

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: MyCare Ohio plan rules

Rule Number(s): 5160-58-02.1, 5160-58-03, 5160-58-03.2, 5160-58-05.3

and 5160-58-08.4

Date: October 31, 2013

Rule Type:

☒ New

☐ Amended

Year Review

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

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Governor Kasich's first Jobs Budget authorized Ohio Medicaid to seek approval through the federal Center for Medicare and Medicaid Innovation (CMMI) to design and implement a Medicare-Medicaid Integrated Care Delivery System (ICDS), which will be known as MyCare Ohio. The goal of MyCare Ohio is to manage the full continuum of Medicare and Medicaid benefits for Medicare-Medicaid Enrollees. For many of the 182,000 Ohioans who currently receive poorly coordinated services through separate Medicare and Medicaid programs, MyCare Ohio will provide unprecedented coordination of long-term care services, behavioral health services, and physical health services. These services will be provided by five managed care plans that sought out this business, and which were selected via competitive procurement in 2012. While many of the requirements for the MyCare Ohio program are not new to these plans and their contracted service providers (as four out of the five plans already provide Medicaid-only managed care), there are some unique aspects to the integration of Medicare and Medicaid services, as well as the three-way relationship between the plans, the State of Ohio, and CMMI, which necessitate adopting several rules to manage MyCare Ohio policy.

OAC 5160-58-02.1

The proposed new rule 5160-58-02.1 establishes reasons for membership termination from a MyCare Ohio plan and the processes to be used when a member is terminated from a MyCare Ohio plan. The proposed rule describes circumstances that will be considered just cause when a member either requests a different MyCare Ohio plan or, where enrollment is not mandatory, requests disenrollment from the MyCare Ohio program. The proposed rule also includes grounds for which a MyCare Ohio plan may seek to terminate a member.

OAC 5160-58-03

The proposed new rule 5160-58-03 describes the obligations of MyCare Ohio plans for ensuring that their members have access to all medically-necessary services covered by Medicaid. When services are provided for an emergency medical condition, a MyCare Ohio plan may be obligated to pay service providers that do not contract with the MyCare Ohio plan. Such payment may be required for the emergency services themselves, and for subsequent services after an emergency medical condition has been stabilized.

OAC 5160-58-03.2

The proposed new rule 5160-58-03.2 outlines the choices and accompanying responsibilities of members enrolled in the MyCare Ohio HCBS waiver program and the support that MyCare Ohio plans shall provide to members enrolled in the waiver. The rule establishes that:

- Members have the ability to select providers from their MyCare Ohio plan's provider panel, and are empowered to take a proactive role in how their MyCare Ohio HCBS waiver program services are furnished.
- Members have a responsibility to work with their providers and their MyCare Ohio plan care manager and trans-disciplinary care management team to ensure services are furnished appropriately and in accordance with program requirements.
- MyCare Ohio plans are required to ensure the health and safety of their enrolled members and comply with the program's incident management protocols including incident reporting.
- MyCare Ohio plans shall furnish waiver service coordination which includes developing waiver service plans, furnishing information and assistance, offering support with selecting providers, and overseeing the delivery of services.
- Members who choose to exercise the program's participant direction authorities (employer and/or budget authority depending on the service), must be determined by the MyCare Ohio plan to be capable of directing their services in a manner that ensures their continued health and safety.

OAC 5160-58-05.3

The proposed new rule 5160-58-05.3 will establish an "incident management system" that applies to Ohio Department of Medicaid (ODM), its designees (which for the purposes of this rule include, unless otherwise stated, MyCare Ohio plans), service providers and individuals who are enrolled on the MyCare Ohio Waiver. This incident management system includes responsibilities for reporting, responding to, investigating and remediating incidents involving individuals. ODM has the authority to designate other agencies or entities to perform one or more of the incident management functions set forth in the rule. Among other things, proposed OAC rule 5160-58-05.3 will establish:

- That ODM and its designees (including the MyCare Ohio plans) must assure the health and welfare of individuals enrolled on the MyCare Ohio Waiver. Further, ODM, its designees and providers are responsible for ensuring that individuals are protected from abuse, neglect, exploitation and other threats to their health, safety and well-being.
- That individuals enrolled on the MyCare Ohio Waiver shall receive a handbook at the time of waiver enrollment and at reassessment that includes information about how to report abuse, neglect, exploitation and other incidents.
- The activities that are considered an incident and/or an alert in the MyCare Ohio Waiver.

- Incident reporter responsibilities, including identification of those incidents that must be reported immediately.
- Case manager responsibilities upon learning of an incident, including ensuring the individual's health and welfare.
- ODM and its designee's responsibilities including incident investigation and follow-up.

OAC 5160-58-08.4

The proposed new rule 5160-58-08.4 requires a MyCare Ohio plan to have three avenues allowing a member to challenge certain actions taken by the MyCare Ohio plan: (1) a grievance process, (2) an appeal to the MyCare Ohio plan, and (3) a process allowing members to access the State's hearing system through the Ohio Department of Job and Family Services (ODJFS).¹ The proposed rule sets forth detailed requirements for each of these three avenues, and prescribes the manner in which members must be advised of actions by the MyCare Ohio plan, so that the members receive clear and timely notice of MyCare Ohio plan actions that will affect the services they receive. It also describes the circumstances under which benefits may be continued while an appeal is pending.

- 2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**
Ohio Revised Code Sections 5164.02, 5166.02, and 5167.02.
- 3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.**

Yes. 42 C.F.R. Part 438 imposes comprehensive requirements on Medicaid managed care plans, including the MyCare Ohio plans. Section 438.56 imposes requirements for disenrollment of members from plans, and Section 438.114 addresses the requirement to provide emergency and post-stabilization services even when they are rendered by providers who do not have contracts with plans. Subpart F of these regulations (42 C.F.R. 438.400—438.424) imposes detailed requirements requiring each Medicaid managed care plan to have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system. Other rules in this Subpart address the requirements for a notice of action that the plan intends to take, the handling of grievances and appeals, and the resolution of appeals and grievances.

¹ Although the MyCare Ohio program is administered by ODM, ODJFS continues to administer state hearings for issues raised by Medicaid recipients in accordance with R.C. 5101.35 and 5160.31.

Ohio was required to seek and obtain federal approval from the Centers for Medicare and Medicaid Services (CMS) for a 1915(b)(c) waiver in order to be able to implement the mandatory enrollment of Medicare-Medicaid beneficiaries in MyCare Ohio plans. In order for the Centers for Medicare and Medicaid Services (CMS) to approve a 1915(c) home and community-based services waiver, a state must make certain assurances concerning the operation of the waiver. These assurances are spelled out in 42 C.F.R 441.302. One of those assurances is health and welfare.

Further, according to waiver guidance provided to ODM by CMS,

- Effective incident management is essential to assuring the health and welfare of waiver participants.
- States are required to describe the operational features of managing incidents at the individual and provider level as well as activities to assure that reports are filed and incidents are investigated in a timely fashion, and to analyze incident data (e.g., about specific types of incidents, providers, individuals' characteristics, results of investigations, the timeliness of reports and investigations) in order to develop strategies to reduce the risk and likelihood of the occurrence of incidents in the future.
- In order to assure individuals' health and welfare and the effective delivery of waiver services, active, continuous monitoring of the implementation of the service plan is an essential component of the waiver. The purpose is to ensure that waiver services are furnished in accordance with the waiver service plan; meet the individual's needs and achieve their intended outcome. Monitoring also is conducted to identify any problems related to the individual's health and welfare that may arise. The State must ensure that there is continuous monitoring of the health and welfare of MyCare Ohio Waiver participants and remediation actions are initiated when appropriate.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Although the federal regulations do not impose requirements directly on Medicaid managed care plans or MyCare Ohio plans, they do require state Medicaid agencies (e.g., ODM) to ensure plan compliance with federal standards.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

These rules perform several functions. They ensure compliance with federal regulations governing Medicaid managed care. They ensure that information maintained by MyCare Ohio plans is readily available for the State, and if requested, for the Centers for Medicare and Medicaid Services (CMS). They assure the health and welfare of participants in the

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MyCare Ohio Waiver as required by 42 C.F.R 441.302(a) by establishing procedures for the reporting, investigation and remediation of incidents, and setting forth the process, procedures and requirements for ongoing monitoring and oversight of waiver service providers and contractors. And they reinforce the State's commitment, through its 1915(c) waiver programs, to empower members and their families to play an active role in their service delivery.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

Through the review of reports, the Agency verifies that plans are complying with federal standards. With five MyCare Ohio plans in the state, all will be expected to provide similar information, making missing information more obvious, measuring the success of the regulation.

The federally approved MyCare Ohio waiver contains several performance measures that gauge the performance of MyCare Ohio plans relative to waiver service coordination, including waiver service plans that reflect members' personal goals (including participant-direction). Furthermore, the expectation is that the improvements in monitoring and oversight will result in a reduced number of incidents that threaten the health and welfare of individuals on the MyCare Ohio Waiver program. Successful outcomes are measured through a finding of compliance with these standards.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

In 2012, Ohio Medicaid issued a request for applications (RFA) for health plans to contract with the State Medicaid agency to serve Medicare-Medicaid enrollees under a fully integrated system of care that comprehensively manages the Medicare-Medicaid benefits for members. The applying plans were aware of the expectations and requirements they would be held to if they were to contract with the State of Ohio. The plans selected for the MyCare Ohio program are Aetna, Buckeye, CareSource, Molina, and UnitedHealthCare.²

² Notably, four of the five plans selected for MyCare Ohio were previously selected to provide services to Ohio's other Medicaid managed care populations and are already required to comply with most, if not all, of the same reporting requirements required by these rules as part of their obligations under Medicaid managed care. The fifth plan, Aetna, is a national Medicaid managed care organization providing services to managed care populations in many states and

Additionally, representatives from the following entities participated in reviewing the incident management rule currently in place for ODM-administered waivers:

The Ohio Council for Home Care and Hospice
Midwest Care Alliance
CareSource (case management contractor)
CareStar (case management contractor)
Public Consulting Group (PCG) (provider oversight contractor)
Ohio Olmstead Task Force
Disability Rights Ohio
Ohio Department of Aging
Ohio Department of Developmental Disabilities
ODM-administered waiver participants

The existing incident management rule was modified for use with the MyCare Ohio Waiver, many of whose participants will transfer in from the ODM-administered nursing facility waivers.

ODM and the MyCare Ohio plans are currently meeting to review the MyCare Ohio waiver and to discuss the department's expectations around waiver service coordination and other program operational matters.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Stakeholders have provided informal input regarding the development of the MyCare Ohio program that has been the basis for the draft regulations. Additionally, bi-weekly meetings have been held with the above-referenced stakeholders since May 2013. A thoughtful and thorough review of the existing rules occurred, and stakeholders were actively involved in the drafting and review of the proposed new rules.

The department plans to continue engaging in dialogue with the MyCare Ohio plans to determine if policy or process changes are needed to ensure the program is implemented as intended.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

No scientific data was used to develop the rules or the measurable outcomes of the rules.

accordingly should be very familiar, and capable of complying with, the federal reporting requirements upon which the Ohio requirements are based.

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10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

ODM and the stakeholder workgroup referenced in the State's response to question #7 considered alternative rule language for rule 5160-58-05.3 as part of their rule development process and settled upon language which was mutually agreed upon and best suited to accomplish the purposes of that rule. Such language had to meet the federal and state guidelines under which ODM-administered waivers are permitted to operate. Other rules are based directly upon federal regulations at 42 C.F.R. Part 438, which do not leave the State much latitude in crafting alternative regulations.

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

No. Performance-based regulations would not comply with federal regulations governing managed care. However, through the submission of the requested information, the Agency is able to determine whether MyCare Ohio plans are meeting the standards specified in federal regulations.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

All Medicaid regulations governing MyCare Ohio plans are promulgated and implemented by ODM only. While other state agencies participated in the rule writing process, they do not impose any requirements that are specific to this program. The regulations were reviewed by Medicaid's legal and legislative staff to ensure that there is no duplication within the rules.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

A robust effort will be employed by the department to notify MyCare Ohio plans and MyCare Ohio Waiver service providers of the rules. A variety of communication methods will be used, including, but not limited to ODM's issuance via remittance advice, email blasts to agency and independent providers, notifications to individuals enrolled on ODM-administered waivers, electronic communication via the myohiohcp.org website and the provider oversight contractor's (PCG) website.

