



## Common Sense Initiative

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

**Sean McCullough**, Director

### Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid (ODM)

Rule Contact Name and Contact Information:

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

Lactation Consulting Services

Rule Number(s): 5160-8-42

For information purposes only: 5160-10-25

Date of Submission for CSI Review: 8/26/2021

Public Comment Period End Date: 9/2/2021

Rule Type/Number of Rules:

New/ 1 rules

No Change/      rules (FYR?     )

Amended/ 1 rules (FYR? N)

Rescinded/      rules (FYR?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.

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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.**

Rule 5160-8-42 will outline coverage for lactation consulting services when provided by physicians, physician assistants, and advanced practice nurses. This rule will also establish coverage for registered nurses who hold a current International Board of Certified Lactation Consultants (IBCLC) credential. This rule includes coverage for individual lactation counseling services when provided in a professional setting.

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.**

5160-8-42: ORC 5164.02

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.*

The proposed rule is not necessitated by federal law; changes are being made to update Medicaid policy and improve administration of the Medicaid program.

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

New rule addresses appropriate certification a registered nurse should possess in order to provide lactation counseling services. ODM needs to ensure a registered nurse is appropriately certified prior to providing lactation counseling services.

- 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 will permit registered nurses who are IBCLC certified to render lactation consulting services for which they can receive Medicaid reimbursement. Medicaid coverage and reimbursement policies for these services are stated in the rule. This is being put into rule for enforcement and program integrity purposes.

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

The success of this rule will be measured by the extent to which providers can submit correct claims and receive correct Medicaid 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?**

No.

### **Development of the Regulation**

- 9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

Stakeholders have been included by ODM in development of the Maternal Infant Support Program (MISP) since early 2020. Most recently stakeholders from the Ohio Lactation Consulting Association (OLCA), Ohio Department of Health (ODH), several community-based organizations (CBOs) as well as individual providers of these services were specifically included in the development of this rule draft via Microsoft Teams call on June 6<sup>th</sup>, 2021. A follow-up stakeholder meeting which included review of this draft rule was held via Microsoft Teams call on August 4<sup>th</sup>, 2021.

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

Stakeholders responded strongly that registered nurses are the most likely provider of these services for breastfeeding women and that the stakeholders would prefer these practitioners be eligible to bill Medicaid directly for these services. This prompted ODM to make a decision to allow these licensed practitioners who hold a current IBCLC credential to provide lactation consulting services.

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Stakeholders also provided feedback that independent IBCLCs who are not another recognized type of Medicaid provider, should eventually be recognized as an independent provider type incorporated into MISD to avoid the potential barrier to care that going through another licensed provider presents, especially when they do not have IBCLC status. ODM is considering this as a next step.

**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?**

ODM reviewed the Ohio Pregnancy Assessment Survey which determined that the most cited reason for discontinued breastfeeding was decreased milk production. This issue is a common breastfeeding problem which is remedied through lactation consulting services. Additionally, fiscal impact data from ODM's Quality Decision Support System was used to determine the estimated uptake and overall utilization of these services based on the number of pregnant women ODM serves each year.

**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?**

Stakeholders provided feedback that independent IBCLCs, of which there are many highly qualified across the state of Ohio, should eventually be recognized as an independent provider type incorporated into MISD to avoid the potential barrier to care that going through another licensed provider presents, especially when they do not have IBCLC status. ODM is considering this as a next step, however there is currently no governing body in Ohio that oversees lactation consultants. ODM may revisit this alternative pending the outcomes of currently pending federal and state legislation.

**13. Did the Agency specifically consider a performance-based regulation? Please explain.**

The concept of performance-based rulemaking does not apply to these rules.

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

ODM has reviewed the Ohio Revised Code as well as the Ohio Administrative Code and determined that these rules do not duplicate any existing rules. Any provision of another rule that applies to these services is incorporated by reference.

**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.**

The policy changes set forth in this rule will be incorporated into (1) internal Medicaid processes; (2) the Medicaid Information Technology System (MITS), which is the department's current electronic claim-payment system; (3) the Provider Network Module

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(PNM) which will be the department's provider enrollment module and (4) transferred to the Fiscal Intermediary which will be the new claims-payment system for ODM. Incorporation into ODM processes and systems will ensure that the rules are applied consistently and predictably.

### **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 rule addressed in this analysis affect the licensed registered nurses enrolled in the Medicaid program as IBCLCs.

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

The rule includes a requirement for registered nurses to hold a current IBCLC certification in order to receive Medicaid reimbursement for lactation consultation services. Administrative activities may be required to obtain and provide evidence of certification to provider enrollment in order to obtain the appropriate billing specialty for claims submission.

**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.*

Quantifying the costs for obtaining an IBCLC credential is difficult because of the significant variance of appropriate educational pathways available to achieve certification. Providers wishing to become IBCLC's are required to select a training curriculum approved by the International Board of Lactation Consultant Examiners however the cost varies based on the source chosen by the provider.

The cost to receive an initial IBCLC certification is \$660. Recertification costs \$330 every ten years or providers can substitute taking the recertification exam with 75 hours of lactation, ethics, or other related education every five years. Recertification also requires 250 hours of clinical practice and basic life support education. Quantifying the cost of education would be difficult given the vast availability of qualifying courses.

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

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The MISP program seeks to reduce infant and maternal mortality rates by providing access to services proven to reduce acute and chronic health conditions related to these outcomes. Many stakeholders, who already hold the appropriate credentials are eager to provide these services to Ohio's Medicaid population. Adding these services will assist ODM and the State of Ohio in achieving the goals of Governor DeWine's children's initiative.

