Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

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Regulation/Package Title (a general description of the rules' substantive content):

Amendment to Ohio Administrative Code Rule 5160-58-03.1 – Primary Care and UM

Rule Number(s): Rule 5160-58-03.1 - amendment

Date of Submission for CSI Review: 06/11/2025

Public Comment Period End Date: 06/18/2025

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? ___)
Amended/__1__ rules (FYR? _X__)
Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   In Ohio, approximately 90% of Medicaid recipients receive their Medicaid services through the managed care delivery system. Managed care organizations (MCOs) are health insurance companies licensed by the Ohio Department of Insurance and have a provider agreement (contract) with the Ohio Department of Medicaid (ODM) to provide coordinated health care to Medicaid beneficiaries. The rules in Ohio Administrative Code (OAC) Chapter 5160-58 govern the MyCare Ohio program. There are five MCOPs in Ohio, each with a network of health care professionals. MyCare Ohio is a managed care program aimed at providing integrated care for individuals who are dually eligible (e.g. members receive both Medicaid and Medicare services).
   OAC rule 5160-58-03.1, entitled "MyCare Ohio plans: Primary Care and Utilization Management" establishes that members have an ongoing source of primary care and assist with care coordination appropriate to the member's needs and defined utilization management structure and processes designed to maximize the effectiveness of the care provided to the member.
   This rule will be proposed to update the standard authorization decision timeframe to align with provisions in the Centers for Medicare & Medicaid Services Interoperability and Prior Authorization Final rule -CMS-0057-F.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Revised Code Section 5164.02, 5166.02, and 5167.02 authorizes ODM to adopt this rule, and 5164.02, 51666.02, and 5167.02 amplify that authority.

4. **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?**

   Yes. 42 CFR Part 438 imposes comprehensive requirements on the state regarding Medicaid managed care programs. The amendment is a result of CMS Interoperability and Prior Authorization Final Rule - CMS-0057-F. Additionally, ODM has entered into a three-way contract with the Centers for Medicare and Medicaid Services (CMS) in the U.S. Department of Health and Human Services and each MCOP to implement the MyCare Ohio demonstration program.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Federal regulations do not impose requirements directly on MCOs; instead they require state Medicaid agencies to ensure MCO compliance with federal standards. This rule is consistent with federal managed care requirements outlined in 42 CFR Part 438 that require the state to implement policies and regulations as the state deems necessary and appropriate. The provisions outlined in CMS Final Rule (CMS-0057-F) pose provisions that require compliance by two separate dates, January 1, 2026 and January 1, 2027.

6. **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)?**

   OAC rule 5160-58-03.1 is necessary for various reasons. Federal regulations require state Medicaid agencies to ensure MCO compliance with federal standards, therefore this rule ensures ODM compliance with federal regulations governing Medicaid managed care programs. The public purpose of this regulation is to:

   - Ensure MyCare Ohio plans (MCOPs) provide or arrange for the delivery of covered health care services either through the use of employees or through contracts with network providers of health care services.
   - Ensure all of the MCOP activities and obligations are performed in accordance with agency 5160 of the Administrative Code, as applicable, the MCOPs provider agreement or contract with ODM, and all applicable federal, state, and local regulations.
   - Ensure members' rights and protections.

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

ODM monitors compliance with the regulation through reporting requirements established within the MyCare Ohio provider agreement. Successful outcomes are measured through a finding of compliance with these standards as determined by monitoring and oversight.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   The stakeholders listed below were provided with the draft rule electronically on 12/09/2024.
   - UnitedHealthcare Community Plan of Ohio, Inc.
   - Molina Healthcare of Ohio, Inc.
   - CareSource Ohio, Inc.
   - Aetna Better Health Ohio, Inc.
   - Buckeye Community Health Plan
   - Community Insurance Company d/b/a Anthem Blue Cross & Blue Shield
   - Amerihealth Caritas Ohio
   - Humana of Ohio
   - Aetna OhioRISE

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

    ODM received one comment from Anthem BCBS and ODM responded to their comment. Anthem sought clarity on whether timeframes for standard decisions on prior authorization will align with both Medicaid managed care organizations and MyCare Ohio plans. No changes to this rule resulted from this comment.

11. **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 this rule or the measurable outcomes of this rule.

12. **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?**
    Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

The amendment to this rule includes general updates to keep this rule current and comply with CMS requirements to the managed care program utilization management program. No alternative regulations were discussed during this rule process for this reason.

