



Common Sense Initiative

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Business Impact Analysis

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

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

Chapter 3701-12 Certificate of Need (CON) Program

Rule Number(s): Amended: 3701-12-01, 3701-12-04 through 3701-12-05, 3701-12-08 through 3701-12-12, 3701-12-18 through 3701-12-20, 3701-12-23 through 3701-12-24

****MINOR CHANGES HIGHLIGHTED IN YELLOW BELOW****

Date of Submission for CSI Review: 2/26/2025

Public Comment Period End Date: 3/26/2025

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ X rules (FYR? X)

Rescinded/___ rules (FYR?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.

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.

Amended:

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.

Changes made:

- Clarified language, fixed grammatical errors, and updated code sections and language to match current statute.
- Removed (EE)(1) and (2) after stakeholder meeting as it was not deemed necessary and language was clarified.

3701-12-04 The rule establishes whether a particular proposed project is a reviewable activity and establishes timeframes for reviewability determinations. This rule also establishes guidelines for appealing the reviewability ruling to the director.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

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 four million dollars or more.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.
- Removed (A)(5) as a reviewable activity. The expenditure no longer needs to be more than one hundred ten percent of the maximum expenditure specified in a CON concerning long-term care beds.

3701-12-08 The rule establishes the CON application process, including the review and decision-making/appeals process subject to Revised Code. The rule also details the determination of completeness for applications.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-09 This rule clarifies the CON application and completeness process for applications filed under 3702.593 of the Revised Code, detailing the application requirements for timely filing and associated requirements, attachments, and fees for each applicant's form.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.
- Updated ORC codes and clarified language and updated references to other paragraphs or subsections.
- Updated the review period to two years instead of four years in paragraph (C) and (E) and the years from 2020 to 2026, and 2023 to 2028.
- Removed (D)(3) as it's no longer a consideration for comparative review.
- Removed "for certificates of need shall" in paragraph (C) to simplify language.
- Added "same" to indicate within the same year in paragraph (I)(4)(d) and (e).

3701-12-10 The rule details the replacement process for CON applications for applicant requests so that the reviewable activity for which the CON was granted can be implemented in a manner that is not in substantial accordance with the approved CON.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-11 This rule offers the opportunity for any affected person to submit written comments regarding a CON application and establishes guidelines for doing so.

Changes made:

- The rule has a revision to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-12 The rule details the revision process for applicants who have a CON application pending, noting the only revision that may be made is the site of the proposed project. The rule also notes that minor changes in the project are not considered to be revisions of the application.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-18 The rule establishes requirements for applicants to validate their CON application, including project implementation monitoring and obligating capital expenditures.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.
- Removed (A)(7) language to reflect ORC changes from HB 33.

3701-12-19 The rule details the monitoring of activities determined to be not reviewable activities by the director, listing the factors for consideration in determining activities that would require monitoring.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-20 This rule lists the criteria for CON review by the director in addition to 3702.51 and 3702.62 of ORC. Consideration is detailed, among other listed criteria, to include the relationship of the project to the long-rang plan of the applicant and the planning process employed, as well as the population served or proposed to be served.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-23 This rule lists the review considerations and criteria for CON by the director for long-term care facilities and beds and establishes the conditions for which applications propose an increase in beds through county relocation of beds. Consideration is also detailed in proposed projects based on proposed facility size being essential for the population served.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.
- (A)(6) language removed to reflect HB 33 changes.
- Updated paragraph letters so they match the current rules as well as updating codes.
- Updated paragraph (G) (1) through (5) to match current ORC 3702.593.
- Updated review process lengths from four years to two years throughout the rule.
- Updated “registration” and “registered” to “licensed” and “license” per the new hospital licensure Chapter 3701-22.
- Removed (M) as it’s not a part of ORC 3701.593.
- Reworded (J)(1)(c) to clarify language.
- Removed (L) as it’s already stated within (G)(4).
- In the new paragraph (L), updated the date from 2023 to 2025 to clarify timelines.

3701-12-23.2 This rule details the criteria in which a CON application would be approved by the director to replace an existing long-term care facility or to relocate long-term care beds between sites. The director will not approve the application unless all criteria under this rule are met.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-12-24 This rule details the director's monitoring of hospital beds that have been recategorized as skilled nursing beds and subsequent reporting of information to better assist and verify compliance with their approved CON application. The rule defines "skilled nursing bed", for the purpose of this rule, as a bed that was approved under former rule 3701-12-23.3 of OAC, effective 5/20/1991, that is in the portion of the hospital that participates in the program for health insurance for the aged and disabled established by Title XVIII of the SSA (1981), 42 U.S.C. 301, as amended.

Changes made:

- The rule has been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

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.

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.

There are federal requirements with respect to the care of the aged and disabled under Title XVIII of the SSA (1981), 42 U.S.C. 301 with respect to hospital bed monitoring.

4. 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.

No.

5. 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 Ohio Revised Code 3702, these rules provide the necessary state-based framework for the Department of Health to ensure the compliance and verification of CON applicants. The rules provide a means by which the Department of Health can review and monitor proposed plans to better ensure public access to long-term care services.

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

Successful outcomes are measured through the population served and the identification of projects and/or facilities that are out of compliance with ODH requirements.

7. 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.

No.

Development of the Regulation

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

A stakeholder meeting was held on January 17, 2025, with the stakeholders listed below. Changes were made to the drafts presented at the meeting based on the stakeholder's input.

Ohio Department of Medicaid
Ohio Department of Aging
Ohio Healthcare Association
LeadingAge
Ohio Ombudsman
Vancrest Healthcare Centers
ROLF Law
Plante Moran, PLLC
McDonald Hopkins, LLC
Taft Law
Dinsmore & Shohl LLP

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

The rules received a five-year review with few revisions. Stakeholders were contacted and input was received on a draft of all the rules that were sent to them before a virtual Teams meeting on January 17, 2025.

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 director will consider measures including proposed facility size, location, feasibility, and contractual obligations in determining CON applications as well as bed need.

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?

The Ohio Department of Health is required to administer CON program as mandated by sections 3702.51 through 3702.62 of the Revised Code.

13. 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 CON.

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.

CON applicants provide a self-attestation of compliance and are additionally required to inform and communicate with ODH on any updates or changes to their projects and programming.

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

Information required from applicants includes, among other criteria, a detailed description of the proposed project and fiscal reporting in determining compliance with CON rules.

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

- Rule 3701-12-08(E) Details that applications include a nonrefundable fee payable to the treasurer of the state of Ohio:
 - a. \$5000 for projects not involving a capital expenditure,
 - b. 1.5% of capital expenditure proposed, with a maximum fee of \$20,000,
 - c. For expedited review requests, an additional fee of \$1000.
- Rule 3701-12-08(G) \$100 application processing fee for applications not accepted.
- Rule 3701-12-09(B) If an application is not timely received, it will not be reviewed, and a \$100 application processing fee will be incurred.

- Rule 3701-12-10(E) Applications for replacement CON must include a non-refundable fee equal to the application fee paid for the approved CON.
- Rule 3701-12-12(D) Revised applications will be accompanied by an additional, non-refundable fee equal to twenty-five percent of the fee charged for the initial application.

16. Are there any proposed changes to the rules that will reduce 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*).

Regulatory restrictions have been removed in accordance with SB 9 of the 134th General Assembly.

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

ODH is required to implement section 3702. of the Ohio Revised Code by establishing safety and quality of care standards for applicants of CON.

Regulatory Flexibility

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

N/A

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 respond to inquiries and provides assistance and guidance to CON applicants during the CON application and review process.