

MEMORANDUM

Date: December 11, 2018

To: Interested Parties

From: Selina G. Jackson, MPA, Office of Health Assurance and Licensing, Ohio
Department of Health

Subject: Draft Amendments to Chapter 3701-12 of the Ohio Administrative Code
("Certificate of Need")

The Ohio Department of Health has drafted amendments to Chapter 3701-12 of the Ohio Administrative Code ("OAC"). Revisions have been made to the rules 3701-12-04, 3701-12-05, 3701-12-08, 3701-12-09, 3701-12-11, and 3701-12-18 to incorporate 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 2017. The 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 including, but not limited to, a thirty day ruling requirement for expedited reviewability determinations, a fee of \$1000 for expedited reviews, and a fourteen day approval period for expedited certificate of need applications.

Please review the draft amended rules and provide any comments you may have by **January 11, 2019** to the address below. Please include the words "CON" in the subject line of all comments sent via regular mail or e-mail. ODH will review and consider the comments received before the rule is submitted for formal rule proposal and adoption proceedings. Thank you.

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3701-12-04

Reviewability determinations; appeals.

(A) The director shall issue a ruling on whether a particular proposed project is a reviewable activity (reviewability determination). The director may request additional information necessary to determine whether the activity is a reviewable activity as described in rule 3701-12-05 of the Administrative Code. Requests for an expedited reviewability determination shall expressly state that an expedited reviewability determination is requested. If a request for a reviewability determination does not expressly state that an expedited reviewability determination is being requested, the director shall consider the request to be for a standard reviewability determination.

(B) The director shall issue a ruling within specified timeframes as follows:

(1) For a standard reviewability determination, the ruling shall be issued not later than forty-five days after receiving a request for the ruling that is accompanied by all of the information necessary to make the ruling; or

(2) For an expedited reviewability determination, the ruling shall be issued not later than thirty days after receiving a request for the ruling that is accompanied by all of the information necessary to make the ruling.

(C) If the director does not issue a ruling within the time frames specified in paragraphs (B)(1) and (B)(2) of this rule, the project shall be considered to have been ruled not a reviewable activity.

(D) The date that the director signs the ruling shall be the date of issuance of the ruling.

(E) Any affected person may appeal a reviewability ruling to the director in accordance with Chapter 119. of the Revised Code. Each person who appeals to the director shall file with the director, not later than thirty days after the decision of the director is mailed, a notice of appeal that designates the decision, ruling, or determination the person is appealing. The director shall conduct an adjudication hearing in accordance with Chapter 119. of the Revised Code.

3701-12-04

Reviewability determinations; appeals.

- ~~(A) The director shall issue a ruling on whether a particular proposed project is a reviewable activity (reviewability determination). The director may request additional information necessary to determine whether the activity is a reviewable activity as described in any provision of rule 3701-12-05 of the Administrative Code. The director shall issue a ruling not later than forty five days after receiving a request for the ruling that is accompanied by the information necessary to make the ruling. The date that the ruling is mailed to the person who filed the request shall be the date of issuance of the ruling. If the director does not issue a ruling in that time, the project shall be considered to have been ruled not a reviewable activity. A determination that a project is not a reviewable activity only relates to the project as described in the request and any additional information and does not authorize conducting a different, reviewable activity.~~
- ~~(B) Any affected person may appeal a reviewability ruling to the director in accordance with Chapter 119. of the Revised Code. The director shall conduct an adjudication hearing in accordance with Chapter 119. of the Revised Code. Each person who appeals to the director shall file with the director, not later than thirty days after the decision of the director is mailed, a notice of appeal that designates the decision, ruling, or determination the person is appealing.~~

3701-12-05

Scope of review: reviewable activities.

(A) The following activities are reviewable activities which shall not be conducted without a valid certificate of need.

(1) The establishment, development, or construction of a new long-term care facility.

(2) The replacement of an existing long-term care facility.

(3) The renovation of or addition to a long-term care facility that involves a capital expenditure of two million dollars or more, not including expenditures for equipment, staffing, or operational costs.

(4) Either of the following:

(a) An increase in long-term care bed capacity; or

(b) A relocation of long-term care beds from one physical facility or site to another, excluding the relocation of long-term care beds within a long-term care facility or among buildings of a long-term care facility at the same site.

