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):

Clinic Services

Rule Number(s): **To Be Rescinded:** 5160-13-01 and **New:** 5160-13-01

Date of Submission for CSI Review: 11/1/2022

Public Comment Period End Date: 11/8/2022

Rule Type/Number of Rules:

New/__1_ rules

Amended/____ rules (FYR? ___)

No Change/____ 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Rescinded/__1__ rules (FYR?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 5160-13-01 of the Ohio Administrative Code sets forth Medicaid coverage and payment for the delivery of services by clinics.

   As a result of five-year review, existing rule 5160-13-01 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:

   - The text of the new rule is being reorganized.
   - The terms “ambulatory health care clinic” and “service-based ambulatory health care clinic” are being changed to “clinic” and “clinic services” to align with federal regulation. Clinic services are defined in 42 CFR 440.90 (October 1, 2022).
   - The payment methodology for clinics is being clarified. Medicaid makes separate payment for each service or item provided in accordance with the chapter or rule of agency 5160 of the Administrative Code that pertains to that service. The Ohio Department of Medicaid does not maintain a separate payment schedule for covered services rendered in a clinic.

- The new rule removes explicit certification and accreditation requirements which previously triggered Ohio Rev. Code 107.52 and instead says the entity must be recognized, associated with, or meet credentialing standards prior to enrolling with Medicaid.

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. The regulation enables ODM to provide coverage for clinic services, a Medicaid benefit described in 42 CFR 440.90.

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.**

   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 clinic 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.

   ODM included the following stakeholders in the initial review and development of the draft regulation for five-year review: Ohio Department of Health, Accreditation Association for Ambulatory Health Care (AAAHC), Healthcare Facilities Accreditation Program of the American Osteopathic Association (AOA), Community Health Accreditation Program (CHAP), providers of professional dental and optometry school clinics, Ohio Speech and Hearing Professionals Board, The Ohio Academy of Audiology, Ohio Speech-Language-Hearing Association, Ohio Physical Therapy Association, Ohio Public Health Partnership, and Association of Ohio Health Commissioners. Stakeholders were contacted by e-mail on August 22, 2022.

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

    Not applicable. No comments were received.

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. Whatever the policy may be, the form of the rule is the same; no alternative is readily apparent.

13. **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.

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 intent and the requirements in the regulation are not changing. Stakeholders will be informed of changes via a public hearing, e-mail, and a Medicaid Transmittal Letter.

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

This regulation applies to practitioners performing services in clinics.

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.

Existing rule 5160-13-01 requires all entities enrolling with Medicaid as "Ambulatory Health Care Clinics" to meet the federal definition of a clinic (the new rule removes this requirement and instead says the entity must be recognized, associated with, or meet credentialing standards prior to enrolling with Medicaid). The existing rule requires:

(1) A dialysis center, defined as a "dialysis facility" in 42 C.F.R. 494.10 (October 1, 2022), must meet the following criteria: (a) It is certified by Medicare as a dialysis facility; (b) It is licensed by the Ohio department of health in accordance with Chapter 3701-83 of the Administrative Code or, if it is located outside of Ohio, is licensed by its respective state's authority; and (c) It provides services in accordance with rule 5160-13-02 of the Administrative Code.

(2) A family planning clinic must meet the following criteria: (a) It is a public or nonprofit organization; (b) It complies with federal guidelines set forth in 42 U.S.C. 300 (as in effect October 1, 2022); (c) It is qualified to receive funding for pregnancy prevention services through Title X of the Public Health Services Act; and (d) It provides pregnancy prevention services in accordance with Chapter 5160-21 of the Administrative Code.

(3) An outpatient rehabilitation clinic must deliver rehabilitation services at a Medicare-certified rehabilitation agency, defined in 42 C.F.R. 485.703 (October 1, 2022), or at a Medicare certified comprehensive outpatient rehabilitation facility (CORF), defined in 42 C.F.R. 485.51 (October 1, 2022).

(4) A primary care clinic must meet either of the following criteria: (a) It receives state or federal grant funds for the provision of health services; or (b) It provides primary care services by virtue of certification or accreditation by one of the following entities: (i) The joint commission; (ii) The accreditation association for ambulatory health care

(AAAHC); (iii) The healthcare facilities accreditation program of the American osteopathic association (AOA); or (iv) The community health accreditation program (CHAP).

