CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)

Regulation/Package Title: Freestanding Birth Centers

Rule Number(s):

Subject to BIA:

New: 5160-18-01 – Freestanding Birth Center Services

To Be Rescinded: 5160-18-01 - Freestanding birth center: eligible providers, covered services and reimbursement

Not Subject to BIA (informational only):

To Be Rescinded: 5160-4-36 - Covered freestanding birth center (FBC) procedures

Date: April 26, 2017

Rule Type:

- ☑ New
- ☐ Amended
- ☑ 5-Year Review
- ☑ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Current rules 5160-18-01 and 5160-4-36 of the Ohio Administrative Code set forth Medicaid payment policy for services provided in freestanding birth centers (FBCs). As a result of five-year rule review, these rules are being rescinded, compiled, and replaced with one new rule numbered 5160-18-01.

   The new rule incorporates two changes of significance:

   - Section 1905(l)(3)(A) of the Social Security Act requires distinct payments for both facility and professional services rendered in a FBC setting. New rule 5160-18-01 states explicitly that a separate professional payment amount, distinct from and in addition to the facility payment amount, may be made for the services of professionals working in FBCs. Actual payment, however, remains the same.
   - The appendix to rule 5160-18-01 has been rescinded. New rule 5160-18-01 instead includes a statement that maximum payments for FBC services are listed in appendix DD to rule 5160-1-60 of the Ohio Administrative Code.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   ODM is promulgating these rules under section 5164.02 of the Ohio Revised Code.

3. **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.

4. **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 exceed federal requirements.

5. **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

rules for freestanding birth centers perform these functions, and no alternative is readily apparent.

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

   The success of these rules can be measured by correct payment of claims by the Medicaid Information Technology System (MITS). Claims payment can be verified both by internal staff and providers by logging onto the MITS web portal.

7. **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 stakeholders included by ODM in the development or initial review of the draft regulation include:

   - Ohio Affiliate, American College of Nurse-Midwives
   - American Association of Birth Centers
   - Commission for the Accreditation of Birth Centers
   - Mahoning Valley Birth Center (freestanding birth center)
   - Middlefield Care Center (freestanding birth center)
   - Ohio Department of Health
   - Medicaid managed care plans

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

   Input provided by the stakeholders included:

   - The Ohio Affiliate of the American College of Nurse-Midwives, American Association of Birth Centers, and the Commission for the Accreditation of Birth Centers provided recommendations to update language in Ohio Administrative Code rules maintained by the Ohio Department of Health. For example, they recommended not to include the following as a condition of licensure: written contracts or transfer agreements with hospitals, certificates of need, or physicians as medical directors. They did, however, recommend that accreditation be a requirement of licensure. One of the Medicaid managed care plans also made a recommendation to require accreditation.
     - ***How input affected the draft regulation:*** These recommendations were forwarded to ODH for consideration since ODH licenses freestanding birth centers. While the ODH and ODM rules touch the same providers of freestanding birth center services, ODM's regulation does not duplicate,

overlap, or contradict existing ODH's or other Ohio regulation. ODM's new rule does reference existing Ohio Department of Health regulation. Providers of FBC services must operate in conformity with rules 3701-83-33 to 3701-83-42 of the Administrative Code.

- The Ohio affiliate of the American College of Nurse-Midwives recommended that the regulation be modified to clearly indicate that a separate professional fee, distinct from and in addition to the facility fee listed in the appendix is made for the services of professionals working in birth centers.

  How input affected the draft regulation: By listing them in separate paragraphs in the coverage section of the new rule, the regulation now clearly indicates separate coverage and payment for facility services and professional 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. 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.

  There is a limitation, however. Separate payment for professional services may only be made to a practitioner who is eligible to be paid independently for professional services rendered in a facility.

- Almost all stakeholders, including Mahoning Valley Birth Center, stated and gave examples of how ODM's payment amounts are significantly lower than other State Medicaid Agencies and commercial payers.

  - ***How input affected the draft regulation:*** Since the existing rules went into effect in 2012, a technical change was made to ODM's claims processing system (Medicaid Information Technology System), which aligns the payment levels with the approved federal state plan. This resulted in several freestanding birth center services being paid at the amounts set forth in the Appendix to rule 5160-1-60. ODM has corrected the rule reference for payment with this proposed rule revision and no additional increase is proposed at this time.

