

Calendar Year 2026
HealthChoice Managed Care Organization Agreement

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HEALTHCHOICE MANAGED CARE ORGANIZATION AGREEMENT

THIS AGREEMENT (Agreement), effective January 1, 2026, is entered into by and between the Maryland Department of Health (MDH) and _____(MCO), a Managed Care Organization with authority to conduct business in the State of Maryland (State).

WHEREAS, MDH has established the Maryland Medicaid Managed Care Program, also known as the Maryland HealthChoice Program (HealthChoice), a waiver program approved by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (DHHS) under §1115 of the Social Security Act and authorized under Maryland Annotated Code, Health-General Article, §§15-101 et seq.

WHEREAS, MDH desires to provide health care services to Medicaid recipients through the MCO.

WHEREAS, the MCO is engaged in the business of arranging and/or providing health care services.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the parties hereto agree as follows:

I. DEFINITIONS AND ACRONYMS

A. For the purposes of this agreement, the following terms have the meaning stated:

1. “Administrative Services Organization” means an organization that manages designated administrative functions while the entity contracting the organization retains the risks and liabilities.
2. “AHEAD” means States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model, a state total cost of care model to drive state and regional health care transformation and multi-payer alignment to improve the total health of a state population and lower costs across all payers.
3. “Biomarker Companion Diagnostic Test” means a test used to determine if a specific medication/therapy will be more effective in treatment, thereby guiding clinical management.
4. "CenteringPregnancy services" means group prenatal care provided by a practice approved, or in the process of obtaining approval, by the Centering Institute.
5. “Collaborative Care Model” means an evidence-based approach for integrating physical and behavioral health services in primary care settings that includes care coordination and management; regular systematic monitoring and treatment using a validated clinical rating

scale; and regular, systematic psychiatric caseload reviews and consultation for patients who do not show clinical improvement.

6. “CRISP” means the designated regional health information exchange that serves Maryland and the District of Columbia.
7. “Direct and indirect remuneration fees” in PBM contracts may include but are not limited to:
 - a. Any pay-to-play for network participation;
 - b. Any fees for periodic reimbursement reconciliations to provide a true-up between a target reimbursement rate in a participating pharmacy agreement and the aggregated effective rate actually realized by a pharmacy or between the aggregate maximum allowable cost (MAC) or adjudicated rate and the aggregate contracted rate; or
 - c. Any payment mechanism to pharmacies for the fulfillment of quality measures or fee assessed to pharmacies for noncompliance with quality measures.
8. “Dual Eligible Special Needs Plan” means a Medicare Advantage health plan offering broader Medicare coverage and benefits to individuals who are dually eligible for Medicare and Medicaid benefits.
9. “Encounter Data” means information documenting a service to an Enrollee.
10. “Enrollee” means a Medicaid recipient who is enrolled in a managed care organization.
11. “Extraordinary Personal Event” means an event that includes any of the following:
 - a. Leave under the Family Medical Leave Act;
 - b. An Incapacitating injury or Incapacitating illness; or
 - c. Other circumstances that in the sole discretion of MDH warrant an extended leave of absence, such as extended jury duty or extended military service that precludes the individual from performing their job duties under the Agreement.
12. “Family Medical Leave Act” means a law that allows eligible employees of covered employers to take unpaid, job-protected leave for specified family and medical reasons with continuation of group health insurance coverage under the same terms and conditions as if the employee had not taken leave.

13. “HealthySteps services” means enhanced pediatric primary care provided by a practice approved, or in the process of obtaining approval, by Zero to Three.
14. “Incapacitating” means any health circumstance that substantially impairs the ability of an individual to perform the job duties described for that individual’s position in the MCO.
15. “Integrated Maternal Health Services initiative” is a grant-funded initiative awarded by the Health Resources and Services Administration that aims to improve rates at which high-risk pregnant and postpartum people are connected to needed services in their communities and to understand the impact of improved use of an integrated system on completed referrals and maternal health outcomes, including maternal mortality in Maryland.
16. “Key Personnel” means all MCO personnel identified in the Agreement as such that are essential to the work being performed under the Agreement.
17. “Maryland Prenatal Risk Assessment” means a form that collects health and other risk information about Medicaid members during their first prenatal care visit. The form’s information is then used to refer pregnant members to services to improve the pregnant person and infant’s health outcomes.
18. “MDH” means the Maryland Department of Health, as defined in COMAR 10.09.36.01, or its authorized agents acting on behalf of MDH.
19. “Medically necessary services” means that the service or benefit is:
 - a. Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
 - b. Consistent with current accepted standards of good medical practice;
 - c. The most cost-efficient service that can be provided without sacrificing effectiveness or access to care; and
 - d. Not primarily for the convenience of the consumer, the consumer's family, or the provider.
20. “Medical loss ratio” means a formula that measures the ratio of MCO spending on medical and related benefits compared to revenue, to ensure that MCOs are spending a sufficient amount of their premium revenue on medical expenses and other high-impact initiatives.

21. “MLR reporting year” means a period of 12 months consistent with the rating period selected by MDH.
22. “Network provider” means a provider that is a member of the MCO’s provider panel. A network provider is not a subcontractor on the sole basis of its network provider agreement with the MCO.
23. “Pharmacy benefit manager” or “PBM” means a third-party administrator of a prescription drug program for an MCO, including but not limited to network management, drug utilization review, outcome management, and disease management.
24. “Potential enrollee” means a recipient who is authorized by MDH to enroll in a managed care organization.
25. “Practice guidelines” means statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.
26. “Program” means the Medical Assistance Program.
27. “Recipient” means an individual who receives benefits under the State Medical Assistance Program.
28. “Reentry Demonstration” means services authorized under the Section 1115 waiver targeting adults involved in the criminal justice system, which includes coordination of care after release.
29. “Self-referral services” are the health care services listed in COMAR 10.67.06.28 for which, under specified circumstances, the MCO is required to pay, without any requirement of referral by the PCP or MCO, when the enrollee accesses the service through a provider other than the enrollee's PCP.
30. “Spread pricing” means a form of reimbursement in which the pharmacy benefits manager (PBM) retains the difference between the amount the MCO pays the PBM and the amount the PBM reimburses the pharmacy for a drug and its associated costs. Spread pricing does not include the MCO paying the PBM reasonable administrative and transactional costs for services.
31. “Sudden Vacancy” means an Extraordinary Personal Event, death, resignation, or termination.
32. “State” means the State of Maryland.
33. “State Plan” means an agreement between the State and the Federal government describing how the State administers its Medicaid and CHIP programs. The State Plan includes the groups of individuals to

be covered, services to be provided, methodologies for providers to be reimbursed, and the administrative activities underway in the State.

34. “Subcontractor” means an individual or entity that has a contract with an MCO that relates directly or indirectly to the performance of the MCO’s obligations under this contract. A network provider agreement with an MCO does not by itself make the network provider a “subcontractor” to an MCO.
35. “Third party liability” means the legal obligation of third parties (for example, certain individuals, entities, insurers, or programs) to pay part or all the expenditures for medical assistance furnished under a Medicaid state plan. By law, all other available third-party resources must meet their legal obligation to pay claims before the Medicaid program pays for the care of an individual eligible for Medicaid.

B. For the purposes of this agreement, the following terms will be addressed using the stated acronym:

1. ACA – Affordable Care Act
2. AHEAD – Advancing All-Payer Health Equity Approaches and Development
3. ASO – Administrative Services Organization
4. BIN – Bank Identification Number
5. CEO – Chief Executive Officer
6. CFO – Chief Financial Officer
7. CIO – Chief Information Officer
8. CMO – Chief Medical Officer
9. CMS – Centers for Medicare and Medicaid Services
10. CoCM – Collaborative Care Model
11. COMAR – Code of Maryland Regulations
12. COO – Chief Operating Officer
13. CQO – Chief Quality Officer
14. CRISP – Chesapeake Regional Information System for our Patients
15. DHHS – U.S. Department of Health and Human Services
16. DPP – Diabetes Prevention Program

17. D-SNP – Dual Eligible Special Needs Plan
18. EMS – Emergency Medical Services
19. EPLS – Excluded Parties List System
20. E&M – Evaluation and Management
21. ePREP – Electronic Provider Revalidation and Enrollment Portal
22. FFS – Fee-for-Service
23. FMLA – Family Medical Leave Act
24. FQHC – Federally Qualified Health Center
25. HEDIS – Healthcare Effectiveness Data and Information Set
26. HSCRC – Health Services Cost Review Commission
27. IMHS – Integrated Maternal Health Services
28. IRO – Independent Review Organization
29. LEIE – List of Excluded Individuals/Entities
30. MCO – Managed Care Organization
31. MHBE – Maryland Health Benefit Exchange
32. MLR – Medical Loss Ratio
33. MPRA – Maryland Prenatal Risk Assessment
34. M-QIP – Maryland Quality Incentive Program
35. NCQA – National Committee for Quality Assurance
36. NDC – National Drug Code
37. NPES – National Plan and Provider Enumeration System
38. OIGH – Office of the Inspector General for Health
39. PBM – Pharmacy Benefit Manager
40. PCN – Processor Control Number
41. PHIP – Population Health Incentive Program
42. SSA-DMF – Social Security Administration Death Master File
43. TPL – Third Party Liability

- 44. TTY/TDD – Teletypewriter/Telecommunication Device for the Deaf
- 45. URAC – Utilization Review Accreditation Commission

II. THE MCO AGREES:

A. General Requirements

- 1. To comply with Maryland Annotated Code Health-General Article, Title 15 and the Insurance Article provisions referenced therein, the regulations of the HealthChoice Program (see Appendix T), several of which are specifically referenced herein, as well as 42 CFR Part 438, any other applicable provisions of federal law, the Maryland Code, COMAR, transmittals, and guidelines issued by MDH in effect at any time during the term of this Agreement.
- 2. Notwithstanding any other provision of this Agreement, to be subject to any change in Federal or State law or regulation, or other policy guidance from CMS or MDH that applies during the term of this Agreement. The MCO retains all rights available to challenge the authority or basis for any such changes.
- 3. To comply with the federal law provisions pertaining to Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972 (regarding education programs and activities), The Age Discrimination Act of 1975, the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990 as amended, and section 1557 of the Patient Protection and Affordable Care Act, as well as the conflict of interest safeguards described in 42 CFR 438.58 and the prohibitions described in section 1902(a)(4)(C) of the Social Security Act applicable to contracting officers, employees, or independent contractors.
- 4. To comply with the requirements of section 5006 of the American Recovery and Reinvestment Act and all applicable federal guidance regarding the rights of Indian Enrollees.
- 5. To comply with the MCO's continuity of operations plan and disaster recovery plan, along with any directives from the State or MDH, in the event of a state of emergency (or other catastrophic event).
 - a. This requirement includes keeping up to date the continuity of operations plan and disaster recovery plan, providing the plans to MDH upon request, and ensuring subcontractors maintain and deploy routinely updated continuity of operations plans and disaster recovery plans when necessary.
 - b. This requirement also includes following directives from the State or MDH for flexibilities, waivers, and other temporary changes

related to service delivery, benefits, and operations impacted by a state of emergency.

6. To execute the most recent State Providers' Amendment to HealthChoice Provider Service Agreements whenever the MCO executes or amends a HealthChoice Provider Service Agreement with a local health department.
7. To comply with the provisions of this Agreement and all appendices contained therein.
8. To execute the Non-Exchange Entity Agreement with the Maryland Health Benefit Exchange (MHBE) and ensure the confidentiality, privacy and security of data accessed by the MCO or exchanged between the MCO and MHBE and compliance with the requirements of the ACA, including 45 CFR 155.260(b)(2) and 45 CFR 155.270(a).
9. To participate in federal grants awarded to MDH and federal grant application processes.
10. To comply with processes and requirements associated with, and/or contained within, the Medicaid provisions in H.R. 1 (2025), as applicable during the Agreement term, including subsequent federal and state sub-regulatory guidance.

B. Enrollment & Disenrollment

1. To accept enrollments of recipients authorized to enroll into an MCO by MDH and process enrollments in accordance with 42 CFR 438.54 and COMAR 10.67.02.02 (Appendix T).
2. To accept enrollment of recipients who are pregnant and postpartum but would otherwise not be eligible for services due to their immigration status, as required by the Healthy Babies Equity Act (Md. Code Ann. Health-General Art. 15-103(a)(3)(xviii)).
3. To request disenrollment only for the reasons set forth in COMAR 10.67.02.06D (Appendix T) and 42 CFR 438.56.
4. To comply with MDH's disenrollment policies and procedures, which are set forth in COMAR 10.67.02.05, 10.67.02.06, and 10.09.69.04 (Appendix T).
5. To submit to MDH, within thirty (30) days of the date the MCO receives information regarding Enrollees, the Medical Assistance Number of the Enrollees, along with the following pertinent information, for any Enrollees who are known to the MCO to have:
 - a. Disenrolled from the HealthChoice Program;

- b. Relocated to a geographic area not serviced by the MCO;
 - c. Become ineligible to receive HealthChoice Program services from the MCO;
 - d. Enrolled in another State Medicaid Program or a Qualified Health Plan;
 - e. Been assigned multiple Medical Assistance Numbers in the State's Medicaid Program; or
 - f. Died.
- 6. To submit any additional information MDH requests about the Enrollees referenced in II.B.4 of this Agreement.
 - 7. To process Enrollee updates provided by MDH in a timely manner, including but not limited to Enrollee demographic updates and Enrollee primary care provider selections.

C. Enrollee Rights

- 1. To permit each Enrollee to choose his or her network provider to the extent possible and appropriate, as set forth in COMAR 10.67.05.05 (Appendix T).
- 2. To provide practice guidelines to Enrollees and potential Enrollees upon request.
- 3. To accord Enrollees all the rights available to them under 42 CFR 438.100; to require their network providers to also respect those rights; and to develop written policies governing the protection of those rights.
- 4. To refrain from discriminating against or using any policy or practice that has the effect of discriminating against Enrollees based on age, sex, gender identity, race, creed, color, marital status, sexual orientation, national origin, physical or mental handicap, health status, or need for health services.
- 5. Not to prohibit or otherwise restrict the advice that a health care professional, with a contractual, referral, or other arrangement with the MCO, gives to an Enrollee who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under this Agreement, if the professional is acting within the lawful scope of practice.

6. To comply with the requirements governing Enrollee appeals and grievances set forth in COMAR 10.67.09 (Appendix T) and 42 CFR 438, subpart F.
 - a. To send written acknowledgment of Enrollee grievances within five (5) days of receipt of the grievance, if the grievance has not been resolved within five (5) days of receipt.
7. To provide the MCO enrollee services phone number on the identification card required in COMAR 10.67.04.02E(3) (Appendix T).
8. To have in place mechanisms to help Enrollees understand the requirements and benefits of the MCO, in accordance with 42 CFR 438.10 and COMAR 10.67.05.01 (Appendix T).

D. Covered Services

1. To cover, for Enrollees:
 - a. In accordance with COMAR 10.67.06 and as defined in COMAR 10.67.01.01B (Appendix T), medically necessary covered services under the Maryland Medicaid State Plan (State Plan) in the amount, duration and scope set forth in the State Plan and in accordance with 42 CFR 438.210 and 42 CFR 440.230.
 - b. Any services or settings that the MCO voluntarily agrees to provide and are identified in Appendix E, the cost of which cannot be included when determining the payment rates under this Agreement.
 - c. Any services necessary for compliance by the MCO with the requirements of subpart K of 42 CFR Part 438, to the extent such services are necessary for the MCO to comply with 42 CFR 438.910.
 - d. CenteringPregnancy services for pregnant and postpartum individuals as part of MCO-covered pregnancy-related benefits.
 - e. HealthySteps services for Enrollees ages 0-3 as part of MCO-covered pediatric benefits.
 - f. Biomarker companion diagnostic tests.
 - g. Sports physicals for Enrollees provided by school-based health centers and other appropriate Network Providers.
 - h. Any services or settings which are in-lieu-of services or settings covered under the State Plan, provided they are approved by MDH and meet the terms outlined in Appendix R of this Agreement.

2. To comply with requirements governing emergency and post-stabilization services under 42 CFR 438.114.
3. To comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions, that are set forth in 42 CFR 434.6(a)(12) and 42 CFR 447.26, and to report all identified provider-preventable conditions in a form or frequency specified by MDH.
4. To cover, when medically necessary, the delivery of anesthesia for the entire duration of a medical procedure, along with medical care related to the delivery of anesthesia for the procedure that is provided immediately before and after the procedure, without establishing, implementing, or enforcing a policy, practice, or procedure that places arbitrary or clinically inappropriate time limitations on the delivery of anesthesia.

E. Quality Improvement

1. To implement an ongoing comprehensive quality assessment and performance improvement program for the services furnished to its Enrollees that includes, but is not limited to:
 - a. Performance improvement projects in accordance with 42 CFR 438.330(d);
 - b. Collection and submission of performance measurement data in accordance with 42 CFR 438.330(c);
 - c. Mechanisms to detect underutilization and overutilization of services; and
 - d. Mechanisms to assess the quality and appropriateness of care furnished to Enrollees with special health care needs.
2. To participate in all quality improvement activities listed in COMAR 10.67.04.03B (Appendix T).
3. To participate in annual validation and evaluation of MCO provider networks.
4. To comply with MDH's Network Adequacy Standards and cooperate with all activities led by MDH or the external quality review organization (EQRO) to validate compliance with the Network Adequacy Standards (Appendix F).
5. To maintain NCQA Health Plan Accreditation and NCQA Health Equity Accreditation, as set forth in 42 CFR §438.332(b) and COMAR 10.67.03.08 (Appendix T).

6. To provide MDH a copy of its most recent accreditation results when available in accordance with COMAR 10.67.04.03D (Appendix T), including:
 - a. Accreditation status, survey type, and level;
 - b. Accreditation results, including:
 - i. Recommended actions or improvements,
 - ii. Corrective action plans, and
 - iii. Summaries of findings; and
 - c. Expiration date of accreditation.
7. To cooperate with any corrective actions and intermediate sanctions arising from MDH's Performance Monitoring Policies (Appendix D).
8. To acknowledge that suspension or termination of NCQA accreditation may result in the imposition of corrective actions and sanctions in accordance with COMAR 10.67.10 (Appendix T), including, but not limited to, suspension of further enrollment or termination of this Agreement.

F. Service Authorization and Utilization Management

1. To place appropriate limits on services for utilization control, provided that:
 - a. The services furnished can reasonably achieve the purpose for which the services are provided;
 - b. The services supporting individuals with ongoing or chronic conditions are authorized in a manner that reflects the Enrollee's ongoing need for such services and supports; and
 - c. Family planning services are provided in a manner that protects and enables the Enrollee's freedom to choose the method of family planning to be used.
2. To adopt, apply, review, and update any practice guidelines in accordance with the requirements of COMAR 10.67.03.09L (Appendix T) and 42 CFR 438.236, and to disseminate practice guidelines to all affected providers.
3. To have in place, and follow (along with its contractors), written policies and procedures for the processing of requests for initial and continuing authorizations of services and have mechanisms to ensure consistent application of review criteria for authorization decisions, including consultations with specialists, as appropriate.

4. To adhere to the requirements for service authorization and notification set forth in 42 CFR 438.210(d) and COMAR 10.67.09.04 (Appendix T).
 - a. For standard authorization decisions, to make a determination within two (2) business days of receipt of necessary clinical information, but not later than seven (7) calendar days from the date of the initial request so as not to adversely affect the health of the enrollee, in accordance with 42 CFR 438.210(d)(1)(i)(B).
5. To implement the following provisions for physician incentive plans in accordance with 42 CFR 438.3(i) and 422.208, and provide the contracts and supporting documentation upon request:
 - a. Have a defined performance period that can be tied to applicable MLR reporting periods;
 - b. Be signed and dated by all appropriate parties before the commencement of the applicable performance period(s);
 - c. Include clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that the Provider must meet to receive the incentive payment;
 - d. Specify a dollar amount or a percentage of a verifiable dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a date of payment; and
 - e. Not to make payment directly or indirectly under a physician incentive plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an individual Enrollee.
6. To comply with the provisions of COMAR 10.67.06.26-03 (Appendix T) and Maryland Annotated Code, Health-General Article, §15-151 for benefit coverage, service delivery, and prior authorization.
7. To execute an agreement with MDH's Independent Review Organization vendor and comply with the standards set forth in COMAR 10.67.13 (Appendix T).

G. Coordination of Care

1. To coordinate care and deliver quality health care to the MCO's Enrollees by providing all necessary information to the Medicaid Program, its authorized agents, the Administrative Services Organizations with which MDH contracts and to any other entity as

directed by MDH, in accordance with applicable federal and state confidentiality laws and regulations.

2. For Enrollees with behavioral health conditions, coordination of care should include but not be limited to:
 - a. Participation in monthly collective MCO medical directors' meetings and one-on-one MCO meetings with the ASO for care coordination,
 - b. Cooperation with MDH's high utilizer pilot program,
 - c. Assistance with the development and coordination of appropriate treatment plans for Enrollees,
 - d. Provider education and promotion for the Screening, Brief Intervention, and Referral to Treatment (SBIRT) process,
 - e. Provider education about the substance use release of information (ROI) process under 42 CFR, Part 2, and
 - f. Provider education for Enrollee identification and referrals to the ASO or core service agencies for behavioral health services,
3. To implement procedures to deliver care to and coordinate services for all Enrollees. These procedures must do the following:
 - a. Ensure that each Enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the Enrollee (e.g., a primary care provider);
 - b. Provide the Enrollee with information on how to contact their designated person or entity;
 - c. Coordinate the services the MCO furnishes to the Enrollee:
 - i. Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;
 - ii. With the services the Enrollee receives from any other MCO;
 - iii. With the services the Enrollee receives in FFS Medicaid; and
 - iv. With the services the Enrollee receives from community and social support providers.

- d. Make a best effort to conduct an initial screening of each Enrollee's needs, within 90 days of the effective date of enrollment for all new Enrollees, including subsequent attempts if the initial attempt to contact the Enrollee is unsuccessful;
 - e. Share with MDH or other MCOs serving the Enrollee the results of any identification and assessment of that Enrollee's needs to prevent duplication of services or benefits;
 - f. Use CRISP to identify new Enrollees and their potential risk categories and to coordinate with other MCOs as appropriate for transition of care activities;
 - g. Ensure that each provider furnishing services to Enrollees maintains and shares, as appropriate, an Enrollee health record in accordance with professional standards; and
 - h. Ensure that in the process of coordinating care, each Enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.
- 4. To complete the MDH-approved standard screening tool as part of a coordinated non-medical drivers of health assessment and referral strategy with Enrollees on a routine basis to assess needs that may impact the Enrollee's health outcomes and participate in data exchanges related to the screening tool with CRISP.
 - 5. To collaborate with MDH to coordinate care for participants who have been recently released from a correctional facility.
 - a. This collaboration includes justice-involved youth as required under the Consolidated Appropriations Act (CAA) Section 5121.
 - b. This collaboration also includes justice-involved adults released from a state-run correctional facility in accordance with the Reentry Demonstration.
 - 6. To agree to coordinate with MDH and the Department of Human Services to ensure children entering state-supervised care receive an initial health screening from an EPSDT-certified provider within five days of entry, in accordance with COMAR 10.67.04.13F (Appendix T).
 - 7. To continue to collaborate with the Department to report on activities related to the Integrated Maternal Health Services (IMHS) initiative, including efforts to improve completion of the digital and paper Maryland Prenatal Risk Assessment (MPRA), in accordance with Appendix R.

H. Information Requirements

1. To comply with all marketing requirements under 42 CFR 438.104 and COMAR 10.67.04.23 (Appendix T).
2. To comply with the rules, language, and format standards for Enrollee information set forth in 42 CFR 438.10(c) and (d) and COMAR 10.67.05.01 (Appendix T).
3. To provide Enrollees with an Enrollee handbook using the model template developed by MDH, and ensure it contains the minimum requirements outlined in 42 CFR 438.10(g)(2) and COMAR 10.67.05.02 (Appendix T).
4. To provide Enrollees with a network provider directory and ensure it contains the minimum information about physicians (including specialists), hospitals, and pharmacies outlined in 42 CFR 438.10(h)(1) and COMAR 10.67.05.02 (Appendix T).
5. To submit changes to Enrollee handbooks and Enrollee notices to MDH for review and approval prior to use and dissemination.

I. Reporting Requirements

1. To prepare and submit to MDH HealthChoice Financial Monitoring Reports in accordance with the following schedule:
 - a. For services incurred January 1 – December 31 of the prior year, reported through March 31 of the current year, the MCO shall submit its HealthChoice Financial Monitoring report no later than May 15 of the current year.
 - b. For services incurred January 1 – December 31 of the prior year, reported through June 30 of the current year, the MCO shall submit its HealthChoice Financial Monitoring report no later than September 1 of the current year.
2. To submit to MDH the reports described in COMAR 10.67.07.03 (Appendix T).
3. To seek and obtain MDH's approval before making or allowing any material deviations in corporate structure, management, or operations from the MCO application and supporting documentation that was provided and approved pursuant to COMAR 10.67.03 (Appendix T).
4. To maintain a health information system that collects, analyzes, integrates, and reports data, including encounter data and that can achieve the objectives of 42 CFR 438, subpart D; and to comply with the requirements of 42 CFR 438.242(b) and (c) and COMAR 10.67.04.15 (Appendix T).

5. To submit encounter data that identifies the provider who delivers any items or services to enrollees at a frequency and level of detail to be specified by CMS and MDH, including, at a minimum:
 - a. Enrollee and provider identifying information;
 - b. Service, procedure, and diagnoses codes;
 - c. Allowed, paid, enrollee responsibility, and third-party liability amounts; and
 - d. Service, claims submission, adjudication, and payment dates.
6. To identify sub-capitated arrangements and denied claims in the 837 encounter data submissions (refer to the MDH 837 Encounter Companion Guides for the appropriate CN1 segment and data elements).
7. To submit to MDH a list of all State fair hearings held, and decisions rendered during the preceding quarter, within 10 calendar days after the close of each calendar quarter, in the format specified by MDH.
8. To transfer historical utilization data upon request for any members who have disenrolled from the MCO in the timeframe and format specified by MDH.
9. To submit information to MDH for a report that is due to CMS on or before October 1, 2026, and provide other information as needed to ensure ongoing compliance with 42 CFR 438, subpart K (applying parity standards from the Mental Health Parity and Addiction Equity Act), including engaging in the following:
 - a. Purchasing a license for and utilizing the URAC Parity Manager Tool;
 - b. Providing comprehensive responses and completing all requested fields in the URAC Parity Manager Tool and updating information on an annual basis; and
 - c. Responding to all follow-up requests by MDH for additional information; and
 - d. Generating and submitting reports as required by MDH to monitor the impact of non-quantitative limits in operation which may include denial rates, prior authorization rates, utilization trends, and results of interrater reliability surveys.
10. To supply other information requested by MDH, given a reasonable period of notice, for the purposes of Maryland Medicaid Managed Care Program administration or MDH's monitoring of MCO

performance pursuant to 42 CFR 438.66 and COMAR 10.67.04.15 (Appendix T).

11. To report TPL collection activities as described in 10.67.04.18 (Appendix T).
 - a. To abide by the data exchange requirements set forth by MDH by electronically delivering all verified TPL data to MDH using the ANSI HIPAA X12 271 transaction set up to update the Medicaid Management Information System (MMIS).
12. To publish on the MCO website the following data about prior authorization (excluding data on any and all drugs covered by the MCO) by March 31 for the previous calendar year, in accordance with 42 CFR 438.210(f):
 - a. A list of all items and services that require prior authorization.
 - b. The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
 - c. The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
 - d. The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
 - e. The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
 - f. The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
 - g. The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
 - h. The average and median time that elapsed between the submission of a request and a determination by the MCO for standard prior authorizations, aggregated for all items and services.
 - i. The average and median time that elapsed between the submission of a request and a decision by the MCO for expedited prior authorizations, aggregated for all items and services.
13. To provide additional data to MDH, including detailed claims data as well as a year-to-date HFMR for calendar year 2026, to support the mid-year rate reopening activities in Appendix C.

J. Financial Requirements

1. To calculate and report a medical loss ratio for each rating year to MDH in the form and manner specified in 42 CFR 438.8 and §II.K of this Agreement.
2. To accept the capitation rates set forth in Appendix C (Managed Care Organization Service Areas and Reimbursement Rates) as payment for services rendered to Enrollees of the Maryland HealthChoice Program.
3. To participate in the Population Health Incentive Program (PHIP) outlined in Appendix N of this Agreement, the funding level for which is 0.25% of the HealthChoice total capitation for the measurement year.
4. To participate in MDH's stop-loss program in accordance with COMAR 10.67.04.22 (Appendix T) and to accept a stop-loss limit of \$175,000 per Enrollee.
5. To accept as payment in full the amounts paid by MDH pursuant to Appendix C, and not to seek or accept additional payment from any Enrollee for any covered service; provided, however, that nothing in this Agreement shall prevent the MCO from seeking coordination of benefits or subrogation recoveries in accordance with applicable rules and regulations.
6. To refrain from making any expenditure for organ transplants, except as provided for in the State Plan and Section 1903(i) of the Social Security Act.
7. Except as provided in Section 1903(i) of the Social Security Act, to refrain from paying for any item or service furnished by any individual or entity to whom the State has failed to suspend payments under the State Plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with federal regulations, unless the State determines in accordance with such regulations there is good cause not to suspend such payment.
8. To refrain from making any expenditure with respect to any amount expended for which funds may not be used under the Assisted Suicide Funding Restriction Act of 1997; or with any respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under the State Plan and Section 1903(i) of the Social Security Act, except as provided for in Section 1903(i) of the Social Security Act.
9. To refrain from paying for an item or service (other than an emergency item or service) for home health care services provided by an agency

or organization unless the agency provides a surety bond as specified in Section 1861(o)(7) of the Social Security Act.

10. Not to hold Enrollees, MDH, or DHHS liable for the debts of the MCO or any of its subcapitated providers in the event of the MCO's insolvency or the insolvency of its subcapitated provider, but nothing in this paragraph shall waive the MCO's right to be paid for the services that it has provided to its members.
11. Not to hold Enrollees or DHHS liable for the debts of the MCO for services provided to the Enrollee:
 - a. If the MCO fails to receive payment from MDH for such services, or
 - b. If a health care provider with a contractual, referral, or other arrangement with the MCO fails to receive payment from MDH or the MCO for such services.
12. To make payment to health care providers for items and services which are subject to this Agreement and that are furnished to the Enrollees on a timely basis consistent with the claims payment procedures described in section §1902(a)(37)(A) of the Social Security Act, 42 CFR 447.46 and the applicable provisions of 42 CFR 447.45, Maryland Annotated Code, Insurance Article, §15-1005 and Health-General Article, §15-102.3 unless the health care provider and the MCO agree to an alternate payment schedule.
13. To make pass-through payments to the Maryland Trauma Physician Services Fund, as set forth in Health General Article § 19-130(b)(2), Maryland Annotated Code.
14. To reimburse Maryland hospital providers based on rates approved by the HSCRC.
15. To reimburse network providers for evaluation and management (E&M) codes at the current Maryland Medicaid Fee-for-Service rates, at a minimum. This includes the higher rates for primary care.
16. To reimburse self-referred services at the current Maryland Medicaid Fee-for-Service rates, at a minimum.
17. To reimburse providers for CoCM services at the current Medicare rate, at a minimum.
18. To reimburse providers (billed through J codes and CPT codes) for vaccines at the Maryland Medicaid Fee-for-Service rates, at a minimum.

19. To acknowledge and adhere to the HealthChoice Financial Sanction Policy, as outlined in Appendix I.
20. To participate in the Maryland Quality Incentive Program (MQIP) as described in Appendix J, contingent upon CMS approval.
21. To reimburse CDC-recognized organizations participating in the HealthChoice Diabetes Prevention Program (DPP) at a rate equal to or greater than the rates specified in the fee schedule in Appendix K.
22. To increase reimbursement for insertion and removal of long-acting reversible contraception in accordance with [Provider Transmittal 59-24](#), effective February 15, 2024.

K. Medical Loss Ratio

1. To provide to MDH a completed Maryland Medicaid MLR Reporting Template, using the template instructions attached hereto as Appendix G, and the template provided to the MCO by MDH or its designee, and in accordance with 42 CFR § 438.8, including the MCO attestation and any additional documentation supporting the MLR reporting template, by September 1 of the calendar year following the MLR reporting year.
2. To provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent.
3. To report fraud prevention activities to MDH as required by 42 CFR 438.8.
4. To recalculate and resubmit the MLR report for all MLR reporting years affected if MDH makes retroactive changes to the capitation payments that impacts the MLR reporting year.
5. To attest to the accuracy of the calculation of the MLR when submitting its report to MDH.
6. To acknowledge the right to appeal a remittance being due to MDH within 30 days of notice, and that filing the appeal does not stay the obligation to remit the amount owed to MDH.

L. Program Integrity

1. To implement on its own behalf and require its responsible subcontractors to implement procedures that are designed to detect and prevent fraud, waste, and abuse set forth in 42 CFR 438.608 and COMAR 10.67.07 (Appendix T).

2. To staff the MCO's program integrity efforts in accordance with COMAR 10.67.07.01A(2) (Appendix T).
3. To permit MDH, the Maryland Office of the Inspector General for Health (OIGH), the Maryland Insurance Administration, and/or DHHS, or any of their respective designees, with respect to the MCO and any of its subcontractors, as required by 42 CFR 438.6(h), to:
 - a. Evaluate the quality, appropriateness, and timeliness of services performed through inspection, or other means, including accessing the MCO and its subcontractors' facilities using enrollment cards and identities established in the manner specified by MDH; and
 - b. Inspect and audit any financial records, including but not limited to reimbursement rates.
4. To inform its subcontractors of the provisions of the Social Security Act §1128 B (Criminal Penalties for Acts Involving Federal Health Care Programs).
5. In accordance with Section 1903(m)(4)(B) of the Social Security Act, to report to the State and, upon request, to the Secretary or the Inspector General for Health and Human Services, the Comptroller General and Enrollees, a description of transactions between the MCO and a party in interest (as defined in section 1318(b) of The Public Health Service Act), including the following transactions:
 - a. Any sale, exchange, or leasing of any property between the MCO and such a party.
 - b. Any furnishing for consideration of goods, services (including management services), or facilities between the MCO and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.
 - c. Any lending of money or other extension of credit between the MCO and such a party.
6. To comply with 42 CFR 438.610 by not knowingly having as a director, officer, partner, owner of more than five percent (5%) of the MCO's equity, a network provider, or a person with an employment, consulting, or other arrangement with the MCO for the provision of items and services that are significant and material to the MCO's obligations under its Agreement with MDH, who is:
 - a. Debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in non-procurement activities under regulations issued under Executive Order No. 12549;

- b. An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph HH(1) above; or
 - c. An individual or entity that is excluded from participation in any Federal health care program under sections 1128 or 1128A of the Social Security Act.
- 7. To acknowledge the sanction provisions under 42 CFR, Part 438, Subpart I, in Health-General Article §15-103(b)(9), and COMAR 10.67.10.01 (Appendix T).
 - 8. To search the DHHS-OIG's List of Excluded Individuals/Entities, the General Services Administration Excluded Parties List System, the Social Security Administration Death Master File, and the National Plan & Provider Enumeration System for individuals excluded from the Medicaid Program. Searches shall be done upon execution of this Agreement, and the LEIE and EPLS shall be checked at least monthly thereafter, using the names of all contracted individuals and entities, those with an ownership or control interest, and their agents and managing employees, in accordance with 42 CFR 455.436.
 - 9. To create and manage processes to verify by sampling or other methods whether services billed by network providers were received by Enrollees at least quarterly in accordance with 42 CFR 438.608(a)(5), report the findings to OIGH on a quarterly basis, and provide evidence of verification efforts through a report to MDH and OIGH annually.
 - 10. To require MCO program integrity representatives to attend in-person meetings with MDH and report ongoing efforts to detect and prevent fraud, waste, and abuse, as requested.
 - 11. To identify and collect monies owing from responsible third parties liable for the cost of medical care furnished by the MCO to Enrollees in accordance with COMAR 10.67.04.18 (Appendix T).
 - 12. To create and manage mechanisms to detect fraud and abuse and report to OIGH, in accordance with OIGH protocols.
 - 13. To report excess capitation or other contract overpayments to MDH or its designee within 60 calendar days of discovery, in accordance with 42 CFR 438.608(d).
 - 14. To develop and maintain adequate overpayment identification, collection, and reporting policies and procedures consistent with 42 CFR 438.608(d)(2).

15. To establish edits in the MCO's claims processing system to cross-reference known deceased Enrollees' names and dates of death.
16. To perform activities to ensure payments are not issued for deceased Enrollees, including but not limited to analytical reviews of encounter data looking for indications of payments for services after death, including billing patterns (e.g., multiple types of service pre-death and only one type of service after death or large differences in spending before and after death).
17. To develop written policies and procedures for payment suspensions in cases of credible allegations of fraud that comply with 42 CFR 455.23 and 438.608(a)(8) and provide these policies and procedures to MDH and OIGH upon request.
18. To provide to MDH, monthly in a format directed by MDH, data on recoveries from responsible third parties at the claim level, including but not limited to:
 - a. Paid amount;
 - b. Other insurance billed/paid;
 - c. Units billed;
 - d. Provider information, including NPI and Tax ID.
19. To attend and participate in quarterly meetings with the Maryland Office of the Inspector General for Health to discuss fraud, waste, and abuse efforts; training initiatives; and other information to strengthen program integrity.
20. To provide to OIGH paid claims data reporting or other ad hoc data reporting upon request.
21. To recover, through claims submission or other appropriate means, from responsible third-party insurers, including but not limited to commercial carriers, Medicaid, and Medicare, within 18 months from the MCO's claims payment date for the cost of covered services incurred by the MCO on behalf of an enrollee for services that should have been paid through a third party, for the full amount of medical assistance provided.
 - a. All recoveries from responsible third-party insurers outside of the 18-month period may be pursued by MDH at MDH's discretion.
 - b. Tort cases are excluded from the third-party insurer recovery process identified above.

22. To notify a health care provider when retroactively denying reimbursement as a result of coordination of benefits by a carrier that is not an MCO through a written statement providing the name and address of the entity acknowledging responsibility for payment of the denied claim.
23. To provide the OIGH with the following information upon request:
 - a. Names and contact information for all program integrity staff engaged pursuant to Paragraph L(2);
 - b. Copies of any plans for program integrity, auditing, or other provider reviews;
 - c. Copies of any policies, procedures, or plans used for conducting audits or other reviews;
 - d. Details regarding all existing or planned data mining algorithms, data surveillance, or ad hoc data runs;
 - e. Quarterly reports showing the results data mining algorithms, data surveillance, or ad hoc data runs; and
 - f. Quarterly reports showing all identified fraud, waste, abuse, and/or overpayments to providers.

M. Subcontractors

1. To comply with the requirements for the service or activity delegated under the subcontract set forth in 42 CFR 438.230 and COMAR 10.67.04.17 (Appendix T).
2. To ensure all written agreements between the MCO and each of its Subcontractors include the contractual provisions outlined in COMAR 10.67.04.17A(3)(a)-(n) (Appendix T).
3. To routinely monitor Subcontractor performance and enforce corrective action for poor performance in all areas under the scope of the agreement between the Subcontractor and the MCO, including but not limited to the areas of enrollee and provider complaints, access issues, quality assurance activities, recordkeeping, and reporting requirements.
4. To report to MDH upon learning of any material deviations from required procedures by its Subcontractor which, in the MCO's judgment, can be expected to have a significant effect on plan responsibilities and/or operations, quality of care, or on Enrollees' ability to access care.
5. To structure compensation to Subcontractors conducting utilization management activities so as not to provide incentives for denying,

limiting, or discontinuing medically necessary services to any Enrollee, in accordance with 42 CFR 438.210(e).

6. To use MDH's Ownership and Control Disclosure Form to collect ownership and control, business transaction, and criminal conviction information from the MCO's Subcontractors and delegated vendors, and to furnish that information to MDH upon request.

N. Network Providers

1. To demonstrate, in accordance with 42 CFR 438.207, COMAR 10.67.03.05, COMAR 10.67.05.05, and COMAR 10.67.05.05-1 (Appendix T) that the MCO:
 - a. Offers an appropriate range of preventive, primary care, and specialty services adequate for the anticipated number of Enrollees in the MCO's service areas.
 - b. Maintains a network of providers sufficient in number, mix, and geographic distribution to meet the needs of the number of Enrollees in the MCO's service areas.
 - c. Ensures that in-plan individual practitioners, based on full-time equivalency, are assigned no more than the number of enrollees that is consistent with a 200:1 ratio of enrollee to practitioner in the local access area.
 - d. Meets MDH's Network Adequacy Standards (Appendix F) in each service areas the MCO plans to enter or is enrolled.
 - e. Demonstrates to MDH's satisfaction the adequacy of its provider network if it cannot meet the Network Adequacy Standards, by providing evidence and assurances of the overall strength of the MCO's network and that the network will enhance recipients' overall access to quality health care services in the area to be served.
2. To maintain written policies and procedures for selecting and retaining network providers in accordance with the requirements of 42 CFR 438.214 and the applicable provider panel provisions of Maryland Insurance Article § 15-112, Code Ann.
3. To ensure network selection policies and procedures do not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment, in accordance with 42 CFR 438.214(c).
4. To ensure that all its network providers are screened, enrolled, and revalidated by the State as Medicaid providers, in accordance with 42

CFR part 455, subparts B and E, and validate enrollment by verifying against MDH's full fee-for-service provider file.

5. To require that network providers enroll and comply with the requirements of MDH's Electronic Provider Revalidation Enrollment Portal (ePREP) in accordance with 42 CFR 438, subpart H.
6. To validate that any network provider rendering or receiving payment for covered services is enrolled and active on the date(s) of service by verifying against the full fee-for-service provider enrollment file from MDH.
7. To accept the Maryland Uniform Credentialing Form for the credentialing of network providers.
8. To refrain from discriminating against providers serving high-risk populations or specializing in conditions requiring costly treatment.
9. To inform all providers at the time of entering a contract with the MCO about the grievance and appeal system, as set forth in 42 CFR 438.414 and 42 CFR 438.10(g)(2)(xi).
10. To monitor MDH's correspondence and any database publicizing Department-initiated terminations of providers from the Program.
11. To terminate the contract of, or refrain from contracting with, providers terminated or excluded from participating in the Program.
12. To develop and distribute a provider manual that includes all the information provided in MDH's template and required in COMAR 10.67.05.04A(2).
13. To distribute to network providers the MCO's practice guidelines, as described in 42 CFR 438.236.
14. To ensure services are delivered in a culturally competent manner to all Enrollees, in accordance with COMAR 10.67.05.01 (Appendix T).
15. To ensure its provider network can provide physical access, reasonable accommodation, and accessible equipment for Enrollees with physical or mental disabilities.
16. To provide and reimburse for necessary services covered under the contract out of network adequately and timely for Enrollees in accordance with 42 CFR 438.206, for as long as the MCO's provider network is unable to provide them under regulatory network adequacy standards as outlined in COMAR 10.67.05.01 *et. seq.* (Appendix T).

O. MCO Appeal Rights

1. To acknowledge its right to appeal under the following grounds:
 - a. Decision to terminate the MCO's participation in the Maryland Medicaid Managed Care Program;
 - b. Decision to impose a fine over the amount of \$50,000 on the MCO;
 - c. Order that the MCO is impaired or in “hazardous financial condition;”
 - d. An adverse decision by the IRO as described in COMAR 10.67.13.08;
 - e. The denial of a hepatitis C payment as described in COMAR 10.67.04.19;
 - f. Overpayments recovered by MDH;
 - g. Remittances to MDH related to MLR reporting.
2. To appeal to the Office of Administrative Hearings as specified in COMAR 10.09.36.09 and COMAR 10.01.03 (Appendix T).
3. To acknowledge and agree that the following sanctions take effect immediately and are not subject to stay during the pendency of an appeal:
 - a. Any fines imposed;
 - b. Any full or partial withhold of the capitation payment;
 - c. Any remittances to MDH related to MLR; or
 - d. Any overpayments recovered by MDH related to program integrity efforts, as described in COMAR 10.67.07.01.
4. To acknowledge and agree that sanctions involving enrollment freezes for different infractions may be applied consecutively at the discretion of MDH without prejudicing the right of the MCO to appeal the sanctions.

P. Pharmacy

1. To maintain drug review and utilization requirements that comply with 42 U.S.C. § 1396a(oo), excluding sections (1)(A)(i)(III) and (B), along with the following drug utilization review requirements from 42 C.F.R. § 456.703:
 - a. Prospective safety edit limitations for opioid prescriptions, on days’ supply for patients not currently receiving opioid therapy for

initial prescription fills; quantity of prescription dispensed for initial and subsequent prescription fills; therapeutically-duplicative initial and subsequent opioid prescription fills; and early refills, for subsequent prescription fills.

- b. Prospective safety edit limitations for opioid prescriptions on the maximum daily morphine milligram equivalent for treatment of pain, for initial and subsequent prescription fills.
 - c. A retrospective claims review automated process that indicates prescription fills of opioids in excess of the prospective safety edit limitations specified in Section II.P.1.A-B to provide for the ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists, and individuals receiving Medicaid benefits.
 - d. A process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State Plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.
 - e. Retrospective claims review automated processes to identify when an Enrollee is prescribed an opioid after the Enrollee has been prescribed one or more drugs used for medication assisted treatment of an opioid use disorder or has been diagnosed with an opioid use disorder, in the absence of a new indication to support utilization of opioids (such as new cancer diagnosis or hospice care); and an Enrollee could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of any FDA-approved opioid antagonist/reversal agent.
- 2. To cover outpatient drugs as defined in 42 U.S.C. § 1396r-8(k)(2) and comply with the requirements outlined in 42 CFR 438.3(s).
 - 3. Pharmacy Benefit Managers (PBMs)
 - a. To disclose for each pharmaceutical claim the amount the MCO paid the PBM, and of that amount, the amount paid to the pharmacy, including identifying the dispensing fee and the ingredient cost (if applicable), in a format and frequency determined by MDH.
 - b. To base PBM reimbursement on the actual amount paid by the PBM to a pharmacy for dispensing and ingredient costs.

- c. To manage or delegate to the PBM any drug pricing appeals from pharmacies and resolve all appeals within 21 days of receipt of the request to review.
 - d. To comply with the requirements in Md. Code, Ins. § 15-1611.1 and Md. Code, Ins. § 15-1628.3.
 - e. To require PBMs to comply with the pharmacy audit provisions in accordance with Md. Code, Health-Gen. § 15-103(b)(33) and Md. Code, Ins. § 15-1629.
 - f. To require PBMs to consider both ingredient costs and dispensing fees when determining reimbursement to pharmacies.
 - g. To comply with the prohibition of spread pricing reimbursement in PBM contracting.
4. To comply with MDH's opioid drug utilization review policies and its corrective managed care regulations set forth in COMAR 10.67.12 (Appendix T), including but not limited to providing provider education about prescribing limits, applying prior authorization requirements, and submitting reports to MDH upon request.
5. To require the PBM, through amending the contract between the MCO and PBM and the contract between the PBM and pharmacy network, to comply with the following prohibitions, which do not preclude the reprocessing of claims due to claims adjudication errors made by the MCO, PBM, or an agent of either entity:
- a. To prohibit the PBM from collecting direct or indirect remuneration fees, membership fees, transaction fees, or similar fees from pharmacies or other contracted entities acting on behalf of pharmacies as a condition of claims payment or network inclusion.
 - b. To prohibit the PBM from implementing retrospective remuneration models, including but not limited to Generic Effective Rates (GERs) and Brand Effective Rates (BERs).
 - c. To implement this requirement, PBMs operating on behalf of the MCO must amend all contracts and/or agreements with participating network pharmacies no later than the end of the term of this Agreement to include the following language:

“Pursuant to contractual requirements of Managed Care Organizations (MCOs) operating within the Maryland HealthChoice Program, any Pharmacy Benefit Manager (PBM) operating on behalf of a Maryland HealthChoice Program MCO is prohibited from collecting direct or indirect remuneration fees,

membership fees, or similar fees associated with Maryland HealthChoice claims from network pharmacies or other contracted entities acting on behalf of network pharmacies as a condition of claims payment or network inclusion. Further, PBMs operating on behalf of a Maryland HealthChoice Program MCO are prohibited from implementing retrospective remuneration models for Maryland HealthChoice claims, including but not limited to Generic Effective Rates (GERs) and Brand Effective Rates (BERs). For purposes of this requirement, “direct or indirect remuneration fees” may include but are not limited to a) any pay-to-play for network participation; b) any fees for periodic reimbursement reconciliations to provide a true-up between a target reimbursement rate in a participating pharmacy agreement and the aggregated effective rate actually realized by a pharmacy or between the aggregate maximum allowable cost (MAC) or adjudicated rate and the aggregate contracted rate; or c) any payment mechanism to pharmacies for the fulfillment of quality measures or fee assessed to pharmacies for noncompliance with quality measures.”

6. To comply with MDH’s high-cost low volume drug risk mitigation policy (Appendix L-1), Hepatitis C risk pool reimbursement method (Appendix L-2), and moderate-cost high volume drug risk mitigation policy (Appendix L-3).
7. To conduct an annual audit to review the performance of the PBM in the following areas, at a minimum:
 - a. Claims processing
 - b. Payment methodology
 - c. Allowable adjustments
8. To require in the PBM contract the hiring of an independent third party to complete an annual Service Organization Controls report (SOC-2, type 2) audit over the PBM’s services and activities by the end of the Agreement term.
9. To submit summary reports of the annual audit findings of the audits required under (7) and (8), including any corrective actions that the MCO will mandate of their PBM, in the event issues have been identified by the audit.
10. To submit unredacted agreements between the MCOs and their PBMs to MDH upon request.

11. To require the PBM to submit unredacted pharmacy network agreements; including contracts, rate sheets, and provider manuals; between the PBMs and their Pharmacy providers to MDH upon request.
12. To disclose to MDH the supplemental rebates allocation methodology between the PBM and the MCO.
13. To disclose to MDH all supplemental rebate revenue from the PBM on the HealthChoice Financial Monitoring Report.
14. To continue monthly reconciliation activities with MDH's Point-Of-Sale vendor for all paid claims processed by the MCO and its respective PBM to ensure all claims are processed through the Coordinated Prospective Drug Utilization Review. The MCO and its respective PBM shall support this process by:
 - a. Sending and receiving files as required,
 - b. Attending all meetings for reconciliation, and
 - c. Working with MDH and its point-of-sale vendor to ensure all discrepancies are resolved and received as directed by MDH.
15. To exclude drugs for treatment of diabetes, HIV, or AIDS from being classified as specialty drugs, in accordance with Md. Code, Health-Gen. § 15-118.1.
16. To eliminate prior authorization requirements for postexposure prophylaxis for the prevention of HIV if prescribed for use in accordance with Centers for Disease Control and Prevention guidelines, in accordance with Md. Code, Ins. § 15-858.
17. To provide coverage and reimbursement for all services rendered by a licensed pharmacist within the pharmacist's lawful scope of practice, in accordance with Md. Health-Gen. Art. §§ 15-148, 15-151, and 15-716.
18. To suspend waiver of pharmacy copays to comply with the federal Mental Health Parity and Addiction Equity Act, and charge no more than the following amounts:
 - a. \$3.00 per prescription on new and refill non-preferred drugs;
 - b. \$1.00 per prescription on new or refill preferred drugs, generic drugs, and HIV/AIDS drugs.
19. To exclude family planning drugs from pharmacy copay requirements.

20. To exclude the following populations from pharmacy copay requirements:
 - a. Individuals under the age of 21;
 - b. Individuals receiving hospice care;
 - c. Pregnant individuals; and
 - d. American Indians.
21. To comply with the requirement of section 11405 of the Inflation Reduction Act (IRA), as it relates to coverage and payment for approved adult vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP) and their administration without Enrollee cost sharing.
22. To comply with directives from the Secretary of MDH as it relates to coverage and payment for pediatric and adult vaccinations and their administration without Enrollee cost sharing.
23. To assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits, in accordance with 42 CFR 438.3(s)(7).

Q. Staffing Requirements

1. To establish a strategic staffing plan that includes standards for implementing an effective system of health care delivery to Enrollees.
2. To present the staffing plan to MDH for review and approval annually by July 1.
3. To submit to MDH any proposed changes to the staffing plan at least thirty (30) days prior to the anticipated changes taking effect for MDH's review and written approval.
4. To submit an alternative staffing plan to MDH for review and approval if anticipated changes due to a Sudden Vacancy results in a decrease in personnel or impact staff identified as Key Personnel.
5. To employ Key Personnel on a full-time basis (minimum of forty [40] hours a week) to work based in the MCO's office in the state of Maryland for a minimum of two (2) days per work week, in alignment with the State of Maryland's [Telework Policy](#).
 - a. Key Personnel positions bear primary responsibility for the requirements included under the Agreement.

- b. Key Personnel positions may not be split or shared among multiple individuals on an MCO's staff.
 - c. Key Personnel may also have shared responsibility for a Maryland-based Dual Eligible Special Needs Plan (D-SNP).
 - d. Approval to provide Key Personnel functions for the MCO and for the D-SNP may be subject to change in subsequent contract years based on the size of the D-SNP.
- 6. To provide to MDH the name, title, qualifications, and contact information of the designated individuals identified to serve in each Key Personnel position.
 - a. If a Key Personnel position is vacant, the MCO agrees to provide a staffing plan that includes a timeline for filling the vacant position, as well as a job posting identifying the responsibilities and qualifications required for the vacant position.
- 7. To share with MDH for review prior to hiring an individual to fill a Key Personnel position, the selected candidate's resume, and allow MDH 14 days to review the resume to determine whether MDH approves the candidate's credentials.
- 8. To require Key Personnel to work continuously in their role at the MCO for the duration of this Agreement.
- 9. To require Key Personnel to be dedicated 100% to HealthChoice, except for the Chief Medical Officer (CMO).
- 10. To submit a substitution request for Key Personnel at least fifteen (15) days prior to the intended change for review and written approval by MDH.
- 11. To identify a suitable replacement in the event of a Sudden Vacancy of a position identified as Key Personnel or required personnel and provide the same information and items required under Section II.Q.6 of this Agreement to MDH:
 - a. Within fifteen (15) days of the actual vacancy occurrence, or
 - b. From when the MCO first knew or should have known that the vacancy would be occurring, whichever is earlier.
- 12. Key Personnel
 - a. To identify and maintain Key Personnel to carry out essential functions at the MCO.

- b. To ensure the following Key Personnel positions, at a minimum, are filled at the beginning of this Agreement term:
 - i. Chief Executive Officer (CEO), who has authority over all aspects of the MCO's Maryland Medicaid line of business;
 - ii. Chief Operating Officer (COO), who is responsible for daily management of all operations and ensuring that performance measures from MDH and CMS requirements are met;
 - a. The COO may also serve as the primary liaison with MDH for any and all operational issues.
 - iii. Chief Financial Officer (CFO), who oversees all budgeting and accounting requirements and systems, including participation in HealthChoice capitation rate setting meetings;
 - iv. Chief Information Officer (CIO), who is responsible for the MCO's Management Information System (MIS) and encounter data oversight;
 - v. CMO, who provides timely medical advice and consultation as needed, and develops, implements, and interprets medical policies and procedures, including but not limited to service authorizations, claims review, discharge planning, credentialing, referral management, culturally and linguistically appropriate care, and medical review of Grievances and Appeals. Other qualifications are listed below:
 - a. The CMO must possess a current unrestricted license in Maryland;
 - b. The CMO must have a minimum of three (3) years of training in a medical specialty and five (5) years of experience providing clinical services;
 - c. The CMO must be board certified in his/her specialty and actively involved in all major clinical, utilization and quality management decisions of the Contractor;
 - d. The CMO must have experience and knowledge of evidence-based population management of diverse, low-income populations.

- e. The CMO must dedicate a minimum of 75% of their time to HealthChoice and any Maryland D-SNPs.

13. Additional Required Personnel

- a. To identify and maintain additional personnel to carry out functions as defined below; the responsibilities of the following personnel shall include, but are not limited to, those listed below:
 - i. Chief Quality Officer (CQO), who engages and leads the MCO, the MCO's Provider network, as well as delegated Providers in continuous quality improvement activities as defined in Section II.E. of the Agreement and COMAR 10.67.04.03;
 - ii. The CQO shall be responsible for several tasks regarding the Quality Assessment and Performance Improvement (QAPI) program and Continuous Quality Improvement (CQI) plan;
- b. Clinical Operations Manager, who is responsible for designing, administering, and evaluating a unique program of mandatory Case Management and Care Coordination for HealthChoice Enrollees;
 - i. The Manager shall be an independent licensed clinical social worker, registered nurse, nurse practitioner, and/or physician licensed to practice in Maryland;
 - ii. This manager shall oversee the provision of a range of targeted, clinical services and benefits in accordance with Section II.D. of the Agreement, COMAR 10.67.04, and COMAR 10.67.06;
- c. Appeals and Grievances Manager, or employee with responsibility for overseeing an Enrollee services program that operates twenty-four (24) hours per day, seven (7) days per week, that is capable of:
 - i. Providing information, answering questions, assisting Enrollees with locating services and maintaining eligibility in a timely fashion;
 - ii. Resolving Enrollee Grievances; and
 - iii. Assisting Enrollees to file and pursue Appeals involving the denial, termination or reduction of benefits and services;

- d. Provider Relations Manager, or employee who administers a Provider services program that:
 - i. Furnishes Network Provider support and as applicable, non-Network Provider support;
 - ii. Serves as an entry point for both network and non-Network Providers that have disputes with the Contractor and wish to participate in the MCO's provider dispute resolution process;
- e. Program Integrity Director, who is responsible for:
 - iii. Developing an effective program to reduce and remediate Provider and beneficiary fraud, waste, and abuse; and
 - iv. Serving as a liaison to the OIG;
- f. Chief Compliance Officer, who is responsible for:
 - i. Developing, implementing, and overseeing policies, procedures, and practices to ensure compliance with the requirements of the contract;
 - ii. Developing an effective program to reduce and remediate Provider and beneficiary fraud, waste, and abuse.
 - iii. The Chief Compliance Officer may also serve as the Program Integrity Director;
- g. Health Equity Director, who is responsible for establishing and overseeing a comprehensive strategy to advance health equity for enrollees;
 - i. This role must have authority to direct and manage financial and operational resources and enact activities to operationalize a comprehensive health equity strategy for the MCO;
 - ii. This role should serve as part of the MCO's senior leadership team;
 - iii. The individual selected should have demonstrated experience with community health services, working with under-resourced areas and communities of disinvestment, and implementing health equity approaches and models for large organizations, as reflected in their resume;

- h. Special Needs Coordinator, who will serve as a point of contact for health care services information and referral for members of special needs populations;
 - i. This role requires the Coordinator to be skilled in communications and sensitive to the unique needs of the population, their families, guardians, and caregivers;
 - ii. This role must participate on the MCO's consumer advisory board, serve as a resource to MCO providers and enrollees, and maintain a record of each denial of treatment and the outcome of the utilization review conducted for individuals identified as members of special needs populations;
 - i. Newborn Coordinator, to provide services for a newborn whose mother is enrolled in the MCO on the date of the newborn's birth and who is enrolled or who is auto assigned to the MCO after birth;
 - i. The role is responsible for researching and confirming the assignment of an eligible newborn to an MCO, working closely with enrollment agents, handling retroactive PCP enrollments, and resolving claims for services provided to newborns;
 - ii. The role requires the Newborn Coordinator to provide guidance to healthcare providers on newborn-related matters, coordinating with ancillary care providers, and authorizing in-network or out-of-network care as necessary;
 - j. Marketing Director, to fulfill the marketing requirements outlined in COMAR 10.67.04.23, along with any other policies developed by MDH.
- 14. To fill any Key Personnel positions vacated during the term of this Agreement within sixty (60) days.
 - 15. To fill any additional required personnel positions vacated during the term of this Agreement within ninety (90) days.
 - 16. To agree if a Key Personnel position or additional required personnel position becomes vacant during the calendar year and remains vacant for more than the timeframes specified, the MCO may be subject to financial sanctions in accordance with the HealthChoice Financial Sanction Policy in Appendix I of this Agreement.

III. MDH AGREES:

A. General Requirements

1. To pay the MCO in accordance with COMAR and Appendix C, which may be amended throughout the term of the Agreement.
2. To develop capitation rates that are:
 - a. Actuarially sound to allow the MCO to effectively deliver covered services to Enrollees in a manner compliant with the requirements of this Agreement and 42 CFR 438.4 through 438.7, and 438.602(i); and
 - b. Based only upon services covered under the State Plan and additional services deemed by the State to be necessary to comply with the requirements of 42 CFR 438, subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act).
3. To develop PHIP incentive payments in accordance with the standards set forth in 42 CFR 438.6(b)(1).
4. To develop stop-loss insurance in according with the standards set forth in 42 CFR 438.4 and 438.5.
5. To produce and make available monthly to the MCO a remittance advice and the following reports:
 - a. MCO Capitation Detail Report;
 - b. MCO Capitation Summary Report;
 - c. MCO Capitation Report by Rate Group;
 - d. MCO Capitated Enrollment Report;
 - e. MCO Capitated Enrollment Summary;
 - f. MCO Disenrollment Report by Site;
 - g. MCO Capitated Disenrollment Summary;
 - h. Zip Code Totals within MCO by Provider;
 - i. MCO Eligibility and Enrollment Renewal Files; and
 - j. Enrollee Bad Address File.
6. To include in the monthly enrollment listings sent to the MCO the adjustments provided by the MCO and accepted by MDH, and other appropriate debit and credit transactions.

7. To provide to the MCO at least 15 days' notice of any policy changes.
8. To make the accreditation status for the MCO available on the Website as required under 42 CFR 438.10(c)(3), including whether the MCO has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level; and update this information at least annually.

B. Monitoring Requirements

1. To review the ownership and control disclosures submitted by the MCO and those of any of the MCO's subcontractors, upon request.
2. To collect (including through its agents and contractors) the following information from the MCO to improve the performance of the managed care program, including at a minimum:
 - a. Enrollment and disenrollment trends in the MCO;
 - b. Member grievance and appeal logs;
 - c. Provider complaint and appeal logs;
 - d. Findings from the State's External Quality Review process;
 - e. Results from any Enrollee or provider satisfaction survey conducted by the State or MCO;
 - f. Performance on required quality measures;
 - g. Medical management committee reports and minutes;
 - h. The annual quality improvement plan for the MCO;
 - i. Audited financial and encounter data submitted by the MCO;
 - j. Network adequacy assurances submitted by the MCO;
 - k. The medical loss ratio summary reports required by 42 CFR 438.8; and
 - l. Customer service performance data submitted by the MCO, and performance data submitted by the beneficiary support system.

C. Prevalent Non-English Languages

1. To specify that, at the time of this Agreement, the prevalent non-English languages spoken by Enrollees and potential Enrollees in the State are as follows:
 - a. Amharic
 - b. Arabic
 - c. Bassa
 - d. Chinese
 - e. Farsi
 - f. French
 - g. Gujarati
 - h. Haitian Creole
 - i. Igbo
 - j. Korean
 - k. Portuguese
 - l. Russian
 - m. Spanish
 - n. Tagalog
 - o. Urdu
 - p. Vietnamese
 - q. Yoruba

D. Imposition of Sanctions

1. To give the MCO timely written notice explaining the basis and nature of any sanctions imposed, in accordance with COMAR 10.67.10.01A (Appendix T). Sanctions may include, but are not limited to:
 - a. Fines;
 - b. Suspension of further enrollment;
 - c. Withholding all or part of the capitation payment;
 - d. Termination of the Agreement;
 - e. Disqualification from future participation in the Maryland Medicaid Managed Care Program; and
 - f. Those actions outlined in 42 CFR 438.700–438.708, as amended.
2. To provide the MCO notice of appeal rights under COMAR 10.67.10.02 (Appendix T).

3. To permit the MCO the opportunity to take corrective action in accordance with COMAR 10.67.10.01B (Appendix T), through a plan approved by MDH.

IV. MDH AND THE MCO MUTUALLY AGREE:

A. Agreement Term and Grounds for Termination

1. That the term of this Agreement shall begin on January 1, 2026, and terminate on December 31, 2026.
2. That the MCO shall provide written notification to MDH of the MCO's intent to terminate this agreement for any future calendar year by October 1 of the prior year according to COMAR 10.67.04.26 (Appendix T).
3. That MDH reserves the right to terminate this Agreement upon:
 - a. Completion or termination of the Section 1115 Demonstration Waiver and Federal funding thereunder;
 - b. Notification by the Maryland Department of Budget and Management that State funds are not available for the continuation of the HealthChoice Program;
 - c. Determination that the MCO or any agent or employee of the MCO, or any person with an ownership interest in the MCO, or a related party of the MCO, has failed to comply with any applicable law, regulation, or Agreement term, or for other good cause shown, pursuant to COMAR 10.67.10 (Appendix T); or
 - d. Determination by MDH of insufficient MCO participation in the HealthChoice Program.
4. That if MDH terminates this Agreement for any reason, it shall not be liable for any costs of the MCO associated with the termination, including but not limited to, any expenditures made by the MCO prior to the termination or related to implementing the termination.
5. That termination of this Agreement shall not discharge the obligations of the MCO with respect to services or items furnished prior to termination, including payment for covered services delivered during the Agreement period, retention of records and restitution to MDH of overpayments.
6. That in the event of the termination of this Agreement either by MDH or by the MCO, the MCO will furnish to MDH all information relating to the reimbursement of any outstanding claims for services rendered

to its Enrollees, including those of its subcontractors, within forty-five (45) days of the effective date of termination.

7. That prior to termination of this Agreement by MDH, MDH shall provide a pre-termination hearing in accordance with 42 CFR 438.710(b).

B. Payment

1. That there will be a mid-year rate evaluation and update in CY 2026 as described in Appendix C.
2. That, except for new Enrollees during the period between ten days after MDH's enrollment agent has notified the MCO of a new enrollment and receipt by the MCO of MDH's next regular monthly payment of capitation payment rates, the MCO is not required to pay for or provide services for any Enrollee for which it has not received a prepaid capitation rate from MDH.
3. That payments made under this Agreement will be denied for new Enrollees enrolled after imposition of such sanction as authorized by 42 CFR §438.702(a)(5):
 - a. When MDH determines that the MCO has acted or failed to act as described in 42 CFR §438.700(b)-(d); and
 - b. Until CMS or MDH is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

C. Miscellaneous

1. That the MCO and MDH shall enter into a data use agreement with University of Maryland, Baltimore County acting through its Hilltop Institute, to facilitate the secure transmission of data to MDH's data warehouse.
2. That this Agreement may be modified only in writing by the parties.
3. That this Agreement shall not be transferable or assignable.
4. That any change in Federal or State law or regulation that affects any provision or term of this Agreement shall automatically become a provision or term of this Agreement.
5. That they shall carry out their mutual obligations as herein provided in a manner prescribed by law and in accordance with all applicable regulations and policies as may from time to time be promulgated by DHHS or any other appropriate Federal or State agency, including compliance with the Agreement provisions or conditions required in all procurement contracts and subcontracts as specified under 45 CFR Part 74.

6. That should any part of the scope of work under this contract relate to a state program that is no longer authorized by law (e.g., which has been vacated by a court of law, or for which CMS has withdrawn federal authority, or which is the subject of a legislative repeal), the MCO must do no work on that part after the effective date of the loss of the program authority.
 - a. MDH must adjust capitation rates to remove costs that are specific to any program or activity that is no longer authorized by law.
 - b. If the MCO works on a program or activity no longer authorized by law after the date the legal authority for the work ends, the MCO will not be paid for that work.
 - c. If MDH paid the MCO in advance to work on a no-longer-authorized program or activity and under the terms of this Agreement, the work was to be performed after the date the legal authority ended, the payment for that work must be returned to MDH.
 - d. However, if the MCO worked on a program prior to the date legal authority ended for that program or activity, and MDH included the cost of performing that work in its payments to the MCO, the MCO may keep the payment for that work even if the payment was made after the date the program or activity lost legal authority.
7. That the MCO shall cooperate in the orderly transition of services upon receipt of a Notice of Termination from the State. Transition shall be provided in a prompt and timely manner and shall proceed in accordance with the schedule provided to the MCO by the State in the Notice of Transition. The MCO shall follow any additional instructions regarding transition services that may be provided in the event of a Notice of Termination issued by the State.
8. That a notice required to be given to the other party under this Agreement, unless specified otherwise, is effective only if the notice is provided in writing and sent by first-class mail, courier or delivery service, or electronic transmittal of original documents with signatures, to the representative and address for that party listed below:
 - a. Notices to MDH shall be sent to:

Monchel Pridget
Deputy Director, Managed Care
Maryland Department of Health
201 W. Preston Street, Room 214A
Baltimore, MD 21201
monchel.pridget@maryland.gov

b. Notices to the MCO shall be sent to:

IN WITNESS WHEREOF, the parties hereto have hereunder executed this Agreement the day and year first above written.

FOR MDH:

Date

Perrie Briskin
Deputy Secretary, Health Care Financing
Medicaid Director
Maryland Department of Health

FOR THE MCO:

Date

Signature

APPROVED AS TO FORM AND LEGAL SUFFICIENCY

Assistant Attorney General

Date

APPENDIX A

HIPAA BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the “Agreement”) is made by and between the Office of Health Care Financing, a unit of the Maryland Department of Health (MDH) (herein referred to as “Covered Entity”) and _____ (hereinafter known as “Business Associate”). Covered Entity and Business Associate shall collectively be known herein as the “Parties.”

WHEREAS, Covered Entity has a business relationship with Business Associate that is in a separate agreement (the “Underlying Agreement”) dated _____, pursuant to which Business Associate may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996 including all pertinent privacy regulations (45 C.F.R. Parts 160 and 164) and security regulations (45 C.F.R. Parts 160, 162, and 164), as amended from time to time, issued by the U.S. Department of Health and Human Services as either have been amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), and the HIPAA Omnibus Final Rule of 2013 (collectively, “HIPAA”); and

WHEREAS, the nature of the contractual relationship between Covered Entity and Business Associate may involve the exchange of Protected Health Information (“PHI”) as that term is defined under HIPAA; and

WHEREAS, for good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this Agreement for the purpose of ensuring compliance with the requirements of HIPAA and the Maryland Confidentiality of Medical Records Act (Md. Ann. Code, Health-General §§4-301 *et seq.*) (“MCMRA”); and

WHEREAS, this Agreement supersedes and replaces any and all Business Associate Agreements the Covered Entity and Business Associate may have entered into prior to the date hereof;

NOW THEREFORE, the premises having been considered and with acknowledgment of the mutual promises and of other good and valuable consideration herein contained, the Parties, intending to be legally bound, hereby agree as follows:

I. DEFINITIONS

A. Catch-all definition. The following terms used in this Agreement, whether capitalized or not, shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

B. Specific definitions:

1. Business Associate. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 C.F.R. § 160.103, and in reference to the party to this Agreement, shall mean _____, the managed care organization (MCO).
2. Covered Entity. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 C.F.R. § 160.103, and in reference to the party to this Agreement shall mean the Maryland Department of Health.
3. HIPAA Rules. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.F.R. Parts 160 and Part 164.
4. Protected Health Information (“PHI”). Protected Health Information or “PHI” shall generally have the same meaning as the term “protected health information” at 45 C.F.R. § 160.103.

II. PERMITTED USES AND DISCLOSURES OF PHI BY BUSINESS ASSOCIATE

- A. Business Associate may only use or disclose PHI as necessary to perform the services set forth in the Underlying Agreement or as required by law.
- B. Business Associate agrees to make uses and disclosures and requests for PHI consistent with Covered Entity’s policies and procedures regarding minimum necessary use of PHI.
- C. Business Associate may not use or disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity.
- D. Business Associate may, if directed to do so in writing by Covered Entity, create a limited data set as defined at 45 C.F.R. § 164.514(e)(2), for use in public health, research, or health care operations. Any such limited data sets shall omit any of the identifying information listed in 45 C.F.R. § 164.514(e)(2). Business Associate will enter into a valid, HIPAA-compliant Data Use Agreement as described in 45 C.F.R. § 164.514(e)(4), with the limited data set recipient. Business Associate will report any material breach or violation of the data use agreement to Covered Entity immediately after it becomes aware of any such material breach or violation.
- E. Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration or legal responsibilities of the Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

- F. The Business Associate shall not directly or indirectly receive remuneration in exchange for any PHI of an individual pursuant to §§ 13405(d)(1) and (2) of the HITECH Act. This prohibition does not apply to the State's payment of Business Associate for its performance pursuant to the Underlying Agreement.
- G. The Business Associate shall comply with the limitations on marketing and fundraising communications provided in § 13406 of the HITECH Act in connection with any PHI of individuals.

III. DUTIES OF BUSINESS ASSOCIATE RELATIVE TO PHI

- A. Business Associate agrees that it will not use or disclose PHI other than as permitted or required by the Agreement, the Underlying Agreement, the MCMRA, as Required by Law, or as authorized by Covered Entity, so long as the authorized use or disclosure is permitted by law.
- B. Business Associate agrees to use appropriate administrative, technical, and physical safeguards to protect the privacy of PHI.
- C. Business Associate agrees to use appropriate safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to electronic PHI, to prevent use or disclosure of PHI other than as provided for by the Agreement.
- D. Reporting Requirements.
 - 1. Business Associate agrees to report to Covered Entity any use or disclosure of PHI not provided for by the Agreement of which it becomes aware, including Breaches of unsecured PHI as required by 45 C.F.R. § 164.410, and any Security Incident of which it becomes aware without unreasonable delay and in no case later than fifteen (15) calendar days after the use or disclosure.
 - 2. If the use or disclosure amounts to a breach of unsecured PHI, the Business Associate shall ensure its report:
 - A. Is made to Covered Entity without unreasonable delay and in no case later than fifteen (15) calendar days after the incident constituting the Breach is first known, except where a law enforcement official determines that a notification would impede a criminal investigation or cause damage to national security. For purposes of clarity for this Section III.D.1, Business Associate must notify Covered Entity of an incident involving the acquisition, access, use or disclosure of PHI in a manner not

permitted under 45 C.F.R. Part E within fifteen (15) calendar days after an incident even if Business Associate has not conclusively determined within that time that the incident constitutes a Breach as defined by HIPAA;

- B. Includes the names of the Individuals whose Unsecured PHI has been, or is reasonably believed to have been, the subject of a Breach;
- C. Is in substantially the same form as Exhibit A hereto.
- E. In addition to its obligations in Sections III. A-D, without unreasonable delay, but no later than 45 calendar days after the incident constituting the Breach is first known, Business Associate shall provide to Covered Entity a draft letter for the Covered Entity to review and approve for use in notifying the Individuals that their Unsecured PHI has been, or is reasonably believed to have been, the subject of a Breach that includes, to the extent possible:
 - 1. A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - 2. A description of the types of Unsecured PHI that were involved in the Breach (such as full name, Social Security number, date of birth, home address, account number, disability code, or other types of information that were involved);
 - 3. Any steps the affected Individuals should take to protect themselves from potential harm resulting from the Breach;
 - 4. A brief description of what the Business Associate is doing to investigate the Breach, to mitigate losses, and to protect against any further Breaches; and
 - 5. Contact procedures for the affected Individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, website, or postal address.
- F. In the event the Breach occurs through the fault of Business Associate, Business Associate shall be responsible for notifying Individuals by sending via First Class U.S. Mail the approved letter described in Section III(E) no later than 60 calendar days after discovery of the Breach.
- G. In the event the Breach occurs through the fault of Covered Entity, Covered Entity shall be responsible for notifying Individuals no later than 60 calendar days after Covered Entity receives notice of the Breach from the Business Associate.

- H. In the event of any Breach, regardless of which party is responsible, Business Associate will provide, without unreasonable delay, but no later than 45 days after the discovery of the Breach a proposed Breach Notification Report to be submitted to HHS Office of Civil Rights (OCR), as required by 45 CFR § 164.408(a).
 - 1. Business Associate and Covered Entity, through its Privacy Officer or their designee, shall cooperate and determine which party will be responsible for filing the Breach Notification Report with OCR and Business Associate shall obtain a written acknowledgment from Covered Entity that assigns this responsibility to either Covered Entity or Business Associate.
 - 2. If Business Associate is assigned the responsibility of filing the Breach Notification Report with OCR, Business Associate shall seek and receive written approval from Covered Entity of the Breach Notification Report prior to it being filed with OCR.
 - 3. Written approval from Covered Entity pursuant to this paragraph shall be from the MDH Privacy Officer or their designee.
- I. In the event of any Breach in which 500 or more individuals of any state or jurisdiction are affected, regardless of which party is responsible, the following provisions will apply, as required by 45 CFR §164.406(a):
 - 1. Covered Entity, through its Private Office or their designee, shall determine, in consultation with Business Associate, which party will be responsible for notifying the media, and shall inform Business Associate in writing as to its determination.
 - 2. If Business Associate is assigned the role of notifying the media, Business Associate shall seek written approval from Covered Entity as to the content of any notification to be made to the media prior to any media outlet being notified of the breach and shall incorporate any language suggested by Covered Entity.
 - 3. If assigned responsibility, Business Associate shall provide its proposed media notification to Covered Entity for review within thirty (30) days of the date of discovery of the breach.
 - 4. Written approval from Covered Entity pursuant to this paragraph shall be from the MDH Privacy Officer or their designee.
 - 5. If Covered Entity assigns the responsibility to itself, it will inform Business Associate in writing as to this determination and will offer Business Associate the opportunity to review and agree to the notification before its dissemination. However, the Covered Entity reserves final

decision-making authority on the content of the notification if a consensus cannot be reached with the Business Associate.

- J. To the extent permitted by the Underlying Agreement, Business Associate may use agents and subcontractors. In accordance with 45 C.F.R. §§ 164.502(e)(1)(ii) and 164.308(b)(2), Business Associate shall ensure that any subcontractors that create, receive, maintain, or transmit PHI on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information, Business Associate must enter into Business Associate Agreements with subcontractors as required by HIPAA;
- K. Business Associate agrees it will make available PHI in a designated record set to the Covered Entity or, as directed by the Covered Entity, to an individual, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.524, including, if requested, a copy in electronic format;
- L. Business Associate agrees it will make any amendment(s) to PHI in a designated record set as directed or agreed to by the Covered Entity pursuant to 45 C.F.R. § 164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.526;
- M. Business Associate agrees to maintain and make available the information required to provide an accounting of disclosures to the Covered Entity or, as directed by the Covered Entity, to an individual, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.528;
- N. To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, Business Associate will comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s);
- O. Business Associate agrees to make its internal practices, books, and records, including PHI, available to the Covered Entity and/or the Secretary of HHS for purposes of determining compliance with the HIPAA Rules.
- P. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

IV. TERM AND TERMINATION

- A. Term. The Term of this Agreement shall be effective as of the effective date of the HealthChoice Managed Care Organization Agreement and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or the PHI

created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, in accordance with the termination provisions in this Section IV, or on the date the Covered Entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner. If it is impossible to return or destroy all the PHI provided by Covered Entity to Business Associate, or the PHI created or received by Business Associate on behalf of Covered Entity, Business Associate's obligations under this contract shall be ongoing with respect to that information, unless and until a separate written agreement regarding that information is entered into with Covered Entity.

- B. Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall:
1. Provide an opportunity for Business Associate to cure the breach or end the violation and, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, terminate this Agreement; or
 2. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and Covered Entity determines or reasonably believes that cure is not possible.
- C. Effect of Termination.
1. Upon termination of this Agreement, for any reason, Business Associate shall return or, if agreed to by Covered Entity, destroy all PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. Business Associate shall retain no copies of the PHI. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.
 2. Should Business Associate make an intentional or grossly negligent Breach of PHI in violation of this Agreement or HIPAA or an intentional or grossly negligent disclosure of information protected by the MCMRA, Covered Entity shall have the right to immediately terminate any contract, other than this Agreement, then in force between the Parties, including the Underlying Agreement.
- D. Survival. The obligations of Business Associate under this Section shall survive the termination of this agreement.

V. CONSIDERATION

Business Associate recognizes that the promises it has made in this Agreement shall, henceforth, be detrimentally relied upon by Covered Entity in choosing to continue or commence a business relationship with Business Associate.

VI. REMEDIES IN EVENT OF BREACH OF AGREEMENT

Business Associate hereby recognizes that irreparable harm will result to Covered Entity, and to the business of Covered Entity, in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of breach of any of the covenants and assurances contained in Sections II or III above, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of Sections II or III. Furthermore, in the event of breach of Sections II or III by Business Associate, Covered Entity is entitled to reimbursement and indemnification from Business Associate for Covered Entity's reasonable attorneys' fees and expenses and costs that were reasonably incurred as a proximate result of Business Associate's breach. The remedies contained in this Section VI shall be in addition to, not in lieu of, any action for damages and/or any other remedy Covered Entity may have for breach of any part of this Agreement or the Underlying Agreement or which may be available to Covered Entity at law or in equity.

VII. MODIFICATION; AMENDMENT

This Agreement may only be modified or amended through a writing signed by the Parties and, thus, no oral modification or amendment hereof shall be permitted. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA rules and any other applicable law.

VIII. INTERPRETATION OF THIS AGREEMENT IN RELATION TO OTHER AGREEMENTS BETWEEN THE PARTIES

Should there be any conflict between the language of this Agreement and any other contract entered into between the Parties (either previous or subsequent to the date of this Agreement), the language and provisions of this Agreement shall control and prevail unless the parties specifically refer in a subsequent written agreement to this Agreement by its title and date and specifically state that the provisions of the later written agreement shall control over this Agreement.

IX. COMPLIANCE WITH STATE LAW

The Business Associate acknowledges that by accepting the PHI from Covered Entity, it becomes a holder of medical information under the MCMRA and is subject to the provisions of that law. If the HIPAA Privacy or Security Rules and the MCMRA conflict regarding the degree of protection provided for PHI, Business Associate shall comply with the more restrictive protection requirement.

X. MISCELLANEOUS

- A. Ambiguity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy and Security Rules.
- B. Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- C. Agency. The Business Associate or Subcontractor is acting as an independent contractor and not as the agent of the Covered Entity or Business Associate. This Agreement does not give the Covered Entity or Business Associate such control over operational activities so as to make the Business Associate the agent of the Covered Entity, or the Subcontractor the agent of the Business Associate.
- D. No Private Cause of Action. This Agreement is not intended to and does not create a private cause of action by any individual, other than the parties to this Agreement, as a result of any claim arising out of the Breach of this Agreement, the HIPAA Standards, or other state or federal law or regulation relating to privacy or confidentiality.
- E. Notice to Covered Entity. Any notice required under this Agreement to be given to Covered Entity shall be made in writing to:

Danielle Owens
 Privacy Officer
 Maryland Department of Health
 Office of Internal Controls and Audit Compliance
 201 W. Preston Street, Floor 5
 Baltimore, MD 21201-2301
 Phone: (410) 767-5411
danielle.owens1@maryland.gov

- F. Notice to Business Associate. Any notice required under this Agreement to be given Business Associate shall be made in writing to:

Address: _____

Attention: _____

Phone: _____

- G. Survival. Any provision of this Agreement which contemplates performance or observance subsequent to any termination or expiration of this contract shall survive termination or expiration of this Agreement and continue in full force and effect.

- H. Severability. If any term contained in this Agreement is held or finally determined to be invalid, illegal, or unenforceable in any respect, in whole or in part, such term shall be severed from this Agreement, and the remaining terms contained herein shall continue in full force and effect, and shall in no way be affected, prejudiced, or disturbed thereby.
- I. Terms. All the terms of this Agreement are contractual and not merely recitals and none may be amended or modified except by a writing executed by all parties hereto.
- J. Priority. This Agreement supersedes and renders null and void any and all prior written or oral undertakings or agreements between the parties regarding the subject matter hereof.

IN WITNESS WHEREOF and acknowledging acceptance and agreement of the foregoing, the Parties affix their signatures hereto.

COVERED ENTITY:

By: _____

Name: Perrie Briskin

Title: Deputy Secretary of Health Care
Financing and Medicaid Director

Date: _____

BUSINESS ASSOCIATE:

By: _____

Name: _____

Title: _____

Date: _____

EXHIBIT A

**FORM OF NOTIFICATION TO COVERED ENTITY OF
BREACH OF UNSECURED PHI**

This notification is made pursuant to Section III.2.D(3) of the Business Associate Agreement between the Maryland Department of Health (MDH), and _____
(Business Associate).