Additionally, implementation of these rules will also be predicated on training that will be provided by ODM and/or its designees (i.e., provider oversight contractor and MyCare Ohio

plans). Additionally, agency providers will be asked to assure that training will be provided at the staff level upon implementation and at least annually thereafter.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;**
- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
- c. Quantify the expected adverse impact from the regulation.**

OAC 5160-58-02.1

- a. This rule only impacts managed care plans that have been selected for MyCare Ohio. The plans that will be impacted are Aetna, Buckeye, CareSource, Molina, and UnitedHealthCare.
- b. Paragraph (B)(5) of this rule requires a MyCare Ohio plan to notify ODM when a member is incarcerated. Paragraph (C)(4)(f)(iii) states that a MyCare Ohio plan may be required to produce documentation to ODM when a member requests termination from a MyCare Ohio plan for good cause. And paragraph (C)(4)(f)(iv) of this rule requires ODM to recover from a MyCare Ohio plan any premium paid for retroactive termination occurring as a result of membership termination when necessary and appropriate.
- c. Through the administrative component of the capitation rate paid to the MyCare Ohio plans by the Department of Medicaid, MyCare Ohio plans will be compensated for the cost of the time required in maintaining and submitting required reports. Furthermore, the MyCare Ohio plans were aware of the need to maintain and submit various reports prior to deciding to do business with the State.

OAC 5160-58-03

- a. This rule only impacts managed care plans that have been selected for MyCare Ohio. The plans that will be impacted are Aetna, Buckeye, CareSource, Molina, and UnitedHealthCare.
- b. Paragraphs (F) and (G) of this rule require MyCare Ohio plans to establish, in writing, the process and procedures for claims submissions from non-contracting providers and to maintain a record of any request for coverage of post-stabilization services.
- c. Through the administrative component of the capitation rate paid to the MyCare Ohio plans by the Department of Medicaid, MyCare Ohio plans will be compensated for the cost of the time required in maintaining and submitting required reports. Furthermore, the

MyCare Ohio plans were aware of the need to maintain and submit various reports prior to deciding to do business with the State.

OAC 5160-58-03.2

- a. This rule only impacts managed care plans that have been selected for MyCare Ohio. The plans that will be impacted are Aetna, Buckeye, CareSource, Molina, and UnitedHealthCare.
- b. Paragraph (D)(2) of this rule requires MyCare Ohio plans to distribute waiver-related information to members. In paragraph (D)(3)(c), MyCare Ohio plans are required to exchange information with members' service providers to assist with the development of a waiver service plan. In paragraph (D)(4), MyCare Ohio plans are required to adhere to the incident management system requirements in rule 5160-58-05.3, which includes issuing notifications and reports regarding incidents involving MyCare Ohio members. Paragraph (D)(6) requires the MyCare Ohio plan to document members' understanding of the services provided and their ability to receive services safely through the waiver. Paragraph (F) requires members to be afforded notice and hearing rights for certain determinations made by waiver service coordinators.
- c. Compliance with program requirements for participating MyCare Ohio plans may include administrative costs associated with, for example, incident reporting, investigation and remediation. When designing the capitation payments for the MyCare Ohio demonstration, the State's actuary accounted for the administrative expenses associated with waiver service coordination, copying and distributing documents and other informational materials, and incident reporting and management to members and their families.

OAC 5160-58-05.3

- a. This rule impacts ODM's provider oversight contractor, the managed care plans that have been selected for MyCare Ohio and the providers that contract with the plans to provide MyCare Ohio waiver services. The plans that will be impacted are Aetna, Buckeye, CareSource, Molina, and UnitedHealthCare.
- b. In paragraph (E), MyCare Ohio plans are required to provide members with a handbook and to obtain written confirmation from the member that they have received this handbook. Under paragraphs (G), (H), (I), (J), and (M), MyCare Ohio plans and their designees, MyCare Ohio waiver providers, and ODM's provider oversight contractor are required to issue notifications and reports regarding incidents involving MyCare Ohio members. Pursuant to paragraph (N), MyCare Ohio providers who do not comply with this rule may be subject to monetary and other sanctions that could result in their inability to participate in the Medicaid waiver program.

c. Compliance with program requirements for providers who choose to participate may include administrative costs associated with, for example, incident reporting, investigation and remediation. When designing the capitation payments for the MyCare Ohio demonstration, the State's actuary accounted for the administrative expenses associated with waiver service coordination, copying and distributing documents and other informational materials, and incident reporting and management to members and their families. Additionally, ODM entered into a competitively bid contract with an entity for provider oversight and reimburses the contractor accordingly.

OAC 5160-58-08.4

- a. This rule only impacts managed care plans that have been selected for MyCare Ohio. The plans that will be impacted are Aetna, Buckeye, CareSource, Molina, and UnitedHealthCare.
- b. A MyCare Ohio plan is required to maintain written policies and procedures governing grievances, appeals to the MyCare Ohio plan, and appeals to the ODJFS state hearing system. These policies and procedures must be described in a handbook distributed to members. A MyCare Ohio plan is required to provide clear and timely notice to a member of any action that will affect a member's services, and notice of the process through which the member can challenge the proposed action. After an appeal to a MyCare Ohio plan is resolved, the MyCare Ohio plan must provide written notice of the decision arising from the appeal. For an appeal to the ODJFS state hearing system, a MyCare Ohio plan is required to complete a written appeal summary that provides all facts and documents relevant to the case. If the member prevails at a state hearing, the MyCare Ohio plan must complete a compliance form which must be returned to the Bureau of State Hearings.
- c. Through the administrative component of the capitation rate paid to the MyCare Ohio plans by the Department of Medicaid, MyCare Ohio plans will be compensated for the cost of the time required in maintaining and submitting required reports, notices, policies and procedures. Furthermore, the MyCare Ohio plans were aware of the need to maintain and submit various reports prior to deciding to do business with the State.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The MyCare Ohio plans were aware of the federal requirements for the reporting of information prior to seeking contracts with the state, as well as before signing their contracts with the state. More importantly, without the requested reports the State would be out of compliance with federal regulations.

The participation of service providers in the MyCare Ohio Waiver is optional and at the providers' sole discretion. Compliance with program requirements is necessary to comply

with the terms of the federal waiver and to ensure the health and safety of individuals enrolled in MyCare Ohio.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No, as none of the five MyCare Ohio plans qualifies as a small business.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Agency will not apply this section of the ORC as the waiving of penalties would render Ohio's Medicaid agency out of compliance with federal regulations.

18. What resources are available to assist small businesses with compliance of the regulation?

None, as none of the five MyCare Ohio plans qualifies as a small business.

5160-58-01

MyCare Ohio plans: definitions.

(A) The definitions set forth in rule 5160-26-01 of the Administrative Code apply to the MyCare Ohio rules set forth in Chapter 5160-58 of the Administrative Code, except that the following definitions apply to MyCare Ohio:

- (1) "Authorized representative" has the same meaning as in rule 5160:1-1-55.1 of the Administrative Code.
- (2) "Covered services" means the set of required services offered by the MyCare Ohio plan pursuant to rule 5160-58-03 of the Administrative Code.
- (3) "Eligible individual" also known as "potential enrollee" means a medicaid recipient who is a legal resident of the MyCare Ohio program service area and who is subject to mandatory enrollment or may voluntarily elect to enroll in a MyCare Ohio plan, but is not yet an enrollee of a specific MyCare Ohio plan.
- (4) "Intermediate care facility for individuals with intellectual disabilities (ICF/IID)" has the same meaning as in rule 5123:2-7-01 of the Administrative Code.
- (5) "Medicaid" means medical assistance as defined in section 5162.01 of the Revised Code.
- (6) "Medically necessary services" means services provided in accordance with medicaid law and regulations, in accordance with clinical coverage guidelines specified in agency 5160 of the Administrative Code.
- (7) "Member," also known as "enrollee," means a medicaid eligible beneficiary that has selected MyCare Ohio plan membership or has been assigned to a MyCare Ohio plan for the purpose of receiving health care services.
- (8) "Nursing facility (NF)" has the same meaning as in section 5165.01 of the Revised Code.
- (9) "Oral interpretation services" means services provided to a limited-reading proficient eligible individual or member to ensure that he or she receives MyCare Ohio plan information in a format and manner that is easily understood by the eligible individual or member.
- (10) "Oral translation services" means services provided to a limited-English proficient eligible individual or member to ensure that he or she receives MyCare Ohio plan information translated into the primary language of the eligible individual or member.
- (11) "PACE" has the same meaning as in rule 5160-36-01 of the Administrative Code.

- (12) "PCP (primary care provider)" means an individual physician (medical doctor or doctor of osteopathy), certain physician group practice, a physician assistant in accordance with 5160-4-03 of the Administrative Code under the supervision of the qualifying treating physician, or advanced practice nurse as defined in section 4723.43 of the Revised Code, or advanced practice nurse group practice within an acceptable specialty, contracting with a MyCare Ohio plan to provide primary care services. Acceptable specialty types include family/general practice, internal medicine, pediatrics, geriatrics and obstetrics/gynecology (OB/GYN).
- (13) "Premium" means the monthly payment amount per member to which the MyCare Ohio plan is entitled as compensation for performing its obligations in accordance with Chapter 5160-58 of the Administrative Code and/or the provider agreement with ODM.
- (14) "Provider" means a hospital, health care facility, physician, dentist, pharmacy, HCBS provider or otherwise licensed, certified, or other appropriate individual or entity, that is authorized to or may be entitled to reimbursement for health care services rendered to a MyCare Ohio plan's member.
- (15) "Provider agreement" means a formal agreement between ODM and a MyCare Ohio plan for the provision of medically necessary services to medicaid members who are enrolled in the MyCare Ohio plan.
- (B) In addition to the definitions set forth in rule 5160-26-01 of the Administrative Code and paragraph (A) of this rule, the following definitions apply to Chapter 5160-58 of the Administrative Code:
- (1) "Assessment" means a comprehensive evaluation of an individual's medical, behavioral health, long term services and supports, and social needs. Results of the assessment process are used to develop the integrated, individualized care plan, inclusive of the waiver services plan.
- (2) "Creditable insurance" or "creditable coverage" means health insurance coverage as defined in 42 U.S.C. 300gg-3(c) (October 17, 2013).
- (3) "Dual benefits (also referred to as "opt-in") member" means a member for whom a MyCare Ohio plan is responsible for the coordination and payment of both medicare and medicaid benefits.
- (4) "Financial management service" or "FMS" means a support that is provided to waiver participants who direct some or all of their waiver services. When used in conjunction with the employer authority, this support includes, but is not necessarily limited to, operating a payroll service for participant employed workers and making required payroll withholdings. When used in conjunction with the budget authority, this support includes, but is not

necessarily limited to, paying invoices for waiver goods and services and tracking expenditures against the participant-directed budget.

(5) "HCBS" means home and community-based services.

(6) "Health and welfare" means a requirement that necessary safeguards are taken to protect the health and welfare of individuals enrolled on HCBS waivers. It includes the following:

(a) Risk and safety planning and evaluations;

(b) Critical incident management;

(c) Housing and environmental safety evaluations;

(d) Behavioral interventions;

(e) Medication management; and

(f) Natural disaster and public emergency response planning.

(7) "Individual care plan" means an integrated, individualized, person-centered care plan developed by the member and his or her MyCare Ohio plan's trans-disciplinary care management team that addresses clinical and non-clinical needs identified in the assessment and includes goals, interventions, and expected outcomes.

(8) "Legally responsible family member," as that term is used in the MyCare Ohio waiver program is an individual's spouse, or in the case of a minor, the individual's birth or adoptive parent, or foster caregiver.

(9) "Medicaid consumer hotline" means an organization or individual under contract with or designated by ODM to provide MyCare Ohio plan information and enrollment services to eligible members.

(10) "Medicaid only (also referred to as "opt-out") member" means a member for whom a MyCareOhio plan is responsible for coordination and payment of medicaid benefits.

(11) "MHAS" means the Ohio department of mental health and addiction services.

(12) "MyCare Ohio plan" means a health insuring corporation contracted to comprehensively manage medicaid benefits for medicare and medicaid eligible members, including home and community-based services. MyCare Ohio plans are also managed care plans in accordance with rule 5160-26-01 of the Administrative Code. For the purpose of this chapter, a MyCare Ohio plan does not include entities approved to operate as a PACE site.