- Documents were submitted concerning the quality, access, and outcomes of services provided at freestanding birth centers.

  - ***How input affected the draft regulation:*** The documents from stakeholders were reviewed and taken under consideration but did not directly affect the draft regulation. The Ohio Department of Health currently manages the quality assessment and performance improvement tool for freestanding birth centers through OAC rule 3701-83-42. Stakeholder comments were forwarded to the Ohio Department of Health for review.

9. 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 the rules or the measureable outcomes of the rules.

10. 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?

The provisions in rules 5160-18-01 and 5160-4-36 were shared with a wide variety of internal and external stakeholders whose input was used to shape the draft regulations.

No alternatives are readily apparent.

11. 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.

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

ODM reviewed existing Ohio regulation, including ODH's freestanding birth center regulation, and determined there is no duplicate, overlapping, or contradicting language in ODM's proposed rule 5160-18-01.

13. 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 implementation plan includes outreaching to stakeholders throughout the rule-making process and offering billing training to Medicaid providers of freestanding birth center services.

Adverse Impact to Business

14. 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;

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

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

Rule 5160-18-01 requires providers to hold a current license to provide freestanding birth center services 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).

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 on providers of freestanding birth centers is not directly attributable to rule 5160-18-01. Any expense for licensure, which is an existing professional standard, would be incurred before providers enroll with Medicaid. There is no expected adverse impact as a result of these rules on existing freestanding birth centers as they already meet this requirement prior to enrolling with Medicaid.

ODM contacted the Ohio Department of Health to find out the cost of licensure. The licensure application fee is $300.00 annually and the licensure inspection fee is $1,750 annually. In addition, it is estimated that staff would spend about 18 hours in filling out the application, preparing the paperwork for a licensure inspection, and participating in the licensure inspection. According to Labor Market Information (LMI) data published by the Ohio Department of Job and Family Services in 2016, the median salary statewide hourly wage for an Administrative Services Manager is $36.46 and adding 30 per cent for fringe benefits brings the figure to $47.40. Therefore, the cost associated with staff time would be about $850. In total, the estimated cost for licensure of a freestanding birth center is about $2,900 annually. Again, this cost is absorbed prior to enrolling with Medicaid.

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

The adverse impact to freestanding birth centers as a result of rule 5160-18-01 is minimal (demonstrating proof of licensure). While ODM must put in place standards for participating in the Medicaid program, ODM is using existing professional standards—what those providers would be required to do even if they did not enroll with Medicaid—to ease the burden on providers. The licensure standard is consistent with existing professional standards, and is only reiterated in this chapter for program integrity and quality of care purposes. Obtaining licensure would happen prior to enrolling with Medicaid. The provider would only need to demonstrate proof of licensure with enrolling with Medicaid as a result of this rule.

Regulatory Flexibility

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

Requirements set forth in this rule are not predicated on the size of the provider, and no alternative means of compliance is available.

17. 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.

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

If providers choose to submit claims through ODM's MITS 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.

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 is the lesser of submitted charge or the amount specified in the applicable rule of agency 5160 of the Administrative Code.

Replaces: 5160-18-01, 5160-4-36

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:	5164.02, 5164.70
Prior Effective Dates:	01/01/2012

TO BE RESCINDED

5160-18-01 **Freestanding birth center: eligible providers, covered services and reimbursement.**

(A) A "freestanding birth center" (FBC) is a facility, operated in compliance with rules 3701-83-33 to 3701-83-42 of the Administrative Code, which provides care during pregnancy, birth and the immediate postpartum period to low-risk expectant mothers. A FBC does not include a hospital registered under section 3701.07 of the Revised Code, or an entity that is reviewed as part of a hospital accreditation or certification program.

(B) To receive medicaid reimbursement a FBC must:

(1) Be currently licensed as a FBC by the Ohio department of health or by the state licensing agency where the FBC is located if the FBC is located outside the state of Ohio;

(2) Have a valid, current provider agreement in accordance with rule 5101:3-1-17.2 of the Administrative Code; and,

(3) Meet the standards provided in 42 U.S.C. 1396d(l)(3)(B) (effective March 23, 2010).