Business Associate hereby notifies MDH that there has been a breach of unsecured (unencrypted) protected health information (PHI) that Business Associate has used or has had access to under the terms of the Business Associate Agreement.

Incident Specific Questions:

1. Please provide a brief description of the incident, including what type of information was disclosed or accessed, who received the information and the manner in which it was accessed or disclosed. Also include the names and contact information for all individuals involved:

2. If you believe this incident was inadvertent, accidental or unintentional, please provide any information you have to support that determination:

3. Was the information viewed or actually retained by someone who should not have the information? If so, please explain:

4. What type of identifying information (e.g. names, SSN, medical record number etc.) was acquired, accessed, or disclosed?

5. If available, please provide any information you have about the person or entity that received the information:

6. What steps, if any, have been taken to contain or mitigate the incident? Please provide as much descriptive information as possible:

Additional Incident Details:

Date incident occurred: _____ Date incident was discovered: _____

Estimate number of individuals affected by the breach: _____

Type of incident (e.g. loss, theft, improper disposal, unauthorized access, hacking):

Location of information breach (e.g. laptop, desktop, email, paper files etc.):

Type of information involved (e.g. demographic, financial, clinical):

Safeguards that were in place prior to the breach (e.g. firewalls, encryptions, locks, training):

Please provide any other information you have or believe may be helpful in investigating or resolving this incident. If you wish to include any attachments to this form, please describe the attachments here:

Name

Date

Signature

Please send this form by email to the MDH Privacy Officer - mdh.privacyofficer@maryland.gov.

**APPENDIX B
AGREEMENT TO PAY FQHCs FOR OUT-OF-NETWORK EMERGENCY
SERVICES**

I. PAYMENT REQUIREMENTS

- A. Effective October 1, 2010, an MCO shall reimburse an out-of-network federally qualified health center (FQHC) for services provided to an Enrollee that are immediately required due to an unforeseen illness, injury, or condition if:
1. The FQHC participates in the Medical Assistance Program;
 2. The FQHC does not have a contract with the MCO;
 3. The services are immediately required due to the Enrollee's unforeseen illness, injury, or condition;
 4. The emergent services are provided on site at the FQHC; and
 5. The FQHC has, before rendering services, verified with the Enrollee's primary care provider that the Enrollee cannot be seen within a reasonable amount of time based on the severity of the Enrollee's condition.
- B. An MCO may require that the FQHC provide documentation that the FQHC has obtained the verification required under A(5) of this agreement. An MCO is not required to reimburse an out-of-network FQHC for emergent services provided to an Enrollee if the FQHC fails to provide the documentation.
- C. An MCO may require that the FQHC provide documentation that services were required for the reasons identified under A (3) of this agreement. An MCO is not required to reimburse an out-of-network FQHC for emergent services provided to an Enrollee if the FQHC fails to provide the documentation.
- D. The rate at which the MCO shall reimburse an out-of-network FQHC for services provided under A of this agreement shall be the rate identified in COMAR 10.67.04.21.
- E. For any reimbursement paid by an MCO under A of this agreement, the Program shall pay the MCO the difference between the rates identified in COMAR 10.67.04.21 and COMAR 10.09.08.05.

Initial Here: _____ Date: _____

APPENDIX C MANAGED CARE ORGANIZATION REIMBURSEMENT

This agreement to establish new reimbursement rates is made this _____ day of _____, 2025, between the Maryland Department of Health (MDH) and _____, a Managed Care Organization (MCO).

I. MCO Reimbursement Rates

WHEREAS, the Centers for Medicare and Medicaid Services (CMS) 2020 Medicaid Managed Care Rate Development Guide requires that states include a Medicaid MCO's rates into the HealthChoice Managed Care Organization Agreement, and amend the Agreement whenever the rates change in accordance with 42 CFR 438.7(c); and

WHEREAS, MDH has established new rates, as set forth in Appendix C, effective January 1, 2026.

NOW, THEREFORE:

1. MCO agrees to accept the reimbursement rates set forth in Appendix C, effective January 1, 2026.
2. MDH agrees to reimburse MCO at the rates set forth in Appendix C, effective January 1, 2026.

II. Mid-Year Rate Re-Opening for Calendar Year 2026

WHEREAS, MDH has established a mid-year rate re-opening methodology for calendar year 2026 that would revisit all unit cost and utilization trend adjustments for all service categories.

WHEREAS, COMAR 10.67.04.19 (D) allows for:

- (c) An increase or decrease in the inpatient charge per case as calculated by the change in the restated unit cost provided annually by the HSCRC as compared to the data originally provided; or
- (d) An increase or decrease in the outpatient charge per visit as calculated by the change in the restated unit cost provided annually by the HSCRC as compared to the data originally provided.

WHEREAS, to account for MCO hospital experience, MDH has established the mid-year rate re-opening methodology for calendar year 2026 that would revisit the hospital unit cost experience.

When COMAR 10.67.04.19 (D) allows for an update for the latest HSCRC information, the actuary will review the latest MCO experience to align all of the updates to the emerging hospital unit cost data trends.

To assist with the assessment, the MCOs will provide additional data to MDH, including detailed claims data as well as a year-to-date HFMR for calendar year 2026.

III. HealthChoice Maternal and Child Health Initiative Risk Corridor for Calendar Year 2026

MDH and the MCO agree to establish the following risk corridor for doulas, home visiting services, CenteringPregnancy services, HealthySteps, and Maternal Opioid Misuse (MOM) for CY 2026:

1. The 2026 risk corridor will include target medical expenditures for the MCO of \$0.50 PMPM.
2. No reconciliation will occur for expenditures within a +/- 10% corridor of the target, or between \$0.45 and \$0.55.
3. For expenditures below \$0.45, the MCO must make a payment back to MDH in the amount below \$0.45 multiplied by enrollment.
4. For expenditures above \$0.55, MDH must make a payment to the MCO in the amount above \$0.55 multiplied by enrollment.

[INSERT RATE TABLE]

[INSERT RATE TABLE]

IN WITNESS WHEREOF, the parties hereto have hereunder executed this Appendix the day and year first above written.

FOR MDH:

Date

Perrie Briskin
Deputy Secretary, Health Care Financing
Medicaid Director
Maryland Department of Health

FOR THE MCO:

Date

Signature

APPENDIX D

HEALTHCHOICE MCO PERFORMANCE MONITORING POLICIES

MDH may choose any of the performance enforcement options described, depending on the severity and persistence of the issue. MDH is not required to use the enforcement tools sequentially as a form of “progressive discipline.” Rather, MDH may use its judgment and discretion, as the oversight agency with fiduciary responsibilities, to utilize the appropriate enforcement tool for the situation.

MDH reserves flexibility in the process and timing for rescinding penalties.

Network Adequacy

COMAR 10.67.05 sets forth network requirements for MCOs. MDH can act when MCOs are not in compliance with 10.67.05 and/or when a provider or recipient submits a complaint.

HEDIS Measures

MDH will send MCOs an annual HEDIS announcement letter containing the specific preliminary measures/elements for the measurement year in the month of October prior to the start of the measurement year. MDH will provide MCOs a 30-day comment period to provide feedback. MDH will respond to comments and finalize the measure set when NCQA releases the Health Plan Accreditation measures in the spring of the measurement year under review. Baseline measures and measures with trending breaks will not be reviewed as part of HEDIS performance monitoring.

The National HEDIS means (NHMs) used for the analysis will return to being sourced from the NCQA national HEDIS Medicaid HMO means and percentiles for the prior measurement year, beginning with HEDIS Measurement Year 2024 and going forward. Historically:

- Performance monitoring comparisons for HEDIS Measurement Years 2022 and 2023 were based on the NCQA national HEDIS Medicaid HMO means and percentiles from the *same* HEDIS measurement year.
- Performance monitoring comparisons for HEDIS Measurement Year 2021 and prior years were based on the NCQA national HEDIS Medicaid HMO means and percentiles from the *prior* HEDIS measurement year.

Low HEDIS scores could result in a consumer report card star rating change or ineligibility for incentives in the Population Health Improvement Program (PHIP) Initiative. For purposes of trending, results from HEDIS Measurement Year 2020 will be removed from consideration when considering potential sanctions.

Enforcement periods consist of a rolling five (5) measurement year review of available HEDIS data and comparisons to the NHMs in effect during the applicable Agreement term, excluding Measurement Year 2020 as indicated above.

The five-year review period is triggered when an MCO receives a finding during the measurement year governed by this Agreement (e.g., if an MCO has 40% or more HEDIS

measures below the prior year's NHM for HEDIS Measurement Year 2026, MDH will then review HEDIS performance monitoring results for Measurement Years 2022-2026 to determine if Moderate or Major HEDIS Problems are present).

Beginning with Measurement Year 2025, an MCO with a HEDIS performance monitoring finding may not participate in the Population Health Incentive Program (PHIP) for that measurement year. However, if an MCO does not have a HEDIS performance monitoring finding, the MCO is eligible to participate in PHIP.

EPSDT/Healthy Kids Review

An assessment is performed for each MCO in each of the following EPSDT components: Health and Developmental History, Comprehensive Physical Examination, Laboratory Tests/At-Risk Screenings, Immunizations, and Health Education and Anticipatory Guidance. The minimum compliance score for each component is 80%.

Systems Performance Review

To relieve administrative burdens on MCOs, MDH switched to administering full SPRs for each MCO on a three-year cycle, beginning in SPR Reporting Year 2016 (Review Year CY 2015). During interim years between triennial reviews, auditors will only review elements or components which received a "partially met" or "unmet" rating to assess MCO CAP implementation.

Performance Improvement Project Validation

Performance improvement projects (PIPs) are evaluated through the external quality review organization (EQRO) PIP Validation process. The EQRO PIP Validation follows the federal PIP validation protocol which assesses the effort and validity of the steps the MCO takes to reach the health outcome or satisfaction improvement goal. The first validation year subject to Performance Monitoring findings is results reported during calendar year 2025.

Part 1. Enforcement Guidelines – Minor Problems

	MCO Network Adequacy	HEDIS Performance	EPSDT/ Healthy Kids Review	Systems Performance Review (SPR)	PIP Validation
Examples of Minor Problems	Minor provider or recipient complaint.	- One year with 40% or more elements with scores below the National Medicaid HEDIS Mean (NHM). - Two consecutive years with 40% or more elements with scores below the NHM.	Receives less than 80% in one or more components for a review year.	Does not receive a “Met” in an element or component.	Receives a “Low Confidence” finding on the annual EQRO PIP validation.
Enforcement	- Verbal request for clarification. - Corrective Action Plan (CAP) to prevent a future network adequacy problem. - Geo-Access Report.	- Letter to MCO advising of monitoring policy, measures below the NHM, and enforcement options. - Exclusion from participation in PHIP.	Written CAP within 45 days of presentation of preliminary report.	- Written CAP within 45 days of presentation of preliminary report. - Focused EQRO audit of specific elements/components on an annual basis.	- Letter to MCO advising of monitoring policy, PIP validation finding, and enforcement options, along with recommendations from MDH Intervention Evaluation Report.

Part 2. Enforcement Guidelines – Moderate Problems

	MCO Network Adequacy	HEDIS Performance	EPSDT/Healthy Kids Review	SPR	PIP Validation
Examples of Moderate Problems	Persistent minor provider or recipient complaints PCP to recipient ratio appears inadequate but recipients are still able to access a PCP.	Three years in a row or three years within a five-year period with 40% or more elements with scores below the NHM.	Receives less than 80% in one or more components for two review years -- this score could be for the same component or different components.	Receives an “Unmet” score two years in a row on the same element (without components) or an “unmet” or “partially met” score on the same component.	Receives a “Not Credible” finding on the annual EQRO PIP validation.
Enforcement	- Written CAP within 30 days of finding. - Geo-Access Report. - Financial sanctions. - Required to pay for out-of-network care and transportation.	- Letter to MCO advising of monitoring policy, measures below the NHM, and enforcement options. - Financial sanctions. - Freeze auto assignments in areas of the state as determined by MDH for one month. - Exclusion from participation in PHIP.	- Written CAP within 45 days of presentation of preliminary report. - Focused provider education project of specific component for two calendar years.	- Second Partially Met score on component will be changed to an Unmet score. - Written CAP within 45 days of presentation of preliminary report. - Focused EQRO audit of specific elements or components on an annual basis. - Monitoring of CAP by EQRO on quarterly basis, with failure to implement linked to freezing auto-assignments, freezing voluntary assignments, or financial sanctions.	- Letter to MCO advising of monitoring policy, PIP validation finding, and enforcement options, along with recommendations from MDH Intervention Evaluation Report. - Written CAP to address improvement of project plan to increase the confidence level.

Part 3. Enforcement Guidelines – Major Problems

	MCO Network Adequacy	HEDIS Performance	EPSDT/Healthy Kids Review	SPR	PIP Validation
Examples of Major Problems	- Persistent PCP to recipient ratio appears inadequate (greater than 1:500) but recipients are still able to access a PCP. - No access to OB/GYN and/or no choice of PCP.	- Four years in a row or four years within a five-year period with 40% or more elements with scores below the NHM.	Receives less than 80% in one or more components for three consecutive years, or for three years within a five-year period – this score could be for the same component or different components.	Receives an “Unmet” score three or more years in a row on the same element (without components) or an “unmet” or “partially met” score on the same component.	Receives a “Not Credible” finding on the EQRO PIP validation for two or more years during the PIP project cycle.
Enforcement	- CAP within 10 days of finding. - Geo Access Report. - Financial Sanction. - Required to pay for out-of-network care and transportation. - Allow recipients in problem service area(s) to voluntarily disenroll from MCO immediately. - Freeze auto assignments in problem service area(s). - Freeze voluntary enrollment in	- Letter to MCO advising of monitoring policy, measures below the NHM, and enforcement options. - Freeze auto assignments in areas of the state as determined by MDH for two months for four years with findings and for three months for five years with findings. - Freeze voluntary enrollment in	- Written CAP within 45 days of presentation of preliminary report. - Monitoring of CAP by EQRO on quarterly basis, with failure to implement linked to freezing auto-assignments or financial sanctions. - Focused provider education project of specific component for three calendar years. - Freeze auto assignments in areas of the state determined by MDH.	- Second Partially Met score on component will be changed to an Unmet score. - Written CAP within 45 days of presentation of preliminary report. - Focused EQRO audit of specific elements or components on an annual basis. - Monitoring of CAP by EQRO on quarterly basis, with failure to implement linked to freezing auto-assignments,	- Written CAP to address improvement of project plan to increase the confidence level. - Continuation of project until permitted to sunset by MDH.

	problem service area(s). - Freeze the MCO to all future enrollment in problem service area(s) (moving current recipients into another MCO of their choice). - Additional financial sanctions beyond paying for out-of-network care and transportation. - Contract termination/MCO closure in all affected counties.	areas of the state as determined by MDH. - Financial sanctions. - Exclusion from participation in PHIP. - Contract termination and MCO closure in all counties.		freezing voluntary assignments, or financial sanctions. - Application of financial sanctions.	
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APPENDIX E

MANAGED CARE ORGANIZATION SERVICE AREA PARTICIPATION AND OPTIONAL SERVICES AND BENEFITS

This agreement to designate Service Area Participation and Optional Services or Benefits is made this _____ day of _____, 2025, between the Maryland Department of Health (MDH) and _____, a Managed Care Organization (MCO).

A. Definitions.

All terms capitalized herein shall have the same meaning as those in the HealthChoice Managed Care Organization agreement, except that the following terms shall have the meanings stated:

1. “Participation” means the arrangement under which the MCO arranges for and/or provides services to Enrollees in approved Service Areas, subject to applicable provisions of federal law, the Maryland Code, COMAR, transmittals, and guidelines issued by MDH in effect at any time during the term of this Agreement. “Participation” includes the MCO’s enrollment of Medicaid recipients who have selected the MCO and those auto-assigned by MDH.
2. “Service Areas” means the 23 counties and Baltimore City that comprise the State of Maryland.
3. “Open” means any Service Area that the MCO has participated in during the previous calendar year.
4. “Closed” means any Service Area in which the MCO has never participated.
5. “Involuntarily Frozen” means any Service Area in which MDH freezes the auto-assignment of enrollees in a Service Area, for reasons including, but not limited to, insufficient provider networks and imposition of sanctions.
6. “Voluntarily Frozen” means any Service Area in which the MCO requests freezing the auto-assignment of enrollees. Being “Voluntarily Frozen” remains in effect for two calendar years.
7. “Request to Open” means a request by the MCO to Open any Service Area that was previously Closed, Voluntarily Frozen, or Involuntarily Frozen, pending review and approval by MDH.
8. “Optional Service or Benefit” means any service that the MCO voluntarily agrees to provide whose cost is not included in the capitation rates determined in Appendix C or future iterations of this Agreement.

B. The MCO agrees:

1. To express its intent to Open, Request to Open, or request to be Voluntarily Frozen in a Service Area during the term of this Agreement, effective January 1, 2026, as identified in this Appendix in accordance with 42 CFR 438.207;
2. That a Request to Open and a request to be Voluntarily Frozen are subject to review and approval by MDH before they become effective;
3. That MDH's approval of a request to be Voluntarily Frozen in a Service Area does not stay any obligation under this Agreement to accept and serve Enrollees who select the MCO;
4. To provide the Optional Services or Benefits during the term of this Agreement, effective January 1, 2026, as identified in this Appendix in accordance with 42 CFR 438.3(e);

C. MDH and the MCO agree:

1. That the costs of any Optional Services or Benefits shall not be included when determining the capitation rates identified in Appendix C of this Agreement or future capitation rate calculations; and
2. That the provision of services identified in this Appendix is subject to approval of this Agreement by the Centers for Medicare and Medicaid Services.

MCO SERVICE AREA PARTICIPATION

Service Area	Current Participation Status	No Change	Request to Open	Request to Voluntarily Freeze Enrollment
Allegany				
Anne Arundel				
Baltimore City				
Baltimore County				
Calvert				
Caroline				
Carroll				
Cecil				
Charles				
Dorchester				
Frederick				
Garrett				
Harford				
Howard				
Kent				
Montgomery				
Prince George's				
Queen Anne's				
St. Mary's				
Somerset				
Talbot				
Washington				
Wicomico				
Worcester				

OPTIONAL BENEFITS OFFERED BY THE MCO

Please complete each field below in detail. The MCO is committing to offering the optional benefits identified below for the entire period of this Agreement.

Benefit <i>Include description of the benefit</i>	Population <i>What age group is this benefit available for?</i>	Limitations (if applicable) <i>Include any quantity limits, maximum allowances, etc.</i>

IN WITNESS WHEREOF, the parties hereto have hereunder executed this Appendix the day and year first above written.

FOR MDH:

Date

Perrie Briskin
Deputy Secretary, Health Care Financing
Medicaid Director
Maryland Department of Health

FOR THE MCO:

Date

Signature

APPENDIX F

HEALTHCHOICE NETWORK ADEQUACY STANDARDS

To comply with the requirements of 42 CFR 438.68, MDH is responsible for developing minimum time and distance standards for HealthChoice MCO provider networks. MDH developed these standards by adapting the Health Service Delivery (HSD) standards for Maryland Medicare Advantage plans and the current HealthChoice regional and distance network standards. For each provider type, MCOs must meet either the time or distance standard for each county in the MCO's service area.

Provider Type	Urban ¹		Suburban ²		Rural ³	
	Max Time (min)	Max Distance (miles)	Max Time (min)	Max Distance (miles)	Max Time (min)	Max Distance (miles)
Primary Care	15	10	30	20	40	30
Primary Care - Pediatric	15	10	30	20	40	30
Pharmacy	15	10	30	20	40	30
Diagnostic Laboratory/X-Ray	15	10	30	20	40	30
Gynecologists	15	10	30	20	40	30
Prenatal Care Providers⁴	15	10	30	20	90	75
Acute Inpatient Hospitals	20	10	45	30	75	60
Core Specialties (Cardiology, ENT, Gastroenterology, Neurology, Oncology, Ophthalmology, Orthopedics, Surgery, Urology)	30	15	60	45	90	75
Major Specialties (Allergy and Immunology, Dermatology, Endocrinology, Infectious Diseases, Nephrology, Pulmonology)	30	15	80	60	110	90
Pediatric Sub-Specialties (Cardiology, Gastroenterology, Neurology, Surgery)	30	15	80	60	250	200

¹ Urban Counties: Baltimore City

² Suburban Counties: Anne Arundel, Baltimore, Carroll, Harford, Howard, Montgomery, Prince George's

³ Rural Counties: Allegany, Calvert, Caroline, Cecil, Charles, Dorchester, Frederick, Garrett, Kent, Queen Anne's, St. Mary's, Somerset, Talbot, Washington, Wicomico, Worcester

⁴ Prenatal Care providers are inclusive of family practitioners who provide prenatal care and perform deliveries, obstetricians, and certified nurse midwives.

ADDITIONAL NETWORK REQUIREMENTS

HealthChoice MCOs must meet all network requirements set forth in COMAR 10.67.05, including:

1. Offering an appropriate range of preventive, primary care, and specialty services adequate for the anticipated number of Enrollees in the MCO's service areas.
2. Maintaining a network of providers sufficient in number, mix, and geographic distribution to meet the needs of the number of Enrollees in the MCO's service areas.
3. Ensuring that in-plan individual practitioners, based on full-time equivalency, are assigned no more than the number of enrollees that is consistent with a 200:1 ratio of enrollee to practitioner in the local access area.
4. Maintaining written policies and procedures for selecting and retaining network providers in accordance with the requirements of 42 CFR 438.214 and the applicable provider panel provisions of Maryland Insurance Article § 15-112, Code Ann.
5. Ensuring that all network providers are screened, enrolled, and revalidated by the State as Medicaid providers, in accordance with 42 CFR part 455, subparts B and E, and validate enrollment by verifying against MDH's full fee-for-service provider file.
6. Accepting the Maryland Uniform Credentialing Form for the credentialing of network providers.
7. Refraining from discriminating against providers serving high-risk populations or specializing in conditions requiring costly treatment.
8. Informing all providers at the time of entering into a contract with the MCO about the grievance and appeal system, as set forth in 42 CFR 438.414 and 42 CFR 438.10(g)(2)(xi).
9. Monitoring MDH's correspondence and any database publicizing Department-initiated terminations of providers from the Program.
10. Terminating the contract of, or refraining from contracting with, providers terminated or excluded from participating in the Program.
11. Developing and distributing a provider manual that includes all the information provided in MDH's template and required in COMAR 10.67.05.04A(2).
12. Ensuring services are delivered in a culturally competent manner to all enrollees, including enrollees with limited English proficiency; enrollees with diverse cultural and ethnic backgrounds; and enrollees of all genders, sexual orientations, and gender identities.
13. Ensuring its provider network can provide physical access, reasonable accommodation, and accessible equipment for Enrollees with physical or mental disabilities.
14. Providing necessary services covered under the contract out of network adequately and timely for a particular Enrollee, for as long as the MCO's provider network is unable to provide them.
15. Doula Quantitative Network Adequacy Standards
 - a. For urban areas (Baltimore City), MCOs are required to have a minimum of four doulas.
 - b. For suburban areas (Anne Arundel, Baltimore, Carroll, Harford, Howard, Montgomery, and Prince George's counties), MCOs are required to have a minimum of four doulas serving each county.
 - c. For rural areas in the Eastern Shore region (Caroline, Cecil, Dorchester, Kent, Queen Anne's, Somerset, Talbot, Wicomico, and Worcester counties), MCOs are required to have a minimum of two doulas serving the region.

- d. For rural areas in Southern Maryland (Calvert, Charles, and St. Mary's counties), MCOs are required to have a minimum of two doulas serving the region.
- e. For rural areas in Western Maryland (Allegany, Garrett, Frederick, and Washington counties), MCOs are required to have a minimum of two doulas serving the region.

MONITORING AND ENFORCEMENT

HealthChoice MCOs will be required to give assurances to MDH annually, along with supporting documentation, demonstrating their provider network's capacity to serve enrollees in a format specified by MDH. When an MCO cannot demonstrate adequate coverage for 90% of enrollees in a service area at the required time or distance, MDH may freeze auto-assignments in the impacted service area.

When an MCO proposes expansion into a new county, MDH will evaluate its provider network according to the time and distance standards in that service area. If the MCO can demonstrate adequate coverage for 90% of enrollees at the required time or distance standards in the county for each provider type, MDH will allow the MCO to open in that county.

If an MCO can otherwise demonstrate to MDH's satisfaction the adequacy of its provider network notwithstanding its inability to meet these requirements, MDH may, in its discretion, approve the network if special circumstances exist which, considered along with the overall strength of the MCO's network, establish that MDH's approval of the network will enhance recipients' overall access to quality health care services in the area to be served.

APPENDIX G

MARYLAND MEDICAID MEDICAL LOSS RATIO (MLR) REPORTING TEMPLATE INSTRUCTIONS

PURPOSE AND OBJECTIVE

The purpose of these instructions is to define the annual financial reporting requirements for the Medical Loss Ratio (MLR) Reporting Template based on the contract with the State of Maryland (State), the Department of Health (Department), to provide services to members of the State's Medicaid managed care program. These instructions are intended to establish consistent and uniform reporting by all health plans. The MCO must use the Maryland Medicaid MLR Reporting Template Instructions contained herein in Appendix G of this Agreement, and the template provided to it by MDH and/or its designee, by September 1 of the calendar year following the measurement year.

The MLR Reporting Template is to be completed and submitted to the Department or its designee by the due date outlined within these instructions. The health plan shall submit the MLR Reporting Template without alteration, unless directed otherwise by the Department or its designee.

Input fields for the MLR Reporting Template are shaded in light yellow. Unanswered questions or blank lines throughout the MLR Reporting Template will render it incomplete and may result in a resubmission request. If no answers or entries are appropriate, enter "Not Applicable (N/A)" or "0" in the input field. Any resubmission must have prior Department approval of the special circumstances.

The health plan must use comments, explanations, and notes any time it is necessary to provide further explanation in support of information reflected within the MLR Reporting Template.

Unless noted otherwise, Generally Accepted Accounting Principles (GAAP) are to be used in the preparation of the MLR Reporting Template. All revenues and expenses are to be reported using the accrual basis of accounting. The accrual basis of accounting recognizes revenue when it is earned and expenses in the period incurred, without regard to the time of receipt or payment of cash.

Any line heading with the description of "Reserved" should be left blank. These lines will be used for future reporting, if necessary.

References throughout the instructions are included for proper citation of guidance. The referencing is related to the MLR reporting, and references are noted within each applicable section.

- The Medicaid and Children's Health Insurance Program (CHIP) rule (CMS-2390-F), published on May 6, 2016 requires all Medicaid and CHIP managed care programs ensure, through contracts for rating periods starting on or after

July 1, 2017, that each health plan calculates and submits an MLR in accordance with 42 Code of Federal Regulations (CFR) § 438.8.

- The Medicaid Program: Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality rule (CMS-2439-F), published on May 10, 2024.

These instructions will be periodically reviewed by the Department to evaluate its applicability to the present circumstances and to recommend changes. The Department may seek input from the health plans, auditors, and actuaries during the review. Any necessary changes will be implemented prior to the new calendar year.

Documentation is necessary to adequately support the reported data per 42 CFR § 438.604. While supporting documentation is not required at the time of the MLR Reporting Template submission, it should be readily available and must be provided upon request for periodic audits in accordance with the requirements of 42 CFR § 438.602(e) unless otherwise requested by the Department.

Per 42 CFR § 438.3(u), health plans and subcontractors, as applicable, are required to retain records for a period of no less than 10 years.

Require any third-party vendor providing services to enrollees to supply all underlying data to that health plan within 180 days of the end of the MLR reporting period or within 30 days of being requested by the health plan, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting per 42 CFR § 438.8(k)(3).

WORKSHEET 1 – OVERVIEW

The Overview tab contains links to all tabs within the Reporting Template Contents, Entity, and Reporting Period tables.

Entity

Input requested health plan information as required.

Per 42 CFR § 438.8(k)(xii), the health plan's aggregation method description for all Medicaid and CHIP populations covered under the contract with the State is required.

Within the input field outline health plan specifics.

42 CFR § 438.8(k)(xii) A description of the aggregation method used under paragraph (i) of this section.

Reporting Period

The MLR Reporting Template captures data on a calendar year (CY) reporting period.

The table below defines the MLR reporting period, based on dates of service (incurred from/through), paid through date, and submission due date.

If the template submission due date is a non-business day, submit on the following business day.

Reporting Period	Incurred From	Incurred Through	Paid Through Date	Template Due Date
Annual (CY)	January 1	December 31	June 30	September 1

WORKSHEET 2 – MLR CALCULATION

The health plan must submit to the Department a report which complies with the requirements concerning premium revenue received and expenses related to Maryland Medicaid enrollees [42 CFR § 438.8(a)]. A June 30 paid through date is required for the annual MLR calculation.

In 42 CFR § 438.4(b)(9), CMS requires the MLR for health plans as calculated and reported under 42 CFR § 438.8 be used in the development of actuarially-sound capitation rates effective for rating periods starting on or after July 1, 2017. The MLR is used to assess whether capitation rates are appropriately set by generally illustrating how these funds are spent on incurred claims and health care quality improvement (HCQI)/health information technology (HIT)/external quality review (EQR) as compared to administrative expenses. The MLR also demonstrates adequate amounts under the capitation payments are spent on services for enrollees.

Incurred Claims Expenditures

For both inpatient and skilled nursing facility (SNF) claims, claims should be reported based on ‘Admit Date’. Therefore, any claim with an ‘Admit Date’ falling within the calendar year under review should be included on the MLR. For any other claims, the earliest ‘First Date of Service (DOS)’ for the claim should be utilized for MLR reporting.

Claims Paid (Non Subcapitated) – Direct claims that the health plan paid to providers for services or supplies covered under the contract. Health care expenses are to be reported net of third party liability (TPL) and coordination of benefits (COB).

42 CFR § 438.8(e)(2) Incurred claims.

(i) Incurred claims must include the following:

(A) Direct claims that the MCO paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and services meeting the requirements of § 438.3(e) provided to enrollees.

Claims Paid (Subcapitated) – Total amounts paid to the providers for each vendor or capitated provider for the dates of service in the MLR reporting period. Any differences related to the per-member per-month (PMPM) compared to the actual amounts paid to providers should be captured in Non-Claims Costs. All arrangements that are not claim based should be reported within the

subcapitated section, including vendors paid based on an invoiced amount. Pharmacy claims should be reflected as the amounts paid to pharmacies.

- Ensure third party capitated providers (directly providing services to enrollees) are also captured within the MLR Reporting Template. If there are capitated providers, the amount should be reported at the cost of the entity performing the services, to separate the direct provision of covered services from administrative costs. See below for additional clarifications.

Per the May 15, 2019 CMCS Information Bulletin (guidance specific to the Medicaid MLR)

An exception to the general approach applies when a subcontractor, through its own employees, provides Medicaid covered services directly to enrollees. In this circumstance, the entire portion of the amount the Medicaid managed care plan pays to the third-party vendor that is attributable to the third-party vendor's direct provision of Medicaid covered services should be included in incurred claims, even if such amount includes reimbursement for the third-party vendor's own administrative costs related to the direct provision of Medicaid covered services. The phrase "through its own employees" does not include a subcontractor's contracted network of providers because such network providers are not considered employees of the third-party vendor. Additionally, when the subcontractor is also performing an administrative function not attributable to its direct provision of Medicaid covered services, such as eligibility and coverage verification, claims processing, utilization review, or network development, payment by the managed care plan to the subcontractor for such functions are a non-claims administrative expense as described in 42 CFR § 438.8(e)(2)(v)(A), and should not be counted as an incurred claim for the purposes of MLR calculations.

42 CFR § 438.8(e)(2) Incurred claims.

(v) Amounts to be excluded from incurred claims:

- (A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:*
- (1) Amounts paid to third party vendors for secondary network savings.*
 - (2) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.*
 - (3) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in § 438.3(e) and provided to an enrollee.*

IBNR Estimates (Non Subcapitated) – Unpaid claims liabilities for the MLR reporting period, including claims reported that are in the process of being adjusted. This should exclude any margin calculated with total reserves.

42 CFR § 438.8(e)(2) Incurred claims.

(i) *Incurred claims must include the following:*

- (B) *Unpaid claims liabilities for the MLR reporting period, including claims reported that are in the process of being adjusted or claims incurred but not reported.*
- (F) *Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity.*

IBNR Estimates (Subcapitated) – See guidance related to IBNR estimates above.

Paid Provider Incentive and Bonus Payments – Incentive and bonus payment amounts paid to providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards based on dates of service for the MLR reporting period. CMS defines a related party to be an entity that is associated with the health plan through any form of common, privately-held ownership, control, or investment. See the guidance in CMS Publication 15-1, Chapter 10. The objective ensures financial arrangements between a health plan and related parties are not significantly different from the financial arrangements that would have been achieved in the absence of the relationship.

Additionally, only provider incentive and bonus payment arrangements in compliance with the contractual and documentation requirements set forth in 42 CFR § 438.3(i)(3) and (4) will be considered for the MLR calculation.

42 CFR § 438.8(e)(2) Incurred claims.

(iii) *Expenditures that must be included in incurred claims includes the following:*

- (A) *The amount of incentive and bonus payments made, or expected to be made, to network providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.*

IBNR for Provider Incentive and Bonus Payments – Unpaid incentive and bonus payment liabilities associated with the MLR reporting period. See guidance related to IBNR estimates above.

Value-Added Services (VAS) – e.g., Vision and Transportation. Vision services for patients under 21 should not be included in VAS. VAS should not include the entire capitation payment amounts to delegated vendors, rather the portion identified as incurred claims paid expense by the delegated vendor to the medical provider or servicer. See commentary from the federal guidance (CMS-2439-F) for application. Under 42 CFR § 438.3(e)(1), a health plan may voluntarily cover, for enrollees, services that are in addition to those covered under the State plan. These services are often referred to as VAS, and the cost of these services may not be included in the capitation rate; however, as outlined in CMS-2390-F, VAS can be considered as incurred claims in the numerator for the

purposes of the MLR calculation if the services are activities that improve health care quality under 45 CFR § 158.150 and are not excluded under 45 CFR § 158.150(c).

State Directed Payments Expense – All expenses related to state directed payment (SDP) revenues, including the Maryland Quality Innovation Program (M-QIP).

42 CFR § 438.8(e)(2) Incurred claims.

(iii) Expenditures that must be included in incurred claims includes the following:

(C) The amount of payments made to providers under State directed payments described in § 438.6(c).

In Lieu of Services – In lieu of services are medically appropriate and cost-effective substitute services that are not covered services in the Department contract. If these are reflected in a paid lag, the expenses should not be reflected within Claims Paid (Non Subcapitated), but reported separately.

42 CFR § 438.3(e) Services that may be covered by an MCO, PIHP, or PAHP.

(2) An MCO, PIHP, or PAHP may cover, for enrollees, services or settings that are in lieu of services or settings covered under the State plan as follows:

(i) The State determines that the alternative service or setting is a medically appropriate and cost-effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the alternative service or setting;

(iii) The approved in lieu of services are authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP; and

(iv) The utilization and actual cost of in lieu of services is taken into account in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise.

Incurred Claims Inclusions, Deductions, and Exclusions

Direct Fraud Recovery Expenses – Input amount of fraud reduction expenses excluding expenditures on activities related to fraud reduction. Fraud reduction activities are incurred subsequent to the payment of a claim to specifically identify and detect fraudulent claims for recoupment. All other post-payment claim review activities ensuring proper claim payment performed by the health plan as part of the program integrity duties are considered administrative expenses and should be reflected within Non- Claims Costs. The amount of fraud reduction expenses must not include expenditures on activities related to fraud prevention, defined below.

Direct Fraud Recoveries – Claims payments recovered through fraud reduction efforts should be included in incurred claims, not to exceed the amount of fraud reduction expenses.

42 CFR § 438.8(e)(2) Incurred claims.

(iii) Expenditures that must be included in incurred claims includes the following:

(B) The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses must not include activities specified in paragraph (e)(4) of this section.

Fraud prevention activity guidance is noted below. These are expenses incurred prior to the payment of a claim to prevent fraudulent claim payments and must exclude expenses directly related to the recovery of fraud-related claims. The CMS-2390-F rule commentary states, “*In light of our recent decision not to incorporate expenses for fraud prevention activities in the MLR for the private market within the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 final rule, which published in the March 8, 2016 Federal Register (81 FR 12204, 12322), we believe that it is similarly premature for Medicaid to adopt a standard for incorporating fraud prevention activities in the MLR. Consideration of fraud prevention activities should be aligned, to the extent possible, across MLR programs. Therefore, we will finalize § 438.8(e)(4) with the heading ‘‘Fraud prevention activities’’ and specify that ‘‘MCO, PIHP, or PAHP expenditures on activities related to fraud prevention as adopted for the private market at 45 CFR part 158’’ would be incorporated into the Medicaid MLR calculation in the event the private market MLR regulations are amended. Therefore, these expenses are considered routine program integrity activities and should be reflected within line [Expenditures related to activities compliant with 42 CFR § 438.608\(a\)\(1\) through \(5\), \(7\), \(8\), and \(b\).](#)*”

42 CFR § 438.8(e)(4) Fraud prevention activities. MCO, PIHP, or PAHP expenditures on activities related to fraud prevention consistent with regulations adopted for the private market at 45 CFR part 158. Expenditures under this paragraph must not include expenses for fraud reduction efforts in paragraph (e)(2)(iii)(B) of this section.

Claim Recoveries Not included in Claims Paid – Claims that are recoverable for anticipated COB and claim payments recoveries received as a result of subrogation. Amounts are a reduction to incurred claims and should include any claim-related recoveries not captured in a paid lag. For example, COB is the payor payment amount when coverage exists in addition to Medicaid for the member or subrogation where the health plan is asserting a claim against an at-fault party.

42 CFR § 438.8(e)(2) Incurred claims.

(i) Incurred claims must include the following:

(D) Claims that are recoverable for anticipated coordination of benefits.

(E) Claims payments recoveries received as a result of subrogation.

Overpayment Recoveries from Providers – Overpayment recoveries received from providers must be deducted from incurred claims.

42 CFR § 438.8(e)(2) Incurred claims.

(ii) Amounts that must be deducted from incurred claims include the following:

(A) Overpayment recoveries received from network providers.

Pharmacy Drug Rebates and Other types of Payments, Fees, or Adjustments (OPFA) – Amounts are a reduction to incurred claims. Note, spread pricing is not allowable as incurred claims, therefore, if pharmacy claims paid are reported based on amounts paid to the pharmacies within Claims Paid (Non Subcapitated), then the amount related to spread pricing should not be reduced from incurred claims.

- Prescription drug rebates accrued and received by the health plan must be deducted from incurred claims, regardless of whether the health plan acts on the collection process. This should include health plan rebates and rebates retained by the PBM.
- PBM and health plan contractual rate guarantee arrangements must be deducted from incurred claims.
- OPFA may be assessed to pharmacies by the PBM and not visible to the health plan. Any fees assessed, such as transmission fees, network access fees, contract rate guarantees, etc. that ultimately reduce the amount paid to the pharmacy and must be deducted from incurred claims. OPFA falls under the definition of “drug rebate.” Contract rate guarantees requiring additional reimbursement to pharmacies from the PBM would be netted within as a positive value.
 - CMS clarifies the below guidance to require anytime a health plan receives something of value for the provision of a Medicaid covered outpatient drug (e.g., manufacturer rebates, incentive payments, direct or indirect remuneration, goods in kind, etc.), regardless from whom the item of value is received (e.g., pharmaceutical manufacturer, wholesaler, retail pharmacy, etc.), the value of that rebate must be deducted from the amount of incurred claims in the MLR calculation. See the Centers for Medicaid and CHIP Services (CMCS) Informational Bulletin: Medicaid Prescription Spread Pricing, dated May 15, 2019 for additional guidance.

42 CFR § 438.8(e)(2) Incurred claims.

(ii) Amounts that must be deducted from incurred claims include the following:

(B) Prescription drug rebates received and accrued.

Carve Out Services Reported in Claims Paid – Input any reductions for carve out services reported within Claims Paid (Non Subcapitated). If carve out services were excluded from claims paid reporting in paid lags, then input as a zero amount.

Provider Settlements Not Included in Claims Paid – Settlements should be reported based on date of service. If there are no settlements outside of the paid lag, then input as a zero amount.

Other Inclusions, Deductions, or Exclusions – Input any other expenses, not separately identified that should be reported.

42 CFR § 438.8(e)(2) Incurred claims.

(i) Incurred claims must include:

(C) Withholds from payments made to network providers.

(G) Changes in other claims-related reserves.

(H) Reserves for contingent benefits and the medical claim portion of lawsuits.

42 CFR § 438.8(e)(2) Incurred claims.

(iv) Amounts that must either be included in or deducted from incurred claims include, respectively, net payments or receipts related to State mandated solvency funds.

(v) Amounts to be excluded from incurred claims:

(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

(4) Fines and penalties assessed by regulatory authorities.

(B) Amounts paid to the State as remittance under paragraph (j) of this section.

(C) Amounts paid to network providers under to § 438.6(d).

HCQI, HIT, and EQR Expenditures

Guidance for HCQI, HIT, and EQR expenses is outlined below.

HCQI Guidance

42 CFR § 438.8(e)(3) Activities that improve health care quality. Activities that improve health care quality must be in one of the following categories:

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR § 158.150(a) and (b) and is not excluded under 45 CFR § 158.150(c).

(ii) An MCO, PIHP, or PAHP activity related to any EQR-related activity as described in § 438.358(b) and (c).

(iii) Any MCO, PIHP, or PAHP expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found

in 45 CFR § 158.151, and is not considered incurred claims, as defined in paragraph (e)(2) of this section.

45 CFR § 158.150 specifically defines the allowable and non-allowable activities related to this expense. The expense must be directly related to the improvement of the health care quality. Direct administrative costs that do not qualify as allowable quality improvement cost should be excluded from the MLR calculation. Specific reporting treatment for HCQI is noted below.

45 CFR § 158.150(a) General requirements. The report required in § 158.110 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

45 CFR § 158.150(b) Activity requirements. Activities conducted by an issuer to improve quality must meet the following requirements:

- (1) The activity must be designed to:*
 - (i) Improve health quality.*
 - (ii) Increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.*
 - (iii) Be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage, as long as no additional costs are incurred due to the non-enrollees.*
 - (iv) Be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.*

Additional examples and further categorization are provided in the guidance at 45 CFR § 158.150(b)(2).

Vendor costs for quality improvement activities (QIA), per clarifying CMS guidance, outline expenses that must be reported at the cost of the vendor providing services. Vendors are limited to the same costs that could be claimed by the health plan should they have done it themselves internally. CMS states “Where an issuer performs its own QIA without engaging a vendor, any “profit” that it makes on such QIA cannot be included in the MLR calculation. Accordingly, where an issuer chooses to outsource its QIA to a third party, rather than developing the necessary skills in-house, as it does for other issuer functions such as claims processing, network development, clinical policies, and case and utilization management, for example, for MLR reporting and rebate purposes that vendor stands in the shoes of the issuer. Consequently, the vendor’s indirect costs, as well as any profit, cannot be reported as a QIA expense that is included in the MLR calculation.”

Indirect or overhead costs have now been specifically identified as non-allowable for reporting of HCQI. Commentary within the Marketplace guidance includes specific

examples such as “Office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of counsel and executives, computer and telephone usage, travel and entertainment, company parties and retreats, IT systems, and marketing of issuers’ products.” This was clarified further in the CMS 2439-F rule to align with Marketplace, reference commentary.

45 CFR § 158.150(c) Exclusions. Expenditures and activities that must not be included in quality improving activities are:

- (1) Those that are designed primarily to control or contain costs;*
- (2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans;*
- (3) Those which otherwise meet the definitions for quality improvement activities but which were paid for with grant money or other funding separate from premium revenue;*
- (4) Those activities that can be billed or allocated by a provider for care delivery and which are, therefore, reimbursed as clinical services;*
- (5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, including maintenance of ICD–10 code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.*
- (6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality;*
- (7) All retrospective and concurrent utilization review;*
- (8) Fraud prevention activities;*
- (9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason;*
- (10) Provider credentialing;*
- (11) Marketing expenses;*
- (12) Costs associated with calculating and administering individual enrollee or employee incentives;*
- (13) That portion of prospective utilization that does not meet the definition of activities that improve health quality; and*
- (14) Any function or activity not expressly included in paragraph (a) or (b) of this section, unless otherwise approved by and within the discretion of the Secretary, upon adequate showing by the issuer that the activity's costs support the definitions and purposes in this part or otherwise support monitoring,*

measuring or reporting health care quality improvement.

HIT Guidance

45 CFR § 158.151 allows HIT expenses to be included to the extent expenses are required to accomplish the activities allowed as HCQI expense. In order to qualify as an allowed HIT expense, the expense must, in whole or in part, contribute to improving the quality of care, provide the technological infrastructure to enhance current quality improvement, or make new quality improvement initiatives possible.

45 CFR § 158.151(a) General requirements. An issuer may include as activities that improve health care quality such Health Information Technology (HIT) expenses as are required to accomplish the activities allowed in § 158.150 of this subpart and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improvement or make new quality improvement initiatives possible by doing one or more of the following:

- (1) Making incentive payments to health care providers for the adoption of certified electronic health record technologies and their “meaningful use” as defined by HHS to the extent such payments are not included in reimbursement for clinical services as defined in § 158.140 of this subpart;*
- (2) Implementing systems to track and verify the adoption of meaningful use of certified electronic health records technologies by health care providers, including those not eligible for Medicare and Medicaid incentive payments;*
- (3) Providing technical assistance to support adoption and meaningful use of certified electronic health record technologies;*
- (4) Monitoring, measuring, or reporting clinical effectiveness including reporting and analysis of costs related to maintaining accreditation by nationally recognized accrediting organizations such as the NCQA or URAC, or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (for example, CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law.*
- (5) Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes.*
- (6) Advancing the ability of enrollees, providers, issuers, or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care, which may include electronic Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient’s medical history and to support care management.*

- (7) *Reformatting, transmitting, or reporting data to national or international government-based health organizations for the purposes of identifying or treating specific conditions or controlling the spread of disease.*
- (8) *Provision of electronic health records, patient portals, and tools to facilitate patient self- management.*

HIT clarifications from CMS include disallowing allocations of general use software. CMS specifically disallows the allocation of dual functioning systems that serve primarily for functions outside of QIA. Unless the software is primarily related to QIA activities, it cannot be included. CMS states, “*We affirm and clarify that HIT expenses that meet the applicable requirements in §§ 158.150 and 158.151 are permissible costs that can be included as QIA expenses. For example, the cost of software designed and used primarily for QIA purposes, such as HEDIS reporting, constitutes a direct expense related to activities that improve health care quality and can be included in QIA expenses for MLR reporting and rebate purposes. In contrast, as explained above and in the proposed rule, the costs of IT infrastructure that primarily supports regular business functions such as billing, enrollment, claims processing, financial analysis, and cost containment, even when the same IT infrastructure also happens to support QIA activities in addition to regular business functions, do not constitute a direct expense related to activities that improve health care quality and cannot be included in QIA expenses for MLR reporting and rebate purposes.*” This was clarified further in the CMS-2439-F rule, reference commentary.

EQR Guidance

Include any EQR-related activity as described in 45 CFR § 438.358(b) and (c) as noted below.

42 CFR § 438.358(b) Mandatory activities.

- (1) *For each MCO, PIHP, or PAHP the following EQR-related activities must be performed:*
 - (i) *Validation of performance improvement projects required in accordance with § 438.330(b)(1) that were underway during the preceding 12 months.*
 - (ii) *Validation of MCO, PIHP, or PAHP performance measures required in accordance with § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the preceding 12 months.*
 - (iii) *A review, conducted within the previous 3-year period, to determine the MCO’s, PIHP’s, or PAHP’s compliance with the standards set forth in subpart D of this part, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.*
 - (iv) *Validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with requirements set forth in § 438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, § 438.14(b)(1).*

- (2) *For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section must be performed.*

42 CFR § 438.358(c) Optional activities. For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed by using information derived during the preceding 12 months:

- (1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).*
- (2) Administration or validation of consumer or provider surveys of quality of care.*
- (3) Calculation of performance measures in addition to those reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) and validated by an EQRO in accordance with paragraph (b)(1)(ii) of this section.*
- (4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) and validated by an EQRO in accordance with paragraph (b)(1)(i) of this section.*
- (5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.*
- (6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with § 438.334.*

Costs For Reporting Purposes Only

Expenditures related to activities compliant with 42 CFR § 438.608(a)(1) through (5), (7), (8), and (b) – Input expenditures related to administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse and costs to ensure provider screening and enrollment requirements. See Worksheet 7 Program Integrity for additional reporting instructions.

42 CFR § 438.608(a) Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.

- (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 Chief Executive Officer and the board of directors.*
 - (iii) The establishment of a Regulatory Compliance Committee 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.*

- (iv) *A system for training and education for the Compliance Officer, the organization's senior management, and the organization's 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*
- (2) *Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.*
 - (3) *Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:*
 - (i) *Changes in the enrollee's residence;*
 - (ii) *The death of an enrollee.*
 - (4) *Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP.*
 - (5) *Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis.*
 - (7) *Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.*
 - (8) *Provision for the MCO's, PIHP's, or PAHP'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.*

42 CFR § 438.608(b) *Provider screening and enrollment requirements. The State, through its contracts with a MCO, PIHP, PAHP, PCCM, or PCCM entity 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*

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of this chapter. This provision does not require the network provider to render services to FFS beneficiaries.

Non-Claims Costs – All other expenses that are not classified as program integrity, incurred claims, or HCQI/HIT/EQR are Non-Claims Costs. Non-Claims Costs are non-determinate of allowability, not included in the MLR calculation, and are informational only.

42 CFR § 438.8(b) Definitions. As used in this section, the following terms have the indicated meanings:

Non-claims costs means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(2) of this section); expenditures on activities that improve health care quality (as defined in paragraph (e)(3) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f)(2) of this section).

42 CFR § 438.8(e)(2)(v)(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

- (1) Amounts paid to third party vendors for secondary network savings.*
- (2) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.*
- (3) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in § 438.3€ and provided to an enrollee.*
- (4) Fines and penalties assessed by regulatory authorities.*

Revenue

Premium revenue is included as the denominator of the MLR calculation, and defined in 42 CFR § 438.8(f)(2), and reflects revenues received from the Department for the MLR reporting period.

Premium Revenue Inclusions

Capitation Revenue Including Delivery Kick Revenues and Excluding Rural Health and PHIP

– Capitation revenues are payments agreed upon in a capitation contract by the health plan and the Medicaid agency for providing core benefits and services as defined in the terms of the contract. A fixed, pre-arranged monthly payment is received by the health plan for each member enrolled with the health plan. The guidance is noted below in (i). The Maternity Case Rate/Kick Payments, noted below in (ii) for the one-time payments for specific life events are developed within the capitation payments.

Payments deemed as pass-through payments per 42 CFR § 438.6(d) should not be included within the MLR calculation.

42 CFR § 438.8(f)(2) Premium revenue. Premium revenue includes the following for the MLR reporting year:

- (i) State capitation payments, developed in accordance with § 438.4, to the MCO, PIHP, or PAHP for all enrollees under a risk contract approved under § 438.3(a), excluding payments made under § 438.6(d).*
- (ii) State-developed one-time payments, for specific life events of enrollees.*
- (iii) Other payments to the MCO, PIHP, or PAHP approved under § 438.6(b)(3).*

Health plan incentive payments developed under 42 CFR § 438.6(b)(2) should be excluded for MLR reporting purposes. This includes Rural Access Incentive Supplemental Payments and the Population Health Improvement Program (PHIP) payments. See below for commentary on health plan incentive payments.

CMS commentary explains that “incentive payments made to the managed care plan in accordance with 438.6(b)(2) should not be included in the denominator as such payments are in addition to the capitation payments received under the contract. The limit on incentive arrangements in § 438.6(b)(2) is not impacted by the requirements in § 438.8. However, payments earned by managed care plans under a withhold arrangement, as specified at § 438.6(b)(3), should be accounted for in premium revenue for purposes of the MLR calculation because the amount of the withhold is considered in the rate development process and reflected in the rate certification. To that end, we are finalizing § 438.8(f)(2)(iii) to clarify that payments to the MCO, PIHP, or PAHP that are approved under § 438.6(b)(3) are included as premium revenue. Amounts earned by the managed care plans under a withhold arrangement will be included in the denominator as premium revenue. Any amounts of the withhold arrangement that are not paid to the managed care plans would not be included as premium revenue.”

42 CFR § 438.6(b)(2) Basic requirements. Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound. For all incentive arrangements, the contract must provide that the arrangement is—

- (i) For a fixed period of time and performance is measured during the rating period under the contract in which the incentive arrangement is applied.*
- (ii) Not to be renewed automatically.*
- (iii) Made available to both public and private contractors under the same terms of performance.*
- (iv) Does not condition MCO, PIHP, or PAHP participation in the incentive arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.*
- (v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy at § 438.340.*

State Directed Payments Revenue – Input amounts for SDP revenue, including M-QIP and Trauma Fund payments.

42 CFR § 438.8(f)(2) Premium revenue. Premium revenue includes the following for the MLR reporting year:

(vii) Payments to the MCO, PIHP, or PAHP for expenditures under State directed payments described in § 438.6(c).

Accrued Risk Corridor Payments/Receipts – The risk corridor calculation is considered a proper risk-sharing mechanism and captured within the MLR calculation.

Net reinsurance premiums and recoveries are potentially reportable based on (vi) below, provided that this is an approved risk sharing mechanism and meets the appropriate development criteria. However, since reinsurance is not contractually mandated in Maryland, this is considered a non-approved risk sharing mechanism and should be excluded from the MLR reporting. If participating in the Department's stop loss program, amounts paid directly (or deducted from premium revenue) for reinsurance premiums should be removed (or added back) to reflect the full capitation, exclusive of any reinsurance transactions.

42 CFR § 438.8(f)(2) Premium revenue.

(vi) Net payments or receipts related to risk sharing mechanisms developed in accordance with § 438.5 or § 438.6.

Mid-Year Supplemental Capitation Adjustment – See guidance requirements above 42 CFR § 438.8(f)(2).

Hepatitis C Capitation Risk Pool Settlement – See guidance requirements above 42 CFR § 438.8(f)(2).

Federally Qualified Health Center (FQHC) Payments – See guidance requirements above 42 CFR § 438.8(f)(2).

Other Revenues – Paid by the Department to the health plan, in addition to capitation for covered services, not included in any other revenues listed above. This should include risk corridor amounts for the Diabetes Prevention Program and for the Maternal and Child, if applicable.

42 CFR § 438.8(f)(2) Premium revenue.

(iv) Unpaid cost-sharing amounts that the MCO, PIHP, or PAHP could have collected from enrollees under the contract, except those amounts the MCO, PIHP, or PAHP can show it made a reasonable, but unsuccessful, effort to collect.

(v) All changes to unearned premium reserves.

Premium Revenue Deductions

Premium Taxes – If applicable, input the amount of premium tax due to the Maryland Department of Insurance associated with the capitation/premium revenue, settlements, and SDPs based on the general ledger. These amounts are calculated based on the State’s required premium tax rate applied to gross premiums. Review the State’s administrative code to determine if the health plan is exempt from paying premium taxes.

42 CFR § 438.8(f)(3) Federal, State, and local taxes and licensing and regulatory fees. Taxes, licensing and regulatory fees for the MLR reporting year include:

(iv) State and local taxes and assessments including:

(E) State or locality premium taxes plus State or locality taxes based on reserves, if in lieu of premium taxes.

Federal, State, and Local Income Taxes – Input federal, state, and local income tax amounts for the MLR reporting period, based on the general ledger.

Remove taxes related to investment income, and if applicable, factor in the change in deferred tax assets. Amounts should be reported consistently year over year, using the same methodology (GAAP or Statutory Accounting Principles [SAP]). If the health plan changes the methodology across all lines of business, an explanation should be input for the basis for the change, see instructions within Worksheet 4.

42 CFR § 438.8(f)(3) Federal, State, and local taxes and licensing and regulatory fees. Taxes, licensing and regulatory fees for the MLR reporting year include:

(iii) Federal taxes and assessments allocated to MCOs, PIHPs, and PAHPs, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

(iv) State and local taxes and assessments including:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State or locality directly.

(B) Guaranty fund assessments.

(C) Assessments of State or locality industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State or locality income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

Other Taxes, Licensing, and Regulatory Fees – Input the Health Insurance Stabilization Assessment (HISA) tax amount and any other qualifying taxes and fees based on guidance below.

42 CFR § 438.8(f)(3) Federal, State, and local taxes and licensing and regulatory fees. Taxes, licensing and regulatory fees for the MLR reporting year include:

- (i) *Statutory assessments to defray the operating expenses of any State or Federal department.*
- (ii) *Examination fees in lieu of premium taxes as specified by State law.*

Community Benefit Expenditures – Input amounts for community benefit expenditures (CBE) are reserved for not-for-profit health plans exempt from federal income taxes.

Community Benefit Expenditures Percentage Calculated - Limited to 3% – Health plans are limited to three percent of earned premiums or the highest premium tax rate in the State, whichever is greater.

42 CFR § 438.8(f)(3) Federal, State, and local taxes and licensing and regulatory fees. Taxes, licensing and regulatory fees for the MLR reporting year include:

- (v) *Payments made by an MCO, PIHP, or PAHP that are otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 CFR 158.162(c), limited to the highest of either:*
 - (A) *Three percent of earned premium; or*
 - (B) *The highest premium tax rate in the State for which the report is being submitted, multiplied by the MCO's, PIHP's, or PAHP's earned premium in the State.*

45 CFR § 158.162(c) Community benefit expenditures. Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden. This includes any of the following activities that:

- (1) *Are available broadly to the public and serve low-income consumers;*
- (2) *Reduce geographic, financial, or cultural barriers to accessing health services, and if ceased to exist would result in access problems (for example, longer wait times or increased travel distances);*
- (3) *Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;*
- (4) *Leverage or enhance public health department activities such as childhood immunization efforts; and*
- (5) *Otherwise would become the responsibility of government or another tax-exempt organization.*

Federal MLR Calculation

Unadjusted MLR – The Unadjusted MLR percentage for each health plan in a MLR reporting period is the ratio of the benefit expense (numerator) to the revenue (denominator). The MLR will be expressed as a percentage rounded to the first decimal

place. For example, an MLR calculated at 84.9 percent does not meet the minimum MLR requirement of 85 percent.

MLR Credibility – The credibility adjustment is calculated based on the table in Worksheet 3. See Worksheet 3 – Credibility Table for additional information.

Adjusted MLR – The Adjusted MLR percentage is the sum of the Unadjusted MLR and the Credibility Adjustment. The Adjusted MLR percentage is expressed as a percentage, rounded to the first decimal place.

Contract Includes Remittance Requirement – A remittance is required based on HealthChoice contractual requirements. Based on federal guidance, states have the option to implement a remittance. If the health plan does not meet the required MLR, the health plan must refund the Department based on the prescribed calculation with the MLR Reporting Template.

State Minimum MLR Requirement – A minimum MLR of 85 percent aggregate for all covered populations must be reported for each MLR reporting year.

Calculated MLR for Remittance Purposes – The MLR percent to be compared to the required minimum to determine the remittance dollar amount owed.

Remittance Dollar Amount Owed for MLR Reporting Period – If applicable based on the health plan contract, the amount owed to the Department for the MLR reporting period. A health plan may appeal the remittance as a sanction pursuant to COMAR 10.67.10.02.

Member Months

Member Months – Member months represents the number of months an enrollee or a group of enrollees is covered by the health plan for the MLR reporting period. Although the member months are not used in the MLR calculation itself, 42 CFR §§ 438.74(a)(2) 438.8 (k)(xiii) requires that member months be reported on the MLR.

WORKSHEET 3 – CREDIBILITY TABLE

The credibility adjustment is calculated to the MLR percentage achieved if the MLR reporting period experience is partially credible based on the number of member months in the MLR reporting period. The credibility adjustment is added to the MLR percentage achieved prior to comparison to the MLR requirement and remittance calculation. On July 31, 2017, CMS published an Information Bulletin, Medical Loss Ratio (MLR) Credibility Adjustments, which provides an overview and methodology for credibility adjustments in the CMS MLR formula. If the MLR period is not a full reporting year, member months will be annualized for the credibility calculation.

CMS will publish base credibility factors that are developed according to 42 CFR § 438.8(h), as needed.

- The CMS credibility adjustment is used to account for random statistical variation related to the number of enrollees in a health plan.
- The credibility adjustment categorizes health plans into three groups:
 - **Fully Credible** – Health plans with sufficient claims experience, measured in terms of member months, are assumed to experience MLRs that are not subject to random variation as observed in statically insignificant samples. Such health plans will not receive a credibility adjustment for the MLRs.
 - **Partially Credible** – Health plans with sufficient claims experience, measured in terms of member months, to calculate an MLR with a reasonable chance that the difference between the actual and target MLR is statistically significant. Such health plans will receive a partial credibility adjustment to the calculated MLRs.
 - **Non-Credible** – Health plans with insufficient claims experience, measured in terms of member months, to calculate a reliable MLR. Such plans will not be measured against the MLR standard. Health plans in this group are presumed to meet or exceed the target MLR standard.

WORKSHEET 4 – ALLOCATION METHODOLOGY EXPLANATIONS

Allocation of Expense

The health plan should utilize consistent allocation factors between MLR reporting periods and reporting entities and are required to submit methodology(ies) for allocation of expenditures per 42 CFR § 438.8(k)(1)(vii). Reporting will apply to Incurred Claims Expenditures; Incurred Claims Inclusions, Deductions, and Exclusions; HCQI, HIT, and EQR Expenditures; Revenue Deductions; and Non-Claims Costs. Additionally, a drop down is included to input the tax reporting basis utilized (GAAP or SAP).

42 CFR § 438.8(g) Allocation of expense -

(1) General requirements.

- (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.*
- (ii) Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.*

(2) Methods used to allocate expenses.

- (i) *Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.*
- (ii) *Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.*
- (iii) *Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.*

42 CFR § 438.8(k) Reporting requirements -

- (1) *The State, through its contracts, must require each MCO, PIHP, or PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:*
 - (vii) *Methodology(ies) for allocation of expenditures, which must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described in 45 CFR § 158.170(b).*

45 CFR § 158.170 Allocation of expenses -

- (b) *Description of the methods used to allocate expenses. The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.*
 - (1) *Allocation to each category should be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories above will generally be the most accurate method. If a specific identification is not feasible, the issuer should provide an explanation of why it believes the more accurate result will be gained from allocation of expenses based upon pertinent factors or ratios such as studies of employee activities, salary ratios or similar analyses.*
 - (2) *Many entities operate within a group where personnel and facilities are shared. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.*
 - (3) *Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses. Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.*

WORKSHEET 5 – ANNUAL FINANCIAL RECONCILIATION STATEMENT

Complete a comparison of the annual MLR reported information to the audited financial report required under 42 CFR § 438.3(m). Include audited financial statements with an underwriting exhibit reflecting HealthChoice only experience for the current year.

For each reporting category enter the corresponding amount from the audited financial statements, the MLR amounts will automatically populate from Worksheet 2 – MLR Calculation. For any variance, provide an explanation for the difference.

WORKSHEET 6 – ATTESTATION AND MLR REPORTING TEMPLATE INSTRUCTIONS

The health plan must attest to the accuracy of the MLR calculation in accordance with requirements of these instructions when submitting the required report [42 CFR § 438.8(n)].

Submit the certification by the health plan's CEO or CFO that data within the MLR Reporting Template is accurate and representative of health plan experience for the reporting period. The health plan must attest to the accuracy of the MLR calculation in accordance with the instructional requirements when submitting the required report.

42 CFR § 438.8(n) Attestation. MCOs, PIHPs, and PAHPs must attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

WORKSHEET 7 – PROGRAM INTEGRITY

Input the detail of program integrity costs by reporting category, additional categories may be added as needed, to equal amounts reported within the MLR calculation. For each reporting category, provide a description of the services provided and any relevant notes or explanations. See guidance in Worksheet 2.

APPENDIX H

MATERNAL OPIOID MISUSE (MOM) PROGRAM

Per the approved §1115 HealthChoice demonstration waiver for the period of calendar years 2022-2026, MCOs will implement the MOM program.

Under the MOM program, MDH will pay HealthChoice MCOs a per-member-per-month (PMPM) payment to provide a set of enhanced case management services, standardized social determinants of health screenings and care coordination. In addition to the care planning and social determinants of health screening activities conducted at intake, MCO case managers will also be responsible for a minimum of at least one monthly connection with MOM participants. In addition, MCOs must ensure each participant receives at least one somatic or behavioral health service per month.

The MOM intervention provides services distinct from case management and care coordination services already available to Maryland Medicaid participants. MCOs must offer MOM case management services to eligible members as a first option for case management.

MCOs are responsible for outreaching potential participants about MOM each month as part of their recruitment responsibilities.

MCOs are responsible for the following submissions monthly:

I. MONTHLY SUBMISSIONS

- A. **Care Delivery Partner (CDP) Report:** The CDP report documents the monthly program activities of the MCOs. The report should be submitted via email 15 days after the end of the month.
- B. **Outreach Attempt Log (“Log”):** The participant recruitment activities should be documented in the Log following the reporting requirements as communicated by MDH staff. The Log should be submitted via secure File Transfer Protocol (sFTP) 15 days after the end of the month.
- C. **Care Coordination Module (CCM):** Case management activities should be documented for each participant in the CCM by the last day of the month.

Following is a description of the MOM program intervention funded via §1115 authority. Additional detail on implementation and documentation requirements can be found in the MOM Case Management Manual, available at <https://health.maryland.gov/mmcp/Pages/MOM-Model.aspx>.

I. CASE MANAGEMENT SERVICES

- A. **Intake:** Prior to MOM program intake, Maryland Medicaid MCOs will engage in a continuous “no wrong door” approach to identifying potential

MOM program participants. MCOs will make every concerted effort to identify eligible members from multiple sources, *e.g.*, local health departments, local behavioral health authorities, community-based organizations, and provider referrals.

- B. **Assessment:** Once an individual consents to participate in the MOM program the MOM case manager will conduct a set of standard screenings, intended to inform the collaborative development of a care plan and will be revisited at various intervals during MOM program participation, such as health-related social needs. After delivery and during the postpartum period, reassessments will center on the infant-mother dyad, with a focus on parenting, managing stress and other activities that will contribute to a stable and healthy family environment for the infant and reduce the risk of recurrence of use or overdose.
- C. **Creation of a Treatment Plan:** Each participant will work jointly with their MOM case manager during the intake session to develop an initial care plan, which will collect information on all providers who the participant sees for healthcare. Using participant engagement best practices such as motivational interviewing and shared decision-making, the MOM participant will work with their MOM case manager to identify two to three goals based on their identified needs, with time-based and achievable objectives for each goal. The MOM case manager will check in with the participant on their progress towards achieving each goal, addressing needs identified through the assessment and identifying any barriers to completing the goals.
- D. **Coordination:** Each participant will be engaged in MOM program services from the time of intake up until 12-months postpartum or until they lose Medicaid eligibility, unless they opt out or become lost to follow-up (after substantial outreach, below) before that time. On a monthly basis, each participant will receive the following five core components of care coordination:
 - 1. Comprehensive case management;
 - 2. Care coordination;
 - 3. Health promotion;
 - 4. Individual and family supports; and
 - 5. Linkages to community and support services.

Each participant will receive support from their case managers to ensure they are able to attend their appointments; this may include arranging for transportation, peer support, or other supports that facilitate the keeping of

scheduled medical appointments and thus remain engaged in the MOM program.

- E. **Referral:** Each participant will work jointly with their case managers to develop an individualized plan when transitioning from MOM program services. Participants will review the goals developed for their care plan, determine areas that may need continued support, and work with their MCO case managers to perform warm handoffs to other programs if warranted.
- F. **Outreach to Disengaged Participants:** Substantial outreach is a specific protocol for re-engaging participants should they become disengaged from care (e.g., miss a doctor's appointment or miss a monthly case manager contact). Per month of substantial outreach, case managers will need to make and document at least three outreach attempts, two of which must be different types of follow-ups (e.g., two phone calls and one letter in the mail).

II. PAYMENT

- A. MDH will provide a PMPM reimbursement of \$208 in accordance with Section I(A)-(E), to provide intake and case management services, along with ongoing and substantive outreach.
- B. Payment of PMPM reimbursement is contingent upon compliance with the documentation and reporting requirements outlined in Section I.

APPENDIX I

HEALTHCHOICE FINANCIAL SANCTION POLICY

This policy outlines financial sanctions that the Maryland Department of Health (MDH) may levy on Managed Care Organizations (MCOs). It does not address other sanctions available under COMAR 10.67.10 which may be used in addition to or instead of the financial sanctions described in this policy.

MDH may impose any of the financial sanctions described, depending on the severity and persistence of the issue. MDH is not required to use the sanctions sequentially as a form of “progressive discipline.” Rather, MDH may use its judgment and discretion, as the oversight agency with fiduciary responsibilities, to utilize the appropriate sanction for the situation. MDH reserves flexibility in the process and timing for rescinding sanctions.

DEFINITIONS

Corrective Action Plan: A written, detailed plan to address non-conformity with a law, regulation, contract term, policy, or deadline.

Deficiency: A failure to comply with any applicable law, regulation, contract term, policy, or deadline established by MDH or its designees. Each failure to comply is a separate deficiency.

FINANCIAL SANCTION GUIDELINES

1. MDH may impose any of the financial sanctions described below.
2. MDH shall notify an MCO of a deficiency in writing to explain the basis and nature of the deficiency, as well as any sanctions MDH will impose.
3. For any deficiency, MDH may impose a sanction of up to \$1,000,000.
 - a. The notice may include an opportunity for the MCO to submit a plan to take corrective action. The corrective action plan (CAP) will be subject to the review and approval of MDH.
 - b. Should the MCO submit and implement a CAP and it fails to remedy the identified deficiencies, MDH may impose the following financial sanctions, in addition to any sanctions initially imposed for the deficiency:
 - i. One failure to implement: up to \$100,000;
 - ii. Two failures to implement: up to \$500,000; and
 - iii. Three or more failures to implement: up to \$1,000,000.
4. If the deficiency involves a failure to submit a report or CAP, submission of an inaccurate or incomplete report or CAP, or a failure to provide other information requested by MDH or its

designee, MDH may impose a sanction of \$250 for each calendar day the information has not been submitted or is late, inaccurate, or incomplete.

- a. An MCO may request an extension and guidance up to 24 hours prior to the deadline for submission, which MDH may approve or deny.
 - b. The sanction will be applied at 5:00 PM on each day the information is not submitted, inaccurate, or incomplete.
 - c. MDH may double the total sanction assessed for each 14-day period that the information has not been submitted or is late, inaccurate, or incomplete.
5. Any financial sanctions described in this policy or implemented under this policy shall not preclude or otherwise impact MDH's pursuit and recovery of actual damages incurred by MDH resulting from the MCO's deficiencies related to its duties and obligations as an MCO in the HealthChoice program.
6. Financial sanctions will be deducted from the MCO's capitation payment and deposited in the HealthChoice Performance Incentive Fund, in compliance with Health-General Art. § 15-103.3.
7. This policy shall apply, at MDH's discretion, to noncompliance regardless of the timing of the noncompliant activity.
8. Financial sanctions under the threshold of \$50,000 are not appealable.

APPENDIX J

MARYLAND QUALITY INCENTIVE PROGRAM (M-QIP) REQUIREMENTS

Contingent on CMS approval, and in accordance with the federal Medicaid directed payment language in 42 CFR 438.6, the M-QIP Program will be implemented to improve quality outcomes, reduce ED utilization for Ambulatory Sensitive Conditions, and increase access to specialty care, and align with the AHEAD model. The program applies to physician and certain non-physician practitioners employed by or affiliated with the University of Maryland.

- I. Eligible Providers as defined below will be eligible for enhanced payments for patient care services provided. For purposes of M-QIP, an Eligible Provider is limited to the following provider types employed by or affiliated with Faculty Physicians, Inc. (FPI) at the University of Maryland:
 - A. Doctor of Medicine
 - B. Doctors of Osteopathy
 - C. Certified Registered Nurse Anesthetists (CRNAs)
 - D. Certified Registered Nurse Practitioners
 - E. Physician Assistants
 - F. Certified Nurse Midwives (CNMs)
 - G. Clinical Social Workers (CSWs)
 - H. Clinical Psychologists
 - I. Optometrists
 - J. Physical Therapist
 - K. Occupational Therapist
 - L. Speech Therapist
 - M. Audiologists
 - N. Any other providers eligible to bill on the CMS 1500 claim form
- II. The M-QIP program applies only to MCOs that have a contract with FPI. The MCO will not be responsible for services that they do not cover or are carved out of the HealthChoice benefit package.
- III. The MCO shall continue to pay their negotiated base rates to eligible providers throughout the year.
- IV. M-QIP will be funded through a separate payment term pool. The separate payment term pool will contain a set dollar amount for each contract period.
- V. MCOs contracted with FPI will receive quarterly payments from MDH. These MCOs will be required to reimburse FPI from these funds according to a schedule determined by MDH.

APPENDIX K

HEALTHCHOICE DIABETES PREVENTION PROGRAM (DPP) FEE SCHEDULES

There are two reimbursement methodologies available to MCOs for HealthChoice DPP. **MCOs are required to pay contracted CDC-recognized type 2 diabetes prevention programs at least the minimum rates outlined in each methodology.**

Section I outlines the session and performance payment approach for reimbursing in-person and virtual CDC-recognized type 2 diabetes prevention programs. Section II outlines the milestone/bundled payment approach for reimbursing virtual CDC-recognized type 2 diabetes prevention programs only.

Section 1: HealthChoice Session and Performance-Based Reimbursement Methodology for In-Person and Virtual DPP Providers

Participating in-person and virtual CDC-recognized type 2 diabetes prevention programs must use the make-up modifiers when submitting claims for make-up sessions using TS and VM modifiers with any code that has a session attached to it (except for the first session). In-person programs should always use the TS modifier for makeup sessions.⁵ Virtual programs should always use the VM modifier for their makeup sessions.

HCPCS code G9891 is a code used to track attendance and indicate that the CDC-recognized type 2 diabetes prevention program furnished a session that was not accounted for using an attendance performance goal code, such as G9874 (4 core sessions attended). G9891 is a non-payable code for reporting services of sessions furnished to participants (i.e. core sessions 2-3, 5-8, and 10-16).

Table 1. *HealthChoice DPP Session-Based Reimbursement Methodology for Minimum Payment Levels for In-Person and Virtual DPP Providers*

Session/Event	HCPCS Code and Description	Payment	Modifiers			Limitation
			In-Person Make-up Session	Virtual Session ⁶	Virtual Make-Up Session	
Session 1	G9873 ⁷ - 1st core session attended	\$100	None	GT ⁸	None	Can be used 1 time in 365 days ⁹

⁵ In-person programs may conduct make-up sessions online, via some other virtual modality, or over the phone; these are still considered to be delivering the program in-person.

⁶ Virtual DPP refers to online, distance learning or combination delivery modes (combination only when online and distance learning DPP services are rendered).

⁷ CDC-recognized type 2 diabetes prevention programs must have confirmed self-referred individuals' eligibility through a blood test, or provider note indicating history of GDM, prior to billing for this code.

⁸ The modifier GT refers to "via interactive audio and video telecommunications systems."

⁹ In cases where MCOs allow individuals to switch DPP Providers after starting the program, the MCO may need to make an exception to the "can be used 1 time in 365 days" limitation.

Session 2-4	G9874 - 4 total core sessions attended ¹⁰	\$120	TS ¹¹	GT	VM ¹²	Can be used 1 time in 365 days ⁹ Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Session 5-9	G9875 - 9 total core sessions attended ¹³	\$140	TS	GT	VM	Can be used 1 time in 365 days ⁹ Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Session 10-19	G9876 - 2 core maintenance sessions attended in months 7-9 (weight-loss goal not achieved or maintained) ¹⁴	\$40	TS	GT	VM	Can be used 1 time in 365 days ⁹ Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Session 20-22	G9877 - 2 core maintenance sessions attended in months 10-12 (weight loss goal not achieved or maintained) ¹⁵	\$40	TS	GT	VM	Can be used 1 time in 365 days ⁹ Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Number of Sessions	G9891 ¹⁶ - MDPP session reported as a line-item on a claim for a payable MDPP service	\$0	None	GT	None	This CPT code is used to track attendance. This is a non-payable code for reporting services of sessions furnished to participants (i.e. core sessions 2-3, 5-8, and 10-16.)

Performance Payments

¹⁰ Bill with counter code G9891 two times to indicate completion of core sessions 2 and 3.

¹¹ The modifier TS refers to “follow-up service.” In-person programs may only use TS to indicate a makeup session of any modality.

¹² The modifier VM refers to “virtual make-up session.” Virtual programs may only use VM to indicate a makeup session.

¹³ Bill with counter code G9891 four times to indicate completion of core sessions 5, 6, 7, and 8.

¹⁴ Bill with counter code G9891 one time to indicate completion of first of two core maintenance sessions in months 7-9.

¹⁵ Bill with counter code G9891 one time to indicate completion of first of two core maintenance sessions in months 10-12.

¹⁶ A HCPCS G-code for a session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable MDPP services HCPCS G-code. This CPT code is used to track attendance. This is a non-payable code for reporting services of sessions furnished to participants (i.e. core sessions 2-3, 5-8, and 10-16.)

HCPSC codes G9878 and G9879 are both enhanced payments for performance: weight loss achieved or maintained for months 7-9 and 10-12. These codes may only be used in conjunction with either HCPSC code G9880 (5% weight loss) or G9881 (9% weight loss).

Table 2. *HealthChoice DPP Performance-Based Reimbursement Methodology for In-Person and Virtual DPP Providers*

Session/ Event	HCPSC Code and Description	Payment	Modifiers			Limitation
			In-Person Make-up Session	Virtual Session	Virtual Make-Up Session	
5% Weight Loss	G9880 – 5 percent weight loss from baseline achieved	\$100	None	GT8	None	Can be used 1 time in 365 days ⁹
9% Weight Loss	G9881 – 9 percent weight loss from baseline achieved	\$50	None	GT	None	Can be used 1 time in 365 days ⁹
Session 10-19 with at least 5% weight loss	G9878 ¹⁷ - 2 core maintenance sessions attended in months 7-9 and weight loss goal achieved or maintained	\$80	TS11	GT	VM12	Can be used 1 time in 365 days ⁹ Cannot be used with G9876 Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Session 20-22 with at least 5% weight loss	G9879 ¹⁸ - 2 core maintenance sessions attended in months 10-12 and weight loss goal achieved or maintained	\$80	TS	GT	VM	Can be used 1 time in 365 days ⁹ Cannot be used with G9877 Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS

¹⁷ In order to bill G9878 for enhanced attendance, must also bill or have previously billed for weight loss achieved from baseline at either 5% (G9880) or 9% (G9881). Bill with counter code G9891 one time to indicate completion of first of two core maintenance sessions in months 7-9.

¹⁸ In order to bill G9879 for enhanced attendance in this period, must also bill or have previously billed for weight loss achieved from baseline at either 5% (G9880) or 9% (G9881). Bill with counter code G9891 one time to indicate completion of first of two core maintenance sessions in months 10-12.

Assuming the enrollee attends all sessions, and all performance outcomes are met, the total payment per enrollee for the CDC-recognized type 2 diabetes prevention programs based on these rates is \$670.

For community and/or virtual DPP providers whose organizations do not meet the descriptions provided for the place of service code set, they may use the place of service code ‘99’.¹⁹

These HCPCS codes may not be billed with or as nutritional counseling, evaluation and management codes, or other procedure codes when billing for the National DPP lifestyle change program.

Section II: HealthChoice Milestone/Bundled Reimbursement Methodology for Virtual DPP Providers⁶

Table 3, below, lists the recommended HCPCS codes and reimbursement for HealthChoice DPP under the virtual DPP milestone/bundled reimbursement methodology. Flexibility in bundled payment distribution across milestones 1-3 and the 5% and 9% performance payouts will be allowed so long as the total payment per enrollee for the CDC-recognized type 2 diabetes prevention program meets or exceeds \$670.

Table 3. *HealthChoice DPP Milestone/Bundled Reimbursement Methodology for Virtual DPP Providers*

Session/Event	HCPCS Code and Description	Payment	Modifiers			Limitation
			In-Person Make-up Session	Virtual Session ⁶	Virtual Make-Up Session	
Milestone 1: May be billed at enrollment or initiation into program; scale is issued; or 1 st core session attended	Available codes: G98736 - 1st core session attended E1639 ²⁰ 0488T ²¹	\$220	Not applicable	GT8	None	Can be used 1 time in 365 days ⁹
Milestone 2: Billed at 4 core sessions attended	G9874 - 4 total core sessions attended	\$160	Not applicable	GT	VM12	Can be used 1 time in 365 days ⁹ Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Milestone 3: Billed at 9 core sessions attended	G9875-9 core sessions attended	\$140	Not applicable	GT	VM	Can be used 1 time in 365 days ⁹

¹⁹ Place of service code ‘99’ refers to “Other place of service not identified above.” Centers for Medicare and Medicaid Services. (2016). Place of Service Code Set: Place of Service Codes for Professional Claims. Retrieved from: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html

²⁰ E1639: Durable Medical Equipment (DME)

²¹ 0488T: Preventive behavior change, online/electronic intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days

						Virtual programs may only use VM to indicate make-up sessions. Do not use GT and VM OR GT and TS
Performance: 5% weight loss achieved	G9880 – 5 percent weight loss from baseline achieved	\$125	Not applicable	GT	None	Can be used 1 time in 365 days ⁹
Performance: 9% weight loss achieved	G9881 - 9 percent weight loss from baseline achieved	\$25	Not applicable	GT	None	Can be used 1 time in 365 days ⁹

As indicated for Milestone 1, MDH will accept one of three possible codes for enrollment or initiation into the program as a first milestone and allow claiming for the scale using either 1) G9873; 2) [E1639](#); or 3) [0488T](#).

Assuming the enrollee attends and meets all milestones and achieves the 5% and 9% performance outcomes, total payment per enrollee for virtual CDC-recognized type 2 diabetes prevention programs based on these rates should equal \$670.

ICD-10 Diagnosis Codes, Descriptions and DPP Provider Assignment Guidance

The following ICD-10 diagnosis codes may be used for billing:

Table 4. *Elevated Blood Glucose Level and Gestational Diabetes ICD-10 Codes*

ICD-10 Code	Description – Elevated Blood Glucose Level	ICD-10 Code	Description - Gestational Diabetes
R73.01	Impaired fasting glucose	Z86.32 ²²	Personal history of gestational diabetes
R73.02	Impaired glucose tolerance - Oral	R73.03	Prediabetes

Table 5. *BMI ICD-10 Codes for BMI 23.0 and greater*

ICD-10 Code	Description – Body Mass Index	ICD-10 Code	Description – Body Mass Index
Z68.23	Body mass index (BMI) 23.0-23.9, adult	Z68.34	Body mass index (BMI) 34.0-34.9, adult
Z68.24	Body mass index (BMI) 24.0-24.9, adult	Z68.35	Body mass index (BMI) 35.0-35.9, adult
Z68.25	Body mass index (BMI) 25.0-25.9, adult	Z68.36	Body mass index (BMI) 36.0-36.9, adult
Z68.26	Body mass index (BMI) 26.0-26.9, adult	Z68.37	Body mass index (BMI) 37.0-37.9, adult

²² DPP providers should include Z86.32 as primary code for all individuals indicating history of gestational diabetes after confirming not currently pregnant.

Z68.27	Body mass index (BMI) 27.0-27.9, adult	Z68.38	Body mass index (BMI) 38.0-38.9, adult
Z68.28	Body mass index (BMI) 28.0-28.9, adult	Z68.39	Body mass index (BMI) 39.0-39.9, adult
Z68.29	Body mass index (BMI) 29.0-29.9, adult	Z68.41	Body mass index (BMI) 40.0-44.9, adult
Z68.30	Body mass index (BMI) 30.0-30.9, adult	Z68.42	Body mass index (BMI) 45.0-49.9, adult
Z68.31	Body mass index (BMI) 31.0-31.9, adult	Z68.43	Body mass index (BMI) 50-59.9, adult
Z68.32	Body mass index (BMI) 32.0-32.9, adult	Z68.44	Body mass index (BMI) 60.0-69.9, adult
Z68.33	Body mass index (BMI) 33.0-33.9, adult	Z68.45	Body mass index (BMI) ≥ 70 , adult

APPENDIX L-1

HIGH-COST LOW VOLUME OUTPATIENT DRUG RISK MITIGATION POLICY

Maryland's Department of Health (MDH) instituted a risk mitigation policy, effective January 1, 2021, to protect the HealthChoice program from utilization fluctuations related to very high-cost drugs. The policy covered both Physician Administered Drugs and retail pharmacy drugs that had an expected annual cost over \$400,000 for CYs 2021 to 2023. This threshold was changed to \$500,000 for CYs 2024, 2025, and 2026.

