

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):		
Provider Disclosure Update		
Rule Number(s): 5160-1-17.3 (Reso	eind); 5160-1-17.3 (New)	
Date of Submission for CSI Review: <u>12/09/2022</u>		
Public Comment Period End Date: 12/16/2022		
Rule Type/Number of Rules:		
New/ <u>1</u> rules	No Change/ rules (FYR?)	
Amended/ rules (FYR?)	Rescinded/ <u>1</u> rules (FYR? <u>Yes</u>)	

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 5160-1-17.3, entitled "Provider disclosure requirements" sets forth the provider disclosure requirements to qualify for an Ohio Medicaid provider agreement. The rule is being proposed for rescission as more than fifty percent of the rule requires amendment. The rule defines the entities and individuals subject to the disclosure requirements. It states the information that must be disclosed to the department and the timeframes in which this information is to be provided. The rule states that failure to disclose the information as required by the rule may result in denial, suspension or termination of the Ohio Medicaid provider agreement.

Rule 5160-1-17.3, entitled "Provider disclosure requirements" is a new proposed rule to replace the proposed rescinded rule with the same number and name. The new rule sets forth the provider disclosure requirements to qualify for an Ohio Medicaid provider agreement.

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The new rule cites the federal regulations requiring the provider disclosures. The provider affiliation disclosure requirements required by 42. C.F.R. 455.107 were added to comply with new federal regulations. The rule was reorganized and reworded for clarity and to adhere with Legislative Service Commission rule writing standards.

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 amplifies the 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. The rule sets forth the provider disclosure requirements found in 42 CFR Section 455 Subpart B. The rule is being adopted to incorporate the new provider affiliation disclosure requirements found in 42 CFR 455.107.

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.

None of the rules in this rule package 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)?

The federal requirement is intended to enhance program integrity in the Medicaid program by enforcing proper screening for providers that do business with, and receive public monies from, the Medicaid program.

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

The success of this regulation will be determined by the number of providers who are properly screened in accordance with federal and state requirements.

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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.

A draft of proposed new rule 5160-1-17.3 was posted on June 15, 2022 for all stakeholders to review for seven calendar days on the ODM rules webpage and notification was sent to the ODM stakeholder list to seek public comment.

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

ODM reached out to stakeholders with these proposed changes and no concerns were expressed.

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?

Scientific data were not applicable to the development of these rules. These rules set forth the federal regulatory requirements for provider disclosure in order to participate in the Medicaid program.

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.

ODM did not consider regulatory alternatives because these provisions directly implement federal requirements. The federal regulations provided ODM with different options to

implement the provider disclosure requirements. Codifying this decision in OAC was necessary to properly enforce this requirement with Ohio Medicaid providers.

ODM did not specifically consider a performance-based regulation because the regulations implement federal requirements that are not performance-based.

13. 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.

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.

The policies set forth in these rules will be incorporated into the Ohio Medicaid Enterprise System as of the effective date of the applicable rule. These regulations will therefore be automatically and consistently applied by the Department's automated Provider Network Management (PNM) Module whenever a provider attempts to enroll, re-enroll, or revalidate in the Medicaid program. Managed Care Entities and fiscal agents will be contractually required to comply with disclosure policies.

Adverse Impact to Business

- 15. 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 Changes to disclosure requirements affect all current and potential Medicaid providers, managed care entities, and fiscal agents.
 - b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,).

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 impacts in both the new and rescinded rules are the employee time to report information to ODM and the sanction and resulting decrease in revenue if an existing

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provider agreement is suspended or terminated for failure to disclose required information.

The costs of the adverse impacts are difficult to quantify but are similar under the rescinded and new rules. The employee time to report the required information would be determined by the amount of information that has to be provided and the time it takes to gather and provide it. The cost would be the employee time multiplied by the employee's rate of pay. The cost may be slightly higher under the new rule if a provider must report the additional information regarding affiliations with any other current or former Medicare or Medicaid provider that has a disclosable event who is not enrolled in Medicare. ODM has no ability to accurately quantify this cost due to the high variance in potential affiliations from effected providers.

The second cost would be the suspension or termination of a Medicaid provider agreement for failure to disclose required information and the loss of any revenue from Medicaid business. This cost would be mitigated by the requirement for CMS to review and approve any such determination which should result in a very limited number of providers being affected. ODM is not able to quantify the cost of this impact since different organizations have vastly different volumes of Medicaid business as well as different reimbursement rates depending on the covered service provided.

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).

The proposed changes to this rule do not reduce the regulatory burden on the impacted business community.

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

Rule 5160-1-17.3 (Rescind)

Not applicable. This rule is being proposed for recission.

Rule 5160-1-17.3 (New)

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These regulations are federally mandated screening requirements that must be met for ODM to qualify for federal funding.

