



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Chapter 3701-12 Certificate of Need Program – No Change

Rule Number(s): 3701-12-01, 3701-12-05, 3701-12--10, 3701-12-11, 3701-12-12, 3701-12-18, 3701-12-19-20, 3701-12-23.2, 3701-12 -24

Date of Submission for CSI Review: 10-15-2020

Public Comment Period End Date: 11-15-2020

Rule Type/Number of Rules:

New/___ rules

No Change/ X___ rules (FYR? X__)

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Rescinded/___ rules (FYR?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.**

The Following rules re being filed with no changes:

3701-12-01- The rule sets forth the definitions utilized throughout the Chapter. Definitions include, but are not limited to, “affiliated person,” “long-term care facility,” and “existing bed” which provide clarification of the elements considered in a CON application.

3701-12-05 – The rule establishes which activities are reviewable under the CON process. Reviewable activities include, but are not limited to, construction of a new long-term care facility, relocation of long-term care beds, and renovations costing two million dollars or more.

3701-12-10 - The rule establishes the replacement CON requirements set forth in ORC section 3702.526, which include, but are not limited to, the source of the beds subject to CON must be the same as the original and the applicant must be the same as the original applicant or an affiliated or related person to the applicant of the original CON.

3701-12-11 – Sets forth the time frame in which affected persons may submit written comments during the course of a CON review at forty-five days for a regular application and twenty-one days for an expedited application.

3701-12-12 – The rule establishes the requirements for revised applications for a CON. Only a change in the site of the project may be considered as a revised application. The rule clarifies that minor changes to the project are not considered as a revised application.

3701-12-18 - This rule establishes the validity, follow-up, and withdrawal requirements for CONs. Capital expenditures are required to be obligated within twenty-four months, and the CON holder must

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commence construction, make reasonable progress, and not go over projected expenditures by more than 10 percent or be subject to a civil monetary penalty.

3701-12-19 - This rule establishes the monitoring requirements for certain activities determined to not be reviewable activities for the purposes of a CON. These activities are monitored to ensure that the project does not change or result in actions that would make those activities reviewable. The requested revision has been made to remove a duplicate word.

3701-12-20 - This rule establishes the general CON review criteria, which include, but are not limited to, cost effectiveness, the needs of the population being served, and the historical performance of the applicant and affiliated parties compliance with past CONs.

3701-12-23.2 – The rule sets forth the additional criteria the Director must consider for an application for a certificate of need to replace an existing long-term care facility or to relocate existing long-term care beds from one site to another.

3701-12-24 – The rule sets forth the requirements pertaining to the monitoring of hospital beds recategorized as skilled nursing beds.

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.

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 3702.52

Amplifies: 3702.51; 3702.511; 3702.52; 3702.521; 3702.522; 3702.523; 3702.524; 3702.525; 3702.526; 3702.527; 3702.53; 3702.531; 3702.54; 3702.55; 3702.56; 3702.57; 3702.59; 3702.592; 3702.593; 3702.594; 3702.60; 3702.62

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?

There are no federal requirements mandating this rule.

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

Not applicable to this rule.

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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 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 review 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?

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.

Initial e-mail notifications and a request for comments were sent to interested parties on October 13, 2020.

Leading Age Ohio
Ohio Health Care Association
Academy of Senior Health Sciences
Taft Law
Rolf Goffman Martin Lang, LLP
Bricker & Eckler, LLP
Benesch Attorneys at law
Dinsmore & Shohl, LLP
Webster & Associates Co., LPA
Ohio Department of Medicaid
Ohio Department of Aging

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The parties listed were additionally involved in the drafting of revisions to rules 3701-12-04, 3701-12-08, 3701-12-09, and 3701-12-23 which are currently awaiting an agency hearing and JCARR hearing.

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 No Change rules.

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 to these No Change 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 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.

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

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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

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 within 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.

Fines and Penalties:

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;

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- 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 expend 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:

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

c. Quantify the expected adverse impact from the regulation.

The simplification and clarification of the application process that result from the requested amendments, is expected to result in a decrease in the request for additional information from CON applicants, thereby reducing the applicant's administrative burden.

Application fee of \$5000 to \$20,000.

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. The amount of work required to provide a reviewability determination or to review a CON application is neither dependent upon nor indicative of the fee that is paid. Projects not involving capital expenditure are charged flat fee, while those involving capital expenditures are charged a minimum fee up to a \$20,000 maximum; yet the CON program staff must dedicate a consistent number of hours to reviewing all applications. As a result, there are often fluctuations in the revenues available each fiscal year.

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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 rule revisions.

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/ogc/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, Division of Quality Assurance, Certificate of Need program staff provides 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.