

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 10, 2013

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☐ Rescinded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. In accordance with statutory changes in H.B. 487, the Ohio Department of Health ("ODH") has drafted revisions to the rules as follows:

3701-12-01- Rescission of existing rule due to Legislative Service Commission rule drafting requirements.

New rule 3701-12-01 removes and replaces all definitions and references to health care facilities with long-term care facilities as CON requirements pertain to only long-term care facilities and beds therein. The rule also establishes a new definition for a "long-term care bed" consistent with

section 3702.51 of the Ohio Revised Code (“ORC”) and adds several new definitions, including “primary service area” and “existing bed” consistent with changes to ORC section 3702.51 with the enactment of H.B. 487.

3701-12-04 – The requested amendments remove all reference to “nonreviewability determinations to be consistent with statutory language pertaining to such definition in ORC section 3702. with the enactment of House Bill 487. Currently, only a determination on whether a project is reviewable under CON criteria is required. Additionally, the appeals language is being amended to be consistent with ORC section 3702.60.

3701-12-05 – The requested amendments will remove all reference to “nonreviewable activities” based on the aforementioned statutory rescission. Amendments further clarify which activities are not subject to review under CON requirements. Additionally, paragraphs pertaining to medical equipment, references to health care facilities and services, and accrediting organizations are being removed as these components are no longer subject to any review requirements.

3701-12-08 - Rescission of existing rule due to Legislative Service Commission rule drafting requirements.

New rule 3701-12-08 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 new rule condenses, simplifies and clarifies the CON application processes and procedures previously set forth in existing rules 3701-12-08 and 3701-12-09. In order to provide clarity, the comparative review requirements specific to CON applications under section 3702.593 that were previously part of this rule, are being addressed independently in new rule 3701-12-09. A new requirement is being requested to the information required on a CON application; applicants will be required to include the “bed tracking number” associated with each bed included in a CON application. This number will be assigned by the Department of Health to each long-term care bed at the start of the application process and will be made available to all licensed providers. Bed tracking numbers will enable the Department to account for the specific location and history of long-term care beds.

In order to improve the sustainability of the fee supported CON program, fee increases are being requested as follows:

- For a project not involving capital expenditure, from current fee of \$3000 to \$5000; and
- For a project involving a capital expenditure, from current the greater of \$3000 or 0.9 percent of the capital expenditure proposed, with a maximum fee of \$20,000; to the greater of \$5000 or 1.5 percent of the capital expenditure proposed, with a maximum fee of \$20,000.

3701-12-09 - Rescission of existing rule due to Legislative Service Commission rule drafting requirements.

New rule 3701-12-09 establishes the CON application and completeness process, public notice, review, decision process, and appeal requirements for CON applications, filed under ORC section 3702.593. This condenses, simplifies, and clarifies the CON application processes and procedures previously set forth in existing rules 3701-12-08 and 3701-12-09 for applications filed under ORC 3702.593 ORC. A new requirement is being requested to the information required on a CON

application; applicants will be required to include the “bed tracking number” associated with each long-term care bed included in a CON application. This number will be assigned by the Department of Health to each long-term care bed as described above with the authority granted by ORC section 3702.593 to relocate long-term care beds across county lines and the specific requirements for doing so. A separate rule is deemed necessary to fully clarify and amplify those requirements. The relocation of long-term care beds is authorized only in four year cycles and the application process contains unique components which are addressed in this rule.

3701-12-10 - This new 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. The ability to file a replacement CON application allows a degree of flexibility for a provider to carry out an approved activity in an alternate manner.

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

New rule 3701-12-11 allows affected persons the opportunity to submit written comments during the course of a CON review to the Director for consideration. This new rule is the result of the removal of statutory requirements in section 3702.52 ORC with the enactment of H.B. 487, which previously required public informational hearings and adjudication hearings for written objections as set forth in existing rules 3701-12-11 and 3701-12-12.

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

New rule 3701-12-12 establishes the conditions under which a revised application for a CON may be filed as authorized by ORC section 3702.522. ORC section 3702.522 only authorizes a revision to a CON application for the proposed site location and this request must be made prior to the mailing of a notice of completeness and include a non-refundable fee of twenty-five percent of the original fee. The enactment of ORC section 3702.522 allows for a CON applicant the opportunity to seek an alternate site for the development of a proposed project under certain conditions. The new rule clarifies those conditions and provides guidance for an applicant to adhere to filing requirements.

3701-12-18 - This rule establishes the validity, follow-up, and withdrawal requirements for CONs. The requested amendments are being made to provide clarification of the definitions of “commence construction” and “to obligate” as they pertain to CON projects and to correspond to information provided in CON application materials. The amplified requirements contained in this rule are consistent with program requirements that have been in place for a number of years that are designed to expedite the development of a CON project once the application has been approved and a need for the activity has been established in the review process. Additional amendments are being made to revise language pertaining to subpoenas to correspond to changes in statutory language and to include licensure, certification, or registration of long-term care beds as acceptable documentation to prove obligation of funds for a CON project.