(5) The expenditure of more than one hundred ten per cent of the maximum expenditure specified in a certificate of need concerning long-term care beds.

(6) Any 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 during the period from the approval of the application until five years after implementation of the reviewable activity for which the certificate was granted.

(B) A project or the portion of a project that meets the requirements of this paragraph is not reviewable. The following activities are not subject to review under paragraph (A) of this rule:

(1) Acquisition of computer hardware or software;

(2) Acquisition of a telephone system;

(3) Construction or acquisition of parking facilities;

- (4) Correction of cited deficiencies that are in violation of federal, state or local fire, building or safety laws, ordinances, rules, or regulations and that constitute an imminent threat to public health or safety;
- (5) Acquisition of an existing long-term care facility that does not involve a change in the number of beds;
- (6) Mergers, consolidations or other corporate reorganizations of long-term care facilities that do not involve a change in the number of beds;
- (7) Construction, repair or renovation of bathroom facilities;
- (8) Construction of laundry facilities, waste disposal facilities, dietary department projects, heating and air conditioning projects, administrative offices and portions of medical office buildings used exclusively for physician services; and
- (9) Removal of asbestos from a long-term care facility.

3701-12-08

Certificate of need application and completeness process; public notice; certificate of need review; certificate of need expedited review; and decision process; appeals.

- (A) Except for applications for certificate of need under section 3702.593 of the Revised Code, any application to conduct a reviewable activity as defined in rule 3701-12-05 of the Administrative Code, shall be subject to this rule.
- (B) Applications for certificate of need that propose an increase in beds that is attributable to a relocation of existing beds from an existing nursing home to another existing nursing home located within a county that is contiguous to the county from which the beds are to be relocated may be submitted at any time and must meet the requirements set forth in paragraph (B) of rule 3701-12-23 of the Administrative Code.
- (C) Applications for certificate of need that propose the conversion of infirmity beds to long-term care beds may be submitted at any time and must meet the requirements set forth in division (C) of section 3702.59 of the Revised Code.
- (D) Each applicant shall submit an original of the application form and necessary attachments in a manner prescribed by the director and shall include, but not be limited to, the following:
- (1) Name of the proposed or existing long-term care facility;
 - (2) Operator of the proposed or existing long-term care facility;
 - (3) A timetable for implementing the project;
 - (4) Identification of a specific site for the project designated by a street address or, if there is no street address, a plot or parcel number;
 - (5) The bed tracking numbers of each long-term care bed that is subject to the certificate of need; **and**
 - (6) A designated authorized representative who shall sign an affidavit that, to the best of his or her knowledge, the information in the application and any accompanying material is true and accurate: and
 - (7) In the case of an application for expedited review, a letter expressly stating that the applicant requests an expedited review of the certificate of need application.

(E) The application shall be accompanied by a nonrefundable fee in the form of a check or a postal money order, payable to the treasurer state of Ohio, in the following amount:

(1) For a project not involving a capital expenditure, five thousand dollars; or

(2) For a project involving a capital expenditure, the greater of five thousand dollars or one point five per cent of the capital expenditure proposed, with a maximum fee of twenty thousand dollars; ~~and~~

(3) For each application for which an expedited review is requested in accordance with paragraph (D)(7) of this rule, an additional fee of one thousand dollars.

(F) Upon acceptance of an application and the appropriate fee, the director shall review the application for completeness of information. The director shall consider an application complete when the applicant:

(1) Furnishes the information specified in paragraph (D) of this rule and information required on the application form;

(2) Pays the fee specified in paragraph (E) of this rule; and

(3) If required to, adequately and completely responds to the director's requests for additional information.

(G) If an application is not accepted, the director shall not review it and shall return the fee specified in paragraph (E) of this rule, minus a one hundred dollar application processing fee.

(H) To determine completeness, the director may request additional information from the applicant but shall not request any information that is not necessary to review the application in relation to the criteria established by this chapter, as the chapter is in effect at the time the request is made.

(1) The director may make two requests for the additional information needed to complete an application under this paragraph.

(2) The applicant shall have the following timeframes ~~ninety days from the date of the letter~~ to respond to a request for additional information:;

(a) For an application under standard review, ninety days from the date of the

letter; or

(b) For an application for which an expedited review was requested in accordance with paragraph (D)(7) of this rule, fourteen days from the date of the letter.

