Ohio | Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

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

Update of Provider Revalidation Rule

Rule Number(s): 5160-1-17.4

Date of Submission for CSI Review: 10/13/2020

Public Comment Period End Date: 10/20/2020

Rule Type/Number of Rules:

New/__ rules

No Change/____ rules (FYR? ___)

Amended/_1_ rules (FYR? _Yes_)

Rescinded/__ rules (FYR?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.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   OAC rule 5160-1-17.4, entitled "Revalidation of provider agreements," is being proposed for amendment to extend flexibilities to address the pandemic as well as to create options to reduce costs for the department. The rule sets forth substantive and procedural policies for how and when a provider will revalidate its provider agreement with the department and the consequences for failure to revalidate in a timely manner. This rule also addresses how a delay by a governmental entity impacts a revalidation application, the effective date of the new provider agreement, hearing rights and on-site reviews.

   This rule provides the process ODM follows when notifying providers that revalidation is required, identifies the methods in which the provider will be contacted and what type of information will be included in the notice. This rule requires the provider to submit all required information and any applicable fees before the revalidation deadline specified in the notice. This rule prohibits providers from revalidating their agreement prior to receiving a revalidation notice and confirms the reporting of changes is the provider's responsibility and does not constitute the initiation of revalidation.

This rule addresses the potential penalties when the provider fails to revalidate or does not revalidate in a timely manner. This rule describes circumstances under which providers may continue operating under an expired provider agreement, and the impact of not timely obtaining renewal of licensure, certification, accreditation or registration due to delay in processing renewals by another government entity.

Related topics such as how agreement effective dates are determined, provider hearing rights afforded, and on-site reviews of providers are addressed in this rule.

Specifically, this rule states that for providers whose professional license or certification expires less than five years from the effective date of its provider agreement, the provider agreement must be revalidated prior to the expiration of the license or certification. This rule requires provider agreements to be revalidated when the risk level of a provider changes, if a provider's license or certification expires less than five years from the effective date of the provider agreement, or no later than five years from the effective date of the most current provider agreement.

The changes to this rule are to allow for the Centers for Medicare and Medicaid Services (CMS) to waive or modify the federally mandated timeline for revalidation of provider agreements such as during a state of emergency. Language concerning revalidation timeframes related to licensure and certification was removed due to no longer being applicable. Also, the requirement that the department send the notices of an upcoming revalidation by regular mail was expanded to also allow the notification to occur via email as well as updating an outdated reference to the CFR.

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.**

   Sections 5164.02 and 5164.32 of the Ohio Revised Code authorize the adoption of the rule. Sections 5162.03, 5164.02, and 5164.32 of the Ohio Revised Code are the statutes that amplify that authority.

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.

   This rule implement federal requirements.

   Provider agreement revalidation as addressed in proposed rule 5160-1-17.4 is a requirement applied to Medicaid providers by CMS under provisions set forth in 42 C.F.R. 455.414.

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

   The federal requirement for revalidation of provider agreements is at least every five years. For providers that are deemed a higher fraud risk by our screening, ODM requires revalidation sooner than five years in order to ensure these providers that are at higher risk of fraudulent behavior or at risk of not being qualified to perform the medical services are screened to ensure the safety of the recipients and protect the taxpayer investment into the program from fraud.

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 proposed rule is necessary to implement federal requirements concerning revalidation of provider enrollment as described in 42 C.F.R. 455.414. The implementation of this rule is important in ensuring patient safety and program integrity. The public purpose of this rule is to communicate to providers and the public how ODM implements this federal requirement.

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

   This rule will be determined successful as providers are revalidated in accordance with state and federal laws.

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.
   The proposed rules are not being submitted pursuant to the listed ORC sections.

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.

   This rule was sent out for stakeholder comment on August 3, 2020 through August 7, 2020. Provisions of this rule are designed to address issues related to the COVID pandemic, which led to a truncated feedback period.

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

The only input received was from the Government Policy Group and their organization requested that revalidation notices be sent by both email and regular mail. The department explained that at this time we are transitioning to utilizing the lower cost electronic notification options due to budgetary concerns.