The specific drugs covered are listed in Exhibit I of this document. This policy is applicable only to Covered Outpatient Drugs as defined in 42 CFR 447.502. The list of drugs is subject to change during the year if a new drug received FDA approval and is a covered Medicaid service with an expected annual cost over \$500,000. No previously approved and covered drugs will be added to the list during the year. If a new drug is approved and reaches the market after this analysis is complete, MDH will evaluate the expected cost of the drug at the NDC level and will add it to the list if the expected annual cost is over \$500,000. The list of covered drugs will be reviewed annually to add in drugs that have increased in price or remove drugs that have decreased in price.

Under this mitigation policy, costs of the High-Cost Low Volume drugs listed in Exhibit I are removed from the rate setting base data and are not included in the standard capitation rate paid to HealthChoice Managed Care Organizations (MCOs). The MCOs are still responsible for authorizing, managing, and paying all claims related to the high-cost drugs, and will invoice MDH for any incurred expenses on a quarterly basis. The MCOs are expected to develop and adhere to medical necessity criteria to ensure that all instances of utilization of drugs listed in Exhibit I follow best clinical practices. MDH reserves the right to audit medical necessity criteria and review the utilization of all High-Cost Low Volume Drugs to ensure adherence to appropriate criteria.

Exhibit I – List of NDCs and HCPCS Codes Covered by High-Cost Low Volume Risk Mitigation Policy (Revised August 2025)

Drug Name	NDC Code	HCPCS Code (if Applicable)
Abecma (idecabtagene vicleucel)	59572-0515-01, 59572-0515-02, 59572-0515-03	J9999
Actimmune (interferon gamma-1B)	75987-0111-11, 75987-0111-10	J9216
Adcetris (brentuximab vedotin)	51144-0050-01	J9042
Alhemo (concizumab)	00169-2080-15, 00169-2084-15, 00169-2081-03	J3590
Altuviiiio (antihemophili factor-recombinant)	71104-0978-01, 71104-0979-01, 71104-0980-01, 71104-0981-01, 71104-0982-01, 71104-0983-01, 71104-0984-01	J7214
Amondys 45 (casimersen)	60923-0227-02	J1426
Andembry (garadacimab)	63833-0925-01	J3590
Anktiva (inbakicept-pmIn)	81481-0803-01	J9028
Aqneursa (levacetylleucine)	83853-0101-01	J8499
Benefix (coagulation factor IX recombinant)	58394-0633-03, 58394-0634-03, 58394-0635-03, 58394-0636-03, 58394-0637-03	J7195
Beqvez (fidanacogene elaparvovec-dzkt)	00069-0422-01, 00069-2004-04, 00069-2004-14, 00069-2005-05, 00069-2005-15, 00069-2006-06, 00069-2006-16, 00069-2007-07, 00069-2007-17	J1414
Breyanzi (lisocabtagene maraleucel)	73153-0900-01	Q2054
Bylvay (odevixibat)	74528-0040-01, 74528-0120-01	J8499
Carvykti (ciltacabtagene autoleucel)	57894-0111-01, 57894-0111-02	J9999, Q2056
Chenodal (chenodiol)	68974-0876-40	J8499
Cholbam (cholic acid)	45043-0002-02	J8499
Cinryze (C1 esterase inhibitor, human)	42227-0083-01	J0598
Ctexli (chenodiol)	79378-0310-90	J8499
Danyelza (naxitamab)	73042-0201-01	J9348
Daybue (trofinetide)	63090-0660-01	J8499
Duvyzat (givinostat)	11797-0110-01, 11797-0110-02	J8499
Elevidys (delandistrogene moxeparvovec-rokl)	60923-0501-10, 60923-0502-11, 60923-0503-12, 60923-0504-	J1413

Drug Name	NDC Code	HCPCS Code (if Applicable)
	13, 60923-0505-14 , 60923-0506-15 , 60923-0507-16, 60923-0508-17, 60923-0509-18, 60923-0510-19, 60923-0511-20, 60923-0512-21, 60923-0513-22, 60923-0514-23, 60923-0515-24, 60923-0516-25, 60923-0517-26, 60923-0518-27, 60923-0519-28, 60923-0520-29, 60923-0521-30, 60923-0522-31, 60923-0523-32, 60923-0524-33, 60923-0525-34, 60923-0526-35, 60923-0527-36, 60923-0528-37, 60923-0529-38, 60923-0530-39, 60923-0531-40, 60923-0532-41, 60923-0533-42, 60923-0534-43, 60923-0535-44, 60923-0536-45, 60923-0537-46, 60923-0538-47, 60923-0539-48, 60923-0540-49, 60923-0541-50, 60923-0542-51, 60923-0543-52, 60923-0544-53, 60923-0545-54, 60923-0546-55, 60923-0547-56, 60923-0548-57, 60923-0549-58, 60923-0550-59, 60923-0551-60, 60923-0552-61, 60923-0553-62, 60923-0554-63, 60923-0555-64, 60923-0556-65, 60923-0557-66, 60923-0558-67, 60923-0559-68, 60923-0560-69, 60923-0561-70	
Eloctate (antihemophilic factor VIII FC fusion protein recombinant)	71104-0801-01, 71104-0802-01, 71104-0803-01, 71104-0805-01, 71104-0806-01;71104-0807-01 71104-0808-01, 71104-0809-01, 71104-0810-01	J7205
Empaveli (pegcetacoplan)	73606-0010-01	J7799
Encelto (revakinagene tarorectcel-lwey)	82958-0501-01	J3590
Evkeeza (evinacumab)	61755-0010-01, 61755-0013-01	J1305
Fabhalta (iptacopan)	00078-1189-20	J8499
Filsuvez (birch triterpenes)	10122-0310-02, 76431-0310-01	J3490
Gattex (Teduglutide)	68875-0101-01, 68875-0102-01 , 68875-0103-01	J3490
Givlaari (Givosiran)	71336-1001-01	J0223

Drug Name	NDC Code	HCPCS Code (if Applicable)
Haegarda (C1 esterase inhibitor, human)	63833-0828-02, 63833-0829-02	J0599
Hemgenix (etranacogene dezaparvovec-drlb)	00053-0099-01, 00053-0100-10, 00053-0110-11, 00053-0120-12, 00053-0130-13, 00053-0140-14, 00053-0150-15, 00053-0160-16, 00053-0170-17, 00053-0180-18, 00053-0190-19, 00053-0200-20, 00053-0210-21, 00053-0220-22, 00053-0230-23, 00053-0240-24, 00053-0250-25, 00053-0260-26, 00053-0270-27, 00053-0280-28, 00053-0290-29, 00053-0300-30, 00053-0310-31, 00053-0320-32, 00053-0330-33, 00053-0340-34, 00053-0350-35, 00053-0360-36, 00053-0370-37, 00053-0380-38, 00053-0390-39, 00053-0400-40, 00053-0410-41, 00053-0420-42, 00053-0430-43, 00053-0440-44, 00053-0450-45, 00053-0460-46, 00053-0470-47, 00053-0480-48	J1411
Hemlibra (etranacogene dezaparvovec)	50242-0920-01; 50242-0921-01; 50242-0922-01; 50242-0923-01; 50242-0927-01; 50242-0930-01	J7170
Hypmavzi (marstacimab-hncq)	00069-2151-01	J7172
Jivi (antihemophilic factor-recombinant pegylated-aucl kit)	00026-3942-25; 00026-3944-25; 00026-3946-25; 00026-3948-25; 00026-3950-50	J7208
Joenja (leniolisib)	71274-0170-60	J8499
Juxtapid (lomitapide mesylate)	10122-0405-28, 10122-0410-28, 10122-0420-28, 10122-0430-28, 76431-0105-01, 76431-0110-01, 76431-0120-01, 76431-0130-01	J8499
Kanuma (sbelipase alfa)	25682-0007-01	J2840
Kimmtrak (tebentafusp-tebn)	80446-0401-01	J9274
Krystexxa (pegloticase)	75987-0080-10	J2507
Lamzede (velmanase alfa-tycv)	10122-0180-02, 10122-0180-05, 10122-0180-10	J0217
Livmarli (maralixibat)	79378-0110-01	J8499

Drug Name	NDC Code	HCPCS Code (if Applicable)
Miplyffa (arimoclomol)	72542-0124-01, 72542-0147-01, 72542-0162-01, 72542-0193-01	J8499
Myalept (metreleptin)	76431-0210-01	J3490
Nexviazyme (avalglucosidase alfa-ngpt)	58468-0426-01	J0219
Novoseven (coagulation factor viia, recombinant)	00169-7201-01, 00169-7202-01, 00169-7205-01, 00169-7208-01, 00169-7211-11, 00169-7212-11, 00169-7215-11, 00169-7218-11	J7189
Nulibry (fesdenopterin)	73129-0001-01	J3490
Olpruva (sodium phenylbutyrate)	72542-0002-01, 72542-0200-02, 72542-0200-09, 72542-0003-01, 72542-0300-02, 72542-0300-09, 72542-0400-02, 72542-0400-18, 72542-0500-02, 72542-0500-18, 72542-0600-02, 72542-0600-18, 72542-0367-01, 72542-0667-02, 72542-0667-18	J8499
Omisirge (omidubicel)	73441-0800-04	J3590
Orladeyo (berotralstat)	72769-0101-01, 72769-0102-01	J8499
Oxlumo (lumasiran)	71336-1002-01	J0224
Pombiliti (cipaglucosidase alfa-atga)	71904-0200-01, 71904-0200-02, 71904-0200-03	J1203
Procysbi (cysteamine bitartrate)	75987-0101-08	J8499
Qfitlia (fitusiran)	58468-0348-01**	J3490
Ravicti (glycerol phenylbutyrate)	75987-0050-06	J8499
Rethymic (allogeneic processed thymus tissue-agdc)	72359-0001-01	J3590
Revcovi (elapegademase-lvlr)	57665-0002-01	J3590
Rivfloza (nedosiran)	00169-5306-10, 00169-5307-08, 00169-5308-01	J3490
Roctavian (valoctocogene roxaparvovec-rvox)	68135-0927-01, 68135-0927-48	J1412
Ryoncil (remestemcel-L-rknd)	73648-0111-01, 73648-0112-02, 73648-0113-03, 73648-0114-01, 73648-0115-02, 73648-0116-03, 73648-0117-04, 73648-0118-02	J3590

Drug Name	NDC Code	HCPCS Code (if Applicable)
Ryplazim (plasminogen, human-tvmh)	70573-0099-01, 70573-0099-02	J2998
Scemblix (asciminib hydrochloride)	00078-1196-20**	J8999
Sohonos (palovarotene)	15054-0010-01, 15054-0015-01, 15054-0025-01, 15054-0050-01, 15054-0100-01	J8499
Soliris (eculizumab)	25682-0001-01	J1299
Spinraza (nusinersen)	64406-0058-01	J2326
Strensiq (asfotase alfa)	25682-0016-12, 25682-0019-12**	J3490
Takhzyro (lanadelumab-flyo)	47783-0644-01; 47783-0646-01	J0593
Tryngolza (olezarsen sodium)	71860-0101-01	J3490
Veopoz (Pozelimab)	61755-0014-01	J9376
Viltepso (viltolarsen)	73292-0011-01	J1427
Vimizim (elosulfase alfa)	68135-0100-01	J1322
Vyjuvek (beremagene geperpavec-svdt)	82194-0510-02	J3401
Vyondys 53 (golodirsen)	60923-0465-02	J1429
Vykat XR (diazoxide choline extended-release)	83860-0075-01, 83860-0150-01**	J8499
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)***	73475-3102-03; 73475-1221-01; 73475-1221-04***	J9334
Wainua (eplontersen)	00310-9400-01	J3490
Xenpozyme (olipudase alfa-rpcp)	58468-0050-01	J0218
Xolremdi (mavorixafor)	83296-0100-12**	J8499
Xyntha (coagulation factor VIII- recombinant)	58394-0016-03, 58394-0022-03, 58394-0023-03, 58394-0024-03, 58394-0025-03, 58394-0012-01, 58394-0013-01, 58394-0014-01, 58394-0015-01	J7185
Yescarta (axicabtagene ciloleucel)	71287-0119-01, 71287-0119-02	Q2041
Zokinvy (lonafarnib)	73079-0050-30, 73079-0075-30	J8499
Zolgensma (onasemnogene abeparvovec-xioi)	71894-0120-02, 71894-0121-03, 71894-0122-03, 71894-0123-03, 71894-0124-04, 71894-0125-04, 71894-0126-04, 71894-0127-05, 71894-0128-05,	J3399

Drug Name	NDC Code	HCPCS Code (if Applicable)
	71894-0129-05, 71894-0130-06, 71894-0131-06, 71894-0132-06, 71894-0133-07, 71894-0134-07, 71894-0135-07, 71894-0136-08, 71894-0137-08, 71894-0138-08, 71894-0139-09, 71894-0140-09, 71894-0141-09; 71894-0156-14; 71894-0142-10; 71894-0143-10; 71894-0144-10; 71894-0145-11; 71894-0146-11; 71894-0147-11; 71894-0148-12; 71894-0149-12; 71894-0150-12; 71894-0151-13; 71894-0152-13; 71894-0153-13; 71894-0154-14; 71894-0155-14	

*On demand bleeding products for hemophilia are not covered as part of the HCLV drug list policy

**Other NDCs are not covered as dosing using these package sizes would not meet the HCLV threshold of >500K annually

***Covered only when used for chronic inflammatory demyelinating polyneuropathy (CIDP)

APPENDIX L-2

HEPATITIS C RISK POOL REIMBURSEMENT METHOD

MDH is continuing to pay for Hepatitis C treatments in the capitation rates while controlling for differences in treatment volume across MCOs with a modification that began in calendar year 2025. The method eliminates the previous Hepatitis C case rate and instead funds Hepatitis C by including the expenses in the capitation rating cohorts. After the contract period has ended, the Hepatitis C prescriptions provided by MCO will be compared to the amount funded via the capitation rates, and a risk pool will be calculated to protect MCOs from adverse selection. The key aspects of the risk pool are:

1. The risk pool will not be budget neutral, meaning that MDH will add/remove dollars to the initial Hepatitis C funding provided via the capitation rates.
2. The cost per prescription used in developing the capitation rates will be adjusted via a risk corridor based on the actual cost per prescription for the MCO.
 - a. The risk corridor is two-sided with a band of +/- 4%.
 - b. If the amount in capitation for claims is insufficient, MDH will make a payment to the MCO.
 - c. If the amount in capitation for claims exceeds cost, the MCO will make a payment to MDH.
 - d. Claims costs are measured after incorporating drug rebates.
3. The MCO's adjusted cost per prescription will be multiplied by the number of prescriptions provided by the MCO to calculate a floor or ceiling cost.
4. The floor or ceiling cost will be compared to the funding received via the capitation rates based on the MCO-specific membership distribution.
5. The difference between actual funding and floor or ceiling cost will be paid to or recouped from the MCOs, respectively.
6. All steps above exclude administration both on the cost side as well as the funding received in the capitation rates.

APPENDIX L-3

MODERATE COST HIGH VOLUME DRUG RISK MITIGATION POLICY

MDH is continuing to implement a risk corridor for moderate cost, high volume drugs in the capitation rates, while controlling for differences in treatment volume across MCOs for calendar year 2026. GLP-1 prescription drugs for the treatment of diabetes are excluded from this risk corridor. The estimated payment threshold of \$30M will be used to incorporate a risk corridor for a drug or a class of drugs. After the contract period has ended, the prescriptions for the drug or class of drugs provided by each MCO will be compared to the amount funded via the capitation rates, and a risk pool will be calculated to protect MCOs from adverse selection. The key aspects of the risk pool are:

1. The risk pool will not be budget neutral, meaning that MDH will add/remove dollars to the initial funding provided via the capitation rates.
2. The cost per prescription used in developing the capitation rates will be adjusted via a risk corridor based on the actual cost per prescription for the MCO.
 - a. The risk corridor is two-sided with a band of +/- 2%.
 - b. If the amount in capitation for claims is insufficient, MDH will make a payment to the MCO.
 - c. If the amount in capitation for claims exceeds cost, the MCO will make a payment to MDH.
 - d. Claims costs are measured after incorporating drug rebates.
3. The MCO's adjusted cost per prescription will be multiplied by the number of prescriptions provided by the MCO to calculate a floor or ceiling cost.
4. The floor or ceiling cost will be compared to the funding received via the capitation rates based on the MCO-specific membership distribution.
5. The difference between actual funding and floor or ceiling cost will be paid to or recouped from the MCOs, respectively.
6. All steps above exclude administration, both on the cost side as well as the funding received in the capitation rates.

APPENDIX L-4

INPATIENT HIGH-COST LOW VOLUME DRUG RISK MITIGATION POLICY

This policy covers inpatient drugs with an expected annual cost over \$1,000,000, beginning with calendar year 2026.

The specific drugs covered are included in **Exhibit 2** of this document. This policy is applicable only to Covered Inpatient Drugs as defined in **42 CFR 447.502**. The list of drugs is subject to change during the year if a new drug received FDA approval and is a covered Medicaid service with an expected annual cost over \$1,000,000. No previously approved and covered drugs will be added to the list during the year.

If a new drug is approved and reaches the market after this analysis is complete, MDH will evaluate the expected cost of the drug at the NDC level and will add it to the list if the expected annual cost is over \$1,000,000. The list of covered drugs will be reviewed annually to add in drugs that have increased in price or remove drugs that have decreased in price.

The MCOs are still responsible for authorizing, managing, and paying all claims related to the high-cost drugs, and will invoice MDH for any incurred expenses on a quarterly basis. The MCOs are expected to develop and adhere to medical necessity criteria to ensure that all instances of utilization of drugs listed in Exhibit 2 follow best clinical practices. MDH reserves the right to audit medical necessity criteria and review the utilization of all High-Cost Low Volume Drugs to ensure adherence to appropriate criteria.

Exhibit 2 – List of NDCs and HCPCS Codes Covered by Inpatient High-Cost Low Volume Risk Mitigation Policy (September 2025)

<u>Drug Name</u>	<u>NDC Code</u>	<u>HCPCS Code (if applicable)</u>
<u>Lenmeldy</u>	83222-0200-01	J3391
<u>Kebilidi</u>	52856-0601-01	
<u>Skysona</u>	73554-2111-01	
<u>Zynteglo</u>	73554-3111-01	J3393

APPENDIX M

CMS INTEROPERABILITY AND PATIENT ACCESS FINAL RULE REQUIREMENTS

The Centers for Medicare and Medicaid Services (CMS) Interoperability and Patient Access Final Rule (CMS-9115-F) focuses on driving interoperability and patient access to health information by facilitating the free and secure flow of data. CMS partnered with the Office of the National Coordinator (ONC) for Health Information Technology to identify Health Level 7 ® (HL7) Fast Healthcare Interoperability Services ® (FHIR) Release 4.0.1 as the foundational standard to support data exchange via secure application programming interfaces (APIs). Additionally, CMS is adopting the standards for FHIR-based APIs finalized by Health and Human Services (HHS) in the ONC 21st Century Cures Rule at 45 CFR 170.215.

The CMS Interoperability Rule requires each Medicaid Managed Care Organization (MCO) to establish, based upon the standards finalized in the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) (I) Patient Access API (42 CFR 422.119(b)(b)(5)); (II) Provider Access API (45 CFR 156.222(a)(2)); (III) Payer to Payer API (45 CFR 156.222(b)(1)); (IV) Prior Authorization API (42 CFR 422.122(b)). Each MCO must implement and maintain a secure, HL7 FHIR Release 4.0.1 standards-based API. All APIs are required to be implemented by January 1, 2027.

- I. **Patient Access API.** To allow patients to easily access their claims information, including cost, as well as a defined subset of clinical information. Starting January 1, 2026, MCOs must annually report certain metrics to CMS about patient data requests made via the Patient Access API.
- II. **Provider Access API.** To maintain a system which includes adjudicated claims and encounter data and excludes provider remittances and patient cost-sharing information.
- III. **Payer-to-Payer API.** To enable the exchange of certain patient clinical data (i.e., the U.S. Core Data for Interoperability [USCDI] version 1 data set), at the patient's request, between payers allowing patients to create a cumulative health record that moves across payers. MCOs will be required to request data from a patient's previous payor, with the patient's permission, no later than one (1) week from the start of the coverage or at the patient's request.
- IV. **Prior Authorization API.** To communicate whether the payer approves the prior authorization request, denied the request, or requests more information.

CMS requires that the implementation of the above APIs is supplemented with additional components, such as an educational page for patients about sharing their health information with third parties. For these requirements, MCOs should refer to the Final Rule, located here: <https://www.federalregister.gov/documents/2025/02/08/2025-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability#h-125>.

APPENDIX N

HEALTHCHOICE POPULATION HEALTH INCENTIVE PROGRAM

Effective January 1, 2022, MDH established the HealthChoice Population Health Incentive Program (PHIP). Updates for measurement year 2026 appear below.

Performance Measures and Funding

An MCO may be eligible for an incentive payment for the following performance measures:

1. Colorectal Cancer Screening (COL) – Total Rate
2. Glycemic Status Assessment for Patients with Diabetes (GSD): Glycemic Status >9.0%
3. Controlling High Blood Pressure (CBP)
4. Prenatal and Postpartum Care (PPC): Timeliness of Prenatal Care
5. Child and Adolescent Well-Care Visits (WCV) – Total Rate
6. Well-Child Visits in the First 30 Months of Life (W30) – Ages 0 – 15 Months
7. Well-Child Visits in the First 30 Months of Life (W30) – Ages 15 –30 Months
8. Immunizations for Adolescents (IMA-E): Combination 2
9. Child Immunization Status (CIS): Combination 3

Each measure identified shall be valued equally at a proportional share of available incentive funds..

There shall be two rounds of potential incentive payments an MCO may earn. Total PHIP funding shall be determined prior to the measurement year and included in the MCO contract. (For MY 2026, PHIP will be funded at 0.25% of HealthChoice total capitation for the measurement year, based on funds available in MDH's FY 2026 and FY 2027 budgets.) All PHIP payments shall be funded independently from and outside of MCO capitation payments during a given calendar year.

Each MCO shall be eligible for no more than 0.5 percent of the plan's measurement year capitation payments, excluding supplemental payments outside of capitation, as total payment from Round One and Round Two. Result findings and the determination of PHIP incentive payments are not subject to appeal pursuant to COMAR 10.67.10.02B.

If MDH determines that the score for any measure may not be comparable due to alterations in measure specifications or other factors, MDH may exclude the measure from the PHIP and adjust the incentive valuation in accordance with the remaining performance measures.

Beginning with measurement year 2025, an MCO that has a finding under the HEDIS Performance Monitoring Policies in Appendix D of this Agreement will be excluded from all rounds of PHIP for that measurement year.

Round One Incentives

An MCO may earn two types of incentives in Round One:

- 1) A performance incentive payment; and
- 2) An improvement incentive payment.

If an MCO does not report a performance measure or an MCO has a performance score of zero percent, then the MCO is awarded no performance or improvement incentive payments for this measure.

Round One Performance Incentive Payments

Performance incentive payments for Round One shall be based on the following categories for each performance measure:

- 1) Superlative performance, meaning the performance measure's score is at or above the 90th percentile of national HEDIS Medicaid HMO performance during the prior measurement year.
- 2) Very strong performance, meaning the performance measure's score is between the 75th to 89th percentiles of national HEDIS Medicaid HMO performance during the prior measurement year.
- 3) Strong performance, meaning the performance measure's score is between the 50th to 74th percentiles of national HEDIS Medicaid HMO performance during the prior measurement year.

Payments for Round One performance incentives shall be allocated as follows:

- 1) For superlative performance, an MCO may earn 100 percent of the incentive allocation for the performance measure.
- 2) For very strong performance, an MCO may earn 66.6 percent of the incentive allocation for the performance measure.
- 3) For strong performance, an MCO may earn 33.3 percent of the incentive allocation for the performance measure.

Any MCO earning a performance measure score below the 50th percentile of national HEDIS Medicaid HMO performance during the prior measurement year on a HEDIS-based measure shall be ineligible for a Round One performance incentive payment.

Round One Improvement Incentive Payments

An MCO may earn an improvement incentive payment of 33.3 percent of the incentive allocation for any performance measure if the following conditions are met:

- 1) The MCO demonstrates improvement of at least 0.5 percentage points in the measure compared to their performance in the previous measurement year, and

- 2) The performance measure score is at or above the 50th percentile of prior measurement year national HEDIS Medicaid HMO performance on a HEDIS-based measure.

Please note:

- An MCO earning a superlative performance incentive payment for a performance measure is ineligible for an improvement incentive payment for the same measure.
- For any performance measures in which a lower score indicates stronger performance, year-over-year improvement is demonstrated by a reduction in the score for that measure.
- If an MCO is missing or zero-valued for a performance measure in the previous year, then no improvement incentive will be awarded in the measurement year.

Round Two Incentives

An MCO may qualify for payments under Round Two if the MCO earned above 75 percent of possible Round One incentive dollars.

Any remaining funds that were unallocated during Round One may be awarded to eligible MCOs in Round Two for a maximum incentive award of up to 0.5 percent of its total capitation payment during the PHIP measurement year, excluding supplemental payments outside of capitation. If any remaining funds that were unallocated during Round One are not sufficient to settle all qualifying MCOs up to 0.5 percent of capitation in Round Two, then the leftover funds will be awarded proportionally among qualifying MCOs based on enrollment.

If additional funds remain after both Round One and Round Two, MDH may, within its discretion, allocate the funding as follows:

- 1) Make additional payments to MCOs that are below 1 percent of capitation based on improvement or performance, or
- 2) Place remaining funds into a non-lapsing pool, subject to approval by the Maryland Department of Budget and Management.

Incentive payments and exclusions from PHIP participation are not appealable under this agreement or COMAR 10.67.10.01.

APPENDIX O

CELL AND GENE THERAPY ACCESS MODEL FOR SICKLE CELL DISEASE

This Appendix outlines the requirements of the Cell and Gene Therapy (CGT) Access Model (Model), implemented by the Centers for Medicare & Medicaid Services (CMS) under Section 1115A of the Social Security Act. The benefit will begin on January 1, 2026.

The initial focus of the CGT Model is to improve access to gene therapy treatments for individuals living with sickle cell disease, a genetic blood disorder. The CGT Model supports outcomes-based agreements between states and manufacturers to provide such treatments.

Both Fee-for-Service (FFS) and Managed Care Organizations (MCOs) will have coverage responsibilities for their respective participants throughout the CGT Model treatment process. The two drugs available in this Model are CASGEVY™, which is manufactured by Vertex Pharmaceuticals, and LYFGENIA™, which is manufactured by Genetix Biotherapeutics (formerly Bluebird Bio). The medications can only be offered by an authorized treatment center (ATC).

Treatment Policies and Network Contracting

There are two ATCs in the Maryland region: Children's National Medical Center (CNMC) and University of Maryland Medical Center (UMMC).

- CNMC offers both LYFGENIA and CASGEVY.
- UMMC offers LYFGENIA.

Both ATCs should be open for HealthChoice participants to receive treatment. If an ATC is out-of-network for the MCO, the model requires the MCO and the ATC to enter into a single case agreement for the participant's treatment. MCOs should ensure CGT beneficiaries have access to the same CGT providers until at least one year after receiving their gene therapy infusion. Monitoring after receiving the therapies will take place over the next ten years with the MCO's in-network hematologists and other providers. MCOs will arrange timely nonemergency medical transportation services and related travel expenses for participants and their caregivers, as applicable.

The MCO will respond to questions and requests within two (2) business days and render decisions for single case agreements within no more than ten (10) business days of the provider's request. MCOs should either have a single case agreement for CGT or a network contract with at least one ATC to administer each drug. The agreement or accompanying documentation must identify which services are provided, considering the entire patient care journey including the following:

1. Initial consultation to determine eligibility;
2. Chemotherapy;
3. Infusion of CASGEVY or LYFGENIA and the associated inpatient stay;

4. Ancillary care (e.g., behavioral health services); and
5. Return visits for long-term follow-up care.

Each MCO must designate primary and secondary points of contact for providers regarding single case agreements, prior authorization, and provider enrollment. Contact information must be made available to all ATCs.

Care Continuity

Continuity of care must be preserved throughout transitions in coverage. This includes situations in which a participant moves between HealthChoice managed care and FFS coverage during therapy, as well as instances where a beneficiary changes from one MCO to another. In such cases, the receiving MCO must honor prior authorizations for all CGT-related services, including evaluations, prescriptions, and follow-up care.

Eligibility for outcomes-based rebates under the CGT Access Model shall continue regardless of changes in the participant's Medicaid status. This includes, but is not limited to, circumstances where the beneficiary loses Medicaid eligibility entirely or transitions to coverage under another participating or non-participating state during the applicable measurement period. CMS shall be responsible for validating any vaso-occlusive crisis events in accordance with the requirements of the Outcomes-Based Supplemental Rebate Agreement with the State.

Additionally, the manufacturers, Bluebird Bio, Inc. and Vertex, are responsible for covering fertility preservation services. Providers must bill the manufacturers directly for this service.

Public Communication of Treatment Availability

The MCO must publish MDH's approved clinical criteria for each drug publicly in a manner that is accessible by in-network providers, out-of-network providers, and participants, along with other materials approved by MDH to promote CGT availability.

Service Authorization

Before the drug is administered, the provider must submit a prior authorization request to the MCO. Each MCO is responsible for ensuring the submitted prior authorization aligns with the approved FFS clinical criteria for each CGT Model drug that is consistent with Model requirements. The MCO is responsible for submitting the complete documentation to Maryland FFS for review and adjudication. FFS will then notify the MCO of its coverage determination within the standard authorization timeframe (e.g., two business days if complete; seven calendar days if incomplete). MCOs must notify Medicaid FFS if a provider requests additional time up to 14 calendar days to produce the information necessary to complete their prior authorization request. If coverage is denied, the participant retains full MCO appeal rights, and FFS will coordinate with the MCO for appeals and state fair hearings related to denials.

Billing/Reimbursement

The MCO will reimburse providers for all components of the care journey—including apheresis and disease management. Reimbursement for CASGEVY or LYFGENIA, as well as the infusion and recovery at the ATC, will follow the procedure in place for the High-Cost Low Volume Inpatient and Outpatient Drug Policies, meaning that the costs for these drugs and the infusion are excluded from the capitation rate base data, and each MCO is still responsible for managing and paying all claims related to the CGT Model drugs. Each MCO with a CGT Model participant will invoice MDH for expenses incurred for CASGEVY or LYFGENIA, their infusion, and the participant's recovery on a quarterly basis. Each MCO is required to reimburse the ATCs for the actual acquisition costs for the CGT Model drugs to receive reimbursement. In cases where the participant is discharged and later readmitted, the MCO remains responsible for payment.

Reporting Requirements

The MCOs will cooperate with MDH, CMS, and/or CMS' designee(s) and provide all data needed by MDH and CMS to evaluate and monitor the CGT Model, including individually identifying information, claims data, and payment information.

The MCOs will maintain records for CGT Model participants for 10 years.

APPENDIX P

HEALTHCHOICE AND MEDICAID ADVANCED PRIMARY CARE PROGRAM

This policy outlines the requirements for MCOs participating in HealthChoice regarding designing and implementing the Medicaid Advanced Primary Care Program (MAPCP), which aligns with the principles of the Maryland Primary Care Program (MDPCP), pending CMS approval for CY 2026. MDH expects that MCOs will follow and meet MDH's requirements for implementing the Medicaid Advanced Primary Care, including all requirements and deadlines for practice contracting, data sharing, and payments.

I. Program Design

MCOs will participate in design meetings with MDH and other entities, as needed, to support the development of the MAPCP, including but not limited to the finalization of the following program components, pending approval by the Center for Medicare and Medicaid Innovation (CMMI):

- Payment model(s) for care transformation and quality
- Quality measures and incentive strategy
- Provider eligibility and attribution
- Care management and engagement strategy
- Standardized data-sharing platform housed in CRISP
- Aligned FQHC program

II. Eligibility, Participation, and Attribution

MCOs will utilize CY 2025 to offer the aligned program to eligible providers in their networks and negotiate contracts for implementation in CY 2026. For providers that accept the offer, contracts must be finalized prior to August 8, 2025. During CY 2026, MCOs will work with the Department to negotiate contracts with newly eligible providers and participating providers interested in continuing the program for a subsequent year, contingent on sustainment of the federal program by CMMI.

Eligible providers shall either be current MDPCP participating providers with at least 250 MCO attributed members (Cohort 1), or State vetted and approved providers with at least 250 MCO attributed members (Cohort 2). Practices in either cohort will need to sign MAPCP-specific contract addendums with each MCO they elect to participate with.

III. Increased Rates Evaluation and Management for Primary Care Providers

As directed by the Department via policy transmittal, MCOs will implement increased Evaluation and Management (E&M) rates, i.e., as a percentage of Medicare, for all participating primary care providers serving HealthChoice enrollees, in line with the Department's definition of a primary care provider.

IV. Care Management Fees

MCOs will provide care management fees on a quarterly basis to qualifying primary care providers participating in the aligned program. The Department will define practice eligibility, care management eligibility, and other program parameters via policy transmittal.

V. Quality Measurement and Incentive Strategy

MCOs will comply with required activities to implement a quality measurement and incentive strategy for qualifying primary care practices, to be developed by the Department and communicated via policy transmittal, pending CMS approval.

VI. Implementation

MCOs will follow and meet MDH's requirements for implementing the Medicaid Advanced Primary Care, including:

- a. Adhering to MDH direction on all requirements.
- b. Following and meeting MDH-set deadlines for practice contracting, data sharing, and payment
- c. Identifying a dedicated point of contact to work directly with MDH on implementation and troubleshooting.

APPENDIX Q

HEALTHCHOICE IN-LIEU-OF SERVICES AND SETTINGS

An “In-Lieu-Of Service or Setting” (ILOS) means a medically appropriate, cost-effective substitute for a covered service or setting under the State Plan. An Enrollee is not required to use the alternative service or setting. Any ILOS is subject to MDH and CMS approval.

ILOS is governed by six principles that must be satisfied for CMS approval:

1. ILOSs must advance the objectives of the Medicaid program.
 - a. ILOSs must not violate any applicable federal requirements, including 42 CFR 438.3(e)(2), general prohibitions on payment for room and board costs under title XIX of the Social Security Act, the Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and the Emergency Medical Treatment and Labor Act.
 - b. ILOSs must be approvable through a state plan amendment authorized through the Social Security Act.
2. ILOSs must be cost effective.
 - a. For a managed care program, the ILOS cost percentage should not exceed five (5) percent.
 - b. The ILOS cost percentage is a calculation of the portion of the total capitation payments attributable to all ILOSs for the managed care program (numerator) divided by the total costs for the specific managed care program that includes all capitation payments, state directed payments, and pass-through payments (denominator). This calculation requires actuarial certification to be submitted with the managed care capitation rate certification.
3. ILOSs must be medically appropriate.
 - a. For any ILOS, the HealthChoice MCO Agreement must include at a minimum:
 - i. The name and definition of each ILOS, and the covered Medicaid State Plan services or settings for which they substitute;
 - ii. The coding to be used on claims and encounter data to identify ILOS;
 - iii. The clinically oriented definitions for the target populations for which MDH has determined each ILOS to be a medically appropriate and cost-effective substitute; and
 - iv. The method the MCO uses to ensure that the provider uses their professional judgment to determine and document that the ILOS is medically appropriate for the specific Enrollee, based on the defined target population.
 - b. MDH may impose additional provider qualifications, limitations, or protocols to ensure ILOS are medically appropriate and cost effective.
4. ILOSs must be provided in a manner that preserves enrollee rights and protections.

- a. MCOs must not require Enrollees to use available ILOSs.
 - b. MCOs must not deny Enrollees access to Medicaid State Plan services or settings on the basis that an Enrollee has been offered and ILOS, is currently receiving an ILOS, or has received an ILOS in the past.
 - c. All appeal and grievance rights and procedures apply to provision and denial of ILOS.
5. ILOSs must be subject to appropriate monitoring and oversight.
- a. MDH is responsible for providing an actuarial report for the ILOS Cost Percentage for the HealthChoice program.
 - b. MDH is responsible for notifying CMS in writing within 30 days of determining an ILOS is no longer a medically appropriate or cost-effective substitute, or if MDH determines any other areas of non-compliance such as failure to protect enrollee rights.
 - i. If CMS determines the ILOS should be terminated, a transition of care policy is required to phase out the ILOS.
 - ii. The transition of care process should not exceed 12 months from the date of the rescission notice from CMS. Enrollees must be notified that the ILOS they are receiving is being terminated as expeditiously as required by the Enrollee's health conditions.
 - iii. The HealthChoice MCO Agreement will also be amended to remove the ILOS, along with rate certifications as necessary.
 - c. MDH must attest to audit encounter, grievance, appeals, and state fair hearing data to ensure accuracy, completeness, and timeliness.
 - i. MDH must also stratify encounter data about ILOS by sex, sexual orientation, gender identity, race, ethnicity, disability status, and language spoken to inform health equity initiatives and efforts to mitigate health disparities.
 - ii. The above stratification must be part of the audited data to evaluate the medical appropriateness and cost effectiveness of each ILOS continually.
 - d. MDH must document for CMS how the utilization and cost of an ILOS, as well as any savings resulting from the use of an ILOS, were considered in the development of the actuarially sound capitation rates and include this information in the rate certification.
6. ILOSs must be subject to retrospective evaluation, when applicable.
- a. If the ILOS Cost Percentage exceeds one point five (1.5) percent, MDH must submit a retrospective evaluation that includes ILOSs to determine their overall impact on furthering the purposes of the Medicaid program. The evaluation must include, at a minimum:

- i. Impact of each ILOS on the utilization of State Plan-covered services or settings, including associated cost savings, trends in MCO and Enrollee use of each ILOS, and impact of each ILOS on quality of care;
 - ii. Assessment of whether encounter data supports MDH's determination that each ILOS is a medically appropriate and cost-effective substitute for identified covered services and settings under the State Plan;
 - iii. The final ILOS Cost Percentage for each year;
 - iv. Appeals, grievances, and state fair hearings data, reported separately and for each ILOS, including volume, reason, resolution status, and trends; and
- b. Evaluations are due to CMS no later than 24 months after the completion of the first five contract years that include ILOSs.

APPENDIX R

INTEGRATED MATERNAL HEALTH SERVICES INITIATIVE

To assist with the implementation of the Integrated Maternal Health Services initiative, MDH will work with the HealthChoice managed care organizations (MCOs) to collect information for all counties through a quarterly report. The MCO will use the template provided by MDH to report the following information:

1. Member-specific data for individuals identified as pregnant, for whom the MCO has received a Maryland Prenatal Risk Assessment (MPRA) via CRISP from the Administrative Care Coordination Unit (ACCU) at the local health departments during the reporting period.
2. The record creation date
3. The risk level of high or low based on responses to the MPRA
4. Race
5. Ethnicity
6. Insurance
7. Preferred Language
8. Last Menstrual Period
9. First Prenatal Visit Date
10. Due Date
11. Trimester of First Prenatal Visit
12. If members began care management
13. Reason Not in Care Management
14. Care Management Start Date
15. If the member has additional needs
16. Were they referred to additional services
17. Reasons not referred to additional services
18. Referral or service type
19. Referral or service description
20. Referral date
21. If the services were obtained

Both parties agree to work collaboratively and adapt as requirements evolve, with any material changes documented in writing.

APPENDIX S

MDH ARTIFICIAL INTELLIGENCE (AI)-BASED PROCESS IMPLEMENTATION GUIDELINES

This Appendix outlines minimum compliance, monitoring, and performance evaluation obligations for organizations implementing AI-based process optimization under the oversight of the Maryland Department of Health (MDH).

1. Data Protection and Security

The MCO shall ensure that all AI systems are designed, developed, and operated in compliance with best practices for data protection, including:

- a. Full adherence to HIPAA, PHI, and PII regulations.
- b. Encryption for stored and in transit protected data.
- c. Role-based access controls to limit exposure of sensitive information.
- d. Documentation of all data flows into, within, and out of the AI and ancillary systems.

2. Auditing and Oversight of AI Decisions

To ensure accountable and legally compliant outcomes, the MCO must:

- a. Maintain a human-in-the-loop (HITL) auditing protocol that reviews both the inputs and outcomes of AI decisions on a scheduled basis.
- b. Instrument AI processes to capture structured operational result metrics in three categories:
 - i. Planned values (target KPIs or expected outcomes based on traditional or policy-defined benchmarks),
 - ii. Actual values (AI-generated decisions or outcomes),
 - iii. Variance (quantitative difference between plan and actual).
- c. Implement a variance detection and alert system that automatically flags material deviations beyond pre-defined tolerances.
- d. Conduct variance and drift analysis at regular intervals using statistical techniques such as ANOVA (Analysis of Variance) or similar, to validate that AI-driven processes do not exhibit significant deviation from non-AI baselines in terms of performance reliability, risk, and compliance.
- e. Archive all variance reports for regulatory review and maintain full traceability of AI decision pathways, including model versioning and training data lineage.

3. Performance Monitoring and Outcome Comparison

To confirm the value and safety of AI adoption, MCOs shall:

- a. Establish baseline process performance ratios and historical KPIs from non-AI implementations. These should include throughput, error rate, cost per transaction, and time to completion.
- b. Compare AI-enabled process performance on an ongoing basis against the established historical baseline.
- c. Ensure that any improvement in cost or throughput does not come at the expense of increased variance, reduced equity, or diminished compliance.
- d. Provide quarterly performance summary reports in a form and manner to be defined by MDH, including:
 - i. Key metrics over time,
 - ii. Any detected deviations from historical norms,
 - iii. Actions taken in response to adverse variances.

APPENDIX T
**CODE OF MARYLAND REGULATIONS (COMAR) PROVISIONS
APPLYING TO HEALTHCHOICE MANAGED CARE
ORGANIZATIONS**

TITLE 10 MARYLAND DEPARTMENT OF HEALTH

SUBTITLE 01 PROCEDURES

**CHAPTER 03 PROCEDURES FOR HEARINGS BEFORE THE MARYLAND SECRETARY OF
HEALTH**

.01 SCOPE.

A. This chapter applies to hearings that the Secretary is required to conduct by statute or regulation except for those hearings for which specific procedural regulations have been promulgated. This chapter does not apply to conferences, investigations, or proceedings at which the general public has been assembled to provide comments and opinions regarding a permit or license proposed to be issued by the Department, or to hearings before the Department's Boards and Commissions, which are authorized by law to conduct their own hearings.

B. These procedures are intended to supplement the procedures required by law. They are not substantive and are not to be construed as creating rights not set out by law. In the event of conflict, statutory provisions take precedence over this chapter.

C. Construction.

(1) In hearings conducted by an administrative law judge of the Office of Administrative Hearings, this chapter shall be construed, whenever possible, as supplementing COMAR 28.02.01.

(2) In a conflict between this chapter and COMAR 28.02.01, this chapter applies.

.02 DEFINITIONS.

A. The following terms have the meanings indicated.

B. Terms Defined.

(1) Civil Penalty.

(a) "Civil penalty" means a monetary penalty authorized by statute or regulation and imposed for a violation of a statute, regulation, permit, or license.

(b) "Civil penalty" does not include statutorily authorized reimbursement of State or federal expenditures.

(2) "Department" means the Maryland Department of Health, or any of its constituent units.

(3) "Hearing" means a contested case hearing as defined by the Administrative Procedure Act, State Government Article, §10-201 et seq., Annotated Code of Maryland.

(4) “Administrative Law Judge (ALJ)” means an administrative law judge of the Office of Administrative Hearings as defined in COMAR 28.02.01.02B(1).

(5) “Office of Administrative Hearings (OAH)” means the independent unit in the Executive Branch of State government authorized to conduct hearings in contested cases, pursuant to the Administrative Procedures Act and this chapter.

(6) “Party” means any person or agency named or admitted as a party, including the Department.

(7) “Person” means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any firm, partnership, association, corporation, or other entity including any public or municipal corporation and any agency, bureau, department, or instrumentality of federal, State, or local government.

(8) “Secretary” means the Secretary of Health, a designee of the Secretary, or that official empowered by statute to render the final agency decision in a contested case.

.03 SANCTIONS.

This chapter shall be construed to secure the just and speedy determination of each action. If a party fails to follow this chapter, the ALJ or the Secretary may enter such orders in regard to the failure as are just, including limiting the issues to be heard and dismissing the request for hearing or entering an order on the merits against the Department.

.04 THE RECORD.

The record in each case shall include:

A. The items listed in COMAR 28.02.01.22B; and

B. In the case of a proposed decision:

(1) Any exceptions filed by any party;

(2) The response to those exceptions;

(3) The final decision; and

(4) Any correspondence relating to the proposed decision, the exceptions process, and the final decision.

.05 NOTICE OF THE RIGHT TO A HEARING.

The Department shall provide the notices of agency action and of the right to a hearing required by law. The notices shall contain the information required by State Government Article, §§10-207 and 10-208, Annotated Code of Maryland.

.06 REQUEST FOR HEARING.

A. A person, either directly or through a representative, may request a hearing by mailing or delivering a written request via U.S. mail, facsimile, or electronic mail to the individual and unit of the Department specified in the notice

B. The request shall state that the person desires a hearing in order to review a matter that is the proper subject of a hearing as provided under Department regulations or other applicable law. In addition, the person requesting the hearing shall enclose a copy of the notice of agency action being appealed.

C. The request shall include a brief statement of the basis for the request, and other information required by law.

D. The Department or constituent unit may require a statement to be made on a form if the person is notified of this requirement and is provided a copy of the form in the notice of the right to a hearing.

E. A request for a hearing shall be deemed filed when received in the unit of the Department specified in the notice required by Regulation .05 of this chapter.

.07 DELEGATION.

A. Contested cases that are authorized by statute to be conducted by the Secretary or the Department shall be conducted by:

(1) OAH in accordance with a letter of delegation from the Secretary; or

(2) Such other person as authorized by law.

B. In all cases delegated to OAH, the delegation is limited to the issues raised by the notice of agency action attached to the transmittal from the agency to OAH.

.08 SERVICE.

When the Department is required to make service, service may be made in any manner reasonably calculated to provide the required notice to the intended recipient. Service upon a party who has applied for a permit, license, or certificate or to whom a permit or license or certificate has been issued by the Department may be made by delivering a copy to the last known address in the Department's records.

.09 CERTIFICATES OF SERVICE.

Whenever a party is required by this chapter to serve a copy of a pleading or memorandum upon another party, a certificate shall be appended to the pleading or memorandum stating:

A. To whom the copy was sent;

B. The address to which the copy was sent;

C. The name of the person who sent the copy; and

D. The date the copy was sent.

.10 CONTINUANCES.

A. On motion or on the Secretary's own initiative, an exceptions hearing may be continued by the Secretary as justice may require.

B. Requests for postponement shall be confirmed in writing, and the written request shall:

(1) Set forth the reason for the request; and

(2) Unless the parties agree to schedule beyond the 45-day period, list at least three dates within the 45-day period following the day originally scheduled on which the party and counsel would be available for a hearing.

(3) Whenever feasible, a postponed hearing shall be rescheduled within the 45-day period.

.11 TIME PERIODS.

For good cause, either the Secretary or the ALJ may shorten, extend, or waive any time periods provided in this chapter.

.12 APPOINTMENT OF INTERPRETER.

A. If a party cannot readily hear, speak, or understand the spoken English language, the Secretary may appoint a qualified interpreter to provide assistance during an exceptions hearing.

B. Costs of an interpreter may be charged to the party on whose behalf the interpreter is obtained.

.13 APPEARANCE OF PARTIES AT HEARINGS; REPRESENTATION.

A. A party to a proceeding may be represented by an attorney, or, if allowed by law, appear in person or through another representative.

B. Except as otherwise provided by law, a person other than an individual shall be represented by an attorney authorized to practice law in the State.

C. Unless the appearance is subsequently withdrawn in writing, any notice, decision, or other matter required to be sent to a party may be sent to the attorney at the attorney's address.

D. When any party is represented by counsel, all submission of evidence, examination, and cross-examination of witnesses, and all objections and motions on its behalf shall be made solely by counsel.

.14 DISCOVERY.

A. Discovery on Request. By written request filed with OAH and served on other parties at least twenty days before the scheduled hearing, a party may require another party to produce, within 15 calendar days:

- (1) A list of witnesses to be called;
- (2) Copies of documents intended to be produced at the hearing; and
- (3) The name and curriculum vitae of any expert who will testify at the hearing.

B. Parties are not entitled to discovery of items other than as listed in §A of this regulation.

.15 OPEN HEARINGS.

A. Unless otherwise provided by law, documents, notices, and records in the possession of the Secretary as a result of these contested case proceedings may be inspected by any person as provided in State Government Article, §10-611 et seq., Annotated Code of Maryland.

B. Cameras and other photographic equipment may be permitted in the exceptions hearing room at the discretion of the Secretary.

C. The Secretary may cause the removal of any person whose conduct impedes the orderly progress of an exceptions hearing, or may recess the hearing until such time as it may proceed in an orderly fashion.

D. The Secretary may exclude from an exceptions hearing a person or persons who have given the Secretary no advance notice of an intention to attend, if the size of the hearing room is too small to accommodate the presence of that person or persons.

E. An exceptions hearing is open to public observation, except for the parts that the Secretary states are to be closed pursuant to a provision of law expressly authorizing that closure. To the extent that a hearing is conducted by telephone, television, or other electronic means, the availability of public observation is satisfied by giving members of the public an opportunity, at reasonable times, to hear the tape recordings, except for such portions of the hearing as are closed pursuant to this section.

.16 BURDEN OF GOING FORWARD AND PERSUASION.

A. When, by specific statute or regulation, the burden of going forward or the burden of persuasion rests upon a certain party, this regulation does not shift those burdens.

B. Except as provided in §A of this regulation:

(1) A party requesting a hearing following notice of the Department's intent to deny or refuse to renew a permit or license bears the burden of going forward to establish a prima facie case of entitlement to the permit or license and the burden of persuasion that the permit or license should be issued;

(2) A party contesting the Department's tentative decision to issue or renew a permit or license bears the burden of going forward to establish a prima facie case that grounds exist for denying the license or permit and the burden of persuasion that the license or permit should be denied;

(3) In a proceeding following notice by the Department of an intent to revoke or suspend a permit or license, the Department bears the burden of going forward to establish a prima facie case as to the existence of grounds for revocation or suspension and the burden of persuasion that the license or permit should be revoked or suspended;

(4) In a proceeding to impose a civil penalty or to issue an order, the Department bears the burden of going forward to establish a prima facie case as to existence of the grounds for imposition of a civil penalty or issuance of an order and the burden of persuasion that the civil penalty should be imposed or order issued; and

(5) In a proceeding in which a party seeks payment from the Department or contests the recoupment by the Department of an alleged overpayment, the party seeking payment or contesting recoupment has burden of going forward and the burden of persuasion.

C. Except as provided by §§A and B of this regulation, the party asserting the affirmative of an issue before the ALJ has the burden of going forward and the burden of persuasion.

D. A party with the burden of persuasion shall be required to present its case first, unless otherwise agreed by the parties.

.17 FINAL DECISION.

A. The Secretary is not bound by the ALJ's proposed decision even in those cases where no exceptions are filed.

B. If no exceptions have been filed and, after reviewing an ALJ's proposed decision, the Secretary concludes that the Secretary is unable to approve that decision as written, the Secretary shall notify all parties and invite argument from the affected parties on the issues the Secretary is reconsidering.

.18 EXCEPTIONS; REQUESTS FOR ORAL ARGUMENT.

- A. Exceptions to an ALJ's proposed decision shall be filed with the Secretary within 21 days after the ALJ's proposed decision is received. Receipt is presumed to occur 3 days after mailing.
- B. Exceptions shall be in writing and contain a concise statement as to each portion of the ALJ's determination to which exception is taken and the asserted basis for taking the exception.
- C. Any party may file a written response to exceptions taken to the ALJ's proposed decision within 14 days of the filing of exceptions.
- D. A copy of the exceptions and any response shall be served on all parties to the proceedings.
- E. The Secretary shall hear oral argument on the exceptions and may limit the time for oral argument in the discretion of the Secretary.
- F. The Secretary shall consider the exceptions filed before rendering the final agency decision.
- G. A party that intends to refer to any evidence produced at the hearing before the ALJ shall notify the agency of the specific evidence in its request for exceptions. That party is responsible for filing with the Secretary a copy of the transcript of the hearing, or relevant portions of it, at that party's expense, at least 5 days before the scheduled exception hearing.
- H. If all parties are in agreement, a stipulation of facts may be submitted instead of a transcript.
- I. Additional evidence may not be introduced, nor may testimony of witnesses be heard by the Secretary. All exception hearings or reviews shall be conducted on the basis of the record compiled before the ALJ.
- J. Within 90 days after the conclusion of the exceptions hearing, the Secretary shall adopt a final decision and, if appropriate, an order. Copies of the final decision and findings of fact and conclusions of law shall be delivered or mailed promptly to all parties or to their attorneys.

.19 STAYS.

- A. Except as prohibited by law, a party that is adversely affected by a final order may request a stay of the order from the Secretary pending judicial review.
- B. A request for a stay shall be filed with the Secretary within 10 days of the date of the final order from which the stay is sought.
- C. A request shall include a statement of the reasons a stay is sought.
- D. A request shall include a statement of the grounds for the appeal to the Board of Review or the petition for judicial appeal.
- E. The Secretary may grant a stay upon such conditions, including security or bond, as the Secretary determines to be proper.
- F. A request for stay may not operate as a stay, nor extend the time for appeal.
- G. The Secretary may hold a hearing on a request for a stay, or rule upon the request without a hearing.

.20 JUDICIAL REVIEW.

Unless otherwise agreed between the parties, a party may not file a petition for the judicial review of a decision of the Secretary unless the party has filed exceptions with the Secretary to the proposed decision and the Secretary has

rendered a final decision. This provision does not apply when the Secretary has delegated final decision-making authority to OAH.

CHAPTER 04 FAIR HEARING APPEALS UNDER THE MARYLAND STATE MEDICAL ASSISTANCE PROGRAM

.01 DEFINITIONS.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Administrative law judge” means an individual appointed by the Chief Administrative Law Judge under State Government Article, §9-1604, Annotated Code of Maryland, or designated by the Chief Administrative Law Judge under State Government Article, §9-1607, Annotated Code of Maryland, to adjudicate contested cases at the Maryland Office of Administrative Hearings.

(2) “Action by an MCO” means:

(a) Denial or limited authorization of a requested service, including:

(i) The type or level of service;

(ii) Requirements for medical necessity;

(iii) Appropriateness;

(iv) Setting; or

(v) Effectiveness of a covered benefit;

(b) Reduction, suspension, or termination of a previously authorized service;

(c) Denial, in whole or part, of payment for a service;

(d) Failure to provide services in a timely manner;

(e) Failure to act within the required time frames; or

(f) The denial of an enrollee’s request to dispute a financial liability, including:

(i) Cost sharing;

(ii) Copayments;

(iii) Premiums;

(iv) Deductibles;

(v) Coinsurance; or

(vi) Other enrollee financial liabilities.

(3) “Affordable Care Act” means the Patient Protection and Affordable Care Act of 2010 (Pub.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub.L. 111-152), as amended by the Three Percent Withholding Repeal and Job Creation Act (Pub.L. 112-56).

(4) “Appellant” means any individual who requests a fair hearing for the reasons specified in Regulation .02 of this chapter or that individual’s authorized representative.

(5) “Authorized representative” has the same meaning as in Regulation .12.

(6) “Consolidated Services Center” means a call center operated by the Maryland Health Benefit Exchange to assist consumers who apply for, or participate in, Insurance Affordability Programs offered through the Maryland Health Connection.

(7) “Delegate agency” means the:

(a) Department of Human Services and its affiliated local departments which, under contractual agreements with the Department, determine initial and continuing eligibility in the Program; and

(b) Maryland Health Benefit Exchange and its designated affiliates.

(8) “Department” means the Maryland Department of Health, the single state agency which, pursuant to Title XIX of the Social Security Act, implements fair hearing requirements for Program applicants and recipients.

(9) “Insurance affordability program” means a program that is one of the following:

(a) The Maryland State Medicaid program;

(b) The Maryland Children’s Health Insurance Program (CHIP), including the program known as Maryland Children’s Health Program (MCHP) Premium;

(c) A State basic health program established under §1331 of the Affordable Care Act;

(d) A program that makes available to eligible individuals coverage in a qualified health plan through the Maryland Health Benefit Exchange with advance payments of the premium tax credit established under §36B of the Internal Revenue Code; and

(e) A program that makes available to eligible individuals coverage in a qualified health plan through the Maryland Health Benefit Exchange with cost-sharing reductions established under §1402 of the Affordable Care Act.

(10) “Maryland Health Benefit Exchange” means the unit of State government that determines initial and continuing eligibility for the MAGI-based insurance affordability programs, including, by delegation, certain eligibility in the Program.

(11) “Maryland Health Connection” means the electronic eligibility system maintained by the Maryland Health Benefit Exchange.

(12) “MCO” means a managed care organization qualified to participate in the Program under COMAR 10.67.04.

(13) “Program” means the Department’s Medical Assistance Program.

.02 OPPORTUNITY FOR A FAIR HEARING.

A. An opportunity for a fair hearing shall be granted if:

- (1) A Program applicant claims their application for Program eligibility is denied;
- (2) A Program applicant claims that the determination of eligibility received through Maryland Health Connection is incorrect;
- (3) A Program applicant claims their application for eligibility, or any part thereof, is not acted upon within:
 - (a) 30 days from the date of application to an insurance affordability program;
 - (b) 45 days from the date of application for aged or blind applicants to the Program; or
 - (c) 60 days from the date of application to the Program in the case of determination of disability;
- (4) A Program recipient asserts their claim for Program services has been erroneously denied or is not acted upon with reasonable promptness;
- (5) A Program recipient asserts that the Program has acted erroneously;
- (6) A Program recipient residing in a skilled nursing facility or nursing home asserts that the recipient has been or will be erroneously transferred or discharged;
- (7) A Program recipient asserts that the Program has made an erroneous decision related to nursing home preadmission and annual review; or
- (8) A Program participant in an MCO is appealing an action by an MCO and the appeal has been filed within 120 days from the date specified in the notice from the MCO as required by COMAR 10.67.09.05.

B. The administrative law judge may not grant a fair hearing if the sole issue is a federal or State law requiring an automatic change adversely affecting some or all Program recipients.

.03 NOTIFICATION OF RIGHT TO REQUEST A FAIR HEARING.

A. The Program, delegate agency, or MCO shall notify an individual and his or her authorized representative, if previously designated by the individual or recognized as valid by the Program, in writing:

- (1) Of the right to obtain a fair hearing;
- (2) Of the method to obtain the hearing; and
- (3) That the individual may represent himself or use an authorized representative at a fair hearing.

B. The notification specified in §A of this regulation shall:

- (1) Be provided by the Program, the MCO, or the delegate agency when:
 - (a) The individual applies for Program benefits;
 - (b) Any Program, MCO, or delegate agency action affects the individual's claim to Program benefits;
 - (c) A skilled nursing facility or a nursing facility notifies the individual that the individual is to be transferred or discharged; and

- (d) The individual receives an adverse determination by the Department or delegate agency with regard to skilled nursing facility or a nursing facility preadmission screening and annual resident review;
- (2) Include a statement of the action the Program, MCO, skilled nursing facility, or nursing facility intends to take;
- (3) Include the reasons for the intended action;
- (4) Include the specific regulations that support, or the change in federal or State law that requires, the action;
- (5) Include an explanation of the individual's right to request a fair hearing, including that expenses incurred in connection with a fair hearing, such as transportation and baby-sitting costs, but not including attorney's fees, shall be paid by the Department when incurred by the appellant and may be paid by the Department when incurred by the appellant's witnesses;
- (6) Include information about fair hearings;
- (7) Include an explanation of the circumstances under which assistance is continued if a fair hearing is requested, as provided in Regulation .04B of this chapter;
- (8) Identify who may act as an authorized representative of the appellant in the fair hearing process, explain how an applicant or recipient may designate an authorized representative, and provide information about designation procedures under 10.09.04.12;
- (9) Specify that the appellant or the appellant's authorized representative may generally examine the appellant's records upon reasonable notice to the Program, MCO, or delegate agency; and
- (10) Except as specified in §C of this regulation, be mailed at least 10 days before the date of action.

C. The notice specified in §A of this regulation may be mailed less than 10 days before but not later than the date of action if:

- (1) The Program has information confirming the recipient's death;
- (2) The Program receives a clear written statement signed by a recipient that:
 - (a) The recipient no longer wishes services; or
 - (b) Gives information that requires termination or reduction of services and indicates that the recipient understands that this change in services is the result of supplying that information;
- (3) The recipient has been admitted to an institution where the recipient is ineligible under the Program for further services;
- (4) Subject to Regulation .10B(4) of this chapter, the recipient's whereabouts are unknown and the post office returns to the Program or delegate agency mail directed to the recipient indicating no forwarding address;
- (5) The Program establishes that the recipient has been accepted for Program services by another local jurisdiction, State, territory, or commonwealth;
- (6) The recipient's physician prescribes a change in the level of care;
- (7) The notice involves an adverse determination made with regard to preadmission screening requirements;

(8) The date of action will occur in less than 10 days and the action involves a long-term care facility's resident transfer or discharge, in which case the notification shall be made as soon as practicable before transfer or discharge in accordance with 42 CFR §438.12;

(9) The Program has facts indicating that action should be taken because of probable fraud by the recipient and the facts have been verified, if possible, through secondary sources, in which case the notification may be mailed 5 days before the date of action; or

(10) The action is an eligibility determination, in which case notice shall be given at the same time as the determination.

.04 REQUEST FOR FAIR HEARING.

A. Statement of Request.

(1) Any individual, either himself or through an authorized representative, may request a fair hearing by giving a clear statement, oral, electronic, or written, to any member of the Department or delegate agency, that the individual desires an opportunity to present for review any matter which is the proper subject of a fair hearing as provided in Regulation .02 of this chapter. The request shall be made by:

(a) Contacting the Program's Office of Health Services in writing, by telephone or by fax, if the appeal concerns a recipient's services being denied, suspended, terminated, or reduced;

(b) Contacting the Maryland Health Benefits Exchange in writing, by telephone, by email, or by fax, if the appeal concerns an applicant's eligibility for insurance affordability programs;

(c) Contacting the Consolidated Services Center maintained by the Maryland Health Benefit Exchange in writing, by telephone, by email, or by fax, if the appeal concerns eligibility for insurance affordability programs; or

(d) Contacting the Office of Administrative Hearings in person, by mail, or by fax, if the appeal concerns the appellant's eligibility for insurance affordability programs.

(2) The Program's Office of Health Services, the Consolidated Services Center, or the delegate agency that receives the request for a hearing shall assist the appellant or the appellant's authorized representative in preparing the request.

(3) The Program's Office of Health Services, the Consolidated Services Center, or the delegate agency that receives a written statement requesting an appeal shall:

(a) Immediately forward an applicant's statement to the Office of Administrative Hearings;

(b) Indicate whether the appeal is for a determination of eligibility under an insurance affordability program or for conventional Medicaid; and

(c) Note in its correspondence with the Office of Administrative Hearings if the appeal:

(i) Concerns the medical necessity of a denied benefit or service to an MCO enrollee or an application for eligibility insurance affordability programs;

(ii) Meets the Program's criteria for an expedited resolution because the Program has determined that taking the time for a standard resolution could seriously jeopardize the individual's life or health or ability to attain, maintain, or regain maximum function; and

(iii) Must be heard and decided upon within 3 working days after the Office of Administrative Hearings receives the fair hearing request.

(4) Appeals of eligibility determinations for insurance affordability programs requested through the Maryland Health Connection shall automatically be transmitted to the Office of Administrative Hearings.

(5) If a request for a hearing is made by someone other than the applicant or recipient, the Office of Administrative Hearings shall:

(a) Treat the appeal as timely noted if it complies with §D of this regulation unless no documentation is provided on or before the hearing date;

(b) Accept appropriate documentation, up to and including the date of the fair hearing, demonstrating that the representative is authorized; and

(c) Accept the representation of any member of the bar of Maryland that the individual appellant is his or her client without further documentation.

B. Acknowledgement. The Office of Administrative Hearings shall:

(1) Promptly acknowledge any request for a fair hearing;

(2) Give advance notice in writing of the date, time, and place of the fair hearing; and

(3) Provide the appellant with the information specified in Regulation .03B of this chapter.

C. Postponements.

(1) If any party notifies the Office of Administrative Hearings that either the time or place designated by the Office of Administrative Hearings is not convenient to the party, and requests a different time or place for the fair hearing, the administrative law judge shall designate another time or place convenient to the parties if the administrative law judge deems that the party has sufficient reason for requesting the change.

(2) If the appellant is employed during the periods when fair hearings are normally held, the administrative law judge shall attempt to schedule the hearing so that the appellant will not be required to miss employment.

D. Timeliness of Appeal. A request for a fair hearing may not be granted unless the request in §A of this regulation is:

(1) Postmarked, delivered in person, or sent by email or facsimile to the Office of Health Services within 120 days of the receipt of the notification specified in Regulation .03A of this chapter, if the appeal concerns services provided or denied by an MCO;

(2) Postmarked, delivered in person, or sent by email or facsimile to the Office of Health Services within 90 days of the receipt of the notification specified in Regulation .03A of this chapter, if the appeal concerns services provided or denied by the fee-for-service program; or

(3) Postmarked, delivered in person, or sent by facsimile to the Office of Administrative Hearings; or emailed to Maryland Health Benefit Exchange; telephoned or faxed to the Consolidated Services Center or postmarked, telephoned, faxed, or delivered in person to the delegate agency within 90 days of the receipt of the notification specified in Regulation .03A of this chapter if the appeal concerns the appellant's eligibility.

E. Dismissal.

(1) The Program, the delegate agency, or the Office of Administrative Hearings may dismiss a request for a fair hearing when the appeal has been:

(a) Withdrawn in writing addressed to the Office of Administrative Hearings, or in writing, by telephone, or by fax to the Office of Health Services, or in writing, by telephone, or electronically to the Maryland Health Benefit Exchange or other delegate agency, by the appellant or his authorized representative; or

(b) Abandoned.

(2) An appellant shall be deemed to have abandoned the appellant's request for a fair hearing if the appellant fails to appear for the fair hearing on the established date without good cause as determined by the administrative law judge.

F. Program's Response. In responding to timely filed requests for a fair hearing, the Office of Administrative Hearings:

(1) May respond to a series of individual requests for hearing by conducting a single group hearing;

(2) May consolidate hearings only in cases in which the sole issue involved is one of federal or State law or policy;

(3) Shall follow the regulations of this chapter governing hearings in all group hearings; and

(4) Shall permit each applicant to present the appellant's own case or be represented by the appellant's authorized representative.

.05 PRE-HEARING PROCEDURES.

A. A hearing summary shall be prepared containing pertinent information detailing the specific action that is the basis for the appeal. The summary shall be forwarded to the appellant or the appellant's authorized representative and to the Office of Administrative Hearings at least 6 days before the hearing date.

B. The appellant and the Department or MCO may request the names of all witnesses that the other party intends to call at the fair hearing.

.06 HEARING PROCEDURES.

A. The appellant, the Program, the MCO, and the delegate agency shall have the opportunity to:

(1) Present witnesses;

(2) Present documentary evidence;

(3) Present oral and written argument without undue interference;

(4) Establish all facts and circumstances the administrative law judge judges to be pertinent; and

(5) Question or refute any testimony or evidence, including an opportunity to confront and cross-examine all witnesses the administrative law judge judges to be adverse.

B. All parties that wish to call a witness at the hearing shall subpoena the witness in accordance with Office of Administrative Hearings procedures in COMAR 28.02.01.11. The appellant or authorized representative may subpoena any employees of the Department, MCO, or delegate agency whose action is being contested

by the appellant or whose testimony may be relevant to the issues under consideration as determined by the administrative law judge.

C. Right to Review Record.

(1) If the Program, MCO, or delegate agency introduces as evidence documents from the case record, special investigation file, or other sources, the appellant shall have the opportunity to examine the:

(a) Persons who prepared the documents; and

(b) Case record or special investigation file for the purpose of discovering information favorable to the appellant's case.

(2) Except as specified in Regulation .05A of this chapter, in addition to the rights specified in §C(1) of this regulation and for purposes of defining reasonable notice under Regulation .03B(9) of this chapter, the appellant or the appellant's authorized representative shall have the opportunity to examine the appellant's case record or investigation file upon reasonable notice to the Program, the MCO, or the delegate agency as specified in COMAR 07.01.02.04.

(3) The Program shall have access to relevant portions of the appellant's medical record in accordance with Health-General Article, §4-305, Annotated Code of Maryland.

D. When a hearing involves a medical issue, such as a diagnosis, an examining physician's report or a medical review team's decision, an additional medical assessment of the appellant's condition shall be obtained and made part of the record if the administrative law judge considers it necessary. Any additional medical assessment shall be made by a person other than the person who made the original medical assessment and shall be obtained at the Department's expense.

E. The delegate agency shall be a party to the fair hearing if the fair hearing involves an issue of eligibility.

F. Appeal for an Individual Enrolled in an MCO.

(1) The parties to the appeal for an individual enrolled in an MCO include the MCO, the enrollee, and the enrollee's representative or the personal representative of a deceased enrollee's estate.

(2) If the appeal concerns the medical necessity of a denied, reduced, suspended, or terminated benefit or service to an MCO enrollee, and if the fair hearing meets the Department-established criteria for an expedited hearing as provided in Regulation .04A(3)(b)(ii) of this chapter, the Office of Administrative Hearings shall:

(a) Schedule the hearing and render a bench decision within 3 working days after the Office of Administrative Hearings receives the fair hearing request; and

(b) Issue a follow-up written decision within 30 days of rendering the bench decision if the Office of Administrative Hearings, the appellant or the appellant's authorized representative, and the MCO agree that a written decision is necessary.

(3) All other appeals from MCO decisions shall be:

(a) Scheduled for a hearing within 30 days of receipt of the appeal and decided on within 30 days of the hearing; and

(b) Otherwise governed by COMAR 10.67.09.05.

.07 THE RECORD.

A. A verbatim recording of the fair hearing shall be made. Nonrecorded or confidential information, which the appellant does not have an opportunity to hear or see, may not be made a part of the hearing record. One transcribed copy of the recording shall be supplied to the appellant at no cost if the appellant takes a further appeal.

B. The following shall constitute the exclusive record of the hearing:

- (1) The transcript or recording of testimony and exhibits, or an official report containing the substance of what happened at the hearing;
- (2) All papers and requests filed in the proceeding; and
- (3) The administrative law judge's decision.

C. The recording of testimony shall remain in the custody of the Office of Administrative Hearings for a period not to exceed 2 years, or until all litigation involving the decision is terminated. All other components of the record shall remain in the custody of the Program for a period not to exceed 2 years, or until all litigation involving the decision is terminated.

.08 FINDINGS, TIMING OF DECISION, AND EFFECT OF DECISION.

A. Findings.

(1) The administrative law judge shall:

- (a) Prepare a written summary of findings and conclusions based exclusively on the record; and
- (b) Make a decision based on his findings and conclusions.

(2) The summary of findings and conclusions shall:

- (a) State the evidence, policies, regulations, or laws upon which the administrative law judge's decision is based; and
- (b) Provide written notice to the appellant that, if they are not satisfied with the decision, they may seek additional appeals as specified in §C of this regulation.

B. Timing of Hearing Decision.

(1) If the appellant is not enrolled in an MCO, the administrative law judge shall forward to the appellant a copy of the findings, conclusions, and decision within 90 days from the earlier of the following:

- (a) The date the appellant postmarked, delivered in person, or sent by email or facsimile to the Office of Health Services a request for a fair hearing pursuant to Regulation .04D(1) of this chapter;
- (b) The date the appellant postmarked, delivered in person, or sent by facsimile to the Office of Administrative Hearings or the delegate agency a request for a fair hearing pursuant to Regulation .04D(2) of this chapter;
- (c) The date the appellant emailed, postmarked or delivered in person to the Maryland Health Benefit Exchange a request for a fair hearing pursuant to Regulation .04D(2) of this chapter; or
- (d) The date the appellant called or sent by facsimile to the Consolidated Services Center a request for a fair hearing pursuant to Regulation .04D(2) of this chapter.

(2) If the appellant is enrolled in an MCO, the administrative law judge shall forward to the appellant or the appellant's authorized representative a copy of the findings, conclusions, and decision within:

(a) 3 working days after the Office of Administrative Hearings receives the fair hearing request if the appeal concerns the medical necessity of a denied benefit or service, and the hearing that meets the criteria, as determined by the Department, for an expedited hearing as provided in Regulation .04A(3)(b)(ii) of this chapter; or

(b) 30 days of the hearing if the appeal does not concern the medical necessity of a denied benefit or service.

(3) If the date of the fair hearing is postponed at the appellant's request, the length of the postponement may not be counted as part of any of the time periods specified in §B(1) or (2) of this regulation.

C. Appeal Rights.

(1) Any party may seek administrative review of the administrative law judge's decision as provided in Health-General Article, §§2-206 and 2-207, Annotated Code of Maryland, and subsequent judicial review as provided in State Government Article, §10-215, Annotated Code of Maryland, except if the appeal is solely of a decision of the Maryland Health Benefit Exchange, in which case any party may seek judicial review as provided in State Government Article, §10-215, Annotated Code of Maryland.

(2) An administrative law judge's decision adverse to the appellant shall be implemented immediately.

(3) To the extent an administrative law judge's decision upholds the determination of the Maryland Health Benefit Exchange with respect to an applicant for an insurance affordability program described in Regulation .01B(9)(a)—(e), the applicant may appeal to the United States Department of Health and Human Services.

D. Effect of Decision.

(1) When the decision requires action by the delegate agency, that agency shall notify the Program of its compliance with the decision.

(2) When the decision is favorable to the appellant, or when the Department, Program, or delegate agency grants the appellant the relief the appellant requests before the decision, the Department, Program, or delegate agency, where applicable, shall:

(a) Authorize corrected payments or relief retroactive to the date the incorrect action was taken; and

(b) If appropriate, provide for admission or readmission of the appellant to a facility.

(3) Any payment or action by the Department, Program, or delegate agency in §D(2) of this regulation may not constitute a waiver of the Department's, Program's or delegate agency's sovereign immunity from suit.

(4) When the decision is favorable to the appellant and is an MCO service, the MCO shall authorize or provide the disputed services no later than 72 hours from the date it receives notice reversing the MCO's determination.

.09 CONFIDENTIALITY.

A. If the appellant waives in writing his privilege of confidentiality as to the fair hearing, the administrative law judge shall permit members of the public to attend the hearing.

B. The administrative law judge may cause the removal of any member of the public whose conduct impedes the orderly progress of the hearing, or recess the hearing until it may proceed in orderly fashion.

C. The administrative law judge may exclude from the hearing individuals who have not given the Department or MCO advance notice of their intention to attend if the size of the hearing room is too small to accommodate them.

.10 BENEFITS DURING APPEALS PROCESS.

A. Benefits Pending Outcome of the Hearing.

(1) The Program may terminate or reduce services effective as of the date specified in the notice if the Program timely mails the notice as required under Regulation .03 of this chapter and:

(a) The appellant or the appellant's authorized representative does not timely request a hearing in accordance with Regulation .04 of this chapter; or

(b) The appellant or the appellant's authorized representative withdraws in writing or abandons a request for a fair hearing.

(2) Except as provided in §A(3) of this regulation, the Program may not terminate or reduce services until a decision is rendered after the hearing if:

(a) The Program timely mails the notice as required under Regulation .03 of this chapter; and

(b) The appellant requests a hearing before the date specified in the notice.

(3) The Program may terminate or reduce services before an administrative law judge renders a decision after a hearing if:

(a) The administrative law judge determines at the hearing that the sole issue is one of federal or State law or policy, or the request for a fair hearing is withdrawn in writing or abandoned; and

(b) The Program includes in the notification required by Regulation .03 of this chapter that services are to be terminated or reduced pending the hearing decision.

(4) The MCO shall continue benefits pending the outcome of the State fair hearing as described in COMAR 10.67.09.05F.

B. Reinstating Benefits.

(1) If the Program terminates or reduces services pursuant to §A of this regulation, the Program may reinstate services if a Program recipient requests a hearing not more than 10 days after the date specified in the notice.

(2) The reinstated services shall continue until a hearing decision, unless, at the hearing, the administrative law judge determines that the sole issue is one of federal or State law or policy.

(3) The Program shall reinstate and continue services until a decision is rendered after a hearing if:

(a) Action is taken without the advance notice being given to the recipient as required by Regulation .03 of this chapter;

(b) The recipient requests a hearing within 10 days of the mailing of the notice; and

(c) The Program determines that the action resulted from other than the application of federal or State law or policy.

(4) If a recipient's whereabouts are unknown, as indicated by the return of unforwardable Program mail directed to the recipient, any discontinued services shall be reinstated if the recipient's whereabouts become known during the time the recipient is eligible for services.

(5) The administrative law judge may provide for an additional period during which time the request for a fair hearing will result in reinstatement of a recipient's assistance to be continued until the hearing decision.

.11 APPLICABILITY OF REGULATIONS.

If a conflict exists between this chapter and the Rules of Procedure of the Office of Administrative Hearings in COMAR 28.02.01, this chapter shall govern.

.12 AUTHORIZED REPRESENTATIVES.

A. Definitions.

(1) "Authorized representative" means an individual or organization acting responsibly on behalf of the applicant or recipient in accordance with §§B, C, D, and E of this regulation, in assisting with an applicant or recipient's application, renewal of eligibility, appeals, and other ongoing communications with the agency.

(2) "Signature" includes electronic, including telephonically recorded, signatures and handwritten signatures transmitted by facsimile or other electronic transmissions.

B. Designating an Authorized Representative.

(1) An applicant or recipient may designate any individual or organization to serve as an authorized representative.

(2) An authorized representative may be designated either:

(a) In writing, including the applicant or recipient's signature; or

(b) By providing proof of legal authority to act on behalf of an applicant or recipient.

(3) Legal authority includes, but is not limited to those who are the:

(a) Applicant or, if applicant or recipient is a minor, recipient's parent;

(b) Applicant or recipient's legal guardian, if one has been appointed, or a person who has in good faith filed an application to be appointed the applicant or recipient's legal guardian but who has not yet been appointed the applicant or recipient's legal guardian;

(c) Applicant or recipient's healthcare surrogate as defined in Health General Article, §5-605, Annotated Code of Maryland;

(d) Personal representative of the applicant or recipient's estate, or a person who has in good faith filed an application to be appointed the personal representative of the applicant or recipient's estate but who has not yet been appointed the personal representative of the applicant or recipient's estate;

(e) Individual appointed to make legal or medical decisions on behalf of the applicant or recipient pursuant to a validly executed power of attorney; or

(f) Attorney or paralegal retained by the individual.

(4) For individuals who lack the capacity to designate an authorized representative and for whom no other individual or organization has the legal authority to act under §B(2) of this regulation, an authorized representative can be any individual or organization acting responsibly on behalf of the applicant or recipient who:

- (a) In good faith, is acting in the best interest of the applicant or recipient; and
- (b) Declares the applicant or recipient lacks legal capacity, and for organizations, declares that its directors, employees, officers or employers, if any, do not have a direct financial interest in the outcome of the fair hearing.

(5) For individuals who lack the capacity to designate an authorized representative, for whom no other individual or organization has the legal authority to act under §B(2) of this regulation, and on behalf of whom no individual or organization covered by §B(4) of this regulation is willing and able to act, an authorized representative can be any individual or organization with a direct financial interest in the outcome of the hearing or whose employer has a direct financial interest in the outcome of the hearing who:

- (a) In good faith is acting in the best interest of the applicant or recipient;
- (b) Declares that the applicant or recipient lacks legal capacity; and
- (c) Declares that to the best of his or her belief, no other individual or organization is willing and able to act on the applicant or recipient's behalf.

C. Time for Authorization. Designation of an authorized representative or the declarations by an individual or organization required under §B(4) and (5) of this regulation to become an authorized representative can take place at any time, including, but not limited to, the time of application, upon redetermination, upon filing an appeal, and at the appeal hearing.

D. Validity of Representation. The power to act as an authorized representative is valid until the applicant or recipient modifies the authorization or notifies the agency that the representative is no longer authorized to act on his or her behalf, or the authorized representative informs the agency that the authorized representative is no longer acting in such capacity, or there is a change in the legal authority upon which the individual or organization's authority was based. This notice shall be in writing and shall include the applicant or recipient's signature or the authorized representative's signature as appropriate.

E. Powers of Authorized Representative. Authorized representatives may be authorized to:

- (1) Sign an application on the applicant's behalf;
- (2) Complete and submit an update, a renewal form, or respond to a request for redetermination;
- (3) Receive copies of the applicant or recipient's notice and other communications from the agency; and
- (4) Act on behalf of the applicant or recipient in all matters with the agency including appeals.

F. Obligations of the Authorized Representative. An authorized representative:

- (1) Is responsible for fulfilling all the responsibilities encompassed within the scope of the authorized representation as described in §E of this regulation to the same extent as the individuals the authorized representative represents; and
- (2) Shall agree to maintain, or be legally bound to maintain, the confidentiality of any information regarding the applicant or recipient provided by the agency.

G. Authorized Representatives Through an Organization. A provider, staff member or volunteer of an organization shall sign an agreement that he or she will adhere to the federal regulations governing authorized representatives as laid out in 42 CFR §435.923 or 45 CFR §155.227, or both, as well as relevant State and federal laws concerning conflicts of interest and confidentiality of information.

SUBTITLE 09 MEDICAL CARE PROGRAMS

CHAPTER 08 FREESTANDING CLINICS

.05 FEDERALLY QUALIFIED HEALTH CENTER SERVICES.

A. To participate as a federally qualified health center, the provider shall meet the requirements of Regulations .03 and .04B of this chapter and shall:

- (1) Meet the conditions for coverage in accordance with 42 CFR §491, Subpart A;
- (2) Be enrolled in the EPSDT/Healthy Kids Program as provided in COMAR 10.09.23 and provide EPSDT/Healthy Kids services to participants who are eligible to receive them;
- (3) Supply the Department with financial and other information as requested;
- (4) Meet one of the following conditions:
 - (a) Meet all of the requirements for receiving a grant under §329, 330, or 340 of the Public Health Service Act, 42 U.S.C. §254(c), as determined by the Secretary of the United States Department of Health, and in accordance with 42 CFR §405.2401;
 - (b) Receive a waiver from the Secretary of the United States Department of Health and Human Services of one or more of the requirements for receiving a grant pursuant to §329, 330, or 340 of the Public Health Service Act; or
 - (c) Be an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act;
- (5) Comply with the requirements contained in COMAR 10.09.59 if delivering mental health services and COMAR 10.09.80 when providing substance use disorder services; and
- (6) Comply with the requirements contained in COMAR 10.09.05, if rendering dental services.

B. Covered services are the same as those authorized to be provided by rural health clinics as described in 42 CFR §440.20(b), rural health clinic services, and 42 CFR §440.20(c), other ambulatory services furnished by a rural health clinic.

C. In the event that the provider elects to institute a scope of services change, the provider shall:

- (1) Notify the Department of its intent to institute the scope of services change:
 - (a) Not later than 30 days before it begins to deliver services under the scope of services change; or
 - (b) Within 30 days after the adoption of this section; and
- (2) Provide the Department with any information the Department needs to:
 - (a) Assure continuity of care for enrollees;

(b) Arrange for the processing and payment of claims; or

(c) Otherwise administer services to Medical Assistance participants under the provider's scope of services change.

D. Rate Revisions for FQHCs Due to Scope of Services Change or Extraordinary One-Time Circumstance.

(1) If an FQHC implements a change in the FQHCs scope of services or if the FQHC experiences an extraordinary one-time circumstance, the FQHC or the Department may request a revision of the FQHC's prospective rate of reimbursement.

(2) The FQHC shall provide the Department with written notification no later than 30 days after the implementation of the scope of services change or the occurrence of the one-time circumstance.