- (3) The director shall deem an application incomplete if the applicant does not timely respond to the director's request for additional information or if the director does not receive the information necessary to complete the application within the appropriate time frame specified in this rule.
- (4) When responding to requests for additional information, applicants shall submit responses in the manner prescribed by the director.
- (I) If a revision to an application is filed in accordance with rule 3701-12-12 of the ~~Administrative~~ Administrative Code, the director may make an additional request within thirty days of receipt of the revised application for information even if two requests have already been made. The applicant shall have ninety days to respond to a request for additional information after the filing of a revised application.
- (J) The director shall determine completeness of a certificate of need application as follows:
 - (1) ~~For an application under standard review: No later than thirty days after the director receives the application and the appropriate fee or thirty days after the director receives additional information submitted in response to the first request, the director shall mail to the applicant by certified mail notice of completeness or a second request for additional information.~~
 - (a) No later than thirty days after the director receives the application and the appropriate fee or thirty days after the director receives additional information submitted in response to the first request, the director shall mail to the applicant by certified mail either a notice of completeness or a second request for additional information.
 - (b) No later than thirty days after the director receives additional information submitted in response to the second request, the director shall mail to the applicant by certified mail a notice of completeness or deem the application incomplete.
 - (2) ~~No later than thirty days after the director receives additional information submitted in response to the second request, the director shall mail to the applicant by certified mail notice of completeness or shall deem the application incomplete.~~ For an application under expedited review:

- (a) No later than fourteen days after the director receives the application and the appropriate fee or fourteen days after the director receives additional information submitted in response to the first request, the director shall mail to the applicant by certified mail either a notice of completeness or a second request for additional information.
- (b) No later than fourteen days after the director receives additional information submitted in response to the second request, the director shall mail to the applicant by certified mail notice of completeness or shall deem the application incomplete.
- (3) In the case of a revised application, if ~~H~~ a third request for additional information is made after ~~a~~ the revised application is filed, no later than thirty days after the director receives additional information submitted in response to the third request, the director shall mail to the applicant by certified mail notice of completeness or shall deem the application incomplete.
- (K) Except as necessary to comply with a subpoena issued under division (F) of section 3702.52 of the Revised Code, after a notice of completeness has been received, no person shall make revisions to information that was submitted to the director before the director mailed the notice of completeness or knowingly discuss in person, by telephone, or electronically the merits of the application with the director. A person may supplement an application after a notice of completeness has been received by submitting clarifying information to the director.
- (L) The director may deny an application for any false statement knowingly made in the application or in supplemental information submitted pursuant to this rule.
- (M) If the director deems an application incomplete as authorized by this rule, the director shall notify the applicant by certified mail, not process the application, and keep the fee specified in paragraph (E) this rule. The director's act of deeming an application incomplete and any of the other actions specified in this paragraph shall not be subject to appeal.
- (N) The director shall review applications for certificates of need which have been declared complete to determine whether a certificate should be granted.
- (O) As provided in divisions (C)(5) of section 3702.52 of the Revised Code, the director or the applicant may extend the review period once, for no longer than thirty days, by written notice within thirty days after the mailing of the notice of completeness.
- (P) After the date of mailing of a notice of completeness under paragraph (J) of this

~~Except~~ except as provided in division (C)(5) of section 3702.52 of the Revised Code, the director shall grant or deny all completed applications for certificate of need no later than sixty days the following: after the date of mailing of notice of completeness under paragraph (J) of this rule.

(1) Sixty days for an application under standard review; or

(2) Thirty days for an application under expedited review.