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?

No scientific data was necessary to develop this Medicaid policy.

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?

No other alternative regulations were considered. ODM considers administrative rules the most appropriate method of regulating the processes outlined in these rules.

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.***

ODM did not specifically consider a performance-based regulation because this rule implements federal requirements and is not performance-based.

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

This rule was thoroughly reviewed by ODM staff to ensure it does not duplicate an existing Ohio regulation.

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 requirements of this rule are already in place and will continue to be implemented as they are today through ODM's provider enrollment department and in the Medicaid Information Technology System (MITS) where provider revalidation applications are

processed. The ability to deliver provider revalidation notices via email is a feature of the new provider module system that will be implemented next year.

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 impacted business community includes any individual or organization who applies to become an Ohio Medicaid provider or currently holds an Ohio Medicaid provider agreement.

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

The nature of the adverse impact for this rule is primarily administrative in employee time but may also be monetary in nature.

Rule 5160-1-17.4 requires Ohio Medicaid providers to renew and revalidate its provider agreement every five years or sooner when certain circumstances apply. This rule requires provider agreements to be revalidated when the risk level of a provider changes, or no later than five years from the effective date of the most current provider agreement barring a waiver or modification by CMS.

This rule requires the provider to meet all conditions for participation as an eligible provider and submit all required information and pay the application fee, if applicable, before the revalidation deadline specified in the notice.

For providers who fail to timely or properly revalidate, this rule indicates what actions ODM may take including denying the revalidation application and-terminating the provider agreement.

This rule requires providers to disclose any changes to its existing provider agreement in accordance with Administrative Code rule 5160-1-17.3.

As part of the revalidation process, providers may be subject to an on-site review at the provider's facility, place of business, or both, as ODM deems necessary to ensure program integrity.

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.

This rule requires provider agreements to be revalidated when the risk level of a provider changes or no later than five years from the effective date of the most current provider agreement barring waiver or modification by CMS.

This rule requires the provider to meet all conditions for participation as an eligible provider and submit all required information and any applicable fees before the revalidation deadline specified in the notice.

The information, documentation, and fees required in the revalidation process will vary based on provider type and whether it is for an individual provider, group practice or a facility-based provider. Individual providers are not subject to an application fee while institutional and group providers are required to pay a $595 application fee. This fee may be waived if certain exemptions apply and the required documentation of evidence is provided. The reporting of the re-enrollment information may require the individual or staff to gather necessary documentation to be reported and submitted with the re-enrollment application.

According to the Bureau of Labor Statistics, the average salary (with fringe benefits) for a First-Line Supervisor of a Physician's Office is $57,240. Based on this figure, the estimated ten (10) minutes it takes to complete the revalidation application, report information, or provide documentation would cost the provider approximately $4.59 to revalidate the provider agreement. This cost would be incurred once during a period not to exceed every five (5) years unless the provider has changes to report before the next revalidation period.

For providers who fail to timely and properly revalidate, this rule indicates what actions ODM may take including denying the re-enrollment application and terminating the provider agreement. The cost of this sanction will vary by provider. It will depend on the number of Medicaid recipients being served in the facility as the facility will no longer be eligible to receive reimbursement from ODM for services provided to Medicaid recipients.

This rule requires providers to disclose any changes to its existing provider agreement in accordance with Administrative Code rule 5160-1-17.3. The reporting of changes that occur to an existing provider agreement may result in additional administrative

costs that will vary based on the provider type and required changes. The costs will be determined by the amount of time required to disclose the changes and the hourly rate of the disclosing employee.

As part of the revalidation process, providers may be subject to an on-site review at the provider's facility, place of business, or both, as ODM deems necessary to ensure program integrity.

The provider may experience additional administrative costs in this case. These costs may include staff time required to prepare for on-site review and staff time lost if the reviewer requires a provider representative to be present or available during the review to answer the reviewer's questions and provide information needed for the review. The exact cost cannot be quantified because it will vary greatly depending on the circumstances of the on-site review but will include the time to gather and provide the information requested, the time to complete the review and the personnel required to assist.

