Ohio | Common Sense Initiative

Mike DeWine, Governor
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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):

Freestanding Birth Center (FBC) Services

Rule Number(s):

To Be Rescinded: 5160-18-01

New (for informational purposes only): 5160-18-01

Date of Submission for CSI Review: 06/27/2022

Public Comment Period End Date: 07/05/2022

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 ___) | **Rescinded/__1_ rules (FYR?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.

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 5160-18-01 of the Ohio Administrative Code sets forth Medicaid coverage and payment for the delivery of services by Freestanding Birth Centers (FBCs).

   As a result of five-year review, existing rule 5160-18-01 is being rescinded and replaced with a new rule of the same number. On the whole, the intent of the new rule remains the same, but some differences should be noted:

   - Am. Sub. H. B. 166 (133rd G. A.) lists six terms that cause a rule to be deemed to contain regulatory restrictions: 'shall', 'shall not', 'must', 'may not', 'require', and 'prohibit'. All of these terms are being removed from this rule, and the passages in which they appear have been recast.
   - The text of the new rule is being reorganized and streamlined.
   - Provider requirements listed in the rescinded rule are being omitted from the new rule. Those provisions are not Medicaid requirements; they are set forth in non-Medicaid parts of the Ohio Revised Code and the Ohio Administrative Code.
   - The limitations paragraph in the rescinded rule is being removed and its content recast in other sections of the new rule.

- In the new rule, coverage and payment provisions for facility and professional services are being clarified.
- In the new rule, ODM is adding coverage of intrapartum care.

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.**

   ODM is promulgating these rules under section 5164.02 of the Ohio Revised Code. The statutes that amplify that authority are as follows: sections 5164.02 and 5164.70 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?**
   If yes, please briefly explain the source and substance of the federal requirement.

   Yes. Section 1905(l)(3)(A) of the Social Security Act (42 U.S.C. 1396d(l)(3)(B)) defines a freestanding birth center and mandates that a State provide separate payment to providers administering prenatal labor and delivery or postpartum care.

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

   These rules do not impose any conditions beyond what is required by the federal government.

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)?**

   Medicaid rules perform several core business functions: They establish and update coverage and payment policies for medical goods and services. They set limits on the types of entities that can receive Medicaid payment for these goods and services. They publish payment formulas or fee schedules for the use of providers and the general public. The administrative rule for FBC services perform these functions, and no alternative is readily apparent. Further, ODM is required to adopt such rules under R.C. 5164.02.

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.

   Not Applicable.

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.

   The following stakeholders were included by ODM in the initial review and development of the draft regulation for five-year review: American Association of Birth Centers, Ohio Affiliate of the American College of Nurse Midwives, Commission for the Accreditation of Birth Centers, Ohio Association of Advanced Practice Nurses, Ohio Hospital Association, Ohio Department of Health, and the Medicaid managed care entities. On March 22, 2021 during the pre-clearance period, ODM sent a message via e-mail to the above-mentioned stakeholders asking for comments on rule 5160-18-01. Stakeholder sent written comments and a meeting was held on August 16, 2021. After the meeting, ODM incorporated stakeholder comments and on March 9, 2022, ODM sent the final version to stakeholders to obtain their input one last time.

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 in the course of discussion were accepted by both FBC stakeholders and ODM and were incorporated into the new rule.

    As a result of stakeholder input, in paragraph (B)(1), ODM added facility payment for discrete services in the event the delivery was moved to a hospital. In paragraphs (B)(1) and (B)(2), ODM added the headings “facility services” and “professional services” for the sake of clarity. Coverage of intrapartum care was also added to the rule (but is already an ODM covered service).

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?**

ODM is required to adopt rules to establish coverage of and payment for Medicaid services. Whatever the policy may be, the form of the rule is the same; no alternative is readily apparent.

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.***

    The concept of performance-based regulation does not apply to these services.

