Ohio | Common Sense Initiative

**Mike DeWine**, Governor
**Jon Husted**, Lt. Governor

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# Business Impact Analysis

**Agency, Board, or Commission Name:** __Ohio Department of Medicaid_____

**Rule Contact Name and Contact Information:**

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

___Prior Authorization_____

**Rule Number(s):** ___5160-1-31 (Rescind and New)_____

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**Date of Submission for CSI Review:** _____8/4/2021__

**Public Comment Period End Date:** _____8/11/2021__

**Rule Type/Number of Rules:**

**New/_1_ rules** **No Change/____ rules (FYR? ___)**

**Amended/____ rules (FYR? ___)** **Rescinded/__1_ rules (FYR? _Yes_)**

**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.**

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## 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.***

   **Rule 5160-1-31**, entitled "Prior authorization [except for service provided through medicaid contracting managed care plans (MCPs)]", has been reviewed as part of the five-year review process and is being proposed for rescission as more than fifty percent of the language has been amended. This rule sets forth the general policy regarding prior authorization (PA) for Medicaid covered services that require it. The rule informs providers how to submit PA requests and explains that paper requests will not be processed. The rule describes notifications when a PA is approved or denied. The rule also describes the exception to the PA requirement for emergency services and the recipient's state hearing rights if the PA request is denied.

   New rule 5160-1-31, entitled "Prior authorization", is being proposed for adoption to update policy and outdated information regarding prior authorization (PA) and to remove unnecessary language. It replaces the existing rule which is being proposed for rescission. This rule now governs managed care entities (MCE) PA requirements, and corresponding language was added throughout. This rule updates references to the Ohio Administrative

Code and Ohio Revised Code, and changes references from Ohio Department of Job and Family Services (ODJFS) to Ohio Department of Medicaid (ODM), reflecting the change in oversight of the Medicaid program. The rule clarifies that in cases of emergency situations for prescribed drugs requiring prior authorization, prior authorization is governed by Ohio Administrative Code rule 5160-9-03. The rule incorporates the provisions from Ohio Revised Code (ORC) 5160.34. Sections of the rule concerning PA procedures such as the use of the assigned PA number for submitting claims and language to provide a written denial and hearing rights have been removed. This rule includes language directing providers to the ODM main website to locate PA submission guidance in accordance with ORC 5160.34.

The rule also includes a new ODM process by which a provider who has received a denied PA request may have that denial reviewed by ODM or its designee. Information that must be submitted in the reconsideration is stated as well as relevant time frames. For denials made by a MCE or transplant consortium, the rule explains the organization's process for reconsideration must be followed by the provider. The rule also excludes certain inpatient and outpatient hospital services and instead refers to a separate OAC rule to govern the specific PA requirements for these services.

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.**

   Section 5164.02 authorizes the rule and Sections 5160.34 and 5164.02 of the Ohio Revised Code 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.***

   No.

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

   Neither the new rule, which is proposed for adoption, nor the rule proposed for rescission exceed federal requirements.

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)?**

A PA rule is necessary to support Medicaid program integrity and patient safety by requiring that Medicaid providers provide evidence that services subject to PA are medically necessary and therefore should be rendered and reimbursed by Medicaid. Including this information in a regulation ensures consistent application of the PA requirements.

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

   The new rule is determined successful by providers obtaining prior approval for medically necessary services and receiving reimbursement.

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.***

   The proposed rules are not being submitted pursuant to any of the listed ORC sections.

## 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 utilized its Clearance process to inform stakeholders of the intended changes in rule 5160-1-31 and solicit feedback concerning the proposed changes.

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

    The Legal Aid Society of Columbus provided feedback regarding the rule, and the suggested changes regarding provider notification of a denied PA were later adopted into the rule. The suggested changes not incorporated in the rule were contrary to LSC rule drafting guidance.