(3) After receiving notification from an FQHC that the FQHC plans to institute a scope of services change, the Department shall notify the FQHC within 30 days if the Department wishes to request a revision to an FQHC's rate.

(4) An FQHC or the Department may not request more than one rate revision per FQHC per calendar year under this regulation.

(5) When an FQHC or the Department requests a rate revision based on §D(1) of this regulation, the FQHC shall submit to the Department or its designee a cost report and supporting documentation.

(6) The cost report and supporting documentation required under §D(5) of this regulation shall:

(a) Be submitted within 90 days after the end of the first 1-year period immediately following the implementation of the scope of service change or the occurrence of the extraordinary one-time circumstance;

(b) Reflect the change in costs relating to the rate revision request for the center's operations for the first 1-year period immediately following the implementation of the scope of service change or the occurrence of the extraordinary one-time circumstance;

(c) Conform with the standards described in §C of this regulation and instructions issued by the Department or its designee;

(d) Contain an explanation of the scope of services change or extraordinary one-time circumstance and schedules to support the calculation of the change in the cost-per-visit rate; and

(e) Be subject to verification and adjustment by the Department or its designee.

(7) Rate revisions granted under this section shall be effective the date the change of scope was approved by the Health Resources and Services Administration (HRSA) or the occurrence of the extraordinary one-time circumstance.

(8) The revised rate granted under this section shall be the rate referenced in §A(3) of this regulation.

E. Rates of reimbursement established according to this regulation shall be for:

(1) Payment of covered services rendered to participants; and

(2) Determining supplemental payments under COMAR 10.09.65.21A.

CHAPTER 36 GENERAL MEDICAL ASSISTANCE PROVIDER PARTICIPATION CRITERIA

.01 DEFINITIONS.

A. The following terms apply to Medical Assistance providers. Additional defined terms, unique to Medical Assistance provided services, are found in Medical Assistance service-specific chapters.

B. Terms Defined.

- (1) “Abandoned” means failing to appear for a hearing on the established date without good cause.
- (2) “Administrative law judge” means an individual appointed by the Chief Administrative Law Judge under State Government Article, §9-1604, Annotated Code of Maryland, or designated by the Chief Administrative Law Judge under State Government Article, §9-1607, Annotated Code of Maryland, to:
 - (a) Adjudicate contested cases at the Maryland Office of Administrative Hearings; and
 - (b) Render a proposed decision for purposes of COMAR 28.02.01.22.
- (3) “Care manager” means a:
 - (a) Primary medical provider under the Diabetes Care Program, in accordance with COMAR 10.09.43, or the Maryland Access to Care Program, in accordance with COMAR 10.09.44;
 - (b) Primary care provider under the corrective managed care program, in accordance with COMAR 10.09.24.15B and 10.09.25.14B; or
 - (c) Hospice provider under the hospice care program, in accordance with COMAR 10.09.35.
- (4) “Claim” means:
 - (a) A bill for services;
 - (b) A line item of service; or
 - (c) All services for one participant within a bill.
- (5) Clean Claim.
 - (a) “Clean claim” means a claim that can be processed consistent with applicable regulations without obtaining additional information from the provider of the service or from a third party.
 - (b) “Clean claim” includes a claim with errors originating in a State's claims system;
 - (c) “Clean claim” does not include a claim:
 - (i) From a provider who is under investigation for fraud or abuse; or
- (6) “Current Procedural Terminology (CPT)” means the American Medical Association’s uniform nomenclature for coding medical procedures and services.
- (7) “Customary charge” means the uniform amount that the provider charges in the majority of cases for a specific item or service, excluding token charges for charity patients and substandard charges for welfare and other low-income patients.

(8) “Department” means the Maryland Department of Health, which is the single state agency designated to administer the Maryland Medical Assistance Program pursuant to Title XIX of the Social Security Act, 42 U.S.C. §1396 et seq.

(9) “Emergency services” means those services which are provided in hospital emergency facilities after the onset of a medical condition manifesting itself by symptoms of sufficient severity that the absence of immediate medical attention could reasonably be expected by a prudent layperson, possessing an average knowledge of health and medicine, to result in:

- (a) Placing health in jeopardy;
- (b) Serious impairment to bodily functions;
- (c) Serious dysfunction of any bodily organ or part; or
- (d) Development or continuance of severe pain.

(10) “Healthcare Common Procedure Coding System (HCPCS)” means the specified code set for procedures and services, according to the Health Insurance Portability and Accountability Act (HIPAA).

(11) “Managed care” means the care manager's provision of comprehensive primary care and referral services to an enrollee in a managed care program.

(12) “Managed care program” means:

- (a) Maryland Access to Care Program under COMAR 10.09.44;
- (b) Diabetes Care Program under COMAR 10.09.43;
- (c) Corrective managed care under COMAR 10.09.24.15B or 10.09.25.14B; or
- (d) Hospice care under COMAR 10.09.35.

(13) “Medical Assistance Program” means the program of comprehensive medical and other health-related care for indigent and medically indigent persons.

(14) “Medical Care Programs” means the unit of the Department responsible for the administration of the Medical Assistance Program.

(15) “Medically necessary” means that the service or benefit is:

- (a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
- (b) Consistent with currently accepted standards of good medical practice;
- (c) The most cost efficient service that can be provided without sacrificing effectiveness or access to care; and
- (d) Not primarily for the convenience of the consumer, family, or provider.

(16) “Medicare” means the insurance program administered by the federal government under Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq.

(17) Overpayment.

(a) “Overpayment” means any payment made by the Medicaid Program to a provider for medical care provided to a participant which at the time of payment, or at a subsequent date, is determined to be:

(i) A duplicate payment;

(ii) A payment for services for which reimbursement is claimed when all or any part of the claim submitted to the Department is for services that were provided in violation of one or more regulations;

(iii) Excessive in amount; or

(iv) The primary obligation of a health insurance carrier or any other person, including the participant, who is legally or contractually obligated to pay for that medical care.

(b) “Overpayment” does not include an amount recovered as part of a routine cost settlement process.

(18) “Participant” means a person who is certified as eligible for, and is receiving, Medical Assistance benefits.

(19) “Primary care” means that medical care which addresses a patient's general health needs including the coordination of the patient's health care, with the responsibility for the prevention of disease, promotion and maintenance of health, treatment of illness, and referral to other specialists for more intensive care when appropriate.

(20) “Program” means the Medical Assistance Program.

(21) “Provider” means:

(a) An individual, association, partnership, corporation, unincorporated group, or any other person authorized, licensed, or certified to provide services for Program participants and who, through appropriate agreement with the Department, has been identified as a Program provider by the issuance of an individual account number;

(b) An agent, employee, or related party of a person identified in §B(19)(a) of this regulation; or

(c) An individual or any other person with an ownership interest in a person identified in §B(19)(a) of this regulation.

(22) “State Department of Assessments and Taxation (SDAT)” means the State Department of Assessments and Taxation as described in COMAR Title 18.

(23) “Withhold payment” means the Program's decision to not pay or suspend payment to a provider as a sanction for failure to comply with applicable federal or State laws or regulations or because of a credible allegation of fraud.

.09 FILING APPEAL.

A. Source of Appeals.

(1) A provider may file an appeal from a proposed Program action to:

(a) Suspend the provider from the Program;

(b) Withhold payment by the Program;

(c) Recover an overpayment;

(d) Remove the provider from the Program; or

(e) Disqualify the provider from future participation in the Program, either as a provider or as a person providing services for which Program payment will be claimed.

(2) A provider shall submit an appeal according to:

(a) COMAR 10.01.03;

(b) State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland;

(c) Health-General Article, §§2-201—2-207, Annotated Code of Maryland; and

(d) COMAR 28.02.01.

(3) A provider may not file an appeal from a Program action to terminate the provider when that action is the result of either:

(a) Termination of the provider or an owner by the federal government or another state Medicaid agency pursuant to 42 CFR §445.416; or

(b) Suspension or termination of the provider's license or certificate by their respective licensing or certification authority.

B. Request for a Hearing.

(1) An appeal of a proposed Program action shall be filed in writing with the Program within 30 days of the date of the notice of the proposed Program action. The Program shall make reasonable accommodation if a provider cannot submit a written request because of a disability.

(2) The Program shall immediately forward a written appeal request to the Office of Administrative Hearings.

(3) The Office of Administrative Hearings shall:

(a) Promptly acknowledge any appeal; and

(b) Notify the provider and the Program in writing of the date, time, and place of the hearing.

C. Effective Date. The proposed Program action shall be effective on:

(1) The date of the proposed Program action notice if the Program:

(a) Determines that the provider poses an imminent threat to public health, safety, or welfare that requires emergency action; and

(b) Notifies the provider of this determination in the proposed Program action notice;

(2) The date specified in the proposed Program action notice if the provider:

(a) Does not request a hearing within 30 days of the date of the notice of the proposed Program action; or

(b) Withdraws in writing or abandons a request for a hearing before the effective date of the proposed Program action;

(3) The first payment date following the date of the Program action notice if the Program action involves withholding payment to the provider because the Program discovered an overpayment to the provider;

- (4) The date the administrative law judge renders a decision in favor of the Program if the provider:
- (a) Fails to timely file exceptions to the administrative law judge's decision with the Secretary pursuant to §D of this regulation; or
 - (b) Withdraws in writing or abandons a request for an exceptions hearing before the date of the exceptions hearing; or
- (5) The date the Secretary renders a decision in favor of the Program pursuant to COMAR 10.01.03 if any party files exceptions with the Secretary in accordance with §E(1) of this regulation.

D. A Program determination to suspend payments due to a credible allegation of fraud shall be effective immediately unless the Department determines, consistent with 42 CFR §455.23, that a good cause exception to immediate suspension exists.

E. Exceptions and Outcomes.

- (1) A party may seek additional administrative review of the administrative law judge's decision by filing in writing exceptions with the Secretary within 30 days of the date of the administrative law judge's decision pursuant to COMAR 10.01.03.
- (2) If the Secretary's decision is favorable to the Program, the Program may:
- (a) Immediately implement the proposed Program action; and
 - (b) Institute recovery procedures against the provider to recoup the cost of any payments made to the provider to the extent the payments were made solely because the provider was permitted to continue to submit claims to the Department because of §C(5) of this regulation.
- (3) If the proposed Program action was effective on the date of the notice as provided for in §B(1) of this regulation, the Program shall authorize corrected payments or relief retroactive to the date of the notice if:
- (a) The Secretary's decision is favorable to the provider; or
 - (b) The Program grants the provider the relief the provider requests before the Secretary's decision.

F. Further Appeals. The provider may seek additional administrative review of the Secretary's decision as provided in Health-General Article, §§2-206 and 2-207, Annotated Code of Maryland, and subsequent judicial review as provided in State Government Article, §10-215, Annotated Code of Maryland.

CHAPTER 69 MARYLAND MEDICAID MANAGED CARE PROGRAM: RARE AND EXPENSIVE CASE MANAGEMENT

.01 PURPOSE.

- A. The purpose of the Rare and Expensive Case Management (REM) program is to provide case management services and subspecialty care for Maryland Medicaid Managed Care Program eligible individuals with rare and expensive conditions.
- B. The program is designed to provide Maryland Medicaid Managed Care Program eligible individuals diagnosed with qualifying rare and expensive conditions the following benefits when the individual elects to participate in the program:
- (1) Case management services; and

(2) REM optional services.

.02 DEFINITIONS.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Activities of daily living” means tasks or activities that include but are not limited to bathing, feeding, toileting, dressing, and ambulation.

(2) “Business day” means any day except Saturday, Sunday, or a holiday on which State offices are closed.

(3) “Caregiver” means a willing and able individual who is trained in providing care to the participant.

(4) “Case management” means assessing, planning, coordinating, and monitoring the delivery of medically necessary health-related services.

(5) “Case management provider” means the Department's designee, or a subcontractor of the designee, which provides case management to participants assigned to it by the Department.

(6) “Case manager” means, an individual who is:

(a) A social worker with active and nationally recognized certification in case management or an RN;

(b) Employed by the Department's designee; and

(c) Assigned by the Department's designee to manage the care of some or all of the participants.

(7) “Cause” means a significant change in medical condition such that it is no longer medically efficacious for the individual to remain in the MCO as determined by the Department.

(8) “Certified medication technician (CMT)” means an individual who:

(a) Completes a 20-hour course in medication administration approved by the Maryland Board of Nursing;

(b) Is certified by the Maryland Board of Nursing under COMAR 10.39.04; and

(c) Performs medication administration tasks delegated by a nurse in accordance with COMAR 10.27.11.

(9) “Certified nursing assistant (CNA)” means an individual who:

(a) Is certified by the Maryland Board of Nursing under COMAR 10.39.05; and

(b) Routinely performs nursing tasks delegated by a nurse in accordance with COMAR 10.27.11.

(10) “Certified nursing assistant certified as a CMT (CNA-CMT)” means an individual who:

(a) Is certified by the Maryland Board of Nursing under COMAR 10.39.05 and 10.39.04;

(b) Completes a 20-hour course in medication administration approved by the Maryland Board of Nursing; and

(c) Routinely performs nursing tasks including medication administration tasks delegated by a nurse in accordance with COMAR 10.27.11.

(11) “Chiropractor” means an individual who is licensed by the Maryland State Board of Chiropractic Examiners to practice chiropractic in Maryland.

(12) “Delegated nursing services” means nursing services provided to a participant by a CNA, CNA-CMT, HHA, or HHA-CMT under the supervision of an RN in accordance with COMAR 10.27.11.

(13) “Dental service provider” means an individual who is licensed and legally authorized to practice dentistry in the state in which the service is provided.

(14) “Department” means the Department of Health, as defined in COMAR 10.09.36.01, or its authorized agents acting on behalf of the Department.

(15) “Dietitian-nutritionist” means an individual who is licensed as a dietitian-nutritionist by the Maryland State Board of Dietetic Practice to practice dietetics in Maryland.

(16) “Early and periodic screening, diagnosis, and treatment (EPSDT)” means the provision, to individuals younger than 21 years old, of preventive health care pursuant to 42 CFR §441.50 et seq., as amended, and other health care services, diagnostic services, and treatment services that are necessary to correct or ameliorate defects, physical and mental illnesses, and conditions discovered by EPSDT screening services.

(17) “EPSDT-certified provider” means a physician, physician assistant or nurse practitioner who is certified by the Department's EPSDT program to provide well-child services according to the Department's periodicity schedule and program standards to enrollees younger than 21 years old.

(18) “EPSDT periodicity schedule” means the list approved by the Department of required or recommended preventive health care services for children and adolescents.

(19) “EPSDT services” means:

(a) Screening services provided by an EPSDT-certified provider that are required or recommended on the EPSDT periodicity schedule; and

(b) Health care services performed to diagnose, treat, or refer problems or conditions discovered during the comprehensive well-child service.

(20) “Evaluation” means a determination of the health status of a patient in a patient's home or any other appropriate setting by a licensed professional for the purpose of designing an individual plan of care, which incorporates the modalities of treatment that will promote optimal functional ability and recuperation.

(21) “Family member” means an adult who:

(a) Lives with or provides care to the participant; and

(b) Is not paid to provide the care under the REM program.

(22) “HealthChoice” means Maryland Medicaid's Statewide mandatory managed care program as defined in COMAR 10.67.04.

(23) “Home” means the place of residence, occupied by the participant, other than a residence or facility where nursing services are included in the living arrangement by regulation or statute, or otherwise provided for payment.

(24) “Home health agency” means an agency licensed by the Department in accordance with COMAR 10.07.10.

(25) “Home health aide (HHA)” means an individual who meets all the conditions of participation specified in:

(a) 42 CFR §484.36; and

(b) Health Occupations Article, Title 8, Annotated Code of Maryland.

(26) “Home health aide certified as a CMT (HHA-CMT)” means an individual who:

(a) Meets all the conditions of participation specified in 42 CFR §484.36 and Health Occupations Article, Title 8, Annotated Code of Maryland; and

(b) Completes a 20-hour course in medication administration approved by the Maryland Board of Nursing.

(27) “Hospital” means an institution licensed by and providing services in accordance with Health-General Article, §19-301, Annotated Code of Maryland.

(28) “Individualized education program (IEP)” means a written description of special education and related services developed by an IEP team to be implemented to meet the individual needs of a child.

(29) “Individualized family service plan (IFSP)” means a written plan for providing early intervention and other services to an eligible child and the child's family developed by an IFSP team.

(30) “Interdisciplinary team” means the group comprised of the case manager and relevant service providers to develop the case management plan under the overall direction and coordination of the case manager, in consultation with the participant and, when applicable, the participant's family.

(31) “Intermediate care facility for individuals with intellectual disabilities or individuals with related conditions (ICF-IID)” means an institution licensed by the Department under COMAR 10.07.20 that provides health-related services or health rehabilitative services for individuals with intellectual disabilities or related conditions.

(32) “Licensed practical nurse (LPN)” means an individual licensed to practice licensed practical nursing as defined in Health Occupations Article, §8-301, Annotated Code of Maryland.

(33) “Managed care organization (MCO)” has the meaning stated in Health-General Article, §15-101, Annotated Code of Maryland.

(34) “Medical Assistance” means the program administered by the State under Title XIX of the Social Security Act which provides comprehensive medical and other health-related care for categorically eligible and medically needy individuals.

(35) “Medically necessary” means that the service or benefit is:

(a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;

(b) Consistent with current accepted standards of good medical practice;

(c) The most cost-efficient service that can be provided without sacrificing effectiveness or access to care; and

(d) Not primarily for the convenience of the participant, the participant's family, or the provider.

(36) “Medicare” means the federal program that provides benefits to the aged and disabled under Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq.

- (37) “Nurse” means an individual who is licensed to practice as a registered nurse (RN) or a licensed practical nurse (LPN) in the jurisdiction in which services are provided.
- (38) “Nurse practitioner” means an individual who is licensed and certified to practice as a nurse practitioner in the jurisdiction in which services are provided.
- (39) “Nursing facility” has the meaning stated in COMAR 10.09.10.01B.
- (40) “Nutritional counseling” means the assessment of the participant's nutritional status and education about improving their nutritional status provided by a licensed dietitian-nutritionist.
- (41) “Nutritional supplements” means enteral feeding which is medically indicated as either the sole source of nutrition or a supplement that enhances the physical well-being of the participant.
- (42) “Occupational therapist” means an individual licensed by the Maryland State Board of Occupational Therapy Practice to practice occupational therapy in Maryland.
- (43) “Participant” means an eligible individual who is enrolled in the Program.
- (44) “Physician” means an individual who is licensed or otherwise legally authorized to practice in the jurisdiction in which the services are rendered.
- (45) “Physician assistant” means an individual who is licensed to practice medicine with physician supervision as stated in the Health Occupations Article, §§15-301(d) and (e) and 15-302, Annotated Code of Maryland.
- (46) “Plan of care” means the document which governs a participant's care management which includes the:
- (a) Case management assessment report;
 - (b) Interdisciplinary plan of care; and
 - (c) Case management plan.
- (47) “Preauthorization” means the approval required from the Department or its designee before specific services may be rendered.
- (48) “Primary care provider (PCP)” means a physician, physician assistant, or nurse practitioner who is the primary coordinator of care for the participant, and whose responsibility it is to provide accessible, continuous, comprehensive, and coordinated health care services covering the full range of benefits required by the Maryland Medicaid Managed Care Program, as specified in COMAR 10.67.06.
- (49) “Private duty nursing” means skilled nursing services for participants, who require more individual and continuous care than is available under the home health program, which are provided by a registered nurse (RN) or a licensed practical nurse (LPN), in a participant's home or another setting when normal life activities take the participant outside his or her home.
- (50) “Program”, unless the context indicates otherwise, has the meaning stated in COMAR 10.09.36.01B.
- (51) “Progress note” means a signed and dated written notation by the RN, LPN, CNA, CNA-CMT, HHA, or HHA-CMT, which:
- (a) Summarizes facts about the care given and the participant's response during a given period of time;
 - (b) Specifically addresses the established goals of treatment;
 - (c) Is consistent with the participant's plan of care; and

(d) Is written during the course of care.

(52) “Provider” means an individual, agency, or facility, which is enrolled in the Program through an agreement with the Department, and has been identified as a Program provider by the issuance of a provider number.

(53) “Rare and expensive case management (REM)” means a Maryland Medical Assistance program that provides case management services and optional services to eligible individuals with specific rare and expensive conditions.

(54) “Rare and expensive condition” means a medical diagnosis or condition identified in Regulation .16 of this chapter.

(55) “Registered nurse (RN)” means an individual licensed to practice registered nursing as defined in Health Occupations Article, §8-301, Annotated Code of Maryland.

(56) “REM optional services” means the services listed in Regulations .10 and .11 of this chapter, which meet the general requirements under Regulation .09 of this chapter.

(57) “Residential service agency” means an agency licensed by the Department in accordance with COMAR 10.07.05.

(58) “Residential treatment center” means any institution which falls within the jurisdiction of Health-General Article, §19-308, Annotated Code of Maryland, and is licensed as required by COMAR 10.07.04 or other applicable standards established by the state in which the service is provided.

(59) “School” means courses or classes for the acquisition of a General Education Diploma, a high school diploma, an associate degree, or a first-time bachelor’s degree.

(60) “Social worker” means an individual who is licensed by the Maryland State Board of Social Work Examiners to practice social work in Maryland.

(61) “Speech-language pathologist” means an individual who is licensed by the Maryland Board of Examiners for Audiologists, Hearing Aid Dispensers, and Speech-Language Pathologists to practice speech-language pathology in Maryland.

.03 REM ELIGIBILITY.

A. An individual is eligible to participate in the REM program if the individual:

(1) Is eligible for Maryland Medicaid Managed Care as specified in COMAR 10.67.02.01;

(2) Has one or more of the diagnoses specified in Regulation .17 of this chapter; and

(3) Elects to participate in the REM program.

B. The Department shall render a determination of an individual's eligibility within 5 business days on receipt of:

(1) A completed REM application;

(2) Any requested documentation verifying an individual meets the criteria set forth in §A of this regulation; and

(3) Verbal or written confirmation an individual elects to participate.

.04 PARTICIPANT ENROLLMENT AND DISENROLLMENT.

A. Anyone may refer an individual into the REM program including, but not limited to a:

- (1) Family member;
- (2) Physician;
- (3) Discharge planner;
- (4) Hospital;
- (5) Clinic;
- (6) Social worker; and
- (7) Managed care organization (MCO).

B. The Department shall enroll an individual determined eligible in the REM program when:

- (1) All pertinent documentation regarding needed medical services is received, reviewed, and approved;
- (2) Confirmation of the individual's election to participate in the program is received; and
- (3) The individual is being discharged from an institution or transitioning from an MCO and service coordination is complete.

C. When an MCO participant is referred to the REM program for enrollment, the MCO shall:

- (1) Provide confirmation of the qualifying diagnosis to the Department; and
- (2) Continue to provide the MCO participant's care until the Department confirms the diagnosis and enrolls the MCO participant into REM.

D. An individual shall be enrolled in or auto-assigned into an MCO as specified in COMAR 10.67.02, not later than 60 days from the date the individual becomes ineligible for REM, as a result of changes in the diagnosis or age group criteria specified in Regulation .17 of this chapter, except when the individual was allowed to remain in REM in accordance with §I of this reregulation.

E. A REM participant may elect to disenroll from REM and enroll in an MCO by notifying the Department of that decision except when the individual was allowed to remain in REM in accordance with §I of this regulation.

F. Election to Remain in MCO.

- (1) An individual who becomes eligible for REM while enrolled in an MCO may elect to remain in an MCO by notifying the Department of that decision.
- (2) When a REM-eligible individual elects to remain in an MCO, the Department, in consultation with the MCO and the REM-eligible individual, may determine whether the MCO can appropriately meet the individual's medical needs within the parameters of the program benefit package as described in COMAR 10.67.06.
- (3) If the MCO determines it cannot appropriately meet the individual's medical needs, the MCO shall submit to the Department written justification for its decision.
- (4) If the Department determines the MCO can meet the individual's medical needs, the Department shall notify the MCO of its decision in writing.

(5) If the Department determines that the MCO cannot appropriately meet the individual's needs, the Department shall issue a written determination to the individual and the MCO which includes:

(a) The reason for the determination; and

(b) An explanation of the individual's right to appeal the determination according to the procedures set forth in COMAR 10.01.04.

(6) If the Department determines that the MCO can appropriately meet the individual's medical needs, the individual's election becomes effective and cannot be revoked without cause for a period of 1 year from the effective date.

G. The Department shall allow an individual who, immediately before enrollment in REM, was receiving medical services from a specialty clinic or other setting to continue to receive services in that setting on enrollment in the REM program when the provider is willing to participate as a Medical Assistance fee-for-service provider.

H. An individual eligible for REM who has elected to enroll in an MCO or to remain enrolled in an MCO may not receive REM services under the REM program.

I. The Department shall disenroll from the REM program a participant who no longer meets the conditions specified in Regulation .03 of this chapter unless:

(1) The participant does not meet the condition under Regulation .03A(1) of this chapter because the participant becomes eligible for Medicare; and

(2) At the time the participant became eligible for Medicare the participant was approved for and was receiving private duty nursing, CNA, CNA-CMT, HHA, or HHA-CMT services under the REM program.

J. An individual disenrolled from REM by the Department who maintains HealthChoice eligibility is subject to the MCO enrollment provisions specified in COMAR 10.67.02 except when the individual was allowed to remain in REM in accordance with §I of this regulation.

K. Department-Initiated Disenrollment. The Department shall disenroll from REM an enrollee:

(1) Who has been continuously institutionalized for a period of more than 90 successive days in a long-term care facility, subject to the long-term care facility obtaining the Department's determination that the enrollee's institutionalization has been medically necessary;

(2) Who has been, or is expected to be, continuously institutionalized for more than 30 successive days in an institution for mental disease (IMD);

(3) Upon admission to an intermediate care facility for individuals with intellectual disabilities or persons with related conditions (ICF/IID);

(4) Who loses Medicaid eligibility or who changes to an assistance category not eligible for MCO enrollment, subject to COMAR 10.67.02;

(5) Who has died; or

(6) Who is an inmate of a public institution, including a State-operated institution or facility.

L. Effective Date of Disenrollment. An enrollee's disenrollment shall take effect:

(1) Immediately when the enrollee dies;

- (2) From the first day of the month following the month in which the enrollee lost Medicaid eligibility;
- (3) On the first day of the month following the month in which the Department receives the required notification, when the enrollee permanently relocates outside of the State; or
- (4) From the first day of the month following the month in which the Department verifies an enrollee is an inmate.

.05 BENEFITS.

A REM participant is eligible for the following:

A. Fee-for-service Medical Assistance benefits available to a Medical Assistance participant not enrolled in an MCO;

B. Services described in Regulations .10 and .11 of this chapter when determined medically necessary by the Department;

C. A case management assessment performed by a REM case manager who shall:

- (1) Gather all relevant information needed to determine the participant's condition and needs including the participant's medical records;
- (2) Consult with the participant's current service providers; and
- (3) Evaluate the relevant information and complete a needs analysis including medical, psychosocial, environmental, and functional assessments; and

D. Case management services performed by a REM case manager who shall:

- (1) When necessary, assist the REM participant, offering the participant a choice, if possible, in selecting and obtaining a PCP, who may be a specialist to the participant's condition, giving preference to any pre-established relationships between the participant and the participant's PCP;
- (2) Develop a plan of care in consultation with the participant, the participant's family members as authorized by the participant when possible, the PCP, and other providers rendering care that:
 - (a) Includes the participant's health status and needs for medical, health-related, housing, and social services including, but not limited to:
 - (i) All pertinent diagnoses including the REM qualifying diagnosis;
 - (ii) Type, frequency, and duration of services;
 - (iii) Treatment goals for each type of service;
 - (iv) Medical equipment and supplies;
 - (v) Medication;
 - (vi) Social support structure;
 - (vii) Current service providers;
 - (viii) Assigned level of care;

- (ix) Nutritional status;
 - (x) Education or vocational information;
 - (xi) Current living arrangement; and
 - (xii) Emergency plan, if appropriate; and
- (b) Is developed in consultation with the interdisciplinary team;
- (3) Implement the plan of care and assist the participant in gaining access to medically necessary services by linking the participant to those services;
- (4) Monitor service delivery, perform record reviews, and maintain contacts with the participant, services providers, and family members to evaluate the participant's condition and progress and to determine whether revision is needed in the plan of care or in services' delivery;
- (5) As necessary, initiate and implement modifications to the plan of care and communicate these changes to the participant, parents or caregivers, and pertinent health care providers;
- (6) Monitor a participant's receipt of EPSDT services as specified in COMAR 10.67.06; and
- (7) Assist the participant with the coordination of school health-related services such as the IEP or the IFSP as described in COMAR 10.09.50.

.06 REQUIREMENTS FOR PROVIDER QUALIFICATION.

A. A case manager providing case management under this chapter shall be:

- (1) An RN; or
- (2) A social worker.

B. The following professionals providing services under this chapter to REM participants shall be licensed, certified, or otherwise legally authorized to practice in the jurisdiction in which the services are rendered:

- (1) Physicians;
- (2) Physician Assistants;
- (3) Nurse Practitioners;
- (4) RNs and LPNs;
- (5) Chiropractors;
- (6) Dentists;
- (7) Dietitian-Nutritionists;
- (8) Occupational therapists;
- (9) Social workers;

(10) Speech-language pathologists; and

(11) CNAs, HHAs, CNA-CMTs, and HHA-CMTs.

C. A provider rendering services pursuant to this chapter shall meet all applicable licensure and certification requirements of the jurisdiction in which the provider is providing services.

D. A provider rendering services to REM participants, pursuant to this chapter, may not have current sanctions or current disciplinary actions imposed by:

(1) The jurisdictional licensing or certification authority;

(2) The Medicare Program;

(3) The Program; or

(4) Other federally funded healthcare programs.

.07 CONDITIONS FOR PARTICIPATION — GENERAL REQUIREMENTS.

A provider rendering services pursuant to this chapter shall:

A. Meet the applicable conditions for participation set forth in COMAR 10.09.36;

B. Meet the provider qualification requirements specified in Regulation .06 of this chapter for its provider type;

C. Meet the specific conditions for provider participation set forth in this chapter;

D. Provide services in accordance with the applicable requirements of this chapter and all other relevant State and local laws and regulations;

E. Verify the qualifications of all subcontracted or employed professionals and individuals engaged by the provider agency to render services covered under this chapter and provide a copy of their current licensure and credentials on request to the Department;

F. Provide services to REM program participants in a manner consistent with the REM participant's plan of care; and

G. When the Department determines it is necessary, participate in the interdisciplinary team meetings for the purpose of:

(1) Developing and implementing a participant's treatment plan or plan of care with the Department; or

(2) Accessing a specific service.

.08 SPECIFIC CONDITIONS FOR PROVIDER PARTICIPATION.

A. Case Management Providers. To participate in the Program, a case management provider shall meet the conditions set forth in Regulations .06 and .07 of this chapter.

B. Chiropractic Service Providers. To participate in the Program, the chiropractic service provider shall:

(1) Meet the:

- (a) Conditions set forth in Regulation .07 of this chapter; and
 - (b) Requirements for chiropractic providers specified in COMAR 10.43.04;
- (2) Develop a goal-directed treatment plan that is based on an evaluation conducted during the initial assessment, which requires:
- (a) A review or evaluation of the treatment plan 30 days after the initial assessment; and
 - (b) A review and update of the treatment plan every 90 days; and
- (3) Render services in accordance with orders written by a physician, physician assistant, or nurse practitioner.

C. Dental Service Providers. To participate in the Program, the dental service provider shall meet the:

- (1) Conditions set forth in Regulation .07 of this chapter; and
- (2) Requirements for dental providers specified in COMAR 10.09.05.

D. Nutritional Supplement Providers. To participate as a provider of nutritional supplements, a provider shall meet the:

- (1) Conditions of participation as set forth in Regulation .07 of this chapter; and
- (2) Criteria of the conditions for participation for pharmacy providers set forth in COMAR 10.09.03.

E. Shift Private Duty Nursing/CNA/CNA-CMT/HHA/HHA-CMT Providers. To participate as a provider agency for shift private duty nursing, CNA, CNA-CMT, HHA, or HHA-CMT services, a provider shall:

- (1) Meet the conditions set forth in Regulation .07 of this chapter;
- (2) Meet all requirements of conditions for participation set forth in COMAR 10.09.53.03;
- (3) Participate in interdisciplinary team meetings, when requested by the Department or its designee;
- (4) Develop a goal-directed written nursing care plan that is based on an evaluation conducted during the initial assessment, which requires:
 - (a) A review or evaluation of the nursing care plan 30 days after the initial assessment; and
 - (b) A review and update of the nursing care plan every 90 days;
- (5) Ensure timesheets are signed by the individual rendering services;
- (6) Ensure a nurse's, CNA's, CNA-CMT's, HHA's, or HHA-CMT's shift to be not more than a total of 60 hours per week or 16 consecutive hours and that the individual is off 8 or more hours before starting another shift unless otherwise authorized by the Department;
- (7) Obtain the participant's signature or the signature of the participant's witness on the provider's official forms to verify receipt of service; and
- (8) Be licensed as a:
 - (a) Residential service agency in accordance with COMAR 10.07.05; or

(b) Home health agency in accordance with COMAR 10.07.10 which meets the conditions of participation specified by the Medicare program in 42 CFR §484.36.

F. Occupational Therapy Providers. To participate in the Program as a provider of occupational therapy services, a provider shall:

- (1) Meet the conditions set forth in Regulation .07 of this chapter;
- (2) Be a self-employed occupational therapist licensed according to COMAR 10.46.01;
- (3) Be an agency or clinic which employs occupational therapists or be a Program provider of home health services under COMAR 10.09.04; and
- (4) Develop a goal-directed written treatment plan that is based on an evaluation conducted during the initial assessment which requires:
 - (a) A review or evaluation of the treatment plan 30 days after the initial assessment; and
 - (b) A review and update of the treatment plan every 90 days.

G. Speech-Language Pathology Providers. To participate in the Program, a speech-language pathology provider shall:

- (1) Meet the conditions set forth in Regulation .07 of this chapter;
- (2) Be a self-employed speech-language pathologist according to COMAR 10.41.03 or be a Program provider of home health services under COMAR 10.09.04;
- (3) Be an agency or clinic that employs speech-language pathologists; and
- (4) Develop a goal-directed written treatment plan that is based on an initial assessment, which requires:
 - (a) A review or evaluation of the treatment plan 30 days after the initial assessment; and
 - (b) A review and update of the treatment plan every 90 days.

.09 COVERED SERVICES — GENERAL REQUIREMENTS.

For participants in the REM program, the Program covers and shall reimburse for services specified in Regulations .10 and .11 of this chapter when these services are:

A. Medically necessary;

B. Prescribed by a:

- (1) Physician;
- (2) Physician assistant; or
- (3) Nurse practitioner;

C. Preauthorized, when required, by the Department;

D. Rendered in accordance with accepted health professional standards;

E. Rendered in accordance with the treatment plan or physician's, physician assistant's, or nurse practitioner's order, or both; and

F. Delivered by an enrolled Medical Assistance provider.

.10 COVERED SERVICES.

A. Chiropractic services are covered for REM participants when:

- (1) Services are provided to a REM participant who is 21 years old or older;
- (2) Services are provided by a physician or chiropractor;
- (3) The qualifying REM diagnosis or related illness shows deterioration or worsening symptoms and other traditional treatments have been ineffective;
- (4) The treatment enhances or restores the participant's level of functioning; or
- (5) Symptoms resulting from the REM diagnosis or related illness impairs a participant's activities of daily living.

B. Dental services are covered when services are:

- (1) Provided to a REM participant who is 21 years old or older; and
- (2) Rendered as specified in COMAR 10.09.05.

C. Nutritional counseling services are covered when services are provided:

- (1) To a REM participant who is 21 years old or older; and
- (2) By a dietitian-nutritionist.

D. Nutritional supplements are covered when the services:

- (1) Include nutritional supplements or enteral feeding when medically necessary other than those administered by tube; and
- (2) Are as described in COMAR 10.09.03.

E. The Department shall cover a physician's, physician assistant's, or nurse practitioner's participation at interdisciplinary team meetings when the case manager, in conjunction with the team or specific team members, convenes the team meeting for the purpose of developing or reviewing the REM participant's plan of care to ensure continuity of care or access to a specific service.

F. Occupational therapy services are covered when services are provided:

- (1) To a REM participant who is 21 years old or older;
- (2) By an occupational therapist; and
- (3) In accordance with COMAR 10.46.01 and 10.46.02.

G. Speech-language pathology services include only those services that are provided:

- (1) To a REM participant who is 21 years old or older;
- (2) By a speech-language pathologist; and
- (3) In accordance with COMAR 10.41.02 and 10.41.03.

.11 COVERED OPTIONAL SERVICES — PRIVATE DUTY NURSING, CERTIFIED NURSING ASSISTANT, CERTIFIED NURSING ASSISTANT CERTIFIED AS A CERTIFIED MEDICATION TECHNICIAN, HOME HEALTH AIDE AND HOME HEALTH AIDE CERTIFIED AS A CERTIFIED MEDICATION TECHNICIAN.

A. The Program shall cover shift nursing services provided by an RN or LPN when:

- (1) The services are more individualized and continuous than what is available under the home health program;
- (2) The services are delivered to the participant in the participant's home, in school, or in other normal life activity setting or settings which occur outside the participant's home;
- (3) Services are provided to a REM participant who is 21 years old or older;
- (4) Services are determined medically necessary for a participant after the provider has completed an initial nursing assessment that reflects the participant's need for an awake and alert caregiver;
- (5) The participant has at least one caregiver willing and able to accept responsibility for the participant's care when the nurse, CNA, or HHA is not available;
- (6) The caregiver provides documentation of each of the following when applicable:
 - (a) The caregiver's work schedule along with commuting times;
 - (b) The caregiver's school attendance as defined in Regulation .02 of this chapter along with commuting times; and
 - (c) Emergency circumstances, as determined by the Department, including but not limited to the inability of the primary caregiver to provide care due to hospitalization or an acute debilitating illness for up to a 60-day period;
- (7) Services are provided only in the absence of the willing and able caregiver during the sleeping hours and during the times documented in §A(6) of this regulation;
- (8) Services are rendered in accordance with Health Occupations Article, Title 8, Annotated Code of Maryland;
- (9) Sufficient documentation concerning the services provided is maintained by the RN or LPN including:
 - (a) Verification of the participant's receipt of services as documented by the participant's signature or the signature of the participant's witness on the provider's official forms; and
 - (b) Signed and dated progress notes which are reviewed monthly by the RN supervisor;
- (10) The nurse's shift is limited to not more than a total of 60 hours per week or 16 consecutive hours and the nurse is off 8 or more hours before starting another shift unless otherwise authorized by the Department;
- (11) Services are rendered by an RN or an LPN who is certified in cardiopulmonary resuscitation and the certification is renewed every 2 years; and

(12) Monthly supervisory visits of an RN or an LPN are:

- (a) Conducted and documented by an RN supervisor; and
- (b) Based on acceptable standards of practice.

B. The Program shall cover service's provided by a CNA or CNA-CMT when:

- (1) The CNA or CNA-CMT is certified by the Maryland Board of Nursing and meets all the requirements to render services pursuant to Health Occupations Article, Title 8, Annotated Code of Maryland;
- (2) The CNA-CMT has completed the training and has been certified by the Maryland Board of Nursing as a CMT;
- (3) Services are of a scope that is more individual and continuous than what is available under the home health program;
- (4) The services provided include but are not limited to:
 - (a) Assistance with activities of daily living when performed in conjunction with other delegated nursing services; or
 - (b) Other health care services properly delegated by an RN or an LPN pursuant to Health Occupations Article, Title 8, Annotated Code of Maryland;
- (5) Services are rendered by a CNA or CNA-CMT who is certified in cardiopulmonary resuscitation and the certification is renewed every 2 years;
- (6) The CNAs or CNA-CMTs shift is limited to not more than a total of 60 hours per week or 16 consecutive hours and the CNA or CNA-CMT has 8 hours or more off before starting another shift unless otherwise authorized by the Department;
- (7) Sufficient documentation concerning the services provided is maintained by the CNA or CNA-CMT including:
 - (a) Verification of the participant's receipt of services as documented by the participant's signature or the signature of the participant's witness on the provider's official forms; and
 - (b) Signed and dated progress notes which are reviewed every 2 weeks by the RN supervisor;
- (8) Supervisory visits are conducted and documented every 2 weeks by an RN;
- (9) The services are included in the REM participant's plan of care developed by the case manager; and
- (10) Services are preauthorized by the Department.

C. The Program shall cover services provided by a HHA or HHA-CMT when:

- (1) Services are provided by an unlicensed individual who meets all the conditions of participation specified by the Medicare program in 42 CFR §484.36 and Health Occupations Article, Title 8, Annotated Code of Maryland;
- (2) The HHA-CMT has completed the training and has been certified by the Maryland Board of Nursing as a CMT;
- (3) Services are more individualized and continuous than what is available under the home health program;
- (4) The services provided include but are not limited to:

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- (a) Assistance with activities of daily living when performed in conjunction with other delegated nursing services; or
- (b) Other health care services properly delegated by an RN or LPN pursuant to Health Occupations Article, Title 8, Annotated Code of Maryland;
- (5) Services are rendered by a HHA or HHA-CMT who is certified in cardiopulmonary resuscitation and the certification is renewed every 2 years;
- (6) The HHAs or HHA-CMTs shift is limited to not more than a total of 60 hours per week or 16 consecutive hours and the HHA or HHA-CMT has 8 hours or more off before starting another shift unless otherwise authorized by the Department;
- (7) Sufficient documentation is maintained by the HHA or HHA-CMT including:
 - (a) Verification of the participant's receipt of services as documented by the participant's signature or the signature of the participant's witness on the provider's official forms; and
 - (b) Signed and dated progress notes which are reviewed every 2 weeks by the RN supervisor;
- (8) Supervisory visits are conducted and documented every 2 weeks by an RN;
- (9) The services are included in the REM participant's plan of care developed by the case manager; and
- (10) Services are preauthorized by the Department.

.12 LIMITATIONS.

A. The Department shall pay for services specified in this chapter delivered to a REM participant only if the services have been ordered by the participant's physician or nurse practitioner, and preauthorized, when necessary, by the Department or its designee.

B. For REM participants, the Department may not pay for the following comparable case management services:

- (1) HIV targeted case management as described in COMAR 10.09.32, except for HIV Diagnostic Evaluation Services as described in COMAR 10.09.32.03C and .04A; and
- (2) Model Waiver case management as described in COMAR 10.09.27.

C. The REM program does not cover the following:

- (1) Shift private duty nursing, CNA or CNA-CMT, or HHA or HHA-CMT services rendered by a nurse, CNA, HHA, CNA-CMT, or HHA-CMT who is a member of the participant's immediate family or who ordinarily resides with the participant;
- (2) Services which are not medically necessary;
- (3) Services not supervised by an RN when delivered by the following:
 - (a) An RN or an LPN;
 - (b) A CNA;
 - (c) An HHA;

- (d) A CNA-CMT; or
- (e) An HHA-CMT.
- (4) REM optional services not preauthorized as required by the Department or its designee;
- (5) REM optional services not prescribed by the participant's physician, physician assistant, or nurse practitioner;
- (6) Services specified in this chapter which duplicate or supplant services rendered by the participant's family caregivers or primary caregivers as well as other insurance, privilege, entitlement, or Program services that the participant receives or is eligible to receive;
- (7) Services provided for the convenience or preference of the participant or the primary caregiver rather than required by the participant's medical condition;
- (8) Speech, language, or occupational therapy services rendered in a classroom setting;
- (9) Shift private duty nursing, CNA, CNA-CMT, HHA, or HHA-CMT services ordered by a physician assistant;
- (10) Custodial services;
- (11) Services provided to a participant in a:
 - (a) Hospital;
 - (b) Residential treatment center;
 - (c) Intermediate care facility for individuals with intellectual disabilities; or
 - (d) Residence or facility where nursing services are included in the living arrangement by regulation or statute, or otherwise provided for payment;
- (12) Services not directly related to the participant's plan of care;
- (13) Services described in the plan of care whenever a major change occurs in the participant's medical condition or skilled nursing care needs that indicates such services are no longer necessary;
- (14) Services which are not initially ordered before the start of care and renewed every 60 days by the participant's primary medical provider;
- (15) Services provided by a nurse, CNA, or HHA who does not possess a valid, current, and nontemporary nursing license or certifications to provide services in the jurisdiction in which nursing services are rendered;
- (16) Services provided by a nurse, CNA, or HHA who does not have a current cardiopulmonary resuscitation (CPR) certification for the period during which the services are rendered;
- (17) Direct payment for supervisory visits that do not meet acceptable standards of practice in accordance with COMAR 10.27.09, 10.27.10, and 10.27.11;
- (18) Services rendered to a participant by a nurse, CNA, or HHA in the assigned staff's home;
- (19) Services not documented; and
- (20) Respite services.

D. The Program shall only cover one-to-one nursing when a participant's condition requires that level of service and shared services are not an option.

E. The Program shall only cover nursing services ordered by an individual who is enrolled as a provider in the Program with an active status on the date of service.

.13 PREAUTHORIZATION REQUIREMENTS.

A. Except for initial assessments unless otherwise specified, preauthorization by the Department or its designee is required for all services under Regulations .10 and .11 of this chapter.

B. The Department or its designee shall issue preauthorization when the Department:

- (1) Determines that services are medically necessary; and
- (2) Authorizes the services before the initiation or continuance of the requested service.

C. Authorization of services shall be rescinded by the Department or its designee when:

- (1) The participant is admitted to a hospital, residential treatment center, nursing facility, or ICF/IID;
- (2) The participant is no longer REM eligible;
- (3) The Department determines the care is no longer medically necessary; or
- (4) The participant dies.

.14 PAYMENT PROCEDURES — REQUEST FOR PAYMENT.

A. A provider shall submit a request for payment for the services covered under this chapter according to the procedures set forth in COMAR 10.09.36.

B. Billing time limitations for the services covered under this chapter are the same as those set forth in COMAR 10.09.36.

C. The Department shall pay for covered services at the lower of:

- (1) The lowest price, including negotiated contract prices, that is offered to any other purchaser for the same or similar service during the same time period, after extending to the Program all rebates, coupons, and negotiated discounts;
- (2) The actual charge billed by the provider; or
- (3) Any fee schedule developed for reimbursement of the same service provided under Medical Assistance.

D. For dates of service from January 1, 2021, through June 30, 2022, the Department shall pay \$445.86 for a case management assessment, as described in Regulation .05C of this chapter.

E. For dates of service from January 1, 2021, through June 30, 2022, the Department shall make payments monthly for case management services at one of the rates specified below:

- (1) Level of Care 1: \$329.22;

(2) Level of Care 2: \$196.22; or

(3) Level of Care 3: \$103.56.

F. Effective July 1, 2022, the Department shall pay \$463.69 for a case management assessment, as described in Regulation .05C of this chapter.

G. Effective July 1, 2022, the Department shall make payments monthly for case management services at one of the rates specified below:

(1) Level of Care 1: \$342.39;

(2) Level of Care 2: \$204.07; or

(3) Level of Care 3: \$107.70.

H. The rates found in §§E and G of this regulation are the monthly rates paid by the Department for a participant receiving case management as follows:

(1) Level of Care 1 is intensive level of case management, assessment, and coordination of services for a participant who:

(a) Is acutely ill;

(b) Has an unstable clinical condition;

(c) Has an exacerbated chronic illness; or

(d) Has a newly diagnosed condition;

(2) Level of Care 2 is case management to a participant who has a history of exacerbations of medical issues requiring services on an ongoing basis to attain stable service or treatment plans; and

(3) Level of Care 3 is case management that is required on an ongoing basis to monitor a participant's stability and treatment plans.

.15 RECOVERY AND REIMBURSEMENT.

Recovery and reimbursement under this chapter are set forth in COMAR 10.09.36.

.16 CAUSE FOR SUSPENSION OR REMOVAL AND IMPOSITION OF SANCTIONS.

Cause for suspension or removal and imposition of sanctions is set forth in COMAR 10.09.36.

.17 TABLE OF RARE AND EXPENSIVE DISEASE DIAGNOSES.

ICD10	ICD 10 DESCRIPTION	AGE LIMIT
B20	Human immunodeficiency virus (HIV) disease	0—20
C96.0	Multifocal and multisystemic Langerhans-cell histiocytosis	0—64

C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis	0—64
C96.6	Unifocal Langerhans-cell histiocytosis	0—64
D61.01	Constitutional (pure) red blood cell aplasia	0—20
D61.09	Other constitutional aplastic anemia	0—20
D66	Hereditary factor VIII deficiency	0—64
D67	Hereditary factor IX deficiency	0—64
D68.00	Von Willebrand disease, unspecified	0—64
D68.01	Von Willebrand disease, type 1	0—64
D68.020	Von Willebrand disease, type 2A	0—64
D68.021	Von Willebrand disease, type 2B	0—64
D68.022	Von Willebrand disease, type 2M	0—64
D68.023	Von Willebrand disease, type 2N	0—64
D68.029	Von Willebrand disease, type 2, unspecified	0—64
D68.03	Von Willebrand disease, type 3	0—64
D68.04	Acquired von Willebrand disease	0—64
D68.09	Other von Willebrand disease	0—64
D68.1	Hereditary factor XI deficiency	0—64
D68.2	Hereditary deficiency of other clotting factors	0—64
E70.0	Classical phenylketonuria	0—20
E70.1	Other hyperphenylalaninemias	0—20
E70.20	Disorder of tyrosine metabolism, unspecified	0—20
E70.21	Tyrosinemia	0—20
E70.29	Other disorders of tyrosine metabolism	0—20
E70.30	Albinism, unspecified	0—20

E70.40	Disorders of histidine metabolism, unspecified	0—20
E70.41	Histidinemia	0—20
E70.49	Other disorders of histidine metabolism	0—20
E70.5	Disorders of tryptophan metabolism	0—20
E70.81	Aromatic L-amino acid decarboxylase deficiency	0—20
E70.89	Other disorders of amino-acid metabolism	0—20
E71.110	Isovaleric acidemia	0—20
E71.111	3-methylglutaconic aciduria	0—20
E71.118	Other branched-chain organic acidurias	0—20
E71.120	Methylmalonic acidemia	0—20
E71.121	Propionic acidemia	0—20
E71.128	Other disorders of propionate metabolism	0—20
E71.19	Other disorders of branched-chain amino-acid metabolism	0—20
E71.2	Disorder of branched-chain amino-acid metabolism, unspecified	0—20
E71.310	Long chain/very long chain acyl CoA dehydrogenase deficiency	0—64
E71.311	Medium chain acyl CoA dehydrogenase deficiency	0—64
E71.312	Short chain acyl CoA dehydrogenase deficiency	0—64
E71.313	Glutaric aciduria type II	0—64
E71.314	Muscle carnitine palmitoyltransferase deficiency	0—64
E71.318	Other disorders of fatty-acid oxidation	0—64
E71.32	Disorders of ketone metabolism	0—64
E71.39	Other disorders of fatty-acid metabolism	0—64
E71.41	Primary carnitine deficiency	0—64
E71.42	Carnitine deficiency due to inborn errors of metabolism	0—64

E71.50	Peroxisomal disorder, unspecified	0—64
E71.510	Zellweger syndrome	0—64
E71.511	Neonatal adrenoleukodystrophy	0—64
E71.518	Other disorders of peroxisome biogenesis	0—64
E71.520	Childhood cerebral X-linked adrenoleukodystrophy	0—64
E71.521	Adolescent X-linked adrenoleukodystrophy	0—64
E71.522	Adrenomyeloneuropathy	0—64
E71.528	Other X-linked adrenoleukodystrophy	0—64
E71.529	X-linked adrenoleukodystrophy, unspecified type	0—64
E71.53	Other group 2 peroxisomal disorders	0—64
E71.540	Rhizomelic chondrodysplasia punctata	0—64
E71.541	Zellweger-like syndrome	0—64
E71.542	Other group 3 peroxisomal disorders	0—64
E71.548	Other peroxisomal disorders	0—64
E72.01	Cystinuria	0—20
E72.02	Hartnup's disease	0—20
E72.03	Lowe's syndrome	0—20
E72.04	Cystinosis	0—20
E72.09	Other disorders of amino-acid transport	0—20
E72.11	Homocystinuria	0—20
E72.12	Methylenetetrahydrofolate reductase deficiency	0—20
E72.19	Other disorders of sulfur-bearing amino-acid metabolism	0—20
E72.20	Disorder of urea cycle metabolism, unspecified	0—20
E72.21	Argininemia	0—20

E72.22	Arginosuccinic aciduria	0—20
E72.23	Citrullinemia	0—20
E72.29	Other disorders of urea cycle metabolism	0—20
E72.3	Disorders of lysine and hydroxylysine metabolism	0—20
E72.4	Disorders of ornithine metabolism	0—20
E72.51	Non-ketotic hyperglycinemia	0—20
E72.52	Trimethylaminuria	0—20
E72.53	Primary hyperoxaluria	0—20
E72.59	Other disorders of glycine metabolism	0—20
E72.81	Disorders of gamma aminobutyric acid metabolism	0—20
E72.89	Other specified disorders of amino-acid metabolism	0—20
E74.00	Glycogen storage disease, unspecified	0—20
E74.01	von Gierke disease	0—20
E74.02	Pompe disease	0—20
E74.03	Cori disease	0—20
E74.04	McArdle disease	0—20
E74.09	Other glycogen storage disease	0—20
E74.12	Hereditary fructose intolerance	0—20
E74.19	Other disorders of fructose metabolism	0—20
E74.21	Galactosemia	0—20
E74.29	Other disorders of galactose metabolism	0—20
E74.4	Disorders of pyruvate metabolism and gluconeogenesis	0—20
E75.00	GM2 gangliosidosis, unspecified	0—20
E75.01	Sandhoff disease	0—20

E75.02	Tay-Sachs disease	0—20
E75.09	Other GM2 gangliosidosis	0—20
E75.10	Unspecified gangliosidosis	0—20
E75.11	Mucopolipidosis IV	0—20
E75.19	Other gangliosidosis	0—20
E75.21	Fabry (-Anderson) disease	0—20
E75.22	Gaucher disease	0—20
E75.23	Krabbe disease	0—20
E75.242	Niemann-Pick disease type C	0—20
E75.243	Niemann-Pick disease type D	0—20
E75.244	Niemann-Pick disease type A/B	0—20
E75.25	Metachromatic leukodystrophy	0—20
E75.26	Sulfatase deficiency	0—20
E75.29	Other sphingolipidosis	0—20
E75.3	Sphingolipidosis, unspecified	0—20
E75.4	Neuronal ceroid lipofuscinosis	0—20
E75.5	Other lipid storage disorders	0—20
E76.01	Hurler's syndrome	0—64
E76.02	Hurler-Scheie syndrome	0—64
E76.03	Scheie's syndrome	0—64
E76.1	Mucopolysaccharidosis, type II	0—64
E76.210	Morquio A mucopolysaccharidoses	0—64
E76.211	Morquio B mucopolysaccharidoses	0—64
E76.219	Morquio mucopolysaccharidoses, unspecified	0—64

E76.22	Sanfilippo mucopolysaccharidoses	0—64
E76.29	Other mucopolysaccharidoses	0—64
E76.3	Mucopolysaccharidosis, unspecified	0—64
E76.8	Other disorders of glucosaminoglycan metabolism	0—64
E77.0	Defects in post-translational mod of lysosomal enzymes	0—20
E77.1	Defects in glycoprotein degradation	0—20
E77.8	Other disorders of glycoprotein metabolism	0—20
E79.1	Lesch-Nyhan syndrome	0—64
E79.2	Myoadenylate deaminase deficiency	0—64
E79.8	Other disorders of purine and pyrimidine metabolism	0—64
E79.9	Disorder of purine and pyrimidine metabolism, unspecified	0—64
E80.3	Defects of catalase and peroxidase	0—64
E84.0	Cystic fibrosis with pulmonary manifestations	0—64
E84.11	Meconium ileus in cystic fibrosis	0—64
E84.19	Cystic fibrosis with other intestinal manifestations	0—64
E84.8	Cystic fibrosis with other manifestations	0—64
E84.9	Cystic fibrosis, unspecified	0—64
E88.40	Mitochondrial metabolism disorder, unspecified	0—64
E88.41	MELAS syndrome	0—64
E88.42	MERRF syndrome	0—64
E88.49	Other mitochondrial metabolism disorders	0—64
E88.89	Other specified metabolic disorders	0—64
F84.2	Rett's syndrome	0—20
G11.0	Congenital nonprogressive ataxia	0—20

G11.10	Early-onset cerebellar ataxia, unspecified	0—20
G11.11	Friedreich ataxia	0—20
G11.19	Other early-onset cerebellar ataxia	0—20
G11.2	Late-onset cerebellar ataxia	0—20
G11.3	Cerebellar ataxia with defective DNA repair	0—20
G11.4	Hereditary spastic paraplegia	0—20
G11.8	Other hereditary ataxias	0—20
G11.9	Hereditary ataxia, unspecified	0—20
G12.0	Infantile spinal muscular atrophy, type I (Werdnig-Hoffman)	0—20
G12.1	Other inherited spinal muscular atrophy	0—20
G12.21	Amyotrophic lateral sclerosis	0—20
G12.22	Progressive bulbar palsy	0—20
G12.29	Other motor neuron disease	0—20
G12.8	Other spinal muscular atrophies and related syndromes	0—20
G12.9	Spinal muscular atrophy, unspecified	0—20
G24.1	Genetic torsion dystonia	0—64
G24.8	Other dystonia	0—64
G25.3	Myoclonus	0—5
G25.9	Extrapyramidal and movement disorder, unspecified	0—20
G31.81	Alpers disease	0—20
G31.82	Leigh's disease	0—20
G31.9	Degenerative disease of nervous system, unspecified	0—20
G32.81	Cerebellar ataxia in diseases classified elsewhere	0—20
G37.0	Diffuse sclerosis of central nervous system	0—64

G37.5	Concentric sclerosis (Balo) of central nervous system	0—64
G71.00	Muscular dystrophy, unspecified	0—64
G71.01	Duchenne or Becker muscular dystrophy	0—64
G71.02	Facioscapulohumeral muscular dystrophy	0—64
G71.031	Autosomal dominant limb girdle muscular dystrophy	0—64
G71.032	Autosomal recessive limb girdle muscular dystrophy due to calpain-3 dysfunction	0—64
G71.033	Limb girdle muscular dystrophy due to dysferlin dysfunction	0—64
G71.0340	Limb girdle muscular dystrophy due to sarcoglycan dysfunction, unspecified	0—64
G71.0341	Limb girdle muscular dystrophy due to alpha sarcoglycan dysfunction	0—64
G71.0342	Limb girdle muscular dystrophy due to beta sarcoglycan dysfunction	0—64
G71.0349	Limb girdle muscular dystrophy due to other sarcoglycan dysfunction	0—64
G71.035	Limb girdle muscular dystrophy due to anoctamin-5 dysfunction	0—64
G71.038	Other limb girdle muscular dystrophy	0—64
G71.039	Limb girdle muscular dystrophy, unspecified	0—64
G71.09	Other specified muscular dystrophies	0—64
G71.11	Myotonic muscular dystrophy	0—64
G71.20	Congenital myopathy, unspecified	0—64
G71.21	Nemaline myopathy	0—64
G71.220	Centronuclear myopathy	0—64
G71.228	Other centronuclear myopathy	0—64
G71.29	Other congenial myopathy	0—64
G80.0	Spastic quadriplegic cerebral palsy	0—64
G80.1	Spastic diplegic cerebral palsy	0—20
G80.3	Athetoid cerebral palsy	0—64

G82.50	Quadriplegia, unspecified	0—64
G82.51	Quadriplegia, C1-C4 complete	0—64
G82.52	Quadriplegia, C1-C4 incomplete	0—64
G82.53	Quadriplegia, C5-C7 complete	0—64
G82.54	Quadriplegia, C5-C7 incomplete	0—64
G91.0	Communicating hydrocephalus	0—20
G91.1	Obstructive hydrocephalus	0—20
I67.5	Moyamoya disease	0—64
K91.2	Postsurgical malabsorption, not elsewhere classified	0—20
N03.A	Chronic nephritic syndrome with C3 glomerulonephritis	0—20
N03.1	Chronic nephritic syndrome with focal and segmental glomerular lesions	0—20
N03.2	Chronic nephritic syndrome w diffuse membranous glomrlneph	0—20
N03.3	Chronic neph syndrome w diffuse mesangial prolif glomrlneph	0—20
N03.4	Chronic neph syndrome w diffuse endocaply prolif glomrlneph	0—20
N03.5	Chronic nephritic syndrome w diffuse mesangiocap glomrlneph	0—20
N03.6	Chronic nephritic syndrome with dense deposit disease	0—20
N03.7	Chronic nephritic syndrome w diffuse crescentic glomrlneph	0—20
N03.8	Chronic nephritic syndrome with other morphologic changes	0—20
N03.9	Chronic nephritic syndrome with unspecified morphologic changes	0—20
N08	Glomerular disorders in diseases classified elsewhere	0—20
N18.1	Chronic kidney disease, stage 1	0—20
N18.2	Chronic kidney disease, stage 2 (mild)	0—20
N18.30	Chronic kidney disease, stage 3, unspecified	0—20
N18.31	Chronic kidney disease, stage 3a	0—20

N18.32	Chronic kidney disease, stage 3b	0—20
N18.4	Chronic kidney disease, stage 4 (severe)	0—20
N18.5	Chronic kidney disease, stage 5	0—20
N18.6	End stage renal disease	0—20
N18.9	Chronic kidney disease, unspecified	0—20
Q01.9	Encephalocele, unspecified	0—20
Q02	Microcephaly	0—20
Q03.0	Malformations of aqueduct of Sylvius	0—20
Q03.1	Atresia of foramina of Magendie and Luschka	0—20
Q03.8	Other congenital hydrocephalus	0—20
Q03.9	Congenital hydrocephalus, unspecified	0—20
Q04.3	Other reduction deformities of brain	0—20
Q04.5	Megalencephaly	0—20
Q04.6	Congenital cerebral cysts	0—20
Q04.8	Other specified congenital malformations of brain	0—20
Q05.0	Cervical spina bifida with hydrocephalus	0—64
Q05.1	Thoracic spina bifida with hydrocephalus	0—64
Q05.2	Lumbar spina bifida with hydrocephalus	0—64
Q05.3	Sacral spina bifida with hydrocephalus	0—64
Q05.4	Unspecified spina bifida with hydrocephalus	0—64
Q05.5	Cervical spina bifida without hydrocephalus	0—64
Q05.6	Thoracic spina bifida without hydrocephalus	0—64
Q05.7	Lumbar spina bifida without hydrocephalus	0—64
Q05.8	Sacral spina bifida without hydrocephalus	0—64

Q05.9	Spina bifida, unspecified	0—64
Q06.0	Amyelia	0—64
Q06.1	Hypoplasia and dysplasia of spinal cord	0—64
Q06.2	Diastematomyelia	0—64
Q06.3	Other congenital cauda equina malformations	0—64
Q06.4	Hydromyelia	0—64
Q06.8	Other specified congenital malformations of spinal cord	0—64
Q07.01	Arnold-Chiari syndrome with spina bifida	0—64
Q07.02	Arnold-Chiari syndrome with hydrocephalus	0—64
Q07.03	Arnold-Chiari syndrome with spina bifida and hydrocephalus	0—64
Q30.1	Agenesis and underdevelopment of nose, cleft or absent nose only	0—5
Q30.2	Fissured, notched and cleft nose, cleft or absent nose only	0—5
Q31.0	Web of larynx	0—20
Q31.8	Other congenital malformations of larynx, atresia or agenesis of larynx only	0—20
Q32.1	Other congenital malformations of trachea, atresia or agenesis of trachea only	0—20
Q32.4	Other congenital malformations of bronchus, atresia or agenesis of bronchus only	0—20
Q33.0	Congenital cystic lung	0—20
Q33.2	Sequestration of lung	0—20
Q33.3	Agenesis of lung	0—20
Q33.6	Congenital hypoplasia and dysplasia of lung	0—20
Q35.1	Cleft hard palate	0—20
Q35.3	Cleft soft palate	0—20
Q35.5	Cleft hard palate with cleft soft palate	0—20
Q35.9	Cleft palate, unspecified	0—20

Q37.0	Cleft hard palate with bilateral cleft lip	0—20
Q37.1	Cleft hard palate with unilateral cleft lip	0—20
Q37.2	Cleft soft palate with bilateral cleft lip	0—20
Q37.3	Cleft soft palate with unilateral cleft lip	0—20
Q37.4	Cleft hard and soft palate with bilateral cleft lip	0—20
Q37.5	Cleft hard and soft palate with unilateral cleft lip	0—20
Q37.8	Unspecified cleft palate with bilateral cleft lip	0—20
Q37.9	Unspecified cleft palate with unilateral cleft lip	0—20
Q39.0	Atresia of esophagus without fistula	0—3
Q39.1	Atresia of esophagus with tracheo-esophageal fistula	0—3
Q39.2	Congenital tracheo-esophageal fistula without atresia	0—3
Q39.3	Congenital stenosis and stricture of esophagus	0—3
Q39.4	Esophageal web	0—3
Q42.0	Congenital absence, atresia and stenosis of rectum with fistula	0—5
Q42.1	Congenital absence, atresia and stenosis of rectum without fistula	0—5
Q42.2	Congenital absence, atresia and stenosis of anus with fistula	0—5
Q42.3	Congenital absence, atresia and stenosis of anus without fistula	0—5
Q42.8	Congenital absence, atresia and stenosis of other parts of large intestine	0—5
Q42.9	Congenital absence, atresia and stenosis of large intestine, part unspecified	0—5
Q43.1	Hirschsprung's disease	0—15
Q44.2	Atresia of bile ducts	0—20
Q44.3	Congenital stenosis and stricture of bile ducts	0—20
Q44.6	Cystic disease of liver	0—20
Q45.0	Agenesis, aplasia and hypoplasia of pancreas	0—5

Q45.1	Annular pancreas	0—5
Q45.3	Other congenital malformations of pancreas and pancreatic duct	0—5
Q45.8	Other specified congenital malformations of digestive system	0—10
Q60.1	Renal agenesis, bilateral	0—20
Q60.4	Renal hypoplasia, bilateral	0—20
Q60.6	Potter's syndrome, with bilateral renal agenesis only	0—20
Q61.02	Congenital multiple renal cysts, bilateral only	0—20
Q61.19	Other polycystic kidney, infantile type, bilateral only	0—20
Q61.2	Polycystic kidney, adult type, bilateral only	0—20
Q61.3	Polycystic kidney, unspecified, bilateral only	0—20
Q61.4	Renal dysplasia, bilateral only	0—20
Q61.5	Medullary cystic kidney, bilateral only	0—20
Q61.9	Cystic kidney disease, unspecified, bilateral only	0—20
Q64.10	Exstrophy of urinary bladder, unspecified	0—20
Q64.12	Cloacal extrophy of urinary bladder	0—20
Q64.19	Other exstrophy of urinary bladder	0—20
Q75.0	Craniosynostosis	0—20
Q75.1	Craniofacial dysostosis	0—20
Q75.2	Hypertelorism	0—20
Q75.4	Mandibulofacial dysostosis	0—20
Q75.5	Oculomandibular dysostosis	0—20
Q75.8	Other congenital malformations of skull and face bones	0—20
Q77.4	Achondroplasia	0—1
Q77.6	Chondroectodermal dysplasia	0—1

Q77.8	Other osteochondrodysplasia with defects of growth of tubular bones and spine	0—1
Q78.0	Osteogenesis imperfecta	0—20
Q78.1	Polyostotic fibrous dysplasia	0—1
Q78.2	Osteopetrosis	0—1
Q78.3	Progressive diaphyseal dysplasia	0—1
Q78.4	Enchondromatosis	0—1
Q78.6	Multiple congenital exostoses	0—1
Q78.8	Other specified osteochondrodysplasias	0—1
Q78.9	Osteochondrodysplasia, unspecified	0—1
Q79.0	Congenital diaphragmatic hernia	0—1
Q79.1	Other congenital malformations of diaphragm	0—1
Q79.2	Exomphalos	0—1
Q79.3	Gastroschisis	0—1
Q79.4	Prune belly syndrome	0—1
Q79.59	Other congenital malformations of abdominal wall	0—1
Q89.7	Multiple congenital malformations, not elsewhere classified	0—10
R75	Inconclusive laboratory evidence of HIV	0—12 months
Z21	Asymptomatic human immunodeficiency virus infection status	0—20
Z99.11	Dependence on respirator (ventilator) status	1—64
Z99.2	Dependence on renal dialysis	21—64

.18 APPEALS PROCEDURES.

Appeal procedures are as set forth in COMAR 10.01.04 and 10.09.36.

SUBTITLE 67 MARYLAND HEALTHCHOICE PROGRAM

CHAPTER 01 MARYLAND MEDICAID MANAGED CARE PROGRAMS: DEFINITIONS

.01 DEFINITIONS.

A. Except as expressly limited, in COMAR 10.67.01—.12 the following terms have the meanings indicated.

B. Terms Defined.

(1) "ACOG guidelines" means the American College of Obstetricians and Gynecologists' Guidelines for Perinatal Care that specify the recommended periodicity and content of prenatal, perinatal, and postpartum care, and are incorporated by reference in COMAR 10.67.04.01.

(2) "Acquired immune deficiency syndrome (AIDS)" has the meaning stated in COMAR 10.52.06.01B.

(3) "Action" means:

(a) Denial or limited authorization of a requested service, including:

(i) The type or level of service;

(ii) Requirements for medical necessity;

(iii) Appropriateness;

(iv) Setting; or

(v) Effectiveness of a covered benefit.

(b) Reduction, suspension, or termination of a previously authorized service;

(c) Denial, in whole or part, of payment for a service, except for administrative denials of unclear claims;

(d) Failure to provide services in a timely manner;

(e) Failure of an MCO to act within the required time frames; or

(f) The denial of an enrollee's request to dispute a financial liability, including:

(i) Cost sharing;

(ii) Copayments;

(iii) Premiums;

(iv) Deductibles;

(v) Coinsurance; or

(vi) Other enrollee financial liabilities.

(4) "Activities of daily living" means, in the context of COMAR 10.09.69, bathing, feeding, toileting, dressing, and ambulation;

(5) "Adjusted clinical group (ACG)" means a method for categorizing individuals into a case mix category based on the diagnoses assigned by their clinicians over a predetermined period of time.

(6) Administrative Services Organization.

(a) "Administrative services organization (ASO)" means an organization with which the Department contracts to assist in the management of behavioral health services.

(b) "Administrative services organization" does not mean an organization that directly provides health care services to waiver-eligible individuals.

(7) "Advanced practice nurse" means a nurse practitioner, nurse midwife, nurse anesthetist, or nurse psychotherapist who is licensed and certified under Health Occupations Article, Title 8, Annotated Code of Maryland, and COMAR 10.27.01

(8) "Aged" has the meaning stated in COMAR 10.09.24.02B.

(9) "AIDS payment category" means one of the two payment categories represented as individual rate cells within the rate table set forth in COMAR 10.67.04.19B(4)(b) to which enrollees with AIDS are assigned pursuant to COMAR 10.67.04.19B(2)(c)(ii).

(10) "Alcohol abuse" has the meaning stated in Health-General Article, §8-101(e), Annotated Code of Maryland.

(11) "Ancillary services" means diagnostic and somatic therapeutic services, including but not limited to radiology, laboratory services, cardiac diagnostics, neurology diagnostics, occupational therapy, physical therapy, durable medical equipment, disposable medical supplies, audiology, speech therapy, and cardiac rehabilitation therapy.

(12) "Annual quality assurance (QA) audit" means a systems performance review and a clinical care review.

(13) "Appeal" means a request for review of an action.

(14) "Applicant" means an entity that seeks approval from the Department to operate as a managed care organization in the Maryland Medicaid Managed Care Program.

(15) "Benefits package" means a set of health care services to which an MCO's enrollees are entitled, when the services are medically necessary, and which the MCO delivers to its enrollees either through providers with which it has employment or contractual relationships, or through reimbursement for services provided to the MCO's enrollees.

(16) "Blind" means having a condition in which a person is certified by an ophthalmologist as having either central visual acuity of 20/200 or less in the better eye with correcting glasses, or a field defect in which the peripheral field has contracted to such an extent that the widest diameter of the visual field subtends an angular distance of no greater than 20 degrees.

(17) "Business day" means any day except Saturday, Sunday, or a holiday on which State offices are closed.

(18) "Caller abandonment rates" means the percentage of calls terminated by callers without speaking to a live operator.

(19) "Caller average hold time" means an average amount of time a call is on hold after being answered.

(20) "Caller service level" means the speed of answering the telephone.

(21) "Capitation payment" means the sum of money paid in advance on a monthly per capita basis by the Department for a fixed benefit package.

(22) "CARF" means the Commission on Accreditation of Rehabilitation Facilities (also known as the Rehabilitation Accreditation Commission), which is an organization that:

- (a) Establishes quality standards for rehabilitative services; and
- (b) Determines, in the context of its accreditation process, the extent to which rehabilitative service providers are in compliance with CARF quality standards.

(23) "Case management" means, assessing, planning, coordinating, monitoring, and arranging the delivery of medically necessary health-related services.

(24) "Case management contractor" means, in the context of COMAR 10.09.69, the Department's designee, or a subcontractor of the designee, which provides case management to participants assigned to it by the Department.

(25) "Case manager" means, in the context of COMAR 10.09.69, the individual who:

- (a) Is employed by the Department's designee or a case management contractor;(
- b) Is assigned by a case management contractor to manage the care of some or all of the participants assigned to that case management contractor;
- (c) Participates in the meetings of the interdisciplinary team;
- (d) Is responsible for the development of an individual's case management plan by the interdisciplinary team;
- (e) Is responsible for implementing the participant's case management plan; and
- (f) Is responsible for modifying the case management plan when information regarding a change in the participant's condition or status is received.

(26) "CDS license" means the State licensure authorizing a health care practitioner to prescribe controlled dangerous substances.

(27) "Certified nursing assistant" means, in the context of COMAR 10.09.69, an individual:

- (a) Certified as a nursing assistant by the Maryland Board of Nursing; and
- (b) Who performs nursing tasks delegated by a registered nurse or licensed practical nurse pursuant to Health Occupations Article, Title 8, Annotated Code of Maryland.

(28) "Child in State-supervised care" means a waiver-eligible child who is in the care and custody of a State agency pursuant to a court order or a voluntary placement agreement, including, but not limited to, waiver-eligible children:

- (a) Under the supervision of the Department of Juvenile Services;
- (b) In kinship or foster care under the Department of Human Services; and
- (c) In residential treatment centers or psychiatric hospitals for the first 30 days after admission.

(29) "Child with a special health care need" means an individual younger than 21 years old, regardless of marital status, suffering from a moderate to severe chronic health condition:

- (a) With significant potential or actual impact on health and ability to function;

(b) Which requires special health care services; and

(c) Which is expected to last longer than 6 months.

(29-1) "CHIP Health Services Initiative" means services offered to improve the health of low-income children pursuant to 5 U.S.C. §2105(a)(1)(D)(ii) of the Social Security Act.

(30) "Chronic hospital" has the meaning stated in COMAR 10.09.06.01B(4).

(31) "Clinical care review" means a review of the quality of clinical health care delivered by an MCO, which is:

(a) Required by federal law; and

(b) A component of an annual quality assurance (QA) audit.

(32) "CMS" means Centers for Medicare and Medicaid Services.

(33) "Cold call marketing" means any unsolicited personal contact by the MCO with a potential enrollee for the purpose of marketing.

(33-1) "Collaborative Care Model" means the Psychiatric Collaborative Care Model, a patient-centered, evidence-based approach for integrating physical and behavioral health services in primary care settings that includes:

(a) Care coordination and management;

(b) Regular, systematic monitoring and treatment using a validated clinical rating scale;

(c) Regular, systematic psychiatric or substance use disorder caseload reviews, or both; and

(d) Regular, systematic consultation for patients who do not show clinical improvement.

(34) "Commissioner" means the Maryland Insurance Commissioner of the Maryland Insurance Administration.

(35) "Community-based substance abuse program" means a program that:

(a) Is certified by the Office of Health Care Quality (OHCQ); and

(b) Provides services in community settings not regulated by the Health Services Cost Review Commission.

(36) "Complaint" means an expression of dissatisfaction that results in either an appeal or a grievance.

(37) "Contract year" means the period of time to which the Maryland Medicaid Managed Care Program agreement between the Department and an MCO applies.

(38) "Core service agency (CSA)" means, in the context of COMAR 10.67.08, the county or multicounty authority, designated under Health-General Article, Title 10, Subtitle 12, Annotated Code of Maryland, and approved by the Department, that is responsible for planning, managing, and monitoring publicly funded mental health services.

(39) "Corporation" means:

(a) An entity formed under and meeting the requirements of Corporations and Associations Article, §2-101 et seq., Annotated Code of Maryland; or

(b) A foreign corporation registered with the Maryland Department of Assessments and Taxation.

(40) "County" means a county of this State and, unless expressly provided otherwise, Baltimore City.

(40-1) "Credibility adjustment" means an adjustment to the MLR for a partially credible MCO to account for a difference between the actual and target MLRs that may be due to random statistical variation.

(41) "Days" means, unless otherwise expressly indicated, calendar days.

(42) "DEA license" means the federal license authorizing a health care practitioner to prescribe controlled substances.

(42-1) "Definitive drug test" means drug screening tests that include:

(a) The ability to identify individual drugs and distinguish between structural isomers, but not necessarily stereoisomers, using:

(i) Gas chromatography or mass spectrometry; and

(ii) Liquid chromatography or mass spectrometry;

(b) Qualitative or quantitative results;

(c) All source types for specimen selection;

(d) Specimen validity testing, per day, 1—22 or more drug classes including metabolites, if performed.

(43) "Department" means the Maryland Department of Health, as defined in COMAR 10.09.36.01, or its authorized agents acting on behalf of the Department.

(44) "Diagnostic evaluation services (DES)" has the meaning stated in COMAR 10.09.32.01B, and includes the services described in COMAR 10.09.32.04A.

(45) Direct Medical Education Costs (DME Costs).

(a) "Direct medical education costs (DME costs)" means costs associated with providing graduate medical education that are measurable using accounting data.

(b) "Direct medical education costs (DME costs)" includes, but is not limited to:

(i) Salaries;

(ii) Supervision costs; and

(iii) Allocated overhead.

(46) "Disabled" has the meaning stated in COMAR 10.09.24.02B.

(47) "Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)" means the provision, to individuals younger than 21 years old, of preventive health care pursuant to 42 CFR §441.50 et seq. (1981), and other health care services, diagnostic services, and treatment services that are necessary to correct or ameliorate defects and physical and mental illnesses and conditions discovered by EPSDT screening services.

(48) "Emergency medical condition" means a medical condition characterized by sudden onset symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent lay person, who possesses an average knowledge of health and medicine, to result in:

(a) Placing the patient's health, or with respect to a pregnant woman, the health of the woman or unborn child in serious jeopardy;

(b) Serious impairment to bodily functions; or

(c) Serious dysfunction of any bodily organ or part.

(49) "Emergency services" means those health care services that are provided in a hospital emergency facility after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent lay person, who possesses an average knowledge of health and medicine, to result in:

(a) Placing the patient's health, or with respect to a pregnant woman, the health of the woman, or unborn child, in serious jeopardy;

(b) Serious impairment to bodily functions; or

(c) Serious dysfunction of any bodily organ or part.

(50) "Encounter data" means information documenting a service to an enrollee.

(51) "Enrollee" has the meaning indicated in Health-General Article, §15-101(b), Annotated Code of Maryland.

(52) "EPSDT-certified provider" means a physician or nurse practitioner who is certified by the Department's EPSDT program to provide comprehensive well-child services according to the Department's periodicity schedule and program standards to enrollees younger than 21 years old.

(53) "EPSDT comprehensive well-child services" means:

(a) All the screening services provided by an EPSDT-certified provider that are required or recommended on the EPSDT periodicity schedule; and

(b) Health care services to diagnose, treat, or refer problems or conditions discovered during the comprehensive well-child service.

(54) "EPSDT partial or interperiodic well-child service" means:(a) A well-child service provided at times different than those outlined in the EPSDT periodicity schedule; or(b) Any encounter by a health care practitioner necessary to diagnose or identify a condition and recommend a course of treatment.

(55) "EPSDT periodicity schedule" means the Departmentally approved list of required or recommended preventive health care services which are to be performed at specified ages.

(56) "Evaluations" means, in the context of COMAR 10.09.69, a determination of the health status of a patient in a patient's home or any other appropriate setting by a licensed professional for the purpose of designing an individual plan of care which incorporates the modalities of treatment which will promote optimal functional ability and recuperation.

(57) "External quality review organization (EQRO)" means a utilization and quality control peer review entity or a private review agent meeting the requirements of §1902(a)(30) of the Social Security Act, 42 U.S.C. §1396a(a)(30), which performs an independent external review of health care services furnished under a contract under §1903(m) of the Social Security Act, 42 U.S.C. §1396b.

(58) "Family planning" means providing individuals with the information and means to prevent unwanted pregnancy and maintain reproductive health.

(59) "Federally qualified health center (FQHC)" means a clinic which either:

(a) Receives a grant under §329, 330, or 340 of the Public Health Services Act, 42 U.S.C. §254c;

(b) Meets the requirements for a grant under §329, 330, or 340 of the Public Health Services Act, 42 U.S.C. §254c;
or

(c) Qualifies as a FQHC pursuant to a waiver from the Secretary of the U.S. Department of Health and Human Services of one or more of the requirements for receiving a grant under §329, 330, or 340 of the Public Health Services Act, 42 U.S.C. §254c.

(60) "Fiscal year (FY)" means the time period beginning the preceding July 1 and ending on June 30 of the referenced year.

(61) "Free-standing birth center" means a free-standing facility not associated with a hospital that provides nurse midwife services under Health Occupations Article, Title 8, Subtitle 6, Annotated Code of Maryland.

(61-1) "Full credibility" means a standard for which the experience of an MCO is determined to be sufficient for the calculation of an MLR with a minimal chance that the difference between the actual and target MLR is not statistically significant.

(62) "Graduate medical education (GME)" means the training of physician interns and residents after completion of a medical degree program

(63) "Graduate medical education costs (GME costs)" means the amount it costs a hospital to train physician interns and residents after their completion of a medical degree program, including both direct medical education costs and indirect medical education costs.

(64) "Grievance" means an expression of dissatisfaction about any matter other than an action, including but not limited to:

(a) The quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee;

(b) Failure to respect the enrollee's rights regardless of whether remedial action is requested; or

(c) A dispute over an extension of time proposed by the MCO to make an authorized decision.

(65) "HCQIS" means the Health Care Quality Improvement System produced by the Centers for Medicare and Medicaid Services.

(66) "Health care service" has the meaning stated in Health-General Article, §19-132, Annotated Code of Maryland.

(67) "HealthChoice Financial Monitoring Report (HFMR)" means an annual financial report of an MCO's MMMCP-related activities during a specified calendar year that:

(a) Is submitted to the Department by an MCO pursuant to COMAR 10.67.04.15;

(b) Serves as a supplemental schedule to an MCO's quarterly and annual reports to the Maryland Insurance Administration; and

(c) Includes a completed HFMR form provided by the Department and any supplemental schedules required by the Department.

(68) "Health home" means a provider designated to offer enhanced care coordination and management services to individuals affected by, or at risk for, chronic conditions.

(69) "Health maintenance organization (HMO)" has the meaning stated in Health-General Article, §19-701, Annotated Code of Maryland.

(70) Health Service Needs Information.

(a) "Health service needs information" means an instrument to identify new Maryland Medicaid Managed Care Program enrollees who require immediate or specialized health care services.

(b) "Health service needs information" does not mean an initial health screen performed by an MCO.

(71) "HEDIS" means the Healthcare Effectiveness Data Information Set, a set of indicators of managed care plan performance developed by the National Committee for Quality Assurance.

(72) "Hepatitis C" means having one of the following as a primary, secondary, tertiary, or level 4 diagnosis:

(a) 070.41 — Acute or Unspecified Hepatitis C with hepatic coma;

(b) 070.44 — Chronic Hepatitis C with hepatic coma;

(c) 070.51 — Acute or unspecified Hepatitis C without mention of hepatic coma; or

(d) 070.54 — Chronic Hepatitis C without mention of hepatic coma.

