

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): 3701-12-04, 3701-12-08, 3701-12-09, 3701-12-11, and 3701-12-18

Date: December 11, 2018

Rule Type:

☒ New

☐ 5-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☒ Rescinded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. Revisions have been made to the rules to incorporate recent changes to Section 3702.52 of the Ohio Revised Code that were included in House Bill 49 as well as a change to Section 3702.511 from House Bill 470 in March of this year. The new statutory language requires the implementation of an expedited process for reviewability determinations and certificate of need applications. The revisions set forth the requirements for both applicants and the Ohio Department of Health.

Revisions have been made to the following rules

3701-12-05 The rule establishes the scope of review for certificate of need projects by detailing what is and what is not a reviewable activity. The rule has been revised to include revisions to section 3702.511 that were included in HB 470 of the 131st General Assembly in March 2017. This revision adds to the list of reviewable activities the failure to conduct a reviewable activity in substantial accordance with the approved application for which a certificate of need was granted, including a change in the site, if the failure occurs from the time the application is approved until five years after implementation of the reviewable activity for which the certificate was granted.

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. The rule has been revised to incorporate the statutory changes to section 3702.52 of the Revised Code that were included in HB 49. These revisions include requiring an applicant to submit a letter expressly requesting an expedited review in addition to the information already required of paragraph (D). Paragraph (H) has been revised to require applicants who have requested an expedited review to provide a response to a director's request for additional information within fourteen days from the date of the letter. Revisions also include the incorporation of a fourteen day timeframe for the director's determination of completeness for expedited reviews and that the notice of completeness for an expedited review must be granted or denied by the director within thirty days. Finally, paragraph (E) has been revised to include an additional fee of \$1000 for each request for an expedited review.

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 include required dates for citations to federal code.

3701-12-18 This rule establishes the validity, follow-up, and withdrawal requirements for CONs. The rule is being revised to incorporate the statutory changes to section 3702.52 of the Revised Code that were included in HB 49 that a reviewable activity shall not be determined to not be in substantial accordance with a certificate of need solely because of a decrease in bed capacity or a change in the owner or operator of the facility unless any of the circumstances specified in (B) of section 3702.59 of the Revised Code apply to the new owner or operator.

New Rule

3701-12-04 This new rule replaces the existing rule in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule. 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. The rule has been revised to incorporate the statutory changes to section 3702.52 of the Revised Code that were included in HB 49. These revisions include the allowance 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.

3701-12-11 This new rule replaces the existing rule in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule. The rule establishes the timeframes in which affected persons can file written comments during the course of a CON review. The rule has been revised to require written comments on an

application that is under an expedited review, to be submitted within 21 days after the application has been accepted for processing by the director. This revision will allow for the consideration of comments and meet the expedited review timelines set in statute.

Rescinded Rule

3701-12-04 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.

3701-12-11 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.

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 these rules.

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, 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 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.

A draft version of the rules was sent to identified stakeholders on August 29, 2017.

Webster & Associates
The Academy of Senior Health Sciences
Benesch Attorneys at law
ROLF
Ohio Long-term Care Ombudsman
Ohio Department of Aging
Bricker & Eckler Attorneys at Law
Ohio Department of Medicaid
Ohio Health Care Association

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

Minor changes were made to the draft rules as a result of comments. These changes were specific to including an express statement that an expedited reviewability determination is being requested by an applicant.

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:

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 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.

For each expedited review

- \$1000 for each expedited review

Fines and Penalties:

Although not associated with the recommended change, 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 of fourteen days for response to a Director's request for additional information for an application under expedited review.

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.

No fees are currently charged for reviewability ruling requests and no fees will be charged for an expedited reviewability ruling request. CON application fees remain unchanged. The CON application review process is set forth in law and mandates the review of specific aspects of the proposed project prior to the Director rendering a decision. The law also mandates a period of monitoring for CON review activity following a decision. The law requires the collection of follow-up documents relating to the project until a point in time when the applicant implements the project. At this point, the CON project is "closed" (although the law also requires an additional 5 year "monitoring" period to ensure substantial accordance with the approved project). CON reviewers are responsible for reviewing their assigned applications and making a recommendation to the Director. Once a decision is rendered on the application, the CON reviewer is then responsible for the collection of documents relating to that project. This post-decision collection process often occurs over a span of several years as CON projects are generally completed over several years.

The proposed fee amount of \$1000 for each expedited review is being requested to accommodate the potential for increased workloads of current staff. In the event that multiple expedited reviews are received by the CON program, comprised of only two staff reviewers, it is more likely than not, that work schedules will require overtime accommodations to complete the work in the required timeframes.

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 has set forth a policy for ODH 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/regulatory.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, 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:

<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.