    The Legal Aid Society of Greater Cincinnati provided feedback regarding the rule, and suggested change was not incorporated as it was contrary to ORC 106.03 rulemaking requirements.

**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 Medicaid policy.

**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?**

No other alternative regulations were considered. ODM considers administrative rules the most appropriate method of regulating PAs.

**13. 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*****.**

ODM did not specifically consider a performance-based regulation because the regulations stated in the new rule do not lend themselves to being performance-based.

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

The new rule was thoroughly reviewed by ODM staff to ensure it does not duplicate an existing Ohio regulation.

**15. 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.**

To implement these regulations, ODM will provide a notice of changes to providers and other interested parties. ODM's designee for PA request adjudication has revised their procedures to accommodate the provider reconsideration process. ODM will post this information on the agency website to ensure thorough communication with the regulated community.

## Adverse Impact to Business

**16. 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; and**

The impacted business community includes any individual or organization who is a current Medicaid provider and submits claims to Medicaid for reimbursement.

**b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**

The adverse impact of the new and rescinded rules would be the cost of staff time to submit PA requests, the report of information to support the request of PA, the need for PA to obtain payment for certain claims, the sanction related to the denial of payment for claims if a PA is denied, and the loss of revenue on any claims not paid as a result of failure to obtain PA. Also, PA requests submitted via paper are not processed. The adverse impact specific to the new rule only would be the staff time to submit the request for reconsideration of a denied PA along with providing any further documentation to support the reconsideration request.

**c. Quantify the expected adverse impact from the regulation.**
***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.***

The adverse impact of the rescinded and new rules to providers would be the staff time necessary to submit the PA request, or the request for reconsideration, in the case of the new rule, and any additional documentation. The timeframe to gather the documentation required to justify the medical necessity of the PA request or reconsideration cannot be easily quantified given the high variability between different procedures and the unique circumstances of each patient. If a paper PA request is submitted, there would be additional staff time to resubmit the request electronically. The total adverse impact in staff time would be the time multiplied by the staff's hourly wage.

The potential sanction and lost revenue adverse impacts for the rescinded and new rules would be if a PA request or reconsideration was denied which would result in the denial of any claims requiring PA for payment. The adverse impact of the sanction and any loss of revenue is difficult to calculate due to the high variability in the reimbursement for

different procedure types and the volume of claims generated by a particular provider requiring PA.

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

The adverse impact of these rules is justified by the necessity to ensure program integrity and patient safety by requiring that Medicaid providers provide evidence that services subject to PA are medically necessary and therefore should be rendered and reimbursed by Medicaid.

## Regulatory Flexibility

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

There are no alternate means of compliance because this regulation applies to all provider types enrolled in Medicaid. No exception can be made on the basis of the provider group or agency 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?**

These rules do not impose a fine or penalty for first-time paperwork violations.

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

The Ohio Department of Medicaid website, www.medicaid.ohio.gov, has instructions listing PA requirements and relevant contact information based on service type.

TO BE RESCINDED

5160-1-31 **Prior authorization [except for services provided through medicaid contracting managed care plans (MCPs)].**

(A) Reimbursement for some items and/or services covered under the medicaid program is available only upon obtaining prior authorization from the Ohio department of job and family services (ODJFS). Prior authorization must be obtained from ODJFS or its designee by the provider before the services are rendered or the items delivered, unless the services meet the provisions in paragraph (F) of this rule. .

(B) Services, supplies or prescription drugs that require prior authorization by the department are identified in Chapters 5101:3-2 to 5101:3-56 of the Administrative Code.

(C) All prior authorization requests must be submitted through the medicaid information technology system (MITS) web portal. Paper prior authorization requests will be returned to the provider unprocessed.

(D) When the prior authorization request has been processed by ODJFS or its designee, the provider will receive notification indicating the decision for each service, supply or prescription drug. Only those services, supplies or prescription drugs approved in the prior authorization notice will be reimbursed.

