



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

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

Rule Contact Name and Contact Information:

Selina Jackson, MPA 614-466-4792

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

Chapter 3701-12 Certificate of Need

Rule Number(s): 3701-12-04, 3701-12-08, 3701-12-09 Amend; 3701-12-23 New;

3701-12-23 New

Date of Submission for CSI Review: 12/10/2019

Public Comment Period End Date: 01/10/2020

Rule Type/Number of Rules:

New/ 1 rules

No Change/ 0 rules (FYR?)

Amended/ 3 rules (FYR? No)

Rescinded/ 1 rules (FYR? No)

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.**

The rules set forth in Chapter 3701-12 of the Ohio Administrative Code (“OAC”) establish the reviewability, application, approval and monitoring requirements for the Certificate of Need (“CON”) program. The CON program ensures the public access to quality long-term care services by requiring review and approval of activities involving the location and utilization of long-term care beds and services. Revisions have been made to the rules to incorporate recent changes to Chapter 3702. of the Ohio Revised Code that include, but are not limited to, requiring the Director of Health to issue a determination within 180 days of declaring an application complete, eliminates the right of an affected person to request an appeal and replaces it with the right to receive an administrative review, and reduces the number of days a person has to request a reviewability ruling from 30 to 14. The revisions set forth the requirements for both applicants and the Ohio Department of Health.

Revisions have been made to the following rules

3701-12-04 The rule sets forth the requirements pertaining to reviewability determinations. These requirements include, but are not limited to, the director issuing a reviewability determination within specified timeframes and any affected person may appeal a reviewability determination. Additionally, the rule allows for an expedited reviewability determination to be issued within thirty days of receipt by the director and that the date the director signs the reviewability ruling shall be the date of issuance. The rule has been revised to incorporate statutory changes to Chapter 3702. ORC that were included

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in HB 166 including removing the term affected person and clarifying that the person that requested a reviewability ruling may appeal the ruling to the director.

3701-12-08 The rule establishes the CON application and completeness process, public notice, review, decision process, and appeal requirements for all CON applications, except those CON applications filed under section 3702.593 ORC. The rule has been revised to incorporate statutory changes to Chapter 3702. ORC that were included in HB 166. These revisions include removing bed tracking numbers from the information that must be included with a CON application. The time frame an applicant has to respond to requests for additional information has been reduced from 90 to 30 days and increases the time the Director has to grant or deny a CON after issuing a notice of completeness for the application, from 30 to 45 days. Finally, the term “affected person” has been removed throughout the rule as a party that may request an appeal of a Director’s decision.

3701-12-09 The rule establishes the CON application and completeness process, public notice, review, decision process, and appeal requirements for CON applications, filed under ORC section 3702.593. The rule has been revised to establish the new review period for CON applications filed under section 3702.593. ORC as January 1, 2020 to December 31, 2023. Furthermore, new timelines for the submission of applications under comparative review have been incorporated throughout the rule and bed tracking numbers have been removed from the information that must be included with a CON application. Finally, the rule has been revised to require the Director to grant or deny a completed application for a CON no later than 60 days after the mailing of the notice of completeness or no later than November 30th in the year the application was received for applications under comparative review.

New Rule

3701-12-23 This new rule replaces the existing rule in accordance with Legislative Service Commission rule drafting requirements. This rule establishes the long-term care facilities and beds review criteria and the state and county bed need calculation formula as authorized by ORC section 3702.593. Additionally, the rule sets forth the requirements for comparative review of certain applications and the requirements for CON applications involving movement of beds within contiguous counties. Revisions have been made to replace the term “nursing home” with the term “long-term care facility” throughout the rule and to remove the term “skilled nursing beds” from the rule. Additional revisions remove restriction on the Director from granting CON applications involving facilities with more than 150 beds, remove requirements related to community resources associated with inter county transfer of beds, and remove requirements previously associated with the second phase of a four-year comparative review process. Finally, the detailed listing of conditions for denial of a CON application has been replaced with a citation to division (B) of section 3702.59 ORC and the bed need formula has been moved to the end of the rule to improve continuity and flow of information.

Rescinded Rule

3701-12-23 This rule is being rescinded in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule.

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- 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.**

Ohio Revised Code section 3702.51; 3702.52; 3702.57; 3702.59; 3702.592; 3702.593; 3702.60

- 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?**

No

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

Not applicable.

- 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)?**

As required by Revised Code Section 3702.52 OAC, the Chapter 12 rules provide the necessary framework for the CON program to ensure the public access to quality, long-term care services by requiring review and approval of activities involving long-term care beds. In the absence of a review process there would be no assurance of the equitable and efficient distribution of long-term care beds and facilities in each of Ohio's counties. The rigorous application and review process ensure that providers of long-term care services have adequately carried out a detailed due diligence program.

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

Successful outcomes for the CON rules are measured through the following criteria:

The majority of CON projects are completed in substantial accordance with the approved application; very rarely will an approved CON fail to meet its implementation goals or allow for the CON to expire.

The majority of approved CON projects meet established timeframes for the obligation of funds, commencement of construction, and the final completion and implementation of the activity, which in many cases facilitates the construction of new facilities' and the renovation of existing facilities within the established guidelines

- 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

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Development of the Regulation

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

Stakeholders were aware of and involved in the process of the revision of the authorizing statutes and include:

Webster & Associates

ROLF

Bricker & Eckler Attorneys at Law

Ohio Department of Medicaid

Ohio Health Care Association

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

Not applicable to these statutory changes.