(73) "Hepatitis C plan risk factor" means an MCO-specific risk adjustment factor reflecting the level of risk associated with the proportion of the MCO's HIV/AIDS enrollees who also have Hepatitis C.

(74) "HIPAA" means the Health Insurance Portability and Accountability Act, a federal law enacted on August 21, 1996, whose purpose is to improve the efficiency and effectiveness of the health care system by standardizing the electronic exchange of administrative and financial data, provide security requirements for transmitted information, and protect the privacy of identifiable health information.

(75) "Historical diagnostic period" means the time period under consideration for the cumulative chronological determination of an enrollee's Hepatitis C status and ending:

(a) For the initial rate adjustment period, on June 30 of the calendar year before the rate year; or

(b) For the mid-year rate adjustment period, on December 31 of the calendar year before the rate year.

(76) "HIV" means infection with the human immunodeficiency virus.

(77) "HIV/AIDS" means:

(a) Infection with the human immunodeficiency virus; or

(b) Acquired immune deficiency syndrome.

(78) "HIV/AIDS enrollee" means an enrollee who is infected with HIV or has AIDS and is assigned to an HIV or AIDS payment category.

(79) "HIV payment category" means one of the four payment categories represented as individual rate cells within the rate tables set forth in COMAR 10.67.04.19B(4)(a) and (b), to which enrollees with HIV are assigned pursuant to COMAR 10.67.04.19B(1)(c)(ii) or (2)(c)(i).

(80) "Home", in the context of COMAR 10.09.69, has the meaning stated in COMAR 10.09.53.

(81) "Home health agency" means, in the context of COMAR 10.09.69, an agency licensed by the Department in accordance with COMAR 10.07.10.

(82) "Home health aide" means, in the context of COMAR 10.09.69, an individual who meets all the conditions of participation specified in:

(a) 42 CFR §484.36; and

(b) Health Occupations Article, Title 8, Annotated Code of Maryland.

(83) "Homeless person" means an individual who, as defined by §340 of the Public Health Services Act, lacks housing, without regard to whether an individual is a member of a family, including an individual:

(a) Who is a resident in transitional housing; or

(b) Whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations.

(84) "Hospital" has the meaning stated in Health-General Article, §19-301, Annotated Code of Maryland.

(85) "HSCRC" means the Health Services Cost Review Commission, an independent agency functioning in the Department with the powers and duties set forth in Health-General Article, §19-201 et seq., Annotated Code of Maryland.

(86) "Indirect medical education costs (IME costs)" means costs associated with providing graduate medical education that, although not measurable using accounting data, are subject to assessment by application of a regression analysis methodology that:

(a) Estimates teaching hospitals' extra costs attributable to factors including, but not necessarily limited to the:

(i) Lower productivity of inexperienced residents, and

(ii) Adoption of advanced technology; and

(b) Controls, where possible, for confounding variables such as differences in:

(i) Area labor costs,

(ii) Uncompensated care, and

(iii) Case mix.

(87) "Individualized education program (IEP)" means a written description of special education and related services developed by a multidisciplinary team to be implemented to meet the individual needs of a child pursuant to COMAR 13A.05.01.09.

(88) "Individualized family service plan (IFSP)" means a written plan for providing early intervention and other services to an eligible child and the child's family pursuant to COMAR 13A.13.01.02B.

(89) "Individual with a developmental disability" means an individual who, as defined in P.L. 101-330, Americans with Disabilities Act of 1990, 42 U.S.C. §12101 et seq., has a physical or mental impairment arising before the age of 22, except for the sole diagnosis of mental disorder, that substantially limits one or more major life activities, and which may include, but is not limited to, an intellectual disability, specific learning disabilities, head injury, epilepsy, and muscular dystrophy.

(90) "Individual with a physical disability" means an individual who, as defined in P.L. 101-330, the Americans with Disabilities Act of 1990, 42 U.S.C. §12101 et seq., has a physical impairment, either sensory or motor, that substantially limits one or more major life activities, and which may include, but is not limited to, orthopedic impairment, vision, speech, or hearing impairment, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, HIV/AIDS, and tuberculosis.

(91) "Initial health screen" means the comprehensive evaluation performed by the PCP, that includes a comprehensive history and physical examination to determine the new enrollee's baseline health status and health needs.

(92) "Initial rate adjustment period" has the meaning stated in COMAR 10.67.04.19-3A.

(93) "Inmate" means an individual who is serving time for a criminal offense and is confined involuntarily in State or federal prisons, jail, detention centers, or other penal facilities or who has been placed on home detention.

(94) Institution for Mental Disease.

(a) "Institution for mental disease (IMD)" means a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases or substance abuse problems, including medical attention, nursing care, and related health care services.

(b) "Institution for mental disease (IMD)" includes the following categories of facilities, if the particular facility has more than 16 beds:

(i) Psychiatric hospitals;

(ii) Residential treatment centers;

(iii) In the context of admissions of enrollees who are 21 years old or older, intermediate care facilities-alcoholic (ICF-A) facilities; and

(iv) Residential drug-free treatment programs.

(c) "Institution for mental disease" does not include intermediate care facilities-alcoholic (ICF-A) facilities, except in the context of admission of enrollees who are 21 years old or older.a(95) "Interdisciplinary team" means, in the context of COMAR 10.09.69, the group convened and conducted by the case manager, consisting of the case manager and relevant service providers, that established the case management plan under the overall direction and coordination of the case manager and in consultation with the participant and, when applicable, the participant's family.

(96) "Intermediate care facility for individuals with intellectual disabilities or persons with related conditions (ICF/IID)" means a residential facility providing care and services for individuals with an intellectual disability or developmental disabilities, or both.

(96-1) "Limited English proficiency" means the special need status of potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English, and are therefore eligible to receive language assistance for a particular type of service, benefit, or encounter.

(97) "Local access area" means the local geographical area, as identified by the zip code groupings in COMAR 10.67.05.06D, that is located within the relevant MCO's service area and in which the relevant enrollee resides.

(98) "Local transportation grantee agency" means the county entity, usually the local health department, that receives transportation grant funds pursuant to COMAR 10.09.19.

(99) "Long-term care facility" means a chronic hospital, a chronic rehabilitation hospital, a nursing facility, or a special pediatric hospital.

(100) Long-Term Care Services.

(a) "Long-term care services" means the medical and support services required by an individual who, due to chronic illness or mental or physical disability, requires long-term care facility services over an extended period of time.

(b) "Long-term care services" includes services provided to a patient in a long-term care facility after the 30th day of continuous care following the enrollee's admission to the facility.

(c) "Long-term care services" do not include services provided to an enrollee admitted to a long-term care facility for a stay of less than 31 days of continuous care following the enrollee's admission to the facility.

(101) "Loss ratio" means the ratio of an MCO's:

(a) Net medical expenses plus medical management expenses which:

(i) Are quantified according to COMAR 10.67.04.19-4;

(ii) Relate solely to the MCO's MMMCP line of business; and

(iii) Are incurred during a specified period; and

(b) Net revenues which:

(i) Relate solely to the MCO's MMMCP line of business; and

(ii) Are earned during the same specified period in which the expenses referenced in §B(98)(a) of this regulation are incurred.

(102) "Managed care organization (MCO)" has the meaning stated in Health-General Article, §15-101, Annotated Code of Maryland.

(103) "Marketing" means any communication, from an MCO to a Medicaid recipient who is not enrolled in that MCO, that can reasonably be interpreted as intended to influence the recipient:

(a) To enroll in that particular MCO; or

(b) To not enroll in or to disenroll from another MCO.

(104) "Marketing materials" means materials that are produced in any medium, by or on behalf of an MCO, that can reasonably be interpreted as intended to market to potential enrollees.

(105) "Maryland Children's Health Program" means the State program for uninsured, low-income children with federal matching funds provided under Title XXI of the Social Security Act.

(106) "Maryland Medicaid Managed Care Program (MMMCP)" means the Medicaid reform program established in this subtitle, as authorized by Health-General Article, Title 15, Subtitle 1, Annotated Code of Maryland, and by a §1115 waiver issued by the federal government.

(107) "Medicaid" has the meaning stated in COMAR 10.09.24.02.

(108) "Medical Assistance" has the meaning stated in COMAR 10.09.24.02.

(109) "Medical day care for adults" means a program of medically supervised, health-related services provided in an ambulatory setting to medically handicapped adults who, due to their degrees of impairment, need health maintenance and restorative services supportive to their community living.

(110) "Medical day care for children" means a program of medically supervised health-related services provided in an ambulatory setting to children with complex medical needs who do not require 24-hour inpatient care, but, due to their specialized medical needs, cannot be managed in a typical day care setting.

(111) "Medical expense" means costs incurred by an MCO in connection with providing health care services to its enrollees.

(111-1) "Medical loss ratio (MLR)" means a formula that measures the ratio of MCO spending on medical and related benefits compared to revenue, to ensure MCOs are spending a sufficient amount of their premium revenue on medical expenses and other high-impact initiatives.

(112) "Medically necessary" means that the service or benefit is:

(a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;

(b) Consistent with current accepted standards of good medical practice;

(c) The most cost efficient service that can be provided without sacrificing effectiveness or access to care; and

(d) Not primarily for the convenience of the consumer, the consumer's family, or the provider.

(113) "Medically needy" has the meaning stated in COMAR 10.09.24.02.

(114) "Medical management expense" means costs incurred by an MCO in connection with outreach and utilization management activities as specified in COMAR 10.67.04.19-4.

(115) "Medical necessity" means what is medically necessary.

(115-1) "Medically underserved area" means an area designated by the Health Resources and Services Administration (HRSA) as having shortages of primary care, dental care, or mental health providers.

(116) "Medicare" means the federal program that provides benefits to the aged and disabled under Title XVIII of the Social Security Act.

(117) "MIA" means the Maryland Insurance Administration.

(118) "Mid-year rate adjustment period" has the meaning stated in COMAR 10.67.04.19-4A.

(119) "MIEMSS" means the Maryland Institute for Emergency Medical Service Systems.

(119-1) "MLR reporting year" means a period of 12 months consistent with the rating period selected by the Department.

(120) "Model Waiver Program" means the Home Care for Disabled Children under a Model Waiver as established in COMAR 10.09.27.

(120-1) "National Diabetes Prevention Program" means an evidence-based diabetes prevention program established by the Centers for Disease Control and Prevention.

(121) "Net medical expenses" means an MCO's total medical expenses less reinsurance recoveries.

(122) "Net revenues" means an MCO's total revenues less reinsurance premiums.

(123) "Network" has the same meaning as "provider panel", as specified in this regulation.

(123-1) "Network provider" means a provider that is a member of the MCO's provider panel.

(123-2) "No credibility" means a standard for which the experience of an MCO is determined to be insufficient for the calculation of an MLR.

(123-3) "Non-claims costs" means expenses for administrative services other than:

- (a) Incurred claims;
- (b) Expenditures on activities that improve health care quality;
- (c) Licensing and regulatory fees; or
- (d) Federal and State taxes.

(124) "Nursing facility" has the meaning stated in COMAR 10.09.10.01B.

(125) Nutritional Counseling.

(a) "Nutritional counseling" means, in the context of COMAR 10.09.69, the review of the patient's nutritional status and advice on its improvement when medically necessary.

(b) "Nutritional counseling" includes family education provided by either a licensed dietitian or licensed nutritionist.

(126) "Nutritional supplements" means, in the context of COMAR 10.09.69, enteral feeding which is either the sole source of nutrition or a supplement which enhances the physical well-being of the patient and is medically indicated.

(127) "Ombudsman" or "ombudsman program" has the meaning stated in Health-General Article, §15-101(g), Annotated Code of Maryland.

(128) "Out-of-plan provider" means a provider that is neither the employee nor the subcontractor of the enrollee's assigned MCO.

(129) "Outreach services" means efforts to contact enrollees and bring them into care, as described in COMAR 10.67.05.03.

(130) "Overpayment" means:

(a) Any payment made by the Program to a provider in excess of the correct Program payment amount for a service; or

(b) Any payment for services under COMAR 10.67.06 made by the Program or an MCO which at the time of payment, or at a subsequent date, is determined to be inappropriate, inaccurate or in excess of the correct amount of the procedural code billed, for reasons including but not limited to:

(i) Improper claiming;

(ii) Lack of medical necessity;

(iii) Unacceptable practices;

(iv) Fraud, waste, or abuse; or

(v) Provider mistake.

(130-1) "Partial credibility" means a standard for which the experience of an MCO is determined to be sufficient for the calculation of an MLR but with a non-negligible chance that the difference between the actual and target medical loss ratios is statistically significant.

(131) "Peer review organization" means an organization qualified by the Centers for Medicare and Medicaid Services in accordance with 42 CFR 462 that reviews health care practitioners, and the health care services they order or furnish, utilizing other practitioners from the same field of practice.

(132) "Personal care" has the meaning stated in COMAR 10.09.20.01B.

(133) "Plan of care" means, in the context of COMAR 10.09.69, the document which governs a participant's care management, and which:

(a) Includes the:

(i) Case management assessment report;;

(ii) Interdisciplinary plan of care; and,

(iii) Case management plan;

(b) Is composed of the participant's health status and needs for medical, health-related, housing, and social services including, but not limited to:

(i) All pertinent diagnoses;

(ii) Functional status;;

(iii) Type, frequency, and duration of services;;(iv) Treatment goals for each type of service;

(v) Medication;;

(vi) Social support structure;;(vii) Current service providers;;(viii) Assigned level of care;

(ix) Diet;

(x) Current living arrangement; and

(xi) Emergency plan, if appropriate; and

(c) Is established in consultation with the interdisciplinary team.

(134) "Postpartum" means within 2 months after delivery of a child.

(135) "Poststabilization care services" means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or under the circumstances described in 42 CFR §438.114(e), as amended, to improve or resolve the enrollee's condition.

(136) "Potential enrollee" means a Medicaid recipient who is determined eligible for the HealthChoice program but is not yet an enrollee of a specific MCO.

(137) "Practitioner" means an individual who is licensed, certified, or otherwise authorized under Health Occupations Article, Annotated Code of Maryland, or under the laws of the District of Columbia or a state contiguous to Maryland, to provide health care services in the ordinary course of business or practice of a profession or in an approved education or training program.

(138) "Preauthorization", in the context of COMAR 10.09.69, has the meaning stated in COMAR 10.09.53.

(139) "Pregnant" means the period beginning with conception and ending at delivery.

(139-1) "Presumptive drug tests" means drug screening tests that include:

(a) Any number of drug classes;

(b) Any number of devices;

(c) Sample validation; and

(d) The use of:

(i) Direct optical observation;

(ii) Instrument assisted direct optical observation; or (iii) Instrumented chemistry analyzers.

(140) "Primary care" means medical care that addresses a patient's general health needs, including the coordination of the patient's health care, with the responsibility for the prevention of disease, promotion and maintenance of health, treatment of illness, maintenance of the enrollee's health records, and referral for medically necessary specialty care.

(141) "Primary care provider (PCP)" means a practitioner who is the primary coordinator of care for the enrollee, and whose responsibility it is to provide accessible, continuous, comprehensive, and coordinated health care services covering the full range of benefits required by the Maryland Medicaid Managed Care Program, as specified in COMAR 10.67.06.

(142) "Primary care residency slots" means, in the context of COMAR 10.67.11, positions in a teaching hospital's residency program occupied after completion of a medical degree program by physicians who have trained in family medicine, internal medicine, pediatrics, or obstetrics and gynecology.

a) Summarizes facts about the care given and the participant's response during a given period of time;

(141) "Primary care provider (PCP)" means a practitioner who is the primary coordinator of care for the enrollee, and whose responsibility it is to provide accessible, continuous, comprehensive, and coordinated health care services

covering the full range of benefits required by the Maryland Medicaid Managed Care Program, as specified in COMAR 10.67.06.

(142) "Primary care residency slots" means, in the context of COMAR 10.67.11, positions in a teaching hospital's residency program occupied after completion of a medical degree program by physicians who have trained in family medicine, internal medicine, pediatrics, or obstetrics and gynecology.

(143) "Primary mental health services" means the clinical evaluation and assessment of mental health services needed by an individual and the provision of services or referral for additional services as deemed medically necessary by a primary care provider.

(144) "Private duty nursing" means, in the context of COMAR 10.09.69, skilled nursing services for recipients who require more individual and continuous care than is available under the Medicaid State Plan, and which are provided by a registered nurse or a licensed

(b) Specifically addresses the established goals of treatment;

(c) Is consistent with the participant's case management plan; and

(d) Is written during the course of care.

(145) "Program", unless the context indicates otherwise, has the meaning stated in COMAR 10.09.36.01B.o(146) "Progress note" means, in the context of COMAR 10.09.69, a signed and dated written notation by the home care nurse, home health aide, or certified nursing assistant which

(147) "Provider" has the same meaning as "health care provider", as stated in Health-General Article, §19-132, Annotated Code of Maryland.

(148) "Provider panel" means that group of providers employed by the MCO or with which the MCO contracts to provide services to the MCO's enrollees under the MCO's health benefit plan, which is at least equivalent to the benefits specified in COMAR 10.67.06.

(149) "Public institution" has the meaning stated in COMAR 10.09.24.02.

(150) "Quality assurance plan (QAP)" means a document or series of documents that set forth an MCO's strategy for systematically monitoring, evaluating, and improving all facets of MCO operations, including, but not limited to, clinical health care delivery, enrollee assistance and outreach services, and administrative services.

(151) "Rare and expensive case management" means the method of health care delivery provided to individuals with rare and expensive conditions.

(152) "Rare and expensive condition" means a medical diagnosis or condition identified in COMAR 10.09.69.o(153) "Rate adjustment period" has the meaning stated in COMAR 10.67.02.19-4A.

(153-1) "Rate year" has the meaning stated in COMAR 10.67.04.19-4A.

(154) "Readily accessible" means electronic information and services which comply with modern accessibility standards such as:

(a) Section 508 guidelines;

(b) Section 504 of the Rehabilitation Act; or

(c) W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

Appendix T

(155) "Reasonable allowable costs" means costs that are related to the provision of covered Medicaid services and are determined to be allowable in accordance with Medicare principles of reasonable cost reimbursement in 42 CFR 413, subject to the limitations specified in COMAR 10.09.08.05C.

(156) "Recipient" or "Program recipient" means an individual who is certified as eligible to receive Medical Assistance benefits, as provided in COMAR 10.09.24.

(157) "REM optional services" means, in the context of COMAR 10.09.69, the services which meet the general requirements under Regulation .08 and are listed in Regulations .10 and .11 of that chapter.

(158) "School-based health center (SBHC)" means a provider located on school grounds that meets the requirements set forth in COMAR 10.09.76.

(159) "Secretary" means the Secretary of Health.

(160) "Self-referral services" are the health care services listed in COMAR 10.67.06.28 for which, under specified circumstances, the MCO is required to pay, without any requirement of referral by the PCP or MCO, when the enrollee accesses the service through a provider other than the enrollee's PCP.

(161) "Service area" means a geographical area, comprised of one or more of Maryland's counties, with each selected county included in its entirety.

(162) "Service year" in the context of COMAR 10.67.04.19-4, means the calendar year in which an MCO incurs the expenses reported pursuant to COMAR 10.67.04.15E(5)(c).

(163) "Somatic care" means medical care that addresses an individual's physical health care needs.

(164) "Special needs population" means a group of recipients who share a special health care need as specified in COMAR 10.67.04.04.

(165) "Special rehabilitation hospital" has the meaning stated in Health-General Article, §19-307(a)(iii), Annotated Code of Maryland.

(166) "Specialty behavioral health services" means any behavioral health services other than primary behavioral health services.

(167) "Specialty care" means health care services that are either outside the PCP's scope of practice or, in the judgment of the PCP, are not services that the PCP customarily provides, is specifically trained for, or is experienced in.

(168) "Specialty care residency slots" means, in the context of COMAR 10.67.11, positions in a teaching hospital's residency program occupied after completion of a medical degree program by physicians who have trained in specialties other than family medicine, internal medicine, pediatrics, or obstetrics and gynecology.

(169) "Spend down" means a procedure by which an individual applying for Medical Assistance who is otherwise ineligible due to excess income becomes eligible by deducting incurred medical expenses from excess income.

(170) "State fair hearing" means a hearing, conducted by the Office of Administrative Hearings, for the purpose of ensuring the right of recipients to be treated in a fair and unbiased manner in their efforts to resolve disputes with the Department or an MCO.

(171) "Subcontract" means a written agreement between an MCO and a third party, under which the third party performs any one or more of the MCO's obligations required by the Department.

(172) "Subcontractor" means an individual or entity that has a contract with an MCO that relates directly or indirectly to the performance of the MCO's obligations under its contract with the Department; provided, however, that a contract does not by itself cause an MCO's network provider to be a subcontractor.

(173) "Substantial minority" means an ethnic or linguistic group that comprises 5 percent or more of the Medicaid population in the county to be served.

(174) "Supplemental Security Income (SSI)" means a federally administered program providing benefits to needy aged, blind, and disabled individuals under Title XVI of the Social Security Act, 42 U.S.C. §1381 et seq.

(175) "Systems performance review (SPR)" means an assessment, as a component of the quality assurance (QA) audit, of quality assurance operations taking place in the MCO.

(176) "Teaching hospital" means a hospital that

(a) Had HSCRC-approved rates for FY 1995 that included an allowance for GME costs; and

(b) During the contract year, operates a graduate medical education program that is accredited by the Accreditation Council for Graduate Medical Education.

(177) "Temporary Cash Assistance (TCA)" means a form of cash assistance provided, pursuant to Article 88A, §44A et seq., Annotated Code of Maryland, to assistance units which are technically and financially eligible.

(178) "Tertiary care" means health care services provided by highly specialized health care providers which are usually diagnostic or therapeutic in nature and often require highly sophisticated technological and support facilities.

(179) "Urgent care" means health care services for a medical condition that manifests itself by symptoms of sufficient severity that the absence of medical attention within 48 hours could reasonably be expected, by a prudent layperson who possesses an average knowledge of health and medicine, to result in an emergency medical condition.

(180) "Waiver-eligible" means an individual who qualifies for enrollment in the Maryland Medicaid Managed Care Program.

(181) "Whistleblower" means an individual who exposes any kind of information or activity that alleges any violation of regulation, statute, contract, policy, or unethical behavior that may be indicative of an individual or entity committing fraud, waste, or abuse against the Medicaid program.

(182) "Witness", in the context of COMAR 10.09.69, has the meaning stated in COMAR 10.09.53.

SUBTITLE 67 MARYLAND HEALTHCHOICE PROGRAM

CHAPTER 02 ELIGIBILITY AND ENROLLMENT

.01 ELIGIBILITY.

A. Criteria. Except as provided in §B of this regulation, a Program participant shall be enrolled in the Maryland Medicaid Managed Care Program, described in this chapter, if the participant is eligible for receipt of Medical Assistance benefits by qualifying:

(1) As categorically needy or medically needy under COMAR 10.09.24, unless the participant is:

(a) 65 years old or older;

- (b) Newly eligible and 64 1/2 years old or older;
- (c) Eligible to receive Medicare benefits;
- (d) Determined medically needy under a spend down; or
- (e) Otherwise certified for a period of less than 9 months;
- (2) For the Pregnant Women and Children's Program on or after January 1, 1997; or
- (3) For the Maryland Children's Health Program on or after July 1, 1998; or
- (4) For the Separate CHIP Program and CHIP Health Services Initiative on or after July 1, 2023.

B. A participant is not eligible for the Maryland Medicaid Managed Care Program if the participant:

- (1) Has been, or is expected to be, continuously institutionalized for more than:
 - (a) 90 successive days in a long-term care facility; or
 - (b) 30 successive days in an institution for mental disease (IMD);
- (2) Is institutionalized in an intermediate care facility for individuals with intellectual disabilities or persons with related conditions (ICF/IID);
- (3) Is enrolled in:
 - (a) Home Care for Disabled Children under a Model Waiver, pursuant to COMAR 10.09.27;
 - (b) The Family Planning Waiver Program pursuant to COMAR 10.09.58; or
 - (c) The Employed Individuals with Disabilities Program pursuant to COMAR 10.09.41;
- (4) Is a child receiving adoption subsidy who is covered under the parent's private insurance;
- (5) Is a child under State supervision receiving adoption subsidy who lives outside of the State;
- (6) Is a child in an out-of-State placement; or
- (7) Is an inmate as defined in COMAR 10.67.01.01.

.02 ENROLLMENT.

A. The Department shall make available through its website and upon request provide a paper copy of the following: ss(1) Materials regarding each MCO providing services in the eligible individual's county of residence including, but not limited to: ss(a) Information about how to access the provider directory and drug formulary, with instructions for how to request paper copies if needed; ss(b) A schedule of the benefits offered, including any benefits offered beyond the basic required package described in COMAR 10.67.06;

- (c) Which, if any, benefits are provided directly by the Department;
- (d) If applicable, a list of services that the MCO does not provide, reimburse for, or provide coverage of, because of moral or religious objections, and information about where and how to obtain these services;

(e) The requirements for each MCO to provide adequate access to covered services, including the network adequacy standards established in COMAR 10.67.05; and

(f) Quality and performance indicators for each MCO, including enrollee satisfaction; and

(2) Materials about the managed care program, including:

(a) The MCO enrollment and disenrollment process; and

(b) The basic features of managed care.

(3) Any forms necessary to select an MCO; and

(4) The toll-free telephone number of the enrollment unit.

B. Only the Department, or its designee, is authorized to enroll individuals into MCOs.

C. A participant found eligible for Maryland Medicaid under 42 U.S.C §1902(a)(10)A(i) shall be assigned to:

(1) The MCO the participant chooses at the time of application; or

(2) If the participant does not choose, an MCO with available capacity that is accepting new participants in the participant's service area.

D. Except for a participant found eligible as described in §C of this regulation, a participant, including a child in foster care or kinship care, shall:

(1) Have 28 days from the day the Department mails its eligibility notification in which to select an MCO; or

(2) Be assigned to an MCO with available capacity that is accepting new participants in the participant's service area.

E. All Managed Care Program eligible family members who live in the same household shall be assigned to the same MCO.

F. Newborns.

(1) A newborn shall be automatically enrolled from birth in its biological mother's MCO.

(2) The MCO is responsible for the newborn's health care from birth until the newborn enrolls into another MCO.

(3) A newborn, automatically assigned to its biological mother's MCO, is not eligible to change MCOs for family unity as described in COMAR 10.67.02.06A(1)(b) and (c) during the first 90 days of enrollment.

G. Effective Date of Enrollment. Enrollment in an MCO shall be effective at 12:01 a.m. on the 10th calendar day beginning with the day on which the Department notifies the MCO of the enrollment.

H. Upon the approval of the Department and the MCO, a participant may select an MCO that does not serve the participant's service area.

I. The Department or its designee shall submit the enrollee's choice of PCP to the enrollee's selected MCO at the time of enrollment.

.03 HEALTH SERVICE NEEDS INFORMATION.

A. The Department, MCO, or agents of the Department or MCO shall attempt to complete the health service needs information at the time of enrollment.

B. The Department shall transmit any information obtained from health service needs information to the enrollee's MCO within 5 business days.

C. Upon its receipt and review of the health service needs information, an MCO shall take appropriate action to ensure that a new enrollee, who needs special or immediate health care services, as identified by the health service needs information, receives them in a timely manner.

D. If the Department does not transmit health services needs information for an enrollee to the MCO within 10 days of enrollment, the MCO shall 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 these attempts shall be during non-working hours.

E. The Department shall inform an enrollee identified in connection with the health service needs information as having a behavioral health problem that the individual may self-refer to the behavioral health ASO for services as described in COMAR 10.09.59 and 10.09.80.

.04 ASSIGNMENT TO PRIMARY CARE PROVIDER (PCP).

A. Within 10 days of the notification of enrollment of a new enrollee or within 10 days of any event that requires a change in an existing enrollee's PCP, an MCO shall notify the enrollee of the enrollee's PCP assignment.

B. A Program recipient with no previous affiliation with any of the providers on the MCO's primary care provider panel who:

(1) Indicates a preference for a participating PCP during the enrollment process shall be assigned to that PCP unless the MCO documents in writing, for good cause, its inability to assign the enrollee to that PCP; or

(2) Fails to make known any preference for a PCP shall be assigned to a PCP whose location satisfies the access standards specified in COMAR 10.67.05.06E.

C. Before changing an enrollee's PCP, the MCO shall obtain the Department's approval at least 60 days before the reassignment is effective unless:

(1) The PCP has decided to stop practicing;

(2) The PCP has terminated the relationship with an enrollee due to the enrollee's behavior;

(3) The change is requested by the enrollee; or

(4) The age limits of the PCP's practice no longer meet the needs of the enrollee.

.05 REASSIGNMENT.

A. Once every 12 months, a Program recipient may elect to:

(1) Maintain enrollment with the recipient's current MCO;

(2) Enroll in another MCO in the recipient's local access area; or

(3) Enroll in an MCO outside the recipient's local access area, upon the approval of the Department and the MCO.

B. The Department shall notify the enrollee no less than 60 days before the start of each new enrollment period.

C. The Department shall reassign into the same MCO from which the recipient was last enrolled any recipient disenrolled from an MCO who, within 120 days of disenrollment, regains:

(1) Eligibility for Medicaid; or

(2) Maryland Medicaid Managed Care Program eligibility lost for any of the reasons listed in Regulation .06B of this chapter.

D. The MCO shall assign the recipient to the primary care provider of record at the time of the recipient's disenrollment.

E. A Program participant who has been disenrolled from an MCO because the Department terminated the MCO's contract shall be assigned to another MCO subject to Regulation .02D of this chapter.

.06 DISENROLLMENT

A. Enrollee-Initiated Disenrollment for Cause.

(1) An enrollee may disenroll from an MCO and enroll into another MCO if:

(a) The enrollee moves to a county that is not served by the enrollee's present MCO;

(b) The family members are enrolled in different MCOs and the adult enrollee requests that other family members be enrolled in one of the MCOs in which another family member is currently enrolled;

(c) The enrollee requests enrollment into the MCO that contracts with the PCP of any other family member who is not a HealthChoice enrollee;

(d) The enrollee moves or becomes homeless, creating a transportation hardship that may be resolved by enrollment into another MCO serving the enrollee's new local access areas;

(e) The enrollee requests a change of MCO within 90 days after the termination of the enrollee's primary care provider's (PCP's) contract if the PCP's contract with the enrollee's MCO, MCO's medical management group, or its subcontractors is terminating for the following reasons:

(i) By the MCO for reasons other than the quality of care or the PCP's failure to comply with contractual requirements related to quality assurance activities; or

(ii) The MCO's reduction of PCP's reimbursement to the extent that the reduction in rate is greater than the actual change in capitation paid to the MCO by the Department, and the MCO and PCP's inability to negotiate a mutually acceptable rate;

(f) The enrollee is automatically assigned to an MCO or it is the enrollee's initial enrollment in an MCO as follows:

(i) Only one request during the first 90 days of automatic assignment or initial enrollment into an MCO; and

(ii) The enrollee is not hospitalized at the time of the request;

(g) The MCO terminates its contract with the Department in which case:

(i) The MCO shall provide written notice to the recipient at least 60 days before the date on which the MCO will exit the HealthChoice Program;

- (ii) The MCO shall include in the notice the name and provider number of the PCP assigned to the recipient and the telephone number of the enrollment broker;
- (iii) The Department shall send a notice to every enrollee of the MCO regarding the MCO's termination of its contract with the Department, at least 30 days before the effective date of the termination of the contract;
- (iv) An enrollee shall have at least 30 days before the effective date of the MCO's contract termination with the Department to choose another MCO, or will be assigned to another MCO; and
- (v) An enrollee may choose another MCO one additional time within at least 90 days after reenrollment into the new MCO;
- (h) The MCO is acquired by another entity in which case:
 - (i) The MCO shall provide written notice to the recipient at least 60 days before the date on which the MCO will exit the HealthChoice Program;
 - (ii) The MCO shall include in the notice the name and provider number of the PCP assigned to the recipient and the telephone number of the enrollment broker;
 - (iii) The Department shall send a notice to every enrollee of the MCO regarding the change in ownership, 30 days before the effective date of the change of ownership;
 - (iv) An enrollee shall have 30 days before the change of ownership to disenroll from the MCO into another participating MCO;
 - (v) If an enrollee does not choose to disenroll in accordance with §A(1)(f)(ii) of this regulation, the enrollee will be reenrolled in the newly purchased MCO; and
 - (vi) An enrollee may choose another MCO one additional time within at least 90 days after reenrollment in the newly purchased MCO;
- i) The MCO does not, because of moral or religious objections, cover the service the enrollee seeks;
- (j) All of the following apply:
 - (i) The enrollee needs related services to be performed at the same time;
 - (ii) Not all related services are available within the network; and
 - (iii) The enrollee's PCP or other provider determines that receiving the services separately would subject the enrollee to unnecessary risk; or
- (k) The Department imposes the intermediate sanction specified in 42 CFR §438.702(a) and (b), as amended.
- (2) The Department shall provide timely notification to the affected MCO of an enrollee's intention to disenroll under §A of this regulation.
- (3) The Department shall allow disenrollments, subject to the Department's approval, for other reasons, including but not limited to:
 - (a) Poor quality of care;
 - (b) Lack of access to services covered under the contract; or

(c) Access to providers experienced in dealing with the enrollee's health care needs.

(4) Enrollees shall make an oral or written request to the Department's enrollment agent for disenrollment.

B. Department-Initiated Disenrollment. The Department shall disenroll from an MCO an enrollee:

(1) Subject to the MCO or long-term care facility obtaining the Department's determination that the enrollee's institutionalization has been medically necessary, who has been continuously institutionalized for a period of more than 90 successive days in a long-term care facility;

(2) Upon admission to an intermediate care facility for individuals with intellectual disabilities or persons with related conditions (ICF/IID);

(3) Determined eligible for rare and expensive case management pursuant to COMAR 10.09.69;

(4) Who loses Medicaid eligibility or who changes to an assistance category not eligible for MCO enrollment, subject, however, to Regulation .01 of this chapter;

(5) Upon the termination of the contract between the enrollee's MCO and the Department;

(6) Who has died;

(7) Who has not been validly enrolled in the MCO;

(8) Who is 65 years old or older;

(9) Who is an inmate of a public institution, including a State operated institution or facility; or

(10) Who is eligible to receive Medicare benefits.

C. The Department may disenroll individuals from an MCO which the Maryland Insurance Administration has put into rehabilitation or liquidation pursuant to Health-General Article, §15-102.2, Annotated Code of Maryland.

D. MCO Initiated Disenrollment.

(1) An MCO may request disenrollment of an enrollee who has:

(a) Moved outside of the MCO's service area; or

(b) Become ineligible for continued enrollment for one of the reasons specified in §B of this regulation.

(2) An MCO may not request disenrollment as specified in 42 CFR §438.56(b)(2), as amended.

E. Effective Date of Disenrollment.

(1) Except as specified in §E(2)—(6) of this regulation, an enrollee's disenrollment is effective on the 10th calendar day after the enrollee selects a new MCO.

(2) An enrollee's disenrollment shall take effect:

(a) Immediately when the enrollee dies;

(b) From the first day of the month following the month that the enrollee lost Medicaid eligibility;

- (c) On the first day of the month following the month in which the Department receives the required notification, when the enrollee permanently relocates outside of the State; or
- (d) From the first day of the month following the month in which the Department verifies an enrollee is an inmate.
- (3) When an enrollee becomes eligible for Medicare, the enrollee's disenrollment from the MCO is effective on the:
 - (a) First day of the month following the month in which the Program receives notice of Medicare eligibility; or
 - (b) Last day of the month before the month in which the enrollee turns 65 years old.
- (4) Termination of enrollment resulting from termination of the contract between the Department and an MCO shall be effective on the date the Department terminates the contract.
- (5) Termination of enrollment resulting from the MCO being placed into rehabilitation or liquidation by the Maryland Insurance Administration shall be effective on the date the Department notifies the MCO of the disenrollment.
- (6) In the case of an enrollee's death, the Department has the right to recover any capitation payments made on behalf of an enrollee for the period beginning on the date of death.

F. An MCO shall:

- (1) Make a good faith effort to give written notice to the Department when enrollees have the right to change MCOs under §A(1)(e) of this regulation 90 days before the effective date of the termination;
- (2) Provide the Department with a list of the affected enrollees in a format specified by the Department; and
- (3) If applicable, provide the termination survey required under COMAR 10.67.04.17B(4).

G. The Department shall notify enrollees who may change MCOs under §A(1)(e) of this regulation.

H. At the Department's discretion, an MCO may be required to reimburse the Department for the costs associated with the mailing of the notifications in §G of this regulation.

CHAPTER 03 MARYLAND MEDICAID MANAGED CARE PROGRAM: MCO APPLICATION

.02 APPLICATION.

A. When applying for participation in the Maryland Medicaid Managed Care Program as an MCO, an applicant shall submit an application to the Secretary in the form that the Secretary requires.

B. An applicant may omit from its application any information or documents that it has previously submitted to the Department, if:

- (1) The information or documents are up to date; and
- (2) The applicant identifies in its application the information and documents that it has omitted.

.03 ORGANIZATION, OPERATIONS, AND FINANCING.

Except as provided in Regulation .02B of this chapter, an MCO applicant shall include the following information or descriptions in its application:

- A. An indication whether the applicant is an operating HMO with a certificate of authority from the Maryland Insurance Administration;
- B. A written legal history of the applicant, specific as to dates and parties involved, that includes, but is not limited to:
 - (1) Predecessor corporations;
 - (2) Mergers;
 - (3) Reorganizations; and
 - (4) Changes of ownership;
- C. A copy of the articles of incorporation of the applicant, and any amendments to it, certified by the Maryland Department of Assessments and Taxation;
- D. A copy of the applicant's current bylaws, certified by the appropriate corporate officer;
- E. A written description providing a reason if the applicant has ever defaulted on a contract or otherwise had a contract terminated;
- F. If the applicant is an HMO, the most recent annual loss ratio report provided to the Maryland Insurance Administration pursuant to Insurance Article, §5-605, Annotated Code of Maryland;
- G. A copy of the applicant's business plan provided to the Maryland Insurance Administration pursuant to Insurance Article, §5-605, Annotated Code of Maryland.
- H. Evidence of compliance with Maryland Workers' Compensation Law, as follows:
 - (1) Except as provided in §H(2) of this regulation, the applicant shall submit:
 - (a) The policy number of its Workers' Compensation insurance coverage; and
 - (b) The name of its Workers' Compensation insurance carrier; or
 - (2) If self-insured, the applicant shall submit a certificate of compliance evidencing employee coverage under Workers' Compensation Law, as provided in Labor and Employment Article, Title 9, Annotated Code of Maryland;
- I. The names, addresses, and official capacities of the managing employees or other individuals responsible for the conduct of the affairs of the applicant, including concise position descriptions and background, citing education, training, and experience, for, but not limited to, the applicant's:
 - (1) Chief Executive Officer;
 - (2) Chief Medical Officer;
 - (3) Chief Information Officer;
 - (4) Chief Financial Officer;
 - (5) Chief Quality Officer;
 - (6) Clinical Operations Manager;

(7) Chief Operating Officer;

(8) Marketing Director;

(9) Program Integrity Director;

(10) Health Equity Director;

(11) Chief Compliance Officer;

(12) Appeals and Grievances Manager;

(13) Provider Relations Manager;

(14) Special Needs Coordinator, as defined in COMAR 10.67.04.04; and

(15) Newborn Coordinator, as defined in COMAR 10.67.04.27;

J. A full disclosure of the extent and nature of any contracts or arrangements, including any possible conflicts of interest between the applicant and any individual specified in §I of this regulation;

K. The name and address of each person with a 5 percent or more ownership or controlling interest in the applicant or in any subcontractor or supplier in which the applicant has direct or indirect ownership of 5 percent or more, including identifying whether any person named is related to any other named person as either spouse, parent, child, or sibling;

L. A list of any subcontractors or suppliers owned by the applicant, indicating the percent of financial interest held;

M. A history of any subcontractors with whom the applicant has had business transactions totaling more than \$25,000 during the 12-month period ending on the date of application;

N. A description of the applicant's corporate and organizational structure, and an organizational chart, with detailed lines of authority indicating the relationships among the board of directors, the administrative component, and the medical and health service delivery component of the applicant including, but not limited to, staff positions responsible for the plan's key management functions enumerated in §I of this regulation;

O. A description of all current contractual relationships between the applicant and subcontractors for administrative/management, health, and marketing services, including the subcontractors' names;

P. A description of any contracts the applicant intends to enter into before beginning operation as an MCO;

Q. The name of any person or persons holding an ownership or controlling interest in excess of 5 percent in the applicant, or who is an agent or managing employee of the applicant, who has been subject to a conviction as defined at 42 U.S.C. §1320a-7(i), or a sanction for a Program-related offense;

R. Copies of all standard subcontracts with service and administrative providers who are not salaried employees of the applicant, including identification of any provision in subcontracts which differ from the standard subcontract;

S. A description of the method by which the applicant will accomplish cost avoidance or recovery in the case of third-party liability; and

T. Copies of the applicant's written Medicaid marketing plan including:

(1) A description of how the applicant plans to address the special access provisions in COMAR 10.67.05.01D; and

(2) Sample version of all material and communication the applicant would like to distribute to potential enrollees, including but not limited to:

- (a) Brochures;
- (b) Fact sheets; and
- (c) Posters.

.04 FINANCIAL SOLVENCY.

An applicant that is not a Maryland certified HMO shall include in its application the following information or descriptions:

A. A table labeled "Insurance Coverage", specifying the applicant's coverage in insurance types including, but not limited to, reinsurance, risk of insolvency, medical malpractice, general liability, and fidelity bond, and detailing the:

- (1) Carrier;
- (2) Entity covered;
- (3) Description of coverage including deductibles, coinsurance, and minimum and maximum benefits;
- (4) Premium in effect;
- (5) Any additional policies to cover new risks associated with anticipated MCO functions; and
- (6) Any other pertinent arrangements;

B. Evidence of the applicant's insurance for general liability and medical malpractice in the minimum amounts of \$1,000,000 per loss and \$3,000,000 in the aggregate;

C. Evidence that the applicant has on hand sufficient liquid funds or a reasonably adequate cash flow to meet all organizational and administrative expenses incurred or expected to be incurred before commencing operations;

D. An explanation detailing how the applicant would, if approved, protect itself from insolvency;

E. A description of how the applicant would, if approved, limit its financial risk;

F. Document that the applicant has deposited, in a trust account with the State treasury, \$100,000 in cash or government securities of the type described in Insurance Article, §5-701(b), Annotated Code of Maryland;

G. A financial statement audited by an independent certified public accountant of the financial condition of the applicant, including:

- (1) Assets, liabilities, and minimum tangible net equity;
- (2) A prospective budget and expected cash flow analysis of the applicant for the first 24 months of its anticipated operation demonstrating financial stability based on reasonable assumptions; and
- (3) Any other financial information required by the Commissioner to adequately conduct financial examination of an applicant; and

H. A power of attorney executed by the applicant appointing the Commissioner and the Commissioner's authorized deputies as the true and lawful attorney of the applicant in and for the State upon which may be served all lawful process in any action, proceeding, or cause of action arising in this State against the applicant regarding the solvency and financial condition of the applicant.

.05 ACCESS AND CAPACITY.

A. An MCO applicant shall include in its application the following information or descriptions:

- (1) A map or maps showing the county or counties in which the applicant proposes to provide health care services, and the service area boundaries.
- (2) The name and address of each of the applicant's service delivery sites, and, if applicable, the type of facility licensure of each site, grouped by county;
- (3) If the applicant is an HMO, the applicant's total prepaid enrollment or client population as of the date of application, with a breakdown by payment source, including Medicare, Medicaid, commercial group, commercial individual, and other enrollment;
- (4) If the applicant is an HMO, the total of the applicant's current unduplicated fee-for-service patient count, with a breakdown by payment source, including Medicaid, Medicare, commercial group, commercial individual, and other patients (including self-pay);
- (5) The name and address of each of the applicant's primary and specialty care providers, provided in a format specified by the Department, for distribution to recipients in enrollment packets;
- (6) The following information, grouped by medical specialty and county, regarding each individual practitioner, including primary care providers and specialists, who will act as a health care provider for the applicant:
 - (a) Name, address, and practice location or locations, including a separate line for each location;
 - (b) State licensure number;
 - (c) Specialty, if applicable, indicating the type of services to be provided on behalf of the applicant;
 - (d) Whether the provider will be a primary care provider;
 - (e) A description of the practitioner's employment relationship to the applicant, including, but not limited to:
 - (i) A salaried employee;
 - (ii) A subcontractor;
 - (iii) An employee of a subcontractor; or
 - (iv) Any other form of contractual or employment relationship;
 - (f) Any restrictions as to age of patients or numbers of enrollees the provider will serve;
- (7) The procedures for assuring proper credentialing and recredentialing of providers;
- (8) Documentation that the MCO applicant is able to meet the access standards set forth in COMAR 10.67.05 in each service area the MCO applicant plans to enter;

(9) Documentation of any reasons for which they are unable to meet the access requirements of COMAR 10.67.05 in any service area;

(10) For each primary care practice location, a specification of:

(a) The name, address, and hours of operation; and

(b) The staffing at each location, expressed in full-time equivalencies and grouped by medical specialty; and

(11) Written protocols detailing how the applicant will provide 24-hour per day, 7-day per week coverage for emergency medical situations, including compliance with MIEMSS protocols and the federal Emergency Medical Treatment and Active Labor Act.

B. The service area in §A(1) of this regulation shall include at least two underserved counties as defined in §C of this regulation.

C. An underserved county is a county in which less than three current MCOs are participating and accepting new enrollments.

D. If there are no underserved counties, applications will not be accepted.

.06 ACCESS AND CAPACITY: BENEFITS AND APPOINTMENTS.

An MCO applicant shall include in its application the following information or descriptions:

A. Written evidence of the applicant's preparedness to provide benefits equivalent to the benefit level mandated by the Maryland Medical Assistance Program as described in COMAR 10.67.05;

B. A description of any benefits the applicant proposes to provide in addition to those required by the Maryland Medicaid Managed Care Program, including:

(1) Whether there are any limitations on these services; and

(2) The name, medical specialty, location, and employment status as enumerated in Regulation .05F(5) of this chapter, of any providers rendering additional services;

C. A copy of the written procedures specifying how an enrollee may select and change primary care providers;

D. A written explanation of the applicant's plan to provide adequate case management and continuity of care, including its policies and procedures concerning:

(1) Case management;

(2) Making appointments;

(3) Appointment no-shows;

(4) Follow-up for appointment no-shows who are at-risk patients; and

(5) Referral claims and reimbursement for authorized noncontractual and out-of-plan provider services;

E. Documentation of the applicant's preparedness to collaborate with providers of self-referral services, and reimburse at the Department's established fee-for-service rate, for permissible self-referred services as defined in COMAR 10.67.06.28;

F. Documentation of the applicant's preparedness to provide the full range of EPSDT services;

G. Documentation of the applicant's preparedness to work with the Department's behavioral health ASO for coordination of somatic care, behavioral health care, and all appropriate drug utilization review.

H. A written explanation of the prospective MCO's plan for providing monthly updates to primary care providers of the enrollees assigned to them;

I. Documentation of the applicant's plan to satisfy statutory requirements that enrollees be notified of due dates for obtaining immunizations, examinations, and other wellness services;

J. Documentation of how the applicant will provide timely access to health care services, including but not limited to:

(1) Waiting time for telephone calls to be answered;

(2) Obtaining appointments; and

(3) Waiting times in practitioners' offices;

K. Documentation of access provisions to address the needs of enrollees who:

(1) Do not speak English;

(2) Are deaf; or

(3) Have one or more physical, mental, or developmental disabilities;

L. The applicant's proposed written utilization management program that specifies, at a minimum, policies and procedures for:

(1) Referral processes;

(2) Services requiring preauthorization, including mechanisms for ensuring consistent application and requesting provider consultation when appropriate;

(3) Criteria for determining medical necessity;

(4) Provider responsibilities for utilization management activities;

(5) Case management processes;

(6) Utilization tracking mechanisms and the determination of over-utilization and under-utilization of health care services;

(7) Integration of activities with quality improvement for provider profiling; and

(8) Appeals and grievance processes;

M. The applicant's proposal to establish and utilize a consumer advisory board, including:

(1) The anticipated composition of the board;

(2) Identifying staff responsible for serving board needs; and

(3) Proposed mechanisms by which the board will furnish the MCO with regular enrollee input;

N. A written description of the applicant's proposed member services unit, including a consumer services hotline, describing how the applicant will use this:

(1) As an information source for enrollees;

(2) To respond to enrollees' needs and requests in a timely manner; and

(3) To facilitate enrollees' access to needed health care services, including how the hotline will function as a point of entry for complaint resolution and internal grievance procedures;

O. A written Enrollee Outreach Plan that:

(1) Describes how the MCO intends to comply with the outreach, quality assurance, and provision of health care services requirements of Health-General Article, §15-103(b)(9), Annotated Code of Maryland; and

(2) To the extent that the materials are relevant to the requirements of §O(1) of this regulation, may incorporate by reference written materials provided by the applicant in response to other elements of its application; and

P. Documentation of any service the MCO elects not to provide, reimburse for, or provide coverage of, because of a moral or religious objection, which shall:

(1) Be provided to the Department whenever an MCO adopts the policy during the term of the contract;

(2) Be consistent with the provisions of 42 CFR §438.10, as amended; and

(3) Be provided to enrollees within 90 days after adopting the policy with respect to any particular service.

.07 ACCESS AND CAPACITY: CONTRACTS AND PROVIDER APPLICATIONS.

An MCO applicant shall include in its application the following information or descriptions:

A. A description of the applicant's hiring and subcontracting policies, which shall correspond to the requirements of Insurance Article, §15-112, Annotated Code of Maryland;

B. A blank copy of the provider application form;

C. Documentary assurances that the applicant and its health care providers furnish access on a nondiscriminatory basis, in accordance with State and federal law, to all of their enrollees regardless of gender, race, age, religion, national origin, physical or mental disability, or type of illness or condition;

D. If the applicant is an HMO that will require its panel providers to participate in the MCO, documentation of the mechanism the MCO will use to make an equitable distribution of enrollees among its panel providers so that no provider is assigned a disproportionate number of enrollees;

E. Written evidence of the applicant's organizational capacity to provide special programs adequate to meet the individual needs of all enrollees, including:

(1) Outreach;

(2) Case management;

(3) Home visiting;

(4) Disease management;

(5) Prevention and wellness education; and

(6) All Medicaid-covered services required to comply with State statutes and regulations mandating health and behavioral health services for children in State-supervised care;

F. A written explanation of the applicant's plan for ensuring that each primary and specialty care provider receives a copy of the MCO's Medicaid requirements manual, and any other information necessary to facilitate full compliance with all federal and State Medicaid requirements within 2 weeks after the provider has entered into a contract or has begun employment with the MCO, and updated as necessary thereafter; and

G. A description of the applicant's plan to accommodate the cultural and ethnic diversity of the populations to be served.

.08 NATIONAL COMMITTEE ON QUALITY ASSURANCE (NCQA) ACCREDITATION.

A. Effective July 1, 2012, an MCO applicant shall obtain NCQA health plan accreditation within 2 years of their effective date as an MCO.

B. Effective January 1, 2025, an MCO shall obtain NCQA health equity accreditation within 2 years of their effective date as an MCO.

.09 QUALITY ASSURANCE SYSTEM — GENERAL.

An applicant shall include in its application the following information or descriptions:

A. The applicant's proposed quality assurance plan, that contains, at a minimum, all elements specified by Health-General Article, §15-103(b)(9)(i), Annotated Code of Maryland;

B. A description of any written procedures or protocols regarding physician and nursing care practice the applicant intends to use;

C. A description of the applicant's peer review committee structure and process;

D. A copy of the applicant's case management plan;

E. A description of all mechanisms to be used to ensure the quality of any services, including administrative and clinical, that the applicant intends to delegate to subcontractors;

F. The name and a description of the published standards or guidelines for maintenance of medical records the applicant will follow;

G. A description of how providers will be apprised of medical records, utilization review, and case management requirements;

H. A description of the applicant's system for ensuring inclusion in the medical record of reports of health care services or diagnostic testing performed in a referral setting;

I. A written description of the applicant's internal review system for the handling, monitoring, and resolution of provider complaints, grievances, and appeals;

J. Evidence of an adequate system for medical record retention and retrieval that meets, at minimum, all requirements of Health-General Article, §15-103(b)(9)(xiv), Annotated Code of Maryland;

K. Documentary evidence that the applicant requires school-based clinics to provide information concerning health care services provided to their enrollees;

L. A copy of the applicant's practice guidelines used to assist practitioners in approaching health care issues in a systematic, appropriate manner;

M. A copy of the applicant's health education plan;

N. A written description of the applicant's complaint resolution protocol, which shall, at minimum:

(1) Include an internal grievance procedure by which an enrollee who is dissatisfied with the applicant or its providers may seek recourse within the applicant;

(2) Specify what constitutes a grievance;

(3) Provide for prompt resolution of complaints;

(4) Require participation in the grievance process by individuals within the MCO who have the authority to require corrective action;

(5) Specify how the MCO will handle formal appeals by enrollees;

(6) Include a form that enrollees will use when filing a grievance, including foreign language versions for any substantial minorities in the applicant's proposed MCO service area;

(7) Identify the steps in the grievance process, and what personnel will be responsible for receiving, processing, monitoring, and responding to grievances;

(8) Specify how the enrollee will be informed that the enrollee's grievance is being investigated, and the protocols by which grievances will be resolved;

(9) Describe what methods will be used to inform enrollees about the operation of the grievance procedure; and

(10) Describe whether manual or automated processes will be used to track enrollees' complaints, determine any patterns of complaints, and report findings to the proposed MCO's quality assurance or quality improvement system; and

O. A copy of the MCO's provider education plan.

.10 SPECIAL NEEDS POPULATIONS.

An MCO applicant shall include in its application the following information or descriptions:

A. A narrative description of the clinical expertise and experience of the MCO's network for special needs populations in a format specified by the Department;

B. Written evidence of the applicant's ability to comply with specific quality access, data, and performance measurements to satisfy the general requirements for all special needs populations specified in COMAR 10.67.04.04;

C. Written evidence, including treatment protocols, of the applicant's ability to provide the range of clinical and support services specified in COMAR 10.67.04.05—.10 and .13, to ensure appropriate and coordinated services to the following special populations:

- (1) Children with special health care needs;
- (2) Individuals with a physical disability;
- (3) Individuals with a developmental disability;
- (4) Pregnant and postpartum women;
- (5) Individuals who are homeless; and
- (6) Individuals with HIV/AIDS; and

D. Referral protocols that demonstrate the conditions under which PCPs will make the arrangements for children with special health care needs to be referred to MCO specialty care networks and when appropriate the behavioral health ASO for services as described in COMAR 10.09.59 or 10.09.80.

.11 MANAGEMENT INFORMATION SYSTEM AND DATA REPORTING.

An MCO applicant shall include in its application the following information or descriptions:

A. A description of the applicant's management information system, including, but not limited to:

- (1) Capacities, including:
 - (a) The ability to generate and transmit electronic claims data consistent with the Medicaid Statistical Information System (MSIS) requirements or successor systems;
 - (b) The ability to collect and report data on enrollee and provider characteristics and on all services furnished to enrollees through an encounter data system;
 - (c) The ability to screen the data collected for completeness, logic, and consistency; and
 - (d) The ability to collect and report data from providers in standardized formats using secure information exchanges and technologies utilized for Medicaid quality improvement and care coordination efforts;
- (2) Software;
- (3) Characteristics; and
- (4) Ability to interface with other systems;

B. A description of the applicant's operational procedures for generating service-specific encounter data;

C. Evidence of the applicant's ability to report, on a monthly basis, service-specific encounter data in UB04 or CMS1500 format;

D. A description of the applicant's operational procedures for generating financial reports, including, but not limited to:

- (1) Annual audits;

(2) Annual financial statements; and

(3) Quarterly unaudited financial statements;

E. Evidence of the applicant's ability to collect and report all data necessary to derive indicators for Healthcare Effectiveness Data and Information Set (HEDIS); and

F. A description of the applicant's procedures for verifying the accuracy and timeliness of reported data, including data from network providers the MCO was compensating on the basis of capitation payments or other payment arrangements that are not fee-for-service.

CHAPTER 04 MANAGED CARE ORGANIZATIONS

.02 CONDITIONS FOR PARTICIPATION.

A. An MCO shall have sufficient provider capacity to provide health care services to Program recipients residing in a geographic region no smaller in size than one county or the City of Baltimore.

B. An MCO shall comply with COMAR 10.09.36.

C. An MCO shall enter a memorandum of understanding with each local health department (LHD) in its service area addressing the method by which the MCO and the LHD will collaborate and communicate on matters of mutual interest and concern, including but not limited to the responsibility of the LHD for contact tracing for sexually transmitted diseases and directly observed therapy for tuberculosis.

D. Assurance Against Insolvency.

(1) An MCO shall be actuarially sound.

(2) An applicant shall possess an initial surplus in the amount of \$1,500,000 as specified in Health-General Article, §15-102.4(a)(2)(ii), Annotated Code of Maryland.

(3) If the Commissioner determines and reports to the Secretary that the applicant has an initial surplus that is at least \$1,250,000 but less than \$1,500,000, before approval the Department shall designate funds in trust sufficient to provide an initial surplus of \$1,500,000.

(4) If the Commissioner determines and reports to the Secretary that the applicant's initial surplus is less than \$1,250,000 before approval the Department may, at its discretion, designate funds in trust in an amount equal to:

(a) The sum of the amounts due to the owners of the applicant from the Department for Medicaid services provided on a fee-for-service basis, so long as the owners of the applicant have waived in writing their right to receive Medicaid payments until such time as the Department is permitted to remove its funds from the trust account pursuant to §D(6) of this regulation; or

(b) If a financial guarantor with sufficient net worth and an adequate history of generating net income agrees to pay claims against the MCO in the case of insolvency, the difference between \$1,250,000 and the applicant's initial surplus.

(5) If, in accordance with §D(4) of this regulation, the Department designates funds sufficient to increase the applicants initial surplus to \$1,250,000, the Department shall designate \$250,000 in trust for the applicant.

(6) Funds designated by the Secretary pursuant to §D(3)(5) of this regulation shall remain in trust until such time as the Commissioner has determined that the MCO meets the minimum statutory surplus requirements based on the MCOs annual report submitted pursuant to Insurance Article, §5-605, Annotated Code of Maryland.

(7) Before approval of an applicant, the Secretary shall notify the Commissioner whether the Secretary has placed any money in trust under this section.

(8) In the event of insolvency, the MCO shall cover continuation of services to enrollees for the duration of the period for which capitation payment has been made.

(9) An MCO shall meet the solvency standards established by the State for private HMOs, or be licensed or certified by the State as a risk-bearing entity except if the MCO:

(a) Is a public entity; or

(b) Is, or is controlled by, one or more federally qualified health centers and meets the solvency standards established by the State for those centers;

(c) Has its solvency guaranteed by the State.

E. Health Care Delivery.

(3) Provide each enrollee within 10 days of notification to the MCO of the enrollee's enrollment with a distinctive, durable identification card, clearly indicating the bearer to be a member of the MCO and containing, at a minimum:

(a) The enrollee's Medicaid number;

(b) The MCO's consumer services hotline telephone number;

(c) The Department's enrollee hotline telephone number; and

(d) Enrollee's assigned primary care provider's name and telephone number;

(4) Provide enrollees, within 30 days before the intended effective date, written notice when there is a significant change in the nature or location of services provided; and

(5) Provide on the card required in §E(3) of this regulation, on a separate prescription benefit card, or other technology, prescription billing information that:

(a) Complies with the standards set forth in the National Council for Prescription Drug Programs pharmacy ID card prescription benefit card implementation guide at the time of issuance of the card or other technology; or

(b) Includes, at a minimum, the following data elements:

(i) The name or identifying trademark of the MCO;

(ii) The name and identification number of the recipient;

(iii) The telephone number that providers may call for pharmacy benefit assistance; and

(iv) All electronic transaction routing information and other numbers required by the MCO or its benefit administrator to process a prescription claim electronically.

F. An MCO:

(1) Shall comply with the standards in P.L. 101-336, Americans with Disabilities Act of 1990, 42 U.S.C. §12101 et seq.;

Appendix T

(2) May not discriminate against an enrollee on any basis, including, but not limited to, age, sex, race, creed, color, marital status, sexual orientation, gender identity, national origin, physical or mental handicap, health status, or need for health care services;

(3) Shall prepare and make available all publications in a manner consistent with COMAR 10.67.05.01A, including, but not limited to:

(a) Provider directories;

(b) Enrollee handbooks;

(c) Health education materials; and

(d) Informational brochures.

G. An MCO shall maintain enrollee medical records in compliance with Health-General Article, §4-301 et seq., Annotated Code of Maryland, and the utilization control requirement of 42 CFR Part 456, as amended.

H. An MCO shall permit the enrollment of a waiver-eligible Program recipient who is enrolled by the Department or who selects the MCO, unless the MCO's enrollment meets or exceeds any enrollment limits mutually agreed to by the Department and the MCO.

I. MCO Local Access Area Participation.

(1) Effective January 1, 2014, an MCO shall open in all local access areas located within the same county in which the MCO chooses to participate.

(2) The MCO shall provide written notification to the Department of the MCO's intent to participate and accept new enrollees in each of the counties by September 15 for the next calendar year.

(3) The MCO's decision to accept new enrollees is in effect from January 1 to December 31 unless the Department decides there is adequate justification to waive this requirement, which includes, but is not limited to, a rate cut or an MCO exit from the market.

(4) Unless the Department approves a shorter time frame, an MCO that exits the Program during the calendar year shall submit their exit transition plan to the Department 120 days prior to the effective date of the exit.

(5) If the MCO has not participated in a county for a period of 12 or more consecutive months, the MCO may participate and accept new enrollees in that county by notifying the Department at least 30 days before accepting new enrollees.

(6) An MCO that voluntarily freezes for new enrollments in a county shall remain frozen in that county for the remainder of the calendar year and the following calendar year.

(7) If system modifications require longer than 30 days to implement, the effective date may be extended.

(8) The MCO shall follow the access standards specified in COMAR 10.67.05.06 and .05-1.

J. In counties where the MCO decides to stop accepting new enrollees, the MCO shall:

(1) Continue to accept enrollees who regain eligibility within 120 days of becoming ineligible for the Program;

(2) Accept newborns if the mother is an MCO member at the time of birth; and

(3) Accept the family members of enrollees enrolled with the MCO before the effective date that the MCO stopped accepting new enrollees.

K. An HMO that is approved as an MCO and that requires its panel providers to participate in an MCO shall submit for review by the Secretary its plan to assure the equitable distribution of enrollees and to ensure that a provider is not assigned a disproportionate number of enrollees, as required by Health-General Article, §15-102.5, Annotated Code of Maryland.

L. An MCO shall comply with the provisions of Insurance Article, §15-112, Annotated Code of Maryland when credentialing providers, and during the credentialing process the MCO:

(1) May not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment;

(2) May not employ or contract with providers excluded from participation in federal health care programs under either §1128 or 1128A of the Social Security Act; and

(3) Shall give the affected providers written notice of the reason for its decision if the MCO declines to include the providers in its network.

M. The requirements of Regulation .17A(2) of this chapter, or §L(1) of this regulation, may not be construed to:

(1) Require an MCO to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude an MCO from using different reimbursement amounts:

(a) For different specialties; or

(b) For different practitioners in the same specialty; or

(3) Preclude an MCO from establishing measures that are designed to maintain quality of services and control costs, consistent with its responsibilities to enrollees.

N. Disclosure of Provider Incentive Plans.

(1) An MCO shall disclose to the Department the information on its provider incentive plans listed in 42 CFR §417.479(h)(1):

(a) Prior to approval of its contract or agreement; and

(b) Upon the contract's or agreement's anniversary or renewal effective date.

(2) An MCO shall include in the disclosures required by §N(1) of this regulation information sufficient for the Department to determine whether the incentive plans meet the requirements of 42 CFR §417.479(d)(g) and, as applicable (i), when there exist compensation arrangements under which payment for designated health services furnished to an individual on the basis of a physician referral would otherwise be denied under §1903(a) of the Social Security Act.

O. When making a referral, an MCO shall use the uniform consultation referral form adopted by the Maryland Insurance Administration at COMAR 31.10.12.06.

P. An MCO shall meet all other requirements of applicable State and federal law including but not limited to:

(1) Title VI of the Civil Rights Act of 1964;

- (2) Title IX of the Education Amendments of 1972 regarding education programs and activities;
- (3) The Age Discrimination Act of 1975;
- (4) The Rehabilitation Act of 1973;
- (5) Any laws regarding privacy and confidentiality;
- (6) Any laws that pertain to enrollee rights;
- (7) 45 CFR Part 74, as amended, including particular attention to requirements at 45 CFR §§74.42, 74.43, 74.44, 74.48, and 74.53(a) and (b), and Appendix A; and
- (8) Section 1557 of the Affordable Care Act.

Q. An MCO shall meet all program integrity requirements as set forth in COMAR 10.67.07.

R. The following applies to the Department's Health Home Program as described in COMAR 10.09.33:

- (1) The MCO may not provide services that duplicate the CMS reimbursed health home services for members participating in the State's Health Home Program;
- (2) The State shall inform the MCO of members assigned to the State's Health Home Program so that the MCO can prepare to coordinate care with the health homes;
- (3) The MCO shall provide a point of contact for the health homes to the State who shall share with all the enrolled health homes;
- (4) The MCO shall make referrals to the health homes of members who meet the criteria for enrollment in the program;
- (5) To facilitate this process, the State shall provide information to the MCO on all the enrolled health homes in the MCO's service areas; and
- (6) The MCO shall assist the health homes as necessary in accessing somatic care services for health home recipients.

.03 QUALITY ASSESSMENT AND IMPROVEMENT.

A. An MCO shall have a continuous, systematic program designed to monitor, measure, evaluate, and improve the quality of health care services delivered to enrollees including individuals with special health care needs. At a minimum, the MCO shall:

- (1) Comply with all applicable federal and State laws and regulations;
- (2) Comply with all access and quality standards and levels of performance established by the Department including all standards for individuals with special health care needs in Regulations.04—.10 of this chapter; and
- (3) Be able to provide the Department with timely accurate information in areas including but not limited to:
 - (a) Provider networks;
 - (b) Utilization of services; and

(c) Identification and management of individuals with special health care needs, including but not limited to:

- (i) Enrollees with HIV;
- (ii) Pregnant women;
- (iii) Enrollees with disabilities;
- (iv) Adult enrollees with diabetes;
- (v) Pediatric enrollees with asthma; and
- (vi) Children with special health care needs.

B. An MCO shall participate in all quality assessment activities required by the Department to determine if the MCO is providing medically necessary enrollee health care. These activities include, but are not limited to:

(1) A Systems Performance Review (SPR) performed by an external quality review organization hired by the Department to assess an MCO's structure and operations in order to determine its ability to provide health care to its enrollees as follows:

(a) The SPR shall include, but not be limited to:

- (i) MCO's Quality Assessment and Improvement program;
- (ii) Enrollee rights;
- (iii) Access and availability of services;
- (iv) Care management;
- (v) Enrollee outreach;
- (vi) Utilization management and review; and
- (vii) MCO organization, operations, and financial management;

(b) The results of the SPR shall be reported in draft to the MCOs for comment;

(c) MCO shall submit all comments and any required corrective action within 45 days of receipt of draft report; and

(d) The Department shall issue a final report of the SPR results;

(2) The annual collection, validation, and evaluation of the latest approved version of the Healthcare Effectiveness Data and Information Set (HEDIS) in order to assess the access to and quality of services provided, in addition to any additional performance measures specified by the Department or CMS;

(3) The annual collection and evaluation of a set of performance measures with targets as determined by the Department as follows:

(a) The composition of the core performance measures is listed in §B(3)(d)—(f) of this regulation;

(b) Each year before the audit period begins, the Department shall identify and obtain public input on all measures to be collected as well as the target for each;

(c) In accordance with COMAR 10.67.10, MCOs may receive financial or other types of incentives or disincentives based on performance measure results;

(d) Effective January 1, 2017, the core performance measures are:

- (i) Adolescent well care visits;
- (ii) Adult Body Mass Index (BMI) assessment;
- (iii) Ambulatory care for Supplemental Security Income (SSI) adults;
- (iv) Ambulatory care for Supplemental Security Income (SSI) children;
- (v) Breast cancer screening;
- (vi) Childhood immunizations — Combo 3;
- (vii) Comprehensive diabetes care — HbA1c testing;
- (viii) Controlling high blood pressure;
- (ix) Immunization for adolescents;
- (x) Lead screening for children 12—23 months old;
- (xi) Asthma medication ratio;
- (xii) Postpartum care; and
- (xiii) Well child visits, 3—6 years old;

(e) Effective January 1, 2019, the core performance measures are:

- (i) Adolescent well care visits;
- (ii) Ambulatory care for SSI adults;
- (iii) Ambulatory care for SSI children;
- (iv) Asthma medication ratio;
- (v) Breast cancer screening;
- (vi) Comprehensive diabetes care — HbA1c control (<8.0%);
- (vii) Controlling high blood pressure;
- (viii) Lead screening for children 12 through 23 months old; and
- (ix) Well child visits in the first 15 months of life;

(f) Effective January 1, 2021, the core performance measures are:

- (i) Adolescent well care visits;

- (ii) Ambulatory care for SSI adults;
 - (iii) Ambulatory care for SSI children;
 - (iv) Asthma medication ratio;
 - (v) Breast cancer screening;
 - (vi) Comprehensive diabetes care — HbA1c control (<8.0%);
 - (vii) Controlling high blood pressure;
 - (viii) Lead screening for children 12 through 23 months old;
 - (ix) Postpartum care; and
 - (x) Well child visits in the first 15 months of life;
- (g) Starting with the 2019 performance measures, the Department shall implement the following methodology for imposing penalties and incentives:
- (i) There shall be three levels of performance;
 - (ii) Performance shall be evaluated separately for each measure, and each measure shall have equal weight;
 - (iii) On any of the measures in §B(3)(f)(i)—(ix) of this regulation for which the MCO does not meet the minimum target, as determined by the Department, a penalty of 1/9 of 1 percent of the total capitation amount paid to the MCO during the measurement year shall be collected;
 - (iv) The total amount of the penalties as described in §B(3)(h)(iii) of this regulation may not exceed 1 percent of the total capitation amount paid to the MCO during the same measurement year;
 - (v) On any of the measures in §B(3)(f) of this regulation for which the MCO meets or exceeds the incentive target, as determined by the Department, the MCO shall be paid an incentive payment of up to 1/9 of 1 percent of the total capitation paid to the MCO during that measurement year;
 - (vi) The total amount of the incentive payments as described in §B(3)(h)(v) of this regulation paid to the MCOs each year may not exceed the total amount of the penalties as described in §B(3)(g)(iii) of this regulation collected from the MCOs in that same year, plus any additional funds allocated to the Department for a quality initiative; and
 - (vii) Any funds remaining after the payment of the incentives due under §B(3)(h)(v) of this regulation shall be distributed to the MCOs receiving the four highest normalized scores for Value Based Purchasing for all ten performance measures at a rate calculated by multiplying each MCO's adjusted enrollment as of December 31 of the measurement year by a per enrollee amount;
- (h) Starting with the 2021 performance measures, the Department shall implement the following methodology for imposing penalties and incentives:
- (i) There shall be three levels of performance;
 - (ii) Performance shall be evaluated separately for each measure, and each measure shall have equal weight;

(iii) On any of the measures in §B(3)(f) of this regulation for which the MCO does not meet the minimum target, as determined by the Department, a penalty of 1/10 of 1 percent of the total capitation amount paid to the MCO during the measurement year shall be collected if the conditions in §B(3)(h)(iv) of this regulation do not apply;

(iv) If the Department's actuary determines that the MCO's total capitation amount for the measurement year does not meet the actuarial soundness definition described in 42 CFR §438.4 after collection of the total penalty amount described in §B(3)(h)(iii) of this regulation, the Department's actuary shall calculate the maximum penalty the Department shall apply that results in the MCO's total capitation for the measurement year remaining actuarially sound;

(v) If the MCO's penalty amount is reduced as described in §B(3)(h)(iv) of this regulation, the Department may impose any of the additional sanctions described in COMAR 10.67.10;

(vi) The total amount of the penalties as described in §B(3)(h)(iii) of this regulation may not exceed 1 percent of the total capitation amount paid to the MCO during the same measurement year;

(vii) On any of the measures in §B(3)(f) of this regulation for which the MCO meets or exceeds the incentive target, as determined by the Department, the MCO shall be paid an incentive payment of up to 1/10 of 1 percent of the total capitation paid to the MCO during that measurement year;

(viii) The total amount of the incentive payments as described in §B(3)(h)(vii) of this regulation shall be paid to the MCOs with total amount of the penalties as described in §B(3)(h)(iii) of this regulation collected from the MCOs in that same year, plus additional reserves in the HealthChoice Performance Incentive Fund if the total amount of the penalties collected is insufficient to pay the total amount of the incentive payments;

(ix) 40 percent of any funds remaining after the payment of the incentives due under §B(3)(h)(vii) of this regulation shall be distributed to the MCOs earning net incentives with the four highest normalized scores, at a rate calculated by multiplying each MCO's adjusted enrollment as of December 31 of the measurement year by a per-enrollee amount;

(x) MCOs earning net disincentives are ineligible to receive the funds described in §B(3)(h)(ix) of this regulation;

(xi) 25 percent of any funds remaining after the payment of the incentives due under §B(3)(h)(vii) of this regulation shall be distributed to the MCOs that the Department determines have demonstrated performance improvement in the measurement year, provided that the MCOs use the funding to target performance improvement in areas defined by the Department;

(xii) 25 percent of any funds remaining after the payment of the incentives due under §B(3)(h)(vii) of this regulation shall be retained for health improvement programs under the Maryland Medicaid Managed Care Program;

(xiii) 10 percent of any funds remaining after the payment of the incentives due under §B(3)(h)(vii) of this regulation shall be used to establish a reserve in the HealthChoice Performance Incentive Fund, to be used in any calendar year when the amount of penalties collected is insufficient to pay incentives earned by MCOs; and

(xiv) If the amount in the HealthChoice Performance Incentive Fund exceeds \$5,000,000, the Department shall equally allocate the remaining 10 percent of funds for use in §B(3)(h)(ix)—(xii);

(i) The adjusted enrollment amount in §§B(3)(g)(vii) and B(3)(h)(ix) of this regulation shall be calculated by:

(i) Multiplying four times the enrollment of the MCO with the highest normalized score;

(ii) Multiplying three times the enrollment of the MCO with the second highest normalized score;

(iii) Multiplying two times the enrollment of the MCO with the third highest normalized score; and

- (iv) Using the actual enrollment of the MCO with the fourth highest normalized score;
 - (j) The per enrollee amount in §§B(3)(g)(vii) and B(3)(h)(ix) of this regulation shall be calculated by dividing the sum of the calculations in §B(3)(i)(i)—(iv) of this regulation into the funds remaining as described in §§B(3)(g)(vii) and B(3)(h)(ix) of this regulation; and
 - (k) The methodology described in §B(3)(a)—(j) of this regulation shall remain in effect through December 31, 2021;
- (4) An annual enrollee satisfaction survey using the latest version of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey tool, conducted by an NCQA-certified CAHPS vendor;
- (5) An annual Maryland Healthy Kids audit in order to determine the quality of the clinical care provided to all children younger than 21 years old enrolled in the HealthChoice Program as follows:
- (a) The audit shall include a review of a sample of medical records from each provider reviewed during the calendar year to assess clinical care;
 - (b) The results of the audit that are below minimum EPSDT standards may result in corrective action required by both the provider and the MCO; and
 - (c) The Department shall issue a final report of the audit results;
- (6) Performance improvement projects to be conducted by the MCOs that focus on clinical or nonclinical areas as determined by the Department or CMS and include the following:
- (a) Measurement of performance using objective quality indicators;
 - (b) Implementation of system interventions to achieve improvement in quality;
 - (c) Evaluation of effectiveness of interventions;
 - (d) Planning and initiation of activities to sustain improvement; and
 - (e) Reporting of results to the Department or CMS; and
- (7) Validation and evaluation of MCO provider networks to ensure compliance with the network adequacy and access standards set forth in COMAR 10.67.05.
- C. If an MCO is assessed as deficient in accordance with federal and State standards, the MCO shall submit a plan of corrective action to the Department.
- D. An MCO shall provide the Department a copy of its most recent NCQA accreditation, including:
- (1) Accreditation status, survey type, and level;
 - (2) Accreditation results, including:
 - (a) Recommended actions or improvements;
 - (b) Corrective action plans; and
 - (c) Summaries of findings; and
 - (3) Expiration date of the accreditation.

.03-1 HEALTHCHOICE HEALTH EQUITY INCENTIVE PROGRAM.

A. The Department shall award a defined amount of funding annually to MCOs based on the county of residence of their members and the socioeconomic disadvantage index described in this regulation.

B. Socioeconomic Disadvantage Index.

(1) The Department shall calculate a ranking for each service area in Maryland in accordance with the following domains:

(a) Community safety;

(b) Food security;

(c) Housing security; and

(d) Transportation access.

(2) The Department shall select component measures and calculate rankings that aggregate to the domains defined in B of this regulation.

(3) Rankings shall range from first to twenty-fourth, with first being the lowest ranking for socioeconomic disadvantage and twenty-fourth being the highest ranking for socioeconomic disadvantage.

(4) Each service area shall be assigned a single summary score by calculating the equal-weighted average across each service area's domain rankings.

C. The Department shall award available equity funding to MCOs serving members in Maryland service areas based on the following criteria:

(1) Allocation of equity funding shall be made proportionally to the MCO's membership in the service areas at the top quartile of the socioeconomic disadvantage index.

(2) Funding for each calendar year shall be determined based on available funding in the Department's budget and specified in the annual HealthChoice Managed Care Organization Agreement.

(3) The annual allocation for HealthChoice Health Equity Incentive Program shall be funded outside of managed care capitation rates.

D. Incentive funds awarded under the HealthChoice Health Equity Incentive Program are not appealable under 10.67.10.

.03-2 HEALTHCHOICE POPULATION HEALTH INCENTIVE PROGRAM (PHIP).

A. Effective January 1, 2022, the Department shall establish the HealthChoice Population Health Incentive Program (PHIP).

B. An MCO may be eligible for an incentive payment for the following performance measures:

(1) Ambulatory care visits for Supplemental Security Income (SSI) adults;

- (2) Ambulatory care visits for Supplemental Security Income (SSI) children;
- (3) HEDIS asthma medication ratio;
- (4) Hemoglobin A1c control for patients with diabetes — poor control (>9.0%);
- (5) Lead screening measures:
 - (a) Lead screening measure for children 12--23 months old; and
 - (b) HEDIS lead screening in children;
- (6) HEDIS postpartum care;
- (7) HEDIS risk of continued opioid use ≥ 31 days covered; and
- (8) HEDIS timeliness of prenatal care.

C. Each measure identified in §B of this regulation shall be valued equally at a proportional share of available incentive funds, except for measures §B(5)(a) and (b), which are each valued at half of the available incentive funds relative to one of the other measures.

D. There shall be two rounds of potential incentive payments an MCO may earn.

E. Subject to budget approval, total PHIP funding shall be determined prior to the measurement year and included in the MCO contract.

F. All PHIP payments shall be funded independently from and outside of MCO capitation payments during a given calendar year.

G. Each MCO shall be eligible for no more than 1 percent of the plan's measurement year capitation payments, excluding supplemental payments outside of capitation, as total payment from round one and round two.

H. If the Department determines that the score for any measure identified in §B of this regulation may not be comparable to the previous year's score due to alterations in measure specifications or other factors, the Department may exclude the measure from the PHIP and adjust the incentive valuation in accordance with the remaining performance measures.

I. Round One Incentives.

(1) An MCO may earn two types of incentives in round one:

- (a) A performance incentive payment; and
- (b) An improvement incentive payment.

(2) If an MCO does not report a performance measure or an MCO has a performance score of 0 percent, then the MCO is awarded no performance or improvement incentive payments for this measure.

(3) Performance Incentive Payments for Round One.

(a) Performance incentive payments shall be based on the following categories for each performance measure:

- (i) Superlative performance, meaning the performance measure's score is at or above the 90th percentile of HEDIS Medicaid performance nationwide during the measurement year, or estimated 90th percentile among Maryland HealthChoice MCO performance for non-HEDIS performance measures;

(ii) Very strong performance, meaning the performance measure's score is between the 75th and 89th percentiles, inclusive, of HEDIS Medicaid performance nationwide during the measurement year, or between the estimated 75th and 89th percentiles, inclusive, among Maryland HealthChoice MCO performance for non-HEDIS performance measures; or

(iii) Strong performance, meaning the performance measure's score is between the 50th and 74th percentiles, inclusive, of HEDIS Medicaid performance nationwide during the measurement year, or between the estimated 50th and 74th percentiles, inclusive, among Maryland HealthChoice MCO performance for non-HEDIS performance measures.

(b) Payments for round one performance incentives shall be allocated as follows:

(i) For superlative performance, an MCO may earn 100 percent of the incentive allocation for the performance measure;

(ii) For very strong performance, an MCO may earn 66.6 percent of the incentive allocation for the performance measure;

(iii) For strong performance, an MCO may earn 33.3 percent of the incentive allocation for the performance measure; and

(iv) Any MCO earning a performance measure score below the 50th percentile of HEDIS Medicaid performance nationwide during the measurement year on a HEDIS-based measure, or below the calculated 50th percentile among Maryland HealthChoice MCO performance for a non-HEDIS measure, shall be ineligible for a round one performance incentive payment.

(4) Round One Improvement Incentive Payments.

(a) An MCO may earn an improvement incentive payment of 33.3 percent of the incentive allocation for any performance measure if the following conditions are met:

(i) The MCO demonstrates improvement of at least 0.5 percentage points in the measure compared to the previous measurement year; and

(ii) The performance measure score is at or above the 50th percentile of HEDIS Medicaid performance nationwide on a HEDIS-based measure, or the 50th percentile of Maryland HealthChoice MCO performance for a non-HEDIS measure.

(b) An MCO earning a superlative performance incentive payment for a performance measure is ineligible for an improvement incentive payment for the same measure.

(c) For any performance measures in which a lower score indicates stronger performance, year-over-year improvement is demonstrated by a reduction in the score for that measure.

(d) If an MCO is missing or zero-valued for a performance measure in the previous year, then no improvement incentive will be awarded in the measurement year.

J. Round Two Incentive Payments.

(1) An MCO may qualify for payments under round two if the following conditions are met:

(a) The MCO earned above 80 percent of possible round one incentives; and

(b) The MCO did not have penalties applied during the measurement year for failure to meet the HEDIS MCO Performance Monitoring Policy included in the MCO contract.

(2) Any remaining funds that were unallocated during round one may be awarded to eligible MCOs in round two for a maximum incentive award of up to 1 percent of its total capitation payment during the PHIP measurement year, excluding supplemental payments outside of capitation.

(3) If any remaining funds that were unallocated during round one are not sufficient to settle all qualifying MCOs up to 1 percent of capitation in round two, then the leftover funds will be awarded proportionally among qualifying MCOs based on enrollment.

K. If additional funds remain after both round one and round two, the Department may, within its discretion, allocate the funding as follows:

(1) Make additional payments to MCOs that are below 1 percent of capitation based on improvement or performance; or

(2) Place remaining funds into a nonlapsing pool.

L. Effective measurement year 2025, an MCO with penalties under the HEDIS MCO Performance Monitoring Policy included in the HealthChoice MCO Agreement shall be excluded from all rounds of PHIP for that measurement year.

M. Incentives awarded under this regulation and exclusion from PHIP participation are not appealable under COMAR 10.67.10.

.04 SPECIAL NEEDS POPULATIONS.

A. An MCO shall provide health care services to enrollees who are members of special needs populations.

B. Special needs populations consist of the following non-mutually exclusive populations:

(1) Children with special health care needs;

(2) Individuals with a physical disability;

(3) Individuals with a developmental disability;

(4) Pregnant and postpartum women;

(5) Individuals who are homeless;

(6) Individuals with HIV/AIDS; and

(7) Children in State-supervised care.

C. General Requirements for Special Needs Populations.

(1) An MCO shall demonstrate that its pediatric and adult primary care providers (PCPs) and specialists are clinically qualified based upon generally accepted community standards to provide or arrange for the provision of appropriate health care services to individuals who are members of a special needs population. The MCO shall submit to the Department referral protocols that demonstrate the conditions under which PCPs will make the arrangements for referrals to specialty care networks.