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

    All Medicaid regulations governing Managed care organizations (MCOs) are promulgated and implemented by ODM only. No other state agencies impose requirements that are specific to the Medicaid managed care program, and the rules and regulations rules in Chapter 5160-58 are not duplicated elsewhere, the Ohio Revised Code 5160.34 has similar content but not duplicative.

14. **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.**

    ODM will notify the MCOPs of the final rule change via email notification and collaboratively work through readiness activities as needed. Additionally, per the MCOP provider agreement, MCOPs are required to subscribe to the appropriate distribution lists for notification of all ODM posting of draft rules for public comment and rule filings. This to be proposed change in rule will reduce patient, provider, and payer burden by streamlining prior authorization processes. ODM will ensure MCOPs are made aware of any future rule changes via established communication processes.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
    This rule impacts the MyCare Ohio plans in the State of Ohio (Aetna Better Health Ohio, Buckeye Community Health Plan, CareSource Ohio, Molina Healthcare of Ohio, and UnitedHealthcare Community Plan of Ohio).
    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
    The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

This rule requires MCOPs to report information as a condition of compliance, including the following items:

- Notifying members of any decision to reduce, suspend, terminate, or deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested;
- Maintain and submit as directed by ODM, record of all authorization requests.

MCOPs are paid a per member per month amount. ODM must pay MCOPs rates that are actuarially sound, as determined by an outside actuary in accordance with 42 CFR 438.4, 42 CFR 438.5, and CMS's Medicaid Managed Care Rate Development Guide. ODM's actuary will develop capitation rates for the MCOs and MCOPs that are "actuarially sound" for the period covered by the certification, projected capitation rates and other revenue sources provide for all reasonable, appropriate, and attainable costs. Costs include but are not limited to expected health benefits, health benefit settlement expenses, administrative expenses, the cost of capital and government mandated assessments, fees, and taxes.

All rates and actuarial methods can be found on the ODM website in Appendix E of the MyCare Ohio provider agreement. Through the administrative component of the capitation rate paid to the MCOPs by ODM, MCOPs will be compensated for the cost of the reporting and notice requirements found in this rule.

16. **Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

    This rule amendment will be proposed to align with the CMS Interoperability and Prior Authorization final rule CMS-0057-F, changing standard prior authorization timeframes from 10 days to 7 days and updating legal citations. The to be proposed change does not reduce a regulatory burden imposed on the business community.

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

    The MCOPs are aware of the federal requirements for covered services prior to seeking and signing their contracts with the State. More importantly, without the requirement of certain covered health care services, the State would be out of compliance with federal regulations.

Regulatory Flexibility

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

    The requirements of this rule must be applied uniformly, and no exception is made based on an MCOPs size.

19. **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?**

This rule does not impose any monetary fines or penalties for first-time paperwork violations for small businesses as outlined in ORC section 119.14.

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

There are no small businesses negatively impacted by this rule. The MCOPs may contact ODM directly through their assigned Contract Administrator. Additional resources can be found on the CMS Interoperability website found here Interoperability | CMS.

DRAFT - NOT FOR FILING

5160-58-03.1 MyCare Ohio plans: primary care and utilization management.

(A) A MyCare Ohio plan (MCOP) will ensure each member has a primary care provider (PCP) who will serve as an ongoing source of primary care and assist with care coordination appropriate to the member's needs.

(1) The MCOP will ensure PCPs are in compliance with the following triage requirements. Members with:

(a) Emergency care needs will be triaged and treated immediately on presentation at the PCP site;

(b) Persistent symptoms will be treated no later than the end of the following working day after their initial contact with the PCP site; and

(c) Requests for routine care will be seen within six weeks.

(2) PCP care coordination responsibilities include at a minimum the following:

(a) Assisting with coordination of the member's overall care, as appropriate for the member;

(b) Providing services which are medically necessary as described in rule 5160-1-01 of the Administrative Code;

(c) Serving as the ongoing source of primary and preventative care;

(d) Recommending referrals to specialists, as required; and

(e) Triaging members as described in paragraph (A)(1) of this rule.

(B) The MCOP will have a utilization management (UM) program with clearly defined structures and processes designed to maximize the effectiveness of the care provided to the member. The MCOP will ensure decisions rendered through the UM program are based on medical necessity.