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

    ODM policy and legal staff reviewed the regulation to ensure they are not duplicative of existing Ohio regulations. There are no regulations in the rule that are also found elsewhere in agency 5160. Any provision of another rule that applies specifically 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 policies set forth in the new rule will be incorporated into the Medicaid electronic claim-processing system as of the effective date of the rule. They therefore will be applied by ODM's electronic claim-payment system automatically and consistently whenever an appropriate provider submits a claim for an applicable service. Stakeholders have been and will also be informed of changes via e-mail and a Medicaid transmittal letter.

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

    a. This regulation applies to freestanding birth centers and providers such as physicians and certified nurse midwives who perform services in freestanding birth centers.

    b. Rule 5160-18-01, which is being rescinded, requires providers to hold a current license from the Ohio Department of Health or appropriate authority in another state. It also requires that providers conform to the freestanding birth center rules administered by the Ohio Department

of Health (OAC rules 3701-83-33 to 3701-83-42). This requirement is not found in the proposed new version of the rule.

c. The adverse impact has been quantified for each new regulation separately as follows:

The adverse impact on providers of freestanding birth centers will not be directly attributable to new rule 5160-18-01.

Any expense for licensure required in existing rule 5160-18-01, which is an existing professional standard, would be incurred before providers enroll with Medicaid. On the Ohio Department of Health's website, it states that the initial and renewal licensure application fees are $300.00 each. Again, this cost is absorbed prior to enrolling with Medicaid and this provision is being removed from the new rule since it is not a Medicaid requirement. There is no expected adverse impact as a result of this rule on existing freestanding birth centers as they already meet this requirement prior to enrolling with Medicaid and this provision is being removed from the new rule.

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

The requirement to hold a license helps to maintain professional standards and will be incorporated by reference in the new rule.

Regulatory Flexibility

18. 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.

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?

There are no fines or penalties in these regulations.

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

If providers choose to submit claims through ODM's claims payment system web portal, instructions are available on ODM's website. Providers may also call the Provider Call Center for assistance at: (800) 686-1516.

ODM offers both group and individual billing training.

Information sheets and instruction manuals on various claim-related topics are readily available on ODM's website.

Policy questions may be directed via e-mail to the Non-Institutional Benefit Management section of ODM's policy bureau, at noninstitutional_policy@medicaid.ohio.gov.

TO BE RESCINDED

5160-18-01 **Freestanding birth center services.**

(A) Definitions.

(1) "Freestanding birth center (FBC)" has the same meaning as in 42 U.S.C. 1396d(l)(3)(B) (October 1, 2016).

(2) "Independent practitioner" and "non-independent practitioner" have the same meaning as in rule 5160-4-02 of the Administrative Code.

(3) "Low-risk expectant mother" has the same meaning as in rule 3701-83-33 of the Administrative Code.

(B) Provider requirements. Payment may be made to a FBC only if it meets the following criteria:

(1) It holds a current license to perform FBC services issued by the appropriate authority in the state in which it is located;

(2) It is operated in conformity with rules 3701-83-33 to 3701-83-42 of the Administrative Code; and

(3) It is neither a hospital registered under section 3701.07 of the Revised Code nor an entity that is reviewed as part of a hospital accreditation or certification program.

(C) Coverage.

(1) Facility services. Payment may be made to a FBC either for covered global obstetrical care (i.e., a bundled combination of antepartum, delivery, and postpartum services) or for covered discrete antepartum, delivery, and postpartum services, but not for both.

(2) Professional services. Separate payment may be made to an independent practitioner, or to a FBC on behalf of either an independent practitioner or a non-independent practitioner, for the performance of the following services:

(a) Covered global obstetrical care or covered discrete antepartum, delivery, and postpartum services, but not both;

(b) Care of the newborn provided in accordance with rule 3701-83-36 of the Administrative Code;

(c) A covered medicine, radiology, clinical laboratory, or evaluation and management (E&M) service or the administration of a pharmaceutical; or

(d) The professional component of a covered service comprising both professional and technical components.

(D) Limitations.

(1) Payment may be made for an antepartum, delivery, or postpartum service only if it meets the following criteria:

(a) It is provided to a low-risk expectant mother;

(b) It is covered in accordance with agency 5160 of the Administrative Code; and

(c) It is provided in accordance with rules 3701-83-34 to 3701-83-37 of the Administrative Code.