### **Regulatory Flexibility**

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

Reimbursement policies are applied uniformly, and no exceptions are made based on the provider's practice's 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 impose no first-time paperwork sanctions on providers.

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

Information sheets and instruction manuals on various claim-related topics are readily available on the Medicaid website.

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

Policy questions may be directed via e-mail to the Non-Institutional Policy section of ODM's policy bureau, at [noninstitutional\\_policy@medicaid.ohio.gov](mailto:noninstitutional_policy@medicaid.ohio.gov).

5160-8-42

**Lactation consultation services.**

(A) Scope and definitions.

- (1) This rule sets forth provisions governing payment for professional, non-institutional lactation consulting services.
- (2) "Lactation consultation" is the development and implementation of management strategies for complex problems related to breastfeeding and human lactation.
- (3) "International Board Certified Lactation Consultant" (IBCLC) is a professional member of the healthcare team who has earned and maintains the credential which identifies knowledge and expertise in breastfeeding management and care. This includes insight, skills, and knowledge to identify complex breastfeeding problems and to educate, promote, and facilitate an optimal breastfeeding experience and environment.

(B) Providers.

- (1) Rendering providers. The following eligible providers may render a lactation consultation service:
  - (a) A physician.
  - (b) A physician assistant.
  - (c) An advanced practice registered nurse.
- (2) Billing ("pay-to") providers. The following eligible providers may receive medicaid payment for lactation consultation services on behalf of a rendering provider:
  - (a) A physician;
  - (b) A physician assistant;
  - (c) An advanced practice registered nurse;
  - (d) A professional medical group;
  - (e) A federally qualified health center (FQHC);
  - (f) A rural health clinic (RHC); or
  - (g) An ambulatory health care clinic;

(C) Coverage. Payment may be made for the following lactation consultation services:



- (1) Providing evidence-based information to assist the client to make decisions regarding infant feeding.
- (2) Performing comprehensive maternal, child and feeding assessments.
- (3) Developing and implementing an individualized feeding plan.
- (4) Providing evidence-based information regarding use, during breastfeeding and human lactation, of medications (over-the-counter and prescription), alcohol, tobacco and addictive drugs, and herbs or supplements, and their potential impact on milk production and child safety.
- (5) Providing support and encouragement to successfully meet breastfeeding goals.
- (6) Supporting access to other well-care services for mothers and infants, including connections to other services and supports including the Women, Infants, and Children (WIC) program, primary and pediatric care, and home visiting.

(D) Allowances and limitations

- (1) Payment may be made for lactation consulting services when the following criteria are met:
  - (a) The service is medically necessary in accordance with rule 5160-1-01 of the Administrative Code;
  - (b) The service is performed at the order of a practitioner in accordance with rule 5160-1-17 of the Administrative Code;
  - (c) The individual is not currently receiving nurse home visiting services in accordance with rule 5160-21-05 of the Administrative Code;
- (2) Payment may be made for lactation consulting services performed by a registered nurse who holds a current IBCLC credential, when performed under the supervision of a physician, physician assistant or an advanced practice registered nurse.
- (3) No additional payment is made for lactation consulting services rendered to the same individual on the same date of service as medical nutrition therapy.

(E) Claims payment.

- (1) Payment for a covered lactation consultation service is the lesser of the submitted charge or the amount shown in appendix DD to rule 5160-1-60 of the Administrative Code.



- (2) Payment for a covered lactation consultation service provided by an FQHC or RHC is paid in accordance with chapter 5160-28 of the Administrative Code.
- (3) Payment for a covered lactation consultation service provided in a hospital is paid in accordance with chapter 5160-2 of the Administrative Code.
- (4) Payment for lactation pumps and supplies is made in accordance with rule 5160-10-25 of the Administrative Code.

5160-10-25

**DMEPOS: lactation pumps.**

(A) Definitions and explanations.

- (1) "Multiple-user lactation pump" is a lactation pump that is safe for sequential use by multiple individuals. (The term "hospital-grade," which is often applied to such a pump, is not recognized by the United States food and drug administration.) A multiple-user lactation pump comes with a separate set of accessories (e.g., breast shields, tubing) for each individual, which reduces the risk of contamination. It generally features adjustable suction pressure and adjustable pumping speed. It is intended only for temporary, short-term use.
- (2) The prescriber of a lactation pump may be involved in the care of the individual woman, of the infant, or of both.

(B) Coverage.

- (1) Payment may be made for either or both of the following purposes:
  - (a) Purchase of a single-user manual or electric lactation pump as a medical supply item and purchase of any necessary replacement supplies; or
  - (b) Rental of a multiple-user lactation pump.
- (2) For a single-user manual or electric lactation pump, a prescription is sufficient. No separate certificate of medical necessity (CMN) is needed.
- (3) For a multiple-user lactation pump, the default CMN form is the ODM 01901, "Certificate of Medical Necessity: Multiple-User Lactation Pumps" (rev. 1/2022).
  - (a) On the CMN, the prescriber explains and attests to the medical necessity of the pump.
  - (b) On the CMN, the prescriber specifies the expected number of ninety-day rental periods. If additional rental periods are needed, the prescriber may either revise the existing CMN or complete a new CMN.

(C) Constraints and limitations.

- (1) The warranty period for a covered single-user manual or electric lactation pump is one year from the date of delivery.
- (2) When a manual lactation pump is supplied as part of a pump accessory kit, separate payment will not be made for the manual lactation pump, nor will separate payment be made for an additional manual lactation pump.
- (3) Payment for the rental of a multiple-user lactation pump includes all

5160-10-25

2

accessories, supplies, and cleaning.

(4) The department is not responsible for failure to return a multiple-user lactation pump in working order.