- (13) "NF-based level of care" means the intermediate and skilled levels of care, as described in rule 5160-3-08 of the Administrative Code.
- (14) "Participant direction" means the opportunity for a MyCare Ohio waiver member to exercise choice and control in identifying, accessing, and managing waiver services and other supports in accordance with their needs and personal preferences.
- (15) "Significant change event" is a change experienced by a member that warrants further evaluation. Significant changes include, but are not limited to, a change in health status, caregiver status, or location/residence; referral to or active involvement on the part of a protective service agency; institutionalization; and when the waiver-enrolled individual has not received MyCare Ohio waiver services for ninety calendar days.
- (16) "Trans-disciplinary care management team" means a team of appropriately qualified individuals comprised of the member, the member's family/caregiver, the MyCare Ohio plan manager, the waiver service coordinator, if appropriate, the primary care provider, specialists, and other providers, as applicable, that is designed to effectively meet the enrollee's needs.
- (17) "Waiver services plan" is a component of the care plan that identifies specific goals, objectives and measurable outcomes for a waiver-enrolled member's health and functioning expected as a result of HCBS provided by both formal and informal caregivers, and that addresses the physical and medical conditions of the individual. At a minimum, the waiver services plan shall include:
- (a) Essential information needed to provide care to the member that assures the member's health and welfare;
 - (b) Signatures indicating the member's acceptance or rejection of the waiver services plan; and
 - (c) Information that the waiver services plan is not the same as the physician's plan of care.

5160-58-01.1

MyCare Ohio plans: application of general managed care rules.

(A) MyCare Ohio plans must comply with all of the requirements applicable to managed care plans in the following rules:

- (1) Rule 5160-26-05 of the Administrative Code;
- (2) Rule 5160-26-05.1 of the Administrative Code;
- (3) Rule 5160-26-06 of the Administrative Code;
- (4) Rule 5160-26-07 of the Administrative Code;
- (5) Rule 5160-26-07.1 of the Administrative Code;
- (6) Rule 5160-26-08 of the Administrative Code;
- (7) Rule 5160-26-08.3 of the Administrative Code;
- (8) Rule 5160-26-09 of the Administrative Code;
- (9) Rule 5160-26-09.1 of the Administrative Code;
- (10) Rule 5160-26-10 of the Administrative Code; and
- (11) Rule 5160-26-11 of the Administrative Code.

(B) MyCare Ohio plans must comply with all of the requirements applicable to managed care plans in rule 5160-26-03.1 of the Administrative Code, with the following revisions:

- (1) In paragraph (A)(7)(c)(iv), the references to rules 5101:3-26-08.4 and 5101:3-26-08.5 of the Administrative Code should be replaced by a reference to rule 5160-58-08.4 of the Administrative Code for MyCare Ohio plans.
- (2)) The phrase "seventy-two hours" replaces the phrase "three working days" in paragraph (A)(7)(c)(vi) for MyCare Ohio plans.
- (3) In paragraph (A)(7)(c)(vii), the reference to paragraph (B)(2)(d) of rule 5101:3-26-08.4 of the Administrative Code should be replaced by a reference to paragraph (C) of rule 5160-58-08.4 of the Administrative Code for MyCare Ohio plans.
- (4) The following language replaces all of paragraph (A)(7)(c)(viii) for MyCare Ohio plans: "Prior authorization decisions for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(k)(2) (October 17, 2013) must be made within the timeframes specified in 42 C.F.R. 423.568(b) (October 18, 2013) for

standard decisions and 42 C.F.R. 423.572(a) (October 18, 2013) for expedited decisions. When an emergency situation exists, a seventy-two hour supply of the covered outpatient drug that was prescribed must be authorized. If the plan is unable to obtain the information needed to make the prior authorization decision within seventy-two hours, the decision timeframe has expired and the MCP must give notice to the member as specified in paragraph (C) of rule 5160-58-08.4 of the Administrative Code."

(5) Only the first sentence in paragraph (A)(7)(e) applies to MyCare Ohio plans.

(C) MyCare Ohio plans must comply with all of the requirements applicable to managed care plans in rule 5160-26-08.2 of the Administrative Code, except for the following:

(1) The phrases "by no later than the effective date of coverage" and "prior to the effective date of coverage" in paragraph (B)(3) do not apply to My Care Ohio plans, and

(2) The phrase "prior to the new effective date of coverage" in paragraph (B)(5) does not apply to MyCare Ohio plans.

(D) For all rules listed in paragraphs (A), (B) and (C) of this rule, the following provisions apply to the MyCare Ohio program described in Chapter 5160-58 of the Administrative Code:

(1) All cross-references to rule 5101:3-26-01 of the Administrative Code are replaced by cross-references to rule 5160-58-01 of the Administrative Code for MyCare Ohio plans.

(2) All cross-references to rule 5101:3-26-02 of the Administrative Code are replaced by cross-references to rule 5160-58-02 of the Administrative Code for MyCare Ohio plans.

(3) All cross-references to rule 5101:3-26-02.1 of the Administrative Code are replaced by cross-references to rule 5160-58-02.1 of the Administrative Code for MyCare Ohio plans.

(4) All cross-references to rule 5101:3-26-03 of the Administrative Code are replaced by cross-references to rule 5160-58-03 of the Administrative Code for MyCare Ohio plans.

(5) All cross-references to rules 5101:3-26-08.4 and 5101:3-26-08.5 of the Administrative Code are replaced by cross-references to rule 5160-58-08.4 of the Administrative Code for MyCare Ohio plans.

(E) The following rules in Chapter 5160-26 of the Administrative Code do not apply to MyCare Ohio, as they are replaced by corresponding rules in Chapter 5160-58 of

the Administrative Code:

(1) Rule 5160-26-02 of the Administrative Code

(2) Rule 5160-26-02.1 of the Administrative Code

(3) Rule 5160-26-03 of the Administrative Code, and

(4) Rule 5160-26-08.4 of the Administrative Code.

(F) When an MCP holds provider agreements with ODM for the MyCare Ohio and Medicaid managed care programs, ODM may apply all of the applicable provisions in Chapter 5160-26 of the Administrative Code separately to each of the contracts.

5160-58-02

My Care Ohio plans: eligibility, membership, and automatic renewal of membership.

(A) Eligibility.

(1) In mandatory service areas as permitted by 42 CFR 438.52 (October 1, 2013), an individual must be enrolled in a MyCare Ohio plan (also known as "plan") if he or she meets all of the following criteria:

(a) Age 18 or older at the time of enrollment in the plan;

(b) Eligible for medicare Parts A and B and D, and full benefits under the medicaid program; and

(c) Reside in a plan demonstration county in Ohio. A list of demonstration counties, and the plans available in those counties, is available at <http://medicaid.ohio.gov>.

(2) The following individuals are not eligible for enrollment in a plan:

(a) Individuals with intellectual disabilities who have a level of care that meets the criteria specified in rule 5160-3-07 of the Administrative Code and receive services through a 1915(c) home and community based services (HCBS) waiver or an intermediate care facility for individuals with intellectual disabilities (ICF-IID).

(b) Individuals enrolled in the program of all inclusive care for the elderly (PACE).

(c) Individuals who have other third party creditable health care coverage, except Medicare coverage as authorized by 42 U.S.C. 1395 (October 1, 2013).

(d) Individuals for whom a delayed medicaid spenddown is required.

(3) Indians who are members of federally recognized tribes are not required to enroll in a plan, except as permitted under 42 C.F.R. 438.50(d)(2) (October 1, 2013).

(4) Individuals are eligible for plan membership in the manner prescribed in this rule if ODM has a provider agreement with the plan applicable to the eligible individual's county of residence.

(5) Nothing in this rule shall be construed to limit or in any way jeopardize an eligible individual's basic medicaid eligibility or eligibility for medicare or other non-medicaid benefits to which he or she may be entitled.

(B) MyCare Ohio plan enrollment.

(1) The following applies to plan enrollment:

- (a) The plan must accept eligible individuals without regard to race, color, religion, gender, sexual orientation, age, disability, national origin, veteran's status, military status, genetic information, ancestry, ethnicity, mental ability, behavior, mental or physical disability, use of services, claims experience, appeals, medical history, evidence of insurability, geographic location within the service area, health status or need for health services. The plan will not use any discriminatory policy or practice in accordance with 42 C.F.R. 438.6(d)(4) (September 27, 2013).
- (b) The plan must accept eligible individuals who request plan membership without restriction.
- (c) The plan must accept PCP(s) selected by the members when available, except as otherwise provided in this rule.
- (d) In the event that a plan member loses medicaid eligibility and is terminated from the plan, but regains medicaid eligibility within a period of sixty days or less, his or her membership in the same plan shall be re-instated.
- (e) The plan must cover all members that are designated by ODM in an ODM-produced roster of new members, continuing members, and terminating members.
- (f) The plan shall not be required to provide medicaid coverage to an individual until the individual's membership in the plan is confirmed via an ODM-produced roster or upon mutual agreement between ODM and the plan.

(2) Should a service area change from voluntary to mandatory, the notice rights in this rule must be followed.

- (a) When a service area is initially designated by ODM as mandatory for eligible individuals specified in paragraph (A)(1) of this rule, ODM shall confirm the eligibility of each individual as prescribed in paragraph (A)(1) of this rule. Upon the confirmation of eligibility:
 - (i) Eligible individuals residing in the service area who are currently plan members are deemed participants in the mandatory program; and
 - (ii) All other eligible individuals residing in the mandatory service area may request plan membership at any time but must select a plan

following receipt of a notification of mandatory selection (NMS) issued by ODM.

(b) MyCare Ohio plan membership selection procedures for the mandatory program:

- (i) A newly eligible individual that does not make a choice following issuance of an NMS by ODM and one additional notice will be assigned to a plan by ODM, the medicaid consumer hotline, or other ODM-approved entity.
- (ii) ODM or the medicaid consumer hotline shall assign the individual to a plan based on prior medicaid fee-for-service or plan membership history.

(C) Commencement of coverage.

- (1) Coverage of plan members will be effective on the first day of the calendar month specified on the ODM-produced 834 electronic data interchange (EDI) roster to the plan.

5160-58-02.1

MyCare Ohio Plans: termination of membership.

(A) A member will be terminated from membership in a MyCare Ohio plan ("plan") for any of the following reasons:

- (1) The member becomes ineligible for full medicaid or medicare parts A or B or D. When this occurs, termination of plan membership takes effect at the end of the last day of the month in which the member became ineligible.
- (2) The member's permanent place of residence is moved outside the plan's service area. When this occurs, termination of plan membership takes effect at the end of the last day of the month in which the member moved from the service area.
- (3) The member dies, in which case the period of plan membership ends on the date of death.
- (4) The member is incarcerated for either more than fifteen working days or is incarcerated and has accessed non-emergent medical care. When this occurs and after the Ohio Department of Medicaid (ODM) receives notification from the member's plan, a county department of job and family services (CDJFS), or other public agency, termination of plan membership takes effect the last day of the month prior to incarceration.
- (5) The member is found by ODM to meet the criteria for an intermediate care facility for individuals with intellectual disabilities (ICF-IID) level of care and is then placed in an ICF-IID facility or enrolled in an ICF-IID qualified waiver. After the plan notifies ODM that this has occurred, termination of plan membership takes effect on the last day of the month preceding placement in the ICF-IID facility or enrollment on the ICF-IID waiver.
- (6) The member has third party coverage, excepting medicare coverage, and ODM determines that it is not in the best interest of the member to continue in the plan. When this occurs the effective date of termination shall be determined by ODM but in no event shall the termination date be later than the last day of the month in which ODM approves the termination.
- (7) The provider agreement between ODM and the plan is terminated or not renewed. When this occurs, the effective date of termination shall be the end of the last day of the month of the provider agreement termination or nonrenewal.
- (8) The member is not eligible for enrollment in a plan for one of the reasons set forth in rule 5160-58-02 of the Administrative Code.