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 amendments remove all reference to “nonreviewability rulings” and “nonreviewability determinations” due to recession of statutory language pertaining to such definitions from ORC section 3702.51. Those paragraphs requiring monitoring of hospital beds recategorized as skilled nursing beds that are subject to a CON are being moved to new rule 3701-12-24.

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. The requested amendments involve grammatical and formatting changes, remove and replace references to “health care facilities” with “long-term care” facility, and remove an outdated reference to the “State Health Resources Plan”.

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 amendments:

- Remove and replace references to “health care facilities” with “long-term care” facility;
- Clarify the service area of source facilities defined by ORC section 3702.593 as the “fifteen mile radius” based upon global positioning system data;
- Clarify the requirements of new language in ORC section 3702.594 pertaining to CONs involving the relocation of beds between contiguous counties and the limitation to no more than a total of thirty beds to any one facility.
- Clarify the requirements of new ORC Division 3702.52(D) that requires facilities from which beds are relocated cease operation of the beds through removal from license, surrender of certification, or removal of the beds from registration within fifteen days of the relocation in order to eliminate the possibility of the beds being operated at more than one site. An exception is created in specific cases to allow beds being relocated from one facility to another to continue operation at the source facility for up to fifteen days in order to allow for the orderly relocation of residents.

3701-12-23.2 - This rule establishes the requirements pertaining to the replacement of long-term care facilities and the relocation of long-term care beds. The amendments clarify that applicants must have or have entered in to a contract to have the legal authority to operate the long-term care beds subject to the CON. Additional amendments remove and replace references to “health care facilities” with “long-term care” facility, correct formatting, and update citations.

3701-12-23.4 - Rescission of rule due to removal of statutory requirement for a nursing home placement clearinghouse from section 3702.521ORC with the enactment of H.B. 487 in 2012.

3701-12-24 - This new rule provides for a separate rule establishing the monitoring requirements for hospital beds recategorized as skilled nursing beds. These requirements were previously part of existing rule 3701-12-19, but have been moved to the new independent rule to provide clarification by detailing in rule, the information previously requested on the form prescribed by the director. The information being requested has been significantly reduced and will provide pertinent information regarding the usage of the recategorized beds subject to a CON.

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 December 19, 2012.

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

A stakeholders meeting was conducted on February 19, 2013

An informal request for comments was sent on March 11, 2013, to the Ohio Department of Aging, Long-Term Care Ombudsman and Ohio Medicaid, but no comments were received.

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

Comments were received from the following:

- Academy of Health Sciences
- Bricker & Eckler LLP
- Ohio Health Care Association
- Rolf Goffman Martin Lang LLP
- Webster & Associates

Several revisions were made as a result of the comments received, including clarifying bed relocation language, adding limited liability corporations to the definition of person, updating citations, and minor formatting corrections.

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:

- Current: \$3000
- Proposed \$5000

For a project involving a capital expenditure:

- Current: The greater of \$3000 or 0.9 percent of the capital expenditure proposed, with a maximum fee of \$20,000.
- Proposed: 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.

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.

Applicants for a CON will pay at a minimum, \$2000 more in application fees, but the cap on fees will continue to remain at \$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.

There has not been an increase in CON application fees since 1989 when the current fees were established. The CON program is a fee supported program that has routinely operated at a loss. Following is a listing of CON revenues and expenditures by year for the past five years:

Revenue/ Expenditures by fiscal year and the number of CON applications:

<u>2012</u>	\$357,311	\$665,838	31
<u>2011</u>	\$744,001	\$855,474	54
<u>2010</u>	\$834,576	\$776,327	81
<u>2009</u>	\$552,849	\$896,167	32
<u>2008</u>	\$596,910	\$774,242	33

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. In only one year out of the last five years, has the CON program generated sufficient revenue to exceed its expenditures, 2010 when an unusual number of applications were filed. Due to the enactment of ORC section 3702.593, which authorized the relocation of long-term care beds to underserved counties, in 2010 a significant number of applications proposed the construction of new facilities which entailed, in most cases, the maximum fee of \$20,000. After 2012, that event is only authorized every four years. If the requested fee increase had been applied to the last fiscal year, 2012, the CON program could have seen an increase in revenues of approximately \$200,000. While this amount would still not have been enough to provide 100% fee support for the CON program, combined with the staff and administrative reductions that have been made to the CON program, this goal could have been achieved.

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, although the enactment of 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?

The certificate of need application review process requires specific documentation,

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.