(5) A professional dental school clinic must be associated with an accredited dental school.

(6) A professional optometry school clinic must be associated with an accredited optometry school.

(7) A public health department clinic must meet the following criteria: (a) It has legal status as local health department created by a city health district, general health district, or combined health district in accordance with Chapter 3709. of the Revised Code; and (b) It meets the standards set forth in section 3701.342 of the Revised Code.

(8) A speech-language-audiology clinic must specialize in and provides speech, language, or audiology services delivered by professionals who have been certified by the American speech-language-hearing association (ASHA).requires:

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

As currently written, the existing rule requires certain accreditations, certifications, legal statuses, and/or licensures to be a service-based ambulatory health care clinic operating under a Medicaid provider agreement. From a practical standpoint, however, clinics will have already need met these requirements in order to operate as that provider type. This is true regardless of whether the provider chooses to participate in Ohio's Medicaid program. For that reason, related expenses would not be directly attributable to the existing rule. Nonetheless, under Ohio's statutory scheme, the expressed provider requirements were deemed to have an adverse impact because the references to accreditations, certifications, legal statuses, and/or licensures triggered the application of Ohio Rev. Code 107.52(A) (… requires a license, permit, or any other prior authorization to engage in or operate a line of business). As a result, a Business Impact Analysis was submitted in 2016 and ODM quantified the adverse impact as follows:

> *A positive impact on providers is expected to result from the removal of the Medicare enrollment requirement for certain clinics that will no longer be required to enroll as Medicare providers.*
>
> *The costs to participating providers are estimated in the following paragraphs.*
> *•Primary care clinics are required to: (1) be either certified or accredited by the Joint Commission, Accreditation Association for Ambulatory Health Care (AAAHC), Healthcare Facilities Accreditation Program of the American*

Osteopathic Association, or the Community Health Accreditation Program (CHAP), or (2) receive state or federal grant funds for the provision of health services. Accreditation fees range from about $7,200 a year for small businesses to more than $40,000 a year for large organizations. The cost to apply for a grant is existing staff time. 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 professionals performing services related to accreditation is $24.76 (program director) and adding 30 per cent for fringe benefits brings the figure to $32.19. Therefore, the estimated cost associated with applying for a grant is about $1,300.

•Any organization applying to be a public health department clinic provider with Medicaid must have legal status as a county, city, or combined health district; and meet the standards for boards of health and local health departments in accordance with Chapter 3709 and Section 3701.342 of the Revised Code. ODM reached out to the Ohio Department of Health regarding the cost of their requirement, and they said the cost of this requirement has never been quantified. There is no expected adverse impact as a result of these rules on existing public health department clinics as they already meet this requirement prior to enrolling with Medicaid.

•Outpatient rehabilitation clinics are required by Medicare to be certified by Medicare as either an outpatient rehabilitation agency or a comprehensive outpatient rehabilitation facility (CORF). Outpatient rehabilitation agencies and CORFs are not licensed in Ohio. Federal standards for Medicare certification are found at 42 CFR Part 485, Subpart B, 42 CFR Part 485.703, and 42 CFR Part 485.51. As long as outpatient rehabilitation clinics follow federal standards for Medicare certification, which they must do regardless of whether they enroll in Medicaid, there is no additional adverse impact in order to become a Medicaid provider.

•Family planning clinics are required to comply with federal guidelines set forth in 42 U.S.C. 300 and receive funding for pregnancy prevention services through Title X of the Public Health Services Act. There is no additional adverse impact.

•Professional optometry school clinics are required to be associated with an accredited optometry school. Professional optometry schools are accredited by organizations such as the Accreditation Council on Optometry Education (ACOE) of the American Optometric Association (AOA). According to AOA's website, application and annual fees are: (1) Professional Optometric Degree Programs - $30,629, (2) Optometric Residency Programs - $2,226, and (3) Optometric Technician Programs - $2,226. This requirement is consistent with existing professional standards, not an additional Medicaid requirement or cost.