(B) All of the following apply when membership in a MyCare Ohio plan is terminated for any of the reasons set forth in paragraph (A) of this rule:

- (1) Such terminations may occur either in a mandatory or voluntary service area;
- (2) All such terminations occur at the individual level;
- (3) Such terminations do not require completion of a consumer contact record (CCR).
- (4) If ODM fails to notify the plan of a member's termination from the plan, ODM shall continue to pay the plan the applicable monthly premium rate for the member. The plan shall remain liable for the provision of covered services as set forth in rule 5101:3-58-03 of the Administrative Code, until such time as ODM provides the plan with documentation of the member's termination.
- (5) ODM shall recover from the plan any premium paid for retroactive membership termination occurring as a result of paragraph (A) of this rule.
- (6) A member may lose medicaid eligibility during an annual open enrollment period, and thus become temporarily unable to change to a different plan. If the member then regains medicaid eligibility, he or she may request to change plans within thirty days following reenrollment in the plan.

(C) Member-initiated terminations

- (1) A dual-benefits member may request disenrollment from the plan and transfer between plans on a month-to-month basis any time during the year. Plan coverage continues until the end of the month of disenrollment.
- (2) A medicaid-only member may request a different plan in a mandatory service as follows:
 - (a) From the date of initial enrollment through the first three months of plan membership, whether the first three months of enrollment are dual-benefits or medicaid-only membership periods;
 - (b) During an open enrollment month for the member's service area as described in paragraph (E) of this rule; or
 - (c) At any time, if the just cause request meets one of the reasons for just cause as specified in paragraph (C)(4)(e) of this rule.
- (3) A medicaid-only member may request a different plan if available or be returned to medicaid fee-for-service in a voluntary service area as follows:
 - (a) From the date of enrollment through the initial three months of plan membership;

- (b) During an open enrollment month for the member's service area as described in paragraph (E) of this rule; or
 - (c) At any time, if the just cause request meets one of the reasons for just cause as specified in paragraph (C)(4)(e) of this rule.
- (4) The following provisions apply when a member either requests a different plan in a mandatory service area or requests disenrollment in a voluntary service area:
 - (a) The request may be made by the member, or by the member's authorized representative, as defined in rule 5160-58-01 of the Administrative Code.
 - (b) All member-initiated changes or terminations must be voluntary. Plans are not permitted to encourage members to change or terminate enrollment due to a member's race, color, religion, gender, sexual orientation, age, disability, national origin, veteran's status, military status, genetic information, ancestry, ethnicity, mental ability, behavior, mental or physical disability, use of services, claims experience, appeals, medical history, evidence of insurability, geographic location within the service area, health status or need for health services. Plans may not use a policy or practice that has the effect of discrimination on the basis of the above criteria.
 - (c) If a member requests disenrollment because he or she is a member of a federally-recognized tribe, as described in 42 CFR 438.50(d)(2) (October 18, 2013), the member will be disenrolled after the member notifies the consumer hotline.
 - (d) Disenrollment will take effect on the last day of the calendar month as specified by an ODM-produced 834 electronic data interchange (EDI) transaction to the plan.
 - (e) In accordance with 42 C.F.R. 438.56(d)(2) (October 18, 2013), a change or termination of plan membership may be permitted for any of the following just cause reasons:
 - (i) The member moves out of the plan's service area and a non-emergency service must be provided out of the service area before the effective date of a termination that occurs for one of the reasons set forth in paragraph (A) of this rule;
 - (ii) The plan does not, for moral or religious objections, cover the service the member seeks;

- (iii) The member needs related services to be performed at the same time in a coordinated manner; however, not all related services are available within the plan network, and the member's PCP or another provider determines that receiving services separately would subject the member to unnecessary risk;
- (iv) The member has experienced poor quality of care and the services are not available from another provider within the plan's network;
- (v) The member cannot access medically necessary medicaid-covered services or cannot access the type of providers experienced in dealing with the member's health care needs;
- (vi) The PCP selected by a member leaves the plan's network and is the only available and accessible PCP in the plan who speaks the primary language of the member, and another PCP speaking the member's language is available and accessible in another plan in the member's service area; or
- (vii) ODM determines that continued membership in the plan would be harmful to the interests of the member.
- (f) The following provisions apply when a member seeks a change or termination in plan membership for just cause:
 - (i) The member or an authorized representatives must contact the plan to identify providers of services before seeking a determination of just cause from ODM.
 - (ii) The member may make the request for just cause directly to ODM or an ODM-approved entity, either orally or in writing.
 - (iii) ODM shall review all requests for just cause within seven working days of receipt. ODM may request documentation as necessary from both the member and the plan. ODM shall make a decision within ten working days of receipt of all necessary documentation, or forty-five days from the date ODM receives the just cause request. If ODM fails to make the determination within this timeframe, the just cause request is considered approved.
 - (iv) ODM may establish retroactive termination dates and/or recover premium payments as determined necessary and appropriate.
 - (v) Regardless of the procedures followed, the effective date of an approved just cause request must be no later than the first day of

the second month following the month in which the member requests change or termination.

(vi) If the just cause request is not approved, ODM shall notify the member or the authorized representative of the member's right to a state hearing.

(vii) Requests for just cause may be processed at the individual level or case level as ODM determines necessary and appropriate.

(viii) If a member submits a request to change or terminate membership for just cause, and the member loses medicaid eligibility prior to action by ODM on the request, ODM shall assure that the member's plan membership is not automatically renewed if eligibility for medicaid is reauthorized.

(D) The following provisions apply when a termination in plan membership is initiated by a plan for a medicaid-only member:

(1) A plan may submit a request to ODM for the termination of a member for the following reasons:

(a) Fraudulent behavior by the member; or

(b) Uncooperative or disruptive behavior by the member or someone acting on the member's behalf to the extent that such behavior seriously impairs the plan's ability to provide services to either the member or other plan members.

(2) The plan may not request termination due to a member's race, color, religion, gender, sexual orientation, age, disability, national origin, veteran's status, military status, genetic information, ancestry, ethnicity, mental ability, behavior, mental or physical disability, use of services, claims experience, appeals, medical history, evidence of insurability, geographic location within the service area, health status or need for health services.

(3) The plan must provide covered services to a terminated member through the last day of the month in which the plan membership is terminated.

(4) If ODM approves the plan's request for termination, ODM shall notify in writing the member, the authorized representative, the medicaid consumer hotline and the plan.

(E) Open Enrollment

Open enrollment months will occur at least annually. At least sixty days prior to the designated open enrollment month, ODM will notify eligible individuals by mail of

[the opportunity to change or terminate membership in a plan and will explain how the individual can obtain further information.](#)

5160-58-02.2

MyCare Ohio waiver: eligibility and enrollment.

(A) To be eligible for enrollment in the MyCare Ohio waiver, a member must meet all of the following requirements:

- (1) Be enrolled in the MyCare Ohio demonstration at the time of application for the MyCare Ohio waiver;
- (2) Be determined to have a nursing facility (NF) -based level of care (i.e., intermediate or skilled) in accordance with rule 5160-3-08 of the Administrative Code;
- (3) In the absence of the MyCare Ohio waiver, require hospitalization or institutionalization in a nursing facility (NF) to meet his or her needs;
- (4) Be determined to require at least one waiver service monthly that is otherwise unavailable through another source (including the medicaid state plan) and in an amount sufficient to meet the member's assessed needs;
- (5) Not reside in a hospital, nursing facility (NF), intermediate care facility for individuals with an intellectual disability (ICF-IID) or another licensed/certified facility, any facility covered by section 1616(e) of the Social Security Act (42 U.S.C. 1382(e) (March 2, 2004)), residential care facility (except an assisted living facility that is approved to furnish assisted living services pursuant to rule 5160-58-04 of the Administrative Code), adult foster home or another group living arrangement subject to state licensure or certification.
- (6) Sign an agreement prior to waiver enrollment confirming that the member has been informed of service alternatives, choice of qualified providers available in the MyCare Ohio plan's provider panel and the options of institutional and community-based care, and he or she elects to receive MyCare Ohio waiver services; and
- (7) Be able to have waiver services that can be identified in a waiver service plan that will safely meet his or her assessed needs.

(B) To be enrolled, and maintain enrollment in the MyCare Ohio waiver, a member must be determined by the MyCare Ohio plan to meet all of the following requirements:

- (1) Be determined eligible for the MyCare Ohio waiver in accordance with paragraph (A) of this rule;
- (2) Be able to have his or her health and welfare assured on the waiver;
- (3) Participate in the development and implementation of an integrated, individualized care plan that includes a person-centered waiver service plan, and sign and date the plan as a condition of its acceptance;

- (4) Agree to receive waiver service coordination from the MyCare Ohio plan or its designee; and
- (5) Agree to participate in quality management and evaluation activities during his or her enrollment on the MyCare Ohio waiver.
- (C) If a member fails to meet any of the requirements set forth in paragraph (A) and/or paragraph (B) of this rule, the member shall be denied enrollment on the MyCare Ohio waiver.
- (D) Once enrolled on the MyCare Ohio waiver, a member's NF level of care shall be reassessed at least annually, and more frequently if there is a significant change in the member's situation that may impact his or her health and welfare. If the reassessment determines the member no longer meets the requirements set forth in paragraph (A) and/or paragraph (B) of this rule, he or she shall be disenrolled from the MyCare Ohio waiver.
- (E) If a member enrolled on the MyCare Ohio waiver does not receive at least one waiver service for ninety consecutive days, the MyCare Ohio plan shall, within ten days of the ninetieth day, reassess the member's need for waiver services. If it is determined the member no longer meets the requirements set forth in paragraph (A) and/or paragraph (B) of this rule, he or she shall be disenrolled from the MyCare Ohio waiver.
- (F) If, at any other time, it is determined that a member enrolled on the MyCare Ohio waiver no longer meets the requirements set forth in paragraph (A) and/or paragraph (B) of this rule, he or she shall be disenrolled from the MyCare Ohio waiver.
- (G) If a member is denied enrollment in the MyCare Ohio waiver pursuant to paragraph (C) of this rule, or is disenrolled from the waiver pursuant to paragraph (D), (E) or (F) of this rule, ODM shall afford the member notice and hearing rights in accordance with division 5101:6 of the Administrative Code.

5160-58-03

MyCare Ohio plans: covered services.

(A) A MyCare Ohio plan (plan) must ensure that members have access to all medically-necessary medical, drug, behavioral health, nursing facility and home and community-based services (HCBS) covered by medicaid. After consideration of verified third party liability including medicare coverage pursuant to rule 5160-26-09.1 of the Administrative Code, the plan must ensure that:

- (1) Services are sufficient in amount, duration or scope to reasonably be expected to achieve the purpose for which the services are furnished;
- (2) The amount, duration, or scope of a required service is not arbitrarily denied or reduced solely because of the diagnosis, type of illness, or condition;
- (3) Medicaid coverage decisions are based on the coverage and medical necessity criteria published in agency 5160 of the Administrative Code; and practice guidelines specified in paragraph (B) of rule 5160-26-05.1 of the Administrative Code; and
- (4)) If a member is unable to obtain medically-necessary medicaid services from a plan panel provider, the plan must adequately and timely cover the services out of panel until the plan is able to provide the services from a panel provider.

(B) The plan may place limits on services;

- (1) On the basis of medical necessity;
- (2) Except as otherwise specified in this rule, to available panel providers;
- (3) For the purposes of utilization control, provided the services furnished can be reasonably expected to achieve their purpose as specified in paragraph (A)(1) of this rule.

(C) The plan must cover annual physical examinations for adults.

(D) At the request of a member, a plan must provide for a second opinion from a qualified health care professional within the panel. If such a qualified health care professional is not available within the plan's panel, the plan must arrange for the member to obtain a second opinion outside the panel, at no cost to the member.

(E) The plan must assure that emergency services as defined in rule 5160-26-01 of the Administrative Code are provided and covered twenty-four hours a day, seven days a week. At a minimum, such services must be provided and reimbursed in accordance with the following:

- (1) The plan may not deny payment for treatment obtained when a member had an emergency medical condition as defined in rule 5160-26-01 of the

Administrative Code.