(E) When a request for prior authorization has been approved, the notification will include a prior authorization (PA) number. In order for the provider to be reimbursed, the provider must use the assigned PA number when submitting the claim for payment.

(F) In situations where the provider considers a delay in providing services, supplies or prescription drugs requiring prior authorization to be detrimental to the health of the consumer, the services, supplies or prescription drugs may be rendered or delivered and approval for reimbursement sought after the fact.

(G) When a request for prior authorization is denied, ODJFS or its designee will issue a notice of medical determination and a right to a state hearing to the consumer. A copy of this denial notice will be sent to the county department of job and family services to be filed in the consumer's case record. Providers will also be notified of the denial.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

| | |
|---|---|
| Promulgated Under: | 119.03 |
| Statutory Authority: | 5164.02 |
| Rule Amplifies: | Ohio Revised Code 5160.34 |
| Prior Effective Dates: | 4/7/77, 12/21/77, 12/30/77, 7/1/80, 10/1/87, 7/1/91 (Emer), 9/30/91, 5/30/02, 8/11/05 |

5160-1-31 **Prior authorization.**

(A) Reimbursement for certain items or services covered under the medicaid program is dependent on obtaining prior authorization from the Ohio department of medicaid (ODM), its designee, or a medicaid managed care entity (MCE). Prior authorization requests have to be approved by ODM, its designee, or MCE before the services are rendered or the items are delivered unless the services or items meet the provisions stated in section 5160.34 of the Revised Code or paragraph (D) of this rule.

(B) Except as authorized under section 5160.34 of the Revised Code, prior authorization requests submitted via paper cannot be processed. All other prior authorization requests should be submitted pursuant to the instructions located at www.medicaid.ohio.gov.

(C) For services or items requiring prior authorization, only those approved in the prior authorization determination will be eligible for reimbursement.

(D) In situations where the provider considers a delay in providing services or an item requiring prior authorization to be detrimental to the health of the medicaid recipient, the services or item may be rendered or delivered and approval for reimbursement sought after the fact. In cases of emergency situations for prescribed drugs requiring prior authorization, the prescribed drug may be rendered without prior authorization in accordance with rule 5160-9-03 of the Administrative Code.

(E) A medicaid provider may request a reconsideration of an adverse prior authorization determination in accordance with section 5160.34 of the Revised Code. A reconsideration of an adverse prior authorization determination rendered by an MCE or transplant consortium should be submitted and addressed in accordance with their respective processes for reconsideration. A reconsideration of an adverse prior authorization determination rendered by ODM or its designee should be submitted and addressed in the following manner:

(1) The request for reconsideration has to be received by ODM or its designee within sixty calendar days of the notification to the provider of an adverse determination. A valid request for reconsideration should be submitted pursuant to the instructions located at www.medicaid.ohio.gov and include the following:

(a) Medicaid recipient's name and medicaid number;

(b) Name of requested service or item and billing code;

(c) Date of service or item request;

(d) Clinical documentation supporting medical necessity for the service or item;

(e) A reference to any relevant federal or state law or regulation, if applicable;

(f) An explanation outlining the reason for reconsideration, including supportive information not previously submitted as necessary; and

(g) If applicable, an indication of whether the service or item qualifies as "urgent care services" as defined in section 5160.34 of the Revised Code.

(2) ODM or its designee will make a standard reconsideration determination within ten calendar days of receipt. If an expedited review is requested because the service or item qualifies as urgent care services, the reconsideration determination will be made no later than forty-eight hours after receipt.

(3) The review of the reconsideration will be conducted by a clinical peer appointed or contracted by ODM or its designee.

(4) The provider reconsideration process afforded under this rule does not interfere with the medicaid recipient's right to appeal in accordance with division 5101:6 of the Administrative Code.

(F) The provisions stated in this rule do not apply to prior authorization requests for inpatient or outpatient hospital services, which are subject to the prior authorization provisions in rule 5160-2-40 of the Administrative Code.