•Professional dental school clinics are required to be associated with a professional dental school. Professional dental schools are accredited by organization such as the commission on dental accreditation (CODA) of the American dental association (ADA). According to the ADA's website, application fees for new professional dental schools require a one-time payment of $4,000. Annual fees for existing professional dental schools are currently $6,740. This requirement is consistent with existing professional standards, not an additional Medicaid requirement or cost.

•Professionals working at speech-language/audiology clinics must hold a certificate from the American Speech-Language Hearing Association (ASHA). The cost of a certificate issued by ASHA ranges from $256-$511 (dues and fees are paid annually). The costs, however, are normally assumed by the practitioner working at the clinic and not the clinic itself.

•ESRD dialysis clinics must: (1) be certified by Medicare as a dialysis facility; (2) be licensed by the Ohio Department of Health in accordance with Chapter 3701-83, and (3) if a non-Ohio provider, be licensed by their respective state's authority. All freestanding dialysis centers are required to be licensed by the Ohio Department of Health under section 3702.30 of the Ohio Revised Code. As long as dialysis clinics follow Ohio standards for licensure and federal standards for Medicare certification, which they must do regardless if they enroll in Medicaid, there is no additional adverse impact due to these rules.

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).*

In the new rule, the descriptions of certain provider requirements are being recast to better reflect that ODM's rule does not require a license, permit, or any other prior authorization to engage in or operate a line of business.

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

Holding 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.

5160-13-01 **Clinic services.**

(A) Unless otherwise noted, any limitations or requirements specified in the Revised Code or in agency 5160 of the Administrative Code apply to services addressed in this rule.

(B) This rule does not apply to federally qualified health centers (FQHCs) nor to rural health clinics (RHCs), policies for which are set forth in Chapter 5160-28 of the Administrative Code.

(C) Definition. "Clinic" is an entity that meets all of the following criteria:

(1) It renders healthcare services on an outpatient basis under the direction of a physician or dentist.

(2) It operates from a fixed location, a specifically designed mobile unit, or both.

(3) It is freestanding administratively, organizationally, and financially independent of an institution such as a hospital or long-term care facility. It may be physically located in a hospital or long-term care facility so long as it remains independent.

(4) It does not provide overnight accommodations.

(D) The following entities that meet the definition of a clinic may enroll with the Ohio department of medicaid (ODM) as a clinic provider:

(1) A dialysis center, defined as a "dialysis facility" in 42 C.F.R. 494.10 (October 1, 2022), that meets the following criteria:

(a) It is recognized by medicare as a dialysis facility;

(b) It operates in accordance with Chapter 3701-83 of the Administrative Code or, if it is located outside of Ohio, operates in accordance with its respective state's authority; and

(c) It provides services in accordance with rule 5160-13-02 of the Administrative Code;

(2) A family planning clinic that meets the following criteria:

(a) It is a public or nonprofit organization;

(b) It complies with federal guidelines set forth in 42 C.F.R. Part 59 (October 1, 2022);

(c) It is qualified to receive funding for pregnancy prevention services through Title X of the Public Health Services Act; and

(d) It provides pregnancy prevention services in accordance with Chapter 5160-21 of the Administrative Code;

(3) An outpatient rehabilitation clinic that delivers rehabilitation services at a medicare-certified rehabilitation agency, defined in 42 C.F.R. 485.703 (October 1, 2022), or at a medicare-certified comprehensive outpatient rehabilitation facility (CORF), defined in 42 C.F.R. 485.51 (October 1, 2022);

(4) A primary care clinic that meets either of the following criteria:

(a) It receives state or federal grant funds for the provision of health services; or

(b) It is an accredited provider of primary care services as recognized by one of the following entities:

(i) The joint commission;

(ii) The accreditation association for ambulatory health care (AAAHC);

(iii) The healthcare facilities accreditation program of the American osteopathic association (AOA); or

(iv) The community health accreditation program (CHAP);

(5) A professional dental school clinic associated with an accredited dental school;

(6) A professional optometry school clinic associated with an accredited optometry school;

(7) A public health department clinic that meets the following criteria:

(a) It has legal status as a local health department created by a city health district, a general health district, or a combined health district in accordance with Chapter 3709. of the Revised Code; and

(b) It meets the standards set forth under the authority of section 3701.342 of the Revised Code; or

(8) A speech-language-audiology clinic that specializes in and provides speech, language, or audiology services delivered by professionals who meet the American speech-language-hearing association (ASHA) certification standards as determined by ASHA.