- (2) The plan cannot limit what constitutes an emergency medical condition on the basis of lists of diagnoses or symptoms.
 - (3) The plan must cover all emergency services without requiring prior authorization.
 - (4) The plan must cover medicaid-covered services related to the member's emergency medical condition when the member is instructed to go to an emergency facility by a representative of the plan including but not limited to the member's PCP or the plan's twenty-four-hour toll-free call-in-system.
 - (5) The plan cannot deny payment of emergency services based on the treating provider, hospital, or fiscal representative not notifying the member's PCP of the visit.
 - (6) For the purposes of this rule, "non-contracting provider of emergency services" means any person, institution, or entity who does not contract with the plan but provides emergency services to an plan member, regardless of whether or not that provider has a medicaid provider agreement with ODM. The plan must cover emergency services as defined in rule 5160-26-01 of the Administrative Code when the services are delivered by a non-contracting provider of emergency services. Claims for these services cannot be denied regardless of whether the services meet an emergency medical condition as defined in rule 5160-26-01 of the Administrative Code. Such services must be reimbursed by the plan at the lesser of billed charges or one hundred per cent of the Ohio medicaid program fee-for-service reimbursement rate (less any payments for indirect costs of medical education and direct costs of graduate medical education that is included in the Ohio medicaid program fee-for-service reimbursement rate) in effect for the date of service. If an inpatient admission results, the plan is required to reimburse at this rate only until the member can be transferred to a provider designated by the plan.
 - (7) The plan must adhere to the judgment of the attending provider when the attending provider requests a member's transfer to another facility or discharge. The plan may establish arrangements with hospitals whereby the plan may designate one of its contracting providers to assume the attending provider's responsibilities to stabilize, treat and transfer the member.
 - (8) A member who has had an emergency medical condition may not be held liable for payment of any subsequent screening and treatment needed to diagnose the specific condition or stabilize the member.
- (F) The plan must establish, in writing, the process and procedures for the submission of claims for services delivered by non-contracting providers, including non-contracting providers of emergency services as described in paragraph (E)(6)

of this rule. These written policies and procedures must be made available to non-contracting providers, including non-contracting providers of emergency services, on request. The plan may not establish claims filing and processing procedures for non-contracting providers, including non-contracting providers of emergency services, that are more stringent than those established for their contracting providers.

(G) The plan must assure that post-stabilization care services as defined in rule 5160-26-01 of the Administrative Code are provided and covered twenty-four hours a day, seven days a week.

(1) The plan must designate a telephone line to receive provider requests for coverage of post-stabilization care services. The line must be available twenty-four hours a day, seven days a week. The plan must document that the telephone number and process for obtaining authorization has been provided to each emergency facility in the service area. The plan must maintain a record of any request for coverage of post-stabilization care services that is denied including, at a minimum, the time of the provider's request and the time that the plan communicated the decision in writing to the provider.

(2) At a minimum, post-stabilization care services must be provided and reimbursed in accordance with the following:

(a) The plan must cover services obtained within or outside the plan's panel that have not been pre-approved in writing by a plan provider or other plan representative.

(b) If the plan does not respond within one hour of a provider's request for preapproval of further services that were administered to maintain the member's stabilized condition, the plan must cover the services, whether or not they were provided within the plan's panel.

(c) The plan must cover services obtained within or outside the plan's panel that are not pre-approved by a plan provider or other plan representative but are administered to maintain, improve or resolve the member's stabilized condition if:

(i) The plan fails to respond within one hour to a provider request for authorization to provide such services.

(ii) The plan cannot be contacted.

(iii) The plan's representative and treating provider cannot reach an agreement concerning the member's care and a plan provider is not available for consultation. In this situation, the plan must give the treating provider the opportunity to consult with a plan provider and the treating provider may continue with care until a

plan provider is reached or one of the criteria specified in paragraph (G)(3) of this rule is met.

(3) The plan's financial responsibility for post stabilization care services it has not pre-approved ends when:

(a) A plan provider with privileges at the treating hospital assumes responsibility for the member's care;

(b) A plan provider assumes responsibility for the member's care after the member is transferred to another facility;

(c) A plan representative and the treating provider reach an agreement concerning the member's care; or

(d) The member is discharged.

(H) Exclusions, limitations and clarifications.

(1) The plan must permit members to self-refer to Title X services provided by any qualified family planning provider (QFPP). The plan is responsible for payment of claims for Title X services delivered by QFPPs not contracting with the plan at the lesser of one hundred per cent of the Ohio medicaid program fee-for-service reimbursement rate or billed charges, in effect for the date of service.

(2) The plan must permit members to self-refer to any women's health specialist within the plan's panel for covered care necessary to provide women's routine and preventative health care services. This is in addition to the member's designated PCP if that PCP is not a women's health specialist.

(3) The plan must ensure access to covered services provided by all federally qualified health centers (FQHCs) and rural health clinics (RHCs).

(4) Where available, the plan must ensure access to covered services provided by a certified nurse practitioner.

(5) The plan is not responsible for payment of services provided through the medicaid schools program (MSP) providers pursuant to Chapter 5160-35 of the Administrative Code.

(6) The plan must provide all early and periodic screening, diagnosis and treatment (EPSDT) services, also known as healthchek services, in accordance with the periodicity schedule identified in Chapter 5160-14 of the Administrative Code, to healthchek eligible members and assure that services are delivered and monitored as follows:

- (a) Healthchek exams must include those components specified in Chapter 5160-14 of the Administrative Code. All components of exams must be documented and included in the medical record of each healthchek eligible member and made available for the ODM annual external quality review.
 - (b) The plan or its contracting provider must notify members of the appropriate healthchek exam intervals as specified in Chapter 5160-14 of the Administrative Code.
 - (c) Healthchek exams are to be completed within ninety days of the initial effective date of membership for those children found to have a possible ongoing condition likely to require care management services.
- (I) A plan is not required to cover services provided to members outside the United States.

5160-58-03.2

MyCare Ohio HCBS Waiver Program: Member Choice, Control, Responsibilities, and Participant Direction.

A member and/or their authorized representative who is acting on the member's behalf, who is enrolled on the MyCare Ohio HCBS waiver program in accordance with rule 5160-58-02.2 of the Administrative Code has choice and control over the arrangement and provision of HCBS. Members also have choice over the selection and control over the direction of approved waiver service providers.

For the purpose of this rule, the term "member" includes, as appropriate, an authorized representative who is selected by the member and acts on behalf of the member.

(A) A member may choose to receive MyCare Ohio waiver services from any combination of providers on the provider panel of the MyCare Ohio plan selected by the member and serving in the MyCare Ohio HCBS waiver program pursuant to paragraph (B) of rule 5160-58-04 of the Administrative Code.

(B) A member receiving waiver services from any MyCare Ohio HCBS waiver program provider shall comply with the requirements set forth in paragraphs (B)(1) to (B)(13) of this rule.

(1) Participate with the waiver service coordinator in the development of the waiver service plan and all plans of care including the development of a back-up plan.

(2) Decide who from their trans-disciplinary care management team will participate in the face-to-face development of the integrated, individualized care plan.

(3) Communicate to the service provider and, as appropriate, the provider's management staff, personal preferences about the manner in which duties, tasks and procedures are to be performed.

(4) Work with the waiver service coordinator and the provider to identify and secure additional service provider orientation, training and/or continuing education within the provider's scope of practice in order to meet the member's specific needs.

(5) Shall not direct the provider to act in a manner that is contrary to all relevant MyCare Ohio HCBS waiver program requirements, medicaid rules and regulations, and the provider's policies and procedures.

(6) Understand the responsibilities of the member as set forth in rule 5160-58-05.3 of the Administrative Code relative to incident management and reporting.

(7) Communicate to the waiver service coordinator and/or MyCare Ohio plan care manager any significant changes, as defined in rule 5160-58-01 of the Administrative Code, that may affect the provision of services or result in a need for more or fewer hours of service.

- (8) Sign a complete and accurate timesheet or other documentation, as appropriate, to verify services have been furnished. The member shall never approve blank timesheets, or timesheets that have been completed before services have been furnished. Verification may be written or electronic at the discretion of the MyCare Ohio plan.
- (9) Participate in the recruitment, selection and dismissal of providers in collaboration with the trans-disciplinary care management team.
- (10) In the manner specified by the waiver service coordinator, notify the provider if the member is going to miss a scheduled visit.
- (11) Notify the waiver service coordinator if the assigned provider misses a scheduled visit.
- (12) Notify the waiver service coordinator when any change in provider is necessary. Notification shall include the desired end date of the current provider.
- (13) Participate in the monitoring of the performance of the provider.
- (C) If a member chooses to receive waiver services from any non-agency provider, or is exercising participant-direction over the services in paragraph (F) of rule 5160-58-04 of the Administrative Code using one or more consumer-directed individual providers or consumer-directed personal care providers, the following additional requirements shall apply as appropriate to the service being furnished:
 - (1) In accordance with paragraph (B)(9) of this rule, members shall take a proactive role in the delivery of their MyCare Ohio HCBS waiver program services. This includes, but is not limited to, identifying prospective providers, recruiting and training MyCare Ohio providers to furnish tasks in accordance with the member's needs and preferences, and working with the MyCare Ohio care manager or waiver service coordinator to schedule and manage the delivery of authorized MyCare Ohio HCBS waiver program services.
 - (2) The member shall designate a location in their home in which the member and, as appropriate, the the provider can safely store a copy of the member's records in a manner that protects the confidentiality of the records, and for the purpose of contributing to the continuity of the member's care.
 - (3) The member or, as appropriate, the provider shall make the member's records available upon request by the MyCare Ohio plan, ODM and/or ODM's designee.
 - (4) The member shall not aid the provider in furnishing a service in a manner that does not comply with any rule or law that regulates the provider.

(5) Members who exercise participant-direction of providers under the MyCare Ohio HCBS waiver program shall work with ODM's designated financial management service.

(D) The MyCare Ohio plan shall comply with all of the requirements set forth in this paragraph:

(1) Ensure the health and welfare of the member enrolled in the MyCare Ohio HCBS waiver program while acknowledging the member's right to make informed decisions and accept the resulting consequences that may impact the member's life.

(2) Upon the member's enrollment in the MyCare Ohio HCBS waiver program, provide the member with waiver-related information, including information about the member's rights and responsibilities and opportunities for participant-direction, using communication mechanisms that are most effective for the member. The waiver service coordinator shall review these materials with the member and assist him or her to understand his or her specific responsibilities.

(3) Work with the member to do the following:

(a) Select and direct approved waiver service providers;

(b) Develop the waiver service plan including service back-up plans that meet the needs of the member;

(c) Exchange information with all of the member's service providers for development of the waiver service plan;

(d) Identify provider orientation and training that is within the provider's scope of practice and meets the member's needs; and

(e) Assist the member with resolving conflicts between the member and provider(s) and, upon request, identify and work with the member to secure new providers when the member notifies the waiver service coordinator that a change is necessary.

(4) Adhere to the incident management requirements set forth in rule 5160-58-05.3 of the Administrative Code.

(5) Address significant changes, as defined in rule 5160-58-01 of the Administrative Code, experienced by the member that may affect the provision of services or result in a need for more or fewer hours of service.

(6) Document, in writing, that the member:

- (a) Understands their specific needs;
 - (b) Possesses the skills necessary to meet the requirements set forth in paragraph (B), (C) or (D) of this rule, as appropriate;
 - (c) Demonstrates an understanding of his or her responsibilities pursuant to paragraphs (B) and (C) of this rule; and
 - (d) Identifies the method by which the member will verify that services have been furnished as identified on the waiver service plan.
- (7) Communicate with the member in a manner that protects the member's right to confidentiality.
- (E) If the member elects to receive services from a participant-directed provider, the waiver service coordinator shall assess the member's strengths and weaknesses (and/or, if the member has an authorized representative, the authorized representative's strengths or weaknesses) and ability direct a provider. The waiver service coordinator shall allow the member to direct a provider if the waiver service coordinator establishes that the member demonstrates an understanding of the following:
 - (1) Establishes that the member demonstrates an understanding of the elements of the service the provider shall furnish;
 - (2) An understanding of how to direct the provider; and
 - (3) An understanding of, and ability to, perform the responsibilities of an employer, including:
 - (a) Completion of any training that ODM or the MyCare Ohio plan requires;
 - (b) Understanding which service activities are covered according to rule 5160-58-04 of the Administrative Code;
 - (c) Understanding the methods for selecting and dismissing participant-directed service providers including the requirements for providers to furnish services in the MyCare Ohio waiver;
 - (d) Understanding the methods for entering into written agreements with participant-directed service providers for specific activities;
 - (e) Understanding the methods for training participant-directed service providers to meet the member's specific needs;
 - (f) Understanding the methods for supervising and monitoring the

participant-directed service provider's performance of specific activities, including written approval of the provider's time sheets;

(g) Development of a back-up plan for furnishing services if a provider is unable to furnish the agreed-upon service;

(h) Understanding the methods for filing grievances, including use of the regional and state long term care ombudsman, and familiarity with how to contact the state long-term care ombudsman;

(i) Familiarity with the MyCare Ohio grievance process and the state appeal and fair hearing request procedures;

(j) Understanding and compliance with the State's record-retention requirements; and,

(k) An ability to manage the participant-directed service provider when he or she furnishes a service.