(2) Clinical qualifications are to be determined through the MCO's credentialing and recredentialing processes, including a review of the provider's medical education, special training, and work history and experience.

(3) Specialty and subspecialty providers shall:

(a) Have experience in treating individuals within a special needs population;

(b) Have experience in interdisciplinary medical management; and

(c) Understand the relationship between somatic and behavioral health care issues and interventions.

(4) The MCO shall demonstrate the use of a primary care system of care delivery which includes a comprehensive plan of care for an enrollee who is a member of a special needs population and which uses a coordinated and continuous case management approach, involving the enrollee and, as appropriate, the enrollee's family, guardian, or caregiver, in all aspects of care, including primary, acute, tertiary, and home care.

(5) To meet the commitment outlined in §C(4) of this regulation, an MCO shall:

(a) Provide case management services to adult and pediatric enrollees as appropriate;

(b) Have the capacity to perform home visits as part of the ongoing case management program and have the ability to respond to urgent care needs while in the enrollee's home;

(c) Ensure that, if warranted, a case manager is assigned to an enrollee at the time of the initial health screen by the MCO;

(d) Ensure that the PCP, who may also be the specialist, shall be the admitting or referring provider for all hospital admissions;

(e) Ensure that it will:

(i) Collaborate with inpatient facilities in facilitating preadmission and discharge planning, and

(ii) Communicate all post-discharge home and community arrangements to the enrollee, the PCP, and, as appropriate, the enrollee's family, guardian, and caregiver;

(f) Document the plan of care and treatment modalities provided to enrollees in special populations, assuring that the plan of care:

(i) Is updated at least annually, when the enrollee's circumstances or needs change significantly, or at the enrollee's request; and

(ii) Involves the enrollee and, as appropriate, the enrollee's family, guardian, and caregiver in care decisions; and

(g) Be familiar with community and social support providers for the special populations.

(6) An MCO shall make documented outreach efforts to contact and educate enrollees who fail to appear for appointments or who have been noncompliant with a regimen of care. These efforts may include, but may not be limited to, notification:

(a) By mail;

(b) By telephone;

(c) By email;

(d) By text messaging; and

(e) Through face-to-face contact.

(7) Referral to Local Health Department.

(a) An MCO shall make a written referral, or ensure that the enrollee's provider makes a written referral, to the local health department (LHD) for the county in which an enrollee resides, for assistance in bringing into care an enrollee for whom the MCO has been unsuccessful in its documented out-reach efforts pursuant to §C(6) of this regulation, within 10 business days of whichever first occurs:

(i) The third consecutive missed appointment; or

(ii) The MCO or the enrollee's provider identifies the enrollee's repeated noncompliance with a regimen of care.

(b) The MCO may not include information about an enrollee's HIV status on the form used to refer an enrollee to the local health department.

(8) An MCO shall subject its decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, for an enrollee who is a member of special needs population to utilization review that includes review by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

(9) An MCO shall identify a special needs coordinator, who shall:

(a) Serve as a point of contact for health care services information and referral for members of special needs populations;

(b) Be skilled in communications with, and sensitive to the unique needs of, members of special needs populations, their families, guardians, and caregivers;

(c) Participate on the MCO's consumer advisory board, pursuant to Regulation .12 of this chapter, as a representative of special needs populations;

(d) Serve as a resource to MCO providers and enrollees on the requirements of P.L. 101-330, Americans with Disabilities Act of 1990, 42 U.S.C. §12101 et seq.; and

(e) Maintain a log of each denial of treatment and the outcome of the utilization review conducted pursuant to §C(8) of this regulation.

(10) An MCO shall have mechanisms in place to allow enrollees with special health care needs to access a specialist directly as appropriate for the enrollee's condition and identified needs.

.05 SPECIAL NEEDS POPULATIONS — CHILDREN WITH SPECIAL HEALTH CARE NEEDS.

A. An MCO shall meet the standards set forth in this regulation for treating children with special health care needs.

B. The Department shall maintain a record of the complaints received through the Department's enrollee and provider hotlines which involve the denial of care for children and review these complaint logs as part of its quality assurance system.

C. An MCO shall demonstrate that its therapies provider network is adequate by demonstrating its:

- (1) Providers' pediatric specialties;
- (2) Collaboration with schools that provide IEP or IFSP services to its enrollees, where available; and
- (3) Provision of family-focused services and development of family-focused plans of care.

D. An MCO shall provide case management services to children with special health care needs as appropriate. For complex cases involving multiple medical interventions or social services, or both, a multidisciplinary team shall be used to review and develop the plan of care for special health care needs children.

E. An MCO shall provide coordinated care for special health care needs children in State-supervised care.

F. An MCO shall refer child victims of alleged abuse, neglect, or sexual offense to an appropriate provider capable of:

- (1) Determining if the alleged abuse, neglect, or sexual offense occurred;
- (2) Determining if medical intervention is needed; and
- (3) Ensuring the preservation of evidence.

G. An MCO shall ensure coordination with the Department's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program.

H. An MCO shall establish protocols for effecting medically necessary service referrals to specialty care providers for children with special health care needs.

I. The service referrals referenced in §H of this regulation shall:

- (1) Include services intended to improve or preserve the continuing health and quality of life for children with special health care needs, regardless of the ability of the services to effect permanent cure; and
- (2) Be made when the child is:
 - (a) Identified as being at risk of a developmental delay by the developmental screen required by EPSDT;
 - (b) Experiencing a delay of 25 percent or more in any developmental area as measured by appropriate diagnostic instruments and procedures;
 - (c) Manifesting atypical development or behavior; or
 - (d) Diagnosed with a physical or mental condition that has a high probability of resulting in developmental delay.

J. An MCO shall provide durable medical equipment to a special needs child in a timely manner.

K. When a child, who is an MCO enrollee, is diagnosed with a special health care need requiring a plan of care which includes specialty services, and that health care need was undiagnosed at the time of enrollment, the parent or guardian of that child may request approval from the MCO for a specific out-of-network specialty provider to provide those services when the MCO does not have a local in-network specialty provider with the same professional training and expertise who is reasonably available and provides the same service and modality, subject to the following provisions:

- (1) If the MCO denies the request for an out-of-network provider referral, the child's parent or guardian may initiate the complaint and appeal process set forth at COMAR 10.67.09.05;
- (2) If at any time the MCO decides to terminate or reduce services provided by the approved out-of-network provider, the child's parent or guardian may initiate the complaint and appeal process set forth at COMAR 10.67.09.05;
- (3) The MCO shall continue to cover the services of the out-of-network provider during the course of the appeal until such time as the Office of Administrative Hearings issues its decision.

.06 SPECIAL NEEDS POPULATIONS — INDIVIDUALS WITH A PHYSICAL DISABILITY.

- A. An MCO shall meet the standards set forth in this regulation for treating an individual with a physical disability.
- B. An MCO shall demonstrate that its providers for durable medical equipment and assistive technology provide the appropriate services and are clinically qualified to provide these services to the individual with a physical disability.
- C. Before placement of an individual with a physical disability into an intermediate or long-term care facility, an MCO shall:
 - (1) Recommend that an individual with a physical disability be transferred to an intermediate or long-term care facility only after assessing the needs of the individual and the ability of the MCO to meet these needs in the community as supplemented by other Medicaid services;
 - (2) Conduct a second opinion review of the case, performed by the MCO's medical director, before a transfer to an intermediate care facility or a long-term care facility is implemented; and
 - (3) If the MCO's medical director determines that the transfer to an intermediate or long-term care facility is medically necessary and that the expected stay will be greater than 30 days, obtain approval from the Department before making the transfer.
- D. An MCO shall utilize individuals with expertise in disabilities to review its marketing and informational forms and publications, which shall be provided in alternative formats with reasonable accommodation to people with a physical disability.
- E. An MCO shall provide education for the MCO's member services staff, triage staff, and case managers on special communications requirements for individuals with physical disabilities.

.07 SPECIAL NEEDS POPULATIONS — INDIVIDUALS WITH A DEVELOPMENTAL DISABILITY.

- A. An MCO shall meet the standards set forth in this regulation for treating an individual with a developmental disability.
- B. An MCO shall ensure that its case managers have experience or training related to developmental disabilities.
- C. An MCO shall utilize individuals with expertise in disabilities to review its marketing and informational forms and publications, which shall be provided in alternative formats with reasonable accommodation to people with developmental disabilities.
- D. An MCO shall provide education for the MCO's member services staff, triage staff, and case managers on special communications requirements for individuals with developmental disabilities.

.08 SPECIAL NEEDS POPULATIONS — PREGNANT AND POSTPARTUM WOMEN.

A. An MCO shall meet the standards set forth in this regulation for treating pregnant and postpartum women.

B. An MCO shall ensure access to prenatal care for pregnant women and postpartum care for postpartum women by:

(1) Scheduling an appointment for the first prenatal visit and seeing the woman within 10 days of request;

(2) Scheduling an appointment for a postpartum woman and seeing the woman within 10 days of request;

(3) Arranging for an adequate network of providers including obstetricians, gynecologists, perinatologists, neonatologists, anesthesiologists, and advanced practice nurses who are capable of addressing complex maternal and infant health issues; and

(4) Linking a pregnant woman with a pediatric provider before delivery.

C. An MCO shall ensure that prenatal providers:

(1) Complete a prenatal risk assessment, using an instrument approved by the Department, at the first prenatal visit; and

(2) Within 10 days of completing the prenatal risk assessment, forward this instrument to the local health department in the jurisdiction in which the pregnant enrollee lives.

D. The Department may not include questions about a woman's HIV infection status on the prenatal risk assessment instrument.

E. An MCO shall refer pregnant and postpartum women with a substance use disorder to the behavioral health ASO for substance use treatment within 24 hours of request.

F. An MCO shall refer pregnant and postpartum women, infants, and children younger than 5 years old to the WIC (Special Supplemental Nutrition Program for Women, Infants, and Children) Program, and shall provide to WIC necessary medical information to determine WIC nutritional eligibility.

G. An MCO shall follow, at a minimum, the American College of Obstetricians and Gynecologists (ACOG) guidelines for pregnant and postpartum women.

H. An MCO shall provide risk-related medical and nonmedical preventive treatment services, including nutrition counseling by licensed nutritionists or dietitians and smoking cessation education and treatment for pregnant and postpartum women.

I. An MCO shall provide HIV counseling, including a risk assessment and information about possible transmission of HIV to the fetus.

J. An MCO shall offer its pregnant and postpartum enrollees voluntary HIV counseling and testing following the requirements of COMAR 10.67.06.

K. An MCO shall arrange for the appropriate emergency transfer of pregnant women, newborns, and infants to tertiary care centers.

.09 SPECIAL NEEDS POPULATIONS — HOMELESS INDIVIDUALS.

An MCO's initial health screen shall attempt to identify homeless individuals and link them to the appropriate provider of services.

.10 SPECIAL NEEDS POPULATIONS — INDIVIDUALS WITH HIV/AIDS.

A. An MCO shall meet the standards set forth in this regulation for treating individuals with HIV/AIDS.

B. HIV/AIDS Specialist.

(1) An MCO shall allow an enrollee with HIV/AIDS to choose an HIV/AIDS specialist for treatment and coordination of primary and specialty care.

(2) To qualify as an HIV/AIDS specialist, a health care provider shall be board certified in the field of infectious diseases by a member board of the American Board of Medical Specialties or:

(a) Hold a current, valid, unrevoked, and unsuspended Maryland license or certification as a:

(i) Doctor of medicine;

(ii) Doctor of osteopathy;

(iii) Nurse practitioner; or

(iv) Physician's assistant being supervised by a medical doctor;

(b) Have provided direct, continuous, ongoing care for at least 20 patients with HIV over the past 2 years; and

(c) Have completed one of the following requirements:

(i) If a medical doctor, certified physician's assistant being supervised by a medical doctor, or doctor of osteopathy, at least 30 hours of HIV-related continuing medical education category I credits over the past 2 years;

(ii) If a nurse practitioner, at least 30 hours of HIV-related continuing education units over the past 2 years;

(iii) If a medical doctor, certified physician's assistant being supervised by a medical doctor, doctor of osteopathy, or a nurse practitioner, an accredited training program over the past year; or

(iv) If a medical doctor, certified physician's assistant being supervised by a medical doctor, doctor of osteopathy, or a nurse practitioner, has completed the American Academy of HIV Medicine (AAHIVM) credentialing examination.

C. AIDS Case Management Services.

(1) An MCO shall ensure that an enrollee with HIV/AIDS receives case management services that:

(a) Link the enrollee with the full range of available benefits;

(b) Link the enrollee with any additional needed services including:

(i) Mental health services;

- (ii) Substance abuse services;
 - (iii) Medical services;
 - (iv) Social services;
 - (v) Financial services;
 - (vi) Counseling services;
 - (vii) Educational services;
 - (viii) Housing services; and
 - (ix) Other required support services;
- (c) Ensure timely and coordinated access to medically necessary levels of care that support continuity of care across the continuum of service providers;
- (d) Are performed by licensed physicians, physician assistants, advanced practice nurses, registered nurses, social workers, or other individuals who are appropriately trained, experienced, and supervised by a licensed practitioner; and
- (e) Include, but are not limited to:
- (i) Initial and ongoing assessment of the enrollee's needs and personal support systems, including the MCO offering an enrollee one face-to-face meeting during the initial assessment and documenting the enrollee's acceptance or declination of the face to face meeting;
 - (ii) Development of a comprehensive, individualized service plan, using a multidisciplinary approach;
 - (iii) Coordination of the services required to implement the plan;
 - (iv) Periodic reevaluation and adaptation of the plan as necessary over the life of the enrollee;
 - (v) Development of an outreach system for the enrollee and family by which the case manager and primary care provider track services received, clinical outcomes, and the need for additional follow-up; and
 - (vi) Serving as an effective enrollee advocate to resolve differences between the enrollee and providers of care pertaining to the course or content of therapeutic interventions.
- (2) An enrollee diagnosed with HIV/AIDS shall be offered case management services by the MCO at any time after diagnosis. An enrollee who has previously refused these services may request case management from the MCO at any time.
- D. Diagnostic Evaluation Service (DES) Assessment.
- (1) An MCO shall offer a diagnostic evaluation service (DES) assessment annually and document the enrollee's acceptance or declination.
 - (2) The DES shall consist of a comprehensive medical and psychosocial assessment.
 - (3) A DES provider shall use assessment and care plan forms used by the Department for adult and pediatric assessments.

(4) An individual shall select a DES provider from an approved list of sites, and may select a DES provider which is not part of the individual's MCO if so desired.

(5) An MCO and other qualified institutions may become DES providers as provided in COMAR 10.09.32.03C.

E. An individual with HIV/AIDS who has a substance use disorder shall be referred to the behavioral health ASO for substance abuse treatment within 24 hours of request.

F. Clinical Trials.

(1) An MCO may refer enrollees who are individuals with HIV/AIDS to facilities or organizations that can provide the enrollees' access to clinical trials.

(2) An MCO shall provide enrollees with HIV/AIDS access to clinical trials in accordance with COMAR 10.67.06.26-1.

.12 CONSUMER ADVISORY BOARD.

A. An MCO shall establish a consumer advisory board to facilitate the receipt of input from enrollees.

B. The consumer advisory board membership shall:

(1) Consist of enrollees and enrollees' family members, guardians, or caregivers; and

(2) Be comprised of no less than one third representation from the MCO's special needs populations, or their representatives and the MCO's special needs coordinator.

C. The consumer advisory board shall meet at least 6 times a year.

.13 CHILDREN IN STATE-SUPERVISED CARE.

A. An MCO shall provide or arrange to provide all Medicaid-covered services required to comply with State statutes and regulations mandating health and mental health services for children in State-supervised care.

B. An MCO shall ensure the continuity and coordination of care, provided locally to the extent the services are available, to an enrollee who is a child in State-supervised care.

C. An enrollee who is a child in State-supervised care who moves shall be disenrolled from the recipient's MCO and enrolled in an alternative MCO if the recipient's current MCO does not serve the geographic region to which the child has been relocated.

D. An MCO shall expedite a change of providers within its provider panel upon the move of an enrollee who is a child in State-supervised care to a new geographic area served by the MCO.

E. On request of the responsible State or local agency, a child in State-supervised care may be disenrolled from the current MCO and enrolled in an MCO serving the group facility in which the child resides, members of the foster care family, or other children in foster care placement with the child.

F. Enrollee Self-Referral. An MCO shall permit the self-referral of a child in State-supervised care to an EPSDT certified provider for an initial examination, including a mental health screen, and shall pay for all portions of the examination except for the mental health screen, which shall be paid for by the Specialty Mental Health System.

G. Coordination with Responsible Agency. An MCO shall appoint a liaison to coordinate services to a child in State-supervised care with the responsible State or local agencies.

.14 REFERRAL TO BEHAVIORAL HEALTH ASO.

- A. An MCO is responsible for providing medically necessary primary behavioral health services to their enrollees.
- B. An enrollee may self-refer to the behavioral health ASO for services described in COMAR 10.09.59 or 10.09.80.
- C. If an enrollee's primary care physician determines that primary behavioral health services are not sufficient to meet the enrollee's needs, the primary care physician shall refer the enrollee to the behavioral health ASO for services described in COMAR 10.09.59 or 10.09.80.
- D. If an MCO determines that primary behavioral health services are not sufficient to meet the enrollee's needs, the MCO shall refer the enrollee to the behavioral health ASO for services described in COMAR 10.09.59 or 10.09.80.
- E. An MCO shall cooperate with the behavioral health ASO in developing referral procedures and protocols.

.15 DATA COLLECTION AND REPORTING.

- A. An MCO shall notify the Department immediately when it has knowledge of an enrollee's death.
- B. Encounter Data.
 - (1) An MCO shall submit encounter data reflecting 100 percent of provider-enrollee encounters, in CMS1500 and UB04 format or an alternative format previously approved by the Department.
 - (2) An MCO may use alternative formats including:
 - (a) ASC X12N 837 and NCPDP formats; and
 - (b) ASC X12N 835 format, as appropriate.
 - (3) An MCO shall submit encounter data that identifies the provider who delivers any items or services to enrollees at a frequency and level of detail to be specified by CMS and the Department, including, at a minimum:
 - (a) Enrollee and provider identifying information;
 - (b) Service, procedure, and diagnoses codes;
 - (c) Allowed, paid, enrollee responsibility, and third-party liability amounts; and
 - (d) Service, claims submission, adjudication, and payment dates.
 - (4) An MCO shall report encounter data within 60 calendar days after receipt of the claim from the provider.
 - (5) An MCO shall submit encounter data utilizing a secure on-line data transfer system.
- C. Monthly Reports.
 - (1) An MCO shall provide an updated list of the PCP's assigned enrollees to each PCP at least on a monthly basis.
 - (2) An MCO shall participate in the electronic enrollment reconciliation process to identify discrepancies in enrollment data between the Department and the MCO.
- D. Quarterly Reports. An MCO shall submit to the Department:

(1) Within 30 calendar days of the close of each calendar quarter, quality assurance reports including, but not limited to:

(a) Quality assurance committee meeting minutes reflecting major quality assurance corrective action plans, initiatives, and activities; and

(b) An analysis of recipient appeal and grievance logs including significant trends or anomalies, what caused the trend or anomaly, and any actions taken to address the trend or anomaly;

(2) Within 30 calendar days after the close of each calendar quarter, in the format specified by the Department, a list of all pre-service denials or reduction of services or benefits issued by the MCO or MCO subcontractors during the preceding quarter.

(3) Within 30 calendar days of the close of each calendar quarter, third-party liability collection activities as described in Regulation .18D of this chapter.

(4) In a format specified by the Department, amounts the MCO has cost-avoided and recovered and the number of cases the MCO has handled in each case area during the quarter.

(5) Not later than 45 days after the end of each quarterly rebate period, drug utilization data necessary for the Department to bill manufacturers for rebates in accordance with §1927(b)(1)(A) of the Social Security Act, that:

(a) Include, at a minimum, the following information by National Drug Code of each covered outpatient drug dispensed or covered by the MCO:

(i) Total number of units of each dosage form;

(ii) Total number of units of each dosage strength; and

(iii) Total number of units of each dosage package size; and

(b) Distinguish utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program.

(6) Within 10 calendar days after the close of each calendar quarter, in the format specified by the Department, a list of all State fair hearing outcomes during the preceding quarter.

E. Annual Reports. Except as provided in §E(5) of this regulation, an MCO shall submit to the Department annually, within 90 days after the end of the calendar year:

(1) A summary of the information contained in §D(1)(b) of this regulation;

(2) A report of the MCO's consumer advisory board outlining the board's activities and recommendations;

(3) A copy of the MCO's drug formulary;

(4) Any revisions to the MCOs quality assurance, utilization management, and case management plans;

(5) HealthChoice Financial Monitoring Reports (HFMRs), including any supplemental schedules required by the Department:

(a) In the format required by the Department;

(b) Prepared according to:

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(i) The criteria, set forth in Regulation .19-5 of this chapter, for allocating MCO costs to HFMR expense categories; and

(ii) Reporting instructions provided by the Department for the HFMR form and any required supplemental schedules; and

(c) Submitted according to the following schedule:

(i) Services incurred from January 1 through December 31 of the prior year, reported through March 31 of the current year — due on May 15 of the current year; and

(ii) Services incurred January 1 through December 31 of the prior year, reported through June 30 of the current year — due on September 1 of the current year; and

(6) A detailed description of its drug utilization program activities.

F. Unless the MCO is exempt for good cause, an MCO shall submit to the Department when requested the following reports for its enrollee/member services and provider/authorization/preauthorization lines:

(1) Caller abandonment rates;

(2) Caller service level rates; and

(3) Caller average hold time.

G. If the MCO exits the HealthChoice Program for any reason, including those listed in COMAR 10.67.02.06A(1)(e) and (f):

(1) The MCO shall provide the Department with a list of enrollees and the name of each enrollee's PCP, at least 30 days before exiting the program; and

(2) On receiving the list provided by the MCO, the Department shall provide the list to:

(a) The health benefits exchange to assist and provide outreach to participants in selecting an MCO; and

(b) If permitted by State and federal law, the remaining MCOs for linking participants with a PCP.

H. Jurisdictional Reporting to Local Health Departments. The Department shall:

(1) Aggregate by jurisdiction the encounter data it receives from MCOs; and

(2) Provide to local health departments jurisdiction-specific information based on aggregated encounter data for public health monitoring and assessment.

I. For the purposes of Maryland Medicaid Managed Care Program administration or monitoring MCO performance pursuant to this chapter, the MCO shall supply other information as the Department may from time to time request, given a reasonable period of notice.

J. Nonfederally qualified MCOs shall report a description of certain transactions with parties of interest, as described in §1903(m)(4)(A) of the Social Security Act.

K. Upon request, an MCO whose member has disenrolled shall transfer historical utilization data to the member's new MCO in the time frame and format specified by the Department.

.17 SUBCONTRACTUAL RELATIONSHIPS.

A. Subcontracting Permitted.

(1) Consistent with this regulation, an MCO may subcontract services that it is required to provide to its enrollees under COMAR 10.67.06 to a health care provider that is licensed, certified, or otherwise legally authorized to provide those services.

(2) An MCO may not discriminate for the participation, reimbursement, or indemnification of any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of that license or certification

(3) An MCO shall have written agreements with subcontractors that comply with 42 CFR §§438.214 and 455.105, as amended, and include at least the following:

(a) A provision that the subcontractor be subject to all of the requirements to which the MCO is subject under its contract with the Department and pursuant to the Department's regulations;

(b) A clear description of the services to be performed under the subcontract sufficient to definitively inform the Department which of the MCO's obligations have been subcontracted;

(c) A provision for the subcontractor's release to the MCO and to the Department, upon request, of any information necessary for the MCO to perform any of its contractual and regulatory obligations under its contract with the Department, including, but not limited to, its records, reporting, and quality assurance duties;

(d) A provision requiring that the subcontractor complies with all State and federal requirements regarding audit, inspection, and evaluation;

(e) A provision that copies of the subcontractor's medical records pertaining to the MCO's enrollees shall be furnished to the MCO upon request for transfer to a subsequent provider in the event of a termination of the subcontract;

(f) A provision to the effect that no termination of the subcontract shall be effective without prior written notice to the Department;

(g) An agreement that the subcontractor will look solely to the MCO for compensation for covered services provided to the MCO's enrollees under the subcontract;

(h) An assurance that evidence of the subcontractor's professional liability coverage will be submitted annually to the MCO;

(i) A provision that no assignment of the subcontract by the subcontractor is effective without prior written notice to the Department;

(j) If the subcontractor is authorized by the MCO to make referrals, a provision requiring the subcontractor to use the uniform consultation referral form adopted by the Maryland Insurance Administration at COMAR 31.10.12.06;

(k) A provision to the effect that each provision of the subcontract that is required under this section supersede and be controlling over any conflicting terms that appear in the subcontract;

(l) A provision for revocation of the delegation of activities or obligations, or specifying other remedies in instances where the Department or the MCO determines that the subcontractor has not performed satisfactorily;

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(m) A provision stating that the MCO has the right to audit the subcontractor pursuant to 42 CFR §438.230(c)(3)(i) for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later; and

(n) A provision to the effect that all providers and subcontractors are subject to a grievance and appeal system consistent with the requirements of COMAR 10.67.09.

(4) An MCO may not subcontract for hospital services with a hospital or an entity related to a hospital unless that hospital is in compliance with COMAR 10.37.12 (fixed price contracting regulations).

(5) An MCO may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is the provider's patient for:

(a) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered;

(b) Any information the enrollee needs in order to decide among all relevant treatment options;

(c) The risks, benefits, and consequences of treatment or nontreatment; or

(d) The enrollee's right to participate in decisions regarding the enrollee's own health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

B. Subcontractual Relations Reporting Requirements.

(1) An MCO shall submit its standard subcontract to the Department for its approval at least 30 days in advance of the MCO entering into any subcontracts covered by this regulation.

(2) An MCO shall submit to the Department for its prior approval material modifications to, or deviations from, its approved standard subcontract.

(3) An MCO shall submit to the Department a specification of procedures to be followed when reallocating responsibility in the event of a change in obligations in its approved standard subcontract.

(4) Network Provider Termination.

(a) When an MCO and provider terminate their contract the MCO shall provide the Department with a written notice regarding the termination.

(b) If the MCO is terminating the contract, the notice required in §B(4)(a) of this regulation shall be provided at the later of:

(i) 30 calendar days before the effective date of the termination; or

(ii) 15 calendar days after receipt or issuance of the termination notice.

(c) If the provider is terminating the contract, the notice required in §B(4)(a) of this regulation shall be provided within 15 days after the MCO receives the notice from the terminating provider.

(d) If 50 to 99 enrollees are affected, the notice shall contain the:

(i) Date of termination;

(ii) Name or names of providers or subcontractors terminating;

(iii) Number of enrollees affected; and

(iv) MCO's plan for transitioning enrollees to other providers.

(e) If more than 99 enrollees are affected, the MCO shall provide the Department with a Department-approved termination survey.

(f) In determining the number of enrollees affected under §B(4)(d) and (e) of this regulation, the MCO shall consider:

(i) For PCPs, the number of enrollees assigned to the PCP; and

(ii) For all other providers, the number of enrollees who are in active treatment or who have had an encounter with the provider in the previous 12 months.

(5) Subcontractor Termination.

(a) When an MCO terminates a subcontract impacting its operations, covered services, or enrollees, the MCO shall provide the Department with written notice regarding the termination that describes:

(i) The dollar amount of the subcontract;

(ii) The effect of the termination on MCO operations;

(iii) The effect of the termination on MCO covered services or enrollees; and

(iv) The MCO's plan to replace the subcontractor, if applicable.

(b) If the termination of the subcontract impacts MCO operations, the notice required in §B(5)(a) of this regulation shall be provided at least 90 days before the effective date of the termination.

C. By entering into a subcontract to provide health care services on behalf of an MCO, the subcontractor becomes subject to all the requirements concerning audits and inspections by the Department and other government agencies that are imposed upon the MCO by statute or regulation, or by its contract with the Department.

D. An MCO shall monitor the performance of its subcontractors, including, but not limited to, the areas of enrollee and provider complaints, access issues, quality assurance activities, record keeping, and reporting requirements.

E. An MCO shall report to the Department any material deviations from required procedures by its subcontractor which, in the MCO's judgment, can be expected to have a significant effect on quality of care, or on enrollees' ability to access care.

.18 THIRD PARTY LIABILITY.

A. An MCO is responsible for the identification of, and collection of, moneys owing from responsible third parties liable for the cost of medical care furnished by the MCO to enrollees.

B. Upon request from the Department or the U.S. Department of Health and Human Services, an MCO shall convey any information regarding third-party liability to the Department, to the U.S. Department of Health and Human Services, or to another MCO.

C. The Department shall notify an MCO of any third-party liability identified during the course of eligibility determination.

D. The MCO shall submit to the Department any new or changed third-party information in an automated format on a monthly basis.

E. The Department shall provide the MCOs with any new or changed information on a monthly basis in an automated format.

F. In order to facilitate the Department's and the U.S. Department of Health and Human Services' monitoring of its third-party liability collection activities, an MCO shall:

(1) Submit to the Department, on a monthly basis, reports on third-party collections and activities during the month, including but not limited to amounts the MCO has cost-avoided and recovered and current accounts receivable for all third-party liability cases;

(2) Submit to the Department, on a quarterly basis and in a format specified by the Department, amounts the MCO has cost-avoided and recovered and the number of cases the MCO has handled in each case area during the quarter;

(3) Cooperate in site inspections by either the Department or the U.S. Department of Health and Human Services for monitoring purposes; and

(4) Submit a detailed report of third-party liability collection activities including, but not limited to, cost avoidance, recovered amounts, and current amounts receivable for cases selected by the Department.

G. When both the Department and an MCO have a right of subrogation, they shall coordinate settlement negotiation, ensuring that the funds available are prorated to allow sufficient compensation to settle each party's claim amount.

H. For insurance coverage identified by an MCO with a retroactive effective date, an MCO shall comply with Insurance Article, §15-1008, Annotated Code of Maryland.

I. An MCO may not deny a provider's request for a preauthorization solely because a recipient has, or is thought to have, third-party insurance.

J. The requirement in §I of this regulation may not apply if an MCO has a process in place to ensure that a claim will not be denied for lack of preauthorization if the claim ultimately becomes the MCO's responsibility for one of the following reasons:

(1) The recipient does not have third-party insurance; or

(2) The service received is a noncovered service under the third-party insurance.

K. If an MCO identifies another party as being responsible for retroactive denial of reimbursement, the MCO shall:

(1) Obtain a written statement from the third-party that includes:

(a) The name and address of the third party; and

(b) Acknowledgment of responsibility for payment of the denied claim by the third party;

(2) Send this written statement to the provider seeking reimbursement; and

(3) Provide this written statement or a summary report to the Department upon request.

.19 MCO REIMBURSEMENT.

A. Generally.

- (1) Payment to an MCO for each enrollee shall be at a fixed capitation rate, as specified in §B(4) of this regulation.
- (2) An MCO shall be reimbursed at rates set forth in this regulation only for individuals enrolled under the Maryland Medicaid Managed Care Program.
- (3) The capitation rate paid to an MCO by the Department shall be accepted as payment in full for all benefits provided by the MCO.
- (4) An MCO shall conform to the Department's computer coding requirements.
- (5) A capitation payment may not be made to an MCO on behalf of an enrollee for whom capitation payment for the same period has been made to any other MCO having an agreement with the Department.
- (6) The Department may consider a retroactive capitation payment to an MCO, if the MCO notifies the Department within 9 months of the first missed capitation payment for an enrollee for whom the MCO has not received all appropriate capitation payments.
- (7) Monies collected by an MCO for third party liability, as described in Regulation .18 of this chapter, are considered when calculating the capitation payments in §B(4) of this regulation.

B. Capitation Rate-Setting Methodology.

(1) Families and Children. Capitation rates for enrollees who are waiver-eligible based upon receipt of benefits through TCA or programs for medically needy families and children, including SOBRA children and Maryland Children's Health Program (MCHP), shall be established as follows:

(a) For enrollees eligible under COMAR 10.67.02.01A(1) or (3), and for children eligible under COMAR 10.67.02.01A(2) for whom the Department has sufficient clinical data, the Department shall:

- (i) Determine an adjusted clinical group (ACG) assignment utilizing an enrollee's past diagnostic record;
- (ii) Utilizing aggregated enrollee ACG data, on an annual basis define a limited number of risk adjustment categories that reflect levels of relatively homogenous resource utilization by ACG assignment; and
- (iii) Assign an enrollee to a risk adjustment category based upon the enrollee's ACG assignment;

(b) Except as provided in §B(1)(c) of this regulation, for enrollees for whom the Department has insufficient data to generate an ACG assignment, the Department shall assign the enrollee to a risk adjustment category that reflects the enrollee's:

(i) Age, residence, and gender; and

(ii) Birth weight with respect to an enrollee born after December 31, 2004; and

(c) On the basis of the enrollee's residence, the Department shall assign:

(i) All SOBRA mothers enrolled pursuant to COMAR 10.67.02.01A(2) to one of the two "SOBRA mother" payment categories set forth in §B(4)(a) of this regulation; and

(ii) Enrollees with HIV to one of the two HIV payment categories set forth in §B(4)(a) of this regulation.

(2) Disabled. Capitation rates for enrollees who are waiver-eligible based upon receipt of benefits through SSI or as medically needy, aged, blind, or disabled shall be established as follows:

(a) Except as provided in §B(2)(c) of this regulation, for enrollees for whom the Department has sufficient clinical data, the Department shall:

- (i) Determine an adjusted clinical group (ACG) assignment utilizing an enrollee's diagnostic record;
- (ii) Utilizing aggregated enrollee ACG data, on an annual basis define a limited number of risk adjustment categories that reflect levels of nearly homogenous resource utilization by ACG assignment; and
- (iii) Assign an enrollee to a risk adjustment category (RAC) based upon the enrollee's ACG assignment; and

(b) Except as provided in §B(2)(c) of this regulation, for enrollees for whom the Department has insufficient data to generate an ACG assignment, the Department shall assign the enrollee to a risk adjustment category that reflects the enrollee's age, residence, and gender; and

(c) On the basis of the enrollee's residence, the Department shall assign:

- (i) Enrollees with HIV to one of the two HIV payment categories set forth in §B(4)(b) of this regulation; and
- (ii) Enrollees with AIDS to one of the two AIDS payment categories set forth in §B(4)(b) of this regulation.

(3) Supplemental Delivery/Newborn Payments.

(a) In addition to the monthly payment specified in §B(4)(a) or (b) of this regulation for an enrollee's payment category, the Department shall pay an MCO one supplemental payment per pregnancy in the amount specified in §B(4)(c) of this regulation, upon delivery of one or more infants without regard to method, timing, or place of delivery.

(b) An MCO shall have 12 months from the date of delivery to bill for the supplemental payment.

(4) Except to the extent of adjustments required by §D of this regulation or by Regulations .19-1 through 19-3 of this chapter, the Department shall make payments monthly at the rates specified in the following tables:

(a) Rate Table for Families and Children Effective January 1, 2020—December 31, 2020.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
	Under age 1 Birth Weight 1500 grams or less	Both	\$10,545.89	\$9,424.40	\$9,791.62
	Under age 1 Birth Weight over 1500 grams	Both	\$540.93	\$483.41	\$502.25
	15	Male	\$212.56	\$189.96	\$197.36
		Female	\$179.94	\$160.82	\$167.07
	614	Male	\$128.11	\$114.49	\$118.95

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		Female	\$130.65	\$116.76	\$121.31
	1520	Male	\$156.36	\$139.73	\$145.18
		Female	\$200.42	\$179.11	\$186.09
	2144	Male	\$313.97	\$244.47	\$259.96
		Female	\$423.37	\$329.65	\$350.54
	4564	Male	\$649.86	\$506.01	\$538.07
		Female	\$710.21	\$552.99	\$588.03
ACG-adjusted cells					
ACG 100, 200, 300, 400, 500, 600, 700, 900, 1000, 1100, 1200, 1300, 1600, 1710, 1711, 1712, 1720, 1721, 1722, 1730, 1731, 1732, 1800, 1900, 2000, 2100, 2200, 2300, 2400, 2500, 2800, 2900, 3000, 3100, 3200, 3300, 3400, 3500, 3800, 4210, 5100, 5110, 5200 5230, 5310, 5339	RAC 1F	Both	\$246.88	\$192.23	\$204.41
ACG 800, 1740, 1741, 1742, 1750, 2700, 3600, 1750, 1751, 1752, 2700, 3600, 3700, 3900, 4000, 4100, 4220, 4310, 4410, 4510, 4610, 4710, 4720, 4810, 5340	RAC 2F	Both	\$404.93	\$315.29	\$335.27
ACG 1400, 1500, 1750, 1761, 1762, 1770, 1771, 1772, 2600, 4320, 4520, 4620, 4820	RAC 3F	Both	\$541.50	\$421.63	\$448.35
ACG 4330, 4420, 4830, 4910, 4920, 5010, 5020, 5040	RAC 4F	Both	\$765.47	\$596.02	\$633.79
ACG 4430, 4730, 4930, 5030, 5050	RAC 5F	Both	\$1,093.51	\$851.45	\$905.40
ACG 4940, 5060	RAC 6F	Both	\$1,395.82	\$1,086.83	\$1,155.70
ACG 5070	RAC 7F	Both	\$2,384.13	\$1,856.36	\$1,973.99
ACG 100, 200, 300, 500, 600, 1100, 1600, 2000, 2400, 3400, 5100, 5110, 5200	RAC 1G	Both	\$95.15	\$85.03	\$88.34
ACG 400, 700, 900, 1000, 1200, 1300, 1710, 1711, 1712, 1800, 1900, 2100, 2200, 2300, 2800, 2900, 3000, 3100, 5310	RAC 2G	Both	\$120.44	\$107.63	\$111.83
ACG 1720, 1721, 1722, 1731, 1732, 1730, 2500, 3200, 3300, 3500, 3800, 4210, 5230, 5339	RAC 3G	Both	\$155.94	\$139.35	\$144.78

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ACG 800, 1740, 1741, 1742, 1750, 2700, 3600, 1750, 1751, 1752, 2700, 3600, 3700, 3900, 4000, 4100, 4220, 4310, 4410, 4510, 4610, 4710, 4720, 4810, 5340	RAC 4G	Both	\$216.35	\$193.34	\$200.87
ACG 1400, 1500, 1750, 1761, 1762, 1770, 1771, 1772, 2600, 4320, 4520, 4620, 4820	RAC 5G	Both	\$333.86	\$298.36	\$309.98
ACG 4330, 4420, 4830, 4910, 4920, 5010, 5020, 5040	RAC 6G	Both	\$412.16	\$368.33	\$382.68
ACG 4430, 4730, 4930, 4940, 5030, 5050, 5060, 5070	RAC 7G	Both	\$1,171.43	\$1,046.85	\$1,087.64
SOBRA Mothers			\$782.58	\$609.35	\$647.96
Persons with HIV	ALL	Both	\$2,468.70	\$2,468.70	\$2,468.70

(b) Rate Table for Disabled Individuals Effective January 1, 2020— December 31, 2020.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
	Under Age 1	Both	\$8,185.50	\$8,185.50	\$8,185.50
	15	Male	\$1,118.79	\$1,118.79	\$1,118.79
		Female	\$1,494.58	\$1,494.58	\$1,494.58
	614	Male	\$250.31	\$250.31	\$250.31
		Female	\$489.01	\$489.01	\$489.01
	1520	Male	\$257.52	\$257.72	\$257.52
		Female	\$315.55	\$315.55	\$315.55
	2144	Male	\$837.74	\$685.54	\$717.57
		Female	\$829.48	\$678.78	\$710.49
	4564	Male	\$2,287.81	\$1,872.16	\$959.63
	4564	Female	\$2,675.35	\$2,189.29	\$2,291.58
ACG-adjusted cells					

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ACG 100, 200, 300, 1100, 1300, 1400, 1500, 1600, 1710, 1711, 1712, 1720, 1721, 1722, 1730, 1731, 1732, 1900, 2400, 2600, 2900, 3400, 5100, 5110, 5200, 5310	RAC 10	Both	\$327.55	\$268.04	\$280.57
ACG 400, 500, 700, 900, 1000, 1200, 1740, 1741, 1742, 1750, 1751, 1752 1800, 2000, 2100, 2200, 2300, 2500, 2700, 2800, 3000, 3100, 3200, 3300, 3500, 3900, 4000, 4310, 5330	RAC 11	Both	\$354.27	\$289.90	\$303.45
ACG 600, 1760, 1761, 1762, 3600, 3700, 4100, 4320, 4410, 4710, 4810, 4820	RAC 12	Both	\$691.31	\$565.71	\$592.15
ACG 3800, 4210, 4220, 4330, 4420, 4720, 4910, 5320	RAC 13	Both	\$810.19	\$662.99	\$693.97
ACG 800, 4430, 4510, 4610, 5040, 5340	RAC 14	Both	\$1,071.43	\$876.77	\$917.74
ACG 1770, 1771, 1772, 4520, 4620, 4830, 4920, 5050	RAC 15	Both	\$1,487.90	\$1,217.58	\$1,274.74
ACG 4730, 4930, 5010	RAC 16	Both	\$1,510.41	\$1,235.99	\$1,293.74
ACG 4940, 5020, 5060	RAC 17	Both	\$2,208.93	\$1,807.61	\$1,892.07
ACG 5030, 5070	RAC 18	Both	\$4,013.13	\$3,284.02	\$3,437.46
Persons with AIDS	All	Both	\$4,968.09	\$3,504.83	\$3,504.83
Persons with HIV	All	Both	\$4,255.37	\$4,255.37	\$4,255.37

(c) Rate Table for Supplemental Payments for Delivery/Newborn and Hepatitis C Therapy Effective January 1, 2020 December 31, 2020.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
Supplemental Payment Cells					
Delivery/Newborn-all births except live birth weight 1,500 grams or less and gestational age of 21 weeks or more	All	Both	\$17,039.19	\$13,490.76	\$14,736.04
Delivery/Newborn - live birth weight 1,500 grams or less and a gestational age of 21 weeks or more	All	Both	\$86,856.32	\$86,856.32	\$86,856.32
Delivery/Newborn by same enrollee - subsequent live birth weight 1,500 grams or less with a gestational	All	Both	\$17,039.19	\$13,490.76	\$14,736.04

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age less than 21 weeks or does not meet the requirements in §B(4)(i) of this regulation					
Hepatitis C Therapy	All	Both	\$15,662.46	\$15,662.46	\$15,662.46

(d) Rate Table for Childless Adult Population Effective January 1, 2020—December 31, 2020.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
	1944	Male	\$389.33	\$295.91	\$342.16
	1944	Female	\$476.88	\$361.99	\$418.56
	4564	Male	\$1,069.91	\$812.15	\$939.07
	4564	Female	\$1,039.04	\$788.71	\$911.97
ACG-adjusted cells					
ACG 100, 200, 300, 400, 500, 600, 700, 900, 1000, 1100, 1200, 1300, 1600, 1710, 1711, 1712, 1720, 1721, 1722, 1730, 1731, 1732, 1800, 1900, 2000, 2100, 2200, 2300, 2400, 2500, 2800, 2900, 3000, 3100, 3200, 3300, 3400, 3500, 3800, 4210, 5100, 5110, 5200 5230, 5310, 5339	RAC 1H	Both	\$282.42	\$247.88	\$280.81
ACG 800, 1740, 1741, 1742, 1750, 2700, 3600, 1750, 1751, 1752, 2700, 3600, 3700, 3900, 4000, 4100, 4220, 4310, 4410, 4510, 4610, 4710, 4720, 4810, 5340	RAC 2H	Both	\$471.76	\$414.07	\$422.55
ACG 1400, 1500, 1750, 1761, 1762, 1770, 1771, 1772, 2600, 4320, 4520, 4620, 4820	RAC 3H	Both	\$489.23	\$429.40	\$439.99
ACG 4330, 4420, 4830, 4910, 4920, 5010, 5020, 5040	RAC 4H	Both	\$899.28	\$789.30	\$763.22
ACG 4430, 4730, 4930, 5030, 5050	RAC 5H	Both	\$1,155.28	\$1,014.00	\$955.15
ACG 4940, 5060	RAC 6H	Both	\$1,639.97	\$1,439.41	\$1,234.70
ACG 5070	RAC 7H	Both	\$2,477.09	\$1,880.29	\$2,174.15
HIV	19â64	Both	\$2,991.40	\$2,991.40	\$2,991.40

(e) Rate Table for Families and Children Effective January 1, 2021—December 31, 2021.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
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	Under age 1 Birth Weight 1500 grams or less	Both	\$10,801.56	\$10,084.05	\$10,367.99
	Under age 1 Birth Weight over 1500 grams	Both	\$531.06	\$498.78	\$509.74
	15	Male	\$213.82	\$199.61	\$205.23
		Female	\$176.22	\$164.52	\$169.15
	614	Male	\$112.91	\$105.41	\$108.37
		Female	\$106.03	\$98.98	\$101.77
	1520	Male	\$188.76	\$176.22	\$181.18
		Female	\$185.28	\$172.97	\$177.84
	2144	Male	\$296.27	\$238.54	\$256.08
		Female	\$410.17	\$330.24	\$354.54
	4564	Male	\$727.80	\$585.98	\$629.09
		Female	\$681.00	\$548.30	\$588.63
ACG-adjusted cells					
ACG 100, 200, 300, 400, 500, 600, 700, 900, 1000, 1100, 1200, 1300, 1400, 1500 1600, 1710, 1711, 1712, 1720, 1721, 1722, 1730, 1731, 1732, 1741, 1800, 1900, 2000, 2100, 2200, 2300, 2400, 2500, 2600, 2700, 2800, 2900, 3000, 3100, 3200, 3300, 3900, 3400, 3500, 3800, 4210, 4610, 5100, 5110, 5200 5230, 5310, 5339	RAC 1F	Both	\$207.12	\$166.76	\$179.03
ACG 800, 1740, 1741, 1742, 1750, 2700, 3600, 1732, 1750, 1751, 1752, 1761, 2700, 3200, 3300, 3600, 3700, 3900, 4000, 4100, 4220, 4310, 4320, 4410, 4510, 4610, 4620, 4710, 4720, 4810, 5010, 5340	RAC 2F	Both	\$373.28	\$300.54	\$322.65
ACG 1400, 1500, 1750, 1761, 1762, 1770, 1771, 1772, 2600, 4320, 4330, 4520, 4620, 4730, 4810, 4820, 4910, 5020	RAC 3F	Both	\$571.66	\$494.12	\$460.27

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ACG 0800, 1772, 4330, 4420, 4830, 4910, 4920, 5010, 5020, 5040	RAC 4F	Both	\$735.65	\$592.31	\$635.87
ACG 4430, 4730, 4920, 4930, 5030, 5050	RAC 5F	Both	\$1,044.18	\$840.70	\$902.55
ACG 4940, 5030, 5060	RAC 6F	Both	\$1,428.81	\$1,150.40	\$1,235.01
ACG 5070	RAC 7F	Both	\$2,469.99	\$1,988.70	\$2,134.97
ACG 100, 200, 300, 500, 600, 0400, 0900, 1100, 1300, 1600, 2000, 2400, 3400, 3900, 4000, 4100, 5100, 5110, 5200	RAC 1G	Both	\$78.17	\$72.97	\$75.03
ACG 400, 700, 900, 0100, 1000, 1200, 1300, 1400, 1500, 1710, 1711, 1712, 1800, 1900, 2000, 2100, 2200, 2300, 2400, 2500, 2600, 2800, 2900, 3000, 3100, 3400, 3500, 5310, 5321	RAC 2G	Both	\$109.00	\$101.76	\$104.63
ACG 1200, 1711, 1712, 1720, 1721, 1722, 1731, 1732, 1730, 2500, 2700, 2900, 3200, 3300, 3500, 3600, 3700, 3800, 4210, 5230, 5311, 5339	RAC 3G	Both	\$152.99	\$142.83	\$146.85
ACG 800, 1721, 1722, 1740, 1741, 1742, 1750, 1751, 1752, 2700, 3600, 3700, 3900, 4000, 4100, 4220, 4310, 4410, 4510, 4520, 4610, 4710, 4720, 4810, 4332, 5340	RAC 4G	Both	\$221.94	\$207.20	\$213.03
ACG 1400, 1500, 1731, 1732, 1741, 1750, 1751, 1761, 1762, 1770, 1771, 1772, 2600, 4320, 4520, 4620, 4820, 5010	RAC 5G	Both	\$381.05	\$355.74	\$365.76
ACG 0800, 1771, 1772, 4330, 4420, 4830, 4910, 4920, 5010, 5020, 5040	RAC 6G	Both	\$443.16	\$413.72	\$425.37
ACG 4430, 4730, 4930, 4940, 5030, 5050, 5060, 5070	RAC 7G	Both	\$1,167.92	\$1,090.34	\$1,121.04
SOBRA Mothers			\$756.99	\$609.48	\$654.31
Persons with HIV	ALL	Both	\$2,772.07	\$2,772.07	\$2,772.07

(f) Rate Table for Disabled Individuals Effective January 1, 2021—December 31, 2021.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
Under Age 1	Both		\$7,421.87	\$7,421.87	
	15	Male	\$2,326.06	\$2,326.06	\$2,326.06

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		Female	\$919.92	\$919.92	\$919.92
	614	Male	\$185.04	\$185.04	\$185.04
		Female	\$336.06	\$336.06	\$336.06
	1520	Male	\$158.42	\$158.42	\$158.42
		Female	\$277.79	\$277.79	\$277.79
	2144	Male	\$721.14	\$592.87	\$649.45
		Female	\$789.07	\$648.18	\$710.04
	4564	Male	\$2,317.01	\$1,903.30	\$2,084.95
	4564	Female	\$2,708.00	\$2,224.47	\$2,436.77
ACG-adjusted cells					
ACG 100, 200, 300, 0500, 0600, 0700, 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1710, 1711, 1712, 1720, 1721, 1722, 1730, 1731, 1732, 1741, 1900, 2000, 2100, 2200, 2400, 2500, 2600, 2700, 2900, 3400, 3500, 3800, 5100, 5110, 5200, 5310, 5331	RAC 10	Both	\$244.87	\$201.15	\$220.35
ACG 400, 500, 700, 900, 0300, 1000, 1400, 1200, 1712, 1732, 1740, 1741, 1742, 1750, 1751, 1752, 1800, 1900, 2000, 2100, 2200, 2300, 2500, 2700, 2800, 3000, 3100, 3200, 3300, 3500, 3700, 3900, 4000, 4210, 4310, 4510, 4610, 4710, 5312, 5330	RAC 11	Both	\$324.66	\$266.89	\$292.14
ACG 600, 0100, 1721, 1751, 1752, 1760, 1761, 1762, 2900, 3600, 3700, 4100, 4220, 4320, 4330, 4410, 4710, 4720, 4810, 4820, 5010, 5322	RAC 12	Both	\$575.63	\$472.85	\$517.98
ACG 3800, 4100, 4210, 4220, 4330, 4410, 4420, 4520, 4620, 4720, 4730, 4820, 4910, 5020, 5320	RAC 13	Both	\$815.35	\$699.76	\$733.69
ACG 800, 1771, 4420, 4430, 4510, 4610, 4830, 4910, 5040, 5332, 5340	RAC 14	Both	\$1,152.30	\$946.55	\$1,036.89
ACG 1770, 1771, 1772, 4430, 4520, 4620, 4830, 4920, 5050	RAC 15	Both	\$1,527.61	\$1,254.85	\$1,374.61
ACG 0800, 4730, 4930, 5010, 5050	RAC 16	Both	\$1,483.61	\$1,465.14	\$1,604.97
ACG 4940, 5020, 5060	RAC 17	Both	\$2,371.86	\$1,948.35	\$2,134.30

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ACG 5030, 5070, 5342	RAC 18	Both	\$3,991.27	\$3,278.61	\$3,591.52
Persons with AIDS	All	Both	\$5,003.30	\$3,607.01	\$3,607.01
Persons with HIV	All	Both	\$4,554.33	\$4,554.33	\$4,554.33

(g) Rate Table for Supplemental Payments for Delivery/Newborn and Hepatitis C Therapy Effective January 1, 2021—December 31, 2021.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
Supplemental Payment Cells					
Delivery/Newborn-all births except live birth weight 1,500 grams or less and gestational age of 21 weeks or more	All	Both	\$17,278.93	\$12,566.25	\$14,733.72
Delivery/Newborn - live birth weight 1,500 grams or less and a gestational age of 21 weeks or more	All	Both	\$93,700.08	\$93,700.08	\$93,700.08
Delivery/Newborn by same enrollee - subsequent live birth weight 1,500 grams or less with a gestational age less than 21 weeks or does not meet the requirements in §B(4)(i) of this regulation	All	Both	\$17,278.93	\$12,566.25	\$14,733.72

(h) Rate Table for Childless Adult Population Effective January 1, 2021—December 31, 2021.

	Age/RAC	Gender	PMPM Baltimore City	PMPM Montgomery County	PMPM Rest of State
	1944	Male	\$405.20	\$315.63	\$346.25
	1944	Female	\$484.26	\$377.21	\$413.81
	4564	Male	\$1,142.43	\$889.88	\$976.21
	4564	Female	\$1,144.65	\$891.61	\$978.11
ACG-adjusted cells					
ACG 100, 200, 300, 400, 500, 600, 700, 900, 1000, 1100, 1200, 1300, 1500, 1600, 1710, 1711, 1712, 1720, 1721, 1722, 1730, 1731, 1732, 1741, 1742, 1752, 1800, 1900, 2000, 2100, 2200, 2300, 2400, 2500, 2700, 2800, 2900, 3000, 3100, 3200, 3300, 3400, 3500, 3800, 3900, 4000, 4210, 4310, 4510, 4710, 5100, 5110, 5200, 5230, 5310, 5339	RAC 1H	Both	\$248.20	\$193.33	\$212.09

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ACG 800, 0900, 1000, 1400, 1731, 1740, 1741, 1742, 1750, 1761, 1762, 2300, 2600, 2700, 3600, 1750, 1751, 1752, 2700, 3600, 3700, 3900, 4000, 4100, 4220, 4310, 4320, 4410, 4510, 4610, 4710, 4720, 4810, 4820, 5340	RAC 2H	Both	\$454.46	\$353.99	\$388.34
ACG 1400, 1500, 1711, 1750, 1761, 1762, 1770, 1771, 1772, 2600, 4100, 4320, 4330, 4410, 4520, 4620, 4730, 4820, 5010, 5020	RAC 3H	Both	\$583.20	\$454.27	\$498.34
ACG 0800, 1751, 1772, 4330, 4420, 4830, 4910, 4920, 5010, 5020, 5040	RAC 4H	Both	\$863.24	\$672.41	\$737.65
ACG 4430, 4730, 4920, 4930, 5030, 5050	RAC 5H	Both	\$1,249.46	\$973.25	\$1,067.68
ACG 4930, 4940, 5060	RAC 6H	Both	\$1,680.86	\$1,309.28	\$1,436.31
ACG 5070	RAC 7H	Both	\$2,579.16	\$2,009.00	\$2,203.91
HIV	19a64	Both	\$3,135.78	\$3,135.78	\$3,135.78

(i) Interpretation of Rate Table for Families and Children. The table found at §B(4)(a) of this regulation shows capitation rates for individuals who are:

- (i) Waiver eligible based on receipt of benefits through TCA or programs for medically needy families and children;
- (ii) SOBRA children;
- (iii) SOBRA mothers; and
- (iv) The Maryland Children's Health Program.

(j) Interpretation of Rate Table for Disabled Individuals. The table found at §B(4)(b) of this regulation shows the capitation rates for individuals who are waiver-eligible based upon receipt of benefits through SSI or as medically needy, aged, blind, or disabled.

(k) Interpretation of Rate Table for Supplemental Payment for Delivery/Newborn. The table found at §B(4)(c) of this regulation shows a supplemental payment made in connection with deliveries of MCO enrollees, regardless of the enrollee's payment category under COMAR 10.67.04.19B(4)(a) or (b).

(l) Interpretation of Rate Tables in §B(4) of this regulation. "PMPM" means the per member per month payment rate.

(5) Consistent with the terms set forth in Regulation .19-4 of this chapter, the Department may, in consultation with the Commissioner, adjust the capitation payment of an MCO if it determines that the MCO's loss ratio, not including any rebate received by the MCO is less than 85 percent.

(C)The Department shall reimburse fee-for-service:

(1) The Departmental share for any enrollee participating in the Stop Loss Program pursuant to Regulation .22 of this chapter; and

(2) The cost of those services specified in COMAR 10.09.69.06.13 provided to the participant that have been authorized by the participant's case manager in accordance with the participant's plan of care.

D. Interim Rates Adjustments.

1) Under the circumstances described in §D(2) and (3) of this regulation, the Department shall adjust the capitation rates set forth in §B(4)(a), (b), (e), and (f) of this regulation to reflect changes in service costs during the contract year due to an occurrence listed in §D(2) of this regulation.

(2) The Department shall adjust the payment rates specified in §B(4)(a)(h) of this regulation to reflect service cost changes that qualify under §D(3) of this regulation and result from:

(a) An addition or deletion of services covered under the HealthChoice benefits package;

(b) An increase or decrease in Medicaid fee-for-service payment rates or copayments, if the MCOs are obligated to adjust their payment rates to providers as a result of those fee-for-service rate changes;

(c) An increase or decrease in the inpatient charge per case as calculated by the change in the restated unit cost provided annually by the HSCRC as compared to the data originally provided; or (d) An increase or decrease in the outpatient charge per visit as calculated by the change in the restated unit cost provided annually by the HSCRC as compared to the data originally provided.

(3) The Department shall make an interim rates adjustment if the effect of an occurrence listed in §D(2) of this regulation is sufficient to result in program-wide overpayment or underpayment of at least 0.2 percent because of the difference between:

(a) Service cost projections used to develop the rates set forth in §B(4)(a), (b), (e), and (f) of this regulation; and

(b) Service costs for the same period, taking into account an occurrence that is listed in §D(2) of this regulation.

(4) The Department shall make any interim rate adjustments required by this section in amounts that are proportionate to the overpayments or underpayments described in §D(3) of this regulation.

(5) Provider rate adjustments as specified in §D(2)(b) of this regulation may not require the MCOs to pay providers more than the Medicaid fee-for-service rate.

(6) The Department shall make supplemental payments to an MCO that reflect increases in MCO provider payments for trauma services described in COMAR 10.25.10.

(7) The Department shall make an interim rates adjustment in Calendar Years 2022, 2023, 2024, and 2025 to account for changes in acuity due to alterations in redetermination and enrollment processes related to COVID-19.

E. Interim Rate Adjustment for Calendar Year 2025.

(1) The Department shall re-open the capitation rates for interim rate adjustments in Calendar Year 2025 to revisit the following adjustments:

(a) Risk adjustment;

(b) Trend;

(c) Administration;

(d) Regional factors; and

(e) Relational modeling.

(2) To assist with the assessment, MCOs shall provide additional information to the Department upon request, including detailed claims data as well as a year-to-date HealthChoice Financial Monitoring Report for the calendar year.

.21 PAYMENTS TO FEDERALLY QUALIFIED HEALTH CENTERS (FQHC).

A. FQHC's shall be reimbursed under the Alternative Payment System (APS).

(1) The Department shall:

(a) Pay the MCO a prospective payment based on encounter data; and

(b) Reconcile the prospective amount paid to the MCO with the MCO's actual expenditure amount, after receipt of MCO encounter data; and

(2) MCOs shall reimburse any contracted FQHC, the FQHC's rate established in accordance with COMAR 10.09.08.05-1A.

B. For self-referred services described in Regulation .20 of this chapter, the MCO shall pay the FQHC's usual rate in accordance with §A of this regulation, regardless of the FQHC's contracted status with the MCO.

.22 STOP LOSS PROGRAM.

A. An MCO shall qualify for protection under the Stop Loss Program if:

(1) It was participating in HealthChoice as of April 1, 1999;

(2) It was unable to self-insure or obtain a contract with another entity for Stop Loss reinsurance after July 1, 1999; and

(3) By July 1, 1999, the MCO requested the Department to continue to provide Stop Loss Protection at a rate determined by the Department.

B. An MCO shall notify the Department that the acute inpatient hospital costs of an enrollee are expected to exceed the Stop Loss limit as soon as it knows that this is likely to occur.

C. Upon confirming eligibility for stop loss protection, the Department shall assume liability for reimbursement of 90 percent of accrued acute inpatient hospital charges according to established Medicaid fee-for-service rates for medically necessary acute inpatient treatment rendered to the enrollee above the stop loss limit throughout the remainder of the calendar year.

D. An MCO shall remain financially liable for reimbursing 10 percent of accrued acute inpatient hospital charges for medically necessary treatment rendered to the enrollee above the stop loss limit throughout the remainder of the calendar year, and shall maintain full responsibility for the provision of health care services to the enrollee.

E. At the beginning of the next calendar year, an MCO shall reassume full financial responsibility and full discretion for developing medical treatment plans for any enrollee who qualified for the Stop Loss Program.

F. The Department's Extended Stop Loss Period.

(1) If an inpatient enrollee remains hospitalized at the end of a calendar year and incurs acute hospital costs that exceed the Stop Loss limit into the following calendar year without interruption, the Department's stop loss period shall be extended until the end of that hospitalization.

(2) The MCO shall remain financially liable for costs up to the Stop Loss limit for enrollees who remain hospitalized in an acute setting at the end of the calendar year as specified in §§A and D of this regulation until the enrollee is discharged.

G. For calendar year 2001 and beyond, the MCO shall submit the MCO's Stop Loss Reinsurance Plan or Self-Insurance Plan to the Maryland Insurance Administration.

H. If an MCO chooses to have the Department provide its Stop Loss coverage, an adjustment will be made to the capitation amount the MCO is paid.

I. Upon the termination of the provider agreement between the enrollee's MCO and the Department, if an MCO has failed to fulfill its financial liability under this regulation, the Department shall assume responsibility only for costs that exceed the Stop Loss limit as specified in §C of this regulation.

.23 MARKETING.

A. An MCO may not have face-to-face or telephone contact with a recipient, or otherwise solicit a recipient who is not an enrollee of the MCO, unless authorized by the Department or the recipient initiates the contact.

B. Subject to prior approval by the Department, an MCO may engage in marketing activities designed to make recipients aware of their availability, as well as any special services they offer. Unless they involve face-to-face solicitation, these marketing activities may involve campaigns using but not limited to:

- (1) Television;
- (2) Radio;
- (3) Newspaper;
- (4) Informational booths at public events;
- (5) Billboards and other public displays;
- (6) Addressee-blind informational mailings, but only when mailed to the MCO's entire service area;
- (7) Magazines;
- (8) Airborne marketing displays; or
- (9) Public conveyances.

C. An MCO may not engage in any cold call marketing, including activities using or involving any of the following mechanisms:

- (1) Direct marketing;
- (2) Telephone solicitation;
- (3) Door to door flyers;

- (4) Email;
- (5) Texting;
- (6) Material or financial incentives of any kind, with the exception of advertising trinkets such as balloons or pens that have an acquisition cost of \$5 or less; or
- (7) Influencing enrollment in conjunction with the sale or offer of private insurance.

D. Standards for Departmental Approval of MCO Advertising.

(1) MCO advertising shall:

- (a) Be based on documented fact;
- (b) Identify all telephone numbers used that do not belong to the MCOs;
- (c) Include the statement, "'HealthChoice' is a program of the Maryland Department of Health"; and
- (d) Be at a fifth grade reading level.

(2) MCO advertising may not:

- (a) Be false or misleading;
- (b) Ascribe to the MCO unique coverage or services that are otherwise required by State or federal law or regulation;
- (c) Assert that a recipient shall enroll in the MCO in order to obtain benefits or in order not to lose benefits; or
- (d) Assert that the MCO is endorsed by CMS, the federal or State government or similar entity.

.26 TIME PERIOD FOR TERMINATION OF PROVIDER AGREEMENT.

A. An MCO may terminate its provider agreement with the State as provided in §§B—D of this regulation.

B. The MCO shall provide written notification to the Department of the MCO's intent to terminate the MCO's provider agreement with the State for any given calendar year by the previous October 1.

C. An MCO that has previously terminated the provider agreement with the State and would like to sign a new agreement with the State, shall follow the application process as specified under COMAR 10.67.03.

D. The Department may waive the requirement under §B of this regulation if the Department determines that the circumstances warrant, including but not limited to a reduction in rates outside the normal rate setting process or an MCO exit from the program.

CHAPTER 05 MARYLAND MEDICAID MANAGED CARE PROGRAM: ACCESS

.01 ACCESS STANDARDS: ADDRESSING ENROLLEES' INDIVIDUALIZED NEEDS.

A. An MCO shall provide access to health care services and information in a manner that addresses the individualized needs of its enrollees, regardless of gender, sexual orientation, or gender identity, including, but not limited to, the delivery of services and information to enrollees:

- (1) In a culturally sensitive manner;
- (2) At an appropriate reading comprehension level;
- (3) In the prevalent non-English languages identified by the State; and
- (4) In a manner that accommodates individuals with disabilities consistent with the requirements of the Americans with Disabilities Act of 1990, P.L. 101-330, 42 U.S.C. §12101 et seq., and regulations promulgated under it.

B. Special Access.

(1) An MCO shall notify enrollees of the following services and make them available free of charge to the enrollee:

- (a) Written materials in the prevalent non-English languages identified by the State;
- (b) Written materials in alternative formats;
- (c) Oral interpretation services in all non-English languages; and
- (d) Auxiliary aids and services, such as:
 - (i) Teletypewriter/Telecommunication Device for the Deaf (TTY/TDD); and
 - (ii) American Sign Language.

(2) An MCO shall include taglines with its written materials that:

- (a) Explain the availability of written translation or oral interpretation to understand the information provided; and
- (b) Provide the toll-free and TTY/TDD telephone number of the MCO's customer service unit.

(3) An MCO shall format taglines included with written materials in the following manner:

- (a) In a font size no smaller than 18 point; and
- (b) In the prevalent non-English languages identified by the State.

C. Written Materials. An MCO shall provide all its written materials in the following manner:

- (1) Using language and a format that is easily understood;
- (2) In a font size no smaller than 12 point;
- (3) Available in alternative formats and through the provision of auxiliary aids and services; and
- (4) Available in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

D. An MCO may provide enrollee information electronically so long as all of the following requirements are met:

- (1) The format is readily accessible;
- (2) The information is placed in a location on the MCO's website that is prominent and readily accessible;

- (3) The information is provided in an electronic form which can be electronically retained and printed;
- (4) The information is consistent with the content and language requirements of this section;
- (5) The enrollee is informed that the information is available in paper form without charge upon request; and
- (6) Should the enrollee request it, the MCO provides the information in paper form within 5 business days.

.02 ACCESS STANDARDS: ENROLLEE HANDBOOK AND PROVIDER DIRECTORY.

A. An MCO shall inform and educate its enrollees about:

- (1) Basic information about the MCO;
- (2) The availability of health care services and how to access them;
- (3) The definitions of managed care terminology in accordance with 42 CFR 438.10(c)(4)(i); and
- (4) Enrollee's rights and responsibilities in the MCO, and that the exercise of those rights does not adversely affect the way the MCO, its providers, or the Department treats the enrollee.

B. An MCO shall, at the time of enrollment, and anytime upon request, furnish each enrollee with a copy of the MCO's enrollee handbook that includes all language in the template provided by the Department and the following current information:

- (1) The enrollee's rights and responsibilities in the MCO as described in 42 CFR §438.100(b)(1), as amended;
- (2) Information on how to access urgent care and emergency care services, including:
 - (a) What constitutes an emergency medical condition and emergency services;
 - (b) The following facts:
 - (i) Prior authorization is not required for these services; and
 - (ii) The enrollee has a right to use any hospital or other setting for emergency care;
- (3) The services included in the MCO's benefits package, including optional benefits provided by the MCO;
- (4) How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided;
- (5) The amount, duration, and scope of benefits available in sufficient detail to ensure that enrollees understand the benefits to which they are entitled;
- (6) The availability of behavioral health services that are not included in the MCO's benefits package, and how to access these services;
- (7) Information on the availability of self-referral services as well as any restrictions on the enrollee's freedom of choice among network providers;
- (8) Information about how enrollees may obtain benefits from out-of-network providers;

- (9) Any policies and procedures necessary to facilitate accessing needed services in compliance with the Maryland Medicaid Managed Care Program, including any requirements for service authorizations or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider;
- (10) Information about the availability of EPSDT, prenatal care, family planning, and other wellness services, including education programs;
- (11) A statement that the MCO cannot require an enrollee to obtain a referral before choosing a family planning provider;
- (12) The process of selecting and changing the enrollee's primary care provider;
- (13) A description of any benefits the MCO offers in addition to those required by the Maryland Medicaid Managed Care Program, including applicable terms and conditions for accessing those benefits;
- (14) Information on how to access auxiliary aids and services, including additional information in alternative formats or languages;
- (15) The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees, including:
 - (a) A description of each unit and number;
 - (b) An explanation of how the phone numbers can be used to obtain information and assistance; and
 - (c) An explanation of the MCO's internal grievance procedure.
- (16) Information regarding the importance of scheduling and maintaining appointments for preventive services;
- (17) If applicable, a list of services that are not covered by the MCO because of moral or religious objections, and a statement that informs the enrollee that the State will provide information on how and where to obtain these services;
- (18) The rule pertaining to poststabilization care services, as set forth in Regulation .08G of this chapter;
- (19) Appeal, grievance, and fair hearing procedures and time frames that include the following:
 - (a) The right to a State fair hearing, including the method for obtaining a hearing and the rules that govern representation at the hearing;
 - (b) The right to file appeals and grievances;
 - (c) The requirements and time frames for filing an appeal or grievance;
 - (d) The availability of assistance in the filing process;
 - (e) The toll-free numbers that the enrollee may use to file an appeal or grievance by phone;
 - (f) The fact that, if requested by the enrollee, the benefits will continue if the enrollee files an appeal or a request for a State fair hearing within the time frames specified for filing; and
 - (g) That the enrollee may be required to pay the cost of the services furnished while the appeal is pending, if the final decision is adverse to the enrollee;

- (20) Any appeal rights the State chooses to make available to providers;
- (21) Advanced directives as set forth in 42 CFR §438.3(j)(1), as amended;
- (22) Information on how to report suspected fraud or abuse;
- (23) Additional information that is available upon request, including the following:
 - (a) Information on the structure and operation of the MCO; and
 - (b) Physician incentive plans.
- (24) Information on how to access or obtain the MCO's provider directory.

C. Provider Directory.

- (1) An MCO shall provide enrollees with information regarding their provider networks including:
 - (a) Its primary care service locations;
 - (b) A listing of the MCO's hospital providers, of both inpatient and outpatient services, in the enrollee's county, their addresses, and services provided;
 - (c) A listing of the MCO's pharmacy providers in the enrollee's county and their addresses; and
 - (d) A listing of the individual practitioners who are the MCO's primary and specialty care providers in the enrollee's county, grouped by medical specialty, giving:
 - (i) Name;
 - (ii) Address;
 - (iii) Practice location or locations;
 - (iv) Telephone number or numbers;
 - (v) Website URL, as appropriate;
 - (vi) Any group affiliation, as appropriate;
 - (vii) Cultural and linguistic capabilities, including languages offered by the provider or a skilled medical interpreter at the provider's offices, American Sign Language interpretation, and whether the provider has completed cultural competence training;
 - (viii) An indication of whether the provider's office or facility has accommodations for physical disabilities, including offices, exam room or rooms and equipment;
 - (ix) An indication of whether or not the provider is accepting new patients;
 - (x) An indication of the age range of patients accepted or whether there is no age limit; and
 - (xi) If applicable, how access to the provider is otherwise limited.
- (2) Upon request by an enrollee, an MCO shall furnish a paper copy of the provider directory.

D. An MCO shall notify all enrollees of their right to request and obtain the information listed in §§B and C of this regulation at least once a year.

E. The Department may consider the information listed in §§B and C of this regulation to be provided if the MCO:

- (1) Mails a printed copy of the information to the enrollee's mailing address;
- (2) Provides the information by email after obtaining the enrollee's agreement to receive the information by email;
- (3) Posts the information on the MCO's website and advises the enrollee in paper or electronic form that the information is available on the internet and includes the applicable internet address, provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or
- (4) Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

F. An MCO shall update its online provider directory no later than 30 days after the MCO receives updated provider information.

G. An MCO shall update its paper directory:

- (1) Monthly if the MCO does not have a mobile-enabled electronic directory; or
- (2) Quarterly if the MCO has a mobile-enabled electronic directory.

H. An MCO shall make provider directories available on its website in a machine-readable file and format as specified by the Secretary for the U.S. Department of Health and Human Services.

.03 ACCESS STANDARDS: OUTREACH.

A. An MCO is responsible for delivering needed health care services even when the enrollee is difficult to reach or misses appointments.

B. The assistance of local health departments in contacting and bringing into care enrollees who are difficult to reach or miss appointments is available for the specific categories of enrollees identified in this regulation, but only after the MCO has made documented attempts to contact and bring into care an enrollee who is difficult to reach or misses appointments before seeking the assistance of the local health department.

C. Adults.

(1) An MCO shall, before referring the enrollee to the local health department, make documented attempts to ensure that follow-up appointments are scheduled in accordance with the enrollee's treatment plan by attempting a variety of contact methods, which may include:

- (a) Written correspondence;
- (b) Telephone contact; and
- (c) Face-to-face contact.

(2) If the enrollee, due to impaired cognitive ability or psychosocial problems such as homelessness or other conditions, can be expected to have difficulty understanding the importance of treatment instructions or difficulty navigating the health care system, the MCO shall, after exhausting its best efforts to contact and bring into care the

enrollee in accordance with §C(1) of this regulation, make, or ensure that the enrollee's provider makes, a written referral to the local health department for its assistance within 10 business days of whichever first occurs:

- (a) The third consecutive missed appointment; or
- (b) The MCO or the enrollee's provider identifies the enrollee's repeated noncompliance with a regimen of care.

D. Child Younger than 2 Years Old Needing EPSDT Screening Services.

- (1) An MCO shall ensure that appointments are scheduled in accordance with the EPSDT periodicity schedule or within 30 days of the MCO's receipt of the health risk assessment, whichever is less.
- (2) If the enrollee fails to keep the appointment, the MCO shall ensure that a second appointment is scheduled within 30 days.
- (3) If the enrollee misses the second appointment, a third appointment shall be scheduled within 30 days.
- (4) For each scheduled appointment, the MCO shall:
 - (a) Provide written notice to the enrollee's parent, guardian, or caretaker of the appointment dates; and
 - (b) Attempt to notify the enrollee's parent, guardian, or caretaker of the appointment dates by telephone.
- (5) If the enrollee misses the second appointment in a row, after the MCO has made the notification attempts required by §C(1) of this regulation, the MCO shall, within 10 business days, make, or ensure that the enrollee's provider makes, a written referral to the local health department for its assistance in bringing the enrollee into care.
- (6) After referral to the local health department, the MCO shall continue to work collaboratively with the local health department to bring the enrollee into care until the enrollee comes back into compliance with the EPSDT periodicity schedule.

E. Child Younger than 21 Years Old Needing Follow-up Treatment.

- (1) An MCO shall ensure that an appointment for follow-up care is scheduled at a time interval appropriate to the enrollee's diagnosed condition.
- (2) If the enrollee fails to keep the appointment, the MCO shall reschedule the appointment for the enrollee to be seen within 30 days.
- (3) For each scheduled appointment, the MCO shall:
 - (a) Provide written notice to the enrollee, or to the enrollee's parent, guardian, or caretaker, as appropriate, of the appointment dates by mail; and
 - (b) Attempt to notify the enrollee, or the enrollee's parent, guardian, or caretaker, as appropriate, of the appointment dates by telephone.
- (4) If the enrollee misses the second consecutive follow-up appointment after the MCO has made the notification attempts required by §C(1) of this regulation, the MCO shall, within 10 business days, make, or ensure that the enrollee's provider makes, a written referral to the local health department for its assistance in bringing the enrollee into care.
- (5) After referral to the local health department, the MCO shall work collaboratively with the local health department to bring the enrollee into care.

F. Pregnant or Postpartum Woman Needing Prenatal or Postpartum Care.

(1) Initial Visit. An MCO shall schedule an initial visit for the pregnant or postpartum enrollee to be seen within 10 days of her request for an appointment. If she fails to appear for the appointment, the MCO shall reschedule in a timely manner appropriate to her medical condition.

(2) Follow-Up Appointments. After the enrollee has completed an initial visit that includes a comprehensive history, physical exam, and completion of the Maryland Prenatal Risk Assessment, the MCO shall ensure that appointments are scheduled for the enrollee in compliance with the periodicity schedule of the ACOG guidelines. If the enrollee fails to appear for a scheduled appointment, the MCO shall ensure that the appointment is rescheduled for the enrollee to be seen within 10 days.

(3) For each scheduled appointment, the MCO shall:

(a) Provide written notice to the enrollee of the appointment dates; and

(b) Attempt to notify the enrollee of the appointment dates by telephone.

(4) After making the attempts specified in §F(3) of this regulation, if the MCO is unable to bring the enrollee into care within 30 days of the first missed appointment, the MCO shall, within 10 days of the last missed appointment, make, or ensure that the enrollee's provider makes, a written referral to the local health department for its assistance in bringing the enrollee into care.

(5) After referral to the local health department, the MCO shall work collaboratively with the local health department to bring the patient into care, until the enrollee comes back in compliance with the ACOG periodicity schedule.

.04 ACCESS STANDARDS: INFORMATION FOR PROVIDERS.

A. An MCO shall develop and make available either electronically or by hard copy to all of its PCP and specialty care providers a Medicaid requirements manual, including periodic updates as appropriate, and shall:

(1) Before distribution, file a copy of its manual with the Department for review;

(2) Include in its manual the information necessary to facilitate the providers' full compliance with federal and State Medicaid requirements, including information on:

(a) Medicaid statutes and regulations;

(b) The benefits package, including optional benefits;

(c) Access requirements, which, at a minimum, comply with the requirements of this chapter;

(d) Quality requirements, which shall, at a minimum, comply with the requirements of COMAR 10.67.04.03;

(e) Continuity of care requirements; and

(f) Requirements for referral to specialist, ancillary, and other providers as necessary to provide the full range of medically necessary services that are covered by the Maryland Medicaid Managed Care Program;

(g) The MCO's practice guidelines as described in 42 CFR §438.236.

(3) Inform the MCO's primary and specialty care providers of their responsibility to provide or arrange for medically necessary accessible health care services that are continuous, comprehensive, and coordinated for each enrollee, including:

- (a) Preventive health services;
- (b) Primary acute medical care;
- (c) Chronic medical care;
- (d) Consultation, referral, and follow-up in areas including medical specialties and child dental care;
- (e) Referral for ancillary and support-related services including but not limited to:
 - (i) Drug therapies;
 - (ii) Diagnostic tests;
 - (iii) Medical supplies;
 - (iv) Durable medical equipment; and
 - (v) Case management when appropriate for complex conditions;
 - (f) 24-hour per day, 7-day per week provider coverage for medically necessary services;
 - (g) Maintenance of a medical record, including records of referral arrangements and outcomes of those referrals; and
 - (h) Detection of mental health problems or substance use disorder during routine or follow-up screening, to be treated either through the MCO or referred to the behavioral health ASO for services; and
- (4) Inform the providers of the following enrollee appeal, grievance, and fair hearing procedures and time frames:
 - (a) The enrollee's right to a State fair hearing, how to obtain a hearing, and representation rules at a hearing;
 - (b) The enrollee's right to file appeals and grievances, and the enrollee's requirements and time frames for filing;
 - (c) The availability of assistance in filing;
 - (d) The toll-free numbers to file verbal appeals and grievances;
 - (e) The enrollee's right to request continuation of benefits during an appeal or State fair hearing filing, and that if the MCO action is upheld in a hearing, the enrollee may be liable for the cost of any continued benefits; and
 - (f) The provider's right to appeal, on the enrollee's behalf, the failure of the MCO to cover a service.

B. An MCO shall ensure that its PCP and specialty care providers receive adequate information regarding the Medicaid Program to facilitate full compliance with all federal and State Medicaid requirements. The MCO shall:

- (1) Ensure that each PCP and specialty care provider receives, at the time they enter into a contract, a copy of the MCO's Medicaid requirements manual, and any other pertinent information; and
- (2) Provide each PCP and specialty care provider, on an ongoing basis as appropriate, with periodic updates of the materials required to be provided under §B(1) of this regulation.

C. An MCO shall provide to each PCP an updated list of the PCP's assigned enrollees monthly.

.05 ACCESS STANDARDS: PCPS AND MCO'S PROVIDER NETWORK.

A. Primary Care Provider (PCP).

(1) An MCO shall assign each enrollee to a primary care provider who is:

(a) Chosen by the enrollee from the MCO's panel of qualified providers; or

(b) Chosen by the MCO from its panel of qualified providers if the enrollee has failed to choose a PCP.

(2) An enrollee may request a change of PCP at any time if the PCP is within the recipient's current MCO's panel of providers.

(3) With respect to enrollees younger than 21 years old, an MCO shall assign the enrollee to a PCP who is certified by the EPSDT program, unless the enrollee or the enrollee's parent, guardian, or caretaker, as appropriate, specifically requests assignment to a PCP who is not EPSDT-certified.

(4) If the enrollee's parent, guardian, or caretaker, as appropriate, chooses a non-EPSDT certified PCP in accordance to §A(3) of this regulation, within 30 days of enrollment, the MCO shall:

(a) Notify the parent, guardian, or caretaker, by letter, that a non-EPSDT certified PCP has been chosen; and

(b) Include in the notification an explanation of the:

(i) EPSDT preventive screening services to which an enrollee is entitled according to the EPSDT periodicity schedule;

(ii) Importance of accessing the EPSDT preventive screening services; and

(iii) Process for requesting a change to an EPSDT-certified PCP to obtain preventive screening services.

(5) An MCO may include, as appropriate, any of the following practitioners to serve as the primary care provider for an enrollee:

(a) General practitioner;

(b) Family practitioner;

(c) Internist;

(d) Pediatrician;

(e) OB/GYN;

(f) Physician assistant;

(g) Certified nurse midwife;

(h) Nurse practitioner certified in any of the following areas of specialization:

(i) Adult;

- (ii) Pediatric;
 - (iii) Geriatric;
 - (iv) OB/GYN;
 - (v) School nurse; or
 - (vi) Family; and
- (i) A physician practicing in a specialty area other than those enumerated in §A(5)(b)—(e) of this regulation.
- (6) The enrollee's designated primary care provider (PCP) is the enrollee's primary coordinator of care.
- (7) For female enrollees, if the enrollee's PCP is not a women's health specialist, the MCO shall provide direct access, without the need for a referral, to a women's health specialist within the MCO's network for covered services necessary to provide women's routine and preventive health care services.

B. Adequacy of Provider Network.

- (1) An MCO shall develop and maintain a complete network of adult and pediatric primary care, specialty care, ancillary service, vision, pharmacy, home health, and any other providers adequate to deliver the full scope of benefits as required by this chapter and COMAR 10.67.06.
- (2) An MCO shall clearly define and specify referral requirements to specialty and other providers.
- (3) An MCO shall require the PCP to maintain records of referral arrangements, and the feedback and outcomes of those referrals, within each enrollee's medical records.
- (4) An MCO shall maintain a list of its proposed and existing subcontracts with health care providers who are necessary to fulfill the MCO's service delivery obligations.
- (5) An MCO shall provide a list of its subcontractor providers to the Department.
- (6) An MCO shall ensure services are delivered in a culturally competent manner to all enrollees, including enrollees:
- (a) With limited English proficiency;
 - (b) With diverse cultural and ethnic backgrounds; and
 - (c) Of all genders, sexual orientations, and gender identities.
- (7) For enrollees with physical or mental disabilities, an MCO shall ensure its network providers provide:
- (a) Physical access;
 - (b) Reasonable accommodation; and
 - (c) Accessible equipment.
- (8) Capacity.
- (a) MCOs shall ensure adequate capacity and services, in compliance with 42 CFR §438.206(b)(1)(i), as amended.

(b) The Department shall assess the MCO's provider network and determine its capacity to serve waiver-eligible recipients in each local access area in its service area.

