures that are designed to detect and prevent fraud, waste, and abuse that include a compliance program that, at a minimum, includes specified elements. The elements include:

- written policies, procedures, and standards of conduct that include the MCO’s commitment to comply with the applicable requirements and standards under the contract and specified federal and State requirements;
- the designation of a compliance officer and specified staff members, including an investigator, auditor, and analyst;
- staffing and resources located in Maryland to identify and investigate potential fraud, waste, and abuse based on a criteria determined by the department;
- the establishment of a regulatory compliance committee;
- a training and education system for the compliance officer, senior management, and employees regarding the federal and State standards and requirements under the contract; and
- enforcement of standards through well-publicized disciplinary guidelines.

An MCO must ensure that a subcontractor is legally qualified to furnish the services provided for in the subcontract. The regulations prohibit an MCO from contracting with the State unless conflict of interest safeguards at least equal to specified federal safeguards are in place. The
regulations prohibit an MCO from knowingly having a relationship with specified individuals or entities, including an individual or an entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under federal acquisition regulations or participating in non-procurement activities under specified executive orders. An MCO must terminate a contract or refrain from contracting with providers who have been terminated or excluded from participation in the program.

An MCO must have a mechanism for a network provider to report to the MCO when it has received an overpayment and take specified steps to return the overpayment. Overpayments recovered by an MCO may be retained by the MCO, as long as the overpayment is reported to the department. If the department, federal government, or its agents identify potential fraud, waste, or abuse that resulted in the recovery of funds paid to an MCO provider, and the MCO did not previously identify and report the provider for potential overpayments, the State has the right to recover from the MCO the entire amount of the overpayment. The MCO has the right to appeal the department’s recovery of an overpayment.

Access to Information

The regulations require an MCO, its subcontractors, and its subcontractor’s subcontractors to permit specified organizations or their designees to inspect, evaluate, or audit books, records, contracts, computer or other electronic systems, premises, and facilities that relate to the MCO’s Medicaid enrollees, any aspect of services and activities performed, or determination of amounts payable, under the MCO’s contract with the department, including:

- the department and its agents;
- the Medicaid Fraud Control Unit of the Office of the Attorney General
- the Insurance Fraud Division of the Maryland Insurance Administration;
- CMS;
- the Inspector General of the Department of Health and Human Services;
- the Comptroller General; and
- other authorized State or federal agencies.

The right to inspect, audit, and evaluate exists for 10 years from the final date of the contract period or from the completion of any audit, whichever is later. However, if the department, CMS, or the Inspector General determines there is reasonable likelihood of fraud or similar risk, these agencies may inspect, audit, and evaluate at any time.

Reporting
The regulations require an MCO to submit to the department various data, documentation, and reports, including:

- encounter data in a specified form and manner;
- data required by the department in order to certify the actuarial soundness of capitation rates to an MCO;
- data required by the department to determine MCO compliance with a specified medical loss ratio; and
- data required by the department and the Maryland Insurance Administration to determine that an MCO has made adequate provision against the risk of insolvency.

An MCO must report to the department any identified inaccuracies in the encounter data reported by the MCO or its subcontractors within 30 days of the date discovered regardless of the effect the inaccuracy has on MCO reimbursement. An MCO must report potential fraud, waste, abuse or information it has received from whistleblowers concerning the integrity of the MCO, its network providers, or its subcontractors to the department’s Office of Inspector General, and the Medicaid Fraud Control Unit. The regulations specify the content of the required reports, including the number of complaints, the source of the complaint, the nature of the complaint, the approximate dollar amount involved, and the legal and administrative disposition of the case. The MCO must also provide the department written disclosures of specified information on ownership and control required under federal regulations.

An MCO must also report to the department:

- all overpayments identified and recovered, specifying the overpayments due to fraud;
- third party liability collection activities; and
- the amounts the MCO has cost–avoided and the number of third–party liability cases the MCO has handled.

An MCO must notify the department promptly when it:

- has knowledge of an enrollee’s change of residence or death; and
- receives information about a change in a network provider’s circumstance that may affect the provider’s eligibility to participate in the program, including the termination of the provider agreement with the MCO.

An MCO’s chief executive officer, chief financial officer, or directly–reporting authorized employee must certify to the best of the individual’s information, knowledge, and belief, that any
records, data, or other documents requested under the regulations are accurate, complete, and truthful.

**MCO Dispute Resolution Procedures**

**Internal Complaint Process for Enrollees**

Existing regulations require an MCO to have written complaint procedures for an enrollee who is dissatisfied with the MCO or its network providers, or decisions made by the MCO or a provider, to seek recourse verbally or in writing within the MCO. The regulations clarify that this recourse may occur at any time. An MCO must:

- give enrollees reasonable assistance in completing forms and taking other procedural steps concerning a grievance or an appeal in a specified manner;

- maintain an accurate and accessible record of grievances and appeals for monitoring by the State and CMS; and

- provide in its written procedures that an enrollee may file appeals and grievances orally or in writing.