(F) If the waiver service coordinator determines that the member cannot meet the requirements set forth in paragraph (E) of this rule, and/or the health and welfare of the member receiving services from a non-agency or participant-directed provider cannot be ensured, the waiver service coordinator may require the member to receive services from only agency providers. The member will be afforded notice and hearing rights in accordance with division 5101:6 of the Administrative Code.

5160-58-04

MyCare Ohio HCBS Waiver Program Covered Services and Providers.

- (A) The purpose of this rule is to establish both the services covered by the MyCare Ohio home and community based services (HCBS) waiver program and the providers eligible to furnish those services to members enrolled in the MyCare Ohio waiver.
- (B) Providers seeking to furnish services in the MyCare Ohio HCBS waiver program shall meet the requirements in Chapters 173-39 or 5160-45 of the Administrative Code, as appropriate, prior to furnishing services in the MyCare Ohio HCBS waiver.
- (C) The MyCare Ohio HCBS waiver program's covered services are limited to the following and exclude any reimbursement provisions in the Ohio Administrative Code rules cited therein:
- (1) Adult day health services as set forth in rule 173-39-02.1 or rules 5160-46-04 and 5160-50-04 of the Administrative Code;
 - (2) Alternative meal services as set forth in rule 173-39-02.2 of the Administrative Code;
 - (3) Assisted living services as set forth in rule 173-39-02.16 of the Administrative Code;
 - (4) Choices home care attendant services as set forth in rule 173-39-02.4 of the Administrative Code;
 - (5) Chore services as set forth in rule 173-39-02.5 of the Administrative Code;
 - (6) Community transition services as set forth in rule 173-39-02.17 of the Administrative Code;
 - (7) Emergency response services as set forth in rule 173-39-02.6 or rules 5160-46-04 and 5160-50-04 of the Administrative Code;
 - (8) Enhanced community living services as set forth in rule 173-39-02.20 of the Administrative Code.
 - (9) Homemaker services as set forth in rule 173-39-02.8 of the Administrative Code;
 - (10) Home care attendant services as set forth in rules 5160-46-04.1 and 5160-50-04.1 of the Administrative Code;
 - (11) Home delivered meal services as set forth in rule 173-39-02.14 or rules 5160-46-04 and 5160-50-04 of the Administrative Code;

- (12) Home medical equipment and supplemental adaptive and assistive devices services as set forth in rule 173-39-02.7 or rules 5160-46-04 and 5160-50-04 of the Administrative Code;
 - (13) Home modification, maintenance and repair services as set forth in rule 173-39-02.9 or rules 5160-46-04 and 5160-50-04 of the Administrative Code;
 - (14) Independent living assistance services as set forth in rule 173-39-02.15 of the Administrative Code;
 - (15) Nutrition consultation services as set forth in rule 173-39-02.10 of the Administrative Code;
 - (16) Out-of- home respite services as set forth in rules 5160-46-04 and 5160-50-04 of the Administrative Code;
 - (17) Personal care services as set forth in rule 173-39-02.11 or rules 5160-46-04 and 5160-50-04 of the Administrative Code;
 - (18) Pest control services as set forth in rule 173-39-02.3 of the Administrative Code;
 - (19) Social work counseling services as set forth in rule 173-39-02.12 of the Administrative Code;
 - (20) Waiver nursing services as set forth in rules 5160-46-04 and 5160-50-04 of the Administrative Code; and
 - (21) Waiver transportation services as set forth in rules 173-39-02.13 and 173-39-02.18 or rules 5160-46-04 and 5160-50-04 of the Administrative Code.
- (D) If a member enrolled in the MyCare Ohio HCBS waiver program is also a participant in the helping ohioans move, expanding (HOME) choice demonstration program pursuant to Chapter 5160-51 of the Administrative Code, the members may, at their discretion, use the HOME choice community transitions service in lieu of, but not in addition to, the community transition service available through the MyCare Ohio HCBS waiver program.
- (E) If a member receives enhanced community living services, the member shall not also receive personal care or homemaker services available through the MyCare Ohio HCBS waiver program.
- (F) The following services may be participant directed using budget and/or employer authority. To exercise these authorities, members must demonstrate the ability to direct providers in accordance with paragraph (E) of rule 5160-58-03.2 of the

Administrative Code:

(1) Employer authority which includes, but is not limited to, the ability of the member to hire, fire, and train employees is available for the following services:

(a) Choices home care attendant services provided by a consumer-directed individual provider; and

(b) Personal care services provided by a consumer-directed personal care provider.

(2) Budget authority which includes, but is not limited to, the ability of the member to negotiate rates of reimbursement is available in the following services:

(a) Alternative meals;

(b) Choices home care attendant services;

(c) Home modification, maintenance and repair;

(d) Pest control; and

(e) Home medical equipment and supplemental adaptive and assistive devices.

5160-58-05.3

MyCare Ohio waiver: incident management system.

(A) For the purposes of this rule,

- (1) "Alert" means an incident that must be reported to the Ohio department of medicaid (ODM) due to the severity and/or impact on a member enrolled on the MyCare Ohio waiver or the need for ODM involvement in the incident investigation. Alerts include, but are not limited to the events described in paragraph (J) of this rule.
- (2) "Incident" means an alleged, suspected or actual event that is not consistent with the routine care of, and/or service delivery to, a member. Incidents include, but are not limited to the events described in paragraph (F) of this rule.
- (3) "Provider" means a MyCare Ohio waiver service provider, any other service provider that is directed to adhere to this rule, and all of their respective staff who have direct contact with members.

(B) ODM shall operate an incident management system that includes responsibilities for reporting, responding to, investigating and remediating incidents. This rule sets forth the standards and procedures for operating that system. It applies to ODM, its designees (which, unless otherwise stated, for the purposes of this rule includes, but is not limited to MyCare Ohio plans and their designees), members and providers. ODM may designate other agencies or entities to perform one or more of the incident management functions set forth in this rule.

(C) ODM and its designees shall assure the health and welfare of members enrolled on the MyCare Ohio waiver. ODM, its designees and providers are responsible for ensuring members are protected from abuse, neglect, exploitation and other threats to their health, safety and well-being.

(D) Upon entering into a medicaid provider agreement, and annually thereafter, all providers, including all employees who have direct contact with members enrolled on the MyCare Ohio waiver, must acknowledge in writing they have reviewed this rule and related procedures.

(E) Upon a member's enrollment in the MyCare Ohio waiver, and at the time of each annual reassessment, ODM or the MyCare Ohio plan shall provide the member and/or the member's authorized representative or legal guardian with a waiver handbook that includes information about how to report abuse, neglect, exploitation and other incidents. The MyCare Ohio plan shall secure from the member, authorized representative and/or legal guardian written confirmation of receipt of the handbook and it shall be maintained in the member's case record.

(F) Incidents include, but are not limited to, all of the following:

- (1) Abuse: the injury, confinement, control, intimidation or punishment of a

member by another person that has resulted, or could reasonably be expected to result, in physical harm, pain, fear or mental anguish. Abuse includes, but is not limited to physical, emotional, verbal and/or sexual abuse, and use of restraint, seclusion or restrictive intervention that results in, or could reasonably be expected to result in, physical harm, pain, fear or mental anguish to the member.

(2) Neglect: when there is a duty to do so, the failure to provide goods, services and/or treatment necessary to assure the health and welfare of a member.

(3) Exploitation: the unlawful or improper act of using a member or a member's resources for monetary or personal benefit, profit or gain.

(4) Misappropriation: depriving, defrauding or otherwise obtaining the money, or real or personal property (including medication) of a member by any means prohibited by law.

(5) Death of a member.

(6) Hospitalization or emergency department visit (including observation) as a result of:

(a) Accident, injury or fall;

(b) Injury or illness of an unknown cause or origin; and

(c) Reoccurrence of an illness or medical condition within seven calendar days of the member's discharge from a hospital.

(7) Unauthorized use of restraint, seclusion and/or restrictive intervention that does not result in, or cannot reasonably be expected to result in, injury to the member.

(8) An unexpected crisis in the member's family or environment that results in an inability to assure the member's health and welfare in his or her primary place of residence.

(9) Inappropriate service delivery including, but not limited to:

(a) A provider's violation of the requirements set forth in rule 5160-58-04 of the Administrative Code and/or any other Administrative Code rules referenced therein;

(b) Services provided to the member that are beyond the provider's scope of practice;

(c) Services delivered to the member without, or not in accordance with,

physician's orders; and

(d) Medication administration errors involving the member.

(10) Actions on the part of the member that place the health and welfare of the member or others at risk including, but not limited to:

(a) The member cannot be located;

(b) Activities that involve law enforcement;

(c) Misuse of medications; and

(d) Use of illegal substances.

(G) Incident reporter responsibilities.

(1) ODM, its designees and all providers are required to report incidents in accordance with the procedures set forth in this rule.

(2) Members and/or their authorized representative or legal guardian should report incidents to the member's MyCare Ohio care manager or waiver service coordinator and the appropriate authorities.

(3) If a person or an entity identified in paragraph (G)(1) of this rule learns of an incident, the person or entity shall do all of the following:

(a) Take immediate action to assure the health and welfare of the member which may include, but is not limited to, seeking or providing medical attention.

(b) Immediately report any incident(s) set forth in paragraphs (F)(1) to (F)(5) of this rule to the MyCare Ohio care manager or waiver service coordinator and the appropriate authorities set forth in paragraph (G)(5)(a) of this rule.

(c) Report any incidents set forth in paragraphs (F)(6) to (F)(9) of this rule to the MyCare Ohio care manager or waiver service coordinator within twenty-four hours unless bound by federal, state or local law or professional licensure or certification requirements to report sooner.

(4) At a minimum, all incident reports shall include:

(a) The facts that are relevant to the incident;

(b) The incident type; and

(c) The names of, and when available, the contact information for, all persons involved.

(5) The appropriate authority is dependent upon the nature of the incident. Examples of appropriate authorities include, but are not limited to:

(a) The following agencies that hold investigative and/or protective authority:

(i) Local law enforcement if the incident involves conduct that constitutes a possible criminal act including but not limited to, abuse, neglect, exploitation, misappropriation or death of the member;

(ii) The local coroner's office;

(iii) The local county board of developmental disabilities (CBDD);

(iv) The local public children services agency (PCSA); and

(v) The local public adult protective services agency.

(b) The following regulatory, oversight and/or advocacy agencies:

(i) The Ohio long term care ombudsman;

(ii) The alcohol, drug addiction and mental health service board;

(iii) The Ohio department of health (ODH), or other licensure or certification board or accreditation body when the allegation involves a provider regulated by that entity;

(iv) The Ohio attorney general when the allegation is suspected to involve medicaid fraud; and

(v) The local probate court when the allegation is suspected to involve the legal guardian.

(6) The incident reporter must also notify his or her supervisor if he or she has one.

(H) MyCare Ohio plan responsibilities.

(1) The MyCare Ohio plan shall do all of the following upon discovery of an incident:

(a) Ensure that immediate action was taken to protect the health and welfare of the member and any other members who may be at-risk.

- (b) Notify the appropriate agencies that hold investigative and/or protective authority as set forth in paragraph (G)(5)(a) of this rule if the incident was one of those set forth in paragraphs (F)(1) to (F)(5) of this rule.
- (c) Notify the appropriate additional regulatory, oversight and/or advocacy agencies set forth in paragraph (G)(5)(b) of this rule.
- (d) Notify the member's primary care provider.
- (2) The MyCare Ohio plan shall complete an incident report in ODM's or its provider oversight contractor's electronic incident management system within twenty-four hours of discovery if the incident was one of those set forth in paragraphs (F)(1) to (F)(5) of this rule.
- (3) The MyCare Ohio plan shall complete an incident report in the MyCare Ohio plan's own incident management system within twenty-four hours of discovery if the incident was one of those set forth in paragraphs (F)(6) to (F)(10) of this rule.
- (4) The MyCare Ohio plan shall notify ODM or its provider oversight contractor, as appropriate, within twenty-four hours of any incident that meets the criteria of an alert as set forth in paragraph (J) of this rule.
- (5) The MyCare Ohio plan shall notify the member and/or the member's authorized representative or legal guardian of the incident as long as such notification will not jeopardize the incident investigation and/or place the health and welfare of the member or reporter at risk.
- (6) The MyCare Ohio plan shall submit all incident data resulting from reports filed pursuant to paragraphs (H)(2) and (H)(3) of this rule to ODM or its designee by the close of business on the last business day of the first week following the end of the monthly reporting period.

