



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:

Lactation Consulting Services

Rule Number(s): OAC 5160-8-42 rescind/new

Date of Submission for CSI Review: 6/13/2024

Public Comment Period End Date: 6/20/2024

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded 1 rules (FYR?)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.

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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.**

The Ohio Department of Medicaid (ODM) is proposing to rescind existing rule 5160-8-42 because more than 50% requires amending. This rule will be replaced with a new rule of the same title, number, and content. This rule concerns coverage and payment of lactation consulting 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.**

The Ohio Department of Medicaid (ODM) is promulgating these rules under section 5164.02 of the Ohio Revised Code.

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?**

This regulation does not implement a federal requirement and is not being proposed to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal 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.**

N/A

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)?**

This rule involves the coverage of and payment for lactation consulting services. ODM is required to adopt such rules under R.C. 5164.02. The new proposed rule will expand the practitioner types eligible to render lactation consulting services and increase access for Medicaid recipients.

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

The success of these rules will be measured by the extent to which providers can submit claims and receive correct payment.

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 following associations were sent the draft rule for review and feedback via email on 9/8/2023.

- Ohio Pharmacist Association
- Ohio Dental Association
- Ohio Association of Community Health Centers
- Ohio Association of Advanced Practices Nurses
- Ohio State Medical Association
- Ohio Physical Therapy Association
- Ohio Occupational Therapy Association
- Medicaid Managed Care Organizations (MCO)s

Based on comments from the Ohio State Medical Association and Ohio Association of Advanced Practice Nurses, terminology throughout the rule were updated based on industry standards.

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

Any changes and needed modifications that came to light during discussion were accepted by ODM and incorporated into the new rule.

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?

The use of scientific data does not apply to the development of these rules.

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 is required to adopt rules to establish coverage of and payment for Medicaid services.

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

The rules were reviewed by ODM policy, legislative, and legal staff to ensure no duplication with 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.

ODM will implement this regulation as it does other rules through provider guidance, and training opportunities.

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

- 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.

- a. The changes to this rule will affect Medicaid providers of lactation consulting services.

- b. The adverse impact in the rule is that it requires a license to engage in business as "Lactation consultant" is an individual who has completed a course of study coded 51.0815 in the "Classification of Instructional Programs" developed by the United States department of education's national center for education statistics (NCES). Services provided by a lactation consultant are delineated in the definition of the code. The CIP is available at <https://nces.ed.gov/ipeds/cipcode/>. "Certified lactation consultant," for purposes of this rule, is an individual who holds current certification as an "International Board Certified Lactation Consultant (IBCLC)" credential the fee for obtaining the IBCLC credential is approximately \$660 for initial candidates and \$470 for recertification. Information was obtained from the IBCLC commission: <https://ibclc-commission.org/ibclc-information/fee-guide/>

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*).

No.

17. 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*).

No.

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

IBCLCs may work in a variety of settings, providing care in home, hospitals, birth centers, and via virtual visits. IBCLCs can also assist with common lactation challenges, such as low milk supply, breastfeeding pain, and conditions like mastitis and plugged ducts.

ODM determined that the regulatory intent justifies the adverse impact as by having the IBCLC it expands access to these services for individuals on Medicaid and providing reimbursement to the provider.

Regulatory Flexibility

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

Medicaid rules outline actions all providers must take to receive Medicaid payment. No exception is made based on the size of an entity.

20. 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 sanctions on providers.

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

The Ohio Department of Medicaid website, www.medicaid.ohio.gov, has several resources available for providers related to provider support. ODM's Bureau of Provider Services also renders technical assistance to providers through its provider hotline, (800) 686-1516.