Regulatory Flexibility

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

These regulations do not provide any exemptions or alternative means of compliance for small businesses because the federal regulations necessitating these administrative rules do not allow for any exemptions or alternatives 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?

These rules impose no fines or civil penalties for paperwork violations.

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

The ODM website, <u>www.medicaid.ohio.gov</u>, has several resources available for providers related to enrollment requirements.

ODM's Bureau of Provider Services also renders technical assistance to providers through its provider hotline, (800) 686-1516.

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TO BE RESCINDED

5160-1-17.3 **Provider disclosure requirements.**

(A) Definitions:

- (1) "Disclosing provider" means a medicaid provider, managed care entity, or fiscal agent under contract with the department of medicaid (ODM).
- (2) "Managing employee" means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operation of an institution, organization or agency.
- (3) "Agent" means any person who has been delegated the authority to obligate or act on behalf of a provider.
- (4) "Person with an ownership or control interest" means a person or corporation that meets any of the following:
 - (a) Has an ownership interest totaling five per cent or more in the disclosing provider;
 - (b) Has an indirect ownership interest equal to five per cent or more in the disclosing provider;
 - (c) Has a combination of direct and indirect ownership interest equal to five per cent or more in the disclosing provider;
 - (d) Owns an interest of five per cent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least five per cent of the value of the property or assets of the disclosing provider;
 - (e) Is an officer or director of the disclosing provider that is organized as a corporation or non-profit; or
 - (f) Is a partner in the disclosing provider that is organized as a partnership or limited liability company.

- (5) "Significant business transaction" means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of twenty-five thousand dollars and five per cent of a provider's total operating expenses.
- (6) "Indirect ownership interest" means an ownership interest in an entity that has direct or indirect ownership in the disclosing provider.
- (B) Disclosing providers shall disclose the following information to the department:
 - (1) The name and address of any person (individual or corporation) with an ownership or control interest in the disclosing provider.
 - (a) In the case of an individual, date of birth and social security number.
 - (b) In the case of a corporation, other tax identification number with an ownership or control interest in the disclosing provider or in any subcontractor in which the disclosing provider has a five percent or more interest.
 - (2) Whether the person (individual or corporation) with an ownership or control interest in the disclosing provider is related to another person with ownership or control interest in the disclosing provider as a spouse, parent, child, or sibling.
 - (3) Whether the person (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing provider has a five percent or more interest is related to another person with ownership or control interest in the disclosing provider as a spouse, parent, child, or sibling.
 - (4) The name of any disclosing provider in which an owner of the disclosing provider has an ownership or control interest.
 - (5) The name, address, date of birth, and social security number of any managing employee of the disclosing provider.
 - (6) The identity of any person who has ownership or control interest in the provider, or is an agent or managing employee of the provider and has been convicted of a criminal offense related to that person's involvement in any program under medicare, medicaid, or the title XX services program since the inception of those programs.
 - (7) The ownership of any subcontractor with whom the provider has had business transactions totaling more than twenty-five thousand dollars during the twelvemonth period ending on the date the disclosure is due.

- (8) Any significant business transaction between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the five-year period ending on the date the disclosure is due.
- (C) Disclosures shall be due at any of the following times:
 - (1) Prior to entering into a medicaid provider agreement or contract, during a procurement process, or as part of a request for proposal.
 - (2) Prior to revalidating a medicaid provider agreement, or the renewal or extension of the contract.
 - (3) Within thirty-five days after any change in ownership.
 - (4) At any time within thirty-five days upon written request from the department.
- (D) Failure by the disclosing provider to disclose information in accordance with this rule may result in the denial, suspension, or termination of the medicaid provider agreement or contract.

Replaces:	5160-1-17.3
Effective:	
Five Year Review (FYR) Dates:	
Certification	
Date	

Promulgated Under: 119.03 Statutory Authority: 5164.02 Rule Amplifies: 5164.02

Prior Effective Dates: 04/07/1977, 12/30/1977, 01/01/1979, 03/23/1979,

08/31/1979, 11/01/1979, 07/01/1980, 07/07/1980, 10/01/1987, 05/30/2002, 08/11/2005, 05/23/2007,

07/09/2015

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5160-1-17.3 Provider disclosure requirements.