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?

Not applicable.

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 to this specific rule were not considered. ODH is required by ORC section 3702.52 to administer a CON program. The reviewability determination, application, monitoring, and progress requirements established in Chapter 3701-12 establish the necessary framework for the efficient, equitable, and effective administration of the CON program and ensure that access to long-term care at appropriate levels is available in all Ohio counties.

13. Did the Agency specifically consider a performance-based regulation? Please explain.

Chapter 3701-12 establishes program and application requirements, not industry or provider standards, thus performance-based regulations are not deemed appropriate.

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

The agency conducted a thorough review of the Ohio Revised Code and Ohio Administrative Code to ensure there are no other regulations in place pertaining to these specific requirements.

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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 Certificate of Need program is a well-defined and administered application-based program with evidence-based formulas to ensure the consistent, efficient, and equitable application of standards to all CON applications and requests for reviewability determinations.

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

In general, and not dependent on the recommended changes, all individuals or organizations pursuing:

- The development of a new long-term care facility.
- The replacement of an existing long-term care facility.
- The renovation of or addition to a long-term care facility that involves a capital expenditure of \$2 million or more, not including expenditures for equipment.
- An increase in long-term care bed capacity.
- A relocation of long-term care beds from one site to another.
- Any failure to conduct a reviewable activity in substantial accordance with the approved application for which a Certificate of Need was granted, if the change is made during the period beginning with the approval of the application until five years after implementation.
- The expenditure of more than 110 percent of the maximum expenditure specified in an approved Certificate of Need application.

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

Application Fee:

For a project not involving capital expenditure:

☐ \$5000

For a project involving a capital expenditure:

☐ The greater of \$5000 or 1.5 percent of the capital expenditure proposed, with a maximum fee of \$20,000.

For each expedited review

- \$1000 for each expedited review

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Fines and Penalties:

Although not associated with the revisions, Section 3702.54, Ohio Revised Code, provides for the Director of Health to impose a civil money fine for carrying out a reviewable activity without receiving Certificate of Need approval and may refuse to accept for review any application for subsequent reviewable activities for one to three years. Fines are detailed as:

An amount equal to the greatest of the following:

- Three thousand dollars;
- Five per cent of the operating cost of the activity that constitutes the violation during the period of time it was conducted in violation of section 3702.53 of the Revised Code;
- If a certificate of need was granted, two per cent of the total approved capital cost associated with implementation of the activity for which the certificate of need was granted.
- Not to exceed two hundred fifty thousand dollars.
- Not exceed more than one hundred ten per cent of the maximum capital expenditure stated in the certificate.

A civil monetary penalty may be imposed upon a holder if the more than 110% of the maximum capital expenditure stated in the certificate is expended. The penalty imposed is equal to the amount of the application fee paid for the approved certificate of need plus an amount equal to the expenditure overrun above 110% of the maximum capital expenditure stated in the certificate multiplied by 0.015.

Time for compliance:

In general, the time necessary to prepare, submit, and provide any necessary follow-up information to the Certificate of Need Program (dependent upon the size and complexity of the project) continues to be an identified impact. Ample time is provided for an applicant to thoroughly explore the financial and operational feasibility of a proposed project.

The decreased timeframe from ninety to fourteen days for an applicant to respond to a request for additional information for an application under expedited review is necessary for the CON program to make a timely decision and can be avoided by the applicant if the applicant provides an application with the appropriate documentation and information necessary for CON staff to make a determination. The applicant may also choose to file a regular (non-expedited) application, which includes a longer response time (ninety days).

c. Quantify the expected adverse impact from the regulation.

A shortened timeframe from 90 to 30 days for response to a Director's request for additional information. The elimination of the right of an affected person to request an appeal and replaces it with the right to receive an administrative review and reduces the number of days a person has to request a reviewability ruling from 30 to 14.

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

ODH is required by Revised Code Section 3702.52 to administer a Certificate of Need program to ensure public access to quality long-term care services. The time, manpower, and costs associated with the certificate of need application process is deemed to be a justifiable impact as the review, approval, and monitoring of certificates of need ensures the availability of long-term care at appropriate levels across the state for Ohio's long-term care services consumers. ODH has no expectation that the demand for long-term care services in Ohio will decrease; to the contrary, as the life expectancy in the United States continues to average in the late 70s, the need for long-term care services is expected to increase, and thus the need for regulation will remain.

Regulatory Flexibility

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

There are no exemptions or alternative means of compliance for obtaining or maintaining a certificate of need, however ORC section 3702.522 provides for alternate methods of compliance in certain specific circumstances that are amplified in the rules.

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?

ODH's Regulatory Ombudsman has set forth a policy for ODH to follow regarding the waiver of fines and penalties for paperwork violations and first-time offenders. ODH implements this policy as part of its business process. Information regarding this policy can be found online at:

<https://odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/Office-of-General-Counsel/Statement-on-Paperwork-Violations/>

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

The requirements set forth in Chapter 3701-12 of the Ohio Administrative Code are applicable to all applicants seeking to build or renovate a long-term care facility and those who operate long-term care beds in Ohio. The Ohio Department of Health, Office of Health Assurance and Licensing, Certificate of Need program staff provide information and assistance to CON applicants. Information may be obtained via the ODH website at:

<https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/certificate-of-need/welcome-to>

CON staff routinely responds to inquiries and provides assistance and guidance to CON applicants during the CON application and review process.

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