The regulations make changes to existing regulations relating to the MCO internal complaint process relating to decision makers. An MCO must ensure that decision makers on appeals and grievances:

- were not involved in previous levels of decision-making;

- are not subordinates of people involved in previous levels of decision-making;

- are health care professionals with clinical expertise in treating the enrollee’s conditions or disease under specified circumstances; and

- take into account all comments, documents, records, and other information submitted by the enrollee or the enrollee’s representative, regardless of whether the information was submitted or considered in the initial action.

**Actions and Decisions**

The regulations add conditions for the provision of certain services to enrollees that require preauthorization. For standard authorization decisions, an MCO make a determination within two business days of receipt of necessary clinical information but not later than 14 calendar days from the date of the initial request so as to not adversely affect the health of the enrollee. For expedited authorization decisions, the MCO must make a determination and provide notice no later than 72 hours after the receipt of the request for service, if the provider indicates or the MCO determines that the standard timeframe could jeopardize the enrollee’s life, health, or ability to
attain, maintain, or regain maximum function. For covered outpatient drug authorization decisions, the MCO must provide notice by telephone or other telecommunication device within 24 hours of a preauthorization request in accordance with the Social Security Act. An MCO must ensure that compensation to individuals or entities that conduct utilization management activities is not structured to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

The regulations also establish timeframes for standard and expedited authorization decisions and the extension of these timeframes under certain circumstances. The regulations require a notice of adverse action to contain specified information, including:

- the action the MCO has made or intends to make;
- the reasons for the action, including the right for the enrollee to be provided on request and free of charge reasonable access to and copies of documents and other information relevant to the MCO’s action, including medical necessity criteria;
- the enrollee’s right to request an appeal of the action;
- the procedures for exercising the rights of the enrollee;
- the enrollee’s right to have benefits continue pending resolution of the appeal;
- how to request that benefits be continued; and
- the circumstances under which the enrollee may be required to pay the costs of the services.

**Appeal Process for Enrollees**

The regulations require that an MCO’s appeal process allow an enrollee to request an appeal either orally or in writing. The process must provide that oral requests for appeal are considered the initiation of the appeal to establish the earliest possible filing date, and are confirmed in writing, unless the enrollee, the enrollee’s representative, or the provider requests an expedited appeal. The process must:

- allow the enrollee and the enrollee’s representative the opportunity to examine the enrollee’s case file, free of charge, at least five business days after the enrollee files the appeal; and
- ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee’s appeal.

The regulations establish a process for expedited appeals. An MCO may approve an expedited resolution when the MCO determines or the provider indicates that taking the time for a standard resolution could seriously jeopardize the enrollee’s life, physical or mental health, or
ability to attain, maintain, or regain maximum function. An expedited appeal must be resolved within 72 hours after the MCO receives the appeal. If the MCO denies a request for expedited resolution of an appeal, the MCO must:

- transfer the appeal to the standard time frame of no longer than 30 days from the day the MCO receives the appeal, with a possible 14 day extension; and
- make reasonable efforts to give the enrollee prompt verbal notice of the denial and provide a written notice within two calendar days.

**Departmental Dispute Resolution Procedures**

For appeals or grievances received from the department, an MCO must provide the department with ongoing updates in a timeframe specified by the department, based on the urgency of the appeal or grievance. The regulations add overpayments recovered by the department to a department decision that is appealable by the MCO or MCO applicant.

**Legal Issues**

The regulations present no legal issues of concern.

**Statutory Authority and Legislative Intent**


Section 2–104 authorizes the Secretary of Health to adopt regulations to carry out the provisions of law that are within the jurisdiction of the Secretary.

Title 15, Subtitle 1 establishes the Maryland Medical Assistance Program and its various components. Section 15–101 defines terms for the medical and pharmacy assistance programs in the State. Subject to the limitations of the State budget, § 15–102 requires the department to provide preventive and home care services for indigent and medically indigent individuals. Subject to the limitations of the State budget, § 15–102.1(b)(10) requires the department to encourage the Maryland Medical Assistance Program and the State’s health care regulatory system to work to cooperatively promote the development of an appropriate mix of health care providers, limit cost increases for the delivery of health care to program recipients, and ensure the delivery of quality health care to program recipients. Section 15–103 requires the Secretary to administer the Maryland Medical Assistance Program. As permitted by federal law or waiver, § 15–103(b) authorizes the Secretary to establish a program under which program recipients are required to enroll in managed care organizations. Section 15–103(b)(9)(i)4 requires each managed care organization to have in effect an enrollee grievance system, including an enrollee hotline. Section 15–103(b)(16) requires each managed care organization to develop, in coordination with
participating dentists, enrollees, and families of enrollees, a process to arrange to provide dental therapeutic treatment to individuals under 21 years of age.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

**Fiscal Analysis**

There is no fiscal impact on State or local agencies.

**Agency Estimate of Projected Fiscal Impact**

The regulations comply with federal regulations relating to MCO requirements and oversight. The department advises that the regulations are projected to be cost neutral on MCOs and, thus, have no impact on State or local governments. The Department of Legislative Services concurs.

**Impact on Budget**

There is no impact on the State operating or capital budget.

**Agency Estimate of Projected Small Business Impact**

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

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