(c) Unless the MCO can establish to the Department's satisfaction the adequacy of a higher ratio, the Department shall determine the MCO's capacity with respect to any local access area by assuming that in-plan individual practitioners, based on full-time equivalency, will be assigned no more than the number of enrollees that is consistent with a 200:1 ratio of enrollee to practitioner in the local access area.

(d) The Department may not approve an enrollee-to-PCP ratio that is higher than 2,000:1.

(9) To ensure compliance with the timely access requirements in Regulation .07 of this chapter, an MCO shall:

(a) Establish mechanisms to ensure that network providers comply with access requirements;

(b) Monitor regularly to determine compliance; and

(c) Take corrective action if there is a failure to comply.

.05-1 ACCESS STANDARDS: SPECIALTY PROVIDER NETWORK.

A. Standards and Regions.

(1) The Department shall review an MCO's specialty provider network for MCO's overall network as defined in this regulation.

(2) Overall Network Standards.

(a) An MCO shall meet either the time or distance standard set forth in Regulation .06A of this chapter for core, major, and pediatric specialties.

(b) The 8 core specialties are:

(i) Cardiology;

(ii) Otolaryngology (ENT);

(iii) Gastroenterology;

(iv) Neurology;

(v) Ophthalmology;

(vi) Orthopedics;

(vii) Surgery; and

(viii) Urology.

(c) The 6 major specialties are:

(i) Allergy and immunology;

(ii) Dermatology;

- (iii) Endocrinology;
- (iv) Infectious disease;
- (v) Nephrology; and
- (vi) Pulmonology.

(d) The 4 pediatric subspecialties are:

- (i) Cardiology;
- (ii) Gastroenterology;
- (iii) Neurology; and
- (iv) Surgery.

B. If the Department determines that an MCO does not meet the requirements specified in §A(2)(b)—(d) of this regulation, the MCO may provide additional information to support the adequacy of the MCO's specialty network before any action is taken by the Department.

C. If an MCO fails to meet the requirements established by this regulation, the Department may suspend the automatic assignment to the MCO of recipients who live in the affected local access area. A suspension of automatic assignments may affect the MCO's ability to qualify for the Statewide supplemental payments specified under COMAR 10.67.04.03-1.

.06 GEOGRAPHICAL ACCESS.

A. Except as provided in §C of this regulation, an MCO shall develop and maintain a provider network that meets the following time and distance standards:

(1) For adult and pediatric primary care, pharmacy, diagnostic laboratory and x-ray, and gynecology:

- (a) In urban areas, within 15 minutes or 10 miles;
- (b) In suburban areas, within 30 minutes or 20 miles; and
- (c) In rural areas, within 40 minutes or 30 miles;

(2) For prenatal care, as defined in §B of this regulation:

- (a) In urban areas, within 15 minutes or 10 miles;
- (b) In suburban areas, within 30 minutes or 20 miles; and
- (c) In rural areas, within 90 minutes or 75 miles;

(3) For acute inpatient hospitals:

- (a) In urban areas, within 20 minutes or 10 miles;

- (b) In suburban areas, within 45 minutes or 30 miles; and
- (c) In rural areas, within 75 minutes or 60 miles;
- (4) For core specialty types, as defined in Regulation .05-1A(2)(b) of this chapter:
 - (a) In urban areas, within 30 minutes or 15 miles;
 - (b) In suburban areas, within 60 minutes or 45 miles; and
 - (c) In rural areas, within 90 minutes or 75 miles;
- (5) For major specialty types, as defined in Regulation .05-1A(2)(c) of this chapter:
 - (a) In urban areas, within 30 minutes or 15 miles;
 - (b) In suburban areas, within 80 minutes or 60 miles; and
 - (c) In rural areas, within 110 minutes or 90 miles; and
- (6) For pediatric subspecialty types, as defined in Regulation .05-1A(2)(d) of this chapter:
 - (a) In urban areas, within 30 minutes or 15 miles;
 - (b) In suburban areas, within 80 minutes or 60 miles; and
 - (c) In rural areas, within 250 minutes or 200 miles.

B. Prenatal Care Providers. For the purposes of provider network adequacy, prenatal care providers may include, but are not limited to:

- (1) Obstetricians;
- (2) Certified nurse midwives; and
- (3) Family practitioners who provide prenatal care and perform deliveries.

C. If an MCO can otherwise demonstrate to the Department's satisfaction the adequacy of its provider network notwithstanding its inability to meet the requirements of §A of this regulation, the Department may, in its discretion, approve the network if special circumstances exist which, considered along with the overall strength of the MCO's network, establish that the Department's approval of the network will enhance recipients' overall access to quality health care services in the area to be served.

D. Geographical Access: Local Access Areas.

<i>Local Access Area</i>	<i>Zip Codes</i>
Allegany	21501, 21502, 21503, 21504, 21505, 21521, 21523, 21524, 21528, 21529, 21530, 21532, 21539, 21540, 21542, 21543, 21545, 21546, 21555, 21556, 21557, 21560, 21562, 21766
Anne Arundel North	20701, 20724, 20755, 21056, 21060, 21061, 21076, 21077, 21090, 21108, 21113, 21122, 21123, 21144, 21240

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Anne Arundel South	20711, 20733, 20751, 20764, 20765, 20776, 20778, 20779, 21012, 21032, 21035, 21037, 21054, 21106, 21114, 21140, 21146, 21401, 21402, 21403, 21404, 21405, 21409
Baltimore City SE/Dundalk	21052, 21219, 21222, 21224, 21281
Baltimore City East	21202, 21203, 21205, 21213, 21231, 21287
Baltimore City North Central	21210, 21211, 21218
Baltimore City Northeast	21206, 21212, 21214, 21239
Baltimore City Northwest	21208, 21209, 21215, 21270
Baltimore City South	21225, 21226, 21230
Baltimore City West	21201, 21216, 21217, 21223
Baltimore County East	21021, 21022, 21027, 21051, 21087, 21128, 21156, 21162, 21220, 21221, 21236, 21237
Baltimore County North	21013, 21023, 21030, 21031, 21053, 21057, 21082, 21092, 21093, 21094, 21105, 21111, 21120, 21131, 21139, 21152, 21153, 21155, 21161, 21204, 21234, 21284, 21285, 21286
Baltimore County Northwest	21055, 21071, 21117, 21133, 21136, 21163, 21207, 21244, 21282
Baltimore County Southwest	21227, 21228, 21229
Calvert	20610, 20615, 20629, 20639, 20657, 20676, 20678, 20685, 20688, 20689, 20714, 20732, 20736, 20754, 20758
Caroline	21609, 21629, 21632, 21636, 21639, 21640, 21641, 21649, 21655, 21660, 21670
Carroll	21020, 21048, 21074, 21088, 21102, 21104, 21157, 21158, 21757, 21771, 21776, 21784, 21787, 21791
Cecil	21901, 21902, 21903, 21904, 21911, 21912, 21913, 21914, 21915, 21916, 21917, 21918, 21919, 21920, 21921, 21922, 21930
Charles	20601, 20602, 20603, 20604, 20611, 20612, 20616, 20617, 20622, 20625, 20632, 20637, 20640, 20643, 20645, 20646, 20658, 20661, 20662, 20664, 20675, 20677, 20682, 20693, 20695
Dorchester	21613, 21622, 21626, 21627, 21631, 21634, 21643, 21648, 21659, 21664, 21669, 21672, 21675, 21677, 21835, 21869
Frederick	21701, 21702, 21703, 21704, 21705, 21710, 21714, 21716, 21717, 21718, 21727, 21754, 21755, 21758, 21759, 21762, 21769, 21770, 21773, 21774, 21775, 21777, 21778, 21780, 21788, 21790, 21792, 21793, 21798
Garrett	21520, 21522, 21531, 21536, 21538, 21541, 21550, 21561
Harford East	21001, 21005, 21017, 21018, 21024, 21028, 21034, 21078, 21130
Harford West	21009, 21010, 21014, 21015, 21040, 21047, 21050, 21084, 21085, 21101, 21132, 21154, 21160
Howard County	20723, 20759, 20763, 20777, 20794, 21029, 21036, 21041, 21042, 21043, 21044, 21045, 21046, 21150, 21723, 21737, 21738, 21765, 21794, 21797
Kent	21610, 21620, 21635, 21637, 21645, 21646, 21650, 21661, 21667, 21678
Montgomery Mid-County	20812, 20813, 20814, 20815, 20816, 20817, 20818, 20824, 20825, 20827, 20830, 20832, 20833, 20848, 20849, 20850, 20851, 20852, 20853, 20854, 20855, 20857, 20859, 20889, 20891, 20892, 20895, 20896
Montgomery North	20837, 20838, 20839, 20841, 20842, 20847, 20871, 20872, 20874, 20875, 20876, 20877, 20878, 20879, 20880, 20882, 20883, 20884, 20885, 20886, 20898, 20997
Montgomery - Silver Spring	20860, 20861, 20862, 20866, 20868, 20901, 20902, 20903, 20904, 20905, 20906, 20907, 20908, 20910, 20911, 20912, 20913, 20914, 20915, 20916, 20918, 20990
Prince George's Northeast	20704, 20705, 20707, 20708, 20709, 20715, 20716, 20717, 20718, 20719, 20720, 20721, 20725, 20726, 20769

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Prince George's Northwest	20703, 20706, 20710, 20712, 20722, 20731, 20737, 20738, 20740, 20741, 20742, 20743, 20768, 20770, 20771, 20780, 20781, 20782, 20783, 20784, 20785, 20787, 20788, 20789, 20791, 20792, 20797, 20799
Prince George's Southeast	20608, 20613, 20623, 20735, 20762, 20772, 20773, 20774, 20775
Prince George's Southwest	20607, 20744, 20745, 20746, 20747, 20748, 20749, 20750, 20752, 20753, 20757, 20790
Queen Anne's	21607, 21617, 21619, 21623, 21628, 21638, 21644, 21651, 21656, 21657, 21658, 21666, 21668
Somerset	21816, 21817, 21820, 21821, 21824, 21836, 21838, 21853, 21857, 21866, 21867, 21886, 21870, 21871, 21890
St. Mary's	20606, 20609, 20618, 20619, 20620, 20621, 20624, 20626, 20627, 20628, 20630, 20634, 20635, 20636, 20650, 20653, 20656, 20659, 20660, 20667, 20670, 20674, 20680, 20684, 20686, 20687, 20690, 20692
Talbot	21601, 21612, 21624, 21625, 21647, 21652, 21653, 21654, 21662, 21663, 21665, 21671, 21673, 21676, 21679
Washington	21711, 21713, 21715, 21719, 21720, 21721, 21722, 21733, 21734, 21740, 21741, 21742, 21746, 21750, 21756, 21767, 21779, 21781, 21782, 21783, 21795
Wicomico	21801, 20802, 21803, 21804, 21810, 21814, 21822, 21826, 21830, 21837, 21840, 21849, 21850, 21852, 21856, 21861, 21865, 21874, 21875
Worcester	21811, 21813, 21829, 21841, 21842, 21843, 21851, 21862, 21863, 21864, 21872

E. For purposes of this regulation:

(1) Urban enrollment area includes Baltimore City;

(2) Rural enrollment counties include:

(a) Allegany;

(b) Calvert;

(c) Caroline;

(d) Cecil;

(e) Charles;

(f) Dorchester;

(g) Frederick;

(h) Garrett;

(i) Kent;

(j) Queen Anne's;

(k) Saint Mary's;

(l) Somerset;

- (m) Talbot;
 - (n) Washington;
 - (o) Wicomico; and
 - (p) Worcester; and
- (3) Suburban enrollment counties include:
- (a) Baltimore County;
 - (b) Anne Arundel;
 - (c) Carroll;
 - (d) Harford;
 - (e) Howard;
 - (f) Montgomery; and
 - (g) Prince George's.

.07 ACCESS STANDARDS: CLINICAL AND PHARMACY ACCESS.

A. Appointments.

(1) New Enrollees: Initial Appointment.

- (a) On its receipt and review of the health service needs information of a new enrollee, an MCO shall take appropriate action to ensure that the new enrollee who needs special or immediate health care services, as identified by the health service needs information, receives them in a timely manner.
- (b) Unless the new enrollee is assigned to a PCP who was the enrollee's established provider of care immediately before the enrollee's enrollment, and, consistent with any applicable periodicity schedule, the PCP concludes that no immediate initial appointment is necessary:
 - (i) Unless a shorter time frame otherwise applies, the MCO shall ensure that a new enrollee's initial appointment is scheduled to occur within 90 days of the date of enrollment;
 - (ii) Unless the PCP confirms that the enrollee has elected to continue prenatal care with her established provider pursuant to COMAR 10.67.06.28C, the MCO shall ensure that an initial prenatal appointment is scheduled to occur within 10 days of the date that the MCO receives the enrollee's completed health risk assessment, or within 10 days of the enrollee's request for an appointment, whichever is sooner;
 - (iii) If the new enrollee is a person requesting family planning services, the MCO shall ensure that an initial appointment is scheduled to occur within 10 days of the date of the enrollee's request for an appointment; or
 - (iv) If the new enrollee is identified to be at high risk by the health service needs information form, the MCO shall ensure that an initial appointment is scheduled to occur within 15 business days of the MCO's receipt of the enrollee's completed health risk assessment.

(2) Required Notice to Enrollees of Wellness Services.

(a) An MCO shall notify its enrollees in writing of their due dates for obtaining wellness services, including but not limited to immunizations and examinations, in a timely manner.

(b) An MCO shall perform the notice required in §A(2)(a) of this regulation within 90 days of a new enrollee's enrollment.

(3) Appointment Guidelines.

(a) An MCO shall develop specific guidelines that define how requests for appointments are arranged, which shall include a policy that:

(i) On request, all family members needing appointments will be given appointment times that are approximately concurrent or consecutive, whenever practicable, to facilitate the enrollees' transportation to and from their appointments; and

(ii) When needed, enrollees will be afforded assistance in securing transportation to and from appointments, which shall include, when appropriate, contacting the local transportation grantee agency on behalf of the enrollee for the purpose of securing the enrollee's access to these services.

(b) An MCO shall have procedures that result in an interval between the enrollee's request for an appointment and the actual appointment time being consistent with the following standards:

(i) When §A(3)(b)(i) of this regulation does not apply, well-child assessments shall be scheduled to be completed within 30 days of the request for an appointment;

(ii) Initial assessments of pregnant and postpartum women and individuals requesting family planning services shall be scheduled to be completed within 10 business days of the request for an appointment;

(iii) Individuals requesting urgent care shall be scheduled to be seen within 48 hours of the request;

(iv) Requests for routine and preventative primary care appointments shall be scheduled to be performed within 30 days of the request;

(v) Requests for routine specialist follow-up appointments shall be scheduled to be performed within 30 days of the initial authorization from the enrollee's primary care provider, or sooner as deemed necessary by the primary care provider, whose office staff shall make the appointment directly with the specialist's office;

(vi) At the discretion of the newborn's PCP, the initial visit for newborns shall be scheduled to be performed within 14 days of discharge from the hospital if no home visit has occurred;

(vii) If a home visit has been provided, the initial visit for newborns shall be scheduled to be performed, at the discretion of the newborn's PCP, within 30 days of discharge from the hospital; and

(viii) Requests for regular optometry, lab, and X-ray appointments shall be scheduled to be performed within 30 days of the request, and within 48 hours of the request for urgent care.

B. An MCO shall respond in a timely manner to its enrollees' needs and requests, as follows:

(1) If the enrollee arrives early or on time for a scheduled appointment, waiting time to be seen for a regular office visit may not exceed 1 hour after the scheduled appointment time;

(2) An MCO representative may not leave an enrollee's telephone call on hold for more than 10 minutes; and

(3) An MCO representative shall respond to patient inquiries as to whether or not to use emergency facilities within 30 minutes.

C. Hours of Access for Clinical Services.

(1) An MCO shall establish, or require its subcontractors to establish, a reasonable schedule of operating hours during which its service delivery sites are open to the MCO's enrollees as follows:

(a) For the MCO's employee and subcontractor providers who are individual practitioners, operating hours shall be at least 20 hours per week and at least 3 days per week;

(b) For subcontractors who have contracted with the MCO as a group practice or facility, the operating hours shall be at least 35 hours per week;

(c) The distribution of the hours of service shall be consistent with enrollee utilization patterns, but is otherwise at the discretion of the MCO or its subcontractor; and

(d) The operating hours may not be less than:

(i) The hours of operation offered to commercial enrollees; or

(ii) The hours of operation offered to Medicaid fee-for-service, if the provider serves only Medicaid enrollees.

(2) Hours of Access for Pharmacy Services.

(a) An MCO shall establish reasonable hours of access to pharmacy services, including weekend and evening hours, which are equivalent to the hours pharmacy services are generally available in the local access area to the public at large.

(b) If the MCO determines that weekend and evening pharmacy hours are not generally available in the local access area, it may request approval from the Department to offer only limited pharmacy hours as specified in §C(2)(c) of this regulation.

(c) To seek approval to offer limited pharmacy hours, an MCO shall make its request for approval to the Department, and shall include the following:

(i) A specification of the geographical areas where the MCO intends to have limited pharmacy hours;

(ii) An explanation of why only limited pharmacy hours are available in these areas; and

(iii) An identification of where its enrollees would have to go to secure prescriptions in the evenings and on weekends.

(d) Except as permitted in §C(2)(e) of this regulation, an MCO shall ensure that an enrollee receives at the time the prescription is dispensed to the enrollee any medically necessary disposable medical supplies or durable medical equipment needed by the enrollee to administer or monitor the enrollee's prescriptions.

(e) An MCO shall ensure that any disposable supplies or durable medical equipment necessary to administer or monitor an enrollee's prescriptions, if not available at the pharmacy at the time of the dispensing of the prescription, is received in a manner so as not to adversely affect the health of the enrollee, but not later than 24 hours.

D. Clinical Access Outside the MCO's Service Area.

(1) Subject to §D(2) of this regulation, an MCO shall be financially responsible for medically necessary emergency services delivered to its enrollees outside of the MCO's service area.

(2) With the exception of emergency services, an MCO may require authorization before treatment for services delivered to its enrollees outside of the MCO's service area.

(3) If the MCO's provider network is unable to provide necessary services, covered under the contract, to an enrollee, the MCO shall adequately and timely cover these services out of network for as long as the MCO's provider network is unable to provide them.

E. The Department may not impose any fines or other sanctions against an MCO for failure to comply with the waiting time standards in §B of this regulation unless there is evidence of a pattern of repeated violations by the MCO.

.08 EMERGENCY SERVICES ACCESS.

A. An MCO shall develop and maintain policies and procedures for the adequate provision of emergency services for all its enrollees, including:

(1) Instituting and monitoring a system for responding to enrollees' emergency medical conditions, with provisions for immediate attention to and appropriate disposition of emergency calls; and

(2) Informing and educating its enrollees in the procedures to be followed in the event of an emergency, whether within or outside of the MCO's service area.

B. An MCO shall provide medically necessary emergency services 24 hours per day, 7 days per week.

C. An MCO shall maintain an emergency telephone service, with a physician on call, for the purpose of rendering medical advice and authorizing care at other facilities when use of the MCO's own facilities is impractical.

D. An MCO may provide emergency services access through adequate and appropriate triage assessments performed by qualified medical professionals.

E. An MCO shall utilize the trauma triage and transfer protocols established through the Maryland Institute for Emergency Medical Services Systems (MIEMSS) as the basis for directing the severely injured enrollee to the most appropriate level designated trauma center.

F. An MCO shall reimburse, within 30 days of invoice, the undisputed claims of hospital emergency facilities and providers for the following services provided to the MCO's enrollees:

(1) Emergency services, as defined in COMAR 10.67.01.01B;

(2) Medical screening services based on the federal Emergency Medical Treatment and Active Labor Act (EMTALA);

(3) If the MCO authorized, referred, or otherwise instructed the enrollee to use the emergency facility, medically necessary services that are related to the emergency condition, including poststabilization services; and

(4) If the MCO fails to provide 24 hour access to a physician, medically necessary services that relate to the condition presented and that are provided by the provider in an emergency facility to the enrollee.

G. Poststabilization Services. The MCO may not require preapproval of, and is financially responsible for, poststabilization services obtained in or outside of the MCO's network and administered to maintain, improve, or resolve the enrollee's stabilized condition if:

- (1) The MCO does not respond to a request for a preapproval within 1 hour;
- (2) The MCO cannot be contacted; or
- (3) The MCO representative and the treating physician cannot reach an agreement concerning the enrollee's care, and an MCO physician is not available for consultation, in which case:
 - (a) The MCO shall give the treating physician the opportunity to consult with an MCO physician; and
 - (b) The treating physician may continue care of the patient until a plan is reached or one of the following criteria is met:
 - (i) An MCO physician with privileges at the treating hospital assumes responsibility for the enrollee's care;
 - (ii) An MCO physician assumes responsibility for the enrollee's care through transfer;
 - (iii) An MCO representative and the treating physician reach an agreement concerning the enrollee's care; or
 - (iv) The enrollee is discharged.

H. An MCO may require that any continuing care be obtained from the MCO's providers or from providers approved by the MCO when the following conditions are satisfied:

- (1) The enrollee's medical condition is appropriately stabilized and permits transferring responsibility for the enrollee's care, without medically harmful consequences, to these providers; and
- (2) The transfer is consistent with the requirements of the federal Emergency Medical Treatment and Active Labor Act (EMTALA).

.09 ACCESS: HOSPITALS.

- A. An MCO shall comply with the access standards specified in Regulation .06A of this chapter.
- B. If an MCO's service area includes a county that is designated as a medically underserved area and there is only one hospital in the county, the MCO shall include the hospital in its network.

CHAPTER 06 MARYLAND MEDICAID MANAGED CARE PROGRAM: BENEFITS

.01 REQUIRED BENEFITS PACKAGE — IN GENERAL.

A. Except for non-covered services set forth in Regulation .27 of this chapter and the non-capitated services described in COMAR 10.67.08, an MCO shall provide its enrollees with a benefits package that includes the covered services specified in this chapter when these services are deemed to be medically necessary including services covered under the Maryland Medicaid State Plan in the amount, duration, and scope set forth in the State Plan and in accordance with 42 CFR §440.230.

B. An MCO shall ensure that the services provided are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.

C. An MCO is not required to provide non-covered services even when the service is medically necessary.

D. Any limitations set forth in this chapter on covered services are not applicable to services required by enrollees who are younger than 21 years old when it is shown that the services are medically necessary to correct or lessen health problems detected or suspected by EPSDT screening services, as described in Regulation .20 of this chapter.

E. An MCO may place appropriate limits on a service on the basis of criteria applied under the State plan, such as medical necessity.

F. Cost Sharing and Prohibitions.

(1) Except for the following, an MCO may not charge its enrollees any copayments, premiums, or cost sharing:

- (a) Up to a \$3 copayment for brand-name drugs;
- (b) Up to a \$1 copayment for generic drugs;
- (c) Any other charge up to fee-for-service limits as approved by the Department.

(2) An MCO may not:

- (a) Deny services to an individual who is eligible for services because of the individual's inability to pay the cost sharing;
- (b) Impose copayments for the following:
 - (i) Family planning services and supplies;
 - (ii) Individuals younger than 21 years old;
 - (iii) Pregnant women;
 - (iv) Institutionalized individuals who are inpatients in long-term care facilities or other institutions; and
 - (v) Emergency services.
- (c) Arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the enrollee.

G. An MCO shall ensure that all health care services provided under this chapter are performed, to the extent required by law, by an appropriate health care provider who is licensed, certified, or otherwise legally authorized to practice or deliver the services in the state in which the service is provided.

H. An MCO shall provide for a second opinion from a qualified health care professional within the network, or, if necessary, arrange for the enrollee to obtain one outside the MCO network.

.02 BENEFITS — PRIMARY CARE SERVICES.

An MCO shall provide to its enrollees medically necessary primary care services that are provided:

- A. By the enrollee's PCP;
- B. At the direction of the enrollee's PCP; or
- C. With respect to a primary care service that is self-referred pursuant to Regulation .28 of this chapter:

(1) By an appropriate practitioner, acting within the scope of the practitioner's license, certification, or other legal authorization, and in accordance with the practitioner's training and experience; or

(2) By a clinic that furnishes health care services by or under the direction of a physician.

.03 BENEFITS — PHYSICIAN AND ADVANCED PRACTICE NURSE SPECIALTY CARE SERVICES.

A. An MCO shall provide to its enrollees medically necessary specialty care services that are outside of the enrollee's PCP's scope of practice, or, in the judgment of the enrollee's PCP, are not services that the PCP customarily provides, is specifically trained for, or is experienced in and are provided by:

(1) A physician or an advanced practice nurse, acting within the scope of the individual's license or certification, training, and experience;

(2) A practitioner other than a physician or an advanced practice nurse when the practitioner is in a physician's employ, is under the physician's direct supervision, and performs the service within the scope of the practitioner's license, certification, or other legal authorization, for the purpose of assisting in the provision of the specialty care service;

(3) A clinic that furnishes health care services by or under the direction of a physician; or

(4) For enrollees who are younger than 21 years old, a doctor of dental medicine or dental surgery, if the services are surgical services that are also typically performed by physicians.

B. Notwithstanding §A(2) of this regulation, specialty care services provided under Regulations .04—.25 of this chapter may include medically necessary diagnostic and treatment services provided by a physician or other appropriate practitioner, acting within the scope of the practitioner's license, certification, or other legal authorization, and in accordance with the practitioner's training and experience.

.04 BENEFITS — PHARMACY SERVICES.

A. An MCO shall provide outpatient drugs as defined in §1927(k)(2) of the Social Security Act.

B. An MCO shall provide to its enrollees all medically necessary pharmaceutical services and pharmaceutical counseling, including but not limited to:

(1) Legend drugs;

(2) Insulin;

(3) All FDA approved contraceptives;

(4) Hypodermic needles and syringes;

(5) Enteral nutritional and supplemental vitamins and mineral products given by nasogastric, jejunostomy, or gastrostomy tube in the home;

(6) Enteric coated aspirin prescribed for the treatment of arthritic conditions;

(7) Nonlegend ferrous sulfate oral preparations;

(8) Nonlegend chewable tablets of any ferrous salt when combined with vitamin C, multivitamins, multivitamins and minerals, or other minerals in the formulation when the enrollee is younger than 12 years old;

- (9) Medical supplies used in the preparation of compounded prescriptions for home intravenous therapy;
- (10) Medical supplies or equipment used in the administration or monitoring of medication prescribed or ordered for an enrollee by a qualifying provider as specified in §B of this regulation;
- (11) Latex condoms;
- (12) Nonlegend ergocalciferol liquid (Vitamin D); and
- (13) Emergency contraceptives for female recipients.

C. Except as provided in §B of this regulation, an MCO is required to provide only those drugs and related pharmaceutical products that are prescribed or ordered by:

- (1) An MCO provider;
- (2) An out-of-plan provider, when the pharmacy services are ordered or prescribed in connection with medical care furnished by the provider to the MCO's enrollee:
 - (a) In response to the enrollee's emergency medical condition; or
 - (b) Pursuant to the enrollee's self-referral to the provider, when the care delivered qualifies as a permissible self-referred service under Regulation .28 of this chapter; or
- (3) A behavioral health provider for drugs not in the behavioral health formulary.

D. An MCO shall provide over-the-counter emergency contraceptives and latex condoms to enrollees without requiring an order from an authorized prescriber.

E. An MCO shall provide coverage for the following when performed by a pharmacist:

- (1) Contraceptive services, as follows:
 - (a) A patient assessment performed at the pharmacist's practice location in order to determine:
 - (i) Whether to prescribe contraceptives; and
 - (ii) Which contraceptive options to prescribe; and
 - (b) If contraceptives are prescribed, a referral:
 - (i) To the participant's primary care practitioner or reproductive health care practitioner; or
 - (ii) If the participant does not have a primary care practitioner or a reproductive health care practitioner, to a family planning provider or a licensed clinician who provides reproductive health care services.
- (2) Administration of:
 - (a) Injectable medications for the treatment of sexually transmitted infection; and
 - (b) Maintenance injectables medications.

F. Drug Formulary.

- (1) An MCO shall establish and maintain a drug formulary that is at least equivalent to the standard therapies of the Maryland Medical Assistance Program, and include at a minimum:

- (a) Covered generic and name brand medications; and
 - (b) The tier each medication is on.
- (2) An MCO shall include in its formulary drugs that are appropriate for medical management, safe, and effective.
- (3) An MCO shall expand its formulary, as needed, to include drugs that are equivalent to new drugs approved by the federal Food and Drug Administration, and which are deemed to be appropriate, safe, and efficacious in the medical management of the MCO's enrollees.
- (4) An MCO shall include in its formulary the following drugs:
- (a) Leuprolide acetate;
 - (b) Clonidine;
 - (c) Guanfacine;
 - (d) Medroxyprogesterone; and
 - (e) Liothyronine.
- (5) To ensure that its formulary drugs are medically necessary, safe, and efficacious, an MCO shall:
- (a) Subject its formulary to a review process that is:
 - (i) Established and conducted by the MCO's Pharmacy and Therapeutics Committee;
 - (ii) Approved by the Department; and
 - (iii) Coordinated with the formulary review process of the Specialty Mental Health Services delivery system; and
 - (b) Submit its formulary for the review and approval of the Department, based upon the standards set forth in this regulation.
- (6) Unless approved by the Department, an MCO may not require or utilize prior authorization or step therapy criteria for coverage of formulary drugs if such prior authorization or step therapy requires a recipient to use a drug that is included in the behavioral health formulary.
- G. Any option for accessing pharmacy services by mail order may be implemented only at the request of the enrollee except for when the drug is a specialty drug as defined in §G of this regulation.
- H. In this regulation, the term "specialty drug" means:
- (1) A prescription drug that:
 - (a) Is prescribed for an individual with a complex, chronic or rare medical condition;
 - (b) Costs \$600 or more for up to a 30-day supply;
 - (c) Is not typically stocked at retail pharmacies; and
 - (d) Requires a difficult or unusual process of delivery to the patient in the preparation, handling storage, inventory or distribution of the drug; or

(2) Requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

I. If an enrollee subsequently requests to use a retail pharmacy for specialty drugs the MCO may not limit the enrollee to the use of a mail order pharmacy.

J. An MCO shall:

(1) Establish and maintain a drug utilization review program;

(2) Adhere to the minimum performance standards established by the Department for these programs, whenever used, including but not limited to standards for the following drug use management components:

(a) Formulary management;

(b) Generic substitution;

(c) Therapeutic substitution;

(d) Prior authorization that complies with the requirements of §1927(d)(5) of the Social Security Act;

(e) Drug use evaluation (DUE);

(f) Disease management; and

(g) Pharmacy and Therapeutic Committee;

(3) Establish procedures to distinguish drug utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program; and

(4) Provide to the Department a detailed description of its drug utilization review program activities on an annual basis.

K. The Department shall:

(1) Review each MCO's drug utilization review program annually; and

(2) Notify an MCO annually if any of the standards established in §I(2) of this regulation have not been met.

L. For any performance standard identified in §J(2) of this regulation, MCOs shall acknowledge any deficiencies within 30 days and correct any deficiencies within 90 days or be subject to sanctions listed in COMAR 10.67.10.01A and B.

.05 BENEFITS — HOME HEALTH SERVICES.

A. Subject to the conditions specified in §B of this regulation, an MCO shall provide to its enrollees medically necessary home health services, including:

(1) Skilled nursing services, including the supervisory visits required by §A(2) of this regulation;

(2) Home health aide services, including biweekly supervisory visits by a registered nurse in the recipient's home, every second visit of which includes observations of the delivery of services by the aide to the enrollee;

(3) Physical therapy services;

- (4) Occupational therapy services;
- (5) Speech pathology services; and
- (6) Medical supplies that are used during a home health visit.

B. An MCO shall provide the home health services specified in §A of this regulation that are:

- (1) Certified by the enrollee's PCP or by the enrollee's attending physician to be required on a part-time, intermittent basis; and
- (2) Rendered in the enrollee's home.

.06 BENEFITS — HABILITATION SERVICES FOR MEDICAID EXPANSION POPULATIONS.

A. An MCO shall provide the following medically necessary habilitation services to enrollees eligible for Medical Assistance under §1902 (a)(10)(A)(i)(VIII) of the Social Security Act:

- (1) Physical therapy;
- (2) Occupation therapy; and
- (3) Speech therapy.

B. At a minimum, an MCO shall provide the services in hospital inpatient and outpatient departments and physical therapy in an outpatient community setting.

.07 BENEFITS — INPATIENT HOSPITAL SERVICES.

A. An MCO shall provide to its enrollees medically necessary inpatient hospital services as specified in this regulation.

B. Admission to Long-Term Care Facility.

(1) An MCO shall provide to its enrollees medically necessary long-term care facility services for:

- (a) The first 90 continuous days following the enrollee's admission; and
 - (b) Any days following the first 90 continuous days of an admission until the date the MCO has obtained the Department's determination that the admission is medically necessary as specified in §B(2) of this regulation.
- (2) For any long-term care facility admission that is expected to result in a length of stay exceeding 90 days, an MCO or long-term care facility shall request a determination by the Department that the admission is medically necessary.
- (3) The Department's determination as described in §B(2) of this regulation is only applicable if the enrollee is still in the long-term care facility on the 91st day.
- (4) Acute care services provided within the first 90 days following an enrollee's admission to a long-term care facility do not constitute a break in calculating the 90 continuous day requirement if the enrollee is discharged from the hospital back to the long-term care facility.

C. The Department shall render a determination with respect to the medical necessity of a stay in a long-term care facility as specified in §B of this regulation within 3 business days of receipt of a complete application from the MCO.

D. Childbirth — Length of Stay and Home Visits.

(1) Except as provided in §D(2) and (3) of this regulation, the criteria and standards used by an MCO in performing utilization review of hospital services related to maternity and newborn care, including length of stay, shall be in accordance with the medical criteria outlined in the Guidelines for Perinatal Care, which is incorporated by reference in COMAR 10.67.04.01.

(2) Unless the enrollee decides, in consultation with her attending provider, that less time is needed for recovery, an MCO shall provide or reimburse the cost of hospitalization including at least the following length of stay for an enrollee recovering from childbirth:

(a) 48 hours of inpatient hospitalization care following an uncomplicated vaginal delivery; or

(b) 96 hours of inpatient hospitalization care following an uncomplicated cesarean section.

(3) If the enrollee elects to be discharged earlier than the length of stay specified in §D(2) of this regulation, the MCO is required to provide a home visit or visits pursuant to Regulation .21B—D of this chapter.

E. In addition to the mother's length of stay required to be afforded by §D(2) of this regulation, whenever a mother is required to remain hospitalized after childbirth for medical reasons and she requests that her newborn remain in the hospital while she is hospitalized, the MCO shall afford the newborn additional hospitalization while the mother remains hospitalized, for up to 4 days.

F. If an enrollee is in the hospital at the time of disenrollment from the MCO, and remains eligible for Medical Assistance, the MCO is responsible for covering the remainder of that hospital admission following disenrollment.

G. An MCO shall provide for a private hospital room when:

(1) The enrollee's condition requires a need for isolation; or

(2) The enrollee requires admission and only private rooms are available.

H. Payment for Ancillary Services.

(1) Effective January 1, 2009, an MCO shall pay for all medically necessary ancillary services provided on inpatient hospital days including those days for which the inpatient hospitalization is otherwise appropriately denied.

(2) A denial of an inpatient ancillary service shall be based on the medical necessity of the specific ancillary service.

(3) An MCO is not required to pay for ancillary services if the entire hospitalization in §H(1) of this regulation is appropriately denied.

I. Transports between hospitals are covered by the MCO when:

(1) A medically necessary covered service is not available at the hospital where an enrollee is being treated; and

(2) The enrollee is not being discharged from the sending hospital.

.08 BENEFITS — OUTPATIENT HOSPITAL SERVICES.

An MCO's benefits package shall include medically necessary outpatient hospital services.

.09 BENEFITS — TRANSPLANTS.

An MCO shall provide to its enrollees medically necessary transplants.

.11 BENEFITS — DIAGNOSTIC AND LABORATORY SERVICES.

An MCO shall provide to its enrollees medically necessary:

A. Diagnostic services; and

B. Laboratory services, performed by a provider who:

(1) Is Clinical Laboratory Improvement Amendments (CLIA) certified; or

(2) Has a waiver of a certificate registration along with a CLIA identification number.

.12 BENEFITS — LONG-TERM CARE FACILITY SERVICES.

A. An MCO shall provide to its enrollees medically necessary services in a chronic hospital, a chronic rehabilitation hospital, or a nursing facility for:

(1) The first 90 continuous days following the enrollee's admission; and

(2) Any days following the first 90 continuous days of an admission until the date the MCO has obtained the Department's determination that the admission is medically necessary as specified in §C of this regulation.

B. Acute care services provided within the first 90 days following an enrollee's admission to a long-term care facility do not constitute a break in calculating the 90 continuous day requirement if the enrollee is discharged from the hospital back to the long-term care facility.

C. For any long-term care facility admission that is expected to result in a length of stay exceeding 90 days, an MCO or long-term care facility shall request a determination by the Department that the admission is medically necessary.

D. The Department's determination as described in §C of this regulation is only applicable if the enrollee is still in the long-term care facility on the 91st day.

E. The Department shall render a determination with respect to the medical necessity of a stay in a nursing facility as specified in §C of this regulation within 3 business days of receipt of a complete application from the MCO.

F. A determination by the Department that the admission is medically necessary does not relieve the MCO of the obligation to pay for the admission through the day on which the determination is made.

G. An MCO shall use the Department's criteria for determining medical necessity for the days described in §A(1) of this regulation.

.13 BENEFITS — DISPOSABLE MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPMENT.

A. An MCO shall provide to its enrollees medically necessary disposable medical supplies and durable medical equipment, including but not limited to:

- (1) All supplies and equipment used in the administration or monitoring of prescriptions by the enrollees; and
 - (2) Incontinency pants and disposable underpads for medical conditions associated with prolonged urinary or bowel incontinence if necessary to prevent institutionalization or infection.
- B. Except as required in §C(1), an MCO shall provide preauthorization within 72 hours for DMS/DME services and supplies that require preauthorization by the MCO.
- C. An MCO shall provide its enrollees the disposable medical supplies and durable medical equipment in a timely manner so as to not adversely affect the health of the enrollees, in accordance with the following:
- (1) For medical equipment or supplies, or both, when there is an urgent medical need such as to facilitate hospital discharge or when a potential exists for worsening of enrollee's condition, the MCO shall provide needed items within 24 hours of request; and
 - (2) For all other requests for DMS/DME, the MCO shall provide these items within 7 days from the date of request unless the MCO can document to the Department that justification for additional time is necessary.
- D. An MCO is responsible for paying for any durable medical equipment authorized and ordered while the member is active with the MCO if:
- (1) The delivery of the item occurs within 90 days after the member's termination date from the MCO; and
 - (2) The member remains a Medicaid recipient.

.14 BENEFITS — VISION CARE SERVICES.

- A. An MCO shall provide to its enrollees medically necessary vision care services as specified in this regulation.
- B. For enrollees who are 21 years old or older, the MCO is responsible for providing at least one eye examination every 2 years.
- C. For its enrollees who are younger than 21 years old, the MCO is responsible for providing medically necessary vision services, including but not limited to:
- (1) At least one eye examination every year in addition to any vision screen performed as part of an EPSDT screen;
 - (2) Eyeglasses, limited to one pair per year unless lost, stolen, broken, or no longer vision appropriate; and
 - (3) Contact lenses, if medically necessary and if eyeglasses are not efficacious for the condition.

.15 BENEFITS — PODIATRY SERVICES.

- A. An MCO shall provide for its enrollees medically necessary podiatry services.
- B. In addition to the services described in §A of this regulation, an MCO shall provide:
- (1) Diabetes care services specified in COMAR 10.67.06.24; and
 - (2) Routine foot care for enrollees, 21 years old or older with vascular disease affecting the lower extremities

.16 BENEFITS — OUTPATIENT REHABILITATIVE SERVICES.

An MCO shall provide to its enrollees medically necessary outpatient rehabilitative services, including but not limited to physical therapy for adult enrollees.

.17 BENEFITS — OXYGEN AND RELATED RESPIRATORY EQUIPMENT.

An MCO shall provide to its enrollees medically necessary oxygen and related respiratory equipment services.

.18 BENEFITS — DIALYSIS SERVICES.

An MCO shall provide to its enrollees medically necessary dialysis services.

.19 BENEFITS — FAMILY PLANNING SERVICES.

A. An MCO shall provide to its enrollees comprehensive family planning services, including but not limited to medically necessary office visits and laboratory tests, all FDA-approved contraceptive devices, methods, and supplies, and voluntary sterilizations.

B. An MCO may place appropriate limits on family planning services for the purpose of utilization control, provided that 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 42 CFR §441.20.

C. An MCO may not apply a copayment or coinsurance requirement for contraceptive drugs or devices.

D. An MCO shall provide coverage for a single dispensing of a supply of prescription contraceptives for a 12-month period.

.20 BENEFITS — EPSDT SERVICES.

A. An MCO shall provide, to enrollees younger than 21 years old, medically necessary Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services, including:

(1) EPSDT comprehensive well-child services provided in accordance with the EPSDT periodicity schedule and performed by an EPSDT-certified provider, including:

(a) A comprehensive health and developmental history, including an evaluation of both physical and mental health development;

(b) A comprehensive unclothed physical exam;

(c) Immunizations appropriate to age and health history;

(d) Laboratory tests, including blood lead level assessment, as appropriate to age and risk;

(e) Health education, including anticipatory guidance; and

(f) Vision, hearing, and dental screening;

(2) EPSDT partial or interperiodic well-child services; and

(3) Health care services that are:

(a) Necessary to prevent, treat, or ameliorate physical, mental, or developmental problems or conditions identified by an EPSDT-certified provider or other health professional;

(b) Sufficient in amount, duration, and scope to treat the identified condition; and

(c) Subject to limitation only on the basis of medical necessity.

B. The health care services described in §A(3) of this regulation shall include, at a minimum, all services described in this chapter, and the following:

(1) Chiropractic services;

(2) Nutrition counseling services;

(3) Private duty nursing services including:

(a) An initial assessment and development of a plan of care by a registered nurse; and

(b) On-going private duty nursing services delivered by a licensed practical nurse or a registered nurse; and

(4) Durable medical equipment.

C. An MCO shall provide referrals for services not covered by Medicaid, but which are furnished at little or no cost to recipients, including appropriate referrals to:

(1) The Head Start Program;

(2) The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC);

(3) School Health-Related Special Education Services;

(4) Vocational Rehabilitation; and

(5) Maternal and Child Health Services located at local health departments.

.21 BENEFITS — PREGNANCY-RELATED SERVICES

A. An MCO shall provide to its pregnant and postpartum enrollees medically necessary pregnancy-related services, including:

(1) Comprehensive prenatal, perinatal, and postpartum care, including high-risk specialty care when appropriate;

(2) Prenatal risk assessment and development of an individualized plan of care that specifies the actions required to address each identified need and is appropriately modified during the course of care;

(3) Enriched maternity services, including:

(a) Prenatal and postpartum counseling and education;

(b) Basic nutritional education;

(c) Substance abuse treatment, as provided in Regulation .10 of this chapter;

(d) Appropriate referrals to services that may improve the pregnancy outcome, including:

- (i) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and
- (ii) Healthy Start services;
- (e) High-risk nutrition counseling services for nutritionally high-risk pregnant women;
- (f) Appropriate levels of inpatient care, including emergency transfer of pregnant women and newborns to tertiary care centers;
- (g) Smoking cessation education and treatment;
- (h) Doula services; and
- (i) Home visiting services.

B. When an enrollee recovering from childbirth elects to be discharged before 48 hours following a normal vaginal delivery or 96 hours following an uncomplicated cesarean section, the MCO is responsible for providing:

- (1) One home visit scheduled to occur within 24 hours after discharge; and
- (2) An additional home visit as may be prescribed by the attending provider.

C. When an enrollee recovering from childbirth and her newborn enrollee remain in the hospital for at least as long as the period of time provided under §B of this regulation, the MCO shall provide a home visit as prescribed by the attending provider.

D. An MCO shall provide for home visits required by §§B and C of this regulation to be performed by a registered nurse and in accordance with generally accepted standards of nursing practice for home care of a mother and newborn child, including:

- (1) An evaluation of the presence of immediate problems of dehydration, sepsis, infection, jaundice, respiratory distress, cardiac distress, or other adverse physical symptoms of the infant;
- (2) An evaluation of the presence of immediate problems of dehydration, sepsis, infection, bleeding, pain, or other adverse symptoms of the mother;
- (3) Collection of a blood specimen for newborn screening if not previously completed;
- (4) Referrals for any medically necessary continuing health care services; and
- (5) Any other nursing services ordered by the referring provider.

.22 BENEFITS — CASE MANAGEMENT SERVICES FOR HIV-INFECTED INDIVIDUALS

An MCO shall provide medically necessary case management services to its qualifying enrollees, as specified in COMAR 10.67.04.10C.

.23 BENEFITS — HOSPICE CARE SERVICES

A. An MCO shall include in its benefits package medically necessary hospice care services to enrollees who are terminally ill.

B. The Department shall allow an enrollee to disenroll from an MCO and choose a new MCO if:

(1) The enrollee was auto-assigned to the MCO; and

(2) The enrollee's hospice provider does not contract with the enrollee's assigned MCO.

C. If an enrollee who is in a hospice that does not contract with the enrollee's MCO and the enrollee will not voluntarily choose a new MCO, the enrollee's current MCO:

(1) Shall authorize and pay the out-of-network hospice provider at the established Medicaid rate, to ensure continuity of care; and

(2) May not require the hospice care enrollee to change their out-of-network hospice provider to an in-network hospice provider.

.24 BENEFITS – DIABETIC CARE SERVICES.

A. An MCO shall provide to its qualifying enrollees medically necessary diabetes prevention and care services as specified in this regulation.

B. National Diabetes Prevention Program.

(1) In addition to the services included in its usual benefits package, an MCO shall make available to its enrollees who meet the Centers for Disease Control and Prevention (CDC) eligibility criteria defined in §B(2) of this regulation the National Diabetes Prevention Program through a CDC-recognized lifestyle change organization.

(2) To be eligible for participation in the National Diabetes Prevention Program, a HealthChoice enrollee:

(a) Shall be 18 through 64 years old;

(b) Shall be overweight or obese;

(c) Shall have an elevated blood glucose level or a history of gestational diabetes mellitus;

(d) May not have a previous diagnosis of type 1 or type 2 diabetes prior to enrollment; and

(e) May not be currently pregnant.

C. In addition to the services included in its usual benefits package, an MCO shall provide enrollees with a diabetes diagnosis the following medically necessary special diabetes-related services:

(1) Diabetes nutrition counseling, consisting of one initial one-on-one session and up to 4 subsequent sessions annually;

(2) Diabetes outpatient education;

(3) Diabetes-related durable medical equipment, disposable medical supplies, and therapeutic footwear and related services, when ordered as medically necessary, including:

(a) Therapeutic footwear, orthopedic shoes, arch supports, orthotic devices, in-shoe supports, elastic support, or examinations for prescription or fitting and related services to prevent or delay a foot amputation that would be highly probable in the absence of the specialized footwear;

(b) Blood glucose monitoring supplies;

(c) Diagnostic reagent strips and tablets used in testing for ketones and glucose in urine and glucose in blood;

- (d) Finger-sticking devices used in obtaining blood samples for blood glucose testing; and
- (e) Blood glucose reflectance meters for home use;
- (4) Routine foot care; and
- (5) Vision care consisting of:
 - (a) One ophthalmologic examination per year; and
 - (b) One pair of eyeglasses per year.

.25 BENEFITS – BLOOD AND BLOOD PRODUCTS.

An MCO shall provide to its enrollees medically necessary blood, blood products, derivatives, components, biologics, and serums to include autologous services, whole blood, red blood cells, platelets, plasma, immunoglobulin, and albumin.

.26 BENEFITS – PRIMARY MENTAL HEALTH SERVICES.

A. An MCO shall provide to its enrollees medically necessary primary mental health services, including appropriate referrals for service to the Department's behavioral health ASO as described in COMAR 10.09.59.

B. Effective October 1, 2023, MCOs shall provide their enrollees medically necessary primary mental health services, including the Collaborative Care Model, pursuant to COMAR 10.09.64.

.26-1 CLINICAL TRIAL ITEMS AND SERVICES – COVERAGE FOR ROUTINE COSTS.

A. Subject to the conditions specified in §§B—F of this regulation, an MCO shall provide coverage for cost to an enrollee in an approved clinical trial for:

- (1) Treatment provided for life-threatening conditions; or
- (2) Prevention, early detection, and treatment studies on cancer.

B. Clinical trials are deemed to be automatically approved if:

- (1) The treatment is:
 - (a) Being provided or the studies are being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trials for cancer; or
 - (b) Being provided in Phase I, Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition;
- (2) The treatment is being provided in a clinical trial:
 - (a) Approved by:
 - (i) The National Institutes of Health (NIH);
 - (ii) An NIH cooperative group or an NIH center;
 - (iii) The Centers for Disease Control and Prevention;

- (iv) The Agency for Healthcare Research and Quality;
- (v) The Centers for Medicare and Medicaid Services (CMS);
- (vi) The Department of Defense;
- (vii) The Department of Veterans Affairs; or
- (viii) An institutional review board of an institution in the State that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NIH; or

(b) Conducted:

- (i) At National Cancer Institute Centers;
 - (ii) Under Investigational New Drug application (IND) reviewed by the Food and Drug Administration (FDA); or
 - (iii) As a clinical trial with deemed status through an exemption from having an IND under 21 CFR §312.2(b)(1);
- (3) The facility and the personnel providing the treatment are capable of doing so by virtue of the facility and the personnel's experience, training, and volume of patients treated to maintain expertise;
- (4) There is no clearly superior, non-investigational treatment alternative; and
- (5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative.

C. Enrollee cost includes the following:

- (1) The cost of all medically necessary items and services that are otherwise available to Medicaid beneficiaries such as hospital services, physician services, or diagnostic tests; and
- (2) The cost of medically necessary items or services required solely for the provision of the following:
 - (a) Investigational item or service such as administration of a noncovered chemotherapeutic agent;
 - (b) The clinically appropriate monitoring of the effects of the item or service; or
 - (c) The prevention, diagnosis, and treatment of complications.

D. Enrollee cost does not include the following:

- (1) The cost of the investigational item or service itself;
- (2) The cost of items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the enrollee;
- (3) The cost of items and services customarily provided by the research sponsors free of charge for any enrollee in the trial; and
- (4) The cost of non-health care services that an enrollee may be required to receive as a result of the treatment being provided for purposes of the clinical trial.

E. If the enrollee has insurance or other coverage, or if any other person is obligated, either legally or contractually, to pay for, or to reimburse the enrollee for, services covered by this regulation, the provider shall seek payment from that source first.

F. The MCO shall authorize the request for participation in an approved clinical trial within 5 working days of the request.

.26-2 PLASTIC AND RESTORATIVE SURGERY.

An MCO shall provide to an enrollee medically necessary surgery to correct a deformity from disease, trauma, congenital or developmental anomalies, or to restore body functions.

.26-3 GENDER-AFFIRMING TREATMENT.

A. An MCO shall provide medically necessary gender-affirming treatment services which include but are not limited to the following:

- (1) Hormone therapy, hormone blockers, and puberty blockers;
- (2) Hair alteration for the purposes of altering secondary sex characteristics and surgical site preparation;
- (3) Alterations to voice, voice therapy, and voice lessons;
- (4) Alterations to abdomen, chest, trunk, and buttocks;
- (5) Alterations to the face and neck;
- (6) Alterations to the genitals and gonads;
- (7) Laser treatment for scars from gender-affirming treatment;
- (8) Standard fertility preservation procedures as set forth in Insurance Article, §15-810.1, Annotated Code of Maryland;
- (9) Revisions to previous treatments and reversal of treatments;
- (10) Combinations of gender-affirming procedures; and
- (11) Other treatments as prescribed to suppress the development of endogenous secondary sex characteristics, align the individual's appearance of physical body with gender identity, and alleviate symptoms of clinically significant distress resulting from gender dysphoria.

B. An MCO may not issue an adverse benefit determination denying or limiting access to gender-affirming treatment unless a health care provider with experience prescribing or delivering gender-affirming treatment has reviewed and confirmed the appropriateness of the adverse benefit determination.

.26-4 AUDIOLOGY.

An MCO shall provide enrollees medically necessary audiology services as described in COMAR 10.09.51, including:

- A. Hearing aids;

B. Cochlear implants;

C. Auditory osseointegrated devices; and

D. Related services.

.26-5 REMOTE PATIENT MONITORING.

An MCO shall provide its enrollees medically necessary remote patient monitoring services as described in COMAR 10.09.96.

.26-6 MONILE INTEGRATED HEALTH SERVICES.

An MCO shall provide its enrollees medically necessary mobile integrated health services as described in COMAR 10.09.31.

.26-7 SOCIAL DETERMINANTS OF HEALTH.

Subject to COMAR 10.09.63, an MCO shall provide coverage for community violence prevention.

.27 BENEFITS – LIMITATIONS.

A. The benefits or services not required to be provided by an MCO are as follows:

- (1) Experimental or investigational services, including organ transplants determined by Medicare to be experimental, except when an enrollee is participating in an authorized clinical trial as specified in Regulation .26-1 of this chapter;
- (2) Any service or treatment that is not medically necessary;
- (3) Services performed or prescribed under the direction of a person who is not a health care practitioner;
- (4) Services that are beyond the scope of practice of the health care practitioner performing the service;
- (5) Transportation services provided through grants to local governments pursuant to COMAR 10.09.19, other than assisting enrollees to access nonemergency transportation services through their local transportation grantee agency;
- (6) Health-related services and targeted case management services provided to children when the services are:
 - (a) Specified in the enrollee's individualized family service plan (IFSP), or an individualized education program (IEP); and
 - (b) Delivered in the schools or through Children's Medical Services community-based providers;
- (7) Autopsies;
- (8) Immunizations required for travel outside the continental United States;
- (9) Services received while the enrollee is outside the United States;
- (10) Abortions;
- (11) Diet and exercise programs for the loss of weight;

- (12) Prescriptions or injections for central nervous system stimulants and anorectic agents when used for controlling weight;
- (13) In vitro fertilization, ovum transplants and gamete intrafallopian tube transfer, zygote intrafallopian transfer, or cryogenic or other preservation techniques used in these or similar procedures;
- (14) Services to reverse a voluntary sterilization procedure;
- (15) Lifestyle improvements, including smoking cessation, nutrition counseling, or physical fitness programs, unless specifically included as a covered service;
- (16) Nonmedical ancillary services such as vocational rehabilitation, employment counseling, or educational therapy;
- (17) Private duty nursing for adults 21 years old and older;
- (18) Services incurred before the effective date of coverage for an enrollee;
- (19) Dental or orthodontic care for adults 21 years old or older;
- (20) Piped-in oxygen or oxygen prescribed for standby purposes or on an as-needed basis;
- (22) Cosmetic surgery when performed solely to maintain normal physical appearance or enhance beyond average level toward an aesthetic ideal; and

B. An MCO is not required to provide any of the benefits or services which are reimbursed directly by the Department as described in COMAR 10.67.08.

.28 BENEFITS – SELF-REFERRAL SERVICES.

A. An MCO shall be financially responsible for reimbursing, in accordance with COMAR 10.67.04.20, an out-of-plan provider chosen by the participant for the following services:

- (1) Family planning services specified in COMAR 10.67.04.20A(2), (6), and (7);
- (2) Services performed by school-based health centers (SBHCs), as provided in COMAR 10.09.76;
- (3) Pregnancy-related services for women who are pregnant and, at the time of initial enrollment, have received prenatal care during their current pregnancy from an out-of-plan provider, and this pre-enrollment care consists of at least the following:
 - (a) A full prenatal examination;
 - (b) A risk assessment; and
 - (c) Appropriate laboratory services;
- (4) Initial medical examination for children in State custody when performed by an EPSDT certified provider;
- (5) One annual diagnostic and evaluation service (DES) visit for any enrollee diagnosed with HIV/AIDS, which the MCO is responsible for facilitating on the enrollee's behalf;
- (6) Renal dialysis services performed in a Medicare-certified facility;

(7) Initial medical examination of a newborn when the:

(a) Examination is performed in a hospital by an on-call physician; and

(b) MCO failed to provide for the service before the newborn's discharge from the hospital;

(8) Emergency services as described in COMAR 10.67.05.08B; and

(9) Prenatal, intrapartum, and postpartum services performed at a free-standing birth center located in Maryland or a contiguous state.

(10) Doula services, through December 31, 2025.

B. An MCO shall pay undisputed claims of the SBHC for services provided to its participants within 30 days of the MCO's receipt of the invoice.

C. An MCO shall provide SBHCs in its service area with the current information needed to facilitate communication between the SBHC, PCP, and the MCO regarding care provided to the MCO's participant, and to effect reimbursement by the MCO, including:

(1) Information concerning the MCO's policies and procedures regarding the provision of pharmacy and laboratory services;

(2) Instructions for submitting claims; and

(3) Contact information, including names and phone numbers of the following individuals:

(a) The MCO representative who serves as an SBHC's contact person for coordination of care; and

(b) The student-participant's PCP.

.29 OPTIONAL SERVICES.

A. An MCO may provide its enrollees with additional health care services that are not required by this chapter.

B. Optional health care services that an applicant intends to include in its benefits package shall be specified, including the terms and conditions for, and limitations to the provision of these services, in the applicant's initial application to the Department, as well as for periodic Departmental review.

C. An MCO's provision of optional services that it has represented to be available to its enrollees is subject to monitoring of complaints and consumer satisfaction surveys, and to random audits.

D. An MCO's provision of additional services that are not required by this regulation may not be taken into account when setting the MCO's capitation rate.

E. Effective January 1, 2015, any changes to the health care services being offered by the MCO under §A of this regulation, including reducing or waiving pharmacy co-pays, shall be effective for an entire calendar year.

F. An MCO shall notify the Department of any changes to their optional services by September 15 for the following calendar year.

G. The Department may waive the requirement under §E of this regulation if the Department determines that the circumstance warrant, including but not limited to a reduction in rates outside the normal rate setting process.

.30 FERTILITY PRESERVATION.

A. An MCO shall provide medically necessary fertility preservation services for the following individuals:

- (1) Individuals who have iatrogenic infertility;
- (2) Individuals who are receiving medical treatment that may directly or indirectly cause iatrogenic infertility; or
- (3) Individuals who are receiving gender-affirming treatment.

B. Fertility preservation services include sperm and oocyte cryopreservation and evaluations, laboratory assessments, medications, and treatments associated with sperm and oocyte cryopreservation.

C. Fertility preservation services do not include the storage of sperm or oocytes.

.31 BENEFITS — TELEMEDICINE SERVICES

An MCO shall provide to its enrollees medically necessary telemedicine services as described in COMAR 10.09.49.

CHAPTER 07 MARYLAND MEDICAID MANAGED CARE PROGRAM: PROGRAM INTEGRITY**.01 REQUIREMENTS TO DETECT AND PREVENT FRAUD, WASTE, AND ABUSE.**

A. An MCO or its responsible subcontractor shall implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse, which includes a compliance program that has, at a minimum, the following elements:

- (1) Written policies, procedures, and standards of conduct that include the MCO's commitment to comply with all applicable:
 - (a) Requirements and standards under the contract; and
 - (b) Federal and State requirements including:
 - (i) Written policies for all employees and those of any contractor or agent that provide detailed information about the False Claims Act and other Federal and State laws described in §1902(a)(68) of the Social Security Act; and
 - (ii) Information about rights of employees to be protected as whistleblowers.
- (2) The designation of a compliance officer, who reports directly to the chief executive officer and the board of directors and is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract, and at minimum the following staff members:
 - (a) An investigator who is responsible for fraud, waste, and abuse investigations;
 - (b) An auditor who is responsible for identifying potential fraud, waste, and abuse through analysis of claims and related information; and
 - (c) An analyst capable of reviewing data and codes who is responsible for reviewing and researching evidence of potential fraud, waste, and abuse.
- (3) Staffing and resources located in Maryland to identify and investigate potential fraud, waste, and abuse, which shall be based on criteria determined by the Department that may include but are not limited to:

- (a) Number of enrollees;
 - (b) Number of claims received on an annual basis;
 - (c) Volume of suspected fraudulent and abusive claims currently being detected;
 - (d) Other factors relating to the vulnerability of the MCO to fraud and abuse; and
 - (e) An assessment of optimal caseload which can be handled by an investigator on an annual basis.
- (4) The establishment of a regulatory compliance committee, which reports to the board of directors and to the MCO's senior management level and is charged with overseeing the organization's compliance program and its compliance with the requirements under the contract;
- (5) A system for training and educating the compliance officer, the organization's senior management, and the organization's employees regarding the federal and State standards and requirements under the contract;
- (6) Effective lines of communication between the compliance officer and the organization's employees;
- (7) Enforcement of standards through well-publicized disciplinary guidelines;
- (8) Establishment and implementation of procedures and a system with dedicated staff for:
- (a) Routine internal monitoring and auditing of compliance risks;
 - (b) Prompt response to compliance issues as they are raised;
 - (c) Investigation of potential compliance problems as identified in the course of self-evaluation and audits;
 - (d) Correction of problems, identified under §A(7)(c) of this regulation, promptly and thoroughly, or coordination of suspected criminal acts with law enforcement agencies, to reduce the potential for recurrence; and
 - (e) Ongoing compliance with the requirements under the contract.
- B. An MCO shall ensure that a subcontractor is legally qualified to furnish the services provided for in the subcontract.
- C. An MCO may not contract with the State unless conflict of interest safeguards at least equal to federal safeguards under section 27 of 41 U.S.C. §423, as amended, are in place.
- D. An MCO may not knowingly have a relationship of the type described in §E of this regulation with the following:
- (1) An individual or entity that is debarred, suspended, or otherwise excluded from:
 - (a) Participating in procurement activities under the Federal Acquisition Regulation; or
 - (b) Participating in non-procurement activities under Executive Order Number 12549, 3 CFR 189 (1986); or
 - (2) An individual or entity who is an affiliate, as defined in 48 CFR §2.101, of a person described in §D(1) of this regulation.
- E. The relationships described in §D of this Regulation, are as follows:
- (1) A director, officer, or partner of the MCO;

(2) A subcontractor of the MCO;

(3) A person with beneficial ownership of 5 percent or more of the MCO's equity; or

(4) A network provider or person with an employment, consulting or other arrangement with the MCO for the provision of items and services that is significant and material to the MCO's obligations under its contract with the Department.

F. An MCO 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 of the Social Security Act.

G. An MCO shall monitor the Department's correspondence and any database publicizing Department-initiated terminations of providers from the Program.

H. An MCO shall terminate the contract of, or refrain from contracting with, providers terminated or excluded from participation in the Program.

I. An MCO shall suspend payments to a network provider for which the Department has determined that there is a credible allegation of fraud in accordance with 42 CFR §455.23.

J. An MCO shall establish a system to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and shall apply such verification processes at least annually.

K. An MCO shall require and have a mechanism for a network provider to report to the MCO when it has received an overpayment and to:

(1) Return the overpayment to the MCO within 60 calendar days after the date on which the overpayment was identified; and

(2) Notify the MCO in writing of the reason for the overpayment.

L. Overpayments to Providers and Subcontractors.

(1) Overpayments recovered by an MCO, including those recovered due to waste, fraud and abuse, may be retained by the MCO, so long as it is reported to the Department.

(2) If the Department, Federal government, or its agents identified the potential fraud, waste, or abuse that leads to recovery of funds paid to an MCO provider, and the MCO did not previously identify and report the provider for potential overpayments, the State shall have the right to recover from the MCO the entire amount of the overpayment.

(3) The State shall have the sole right of recovery of an overpayment when the MCO has identified the overpayment and the MCO has not initiated recovery within 90 days after the completion of the MCO's investigation.

(4) The MCO shall have the right to appeal, pursuant to COMAR 10.67.10.02, the Department's recovery of an overpayment.

M. The Department has the authority to recover any overpayments made to MCOs.

N. An MCO shall ensure that all of its network providers are screened, enrolled, and revalidated by the State as Medicaid providers, in accordance with 42 CFR part 455, subparts B and E.

.02 ACCESS TO INFORMATION.

A. An MCO, its subcontractors, and its subcontractor's subcontractors shall permit the following organizations or their designees to inspect, evaluate, or audit books, records, contracts, computer or other electronic systems, premises, and facilities that pertain to the MCO's Medicaid enrollees, and any aspect of services and activities performed, or determination of amounts payable under, the MCO's contract with the Department:

- (1) The Department and its agents;
- (2) The Medicaid Fraud Control Unit of the Office of the Attorney General;
- (3) The Insurance Fraud Division of the Maryland Insurance Administration;
- (4) The Centers for Medicare and Medicaid Services;
- (5) The Inspector General of the Department of Health and Human Services;
- (6) The Comptroller General; and
- (7) Other authorized State or federal agencies.

B. The right to inspect, audit, and evaluate shall exist for 10 years from the final date of the contract period or from the completion of any audit, whichever is later, except, if the Department, Centers for Medicare and Medicaid Services, or the Department of Health and Human Services Inspector General determines that there is a reasonable possibility of fraud, or similar risk, those agencies may inspect, audit, and evaluate at any time.

C. Notwithstanding §B of this regulation, the Department has the right to inspect the accuracy, truthfulness, and completeness of the encounter data submitted by, or on behalf of, the MCO.

.03 REPORTING.

A. An MCO shall submit to the Department the following:

- (1) Encounter data in the form and manner described in COMAR 10.67.04.15B, 42 CFR §438.242(c), and 42 CFR §438.818.
- (2) Data required by the Department in order to certify the actuarial soundness of capitation rates to an MCO, under 42 CFR §438.3, including base data described in 42 CFR §438.5(c) that is generated by the MCO.
- (3) Data required by the Department to determine compliance of the MCO with the medical loss ratio requirement described in 42 CFR §438.8.
- (4) Data required by the Department and the Maryland Insurance Administration to determine that the MCO has made adequate provision against the risk of insolvency as required under 42 CFR §438.116.
- (5) Documentation described in 42 CFR §438.207(b) on which the Department bases its certification that the MCO has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in 42 CFR §438.206.
- (6) In accordance with §F of this regulation, information on ownership and control described in 42 CFR §455.104 from an MCO and its subcontractors, as governed by 42 CFR §438.230.
- (7) An annual report of overpayment recoveries as required in 42 CFR §438.608(d)(3).

(8) Any other data, documentation, or information relating to the performance of the entity's obligations under its contract with the Department, or required by the Department or the Secretary of the Department of Health and Human Services.

B. An MCO shall 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 which the inaccuracy has upon MCO reimbursement.

C. An MCO shall promptly report to the Department's Office of Inspector General (OIG) any potential fraud, waste, abuse, or information it has received from whistleblowers relating to the integrity of the MCO, its network providers, or its subcontractors.

D. An MCO shall report any potential fraud directly to the Medicaid Fraud Control Unit and the Department's OIG, including fraud by providers, employees and subcontractors of the MCO, enrollment agents, and enrollees.

E. After reporting any potential fraud, waste, or abuse to the Department's OIG and to the Medicaid Fraud Control Unit, the MCO may not take the following actions without prior written approval from the State:

- (1) Contact the subject of the investigation about any matter related to the investigation;
- (2) Enter into or attempt to negotiate any settlement or agreement regarding the incident; or
- (3) Accept any monetary or other type of consideration offered by the subject of the investigation in connection with the incident.

F. For complaints of provider fraud and abuse that warrant a preliminary investigation, the MCO's reports required in §§C and D of this regulation shall include:

- (1) The number of complaints;
- (2) The name and identification number of the provider being investigated;
- (3) The source of the complaint;
- (4) The type of provider;
- (5) The nature of the complaint;
- (6) The approximate dollar amount involved;
- (7) The legal and administrative disposition of the case; and
- (8) The method by which the MCO verified that the services being investigated were actually provided to the enrollee.

G. An MCO shall provide to the Department written disclosure of any affiliation prohibited under 42 CFR §438.610 and take action as directed by the Department.

H. An MCO shall provide to the Department written disclosures of information on ownership and control required under 42 CFR §455.104, including:

- (1) The following information for any individual or corporation with an ownership or control interest in the MCO:
 - (a) For individuals:

- (i) Name;
- (ii) Address;
- (iii) Date of birth; and
- (iv) Social Security number; and
- (b) For corporate entities:
 - (i) Name;
 - (ii) Applicable primary business address;
 - (iii) Every business location and applicable P.O. Box address; and
 - (iv) Other tax identification number or any subcontractor in which the MCO has a 5 percent or more interest;
- (2) Whether the individual or corporation with an ownership or control interest in the MCO:
 - (a) Is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling; or
 - (b) Whether the individual or corporation with an ownership or control interest in any subcontractor in which the MCO has a 5 percent or more interest is related to another person with ownership or control interest in the MCO as a spouse, parent, child, or sibling;
- (3) The name of any other MCO in which an owner of the MCO has an ownership or control interest;
- (4) The name, address, date of birth, and Social Security number of any managing employee or agent of the MCO;
- (5) Disclosures of ownership and control information from MCOs are due at the following times:
 - (a) Upon application;
 - (b) Upon the managed care entity executing the contract with the State;
 - (c) Upon renewal or extension of the contract; and
 - (d) Within 35 days after any change in ownership of the managed care entity.
- I. An MCO shall report to the Department all overpayments identified and recovered, specifying the overpayments due to fraud.
- J. An MCO shall report third-party liability collection activities as described in COMAR 10.67.04.18.
- K. An MCO shall report to the Department the amounts the MCO has cost-avoided and the number of third-party liability cases the MCO has handled.
- L. An MCO shall notify the Department promptly when it has knowledge of an enrollee's change of residence or death.

M. An MCO shall notify the Department promptly when the MCO receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the Program, including the termination of the provider agreement with the MCO.

N. An MCO shall submit all required data, documentation and information in the format specified by the Department.

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

P. As directed by the Department's OIG, the MCO shall submit written reports documenting its Program Integrity efforts, including but not limited to:

- (1) The dollar amount of losses and recoveries attributable to overpayment, abuse, and fraud; and
- (2) The number of referrals to the Department's OIG during the prior State fiscal year.

CHAPTER 08 MARYLAND MEDICAID MANAGED CARE PROGRAM: NON-CAPITATED COVERED SERVICES

.01 SCOPE.

This chapter describes the services that are not the responsibility of the MCOs but are covered by the Department on a fee-for-service basis.

.02 BEHAVIORAL HEALTH NON-CAPITATED COVERED SERVICES.

A. An MCO is not responsible for reimbursing for the following substance use disorder services, regardless of diagnosis:

- (1) Services delivered by a community-based provider as described in COMAR 10.09.80 with the following procedure codes:

H0001	Alcohol/drug assessment
H0004	Alcohol/drug individual counseling and therapy
H0005	Alcohol/drug group counseling
H0014	Alcohol and/or drug services; ambulatory detoxification
H0015	Alcohol and/or drug services; intensive outpatient
H0016	Alcohol and/or drug services; buprenorphine induction
H0020	Alcohol and/or drug services; methadone administration and/or service
H0024	Group peer recovery support services
H0038	Individual peer recovery support services
H0047	Alcohol and/or drug services; buprenorphine administration and/or service
H2036	Alcohol and/or drug services; partial hospitalization
J8499	Prescription drug, oral, non-chemotherapeutic; buprenorphine
J0571	Buprenorphine, oral, 1 mg
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg of buprenorphine
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine

Q9991	Injection, Buprenorphine extended-release, less than or equal to 100 mg
Q9992	Injection, Buprenorphine extended-release, greater than 100 mg

(2) Substance use disorder services provided to children in an ICF-A with the revenue code 0100, Residential Services, child and adolescent.

B. An MCO is not responsible for reimbursing for the following services performed by free-standing laboratories, regardless of diagnosis:

- (1) Presumptive drug tests; and
- (2) Definitive drug tests.

C. An MCO is not responsible for reimbursing for the laboratory services described in §B of this regulation unless billed by a:

- (1) Primary care provider; or
- (2) Other somatic care provider.

D. An MCO is not responsible for reimbursing for the following substance use disorder services if the MCO is billed with a primary diagnosis listed in §M of this regulation:

- (1) Services delivered by an inpatient hospital with the following revenue codes:

0114	Room and Board, Private Bed, Psychiatric
0116	Room and Board, Private Bed, Detoxification
0124	Room and Board, Semi-Private Bed, Psychiatric
0126	Room and Board, Semi-Private Bed, Detoxification
0134	Room and Board, 3-4 Beds, Psychiatric
0136	Room and Board, 3-4 Beds, Detoxification
0154	Room and Board, Ward, Psychiatric
0156	Room and Board, Ward, Detoxification
0169	Administrative Days
0762	Room and Board, Observation Room

(2) Services delivered by an outpatient hospital with the following revenue codes:

0900	Behavioral Health Treatments/Services-General Classification
0905	Intensive Outpatient Services-Psychiatric
0906	Intensive Outpatient Services-Chemical Dependency
0911	Behavioral Health-Rehabilitation
0912	Partial Hospitalization-Less Intensive
0913	Partial Hospitalization-Intensive
0914	Behavioral Health-Individual Therapy
0915	Behavioral Health-Group Therapy
0916	Behavioral Health-Family Therapy
0918	Behavioral Health-Testing
0919	Behavioral Health-Other
0944	Drug rehabilitation
0945	Alcohol rehabilitation

(3) Services delivered by an emergency department with the following revenue codes:

0450	General classification
0451	EMTALA
0452	ER Beyond EMTALA
0456	Urgent Care
0459	Other Emergency Room

E. An MCO is not responsible for reimbursing for mental health services with a primary diagnosis listed in §N of this regulation when the services are provided by a hospital and the services are the result of the treatment of mental health diagnosis.

F. An MCO shall be responsible for reimbursing for behavioral health services delivered by the participant's primary care provider.

G. An MCO shall be responsible for reimbursing for somatic services related to gender identity disorder, including gender reassignment surgery.

H. An MCO is not responsible for reimbursing the behavioral poisoning diagnoses listed in §P of this regulation in an emergency department setting.

I. An MCO is not responsible for services billed by specialty mental health providers listed in COMAR 10.09.59 when the bill includes the specialty behavioral health diagnoses listed in §M or N in the primary diagnosis field.

J. An MCO is not responsible for reimbursement of behavioral

health crisis services as described in COMAR 10.09.16.

