

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Chapter 3701-12 Certificate of Need Program

Rule Number(s): 3701-12-01 through 3701-12-24

Date: April 27, 2015

Rule Type:

☒ New

☐ X5-Year Review

☒ Amended

☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulations 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. The revisions detailed below have been made to incorporate statutory requirements from H.B. 483 (2014) and to provide clarification of CON processes and procedures:

Revisions have been made to the following rules

3701-12-01- The rule sets forth the definitions utilized throughout the Chapter. Revisions have been made throughout to incorporate dates for citations to federal code in compliance with Legislative Service Commission rule drafting requirements. Additionally, the definition of

“affiliated person” has been revised to replace the term ‘person transferring a certificate of need’ to ‘holder of a certificate of need’.

3701-12-05 – The rule establishes which activities are reviewable under the CON process. Revisions have been made to paragraph (A) as it relates to ‘substantial accordance’, bed capacity, and site in accordance with statutory revisions to section 3702.511 of the Revised Code (HB 483).

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 ORC section 3702.593. Revisions have been made to remove the public notice publication requirements of paragraph (M) and the Director’s consideration of failure to publish this notice in paragraph (N) due to changes in industry standards and technology. Publication in newspaper media is no longer a primary means of providing notice to the public; the public is more likely to rely on alternative media sources, such as the internet, to obtain information or notice. The publication requirement is not statutory and the revision will result in a cost savings to applicant.

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. Revisions have been made to remove the public notice publication requirements of paragraph (M) and the Director’s consideration of failure to publish this notice in paragraph (N) due to changes in industry standards and technology. Publication in newspaper media is no longer a primary means of providing notice to the public; the public is more likely to rely on alternative media sources, such as the internet, to obtain information or notice. The publication requirement is not statutory and the revision will result in a cost savings to applicant.

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. Revisions have been made to incorporate statutory revisions to section 3702.526 (HB483).

3701-12-11 - Rescission of existing rule due to Legislative Service Commission rule drafting requirements.

New rule 3701-12-11 increases the time frame in which affected persons may submit written comments during the course of a CON review from thirty to forty five days in accordance with revisions to section 3702.52 (HB483).

3701-12-18 - This rule establishes the validity, follow-up, and withdrawal requirements for CONs. Revisions have been made to incorporate current program practices pertaining to civil monetary penalties imposed for a CON exceeding the maximum capital expenditure cap of 110%. 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. The revisions require notification to the holder of the CON of their hearing right under Chapter 119. of the Revised Code and their option to pay the invoiced penalty in lieu of a hearing.

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. General formatting revisions have been made in compliance with Legislative Service Commission rule drafting requirements.

3701-12-23 - 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. The requested revision has been made to modify the review criteria for long-term care beds in accordance with statutory changes to section 3702.511 of the Revised Code (HB 483) and to remove a less than fifty bed restriction from the CON consideration and from the comparative review criteria for the awarding of points. This revision is the result of industry trends.

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. The requested revision has been made to remove outdated terminology.

3701-12-24 – The rule sets forth the requirements pertaining to the monitoring of hospital beds recategorized as skilled nursing beds. The requested revision has been made to insert appropriate punctuation into a citation.

The following rule is being filed without changes

3701-12-04 – The rule sets forth the requirements pertaining to reviewability review determinations.

2. Please list the Ohio statute authorizing the Agency to adopt these regulations.

Ohio Revised Code section 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

3. Do the regulations implement a federal requirement? Are the proposed regulations 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.

4. 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.

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 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 ensures that providers of long-term care services have adequately carried out a detailed due diligence program.

6. How will the Agency measure the success of these regulations 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.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulations.

Initial e-mail notifications and a request for informal comments were sent to interested parties on January 26, 2015.

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

A stakeholders meeting was conducted on March 4, 2015 and additional confirmation of changes made to the draft rules regarding the removal of the 50 bed language in rule 3701-12-23 was received April 17, 2015.

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

Several minor grammatical and formatting revisions were made as a result of the comments received during the stakeholder meeting as well as the reconsideration of the Department's recommendation pertain to response times for applicants during the application review period, which resulted in maintaining the current standards.

9. 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 this rule.

10. 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.

11. Did the Agency specifically consider performance-based regulations? Please explain.

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

12. What measures did the Agency take to ensure that these regulations do 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.

13. Please describe the Agency's plan for implementation of these regulations, including any measures to ensure that the regulations are 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

14. Provide a summary of the estimated cost of compliance with these rules. Specifically, please do the following:

a. Identify the scope of the impacted business community:

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 the adverse impact (e.g., license 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;
- 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.

15. 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. Following is a listing of CON revenues and expenditures by year for the past five years:

Revenue/ Expenditures by fiscal year:

<u>2014</u>	\$642,234	\$434,104
<u>2013</u>	\$680,492	\$475,266
<u>2012</u>	\$377,311	\$686,589
<u>2011</u>	\$744,001	\$855,474
<u>2010</u>	\$834,576	\$776,327

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. The past two years have seen a decrease in program expenditures due to loss of staff.

Regulatory Flexibility

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

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.

17. 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: <http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx>.

18. 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:

<http://www.odh.ohio.gov/odhprograms/dspc/certn/certneed1.aspx>

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