(I) Incident investigation responsibilities.

- (1) As appropriate, ODM or its provider oversight contractor, or the MyCare Ohio plan must review all reported incidents within one business day of notification via ODM's or its designee's electronic incident management system, and shall do all of the following as part of its review:
 - (a) Verify that immediate action was taken to protect the health and welfare of the member and any other members who may be at-risk. If such action was not taken, the provider oversight contractor must do so immediately.
 - (b) Verify that the county coroner was notified in the event of the death of a

member. If such action was not taken, the provider oversight contractor must do so immediately.

(c) Verify that the appropriate authorities have been notified as required by this rule. If such action was not taken, the provider oversight contractor must do so immediately.

(d) Verify that the incident was reported within the timeframe required by this rule.

(e) Notify ODM of any incident that meets the criteria of an alert as set forth in paragraph (J) of this rule.

(2) As appropriate, the provider oversight contractor or the MyCare Ohio plan shall initiate an investigation no later than two business days after having been notified of an incident. At a minimum, the provider oversight contractor or MyCare Ohio plan shall:

(a) Contact and work cooperatively with protective agencies and any other entities to whom the incident was reported and that may be conducting a separate investigation.

(b) Conduct a review of all relevant documents including, but not limited to, integrated, individualized care plans, assessments, clinical notes, communication notes, coroner's reports, documentation available from other authorities, provider documentation, plans of care, provider billing records, medical reports, police and fire department reports and emergency response system reports.

(c) Conduct and document interviews with anyone who may have information relevant to the incident investigation including, but not limited to, the reporter, members, authorized representatives and/or legal guardians and providers.

(d) Include the member and the reporter in the incident investigation process, as long as such involvement is both safe and appropriate.

(e) When applicable, make referrals to appropriate licensure or certification boards, accreditation bodies, and/or other entities based on the information obtained during the investigation.

(f) Document all investigative activities.

(g) Document if and why any of the steps set forth in paragraph (I) of this rule were omitted from the incident investigation.

(3) If, at any time during the investigation of a death, it is determined the incident

meets the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule, or the death may have been preventable, the provider oversight contractor must notify ODM within twenty-four hours of the contractor's discovery. If ODM agrees the death is suspicious in nature or was preventable, it shall maintain lead responsibility for the investigation and follow all of the steps set forth in paragraph (I) of this rule and the ODM-approved death investigation protocol. All other deaths shall be investigated by the provider oversight contractor in accordance with the steps set forth in paragraph (I) of this rule and the ODM-approved death investigation protocol.

(4) Concluding an incident investigation.

(a) As appropriate, the provider oversight contractor or the MyCare Ohio plan must conclude its incident investigation no later than forty-five days after the provider oversight contractor's initial receipt of the incident report. Extension of this deadline is only permissible upon prior approval by ODM.

(b) At the conclusion of the investigation, the provider oversight contractor or the MyCare Ohio plan shall:

(i) Submit to ODM and the member, authorized representative and/or legal guardian a written report that:

(a) Summarizes the investigation;

(b) Identifies if the incident was substantiated and whether it was preventable; and

(c) Includes a prevention plan for the member that identifies the steps necessary to mitigate the effects of a substantiated incident, eliminate the causes and contributing factors that resulted in risk to the health and welfare of the member and any other persons impacted by the incident and prevent future incidents.

(ii) Notify MyCare Ohio waiver service providers who are subject to the incident investigation in writing upon substantiation of an incident. The notification shall specify:

(a) The findings of the investigation that substantiate the occurrence of the incident;

(b) The Administrative Code rule(s) that support(s) the finding(s) of the investigation;

(c) What steps the provider must take in order to mitigate against the causes of and factors contributing to the incident; and

(d) The timeframe within which the provider must submit a plan of correction in accordance with rule 5160-45-06 of the Administrative Code, not to exceed fifteen calendar days after the notification date.

(iii) Provide a written summary of the investigative findings to the reporter of the incident unless such action could jeopardize the health and welfare of the member.

(iv) Assure that all such reports issued pursuant to paragraph (I)(4) of this rule shall comply with all applicable state and federal confidentiality and information disclosure laws.

(J) Alerts.

(1) As appropriate, the provider oversight contractor or the MyCare Ohio plan shall ensure that incidents that rise to the level of an alert are reported to ODM within twenty-four hours of the incident's identification and report submission.

(2) The following incidents are cause for an alert:

(a) A suspicious death in which the circumstances and/or the cause of death are not related to any known medical condition of the member, and/or; in which someone's action or inaction may have caused or contributed to the member's death.

(b) Abuse or neglect that required the member's removal from his or her place of residence.

(c) Hospitalization or emergency department visit (including observation) as a result of:

(i) Abuse or neglect;

(ii) Accident, injury or fall;

(iii) Injury or illness of an unknown cause or origin; and

(iv) Reoccurrence within seven calendar days of the member's discharge from a hospital.

(d) Harm to multiple members as a result of an incident.

- (e) Injury resulting from the authorized or unauthorized use of a restraint, seclusion or restrictive intervention.
 - (f) Incidents involving an employee of the MyCare Ohio plan or provider oversight contractor.
 - (g) Misappropriation that is valued at five hundred dollars or more.
 - (h) Incidents generated from correspondence received from the Ohio attorney general, office of the governor, the centers for medicare and medicaid services (CMS) or the federal office of civil rights.
 - (i) Incidents identified by a public media source.
- (K) At its discretion, ODM may request further review of any incident under investigation, and/or conduct a separate, independent review or investigation of any incident.
- (L) ODM or its designee shall determine when to close incident investigations, and shall be responsible for ensuring that all investigations are properly closed.
- (M) If, at any time during the discovery or investigation of an incident, it is determined that an employee of the provider oversight contractor or the MyCare Ohio plan is or may be responsible for, or contributed to, the abuse, neglect, exploitation or death of a member, the provider oversight contractor or MyCare Ohio plan shall immediately notify ODM. ODM shall assume responsibility for the investigation in accordance with the procedures set forth in this rule.
- (N) ODM may impose sanctions upon the provider in accordance with rules 5160-45-06 and 5160-45-09 of the Administrative Code or rules 173-39-05 to 173-39-08 of the Administrative Code, as appropriate, based upon the substantiation of an incident, failure to comply with any of the requirements set forth in this rule, failure to assure the health and welfare of the member and/or failure to comply with all applicable federal, state and local laws and regulations.

5160-58-08.4

Appeals and grievances for MyCare Ohio.

(A) Definitions.

For the purposes of this rule the following terms are defined as:

(1) An "action" is the MyCare Ohio plan's

(a) Denial or limited authorization of a requested service, including the type or level of service;

(b) Reduction, suspension, or termination of services prior to the member receiving the services previously authorized by the plan;

(c) Denial, in whole or part, of payment for a service not covered by medicaid, including a service denied through the plan's prior authorization process as not medically necessary;

(d) Denial of a request for a specific plan-contracted non-agency or participant-directed waiver services provider pursuant to Paragraph (F) of rule 5160-58-03.2 of the Administrative Code; or

(e) Failure to provide services in a timely manner as specified in rules 5160-26-03.1 and 5160-58-01.1 of the Administrative Code; or

(f) Failure to act within the resolution timeframes specified in this rule.

(2) An "appeal" is the request for a plan's review of an action.

(3) A "grievance" is an expression of dissatisfaction with any aspect of the plan's or provider's operation, provision of health care services, activities, or behaviors, other than the plan's action as defined in paragraph (A)(1) of this rule.

(4) "Resolution" means a final decision is made by the plan and the decision is communicated to the member.

(5) "Notice of action (NOA)" is the written notice the plan must provide to members when a plan action has occurred or will occur.

(6) "Plan" is a MyCare Ohio plan.

(B) Each plan must have written policies and procedures for an appeal and grievance system for members, in compliance with the requirements of this rule. The policies and procedures must be made available for review by ODM, and must include the following:

(1) A process by which members may file grievances with the plan, in compliance with paragraph (H) of this rule;

(2) A process by which members may file appeals with the plan, in compliance with paragraphs (C) through (G) of this rule; and

(3) A process by which members may access the state's hearing system through the Ohio Department of Job and Family Services (ODJFS), in compliance with paragraph (I) of this rule.

(C) Notice of action (NOA) by a MyCare Ohio plan.

(1) When a plan action has or will occur, the plan must provide the affected member(s) with a written NOA.

(2) The NOA must explain:

(a) The action the plan has taken or intends to take;

(b) The reasons for the action;

(c) The member's or authorized representative's right to file an appeal to the plan;

(d) If applicable, the member's right to request a state hearing through the state's hearing system;

(e) Procedures for exercising the member's rights to appeal or grieve the action;

(f) Circumstances under which expedited resolution is available and how to request it;

(g) If applicable, the member's right to have benefits continue pending the resolution of the appeal, and how to request that benefits be continued;

(h) The date that the notice is being issued;

(i) Oral interpretation is available for any language;

(j) Written translation is available in prevalent languages as applicable;

(k) Written alternative formats may be available as needed; and

(l) How to access the plan's interpretation and translation services as well as alternative formats that can be provided by the plan.

(3) The following language and format requirements apply to a NOA issued by a plan:

- (a) It must be provided in a manner and format that may be easily understood;
- (b) It must be printed in the prevalent non-English languages of members in the plan's service area; and
- (c) It must be available in alternative formats in an appropriate manner that takes into consideration the special needs of members, including but not limited to members who are visually limited and members who have limited reading proficiency.

(4) A plan must give members a written NOA within the following timeframes:

- (a) For a decision to deny or limit authorization of a requested service, including the type or level of service, the plan must issue a NOA simultaneously with the plan's decision.
- (b) For reduction, suspension, or termination of services prior to the member receiving the services previously authorized by the plan, the plan must give notice fifteen calendar days before the date of action except:
 - (i) If probable recipient fraud has been verified, the plan must give notice five calendar days before the date of action.
 - (ii) Under the circumstances set forth in 42 C.F.R. 431.213 (October 1, 2013), the plan must give notice on or before the date of action.
- (c) For denial of payment for a noncovered service, the plan must give notice simultaneously with the plan's action to deny the claim, in whole or part, for a service that is not covered by medicaid, including a service that was determined through the plan's prior authorization process as not medically necessary.
- (d) For denial of a request for a provider pursuant to (A)(1)(d) of this rule, the plan must give notice simultaneously with the plan's decision.
- (e) For untimely prior authorization, appeal or grievance resolution, the plan must give notice simultaneously with the plan becoming aware of the action. Service authorization decisions not reached within the timeframes specified in rules 5160-26-03.1 and 5160-58-01.1 of the Administrative Code constitute a denial and are thus adverse actions. Notice must be given on the date that the authorization decision timeframe expires.

(D) Standard appeal to a MyCare Ohio plan.