(1) The UM program, based on written policies and procedures, will include, at a minimum:

(a) The information sources used to make determinations of medical necessity;

(b) The criteria, based on sound clinical evidence, to make UM decisions and the specific procedures for appropriately applying the criteria;

(c) A specification that written UM criteria will be made available to both contracting and non-contracting providers; and

(d) A description of how the MCOP will monitor the impact of the UM program to detect and correct potential under- and over-utilization.

(2) The MCOP's UM program will ensure and document the following:

(a) An annual review and update of the UM program.

(b) The involvement of a designated senior physician in the UM program.

(c) The use of appropriate qualified licensed health professionals to assess the clinical information used to support UM decisions.

(d) The use of board-certified consultants to assist in making medical necessity determinations, as

necessary.

(e) That UM decisions are consistent with clinical practice guidelines as specified in rule 5160-26-05.1 of the Administrative Code. The MCOP will not impose conditions on the coverage of a medically necessary medicaid-covered service unless they are supported by such clinical practice guidelines.

(f) The reason for each denial of a service, based on sound clinical evidence.

(g) That compensation by the MCOP to individuals or entities that conduct UM activities does not offer incentives to deny, limit, or discontinue medically necessary services to any member.

(h) Compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) requirements outlined in 42 CFR Part 438 Subpart K (October 1, ~~2021~~2025).

(3) The MCOP will process requests for initial and continuing authorizations of services from their providers and members. The MCOP will have written policies and procedures to process initial requests and continuing authorizations. Upon request, the MCOP's policies and procedures for initial and continuing authorizations will be made available for review by the Ohio department of medicaid (ODM). The MCOP's written policies and procedures for initial and continuing authorizations of services will also be made available to contracting and non-contracting providers upon request. The MCOP will ensure and document the following occurs when processing requests for initial and continuing authorizations of services:

(a) Consistent application of review criteria for authorization decisions.

(b) Consultation with the requesting provider, when necessary.

(c) Any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, will be made by a health care professional who has appropriate clinical expertise in treating the member's condition or disease.

(d) That a written notice will be sent to the member and the requesting provider of any decision to reduce, suspend, terminate, or deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The notice to the member has to meet the requirements of division 5101:6 and rule 5160-26-08.4 of the Administrative Code.

(e) For standard authorization decisions, the MCOP will provide notice to the provider and member as expeditiously as the member's health condition requires but no later than ~~ten~~seven calendar days following receipt of the request for service. If requested by the member, provider, or MCOP, standard authorization decisions may be extended up to fourteen additional calendar days. If requested by the MCOP, the MCOP has to submit to ODM for prior-approval, documentation as to how the extension is in the member's interest. If ODM approves the MCOP's extension request, the MCOP will give the member written notice of the reason for the decision to extend the time frame and inform the member of the right to file a grievance if he or she disagrees with that decision. The MCOP will carry out its determination as expeditiously as the member's health condition requires and no later than the date the extension expires.

(f) If a provider indicates or the MCOP determines that following the standard authorization timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain

maximum function, the MCOP will make an expedited authorization decision and provide notice of the authorization decision as expeditiously as the member's health condition requires but no later than forty-eight hours after receipt of the request for service. If requested by the member or MCOP, expedited authorization decisions may be extended up to fourteen additional calendar days. If requested by the MCOP, the MCOP has to submit to ODM for prior-approval, documentation as to how the extension is in the member's interest. If ODM approves the MCOP's extension request, the MCOP will give the member written notice of the reason for the decision to extend the timeframe and inform the member of the right to file a grievance if he or she disagrees with that decision. The MCOP will carry out its determination as expeditiously as the member's health condition requires and no later than the date the extension expires.

(g) For prior authorization of covered outpatient drugs as defined in 42 U.S.C. 1396r-8(k)(2) (as in effect ~~July~~January 1, ~~2022~~2026), the MCOP has to make a decision within the timeframes specified in 42 C.F.R. 423.568(b) (October 1, ~~2021~~2025) for standard decisions and 42 C.F.R. 423.572(a) (October 1, ~~2021~~2025) for expedited decisions. If the prior authorization request is for an emergency situation, a seventy-two hour supply of the covered outpatient drug that was prescribed must be authorized while the MCOP reviews the prior authorization request.

(h) The MCOP will maintain and submit as directed by ODM, a record of all authorization requests, including standard and expedited authorization requests and any extensions granted. The MCOP's records will 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.

(4) The MCOP may, subject to ODM approval, develop other UM programs.