- (Q) The director may grant a certificate of need for all or part of a project that is the subject of the application and may grant the certificate with conditions that must be met by the holder of the certificate.
- (R) If the director does not grant or deny the certificate of need on or before the applicable deadline specified in paragraph (P) of this rule, the certificate shall be considered granted.
- (S) The director shall mail notice of the decision on an application for a certificate of need to the applicant by certified mail and to other persons by electronic or ordinary mail upon request. The notice shall include a statement of the reasons for the decision, citations of the applicable provisions of the Revised Code and Administrative Code, and a description of the right to appeal the decision, in accordance with sections 3702.60 and 119.07 of the Revised Code.
- (T) The applicant or an affected person may appeal to the director a decision to grant or deny a certificate of need application in accordance with Chapter 119. of the Revised Code. The director shall conduct an adjudication hearing in accordance with Chapter 119. of the Revised Code.
- (1) The appellant also shall file notice with the director not later than thirty days after the date the director mailed the order; and
- (2) The appellant or other affected person that appeals the director's decision to grant or deny a certificate of need application must prove by a preponderance of the evidence that the director's decision was not in accordance with sections 3702.52 to 3702.62 of the Revised Code or Chapter 3701-12 of the Administrative Code.
- (U) The applicant or an affected person that was party to and participated in an adjudication hearing as authorized by division (B) of section 3702.60 of the Revised Code and paragraph (T) of this rule may appeal to the tenth district court of appeals the decision issued by the director following the adjudication hearing. Each person who appeals to the tenth district court of appeals shall file with the court, not

later than thirty days after the director's adjudication order is mailed; a notice of appeal that designates the order the person is appealing. The appellant also shall file notice with the director not later than thirty days after the date the director mailed the order.

3701-12-09

Certificate of need application and completeness process for applications filed under section 3702.593 of the Revised Code; comparative review; review and decision process; public notice; appeals.

- (A) Applications for certificate of need filed under section 3702.593 of the Revised Code to conduct a reviewable activity as defined by rule 3701-12-05 of the Administrative Code shall be subject to this rule.
- (B) At the times specified in this rule, the director shall accept certificate of need applications for any of the following purposes if the proposed increase in beds is attributable solely to relocation of existing beds from an existing long-term care facility in a county with excess beds to a long-term care facility in a county in which there are fewer long-term care beds than the county's bed need:
- (1) Approval of beds in a new long-term care facility or an increase of beds in an existing long-term care facility if the beds are proposed to be licensed as nursing home beds under Chapter 3721. of the Revised Code;
 - (2) Approval of beds in a new county home or new county nursing home, or an increase of beds in an existing county home or existing county nursing home if the beds are proposed to be certified as skilled nursing facility beds under the medicare program, Title XVIII of the Social Security Act, 49 Stat. 286 (1965), 42 U.S.C. 1395, as amended ([1981](#)), or nursing facility beds under the medicaid program, Title XIX of the Social Security Act, 49 Stat. 286 (1965), 42 U.S.C. 1396, as amended ([1981](#)); or
 - (3) An increase of hospital beds registered pursuant to section 3701.07 of the Revised Code as long-term care beds.
- (C) The review period for each review process shall be every four years beginning July 1, 2012.
- (1) A four year review process shall consist of two phases:
 - (a) The first phase of a four year review process shall begin July first of the first year.
 - (b) The second phase of a four year review process shall begin July first of the third year.
 - (2) Applications for certificates of need made under the first review process that propose an increase in beds that is attributable solely to relocation of existing

beds from an existing long-term care facility in a county with excess beds to a long-term care facility in a county in which there are fewer long-term care beds than the county's bed need, as published on the department of health's web site, shall be submitted from July 1, 2012 through July 31, 2012 and every four years thereafter.

- (3) If a remaining bed need is published on the department of health's web site for a county, applications for certificates of need made under the second phase of a four year comparative review process that propose the re-distribution of beds made available pursuant to paragraph (O)(3) of rule 3701-12-23 of the Administrative Code, shall be submitted from July 1, 2016 through July 31, 2016 and every four years thereafter.
- (D) Applications made under section 3702.593 of the Revised Code are subject to comparative review if two or more applications are submitted during the same review period and any of the following apply:
- (1) The applications propose to relocate beds from the same county and the number of beds for which certificates of need are being requested for relocation totals more than the number of beds available in the county from which the beds are to be relocated;
 - (2) The applications propose to relocate beds to the same county and the number of beds for which certificates of need are being requested for relocation totals more than the number of beds needed in the county to which the beds are to be relocated;
 - (3) The applications propose to relocate beds from the same service area and the number of beds left in the service area from which the beds are being relocated would be less than the state bed need rate determined under in paragraph (D) of rule 3701-12-23 of the Administrative Code.
- (E) To be considered timely, the director must receive an application made under a review process from July first through July thirty-first in the first year and third years of a four year comparative process that includes the information that complies with paragraph (F) of this rule and is accompanied by the appropriate fee prescribed in paragraph (G) of this rule. If an application made under a comparative review process is not timely received, the director shall not review it and shall return the fee specified in paragraph (G) of this rule, minus a one hundred dollar application processing fee.
- (F) Each applicant shall submit an original of the application form and necessary

attachments in a manner prescribed by the director and shall include, but not be limited to, the following:

- (1) Name of proposed or existing long-term care facility;
 - (2) Name of operator of proposed or existing long-term care facility;
 - (3) A timetable for implementing the project;
 - (4) Identification of a specific site for the project designated by a street address or, if there is no street address, a plot or parcel number;
 - (5) The bed tracking numbers of each long-term care bed that is subject to the certificate of need; and
 - (6) A designated authorized representative who shall sign an affidavit that, to the best of his or her knowledge, the information in the application and any accompanying material is true and accurate.
- (G) The application shall be accompanied by a nonrefundable fee in the form of a check or a postal money order, payable to the treasurer state of Ohio, in the following amount:
- (1) For a project not involving a capital expenditure, five thousand dollars; or
 - (2) For a project involving a capital expenditure, the greater of five thousand dollars or one point five per cent of the capital expenditure proposed, with a maximum fee of twenty thousand dollars.
- (H) Upon acceptance of an application and the appropriate fee, the director shall review the application for completeness of information. The director shall consider an application complete when the applicant:
- (1) Furnishes the information specified in paragraph (F) of this rule and the information required on the application form;
 - (2) Pays the fee specified in paragraph (G) of this rule; and
 - (3) If required to, adequately and completely responds to the director's requests for additional information.

- (I) To determine completeness, the director may request additional information from the applicant but shall not request any information that is not necessary to review the application in relation to the criteria established by this chapter, as the chapter is in effect at the time the request is made.
- (1) The director may make two requests for the additional information needed to complete an application under this paragraph.
 - (2) The director shall deem an application incomplete if the applicant does not timely respond to the director's request for additional information or if the director does not receive the information necessary to complete the application within the appropriate time frame specified in this rule.
 - (3) When responding to requests for additional information, applicants shall submit responses in the manner prescribed by the director.
 - (4) For applications under comparative review, the following deadlines apply:
 - (a) No later than August thirty-first of the same year in which the application is received, the director shall mail to the applicant by certified mail notice that additional information is not necessary or a first request for additional information.
 - (b) No later than October thirty-first of the same year in which the application is received, the applicant shall respond to the first request for additional information.
 - (c) If a first request for additional information is mailed, no later than November thirtieth of the same year in which the application is received, the director shall mail to the applicant by certified mail notice that additional information is not necessary, a second request for additional information, or deem the application incomplete.
 - (d) No later than January thirty-first of the year following the year in which the application is received, the applicant shall respond to the second request for additional information.
 - (e) No later than the last day of February of the year following the year in which the application is received, the director shall mail to the applicant by certified mail, notice of completeness or shall deem the application incomplete.

3701-12-09

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If the dates specified in this paragraph are a weekend or a day when state offices are closed, the deadline shall be moved to the next business day.

- (J) The director shall deem an application incomplete if the applicant does not timely respond to the director's request for additional information or if the director does not receive the information necessary to complete the application within the appropriate time frame specified in this rule.
- (K) Except as necessary to comply with a subpoena issued under division (F) of section 3702.52 of the Revised Code, after a notice of completeness has been received, no person shall make revisions to information that was submitted to the director before the director mailed the notice of completeness or knowingly discuss in person, by telephone, or electronically the merits of the application with the director. A person may supplement an application after a notice of completeness has been received by submitting clarifying information to the director.
- (L) The director may deny an application for any false statement knowingly made in the application or in supplemental information submitted pursuant to this rule.
- (M) If the director deems an application incomplete as authorized by this rule, the director shall notify the applicant by certified mail, not process the application, and keep the fee specified in paragraph (G) this rule. The director's act of deeming an application incomplete and any of the other actions specified in this paragraph shall not be subject to appeal.
- (N) The director shall review applications for certificates of need which have been declared complete to determine whether a certificate should be granted.
- (O) The director may extend the review period once, for no longer than thirty days, by written notice within thirty days after the mailing of the final notice of completeness mailed under paragraph (I) of this rule. An extension by the director shall apply to all applications in a comparative review process. No applicant in a comparative review process may extend the review period.
- (P) Except as provided in division (C)(5) of section 3702.52 of the Revised Code, the director shall grant or deny all completed applications for certificate of need:
 - (1) No later than sixty days after the date of mailing of notice of completeness under paragraph (I) of rule this rule; or
 - (2) No later than April thirtieth, or the next business day if April thirtieth is a

weekend, of the year following the year in which the application is received for applications under a comparative review process and a notice of completeness was mailed under paragraph (I) of this rule.

