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):

Ohio Resilience Through Integrated Systems And Excellence (OhioRISE) UM 5160-59-03.1

Rule Number(s): 5160-59-03.1

Date of Submission for CSI Review: 6/18/2025

Public Comment Period End Date: 6/25/2025

Rule Type/Number of Rules:

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Rescinded/____ rules (FYR?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

   OAC rule 5160-59-03.1, "OhioRISE: utilization management," describes the utilization management program the OhioRISE plan must implement and follow to maximize the effectiveness of the care

   provided to members. This rule will be proposed for amendment to align with the CMS Interoperability and Prior Authorization Final Rule -CMS-0057-F, changing standard prior authorization timelines from 10 days to 7 days.

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 Section 5167.02 authorizes ODM to adopt the rule.

   • Revised Sections 5162.03, 5167.02, 5167.10, 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?**

If yes, please briefly explain the source and substance of the federal requirement.

Yes. 42 CFR Part 438 imposes comprehensive requirements on the state regarding Medicaid managed care programs, however the proposed changes to the rule are related to changes implemented by the 2024 Center for Medicare and Medicaid Services (CMS) Interoperability and Prior Authorization final rule (CMS-0057-F).

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.**

The 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. There is nothing in this rule that goes beyond federal regulations.

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 5160-59-03.1 is necessary for various reasons. Federal regulations require state Medicaid agencies to ensure Prepaid Inpatient Health Plan (PIHP), compliance with federal standards, therefore this rule ensures ODM compliance with federal regulations governing Medicaid managed care programs and the OhioRISE program. The public purpose of this regulation is to:

- Ensure the provision of medically necessary services, emergency services, and post stabilization services to promote the best outcomes for individuals enrolled in the Medicaid managed care program by requiring the OhioRISE plan to follow established guidelines and to ensure providers are paid appropriately for services delivered.
- Ensure that information maintained by the OhioRISE plan is readily available to the State and, if requested, by the Centers for Medicare and Medicaid Services (CMS).
- Ensure oversight of the OhioRISE program and the OhioRISE plan.

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

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

ODM has consistently involved interested parties in the development and operational activities pertaining to managed care and behavioral health. The OhioRISE Advisory Council and its workgroups were developed to obtain critical stakeholder feedback and expert clinical advice for OhioRISE's services and operations. Since the Advisory Council's creation in January 2021, ODM has and currently holds monthly meetings with stakeholders to discuss general program principles and system of care philosophy, federal authorities, and service concepts. The new and enhanced state plan, 1915(b), and 1915(c) waiver behavioral health services, service specifications and regulatory concepts, draft rule language, and service rate setting were also discussed with these groups.

Stakeholders include, but are not limited to:

- The ARC of Ohio
- Ohio Association of Health Plans
- Ohio Association of County Boards Serving People with Developmental Disabilities
- Ohio Family & Children First Councils
- County Public Children Services Agencies
- The Center for Community Solutions
- The Ohio Council for Behavioral Health & Family Services Providers
- Ohio Center for Autism and Low Incidence
- Ohio Children's Alliance
- New Directions and Crossroads Health
- Mercy Health Foundations Behavioral Health Services
- Centers for Innovative Practices, Case Western Reserve University
- Ohio Association of County Behavioral Health Authorities

ODM works collaboratively with other state and local agencies such as Ohio Department of Children and Youth (DCY), County Departments of Job and Family Services (CDJFS), Mental Health Addiction Services (MHAS), Department of Developmental Disabilities (DODD), Department of Youth Services (DYS) and Ohio Department of Education (ODE), Ohio Department of Health (ODH) to keep the focus of the program on the individual with the goal of providing a seamless experience for the members and providers.

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

The planned rule change was sent to OhioRISE stakeholders for feedback and was available for comment from December 5, 2024 through December 11, 2024. There were no comments received during this time period.

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?

Ohio Medicaid claims data were the main source of information used to guide the policy and budget models that undergird this rule. This data was used to determine the fiscal impact on ODM.

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.***

No alternative regulations were considered. ODM edited the rule for revision due to a new CMS utilization management requirement that required a need for a rule change.

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

The ODM OhioRISE policy staff reviewed the rule with other ODM policy areas to ensure no duplication with other ORC and OAC rules. Incorporation by reference is used in the rule to prevent duplication of existing Ohio regulations.