(C) Covered freestanding birth center (FBC) services:

(1) The following FBC services are covered:

(a) Medically necessary services provided during pregnancy, birth and the immediate postpartum period to an eligible medicaid consumer who is a low-risk expectant mother, as defined in rule 3701-83-33 of the Administrative Code, and furnished directly or indirectly by a licensed health care professional within the scope of practice of his or her profession under state law. The services must also be within the scope of FBC licensed services as described in rules 3701-83-33 to 3701-83-37 of the Administrative Code.

(b) "FBC facility services" that are items and services furnished by a FBC and designated as FBC procedures in the appendix to this rule. Facility services include but are not limited to:

(i) Nursing, technician and related services;

(ii) Use of FBC facilities;

(iii) Drugs and equipment directly related to the provision of a FBC procedure; and,

(iv) Diagnostic or therapeutic services or items directly related to the provision of a FBC procedure.

(2) The following facility services are not covered:

(a) Maternity care and delivery services provided to women who are not "low-risk expectant mothers" and

(b) Maternity care and delivery services not provided in accordance with rules 3701-83-34 to 3701-83-37 of the Administrative Code.

(D) Freestanding birth center (FBC) reimbursement:

(1) "Billable services" for a FBC are those identified and provided in accordance with this rule.

(2) "Procedure code" refers to the current procedural terminology (CPT) codes and healthcare common procedure coding system (HCPCS) as defined in rule 5101:3-1-19 of the Administrative Code. Guidelines and definitions for level of care determinations and for new and established patient definitions are as published in the CPT and HCPCS volumes. HCPCS modifier "TH" should be used when obstetrical services, prenatal or postpartum, were provided.

(3) Payment for facility services.

(a) All services must be billed in accordance with Chapter 5101:3-1 of the Administrative Code.

(b) Payment for FBC services is based on a reimbursement rate for each HCPCS code as determined by the department and set forth in the appendix to this rule.

(c) Maximum reimbursement for facility services will be the lesser of the

provider's billed charges or one hundred per cent of the rate as specified in the appendix to this rule.

(d) For facility reimbursement, the department recognizes the CPT codes for global obstetrical care for antepartum, delivery and postpartum services, or single procedure codes. If a provider bills using global codes, then the provider cannot bill separately for single procedure codes.

(4) Reimbursement limitations.

Payment for services associated with global codes is considered payment in full for the services described in paragraph (D)(3) of this rule for the service date spans related to the delivery. If single service procedure codes as described in paragraph (D)(3) of this rule have been billed and the provider then seeks reimbursement for a global code, the provider must reverse all claims with single procedure codes to obtain reimbursement for the global code.

(5) Payment for laboratory services, radiological services, and diagnostic and therapeutic procedures.

In addition to reimbursement for facility services described in this rule, a FBC may also be reimbursed for laboratory procedures, radiological procedures, and diagnostic and therapeutic procedures provided in connection with a covered FBC procedure. To be reimbursed for these procedures, FBC providers must bill using appropriate HCPCS codes.

(a) Payment for laboratory services.

(i) A FBC facility may be reimbursed for covered laboratory services that are provided in accordance with Chapter 5101:3-11 of the Administrative Code

(ii) A FBC will not be reimbursed separately for the professional component of laboratory services.

(b) Payment for radiological services.

(i) A FBC may be reimbursed for radiological procedures that are provided and billed in accordance with rule 5101:3-4-25 of the Administrative Code.

(ii) A FBC will not be reimbursed separately for the professional component of radiological services.

(c) Payment for diagnostic and therapeutic services.

(i) A FBC may be reimbursed for the provision of diagnostic and therapeutic services that are provided in accordance with rules 5101:3-4-11, 5101:3-4-16, 5101:3-4-17 and 5101:3-4-18 of the Administrative Code.

(ii) A FBC will not be reimbursed separately for the professional component of diagnostic and therapeutic services.

(iii) A FBC will not be reimbursed separately for the professional component of any service cited in paragraph (D)(5)(c)(i) of this rule.

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:	5162.03, 5164.02, 5164.70
Prior Effective Dates:	01/01/2012

TO BE RESCINDED

5160-4-36 **Covered freestanding birth center (FBC) procedures.**

(A) A physician may be reimbursed for all covered procedures performed in a freestanding birth center (FBC), as defined in rule 5101:3-18-01 of the Administrative Code.

(B) A physician may be reimbursed for the professional component of a covered laboratory, radiology, diagnostic, or therapeutic service only if the physician personally performed the service in the FBC and the service was not performed by an employee of the FBC.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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