(E) Payment for a covered service furnished in a clinic is made in accordance with the chapter or rule of agency 5160 of the Administrative Code that pertains to that service.

Replaces: 5160-13-01

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, 12/21/1977, 12/30/1977, 01/08/1979, 01/14/1983, 04/02/1983, 06/03/1983, 10/01/1987, 04/01/1988, 09/01/1989, 07/01/1993, 07/12/1993 (Emer.), 10/01/1993, 05/17/2001, 03/01/2005, 01/01/2008, 07/01/2009, 07/01/2017

TO BE RESCINDED

5160-13-01 **Service-based ambulatory health care clinics: general provisions.**

(A) Unless otherwise noted, any limitations or requirements specified in the Revised Code or in agency 5160 of the Administrative Code apply to services addressed in this rule.

(B) Definitions.

(1) "Clinic" is an entity that meets all of the following criteria:

(a) It renders clinic services on an outpatient basis under the direction of a physician or dentist. Clinic services are defined in 42 CFR 440.90 (October 1, 2016).

(b) It operates from a fixed location, a specifically designed mobile unit, or both.

(c) It is freestanding—administratively, organizationally, and financially independent of an institution such as a hospital or long-term care facility. It may be physically located in a hospital or long-term care facility so long as it remains independent.

(d) It does not provide overnight accommodations.

(2) "Service-based ambulatory health care clinic" is a clinic to which medicaid makes separate payment for each service or item provided. Policies governing cost-based clinics (federally qualified health centers, rural health clinics, and outpatient health facilities—to which medicaid makes payment on the basis of a visit or encounter) are set forth in Chapter 5160-28 of the Administrative Code.

(C) The following entities may enroll in medicaid as a service-based ambulatory health care clinic:

(1) An end-stage renal disease (ESRD) dialysis clinic, defined in 42 C.F.R. 494.10 (October 1, 2016), that meets the following criteria:

(a) It is certified by medicare as a dialysis facility;

(b) It is licensed by the Ohio department of health in accordance with Chapter 3701-83 of the Administrative Code or, if it is located outside of Ohio, is licensed by its respective state's authority; and

(c) It provides services in accordance with rule 5160-13-02 of the Administrative Code;

(2) A family planning clinic that meets the following criteria:

(a) It is a public or nonprofit organization;

(b) It complies with federal guidelines set forth in 42 U.S.C. 300 (as in effect October 1, 2016);

(c) It receives funding for pregnancy prevention services through Title X of the Public Health Services Act; and

(d) It provides pregnancy prevention services in accordance with Chapter 5160-21 of the Administrative Code;

(3) An outpatient rehabilitation clinic that delivers rehabilitation services at a medicare-certified rehabilitation agency, defined in 42 C.F.R. 485.703 (October 1, 2016), or at a medicare certified comprehensive outpatient rehabilitation facility (CORF), defined in 42 C.F.R. 485.51 (October 1, 2016);

(4) A primary care clinic that meets either of the following criteria:

(a) It receives state or federal grant funds for the provision of health services; or

(b) It provides primary care services by virtue of certification or accreditation by one of the following entities:

(i) The joint commission;

(ii) The accreditation association for ambulatory health care (AAAHC);

(iii) The healthcare facilities accreditation program of the American osteopathic association (AOA); or

(iv) The community health accreditation program (CHAP);

(5) A professional dental school clinic associated with an accredited dental school;

(6) A professional optometry school clinic associated with an accredited optometry school;

(7) A public health department clinic that meets the following criteria:

(a) It has legal status as local health department created by a city health district, general health district, or combined health district in accordance with Chapter 3709. of the Revised Code; and

(b) It meets the standards set forth in section 3701.342 of the Revised Code; or

(8) A speech-language-audiology clinic that specializes in and provides speech, language, or audiology services delivered by professionals who have been certified by the American speech-language-hearing association (ASHA).

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

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