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 OhioRISE Advisory Council, the OhioRISE plan and other MCOs when the OhioRISE OAC rule has been final filed along with the effective date via email notification. Additionally, per the OhioRISE Plan Provider Agreement, the OhioRISE plan and other MCOs are required to subscribe to the relative distribution lists for notification of OAC rules. ODM will ensure the OhioRISE plan is made aware of any future OAC 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 OAC rule will impact the OhioRISE plan (Aetna Better Health of Ohio) and behavioral health providers that render the services addressed in OAC this rule and provided to Medicaid recipients enrolled in the OhioRISE program that are 21 years of age and younger.

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.

OAC rule 5160-59-03.1 OhioRISE: utilization management requires the OhioRISE plan to share specific information with ODM and certain providers, to maintain a log, and to implement written policies and procedures. The cost would be the staff time to maintain and implement written policies and procedures.

16. Are there any proposed changes to the rules that will reduce 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).***

The 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 regulatory intent of ensuring standard authorizations is determined within the required timeframe justifies the adverse impact to the regulated business community.

Regulatory Flexibility

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

No, to ensure uniform and consistent treatment of Medicaid providers, ODM is not able to make exemptions or provide alternative means for compliance for small businesses.

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 regulation does not apply to this rule package because it does not impose any fine or penalty for a paperwork violation.

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

All Medicaid providers in need of technical assistance can contact the Medicaid Provider Assistance telephone line at 1-800-686-1516. Behavioral health providers impacted by the proposed rules have a unique email address available to them for assistance, OhioRISE@medicaid.ohio.gov. They can also contact the OhioRISE plan, Aetna, through their telephone line at 1-833-711-0773, or by e-mail at OHRise-Network@aetna.com. Providers also have access to detailed information by visiting the dedicated OhioRISE internet site: https://managedcare.medicaid.ohio.gov/wps/portal/gov/manc/managed-care/ohiorise/.

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5160-59-03.1 OhioRISE: utilization management.

(A) The Ohio resilience through integrated systems and excellence (OhioRISE) plan 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.

(1) The OhioRISE plan has to ensure decisions rendered through the UM program are based on medical necessity.

(2) The UM program has to be based on written policies and procedures that 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 OhioRISE plan will monitor the impact of the UM program to detect and correct potential under-and over-utilization.

(3) The OhioRISE plan's UM program has to 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) Review and consideration of the child and family centered care plan;

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

(f) That UM decisions are consistent with clinical practice guidelines as specified in rule 5160-26-05.1 of the Administrative Code. The OhioRISE plan may not impose conditions around the coverage of a medically necessary-covered service unless they are supported by such clinical practice guidelines;

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

(h) That compensation by the OhioRISE plan to individuals or entities that conduct UM activities does not offer incentives to deny, limit, or discontinue medically necessary services to any member; and

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

(B) The OhioRISE plan has to process requests for initial and continuing authorizations of services from their providers and members.

(1) The OhioRISE plan has to have written policies and procedures to process requests. Upon request, the

OhioRISE plan's policies and procedures have to be made available for review by the Ohio department of medicaid (ODM).

(2) The OhioRISE plan's written policies and procedures for initial and continuing authorization of services have to also be made available to contracting and non-contracting providers upon request.

(C) The OhioRISE plan has to ensure and document the following occurs when processing requests for initial and continuing authorizations of services:

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

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

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

(4) 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.

(5) For standard authorization decisions, the OhioRISE plan has to 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 the OhioRISE plan, standard authorization decisions may be extended up to fourteen additional calendar days. If requested by the OhioRISE plan, the OhioRISE plan has to submit to ODM for prior-approval, documentation as to how the extension is in the member's interest. If ODM approves the OhioRISE plan's extension request, the OhioRISE plan has to 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 the member disagrees with that decision. The OhioRISE plan has to carry out its determination as expeditiously as the member's health condition requires and no later than the date the extension expires.

(6) If a provider indicates or the OhioRISE plan 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 OhioRISE plan has to 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 OhioRISE plan, expedited authorization decisions may be extended up to fourteen additional calendar days. If requested by the OhioRISE plan, the OhioRISE plan has to submit to ODM for prior-approval, documentation as to how the extension is in the member's interest. If ODM approves the OhioRISE plan's extension request, the OhioRISE plan has to 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 OhioRISE plan has to carry out its determination as expeditiously as the member's health condition requires and no later than the date the extension expires.

(D) The OhioRISE plan has to maintain and submit as directed by ODM a record of all authorization requests, including standard and expedited authorization requests and any extensions granted. The OhioRISE plan's

records have to 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.