- (A) For the purposes of this rule, the following definitions apply:
 - (1) "Affiliation" has the same meaning as in 42 C.F.R. 455 101 (as in effect on October 1, 2022).
 - (2) "Agent" has the same meaning as in 42 C.F.R. 455.101 (as in effect on October 1, 2022).
 - (3) "Disclosable event" has the same meaning as in 42 C.F.R. 455.101 (as in effect on October 1, 2022).
 - (4) "Disclosing provider" means a medicaid provider, managed care entity, or fiscal agent under contract with the department of medicaid (department) in accordance with 42 C.F.R. 455 101 (as in effect on October 1, 2022).
 - (5) "Indirect ownership interest" means an ownership interest in an entity that has direct or indirect ownership in the disclosing provider.
 - (6) "Managing employee" has the same meaning as in 42 C.F.R. 455.101 (as in effect on October 1, 2022).
 - (7) "Person with an ownership or control interest" means a person or corporation that meets any of the following:
 - (a) Has an ownership interest totaling five per cent or more in the disclosing provider;
 - (b) Has an indirect ownership interest equal to five per cent or more in the disclosing provider;
 - (c) Has a combination of direct and indirect ownership interest equal to five per cent or more in the disclosing provider;
 - (d) Owns an interest of five per cent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least five per cent of the value of the property or assets of the disclosing provider;
 - (e) Is an officer or director of the disclosing provider that is organized as a corporation or non-profit; or
 - (f) Is a partner in the disclosing provider that is organized as a partnership or limited liability company.
 - (8) "Significant business transaction" has the same meaning as in 42 C.F.R. 455.101 (as in effect on October 1, 2022).
- (B) Disclosing providers will disclose the following information to the department in accordance with 42 C.F.R. 455.104 through 42 C.F.R. 455.106 (as in effect on October 1, 2022):
 - (1) The name and address of any person (individual or corporation) with an ownership or control interest in the disclosing provider.
 - (a) In the case of an individual, date of birth and social security number.
 - (b) In the case of a corporation, other tax identification number with an ownership or control interest in the disclosing provider or in any subcontractor in which the disclosing provider has a five percent or more interest.
 - (2) Whether the person (individual or corporation) with an ownership or control interest in the disclosing

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- provider is related to another person with ownership or control interest in the disclosing provider as a spouse, parent, child or sibling.
- (3) Whether the person (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing provider has a five percent or more interest is related to another person with ownership or control interest in the disclosing provider as a spouse, parent, child, or sibling.
- (4) The name of any disclosing provider in which an owner of the disclosing provider has an ownership or control interest.
- (5) The name, address, date of birth, and social security number of any managing employee of the disclosing provider.
- (6) The identity of any person who has ownership or control interest in the disclosing provider or is an agent or managing employee of the disclosing provider, and has been convicted of a criminal offense related to that person's involvement in any program under medicare, medicaid or the title XX services program since the inception of those programs.
- (7) The ownership of any subcontractor with whom the disclosing provider has had business transactions totaling more than twenty-five thousand dollars during the twelve-month period ending on the date the disclosure is due.
- (8) Any significant business transaction between the disclosing provider and any wholly owned supplier, or between the disclosing provider and any subcontractor, during the five-year period ending on the date the disclosure is due.
- (C) Disclosing providers, prior to initial enrollment or revalidation with the Ohio department of medicaid (department), who are not enrolled in medicare, will at the request of the department disclose when a managing employee, within the past five years, has an affiliation with a currently or formerly enrolled medicare, medicaid or child health insurance program (CHIP) provider or supplier that has had a disclosable event in accordance with 42 C.F.R. 455.107 (as in effect on October 1, 2022).
 - (1) Applicable disclosing providers will disclose the following information about each affiliation:
 - (a) General identifying information including:
 - (i) Legal name of the provider as reported to either the internal revenue service (IRS) or social security administration (SSA);
 - (ii) Legal name of any managing employees as reported to either the IRS or SSA;
 - (iii) Tax identification number (TIN); and
 - (iv) National provider identifier (NPI);
 - (b) Length of the relationship;
 - (c) Type of affiliation;
 - (d) Degree or extent of affiliation; and
 - (e) If the affiliation has ended, the reason for the termination.

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- (2) The department, in consultation with the center for medicare and medicaid services (CMS), will decide, utilizing the factors found in 42 C.F.R 455.107 (as in effect on October 1, 2022), whether the affiliation poses an undue risk of fraud, waste and abuse.
 - (a) If the department determines the provider's affiliation poses an undue risk, the provider's application will be denied or if enrolled, will result in the termination of the provider agreement.
 - (b) If enrollment is denied or the provider agreement terminated as a result of the department determining the provider's affiliation poses an undue risk of fraud, waste, and abuse, the provider may request a hearing pursuant to Chapter 119. of the Revised Code.
- (D) Disclosures will be due at any of the following times in accordance with 42 C.F.R 455.104 (as in effect on October 1, 2022):
 - (1) Prior to entering into a medicaid provider agreement or contract, during a procurement process or as part of a request for proposal.
 - (2) Prior to revalidating a medicaid provider agreement, or the renewal or extension of the contract.
 - (3) Within thirty-five days of any change in ownership the occurrence.
 - (4) At any time within thirty-five days upon written request from the department.
- (E) Failure by the disclosing provider to disclose information in accordance with this rule may result in the denial, suspension or termination of the medicaid provider agreement or contract.