



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

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

Rule Contact Name and Contact Information: Tommi Potter

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

Health Care Isolation Centers.

Rule Number(s): 5160-3-80

Date of Submission for CSI Review: 9/22/20

Public Comment Period End Date: 9/29/20

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ rules (FYR?)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.

Rule 5160-3-80, entitled Health Care Isolation Centers (HCIC)s, is being proposed for adoption to establish the HCIC service in the Medicaid program. The HCIC service will meet the unique need for isolation and quarantine services as a result of the COVID-19 pandemic. This rule establishes provider qualifications, obligations and staffing for HCICs, establishes isolation, medication and supplies requirements, defines utilization criteria, provides for oversight and closure of HCICs, and defines Medicaid reimbursement for services provided in HCICs..

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.**

The rule is authorized by Ohio Revised Code section 5164.02.

The rule amplifies Section 14 of Amended Substitute House Bill 197 of the 133rd General Assembly.

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- 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.

No.

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

The regulation does not implement a federal requirement. The service falls within federal requirements for nursing facility services and was created to provide services for individuals who require quarantine or isolation due to COVID-19.

- 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)?**

The COVID-19 pandemic has created a unique need for isolation and quarantine services in Ohio's nursing facilities. The HCICs are able to meet that need, lessening the demand for hospital beds. They also are an important resource for nursing homes and assisted living facilities that do not have the capacity to safely meet the needs of their residents who have been exposed to or diagnosed with COVID-19.

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

In order to monitor the success of this regulation, ODM will monitor the number of HCIC beds that are available in Ohio and the utilization of those beds. In addition, hospital utilization will be monitored to ensure HCICs as a tool to ensure sufficient hospital capacity throughout the pandemic.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

No

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Development of the Regulation

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

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The HCIC service and related regulation were developed with input from the long term care industry. Meetings included the Ohio Health Care Association, The Ohio Academy of Senior Health Sciences, Leading Age Ohio, the Ohio Assisted Living Association and the Ohio Council for Home Care and Hospice. In addition, webinars for the nursing home providers were held.

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

Stakeholders reviewed draft materials during the creation of the HCIC service and provided feedback on that draft. This feedback led to changes in requirements and helped inform the development of the Medicaid rates and reimbursement levels.

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?

Information from the Centers for Disease Control was used to help develop standards of care in health care isolation centers.

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?

None.

Existing nursing home policy was not developed to respond to a pandemic and did not support creation of specialized units to provide quarantine and isolation services, especially in light of the significant clinical needs of some individuals with COVID-19. Administrative alternatives to regulations did not provide clear direction and certainty required by nursing facilities who might choose to become HCICs.

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.*

A performance-based regulation was determined to not be appropriate in this instance. The Ohio Department of Medicaid, in collaboration with the Ohio Department of Health, determined that a consistent standard of care in HCICs was an important element in assuring quality care for individuals who need quarantine or isolation services.

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

Existing regulations addressing Medicaid nursing facility services were reviewed.

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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 rule implementing HCICs will be published on the Ohio Department of Medicaid COVID-19 web page and distributed to the Ohio Health Care Association, Leading Age Ohio, the Academy of Senior Health Sciences, and the Ohio Assisted Living Association.

Applications for HCIC status are reviewed by the Ohio Department of Health and approved by Medicaid. The HCICs are subject to the same oversight that applies to all nursing facilities in the state of Ohio.

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

There are approximately 950 nursing facilities in Ohio that participate in the Ohio Medicaid program. They are all eligible to apply but can choose not to participate in the HCIC program.

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

Nursing facilities who would like to be designated as HCICs must submit a letter from the Hospital Zone Lead documenting the need for the HCIC capacity.

HCICs, like all nursing facilities are subject to state licensure and federal certification requirements. In addition, HCICs are required to meet staffing and other requirements specific to the services being provided.

Operators of HCICs may incur additional costs related to staffing, personal protective equipment, and infection control.

b. Quantify the expected adverse impact from the regulation.

The facility will spend approximately one hour to obtain the letter documenting the need for HCIC capacity from the Hospital Zone Lead. This time may vary depending on individual circumstances surrounding the facility’s application and the zone leadership.

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The cost of complying with state licensure and federal certification requirements varies depending on facility characteristics, including patient acuity, the physical plant, the business model, and number of beds. Those costs include costs related to the physical plant, staffing, food and supplies, utilities, administrative costs and other operating costs. We are unable to calculate an estimated cost given the potential for wide variation among facilities.

Costs per patient day that exceed those of a NF not offering these services may include additional staff costs, additional equipment costs and additional expenditures for personal protective equipment. These costs will vary widely by facility based on the type of service provided, the number of beds included in the HCIC unit, other facility characteristics and the acuity of the individuals served. As a result, we are unable to estimate a cost of to a facility.

It is important to note that the Department of Medicaid has established rates that reflect the additional costs that may be incurred by the operator of an HCIC.

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

Quality care options for individuals in need of isolation or quarantine services due to COVID-19 present unique challenges that are substantially different from the routine operation of a nursing home. The application process is intended to ensure the quality of care provided in the approved HCIC units. The additional requirements related to providing HCIC services are directly related to the needs of individuals with COVID-19. It is important to note that the Department of Medicaid has established rates that reflect the additional costs that may be incurred by the operator of an HCIC.

Regulatory Flexibility

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

No. It is important that consistent standards of care are present in all HCICs to ensure the quality of services provided.

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?

N/A

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

A technical assistance lead has been identified for each hospital zone. Those individuals are available to provide technical assistance to nursing home operators during the application process, the operation of the facility and the closure of the HCIC unit.