(2) Payment will not be made for a service that is outside a practitioner's scope of practice.

(3) Payment will not be made to a FBC (as the rendering provider) for performing the professional component alone of a covered service.

(4) A practitioner and a FBC must not submit a claim for service that would result in duplicate payment.

(E) Claim payment. Payment for a covered item or service in the following list is the lesser of the submitted charge or the maximum amount established in accordance with the indicated paragraph of the Administrative Code:

(1) Laboratory service — rule 5160-11-09;

(2) Medical service or procedure — Chapter 5160-4 of the Administrative Code, for which maximum payment amounts are published in appendix DD to rule 5160-1-60 of the Administrative Code and coverage and payment policy is set forth in the following rules of the Administrative Code:

(a) Physician service — rule 5160-4-01;

(b) Physician assistant (PA) service — rule 5160-4-03;

(c) Advanced practice registered nurse (APRN) service — rule 5160-4-04;

(d) Evaluation and management (E&M) service — rule 5160-4-06;

(e) Surgical service — rule 5160-4-22; or

(f) Radiology or imaging service — rule 5160-4-25;

(3) Immunization, injection or infusion (including trigger-point injection), skin substitute, or provider-administered pharmaceutical — rule 5160-4-12 of the Administrative Code; or

(4) Medical supply item — rule 5160-10-03 of the Administrative Code.

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02, 5164.70
Prior Effective Dates:	01/01/2012, 01/01/2018

5160-18-01 **Freestanding birth center services.**

(A) Definitions.

(1) "Freestanding birth center (FBC)" is an entity defined in 42 U.S.C. 1396d(l)(3)(B) (in effect as of January 1, 2023) that is operated in conformity with rules 3701-83-33 to 3701-83-42 of the Administrative Code.

(2) "Independent practitioner" and "non-independent practitioner" have the same meaning as in rule 5160-4-02 of the Administrative Code.

(3) "Low-risk expectant mother" has the same meaning as in rule 3701-83-33 of the Administrative Code.

(B) Coverage. Payment may be made for covered services provided to a low-risk expectant mother.

(1) Facility services. A single "bundled" payment is made to an FBC for all covered obstetrical care (antepartum, delivery, postpartum, and newborn care services), including healthcare services listed in rule 3701-83-36 of the Administrative Code. If delivery does not occur at the FBC, payment is made for the discrete covered services.

(2) Professional services. Additional professional payment is also made to an independent practitioner, or to an FBC on behalf of either an independent practitioner or a non independent practitioner, for the performance of discrete covered services including but limited to the following examples:

(a) Antepartum services;

(b) Intrapartum services, delivery, postpartum, and newborn care services listed in rule 3701-83-36 of the Administrative Code;

(c) A covered medicine, radiology, clinical laboratory, or evaluation and management (E&M) service;

(d) The administration of a pharmaceutical;

(e) Reproductive health services (including the provision of contraceptive supplies); or

(f) The professional component of a covered service comprising both professional and technical components.

(C) Claim payment. The maximum payment for a covered item or service in the following list is established in accordance with the indicated section of the Administrative Code:

(1) "Bundled" or discrete covered services payment made to an FBC — Appendix DD to rule 5160-1-60;

(2) Professional payment:

(a) Medical or radiological service — Chapter 5160-4, for which maximum payment amounts are published in Appendix DD to rule 5160-1-60;

(b) Immunization, injection or infusion (including trigger-point injection), skin substitute, or provider-administered pharmaceutical — rule 5160-4-12;

(c) Applicable durable medical equipment, prostheses, orthoses, and medical supply items — Chapter 5160-10;

(d) Laboratory service — rule 5160-11-11; or

(e) Reproductive health service — Chapter 5160-21, for which maximum payment amounts are published in Appendix DD to rule 5160-1-60.

Replaces: 5160-18-01

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02, 5164.70
Prior Effective Dates:	01/01/2012, 01/01/2018