- (1) A member, provider, or a member's authorized representative may file an appeal

orally or in writing within ninety days from the date on the NOA. The ninety day period begins on the day after the mailing date of the NOA. An oral filing must be followed with a written appeal. The plan must:

- (a) Assist members that file an oral appeal by immediately converting an oral filing to a written record;
 - (b) Ensure that oral filings are treated as appeals to establish the earliest possible filing date for the appeal; and
 - (c) Consider the date of the oral filing as the filing date if the member follows the oral filing with a written appeal.
- (2) The member's authorized representative or a provider acting on the member's behalf must have the member's written consent to file an appeal. The plan must begin processing the appeal pending receipt of the written consent.
- (3) The plan must acknowledge receipt of each appeal to the individual filing the appeal. At a minimum, acknowledgment must be made in the same manner that the appeal was filed. If an appeal is filed in writing, written acknowledgment must be made by the plan within three working days of the receipt of the appeal.
- (4) The plan must provide members a reasonable opportunity to present evidence and allegations of fact or law, in person as well as in writing. The member and/or member's authorized representative must be allowed to examine the case file, including medical records and any other documents and records, before and during the appeals process.
- (5) The plan must consider the member, member authorized representative, or estate representative of a deceased member as parties to the appeal.
- (6) The plan must review and resolve each appeal as expeditiously as the member's health condition requires but the resolution timeframe must not exceed fifteen calendar days from the receipt of the appeal unless the resolution timeframe is extended as outlined in paragraph (F) of this rule.
- (7) The plan must provide written notice to the parties of the resolution including, at a minimum, the decision and date of the resolution.
- (8) For appeal decisions not resolved wholly in the member's favor, the written notice to the member must also include information regarding:
- (a) Oral interpretation that is available for any language;
 - (b) Written translation that is available in prevalent languages as applicable;

- (c) Written alternative formats that may be available as needed;
- (d) How to access the plan's interpretation and translation services as well as alternative formats that can be provided by the plan;
- (e) The right to request a state hearing through the state's hearing system; and
- (f) How to request a state hearing, and if applicable:
 - (i) The right to continue to receive benefits pending a state hearing; and
 - (ii) How to request the continuation of benefits.

(9) For appeals decided in favor of the member, the plan must:

- (a) Authorize or provide the disputed services promptly and as expeditiously as the member's health condition requires if the services were not furnished while the appeal was pending; and
- (b) Pay for the disputed services if the member received the services while the appeal was pending.

(E) Expedited appeal to a MyCare Ohio plan.

- (1) Each plan must establish and maintain an expedited review process to resolve appeals when the plan determines, or the provider indicates in making the request on the member's behalf or supporting the member's request, that taking the time for a standard resolution could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function.
- (2) In utilizing an expedited appeal process, the plan must comply with the standard appeal process specified in paragraph (E) of this rule, except the plan must:
 - (a) Not require that an oral filing be followed with a written, signed appeal;
 - (b) Make a determination within one working day of the appeal request whether to expedite the appeal resolution;
 - (c) Make reasonable efforts to provide prompt oral notification to the member of the decision to expedite or not expedite the appeal resolution;
 - (d) Inform the member of the limited time available for the member to present evidence and allegations of fact or law in person or in writing;
 - (e) Resolve the appeal as expeditiously as the member's health condition

requires but the resolution timeframe must not exceed 72 hours from receipt of the appeal unless the resolution timeframe is extended as outlined in paragraph (F) of this rule;

(f) Make reasonable efforts to provide oral notice of the appeal resolution in addition to the required written notification;

(g) Ensure that punitive action is not taken against a provider who requests an expedited resolution or supports a member's appeal; and

(h) Notify ODM within one working day of any appeal that meets the criteria for expedited resolution as specified by ODM.

(3) If the plan denies the request for expedited resolution of an appeal, the plan must:

(a) Transfer the appeal to the standard resolution timeframe of fifteen calendar days from the date the appeal was received unless the resolution timeframe is extended as outlined in paragraph (F) of this rule; and

(b) Provide the member written notice of the denial to expedite the resolution within two calendar days of the receipt of the appeal, including information that the member can grieve the decision.

(F) Appeal resolution extensions for an appeal to a MyCare Ohio plan.

(1) A member may request that the plan extend the timeframe to resolve a standard or expedited appeal up to fourteen calendar days.

(2) A plan may request that the timeframe to resolve a standard or expedited appeal be extended up to fourteen calendar days. The plan must seek such an extension from ODM prior to the expiration of the regular appeal resolution timeframe and its request must be supported by documentation that the extension is in the member's best interest. If ODM approves the extension, the plan must immediately give the member written notice of the reason for the extension and the date that a decision must be made.

(3) The plan must maintain documentation of all requests for extension.

(G) Continuation of benefits for an appeal to a MyCare Ohio plan.

(1) The plan must continue a member's benefits when an appeal has been filed if the following conditions are met:

(a) The member or authorized representative files the appeal on or before the later of the following:

- (i) Within fifteen calendar days of the plan mailing the NOA; or
 - (ii) The intended effective date of the plan's proposed action.
- (b) The appeal involves the termination, suspension, or reduction of services prior to the member receiving the previously authorized course of treatment;
- (c) The services were ordered by an authorized provider;
- (d) The authorization period has not expired; and
- (e) The member requests the continuation of benefits.
- (2) If the plan continues or reinstates the member's benefits while the appeal is pending, the benefits must be continued until one of the following occurs:
 - (a) The member withdraws the appeal;
 - (b) A state hearing regarding the reduction, suspension or termination of the benefits is decided adverse to the member; or
 - (c) The initial time period for the authorization expires or the authorization service limits are met.
- (3) At the discretion of ODM, the plan may recover the cost of the continuation of services furnished to the member while the appeal was pending if the final resolution of the appeal upholds the plan's original action.

(H) Grievances to a MyCare Ohio plan.

- (1) A member or authorized representative can file a grievance. An authorized representative must have the member's written consent to file a grievance on the member's behalf.
- (2) Grievances may be filed only with the plan, orally or in writing, within ninety calendar days of the date that the member became aware of the issue.
- (3) The plan must acknowledge the receipt of each grievance to the individual filing the grievance. Oral acknowledgment is acceptable. However, if the grievance is filed in writing, written acknowledgment must be made within three working days of receipt of the grievance.
- (4) The plan must review and resolve all grievances as expeditiously as the member's health condition requires. Grievance resolutions including member notification must meet the following timeframes:

- (a) Within two working days of receipt if the grievance is regarding access to services.
- (b) Within thirty calendar days of receipt for all other grievances that are not regarding access to services.
- (5) At a minimum, the plan must provide oral notification to the member of a grievance resolution. However, if the plan is unable to speak directly with the member and/or the resolution includes information that must be confirmed in writing, the resolution must be provided in writing simultaneously with the plan's decision.
- (6) If the plan's resolution to a grievance is to affirm the denial, reduction, suspension, or termination of a service, denial of a provider pursuant to paragraph (A)(1)(d) of this rule, or billing of a member due to the plan's denial of payment for that service, the plan must notify the member of his or her right to request a state hearing as specified in paragraph (I) of this rule, if the member has not previously been notified.
- (7) If the plan's resolution to a grievance is to affirm the denial, reduction, suspension or termination of a service or denial of a provider pursuant to (A)(1)(d) of this rule, the plan must notify the member of his or her right to request an appeal to the plan as specified in paragraph (C)(4) of this rule, if the member has not previously been notified.

(I) Access to state's hearing system.

- (1) A plan must develop and implement written policies and procedures that ensure the plan's compliance with the state hearing provisions specified in division 5101:6 of the Administrative Code.
- (2) Members are not required to exhaust the appeal or grievance process through the plan in order to access the state's hearing system.
- (3) When required by paragraph (C) of this rule and division 5101:6 of the Administrative Code, a plan must notify members, and any authorized representatives on file with the plan, of the right to a state hearing. The following requirements apply:
 - (a) If the plan denies a request for the authorization of a service, in whole or in part, the plan must simultaneously complete and mail or personally deliver the "Notice of Denial of Medical Services By Your Managed Care Plan" (JFS 04043, rev. 7/2009).
 - (b) If the plan decides to reduce, suspend, or terminate services prior to the member receiving the services as authorized by the plan, the plan must

complete and mail or personally deliver no later than fifteen calendar days prior to the effective date of the proposed reduction, suspension, or termination, the "Notice of Reduction, Suspension or Termination of Medical Services By Your Managed Care Plan" (JFS 04066, 7/2009).

(c) If the plan denies a request for the authorization to receive waiver services from a provider pursuant to paragraph (A)(1)(d) of this rule, the plan must simultaneously complete and mail or personally deliver the required notice of state hearing rights.

(d) If the plan learns that a member has been billed for services received by the member due to the plan's denial of payment, and the plan upholds the denial of payment, the plan must immediately complete and mail or personally deliver the "Notice of Denial of Payment for Medical Services By Your Managed Care Plan" (JFS 04046, rev. 7/2009).

(4) The member or his or her authorized representative may request a state hearing within ninety calendar days by contacting the ODJFS bureau of state hearings or local county department of job and family services (CDJFS). The ninety-day period begins on the day after the mailing date on the state hearing form.

(5) There are no state hearing rights for a member(s) terminated from the plan pursuant to a plan-initiated membership termination as permitted in rule 5160-58-02.1 of the Administrative Code.

(6) Following notification by the bureau of state hearings to a plan that a member has requested a state hearing, the plan must:

(a) Complete the "Appeal Summary for Managed Care Plans" (JFS 01959, rev. 06/03) with appropriate attachments, and file it with the Bureau of State Hearings, at least three business days prior to the scheduled hearing date. The appeal summary must provide all facts and documents relevant to the issue, and be sufficient to demonstrate the basis for the plan's action or decision;

(b) Send a copy of the completed appeal summary to the appellant, the Bureau of State Hearings, the local agency, and the designated ODM contact; and

(c) Continue or reinstate the benefit(s) specified in rule 5101:6-4-01 of the Administrative Code, if the plan is notified that the member's state hearing request was received within the prior notification period and the member requested that the benefits be continued.

(7) The plan must participate in the hearing in person or by telephone, on the date indicated on the "State Hearing Scheduling Notice" (JFS 04002, rev. 09/02)

sent to the plan by the bureau of state hearings.

(8) In addition to the plan and member, other parties to a state hearing may include an authorized representative of a member, or the representative of the member's estate, if the member is deceased.

(9) The plan must comply with the state hearing officer's decision provided to the plan via the "State Hearing Decision" (JFS 04005, rev. 03/03). If the hearing officer's decision is to sustain the member's appeal, the plan must complete the "State Hearing Compliance" form (JFS 04068, rev. 05/01). A copy of the completed form, including applicable documentation, is due by no later than the compliance date specified in the hearing decision to the bureau of state hearings and the designated ODM contact. If applicable, the plan must:

(a) Authorize or provide the disputed services promptly and as expeditiously as the member's health condition requires; and

(b) Pay for the disputed services if the member received the disputed services while the appeal was pending.

(10) The plan must provide a copy of the state hearing forms referenced in this paragraph to ODM, as directed by ODM.

(11) Upon request, the plan's state hearing policies and procedures must be made available for review by ODM.

(J) Logging and reporting of appeals and grievances.

(1) A plan must maintain records of all appeals and grievances including resolutions for a period of eight years, and the records must be made available upon request to ODJFS and the medicaid fraud control unit.

(2) A plan must identify a key staff person responsible for the logging and reporting of appeals and grievances and assuring that the grievance system is in accordance with this rule.

(K) Other duties of a MyCare Ohio plan regarding appeals and grievances.

(1) A plan must give members all reasonable assistance in filing an appeal, a grievance, or accessing the state's hearing system, including but not limited to:

(a) Explaining the plan's process to be followed in resolving the member's appeal or grievance;

(b) Completing forms and taking other procedural steps as outlined in this rule; and

- (c) Providing oral interpreter and oral translation services, sign language assistance, and access to the grievance system through a toll-free number with text telephone yoke (TTY) and interpreter capability.
- (2) The plan must ensure that the individuals who make decisions on appeals and grievances are individuals who:
 - (a) Were not involved in previous levels of review or decision-making; and
 - (b) Are health care professionals who have the appropriate clinical expertise in treating the member's condition or disease, if deciding any of the following:
 - (i) An appeal of a denial that is based on lack of medical necessity;
 - (ii) A grievance regarding the denial of an expedited resolution of an appeal; or
 - (iii) An appeal or grievance that involves clinical issues.
- (3) The procedure to be followed to file an appeal or grievance must be described in the plan's member handbook and must include the telephone number(s) for the plan's toll-free member services hotline, the plan's mailing address, and a copy of the optional form(s) that members may use to file an appeal or grievance with the plan. Copies of the form(s) to file an appeal or grievance must also be made available through the plan's member services program.
- (4) The procedure to be followed to file a state hearing request must be described in the plan's member handbook.
- (5) Appeals and grievance procedures must include the participation of individuals authorized by the plan to require and implement corrective action.
- (6) A plan is prohibited from delegating the appeal or grievance process to another entity.
- (7) A plan must maintain and submit as directed by ODM, a record of all authorization requests, including standard and expedited authorization requests and any extensions granted. Plan records must include member identifying information, service requested, date initial request received, any extension requests, decision made, date of decision, date of member notice, and basis for denial, if applicable.