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

The regulatory intent of this rule is justified by the benefit to Medicaid covered individuals in protecting their safety, and protecting the integrity of the Medicaid program by ensuring compliance with federal requirements related to provider revalidation.

Regulatory Flexibility

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

There are no alternate means of compliance because these regulations apply to all provider types enrolled in Medicaid. No exception can be made on the basis of the provider group or agency 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?

ORC 119.14 does not apply. This rule does not impose fines and penalties for paperwork violations and first-time offenders.

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

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

5160-1-17.4 **Revalidation of provider agreements.**

(A) Revalidation is the process that a provider is required to follow to renew and revalidate its provider agreement. Provider agreements must be revalidated no later than five years from the effective date of the original or the last revalidated provider agreement, whichever is applicable, unless the centers for medicare and medicaid services (CMS) waives or modifies the deadline. In the event CMS waives or modifies the deadline, provider agreements will be revalidated pursuant to the CMS waiver or modification. ~~If a provider's license or certification from its licensing board expires less than five years from the effective date of its provider agreement, the provider agreement must be revalidated prior to the expiration of the license or certification.~~ Provider agreements must also be revalidated whenever there is a change in risk pursuant to 42 C.F.R. 455.450 (as in effect ~~May 29, 2018~~October 1, 2020) The revalidation process is as follows:

(1) The Ohio department of medicaid (ODM) shall send a revalidation notice ~~by regular mail~~ ninety days prior to the expiration date of the provider's time-limited agreement either to the provider's email or mailing address on file notifying the provider that it is required to revalidate its agreement.

(2) The revalidation notice shall instruct the provider what is required to complete the revalidation process. Providers are expected to meet all conditions for participation as an eligible provider that are in effect in Chapter 5160-1 of the Administrative Code at the time of revalidation.

(3) The provider shall submit all required information before the revalidation deadline date specified in the revalidation notice including the required fee as specified in rule 5160-1-17.8 of the Administrative Code.

(4) A provider shall not initiate revalidation prior to the receipt of the revalidation notification sent by ODM. This rule does not negate the requirement that a provider must properly disclose any changes to its provider agreement in accordance with rule 5160-1-17.3 of the Administrative Code. The reporting of changes does not constitute the initiation of revalidation and remains the provider's responsibility.

(5) When a provider fails to revalidate in the time and the manner required by ODM, as specified in this rule and in accordance with the revalidation notice referred to in paragraph (A)(1) of this rule, ODM shall deny an application for revalidation and terminate the time-limited provider agreement. The denial and termination will take effect thirty days after ODM mails a written notice to the provider by regular mail to the address on file notifying the provider of the decision. ODM shall specify in the notice the date on which the provider is required to cease operating under a terminated provider agreement.

(6) If a provider files an application for revalidation within the time and in the manner required, as specified in this rule, but the provider agreement expires before ODM acts on the application or before the effective date of the ODM decision on the application, the provider may continue operating under the terms of the expired agreement until the effective date of the ODM decision.

(7) If a provider files an application for revalidation within the time and in the manner required, as specified in this rule, but has not been able to obtain a renewal of its licensure, certification, accreditation, or registration the application may be accepted and processed by ODM as long as the granting official, board, commission, department, division, bureau, or other agency of state or federal government considers the provider in good standing and that its licensure, certification, accreditation, or registration is still active.

(B) The effective date of a new provider agreement is the date on which the provider signs the application and meets all of the federal and state requirements for participation in the medicaid program. The effective date of a new provider agreement may be made retroactive for up to twelve months prior to the date of application if the provider was properly licensed or certified.

(C) Pursuant to section 5164.38 of the Revised Code, ODM is not required to afford hearing rights, in accordance with Chapter 119. of the Revised Code when terminating a time-limited provider agreement due to the provider's failure to properly file an application for revalidation.

(D) In processing an application for revalidation, ODM reserves the right to conduct an on-site review at the provider's facility, place of business, or both, as ODM deems necessary to ensure program integrity.