K. An MCO is not responsible for behavioral health medications.

L. An MCO is not responsible for reimbursing for services billed by a physician related to prescribing buprenorphine or Vivitrol when the following conditions are met:

- (1) The physician delivering buprenorphine has a DATA 2000 waiver;
- (2) The physician is not the participant's primary care provider;
- (3) The primary diagnosis is substance use disorder;
- (4) The primary reason for the visit is substance use disorder treatment; and
- (5) The procedure code listed on the claims is one of the following:

99202	Evaluation and Management, Straight forward, new patient
99203	Evaluation and Management, Low complexity, new patient
99204	Evaluation and Management, Moderately complex, new patient
99205	Evaluation and Management, Highly complex, new patient
99211	Evaluation and Management, Minimal
99212	Evaluation and Management, Straight forward
99213	Evaluation and Management, Low complexity
99214	Evaluation and Management, Moderately complex
99215	Evaluation and Management, Highly complex
J8499	Prescription drug, oral, non-chemotherapeutic; buprenorphine
J2315	Vivitrol
J0571	Buprenorphine, oral, 1 mg
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg of buprenorphine
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine
Q9991	Injection, Buprenorphine extended-release, less than or equal to 100 mg

Q9992	Injection, Buprenorphine extended-release, greater than 100 mg
80305	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers (e.g., immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service (when provider has appropriately licensed and has adequate instrumentation)

M. Table of Substance Use Disorder diagnoses, for dates of service on or after October 1, 2015:

F1010	Alcohol abuse, uncomplicated
F1011	Alcohol abuse, in remission
F10120	Alcohol abuse with intoxication, uncomplicated
F10121	Alcohol abuse with intoxication delirium
F10129	Alcohol abuse with intoxication, unspecified
F1090	Alcohol use, unspecified, uncomplicated
F1091	Alcohol use, unspecified, in remission
F10130	Alcohol abuse with withdrawal, uncomplicated
F10131	Alcohol abuse with withdrawal delirium
F10132	Alcohol abuse with withdrawal with perceptual disturbance
F10139	Alcohol abuse with withdrawal, unspecified
F1014	Alcohol abuse with alcohol-induced mood disorder
F10150	Alcohol abuse with alcohol-induced psychotic disorder with delusions
F10151	Alcohol abuse with alcohol-induced psychotic disorder with hallucinations
F10159	Alcohol abuse with alcohol-induced psychotic disorder, unspecified
F10180	Alcohol abuse with alcohol-induced anxiety disorder

F10181	Alcohol abuse with alcohol-induced sexual dysfunction
F10182	Alcohol abuse with alcohol-induced sleep disorder
F10188	Alcohol abuse with other alcohol-induced disorder
F1019	Alcohol abuse with unspecified alcohol-induced disorder
F1020	Alcohol dependence, uncomplicated
F1021	Alcohol dependence, in remission
F10220	Alcohol dependence with intoxication, uncomplicated
F10221	Alcohol dependence with intoxication delirium
F10229	Alcohol dependence with intoxication, unspecified
F10230	Alcohol dependence with withdrawal, uncomplicated
F10231	Alcohol dependence with withdrawal delirium
F10232	Alcohol dependence with withdrawal with perceptual disturbance
F10239	Alcohol dependence with withdrawal, unspecified
F1024	Alcohol dependence with alcohol-induced mood disorder
F10250	Alcohol dependence with alcohol-induced psychotic disorder with delusions
F10251	Alcohol dependence with alcohol-induced psychotic disorder with hallucinations

F10259	Alcohol dependence with alcohol-induced psychotic disorder, unspecified
F10280	Alcohol dependence with alcohol-induced anxiety disorder
F10281	Alcohol dependence with alcohol-induced sexual dysfunction
F10282	Alcohol dependence with alcohol-induced sleep disorder
F10288	Alcohol dependence with other alcohol-induced disorder
F1029	Alcohol dependence with unspecified alcohol-induced disorder
F10920	Alcohol use, unspecified with intoxication, uncomplicated
F10921	Alcohol use, unspecified with intoxication delirium
F10929	Alcohol use, unspecified with intoxication, unspecified
F10930	Alcohol use, unspecified with withdrawal, uncomplicated
F10931	Alcohol use, unspecified with withdrawal delirium
F10932	Alcohol use, unspecified with withdrawal with perceptual disturbance
F10939	Alcohol use, unspecified with withdrawal, unspecified
F1094	Alcohol use, unspecified with alcohol-induced mood disorder
F10950	Alcohol use, unspecified with alcohol-induced psychotic disorder with delusions
F10951	Alcohol use, unspecified with alcohol-induced psychotic disorder with hallucinations

F10959	Alcohol use, unspecified with alcohol-induced psychotic disorder, unspecified
F10980	Alcohol use, unspecified with alcohol-induced anxiety disorder
F10981	Alcohol use, unspecified with alcohol-induced sexual dysfunction
F10982	Alcohol use, unspecified with alcohol-induced sleep disorder
F10988	Alcohol use, unspecified with other alcohol-induced disorder
F1099	Alcohol use, unspecified with unspecified alcohol-induced disorder
F1110	Opioid abuse, uncomplicated
F1111	Opioid abuse, in remission
F11120	Opioid abuse with intoxication, uncomplicated
F11121	Opioid abuse with intoxication delirium
F11122	Opioid abuse with intoxication with perceptual disturbance
F11129	Opioid abuse with intoxication, unspecified
F1113	Opioid abuse with withdrawal
F1114	Opioid abuse with opioid-induced mood disorder
F11150	Opioid abuse with opioid-induced psychotic disorder with delusions
F11151	Opioid abuse with opioid-induced psychotic disorder with hallucinations

F11159	Opioid abuse with opioid-induced psychotic disorder, unspecified
F11181	Opioid abuse with opioid-induced sexual dysfunction
F11182	Opioid abuse with opioid-induced sleep disorder
F11188	Opioid abuse with other opioid-induced disorder
F1119	Opioid abuse with unspecified opioid-induced disorder
F1120	Opioid dependence, uncomplicated
F1121	Opioid dependence, in remission
F11220	Opioid dependence with intoxication, uncomplicated
F11221	Opioid dependence with intoxication delirium
F11222	Opioid dependence with intoxication with perceptual disturbance
F11229	Opioid dependence with intoxication, unspecified
F1123	Opioid dependence with withdrawal
F1124	Opioid dependence with opioid-induced mood disorder
F11250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11259	Opioid dependence with opioid-induced psychotic disorder, unspecified

F11281	Opioid dependence with opioid-induced sexual dysfunction
F11282	Opioid dependence with opioid-induced sleep disorder
F11288	Opioid dependence with other opioid-induced disorder
F1129	Opioid dependence with unspecified opioid-induced disorder
F1190	Opioid use, unspecified, uncomplicated
F1191	Opioid use, unspecified, in remission
F11920	Opioid use, unspecified with intoxication, uncomplicated
F11921	Opioid use, unspecified with intoxication delirium
F11922	Opioid use, unspecified with intoxication with perceptual disturbance
F11929	Opioid use, unspecified with intoxication, unspecified
F1193	Opioid use, unspecified with withdrawal
F1194	Opioid use, unspecified with opioid-induced mood disorder
F11950	Opioid use, unspecified with opioid-induced psychotic disorder with delusions
F11951	Opioid use, unspecified with opioid-induced psychotic disorder with hallucinations
F11959	Opioid use, unspecified with opioid-induced psychotic disorder, unspecified
F11981	Opioid use, unspecified with opioid-induced sexual dysfunction

F11982	Opioid use, unspecified with opioid-induced sleep disorder
F11988	Opioid use, unspecified with other opioid-induced disorder
F1199	Opioid use, unspecified with unspecified opioid-induced disorder
F1210	Cannabis abuse, uncomplicated
F1211	Cannabis abuse, in remission
F12120	Cannabis abuse with intoxication, uncomplicated
F12121	Cannabis abuse with intoxication delirium
F12122	Cannabis abuse with intoxication with perceptual disturbance
F12129	Cannabis abuse with intoxication, unspecified
F1213	Cannabis abuse with withdrawal
F12150	Cannabis abuse with psychotic disorder with delusions
F12151	Cannabis abuse with psychotic disorder with hallucinations
F12159	Cannabis abuse with psychotic disorder, unspecified
F12180	Cannabis abuse with cannabis-induced anxiety disorder
F12188	Cannabis abuse with other cannabis-induced disorder
F1219	Cannabis abuse with unspecified cannabis-induced disorder

F1220	Cannabis dependence, uncomplicated
F1221	Cannabis dependence, in remission
F12220	Cannabis dependence with intoxication, uncomplicated
F12221	Cannabis dependence with intoxication delirium
F12222	Cannabis dependence with intoxication with perceptual disturbance
F12229	Cannabis dependence with intoxication, unspecified
F1223	Cannabis dependence with withdrawal
F12250	Cannabis dependence with psychotic disorder with delusions
F12251	Cannabis dependence with psychotic disorder with hallucinations
F12259	Cannabis dependence with psychotic disorder, unspecified
F12280	Cannabis dependence with cannabis-induced anxiety disorder
F12288	Cannabis dependence with other cannabis-induced disorder
F1229	Cannabis dependence with unspecified cannabis-induced disorder
F1290	Cannabis use, unspecified, uncomplicated
F1291	Cannabis use, unspecified, in remission
F12920	Cannabis use, unspecified with intoxication, uncomplicated

F12921	Cannabis use, unspecified with intoxication delirium
F12922	Cannabis use, unspecified with intoxication with perceptual disturbance
F12929	Cannabis use, unspecified with intoxication, unspecified
F1293	Cannabis use, unspecified with withdrawal
F12950	Cannabis use, unspecified with psychotic disorder with delusions
F12951	Cannabis use, unspecified with psychotic disorder with hallucinations
F12959	Cannabis use, unspecified with psychotic disorder, unspecified
F12980	Cannabis use, unspecified with anxiety disorder
F12988	Cannabis use, unspecified with other cannabis-induced disorder
F1299	Cannabis use, unspecified with unspecified cannabis-induced disorder
F1310	Sedative, hypnotic or anxiolytic abuse, uncomplicated
F1311	Sedative, hypnotic or anxiolytic abuse, in remission
F13120	Sedative, hypnotic or anxiolytic abuse with intoxication, uncomplicated
F13121	Sedative, hypnotic or anxiolytic abuse with intoxication delirium
F13129	Sedative, hypnotic or anxiolytic abuse with intoxication, unspecified
F13130	Sedative, hypnotic or anxiolytic abuse with withdrawal, uncomplicated

F13131	Sedative, hypnotic or anxiolytic abuse with withdrawal delirium
F13132	Sedative, hypnotic or anxiolytic abuse with withdrawal with perceptual disturbance
F13139	Sedative, hypnotic or anxiolytic abuse with withdrawal, unspecified
F1314	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced mood disorder
F13150	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions
F13151	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucinations
F13159	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder, unspecified
F13180	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced anxiety disorder
F13181	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced sexual dysfunction
F13182	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced sleep disorder
F13188	Sedative, hypnotic or anxiolytic abuse with other sedative, hypnotic or anxiolytic-induced disorder
F1319	Sedative, hypnotic or anxiolytic abuse with unspecified sedative, hypnotic or anxiolytic-induced disorder
F1320	Sedative, hypnotic or anxiolytic dependence, uncomplicated
F1321	Sedative, hypnotic or anxiolytic dependence, in remission
F13220	Sedative, hypnotic or anxiolytic dependence with intoxication, uncomplicated

F13221	Sedative, hypnotic or anxiolytic dependence with intoxication delirium
F13229	Sedative, hypnotic or anxiolytic dependence with intoxication, unspecified
F13230	Sedative, hypnotic or anxiolytic dependence with withdrawal, uncomplicated
F13231	Sedative, hypnotic or anxiolytic dependence with withdrawal delirium
F13232	Sedative, hypnotic or anxiolytic dependence with withdrawal with perceptual disturbance
F13239	Sedative, hypnotic or anxiolytic dependence with withdrawal, unspecified
F1324	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced mood disorder
F13250	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions
F13251	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucinations
F13259	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder, unspecified
F13280	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced anxiety disorder
F13281	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced sexual dysfunction
F13282	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced sleep disorder
F13288	Sedative, hypnotic or anxiolytic dependence with other sedative, hypnotic or anxiolytic-induced disorder

F1329	Sedative, hypnotic or anxiolytic dependence with unspecified sedative, hypnotic or anxiolytic-induced disorder
F1390	Sedative, hypnotic, or anxiolytic use, unspecified, uncomplicated
F1391	Sedative, hypnotic, or anxiolytic use, unspecified, in remission
F13920	Sedative, hypnotic, or anxiolytic use, unspecified with intoxication, uncomplicated
F13921	Sedative, hypnotic, or anxiolytic use, unspecified with intoxication delirium
F13929	Sedative, hypnotic, or anxiolytic use, unspecified with intoxication, unspecified
F13930	Sedative, hypnotic, or anxiolytic use, unspecified with withdrawal, uncomplicated
F13931	Sedative, hypnotic, or anxiolytic use, unspecified with withdrawal delirium
F13932	Sedative, hypnotic, or anxiolytic use, unspecified with withdrawal with perceptual disturbances
F13939	Sedative, hypnotic, or anxiolytic use, unspecified with withdrawal, unspecified
F1394	Sedative, hypnotic, or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced mood disorder
F13950	Sedative, hypnotic, or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced psychotic disorder with delusions
F13951	Sedative, hypnotic, or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced psychotic disorder with hallucinations
F13959	Sedative, hypnotic, or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced psychotic disorder with, unspecified

F13980	Sedative, hypnotic, or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced anxiety disorder
F13981	Sedative, hypnotic, or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced sexual dysfunction
F13982	Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic, or anxiolytic-induced sleep disorder
F13988	Sedative, hypnotic or anxiolytic use, unspecified with other sedative, hypnotic, or anxiolytic-induced disorder
F1399	Sedative, hypnotic or anxiolytic use, unspecified with unspecified sedative, hypnotic, or anxiolytic-induced disorder
F1410	Cocaine abuse, uncomplicated
F14120	Cocaine abuse with intoxication, uncomplicated
F14121	Cocaine abuse with intoxication with delirium
F14122	Cocaine abuse with intoxication with perceptual disturbance
F14129	Cocaine abuse with intoxication, unspecified
F1413	Cocaine abuse, unspecified with withdrawal
F1414	Cocaine abuse with cocaine-induced mood disorder
F14150	Cocaine abuse with cocaine-induced psychotic disorder with delusions
F14151	Cocaine abuse with cocaine-induced psychotic disorder with hallucinations
F14159	Cocaine abuse with cocaine-induced psychotic disorder, unspecified

F14180	Cocaine abuse with cocaine-induced anxiety disorder
F14181	Cocaine abuse with cocaine-induced sexual dysfunction
F14182	Cocaine abuse with cocaine-induced sleep disorder
F14188	Cocaine abuse with other cocaine-induced disorder
F1419	Cocaine abuse with unspecified cocaine-induced disorder
F1420	Cocaine dependence, uncomplicated
F1421	Cocaine dependence, in remission
F14220	Cocaine dependence with intoxication, uncomplicated
F14221	Cocaine dependence with intoxication delirium
F14222	Cocaine dependence with intoxication with perceptual disturbance
F14229	Cocaine dependence with intoxication, unspecified
F1423	Cocaine dependence with withdrawal
F1424	Cocaine dependence with cocaine-induced mood disorder
F14250	Cocaine dependence with cocaine-induced psychotic disorder with delusions
F14251	Cocaine dependence with cocaine-induced psychotic disorder with hallucinations
F14259	Cocaine dependence with cocaine-induced psychotic disorder, unspecified

F14280	Cocaine dependence with cocaine-induced anxiety disorder
F14281	Cocaine dependence with cocaine-induced sexual dysfunction
F14282	Cocaine dependence with cocaine-induced sleep disorder
F14288	Cocaine dependence with other cocaine-induced disorder
F1429	Cocaine dependence with unspecified cocaine-induced disorder
F1490	Cocaine use, unspecified, uncomplicated
F1491	Cocaine use, unspecified, in remission
F14920	Cocaine use, unspecified with intoxication, uncomplicated
F14921	Cocaine use, unspecified with intoxication delirium
F14922	Cocaine use, unspecified with intoxication with perceptual disturbance
F14929	Cocaine use, unspecified with intoxication, unspecified
F1493	Cocaine use, unspecified with withdrawal
F1494	Cocaine use, unspecified with cocaine-induced mood disorder
F14950	Cocaine use, unspecified with cocaine-induced psychotic disorder with delusions
F14951	Cocaine use, unspecified with cocaine-induced psychotic disorder with hallucinations
F14959	Cocaine use, unspecified with cocaine-induced psychotic disorder, unspecified

F14980	Cocaine use, unspecified with cocaine-induced anxiety disorder
F14981	Cocaine use, unspecified with cocaine-induced sexual dysfunction
F14982	Cocaine use, unspecified with cocaine-induced sleep disorder
F14988	Cocaine use, unspecified with other cocaine-induced disorder
F1499	Cocaine use, unspecified with unspecified cocaine-induced disorder
F1510	Other stimulant abuse, uncomplicated
F15120	Other stimulant abuse with intoxication, uncomplicated
F15121	Other stimulant abuse with intoxication delirium
F15122	Other stimulant abuse with intoxication with perceptual disturbance
F15129	Other stimulant abuse with intoxication, unspecified
F1513	Other stimulant abuse with withdrawal
F1514	Other stimulant abuse with stimulant-induced mood disorder
F15150	Other stimulant abuse with stimulant-induced psychotic disorder with delusions
F15151	Other stimulant abuse with stimulant-induced psychotic disorder with hallucinations
F15159	Other stimulant abuse with stimulant-induced psychotic disorder, unspecified
F15180	Other stimulant abuse with stimulant-induced anxiety disorder

F15181	Other stimulant abuse with stimulant-induced sexual dysfunction
F15182	Other stimulant abuse with stimulant-induced sleep disorder
F15188	Other stimulant abuse with other stimulant-induced disorder
F1519	Other stimulant abuse with unspecified stimulant-induced disorder
F1520	Other stimulant dependence, uncomplicated
F1521	Other stimulant dependence, in remission
F15220	Other stimulant dependence with intoxication, uncomplicated
F15221	Other stimulant dependence with intoxication delirium
F15222	Other stimulant dependence with intoxication with perceptual disturbance
F15229	Other stimulant dependence with intoxication, unspecified
F1523	Other stimulant dependence with withdrawal
F1524	Other stimulant dependence with stimulant-induced mood disorder
F15250	Other stimulant dependence with stimulant-induced psychotic disorder with delusions
F15251	Other stimulant dependence with stimulant-induced psychotic disorder with hallucinations
F15259	Other stimulant dependence with stimulant-induced psychotic disorder, unspecified
F15280	Other stimulant dependence with stimulant-induced anxiety disorder

F15281	Other stimulant dependence with stimulant-induced sexual dysfunction
F15282	Other stimulant dependence with stimulant-induced sleep disorder
F15288	Other stimulant dependence with other stimulant-induced disorder
F1529	Other stimulant dependence with unspecified stimulant-induced disorder
F1590	Other stimulant use, unspecified, uncomplicated
F1591	Other stimulant use, unspecified, in remission
F15920	Other stimulant use, unspecified with intoxication, uncomplicated
F15921	Other stimulant use, unspecified with intoxication delirium
F15922	Other stimulant use, unspecified with intoxication with perceptual disturbance
F15929	Other stimulant use, unspecified with intoxication, unspecified
F1593	Other stimulant use, unspecified with withdrawal
F1594	Other stimulant use, unspecified with stimulant-induced mood disorder
F15950	Other stimulant use, unspecified with stimulant-induced psychotic disorder with delusions
F15951	Other stimulant use, unspecified with stimulant-induced psychotic disorder with hallucinations
F15959	Other stimulant use, unspecified with stimulant-induced psychotic disorder, unspecified
F15980	Other stimulant use, unspecified with stimulant-induced anxiety disorder

F15981	Other stimulant use, unspecified with stimulant-induced sexual dysfunction
F15982	Other stimulant use, unspecified with stimulant-induced sleep disorder
F15988	Other stimulant use, unspecified with other stimulant-induced disorder
F1599	Other stimulant use, unspecified with unspecified stimulant-induced disorder
F1610	Hallucinogen abuse, uncomplicated
F16120	Hallucinogen abuse with intoxication, uncomplicated
F16121	Hallucinogen abuse with intoxication with delirium
F16122	Hallucinogen abuse with intoxication with perceptual disturbance
F16129	Hallucinogen abuse with intoxication, unspecified
F1614	Hallucinogen abuse with hallucinogen-induced mood disorder
F16150	Hallucinogen abuse with hallucinogen-induced psychotic disorder with delusions
F16151	Hallucinogen abuse with hallucinogen-induced psychotic disorder with hallucinations
F16159	Hallucinogen abuse with hallucinogen-induced psychotic disorder, unspecified
F16180	Hallucinogen abuse with hallucinogen-induced anxiety disorder
F16183	Hallucinogen abuse with hallucinogen persisting perception disorder (flashbacks)
F16188	Hallucinogen abuse with other hallucinogen-induced disorder

F1619	Hallucinogen abuse with unspecified hallucinogen-induced disorder
F1620	Hallucinogen dependence, uncomplicated
F1621	Hallucinogen dependence, in remission
F16220	Hallucinogen dependence with intoxication, uncomplicated
F16221	Hallucinogen dependence with intoxication with delirium
F16229	Hallucinogen dependence with intoxication, unspecified
F1624	Hallucinogen dependence with hallucinogen-induced mood disorder
F16250	Hallucinogen dependence with hallucinogen-induced psychotic disorder with delusions
F16251	Hallucinogen dependence with hallucinogen-induced psychotic disorder with hallucinations
F16259	Hallucinogen dependence with hallucinogen-induced psychotic disorder, unspecified
F16280	Hallucinogen dependence with hallucinogen-induced anxiety disorder
F16283	Hallucinogen dependence with hallucinogen persisting perception disorder (flashbacks)
F16288	Hallucinogen dependence with other hallucinogen-induced disorder
F1629	Hallucinogen dependence with unspecified hallucinogen-induced disorder
F1690	Hallucinogen use, unspecified, uncomplicated
F1691	Hallucinogen use, unspecified, in remission

F16920	Hallucinogen use, unspecified with intoxication, uncomplicated
F16921	Hallucinogen use, unspecified with intoxication with delirium
F16929	Hallucinogen use, unspecified with intoxication, unspecified
F1694	Hallucinogen use, unspecified with hallucinogen-induced mood disorder
F16950	Hallucinogen use, unspecified with hallucinogen-induced psychotic disorder with delusions
F16951	Hallucinogen use, unspecified with hallucinogen-induced psychotic disorder with hallucinations
F16959	Hallucinogen use, unspecified with hallucinogen-induced psychotic disorder, unspecified
F16980	Hallucinogen use, unspecified with hallucinogen-induced anxiety disorder
F16983	Hallucinogen use, unspecified with hallucinogen persisting perception disorder (flashbacks)
F16988	Hallucinogen use, unspecified with other hallucinogen-induced disorder
F1699	Hallucinogen use, unspecified with unspecified hallucinogen-induced disorder
F17200	Nicotine dependence, unspecified, uncomplicated
F17201	Nicotine dependence, unspecified, in remission
F17203	Nicotine dependence unspecified, with withdrawal
F17208	Nicotine dependence, unspecified, with other nicotine-induced disorders
F17209	Nicotine dependence, unspecified, with unspecified nicotine-induced disorders

F17210	Nicotine dependence, cigarettes, uncomplicated
F17211	Nicotine dependence, cigarettes, in remission
F17213	Nicotine dependence, cigarettes, with withdrawal
F17218	Nicotine dependence, cigarettes, with other nicotine-induced disorders
F17219	Nicotine dependence, cigarettes, with unspecified nicotine-induced disorders
F17220	Nicotine dependence, chewing tobacco, uncomplicated
F17221	Nicotine dependence, chewing tobacco, in remission
F17223	Nicotine dependence, chewing tobacco, with withdrawal
F17228	Nicotine dependence, chewing tobacco, with other nicotine-induced disorders
F17229	Nicotine dependence, chewing tobacco, with unspecified nicotine-induced disorders
F17290	Nicotine dependence, other tobacco product, uncomplicated
F17291	Nicotine dependence, other tobacco product, in remission
F17293	Nicotine dependence, other tobacco product, with withdrawal
F17298	Nicotine dependence, other tobacco product, with other nicotine-induced disorders
F17299	Nicotine dependence, other tobacco product, with unspecified nicotine-induced disorders
F1810	Inhalant abuse, uncomplicated

F18120	Inhalant abuse with intoxication, uncomplicated
F18121	Inhalant abuse with intoxication delirium
F18129	Inhalant abuse with intoxication, unspecified
F1814	Inhalant abuse with inhalant-induced mood disorder
F18150	Inhalant abuse with inhalant-induced psychotic disorder with delusions
F18151	Inhalant abuse with inhalant-induced psychotic disorder with hallucinations
F18159	Inhalant abuse with inhalant-induced psychotic disorder, unspecified
F1817	Inhalant abuse with inhalant-induced dementia
F18180	Inhalant abuse with inhalant-induced anxiety disorder
F18188	Inhalant abuse with other inhalant-induced disorder
F1819	Inhalant abuse with unspecified inhalant-induced disorder
F1820	Inhalant dependence, uncomplicated
F1821	Inhalant dependence, in remission
F18220	Inhalant dependence with intoxication, uncomplicated
F18221	Inhalant dependence with intoxication delirium
F18229	Inhalant dependence with intoxication, unspecified

F1824	Inhalant dependence with inhalant-induced mood disorder
F18250	Inhalant dependence with inhalant-induced psychotic disorder with delusions
F18251	Inhalant dependence with inhalant-induced psychotic disorder with hallucinations
F18259	Inhalant dependence with inhalant-induced psychotic disorder, unspecified
F1827	Inhalant dependence with inhalant-induced dementia
F18280	Inhalant dependence with inhalant-induced anxiety disorder
F18288	Inhalant dependence with other inhalant-induced disorder
F1829	Inhalant dependence with unspecified inhalant-induced disorder
F1890	Inhalant use, unspecified, uncomplicated
F1891	Hallucinogen use, unspecified, in remission
F18920	Inhalant use, unspecified with intoxication, uncomplicated
F18921	Inhalant use, unspecified with intoxication with delirium
F18929	Inhalant use, unspecified with intoxication, unspecified
F1894	Inhalant use, unspecified with inhalant-induced mood disorder
F18950	Inhalant use, unspecified with inhalant-induced psychotic disorder with delusions
F18951	Inhalant use, unspecified with inhalant-induced psychotic disorder with hallucinations

F18959	Inhalant use, unspecified with inhalant-induced psychotic disorder, unspecified
F18980	Inhalant use, unspecified with inhalant-induced anxiety disorder
F18988	Inhalant use, unspecified with other inhalant-induced disorder
F1899	Inhalant use, unspecified with unspecified inhalant-induced disorder
F1910	Other psychoactive substance abuse, uncomplicated
F19120	Other psychoactive substance abuse with intoxication, uncomplicated
F19121	Other psychoactive substance abuse with intoxication delirium
F19122	Other psychoactive substance abuse with intoxication with perceptual disturbances
F19129	Other psychoactive substance abuse with intoxication, unspecified
F19130	Other psychoactive substance abuse with withdrawal, uncomplicated
F19131	Other psychoactive substance abuse with withdrawal delirium
F19132	Other psychoactive substance abuse with withdrawal with perceptual disturbances
F19139	Other psychoactive substance abuse with withdrawal, unspecified
F1914	Other psychoactive substance abuse with psychoactive substance-induced mood disorder
F19150	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder with delusions
F19151	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder with hallucinations

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F19159	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder, unspecified
F19180	Other psychoactive substance abuse with psychoactive substance-induced anxiety disorder
F19181	Other psychoactive substance abuse with psychoactive substance-induced sexual dysfunction
F19182	Other psychoactive substance abuse with psychoactive substance-induced sleep disorder
F19188	Other psychoactive substance abuse with other psychoactive substance-induced disorder
F1919	Other psychoactive substance abuse with unspecified substance-induced disorder
F1920	Other psychoactive substance dependence, uncomplicated
F1921	Other psychoactive substance dependence, in remission
F19220	Other psychoactive substance dependence with intoxication, uncomplicated
F19221	Other psychoactive substance dependence with intoxication delirium
F19222	Other psychoactive substance dependence with intoxication with perceptual disturbance
F19229	Other psychoactive substance dependence with intoxication, unspecified
F19230	Other psychoactive substance dependence with withdrawal, uncomplicated
F19231	Other psychoactive substance dependence with withdrawal delirium
F19232	Other psychoactive substance dependence with withdrawal with perceptual disturbance
F19239	Other psychoactive substance dependence with withdrawal, unspecified

F1924	Other psychoactive substance dependence with psychoactive substance-induced mood disorder
F19250	Other psychoactive substance dependence with psychoactive substance-induced psychotic disorder with delusions
F19251	Other psychoactive substance dependence with psychoactive substance-induced psychotic disorder with hallucinations
F19259	Other psychoactive substance dependence with substance-induced psychotic disorder, unspecified
F19280	Other psychoactive substance dependence with psychoactive substance-induced anxiety disorder
F19281	Other psychoactive substance dependence with psychoactive substance-induced sexual dysfunction
F19282	Other psychoactive substance dependence with psychoactive substance-induced sleep disorder
F19288	Other psychoactive substance dependence with other psychoactive substance-induced disorder
F1929	Other psychoactive substance dependence with unspecified psychoactive substance-induced disorder
F1990	Other psychoactive substance use, unspecified, uncomplicated
F1991	Other psychoactive substance use, unspecified, in remission
F19920	Other psychoactive substance use, unspecified with intoxication, uncomplicated
F19921	Other psychoactive substance use, unspecified with intoxication with delirium
F19922	Other psychoactive substance use, unspecified with intoxication with perceptual disturbance
F19929	Other psychoactive substance use, unspecified with intoxication, unspecified
F19930	Other psychoactive substance use, unspecified with withdrawal, uncomplicated

F19931	Other psychoactive substance use, unspecified with withdrawal delirium
F19932	Other psychoactive substance use, unspecified with withdrawal with perceptual disturbance
F19939	Other psychoactive substance use, unspecified with withdrawal, unspecified
F1994	Other psychoactive substance use, unspecified with psychoactive substance-induced mood disorder
F19950	Other psychoactive substance use, unspecified with psychoactive substance-induced psychotic disorder with delusions
F19951	Other psychoactive substance use, unspecified with psychoactive substance-induced psychotic disorder with hallucinations
F19959	Other psychoactive substance use, unspecified with psychoactive disorder, unspecified
F19980	Other psychoactive substance use, unspecified with anxiety disorder
F19981	Other psychoactive substance use, unspecified with sexual dysfunction
F19982	Other psychoactive substance use, unspecified with sleep disorder
F19988	Other psychoactive substance use, unspecified with other disorder
F1999	Other psychoactive substance use, unspecified with unspecified disorder
O99310	Alcohol use complicating pregnancy, unspecified trimester
O99311	Alcohol use complicating pregnancy, first trimester
O99312	Alcohol use complicating pregnancy, second trimester
O99313	Alcohol use complicating pregnancy, third trimester

O99314	Alcohol use complicating childbirth
O99315	Alcohol use complicating the puerperium
O99320	Drug use complicating pregnancy, unspecified trimester
O99321	Drug use complicating pregnancy, first trimester
O99322	Drug use complicating pregnancy, second trimester
O99323	Drug use complicating pregnancy, third trimester
O99324	Drug use complicating childbirth
O99325	Drug use complicating the puerperium
R780	Finding of alcohol in blood
R781	Finding of opiate drug in blood
R782	Finding of cocaine in blood
R783	Finding of hallucinogen in blood
R784	Finding of other drugs of addictive potential in blood
R785	Finding of other psychotropic drug in blood

N. Table of Mental Health Diagnoses, for dates of service on or after October 1, 2015:

F200	Paranoid schizophrenia
F201	Disorganized schizophrenia
F202	Catatonic schizophrenia
F203	Undifferentiated schizophrenia
F205	Residual schizophrenia
F2081	Schizophreniform disorder
F2089	Other schizophrenia
F209	Schizophrenia, unspecified
F21	Schizotypal disorder
F22	Delusional disorders
F23	Brief psychotic disorder
F24	Shared psychotic disorder
F250	Schizoaffective disorder, bipolar type
F251	Schizoaffective disorder, depressive type
F258	Other schizoaffective disorders
F259	Schizoaffective disorder, unspecified

F28	Other psychotic disorder not due to a substance or known physiological condition
F29	Unspecified psychosis not due to a substance or known physiological condition
F3010	Manic episode without psychotic symptoms, unspecified
F3011	Manic episode without psychotic symptoms, mild
F3012	Manic episode without psychotic symptoms, moderate
F3013	Manic episode, severe, without psychotic symptoms
F302	Manic episode, severe with psychotic symptoms
F303	Manic episode in partial remission
F304	Manic episode in full remission
F308	Other manic episodes
F309	Manic episode, unspecified
F310	Bipolar disorder, current episode hypomanic
F3110	Bipolar disorder, current episode manic without psychotic features, unspecified
F3111	Bipolar disorder, current episode manic without psychotic features, mild
F3112	Bipolar disorder, current episode manic without psychotic features, mod
F3113	Bipolar disorder, current episode manic without psychotic features, severe

F312	Bipolar disorder, current episode manic severe with psychotic features
F3130	Bipolar disorder, current episode depressed, mild or moderate severity, unspecified
F3131	Bipolar disorder, current episode depressed, mild
F3132	Bipolar disorder, current episode depressed, moderate
F314	Bipolar disorder, current episode depressed, severe, without psychotic features
F315	Bipolar disorder, current episode depressed, severe, with psychotic features
F3160	Bipolar disorder, current episode mixed, unspecified
F3161	Bipolar disorder, current episode mixed, mild
F3162	Bipolar disorder, current episode mixed, moderate
F3163	Bipolar disorder, current episode mixed, severe, without psychotic features
F3164	Bipolar disorder, current episode mixed, severe, with psychotic features
F3170	Bipolar disorder, currently in remission, most recent episode unspecified
F3171	Bipolar disorder, in partial remission, most recent episode hypomanic
F3172	Bipolar disorder, in full remission, most recent episode hypomanic
F3173	Bipolar disorder, in partial remission, most recent episode manic
F3174	Bipolar disorder, in full remission, most recent episode manic

F3175	Bipolar disorder, in partial remission, most recent episode depressed
F3176	Bipolar disorder, in full remission, most recent episode depressed
F3177	Bipolar disorder, in partial remission, most recent episode mixed
F3178	Bipolar disorder, in full remission, most recent episode mixed
F3181	Bipolar II disorder
F3189	Other bipolar disorder
F319	Bipolar disorder, unspecified
F32A	Depression, unspecified
F320	Major depressive disorder, single episode, mild
F321	Major depressive disorder, single episode, moderate
F322	Major depressive disorder, single episode, severe without psychotic features
F323	Major depressive disorder, single episode, severe with psychotic features
F324	Major depressive disorder, single episode, in partial remission
F325	Major depressive disorder, single episode, in full remission
F3281	Premenstrual dysphoric disorder
F3289	Other specified depressive episodes

F329	Major depressive disorder, single episode, unspecified
F330	Major depressive disorder, recurrent, mild
F331	Major depressive disorder, recurrent, moderate
F332	Major depressive disorder, recurrent severe without psychotic features
F333	Major depressive disorder, recurrent, severe with psychotic symptoms
F3340	Major depressive disorder, recurrent, in remission, unspecified
F3341	Major depressive disorder, recurrent, in partial remission
F3342	Major depressive disorder, recurrent, in full remission
F338	Other recurrent depressive disorders
F339	Major depressive disorder, recurrent, unspecified
F340	Cyclothymic disorder
F341	Dysthymic disorder
F3481	Disruptive mood dysregulation disorder
F3489	Other specified persistent mood disorders
F349	Persistent mood (affective) disorder, unspecified
F39	Unspecified mood (affective) disorder

F4000	Agoraphobia, unspecified
F4001	Agoraphobia with panic disorder
F4002	Agoraphobia without panic disorder
F4010	Social phobia, unspecified
F4011	Social phobia, generalized
F40210	Arachnophobia
F40218	Other animal type phobia
F40220	Fear of thunderstorms
F40228	Other natural environment type phobia
F40230	Fear of blood
F40231	Fear of injections and transfusions
F40232	Fear of other medical care
F40233	Fear of injury
F40240	Claustrophobia
F40241	Acrophobia
F40242	Fear of bridges

F40243	Fear of flying
F40248	Other situational type phobia
F40290	Androphobia
F40291	Gynephobia
F40298	Other specified phobia
F408	Other phobic anxiety disorders
F409	Phobic anxiety disorder, unspecified
F410	Panic disorder without agoraphobia
F411	Generalized anxiety disorder
F413	Other mixed anxiety disorders
F418	Other specified anxiety disorders
F419	Anxiety disorder, unspecified
F422	Mixed obsessional thoughts and acts
F423	Hoarding disorder
F424	Excoriation (skin-picking) disorder
F428	Other obsessive compulsive disorder

F429	Obsessive-compulsive disorder, unspecified
F430	Acute stress reaction
F4310	Post-traumatic stress disorder, unspecified
F4311	Post-traumatic stress disorder, acute
F4312	Post-traumatic stress disorder, chronic
F4320	Adjustment disorder, unspecified
F4321	Adjustment disorder with depressed mood
F4322	Adjustment disorder with anxiety
F4323	Adjustment disorder with mixed anxiety and depressed mood
F4324	Adjustment disorder with disturbance of conduct
F4325	Adjustment disorder with mixed disturbance of emotions and conduct
F4329	Adjustment disorder with other symptoms
F4381	Prolonged grief disorder
F4389	Other reactions to severe stress
F439	Reaction to severe stress, unspecified
F440	Dissociative amnesia

F441	Dissociative fugue
F442	Dissociative stupor
F444	Conversion disorder with motor symptom or deficit
F446	Conversion disorder with sensory symptom or deficit
F4481	Dissociative identity disorder
F4489	Other dissociative and conversion disorders
F449	Dissociative and conversion disorder, unspecified
F450	Somatization disorder
F451	Undifferentiated somatoform disorder
F4520	Hypochondriacal disorder, unspecified
F4521	Hypochondriasis
F4522	Body dysmorphic disorder
F4529	Other hypochondriacal disorders
F4541	Pain disorder exclusively related to psychological factors
F458	Other somatoform disorders
F459	Somatoform disorder, unspecified

F481	Depersonalization-derealization syndrome
F488	Other specified nonpsychotic mental disorders
F489	Nonpsychotic mental disorder, unspecified
F5000	Anorexia nervosa, unspecified
F5001	Anorexia nervosa, restricting type
F5002	Anorexia nervosa, binge eating/purging type
F502	Bulimia nervosa
F5081	Binge eating disorder
F5082	Avoidant/restrictive food intake disorder
F5089	Other specified eating disorder
F509	Eating disorder, unspecified
F53	Mental and behavioral disorders associated with the puerperium, not elsewhere classified
F530	Postpartum depression
F531	Puerperal psychosis
F54	Psychological and behavioral factors associated with disorders or diseases classified elsewhere
F600	Paranoid personality disorder

F601	Schizoid personality disorder
F603	Borderline personality disorder
F604	Histrionic personality disorder
F605	Obsessive-compulsive personality disorder
F606	Avoidant personality disorder
F607	Dependent personality disorder
F6081	Narcissistic personality disorder
F6089	Other specific personality disorders
F609	Personality disorder, unspecified
F630	Pathological gambling
F631	Pyromania
F632	Kleptomania
F633	Trichotillomania
F6381	Intermittent explosive disorder
F6389	Other impulse disorders
F639	Impulse disorder, unspecified

F640	Transsexualism
F641	Gender identity disorder in adolescence and adulthood
F642	Gender identity disorder of childhood
F648	Other gender identity disorders
F649	Gender identity disorder, unspecified
F650	Fetishism
F651	Transvestic fetishism
F652	Exhibitionism
F653	Voyeurism
F654	Pedophilia
F6550	Sadomasochism, unspecified
F6551	Sexual masochism
F6552	Sexual sadism
F6581	Frotteurism
F6589	Other paraphilias
F659	Paraphilia, unspecified

F66	Other sexual disorders
F6811	Factitious disorder with predominantly psychological signs and symptoms
F6813	Factitious disorder with combined psychological and physical signs and symptoms
F688	Other specified disorders of adult personality and behavior
F68A	Factitious disorder imposed on another
F69	Unspecified disorder of adult personality and behavior
F843	Other childhood disintegrative disorder
F900	Attention-deficit hyperactivity disorder, predominantly inattentive type
F901	Attention-deficit hyperactivity disorder, predominantly hyperactive type
F902	Attention-deficit hyperactivity disorder, combined type
F908	Attention-deficit hyperactivity disorder, other type
F909	Attention-deficit hyperactivity disorder, unspecified type
F910	Conduct disorder confined to family context
F911	Conduct disorder, childhood-onset type
F912	Conduct disorder, adolescent-onset type
F913	Oppositional defiant disorder

F918	Other conduct disorders
F919	Conduct disorder, unspecified
F930	Separation anxiety disorder of childhood
F938	Other childhood emotional disorders
F939	Childhood emotional disorder, unspecified
F940	Selective mutism
F941	Reactive attachment disorder of childhood
F942	Disinhibited attachment disorder of childhood
F948	Other childhood disorders of social functioning
F949	Childhood disorder of social functioning, unspecified
F980	Enuresis not due to a substance or known physiological condition
F981	Encopresis not due to a substance or known physiological condition
F984	Stereotyped movement disorders
F988	Other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence
F989	Unspecified behavioral and emotional disorders with onset usually occurring in childhood and adolescence
F99	Mental disorder, not otherwise specified

G2111	Neuroleptic induced parkinsonism
G2402	Drug induced acute dystonia
G2589	Other specified extrapyramidal and movement disorders
G259	Extrapyramidal and movement disorder, unspecified
O99340	Other mental disorders complicating pregnancy, unspecified trimester
O99341	Other mental disorders complicating pregnancy, first trimester
O99342	Other mental disorders complicating pregnancy, second trimester
O99343	Other mental disorders complicating pregnancy, third trimester
O99344	Other mental disorders complicating childbirth
O99345	Other mental disorders complicating the puerperium
R457	State of emotional shock and stress, unspecified
R45850	Homicidal ideations
R45851	Suicidal ideations
T1491XA	Suicide attempt, initial
Z046	Encounter for general psychiatric examination requested by the authority

O. An MCO is not responsible for services billed by a psychiatrist when the claim includes one of the following primary diagnoses:

G24.4	Orofacial dyskinesia
G25.1	Drug-induced tremor
G21.0	Neuroleptic malignant syndrome

P. Table of Poisoning Diagnoses, for dates of service on or after July 1, 2016:

T360X2A	Poisoning by penicillins, intentional self-harm
T361X2A	Poisoning by cephalosporins and other beta-lactam antibiotics, intentional self-harm
T362X2A	Poisoning by chloramphenicol group, intentional self-harm
T363X2A	Poisoning by macrolides, intentional self-harm
T364X2A	Poisoning by tetracyclines, intentional self-harm
T365X2A	Poisoning by aminoglycosides, intentional self-harm
T366X2A	Poisoning by rifampicins, intentional self-harm
T367X2A	Poisoning by antifungal antibiotics, systemically used, intentional self-harm
T368X2A	Poisoning by other systemic antibiotics, intentional self-harm
T369X2A	Poisoning by unspecified systemic antibiotic, intentional self-harm
T370X2A	Poisoning by sulfonamides, intentional self-harm
T371X2A	Poisoning by antimycobacterial drugs, intentional self-harm
T372X2A	Poisoning by antimalarials and drugs acting on other blood protozoa, intentional self-harm
T373X2A	Poisoning by other antiprotozoal drugs, intentional self-harm
T374X2A	Poisoning by anthelmintics, intentional self-harm
T375X2A	Poisoning by antiviral drugs, intentional self-harm

T378X2A	Poisoning by other specified systemic anti-infectives and antiparasitics, intentional self-harm
T3792XA	Poisoning by unspecified systemic anti-infective and antiparasitics, intentional self-harm
T380X2A	Poisoning by glucocorticoids and synthetic analogues, intentional self-harm
T381X2A	Poisoning by thyroid hormones and substitutes, intentional self-harm
T382X2A	Poisoning by antithyroid drugs, intentional self-harm
T383X2A	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, intentional self-harm
T384X2A	Poisoning by oral contraceptives, intentional self-harm
T385X2A	Poisoning by other estrogens and progestogens, intentional self-harm
T386X2A	Poisoning by antigonadotrophins, antiestrogens, antiandrogens, not elsewhere classified, intentional self-harm
T387X2A	Poisoning by androgens and anabolic congeners, intentional self-harm
T38802A	Poisoning by unspecified hormones and synthetic substitutes, intentional self-harm
T38812A	Poisoning by anterior pituitary [adenohypophyseal] hormones, intentional self-harm
T38892A	Poisoning by other hormones and synthetic substitutes, intentional self-harm
T38902A	Poisoning by unspecified hormone antagonists, intentional self-harm
T38992A	Poisoning by other hormone antagonists, intentional self-harm
T39012A	Poisoning by aspirin, intentional self-harm

T39092A	Poisoning by salicylates, intentional self-harm
T391X2A	Poisoning by 4-Aminophenol derivatives, intentional self-harm
T392X2A	Poisoning by pyrazolone derivatives, intentional self-harm
T39312A	Poisoning by propionic acid derivatives, intentional self-harm
T39392A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], intentional self-harm
T394X2A	Poisoning by antirheumatics, not elsewhere classified, intentional self-harm
T398X2A	Poisoning by other nonopioid analgesics and antipyretics, not elsewhere classified, intentional self-harm
T3992XA	Poisoning by unspecified nonopioid analgesic, antipyretic and antirheumatic, intentional self-harm
T400X1A	Poisoning by opium, accidental (unintentional), initial encounter
T400X2A	Poisoning by opium, intentional self-harm
T401X1A	Poisoning by heroin, accidental (unintentional), initial encounter
T401X2A	Poisoning by heroin, intentional self-harm
T402X2A	Poisoning by other opioids, intentional self-harm
T403X1A	Poisoning by methadone, accidental (unintentional), initial encounter
T403X2A	Poisoning by methadone, intentional self-harm
T40411A	Poisoning by fentanyl or fentanyl analogs, accidental (unintentional), initial encounter

T40412A	Poisoning by fentanyl or fentanyl analogs, self-harm, initial encounter
T40421A	Poisoning by tramadol, accidental (unintentional), initial encounter
T40422A	Poisoning by tramadol, self-harm, initial encounter
T40491A	Poisoning by other synthetic narcotics, accidental (unintentional), initial encounter
T40492A	Poisoning by other synthetic narcotics, self-harm, initial encounter
T405X1A	Poisoning by cocaine, accidental (unintentional), initial encounter
T405X2A	Poisoning by cocaine, intentional self-harm, initial encounter
T40601A	Poisoning by unspecified narcotics, accidental (unintentional), initial encounter
T40602A	Poisoning by unspecified narcotics, intentional self-harm, initial encounter
T40691A	Poisoning by unspecified narcotics, accidental (unintentional), initial encounter
T40692A	Poisoning by other narcotics, intentional self-harm
T40711A	Poisoning by cannabis, accidental (unintentional), initial encounter
T40712A	Poisoning by cannabis, intentional self-harm, initial encounter
T40721A	Poisoning by synthetic cannabis, accidental (unintentional), initial encounter
T40722A	Poisoning by synthetic cannabis, intentional self-harm, initial encounter
T407X1A	Poisoning by cannabis (derivates), accidental (unintentional), initial encounter

T407X2A	Poisoning by cannabis (derivatives), intentional self-harm
T408X1A	Poisoning by lysergide [LSD], accidental (unintentional), initial encounter
T408X2A	Poisoning by lysergide [LSD], intentional self-harm
T40901A	Poisoning by unspecified psychodysleptics [hallucinogens], accidental (unintentional), initial encounter
T40902A	Poisoning by unspecified psychodysleptics [hallucinogens], intentional self-harm
T40991A	Poisoning by other psychodysleptics [hallucinogens], accidental (unintentional), initial encounter
T40992A	Poisoning by other psychodysleptics [hallucinogens], intentional self-harm
T410X2A	Poisoning by inhaled anesthetics, intentional self-harm
T411X2A	Poisoning by intravenous anesthetics, intentional self-harm
T41202A	Poisoning by unspecified general anesthetics, intentional self-harm
T41292A	Poisoning by other general anesthetics, intentional self-harm
T413X2A	Poisoning by local anesthetics, intentional self-harm
T4142XA	Poisoning by unspecified anesthetic, intentional self-harm
T415X2A	Poisoning by therapeutic gases, intentional self-harm
T420X2A	Poisoning by hydantoin derivatives, intentional self-harm
T421X2A	Poisoning by iminostilbenes, intentional self-harm

T422X2A	Poisoning by succinimides and oxazolidinediones, intentional self-harm
T423X1A	Poisoning by barbiturates, accidental (unintentional), initial encounter
T423X2A	Poisoning by barbiturates, intentional self-harm
T424X1A	Poisoning by benzodiazepines, accidental (unintentional), initial encounter
T424X2A	Poisoning by benzodiazepines, intentional self-harm
T425X2A	Poisoning by mixed antiepileptics, intentional self-harm
T426X2A	Poisoning by other antiepileptic and sedative-hypnotic drugs, intentional self-harm
T4272XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, intentional self-harm
T428X2A	Poisoning by antiparkinsonism drugs and other central muscle-tone depressants, intentional self-harm
T43012A	Poisoning by tricyclic antidepressants, intentional self-harm
T43022A	Poisoning by tetracyclic antidepressants, intentional self-harm
T431X2A	Poisoning by monoamine-oxidase-inhibitor antidepressants, intentional self-harm
T43202A	Poisoning by unspecified antidepressants, intentional self-harm
T43212A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, intentional self-harm
T43222A	Poisoning by selective serotonin reuptake inhibitors, intentional self-harm
T43292A	Poisoning by other antidepressants, intentional self-harm

T433X2A	Poisoning by phenothiazine antipsychotics and neuroleptics, intentional self-harm
T434X2A	Poisoning by butyrophenone and thiothixene neuroleptics, intentional self-harm
T43502A	Poisoning by unspecified antipsychotics and neuroleptics, intentional self-harm
T43592A	Poisoning by other antipsychotics and neuroleptics, intentional self-harm
T43601A	Poisoning by unspecified psychostimulants, accidental (unintentional), initial encounter
T43602A	Poisoning by unspecified psychostimulants, intentional self-harm
T43612A	Poisoning by caffeine, intentional self-harm
T43621A	Poisoning by amphetamines, accidental (unintentional), initial encounter
T43622A	Poisoning by amphetamines, intentional self-harm
T43631A	Poisoning by methylphenidate, accidental (unintentional), initial encounter
T43632A	Poisoning by methylphenidate, intentional self-harm
T43641A	Poisoning by ecstasy, accidental (unintentional), initial encounter
T43651A	Poisoning by methamphetamines, accidental (unintentional), initial encounter
T43652A	Poisoning by methamphetamines, intentional self-harm, intentional encounter
T43692A	Poisoning by other psychostimulants, intentional self-harm
T438X2A	Poisoning by other psychotropic drugs, intentional self-harm

T4392XA	Poisoning by unspecified psychotropic drug, intentional self-harm
T440X2A	Poisoning by anticholinesterase agents, intentional self-harm
T441X2A	Poisoning by other parasympathomimetics [cholinergics], intentional self-harm
T442X2A	Poisoning by ganglionic blocking drugs, intentional self-harm
T443X2A	Poisoning by other parasympatholytics [anticholinergics and antimuscarinics] and spasmolytics, intentional self-harm
T444X2A	Poisoning by predominantly alpha-adrenoreceptor agonists, intentional self-harm
T445X2A	Poisoning by predominantly beta-adrenoreceptor agonists, intentional self-harm
T446X2A	Poisoning by alpha-adrenoreceptor antagonists, intentional self-harm
T447X2A	Poisoning by beta-adrenoreceptor antagonists, intentional self-harm
T448X2A	Poisoning by centrally-acting and adrenergic-neuron-blocking agents, intentional self-harm
T44902A	Poisoning by unspecified drugs primarily affecting the autonomic nervous system, intentional self-harm
T44992A	Poisoning by other drug primarily affecting the autonomic nervous system, intentional self-harm
T450X2A	Poisoning by antiallergic and antiemetic drugs, intentional self-harm
T451X2A	Poisoning by antineoplastic and immunosuppressive drugs, intentional self-harm
T452X2A	Poisoning by vitamins, intentional self-harm
T453X2A	Poisoning by enzymes, intentional self-harm

T454X2A	Poisoning by iron and its compounds, intentional self-harm
T45512A	Poisoning by anticoagulants, intentional self-harm
T45522A	Poisoning by antithrombotic drugs, intentional self-harm
T45602A	Poisoning by unspecified fibrinolysis-affecting drugs, intentional self-harm
T45612A	Poisoning by thrombolytic drug, intentional self-harm
T45622A	Poisoning by hemostatic drug, intentional self-harm
T45692A	Poisoning by other fibrinolysis-affecting drugs, intentional self-harm
T457X2A	Poisoning by anticoagulant antagonists, vitamin K and other coagulants, intentional self-harm
T458X2A	Poisoning by other primarily systemic and hematological agents, intentional self-harm
T4592XA	Poisoning by unspecified primarily systemic and hematological agent, intentional self-harm
T460X2A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm
T461X2A	Poisoning by calcium-channel blockers, intentional self-harm
T462X2A	Poisoning by other antidysrhythmic drugs, intentional self-harm
T463X2A	Poisoning by coronary vasodilators, intentional self-harm
T464X2A	Poisoning by angiotensin-converting-enzyme inhibitors, intentional self-harm
T465X2A	Poisoning by other antihypertensive drugs, intentional self-harm

T466X2A	Poisoning by antihyperlipidemic and antiarteriosclerotic drugs, intentional self-harm
T467X2A	Poisoning by peripheral vasodilators, intentional self-harm
T468X2A	Poisoning by antivaricose drugs, including sclerosing agents, intentional self-harm
T46902A	Poisoning by unspecified agents primarily affecting the cardiovascular system, intentional self-harm
T46992A	Poisoning by other agents primarily affecting the cardiovascular system, intentional self-harm
T470X2A	Poisoning by histamine H2-receptor blockers, intentional self-harm
T471X2A	Poisoning by other antacids and anti-gastric-secretion drugs, intentional self-harm
T472X2A	Poisoning by stimulant laxatives, intentional self-harm
T473X2A	Poisoning by saline and osmotic laxatives, intentional self-harm
T474X2A	Poisoning by other laxatives, intentional self-harm
T475X2A	Poisoning by digestants, intentional self-harm
T476X2A	Poisoning by antidiarrheal drugs, intentional self-harm
T477X2A	Poisoning by emetics, intentional self-harm
T478X2A	Poisoning by other agents primarily affecting gastrointestinal system, intentional self-harm
T4792XA	Poisoning by unspecified agents primarily affecting the gastrointestinal system, intentional self-harm
T480X2A	Poisoning by oxytocic drugs, intentional self-harm

T481X2A	Poisoning by skeletal muscle relaxants [neuromuscular blocking agents], intentional self-harm
T48202A	Poisoning by unspecified drugs acting on muscles, intentional self-harm
T48292A	Poisoning by other drugs acting on muscles, intentional self-harm
T483X2A	Poisoning by antitussives, intentional self-harm
T484X2A	Poisoning by expectorants, intentional self-harm
T485X2A	Poisoning by other anti-common-cold drugs, intentional self-harm
T486X2A	Poisoning by antiasthmatics, intentional self-harm
T48902A	Poisoning by unspecified agents primarily acting on the respiratory system, intentional self-harm
T48992A	Poisoning by other agents primarily acting on the respiratory system, intentional self-harm
T490X2A	Poisoning by local antifungal, anti-infective and anti-inflammatory drugs, intentional self-harm
T491X2A	Poisoning by antipruritics, intentional self-harm
T492X2A	Poisoning by local astringents and local detergents, intentional self-harm
T493X2A	Poisoning by emollients, demulcents and protectants, intentional self-harm
T494X2A	Poisoning by keratolytics, keratoplastics, and other hair treatment drugs and preparations, intentional self-harm
T495X2A	Poisoning by ophthalmological drugs and preparations, intentional self-harm
T496X2A	Poisoning by otorhinolaryngological drugs and preparations, intentional self-harm

T497X2A	Poisoning by dental drugs, topically applied, intentional self-harm
T498X2A	Poisoning by other topical agents, intentional self-harm
T4992XA	Poisoning by unspecified topical agent, intentional self-harm
T500X2A	Poisoning by mineralocorticoids and their antagonists, intentional self-harm
T501X2A	Poisoning by loop [high-ceiling] diuretics, intentional self-harm
T502X2A	Poisoning by carbonic-anhydrase inhibitors, benzothiadiazides and other diuretics, intentional self-harm
T503X2A	Poisoning by electrolytic, caloric and water-balance agents, intentional self-harm
T504X2A	Poisoning by drugs affecting uric acid metabolism, intentional self-harm
T505X2A	Poisoning by appetite depressants, intentional self-harm
T506X2A	Poisoning by antidotes and chelating agents, intentional self-harm
T507X1A	Poisoning by analeptics and opioid receptor antagonists, accidental (unintentional), initial encounter
T507X2A	Poisoning by analeptics and opioid receptor antagonists, intentional self-harm
T508X2A	Poisoning by diagnostic agents, intentional self-harm
T50902A	Poisoning by unspecified drugs, medicaments and biological substances, intentional self-harm
T50912A	Poisoning by multiple unspecified drugs, medications and biological substances, intentional self-harm, initial self-harm, initial encounter

T50992A	Poisoning by other drugs, medicaments and biological substances, intentional self-harm
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.03 NONBEHAVIORAL HEALTH FEE-FOR-SERVICE BENEFITS.

An MCO may not be required to provide any of the following benefits or services that are reimbursed directly by the Department:

A. The remaining days of a hospital admission following enrollment in the MCO if the recipient was admitted to the hospital before the date of the recipient's enrollment;

B. Long-term care services except for those outlined in COMAR 10.67.06.07B and COMAR 10.67.06.12A;

C. Intermediate Care Facilities for Individuals with Intellectual Disabilities or Persons with Related Conditions (ICF/IID) services;

D. Personal care services pursuant to COMAR 10.09.20;

E. Medical day care services, for adults and children;

F. The following HIV/AIDS services:

(1) Genotypic, phenotypic, or other HIV/AIDS drug resistance testing used in the treatment of HIV/AIDS, if the service is:

(a) Rendered by a Department-approved provider; and

(b) Medically necessary; and

(2) Viral load testing used in treatment of HIV/AIDS.

G. Physical therapy, speech therapy, and occupational therapy services when:

(1) The enrollee is younger than 21 years old; and

(2) The services are not part of home health services or an inpatient hospital stay;

H. Augmentative communication devices;

I. All dental services including but not limited to outpatient surgery fees for the facility and general anesthesia.

J. Except when a woman has been determined eligible for Medical Assistance benefits under COMAR 10.09.11, an abortion pursuant to COMAR 10.09.02.04G;

K. Emergency transportation;

L. Transportation services provided through grants to local governments pursuant to COMAR 10.09.19;

M. Services provided to members participating in the State's Health Home Program as described in COMAR 10.09.33;

N. Applied behavioral analysis (ABA) services as described in COMAR 10.09.28; and

O. Abortions performed in accordance with Health-General Article, § 15-103, Annotated Code of Maryland.

CHAPTER 09 MARYLAND MEDICAID MANAGED CARE PROGRAM: MCO DISPUTE RESOLUTION PROCEDURES

.01 MCO ENROLLEE SERVICES.

An MCO shall:

- A. Maintain a member services unit that operates an enrollee services line at least during normal business hours;
- B. Operate its enrollee services line as a triage device to handle or properly refer enrollees' questions or complaints; and
- C. Provide information in the member handbook about how to use the MCO enrollee services line to obtain information and assistance.

.02 MCO ENROLLEE COMPLAINT PROCESS.

A. An MCO shall have written complaint procedures by which an enrollee who is dissatisfied with the MCO or its network providers, or decisions made by the MCO or a provider, may seek recourse verbally or in writing within the MCO at any time.

B. An MCO shall:

- (1) Submit its written internal complaint procedures to the Department for its approval;
- (2) Give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal in a manner consistent with COMAR 10.67.05.01A;
- (3) Prepare the document describing the MCO's internal complaint process:
 - (a) In a culturally sensitive manner;
 - (b) At an appropriate reading comprehension level; and
 - (c) In the prevalent non-English languages, identified by the State;
- (4) Deliver a copy of the MCO's complaint procedures to each enrollee:
 - (a) With the MCO's initial contact with a new enrollee; and
 - (b) At any time upon an enrollee's request;
- (5) Maintain an accurate and accessible record of grievances and appeals for monitoring by the State and CMS, which includes, at a minimum:
 - (a) A general description of the reason for the appeal or grievance;
 - (b) The date received;
 - (c) The date of each review or, if applicable, review meeting;

- (d) Resolution at each level of the appeal or grievance, if applicable;
 - (e) Date of resolution at each level, if applicable; and
 - (f) Name of the enrollee for whom the appeal or grievance was filed; and
 - (6) Provide in its written procedures that an enrollee may file appeals and grievances orally or in writing.
- C. An MCO shall submit for Department approval an internal complaint process detailing the procedures for registering and responding to appeals and grievances in a timely fashion, which:
- (1) Includes a specific standard for grievance decisions, monitored by the MCO for compliance, directing that:
 - (a) The decision time for emergency medically related grievances may not exceed 24 hours;
 - (b) The decision time for nonemergency medically related grievances may not exceed 5 days; and
 - (c) For administrative grievances, the decision time may not exceed 30 days;
 - (2) Includes participation by the provider, if appropriate;
 - (3) Allows participation by the ombudsman, if appropriate;
 - (4) Ensures the participation of individuals within the MCO who have the authority to require corrective action;
 - (5) Requires documentation of the substance of the grievances and steps taken;
 - (6) Includes a procedure for the aggregation and analysis of appeals and grievance data and use of the data for quality improvement;
 - (7) Includes a documented procedure for reporting:
 - (a) Appeals and grievances received by the MCO to:
 - (i) The provider involved;
 - (ii) Appropriate quality assurance committees and departments within the MCO;
 - (iii) The MCO's consumer advisory board; and
 - (iv) The Department as requested; and
 - (b) The quarterly appeal and grievance analysis performed by the MCO as specified in COMAR 10.67.04.15D(1)(b);
 - (8) Includes a documented procedure for written notification of the MCO's determination:
 - (a) To the enrollee who filed the grievance; and
 - (b) To those individuals and entities required to be notified of the grievance pursuant to §C(7) of this regulation;
 - (9) Ensures that decision makers on appeals and grievances:
 - (a) Were not involved in previous levels of decision-making;

- (b) Are not subordinates of people involved in previous levels of decision-making;
- (c) Are healthcare professionals with clinical expertise in treating the enrollee's condition or disease, if any of the following apply:
 - (i) The appeal is a denial based on lack of medical necessity;
 - (ii) The grievance is regarding denial of expedited resolution of an appeal; or
 - (iii) The appeal or grievance involves clinical issues; and
- (d) Take into account all comments, documents, records, and other information submitted by the enrollee or their representative, without regard to whether such information was submitted or considered in the initial action.

.02-1 MEMBER COMPLAINTS – TIME FRAMES FOR MCOs TO RESPOND TO THE DEPARTMENT.

An MCO shall:

- A. Acknowledge an enrollee appeal or grievance reported to it by the Department's complaint resolution unit within 1 business day;
- B. Respond to the Department's request for information regarding disputed nonemergency medical care actions within 3 business days;
- C. Provide updates in a time frame specified by the Department;
- D. Provide medical records within 5 days of the request; and
- E. Provide a corrective action plan upon request and within the time frame specified, but not later than 10 days from the date of the request.

.03 MCO PROVIDER COMPLAINT PROCESS.

A. An MCO shall have a complaint procedure for providers that is:

- (1) Documented in writing;
- (2) Disseminated in writing to all of the MCO's providers at the time they join the MCO's provider panel, and furnished to a provider at any time, upon request; and
- (3) Linked to the MCO's internal quality assurance program.

B. An MCO shall include in its provider complaint process at least the following elements:

- (1) Procedures for registering and responding to provider grievances in a timely fashion, including standards for timeliness that recognize the need for expedited determinations in situations that are time-sensitive, that is, when an enrollee's treatment outcome may be significantly affected by the promptness of treatment, as set forth in Regulation .02C(1)(a) and (b) of this chapter apply;
- (2) Notification to the provider of an MCO's determination that affects the provider or that provider's patient, which includes a description of how to file an internal appeal with the MCO;
- (3) Documentation of the substance of complaints and steps taken;

- (4) Procedures to ensure the timely resolution of the complaint and response by the MCO to the provider;
 - (5) Procedures for the termination or withdrawal of a provider from the MCO's provider panel, including:
 - (a) At least 90 days prior notice to the primary care providers in the MCO's provider panel of the MCO's termination of a specialty services provider when the reason for the termination is unrelated to fraud, patient abuse, incompetency, or loss of licensure status;
 - (b) If possible, at least 90 days prior notice to the primary care providers in the MCO's provider panel of a specialty services provider's withdrawal from the MCO's provider panel; and
 - (c) Notices to primary care providers informing them of the enrollee's right to change MCOs as described in COMAR 10.67.02.06A(1)(e).
 - (6) Mechanisms to aggregate and analyze appeal and grievance data and to use the data for quality improvement;
 - (7) An appeal process which:
 - (a) Is available when the provider's appeal or grievance is not resolved to the provider's satisfaction, or when the MCO acts to reduce, suspend, or terminate provider's privileges with the MCO;
 - (b) Acknowledges receipt of provider appeals within 5 business days of receipt by the MCO;
 - (c) Allows providers 90 business days from the date of a denial to file an initial appeal;
 - (d) Allows providers at least 15 business days from the date of denial to file each subsequent level of appeal;
 - (e) Resolves appeals, regardless of the number of appeal levels allowed by the MCO, within 90 business days of receipt of the initial appeal by the MCO;
 - (f) Pays claim within 30 days of the appeal decision when a claim denial is overturned;
 - (g) Provides at its final level an opportunity for the provider to be heard by the MCO's chief executive officer, or the chief executive officer's designee;
 - (h) Provides timely written notice to the provider of the results of the internal appeal; and
 - (i) Provides for written notice of the substance of the dispute and the result of the internal appeal to appropriate quality assurance committees and departments within the MCO; and
 - (8) A protocol for transmitting provider appeal and grievance reports and aggregate provider grievance and appeal data to the Department when requested.
- C. An MCO may not take any punitive action against a provider for utilizing the MCO provider complaint process, for supporting an enrollee's appeal, or for requesting expedited resolution for an enrollee's appeal.
- D. An MCO or its pharmacy benefits manager shall resolve pharmacy appeals concerning drug pricing within 21 days of the receipt of a request.

.03-1 INDEPENDENT REVIEW ORGANIZATION (IRO).

For provider disputes involving medical necessity, an MCO shall participate in the IRO process as specified in COMAR 10.67.13.

.03-2 PROVIDER COMPLAINTS – TIME FRAMES FOR MCOs TO RESPOND TO THE DEPARTMENT

An MCO shall:

- A. Acknowledge provider grievances within 3 business days;
- B. Provide findings to the Department within 5 days; and
- C. Provide a corrective action plan to the Department within 10 days from the date of the request.

.04 MCO ACTIONS AND DECISIONS.

A. For certain services to enrollees that require preauthorization the following conditions apply:

(1) For standard authorization decisions, the MCO shall make a determination within 2 business days of receipt of necessary clinical information, but not later than 14 calendar days from the date of the initial request so as not to adversely affect the health of the enrollee;

(2) For expedited authorization decisions, the MCO shall make a determination and provide notice no later than 72 hours after receipt of the request for service if the provider indicates or the MCO determines that the standard time frame stated in §A(1) of this regulation could jeopardize:

(a) The enrollee's life;

(b) The enrollee's health; or

(c) The enrollee's ability to attain, maintain, or regain maximum function;

(3) For all covered outpatient drug authorization decisions, the MCO shall provide notice by telephone or other telecommunication device within 24 hours of a preauthorization request in accordance with section 1927(d)(5)(A) of the Social Security Act;

(4) Standard and expedited authorization decisions may be extended up to 14 calendar days, if the following conditions are met:

(a) The enrollee or the provider requests an extension; or

(b) The MCO justifies to the Department, upon request, a need for additional information and how the extension is in the enrollee's interest; and

(5) If the MCO successfully justifies extending the standard service authorization decision time frame, the MCO shall:

(a) Give the enrollee written notice of the reason for the decision to extend the time frame;

(b) Inform the enrollee of the right to file a grievance if he or she disagrees with the extension decision; and

(c) Issue and carry out the MCO's determination as expeditiously as the enrollee's health condition requires but not later than the date the extension expires.

B. Any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested:

(1) Shall be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease; and

(2) May not be based solely on diagnosis, type of illness, or condition.

C. An MCO shall 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.

D. Notices of a decision to deny a standard authorization shall be provided to the enrollee and the requesting provider within 72 hours from the date of determination.

E. An MCO shall give an enrollee written notice of any action within the following time frames:

(1) At least 10 days before the action for termination, suspension, or reduction of a previously authorized covered service;

(2) The notice period is reduced to 5 days if probable enrollee fraud has been verified;

(3) By the date of the action for the following:

(a) The MCO has factual information confirming the death of an enrollee;

(b) A signed written enrollee statement requesting service termination or giving information requiring termination or reduction of services, where the enrollee understands that this is the result of supplying that information;

(c) The enrollee's admission to an institution where they are ineligible for further services;

(d) The enrollee's address is unknown and mail directed to the enrollee has no forwarding address;

(e) The enrollee has been accepted for Medicaid services by another jurisdiction;

(f) The enrollee's physician prescribes a change in the level of medical care; or

(g) An adverse determination made with regard to the preadmission screening requirements for nursing facility admissions; and

(4) As soon as practicable for nursing facility transfers or discharges when:

(a) The safety or health of individuals in the facility would be endangered;

(b) The enrollee's health improves sufficiently to allow a more immediate transfer or discharge; or

(c) An immediate transfer or discharge is required by the enrollee's urgent medical needs; and

(5) For denial of payment, at the time of any action affecting the claim.

F. A notice of adverse action shall:

(1) Be in writing;

(2) Meet the following requirements:

(a) Be translated for enrollees who speak prevalent non-English languages;

- (b) Include language clarifying that oral interpretation is available for all languages and how to access it;
 - (c) Be written in an easily understood language and format that takes into consideration enrollees with special needs;
 - (d) Be available in alternative formats; and
 - (e) Inform enrollees that information is available in alternative formats and how to access those formats; and
- (3) Contain the following information:
- (a) The action the MCO has made or intends to make;
 - (b) The reasons for the action, including the right for the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the MCO's action, including:
 - (i) Medical necessity criteria; and
 - (ii) Any processes, strategies, or evidentiary standards used in setting coverage limits;
 - (c) The enrollee's right to request an appeal of the MCO's action, including information on:
 - (i) Exhausting the MCO's one level of appeal; and
 - (ii) The right to request a State fair hearing;
 - (d) The procedures for exercising the rights described;
 - (e) The circumstances under which an appeal process can be expedited and how to request it;
 - (f) The enrollee's right to have benefits continue pending resolution of the appeal;
 - (g) How to request that benefits be continued; and
 - (h) The circumstances under which the enrollee may be required to pay the costs of the services.

G. If an MCO does not make an authorization decision within the times specified in §A of this regulation, the untimely decision is considered a denial and thus an adverse action subject to the notice requirements in §§C and E of this regulation.

.05 MCO APPEAL PROCESS FOR ENROLLEES.

A. An MCO's appeal process shall:

- (1) Require that an enrollee, or a provider acting on the enrollee's behalf, file an appeal within 60 days from the date on the MCO's notice of action;
- (2) Include procedures for acknowledging receipt of appeals within 5 business days;
- (3) Permit an enrollee to request an appeal either orally or in writing;
- (4) Provide that oral requests for appeal are considered the initiation of the appeal to establish the earliest possible filing date;

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(5) Provide reasonable opportunity to present evidence and allegations of fact or law, in person as well as in writing, and in the case of expedited appeals, the MCO shall inform the enrollee of the limited time available for the enrollee to present this evidence;

(6) Provide the case file upon request to the enrollee and the enrollee's representative, free of charge and sufficiently in advance of the resolution time frame for appeals, which includes:

(a) Medical records;

(b) Other documents and records; and

(c) Any new or additional evidence considered, relied upon, or generated by the MCO in connection with the action.

(7) Allow a provider or authorized representative acting on behalf of an enrollee to file an appeal with the enrollee's written consent;

(8) Consider the enrollee, the enrollee's representative, or the estate representative of a deceased enrollee as parties to the appeal;

(9) Establish and maintain an expedited review process, 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; and

(10) Ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

B. Resolution.

(1) Except for expedited appeals as described in §C, an MCO shall resolve each appeal and provide notice of resolution, as expeditiously as the enrollee's health condition requires, and unless extended pursuant to §B(2) of this regulation, within 30 days from the day the MCO receives the appeal.

(2) The time frames in §B(1) of this regulation may be extended up to 14 calendar days if:

(a) The enrollee requests the extension; or

(b) The MCO shows, upon the Department's request, that there is a need for additional information and how the delay is in the enrollee's interest.

(3) For any extension not requested by the enrollee, the MCO shall:

(a) Give the enrollee written notice; and

(b) Make reasonable efforts to give the enrollee verbal notice of the reason for the delay.

(4) Continuation of Benefits. The MCO shall continue the enrollee's benefits pending the outcome of the appeal if all of the following occur:

(a) The enrollee timely files for continuation of benefits;

(b) The appeal is filed timely, meaning on or before the later of the following:

(i) Within 10 days of the MCO mailing the notice of action; or

- (ii) The intended effective date of the MCO's proposed action;
 - (c) The appeal involves the termination, suspension, or reduction of a previously authorized service;
 - (d) The services were ordered by an authorized provider; and
 - (e) The authorization period has not expired.
- (5) If the MCO continues or reinstates the enrollee's benefits while the appeal is pending, the benefits shall continue until one of the following occurs:
- (a) The enrollee withdraws the appeal;
 - (b) The enrollee fails to request a State fair hearing and continuation of benefits within 10 days after the MCO sends the notice of an adverse resolution to the enrollee's appeal; or
 - (c) A State fair hearing decision adverse to the enrollee is made.
- (6) If the MCO or State fair hearing officer reverses a decision to deny, limit, or delay services, the MCO shall authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours of the date the MCO receives the reversal.

C. Expedited Appeals.

- (1) An expedited resolution may be approved when the MCO determines or the provider indicates that taking the time for a standard resolution could seriously jeopardize:
- (a) The enrollee's life;
 - (b) The enrollee's physical or mental health; or
 - (c) The enrollee's ability to attain, maintain, or regain maximum function.
- (2) Expedited appeals shall be resolved as expeditiously as the enrollee's health condition requires but no later than 72 hours after the MCO receives the appeal.
- (3) If the MCO denies a request for expedited resolution of an appeal, the MCO shall:
- (a) Transfer the appeal to the standard time frame of not longer than 30 days from the day the MCO receives the appeal with a possible 14-day extension as described in §B(2) of this regulation; and
 - (b) Make reasonable efforts to give the enrollee prompt verbal notice of the denial of expedited resolution and provide a written notice within 2 calendar days.

D. Notification.

- (1) The MCO shall provide written notice of resolution which includes:
- (a) The results and date of the appeal resolution;
 - (b) The reasons for the action;
 - (c) For decisions not wholly in the enrollee's favor:

- (i) The right to request a State fair hearing;
- (ii) How to request a State fair hearing;
- (iii) The right to continue to receive benefits pending a hearing;
- (iv) How to request the continuation of benefits; and
- (v) A statement that the enrollee may be liable for the cost of any continued benefits if the MCO's action is upheld in a hearing.

(2) For notice of an expedited resolution, in addition to requirements listed in §D(1) of this regulation, the MCO shall also make reasonable efforts to provide oral notice of the decision.

E. If an MCO fails to adhere to the notice and timing requirements, as described in §§A—D of this regulation, the enrollee is deemed to have exhausted the MCO's appeals process and may initiate a State fair hearing.

F. State Fair Hearing.

(1) An enrollee may exercise State fair hearing rights pursuant to the Department's regulations and State Government Article, §10-201 et seq., Annotated Code of Maryland, subject to the requirements of this regulation.

(2) An enrollee may request a State fair hearing for an MCO appeal resolution after first exhausting the MCO's appeal process by appealing to the Office of Administrative Hearings using the process specified in COMAR 10.01.04.

(3) An enrollee shall file for a State fair hearing within 120 days from the date the MCO provides on the written notice of appeal resolution.

(4) The parties to an appeal to the Office of Administrative Hearings under this section are the:

- (a) MCO;
- (b) Enrollee; and
- (c) Enrollee's representative or the personal representative of a deceased enrollee's estate.

(5) The MCO shall provide documentation regarding medical determinations to enrollees and the Office of Administrative Hearings as required by COMAR 10.01.04 and other applicable law.

(6) The MCO shall continue the enrollee's benefits pending the outcome of the State fair hearing if all of the following occur:

- (a) The enrollee files for continuation of benefits within 10 days of the MCO upholding its action;
- (b) The State fair hearing request is filed timely, meaning on or before the later of the following:
 - (i) 10 days from the date on the MCO's notice of appeal resolution; or
 - (ii) The intended effective date of the MCO's proposed action;
- (c) The State fair hearing involves the termination, suspension, or reduction of a previously authorized service;
- (d) The services were ordered by an authorized provider; and

(e) The authorization period has not expired.

(7) If the MCO continues or reinstates the enrollee's benefits while the State fair hearing is pending, the benefits shall continue until one of the following occurs:

(a) The enrollee withdraws the State fair hearing; or

(b) A State fair hearing decision adverse to the enrollee is issued by the Office of Administrative Hearings.

(8) The final decision of the Office of Administrative Hearings is appealable to the circuit court, and is governed by State Government Article, §10-201 et seq., Annotated Code of Maryland, and the Maryland Rules.

G. The Department may order an MCO to provide a benefit or service based on its evaluation of the MCO's action.

CHAPTER 10 MARYLAND MEDICAID MANAGED CARE PROGRAM: SANCTIONS

.01 SANCTION BY THE DEPARTMENT

A. If the Department determines, after a sufficient investigation, that an MCO or any agent or employee of the MCO, or any person with an ownership interest in an MCO, or related party of the MCO, has failed to comply with any applicable law, regulation, or contract term, or for other good cause shown, the Department may impose sanctions on the MCO, including but not limited to:

(1) Fines;

(2) Suspension of further enrollment;

(3) Withholding all or part of the capitation payment;

(4) Termination of the current HealthChoice Managed Care Organization Agreement;

(5) Disqualification from future participation in the Maryland Medicaid Managed Care Program;

(6) Orders to provide a benefit or service to enrollees; and

(7) Those outlined in 42 CFR §§438.700—438.708, as amended.

B. Corrective Action.

(1) Subject to §B(2) of this regulation, before imposing a sanction pursuant to §A of this regulation, the Department may permit an MCO an opportunity to take corrective action in accordance with a plan approved by the Department.

(2) The MCO shall submit a corrective action plan within a time frame specified by the Department.

.01-1 SANCTION BY CENTER FOR MEDICARE AND MEDICAID SERVICES (CMS)

The Department shall comply with notification requirements of CMS at 42 CFR §438.730 for sanction determinations as specified in 42 CFR §438.700(b)(1)—(b)(6).

.02 APPEALS

A. From the decisions set forth in §B(1)—(8) of this regulation, an MCO may exercise the appeal rights set forth in §C of this regulation.

B. The following Department decisions are appealable by the MCO or MCO applicant:

- (1) Denial of an entity's completed application to become an MCO;
- (2) Decision to terminate the MCO's participation in the Maryland Medicaid Managed Care Program;
- (3) Decision to impose a fine valued at \$50,000 or more on the MCO as described in Regulation .01 of this chapter;
- (4) Order that the MCO is impaired or in "hazardous financial condition";
- (5) An adverse decision by the IRO as described in COMAR 10.67.13.08;
- (6) The denial of a hepatitis C payment as described in COMAR 10.67.04.19;
- (7) Overpayments recovered by the Department as described in COMAR 10.67.07.01; and
- (8) Remittances to the Department as described in COMAR 10.67.04.19-5.

C. An MCO may appeal a decision listed in §B of this regulation to the Office of Administrative Hearings as specified in COMAR 10.01.03 and COMAR 10.09.36.09.

D. The parties to an appeal to the Office of Administrative Hearings under §C of this regulation are the Department and the MCO. The enrollee is not a party at this hearing.

E. The following sanctions shall take effect immediately and are not subject to stay during the pendency of an appeal:

- (1) Any fines imposed;
- (2) Orders to provide a benefit or service to enrollees;
- (3) Any full or partial withhold of the capitation payment;
- (4) Any remittances to the Department as described in COMAR 10.67.04.19-5; or
- (5) Any overpayments recovered by the Department as described in COMAR 10.67.07.01.

.03 INCENTIVES

A. All monies collected from the MCOs as a result of the imposition of a financial sanction shall be deposited in the HealthChoice Performance Incentive Fund.

B. This nonlapsing fund shall include all sanctions imposed on the MCOs starting in calendar year 1999.

C. The fund shall be used to provide financial incentive awards to the MCOs that meet or exceed specific performance targets as established by the Department, unless otherwise directed by law.

CHAPTER 12 MARYLAND MEDICAID MANAGED CARE PROGRAM: CORRECTIVE MANAGED CARE

.01 GENERAL

A. An MCO shall establish a corrective managed care plan that, at minimum, provides for:

- (1) The identification of an enrollee that has abused MCO pharmacy benefits; and
- (2) The enrollment of an enrollee that has been determined to have abused MCO pharmacy benefits in the MCO's corrective managed care plan.

B. Enrollee abuse exists when an enrollee:

- (1) Has engaged in behaviors identified in COMAR 10.09.24.14-1; or
- (2) Engages in Medicaid fraud as defined under COMAR 10.09.24.14.

.02 CORRECTIVE MANAGED CARE PLAN

A. An MCO's corrective managed care plan:

- (1) Shall cover enrollee abuse of medical assistance pharmacy benefits; and
- (2) May cover enrollee abuse of nonpharmacy medical assistance benefits.

B. For all benefit abuse covered by an MCO's corrective managed care plan, the plan shall:

- (1) Use the criteria as described in Regulation .01B of this regulation to determine if enrollees have abused benefits;
- (2) Provide for a medical review of the alleged abuse consistent with §C of this regulation;
- (3) Provide that an enrollee found to have abused benefits will be enrolled in the program for 24 months;
- (4) Provide that an enrollee who has been enrolled in a 24 month plan and is subsequently found to have abused MCO benefits shall be enrolled in the plan for an additional 36 months;
- (5) Provide for the MCO to select any participating provider in the MCO that meets the requirements of COMAR 10.67.05.05A to serve as the enrollee's primary care, specialty care, and pharmacy providers for enrollees in corrective managed care, as appropriate to the type of benefit the enrollee has been found to have abused;
- (6) Require an enrollee to obtain prescribed drugs only from a single designated pharmacy provider, which may be any pharmacy or any single branch of a pharmacy chain that participates in the MCO and meets the requirements of COMAR 10.67.05.06B and .07C(2) unless the prescription is:
 - (a) Pursuant to an emergency department visit;
 - (b) Pursuant to hospital inpatient treatment; or
 - (c) A specialty drug as defined in COMAR 10.67.06.04;
- (7) Provide enrollees determined to have abused benefits the ability to suggest primary care, specialty care, or pharmacy providers;
- (8) Require the MCO to accept the enrollee's suggestion referenced in §B(7) of this regulation unless the MCO determines that the recipient's choice of provider would not serve the enrollee's best interest in achieving appropriate use of the health care systems and benefits available through the MCO;
- (9) Provide an enrollee determined to have abused benefits 20 days from the date of the notice to present additional documentation to explain the facts that serve as the basis for the MCO's determination of benefit abuse, consistent with §D of this regulation;

(10) Provide for the designation of a new primary care, specialty care, or pharmacy provider if the enrollee moves out of the service area of the current primary care or pharmacy provider;

(11) Provide for prompt reporting to the Department the name of any enrollee enrolled in the MCO's program, the duration of enrollment, or any change in the duration of enrollment; and

(12) Be submitted to the Department for review and approval:

(a) Within 60 days of the effective date of this regulation; and

(b) Before the implementation of any modification.

C. The medical review required in §B(2) of this regulation shall:

(1) Be performed by a medical reviewer who is a licensed health care professional;

(2) Consider all information that is relevant and available to the MCO, including but not limited to MCO payment records and information secured from any interviews conducted; and

(3) Where appropriate, consider records obtained from other sources, including:

(a) Providers of medical services;

(b) Statistical reports;

(c) Outside complaints;

(d) Referrals from other agencies; or

(e) Any other appropriate sources.

D. If an enrollee provides additional information pursuant to §B(9) of this regulation within 20 days:

(1) The effective date of the enrollment provided in the notice shall be tolled pending the MCO's review of the additional information;

(2) The MCO shall consider whether the additional information changes the MCO's determination regarding the appropriateness of the enrollee's enrollment in corrective managed care;

(3) The MCO shall notify the enrollee of its decision whether the MCO is affirming or reversing its determination to enroll the enrollee in corrective managed care; and

(4) If the MCO confirms its determination to enroll the enrollee in corrective managed care, the notice shall:

(a) Identify the effective date and duration of that enrollment; and

(b) Include an explanation of the enrollee's right to appeal the determination as described in Regulation .05 of this chapter.

E. An MCO's corrective managed care plan may include a process for re-considering, at any interval of time, a decision to enroll an enrollee in the MCO's corrective managed care plan, if the process entitles the enrollee to appeal the decision pursuant to Regulation .05 of this chapter at the same interval of time.

.03 ENROLLEE NOTICE

The MCO shall provide an enrollee determined to have abused MCO benefits a written notice that includes the following:

- A. An explanation of the reason or reasons for the determination that the enrollee abused benefits;
- B. A statement that the enrollee has 20 days to provide:
 - (1) Additional information for the MCO to consider before enrollment will become effective; and
 - (2) The address where the additional information shall be sent;
- C. A statement that the enrollee will be enrolled in corrective managed care and the effective date and duration of that enrollment;
- D. An explanation that the effective date will be tolled pending the MCO's review of any additional information the enrollee provides pursuant to §B of this regulation;
- E. A statement that the enrollee may identify a preference for an assigned primary medical care provider, specialty care provider, or pharmacy; and
- F. An explanation of the enrollee's right to appeal the MCO's determination as described in Regulation .05 of this chapter.

.04 EFFECTIVE DATE OF ENROLLMENT

- A. Except as provided in §B of this regulation, the effective date of enrollment shall be 20 days from the date of the notice described in Regulation .03A and B of this chapter, whichever is later.
- B. If an enrollee determined to have abused benefits appeals the determination, the effective date of the enrollment shall be tolled pending the outcome of the appeal.
- C. The duration of an enrollee's enrollment in a plan may not be altered because of changes in how the individual receives medical assistance, including but not limited to a change in the enrollee's MCO enrollment.

.05 ENROLLEE APPEAL

- A. An enrollee shall have 20 days to appeal an MCO's determination of benefit abuse.
- B. Except for the time frame specified in §A of this regulation, an appeal shall be handled as specified in COMAR 10.67.09.05.
- C. If the appeal results in a hearing, an MCO shall:
 - (1) Attend the hearing; and
 - (2) Provide justification for enrollment in the program.

CHAPTER 13 MARYLAND MEDICAID MANAGED CARE PROGRAM: INDEPENDENT REVIEW ORGANIZATION (IRO)

.01 SCOPE AND PURPOSE

This chapter provides for a complaint resolution process for disputes between managed care organizations (MCOs) and providers regarding adverse medical necessity decisions made by MCOs. Pursuant to this chapter, providers that receive an adverse medical necessity decision on claims for reimbursement may submit the adverse decision for review by an Independent Review Organization (IRO) designated by the Department.

.02 DEFINITIONS

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Adverse decision" means a review determination by a managed care organization that a health care service for which a provider seeks reimbursement is not medically necessary.

(2) "Affiliate" means a person who, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with another person.

(3) "Case record" means documentation submitted to an independent review organization consisting of:

(a) A claim and only the supporting documentation, including medical records, originally submitted to a managed care organization by a provider prior to the managed care organization's adverse decision on the claim;

(b) The managed care organization's adverse decision; and

(c) The managed care organization's written rationale for the adverse decision.

(4) "Claim" means a clean claim as defined in COMAR 31.10.11.02.

(5) "Complaint" means an appeal of an adverse decision filed with the independent review organization.

(6) "Department" means the Maryland Department of Health.

(7) "Expert reviewer" means a physician or other appropriate health care provider who contracts with the independent review organization to conduct a review of a managed care organization's adverse decision.

(8) "Health care service" means a health or medical care procedure or service rendered by a provider including:

(a) Testing, diagnosis, or treatment of a human disease or dysfunction;

(b) Dispensing of drugs, medical devices, medical appliances, or medical goods for the treatment of a human disease or dysfunction; or

(c) Any other care, service, or treatment of disease or injury, the correction of defects, or the maintenance of the physical and mental well-being of human beings.

(9) "Independent review organization" means an entity that contracts with the Department to conduct independent review of managed care organizations' adverse decisions.

(10) "Managed care organization (MCO)" has the meaning stated in Health-General Article, §15-101, Annotated Code of Maryland.

(11) "Medicaid" means the program administered by the State under Title XIX of the Social Security Act, which provides comprehensive medical and other health-related care for persons.

(12) "Medical record" has the meaning stated in Health-General Article, §4-301, Annotated Code of Maryland.

(13) "Medically necessary" means a health care service that is:

(a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;

(b) Consistent with currently accepted standards of good medical practice;

(c) The most cost-efficient service that can be provided without sacrificing effectiveness or access to care; and

(d) Not primarily for the convenience of the consumer, the consumer's family, or the provider.

(14) "Provider" means any individual or entity that has a valid provider agreement with a Medicaid managed care organization or is a nonparticipating provider rendering covered Medicaid services to the managed care organization's enrollees.

.03 USE OF INDEPENDENT REVIEW ORGANIZATIONS

A. The Department shall procure the services of an IRO to make determinations of medical necessity on provider complaints regarding adverse decisions.

B. An IRO that contracts with the Department shall assure, in accordance with its contract with the Department, the:

(1) Timeliness and quality of the reviews;

(2) Qualifications and independence of the IRO and expert reviewers; and

(3) Confidentiality of medical records and review materials, consistent with federal and State laws.

C. An IRO designated by the Department shall have the authority to conduct the following functions:

(1) Obtaining all case information relative to the complaint from the MCO pursuant to time frames established by the Department;

(2) Assigning an expert reviewer for review of an adverse decision;

(3) Performing conflicts checks relative to the independent review organization and the expert reviewer assigned to review the adverse decision;

(4) Communicating procedural rules, as approved by the Department, and other information regarding appeals to the parties;

(5) Rendering a timely final decision in accordance with Regulation .06F of this chapter.

.04 CONFLICTS OF INTEREST STANDARDS FOR INDEPENDENT REVIEW ORGANIZATIONS AND EXPERT REVIEWERS

A. An IRO or expert reviewer may not be an affiliate or have a financial, familial or professional relationship with any facility, provider, or organization that has filed a complaint.

B. Upon request by the Department, the IRO shall provide to the Department information demonstrating compliance with the requirement in §A of this regulation.

.05 ASSIGNMENT OF AN EXPERT REVIEWER.

A. The IRO shall ensure that an expert reviewer:

(1) Has appropriate clinical expertise in the treatment of the specific medical condition being reviewed and holds a nonrestricted license as a health care provider in the United States; and

(2) Has no history of disciplinary investigations, actions, or sanctions, including loss of staff privileges or participation restrictions that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body.

B. Upon request by the Department, the independent review organization shall provide to the Department information demonstrating compliance with the requirements in §A of this regulation.

.06 INDEPENDENT REVIEW.

A. A provider shall exhaust an MCO's provider appeal process before filing a complaint with the IRO.

B. A provider shall file a complaint with the IRO in the form provided by the IRO not later than 30 calendar days following the date of an MCO's adverse decision.

C. A review of an adverse decision shall be based on the case record.

D. The IRO shall, after reviewing the case record, issue a final decision as to whether the health care services that are the subject of the complaint were medically necessary.

E. The final decision shall state in writing the factual bases for the decision of the expert reviewer and reference the criteria and standards on which the expert reviewer's decision was based.

F. Final decisions shall be rendered within 45 days of submission of the case record, unless the time period is extended by the Department.

.07 PAYMENT OF FEES AND SANCTIONS.

A. In the event that a provider's complaint is unsuccessful, the provider is responsible for paying to the IRO the case review charge established by the Department.

B. The case review charge established by the Department shall be based on the contract between the Department and the IRO arrived at through a competitive procurement process.

C. An MCO that is determined by the IRO to have improperly denied, either in whole or in part, a provider's claim on medical necessity grounds is subject to the following:

(1) Within 60 calendar days of the date of an adverse decision by an IRO, the MCO shall fully reimburse the provider for claims determined to be medically necessary by the IRO, including any interest owed under Health Insurance Article, §15-1005(f), Annotated Code of Maryland; and

(2) Within 60 calendar days of the date of invoice by the IRO, the MCO shall reimburse the IRO the case review charge established by the Department.

D. In the event that the unsuccessful party does not pay the IRO within 60 calendar days of the date of the invoice, the Department shall impose penalties as follows:

(1) First delinquency: 17 percent of the invoice amount;

(2) Second delinquency: 35 percent of the invoice amount; and

(3) Third delinquency: 50 percent of the invoice amount plus:

(a) For providers, suspension from using the independent case review services for 1 year; or

(b) For MCOs, any sanction set forth in COMAR 10.67.10.01A(1)—(5), as determined by the Department.

.08 APPEAL.

A. As a prerequisite for participating in the IRO complaint adjudication process, a provider waives all other administrative and judicial appeal rights and accepts the IRO's decision as final and binding.

B. An MCO that receives an adverse decision from an independent review organization may file an appeal in accordance with COMAR 10.67.10.02.