- (Q) The director may grant a certificate of need for all or part of a project that is the subject of the application and may grant the certificate with conditions that must be met by the holder of the certificate.
- (R) If the director does not grant or deny the certificate of need on or before the applicable deadline specified in paragraph (P) of this rule, the certificate shall be considered granted.
- (S) The director shall mail notice of the decision on an application for a certificate of need to the applicant by certified mail and to other persons by electronic or ordinary mail upon request. The notice shall include a statement of the reasons for the decision, citations of the applicable provisions of the Revised Code and Administrative Code, and a description of the right to appeal the decision, in accordance with sections 3702.60 and 119.07 of the Revised Code.
- (T) The applicant or an affected person may appeal to the director a decision to grant or deny a certificate of need application to the director in accordance with Chapter 119. of the Revised Code. The director shall conduct an adjudication hearing in accordance with Chapter 119. of the Revised Code.
 - (1) The appellant also shall file notice with the director not later than thirty days after the date the director mailed the order; and
 - (2) The appellant or other affected person that appeals the director's decision to grant or deny a certificate of need application must prove by a preponderance of the evidence that the director's decision was not in accordance with sections 3702.52 to 3702.62 of the Revised Code or Chapter 3701-12 of the Administrative Code.
- (U) The applicant or an affected person that was party to and participated in an adjudication hearing as authorized by division (B) of section 3702.60 of the Revised Code and paragraph (T) of this rule may appeal to the tenth district court of appeals the decision issued by the director following the adjudication hearing. Each person who appeals to the tenth district court of appeals shall file with the court, not later than thirty days after the director's adjudication order is mailed; a notice of appeal that designates the order the person is appealing. The appellant also shall file notice with the director not later than thirty days after the date the director mailed the order.

*****DRAFT - NOT FOR FILING*****

3701-12-11 **~~Opportunity to submit written comments during the course of a certificate of need review.~~**

~~(A) Any affected person may submit written comments regarding an application for a certificate of need. Such comments must be received by the forty fifth day after the application is accepted for processing by the director. The director shall consider all written comments received by the established deadline.~~

~~(B) For the purpose of this rule, the date the application is "accepted," means the date the application is made available to the public for review on the Ohio department of health certificate of need project website at http://publicapps.odh.ohio.gov/EID/reports/EID_Report_Criteria.aspx?type=con.~~

*****DRAFT - NOT FOR FILING*****

3701-12-11 **Opportunity to submit written comments during the course of a certificate of need review.**

(A) Any affected person may submit written comments regarding an application for a certificate of need.

(1) Such comments must be received by the following deadlines:

(a) For applications under a standard review, by the forty-fifth day after the application is accepted for processing by the director; or

(b) For an application for which an expedited review was requested in accordance with paragraph (D)(7) of rule 3701-12-08 of the Administrative Code, by the twenty-first day after the application is accepted for processing by the director.

(2) The director shall consider all written comments received by the established deadlines.

(B) For the purpose of this rule, the date the application is "accepted," means the date the application is made available to the public for review on the Ohio department of health certificate of need project website at http://publicapps.odh.ohio.gov/EID/reports/EID_Report_Criteria.aspx?type=con.

3701-12-18

Validity requirements, follow-up and withdrawal of certificates of need.

(A) For the purposes of this rule, "holder" means the applicant to whom a certificate of need was granted. In addition to compliance with validity requirements established by any other rule of this chapter, to maintain the validity of a certificate of need, the holder shall:

(1) Obligate the capital expenditure, within the meaning of paragraph (A)(1)(a) of this rule, within twenty-four months after the date of mailing of the notice that the certificate was granted or, if the grant or denial of the certificate is appealed under section 3702.60 of the Revised Code, within twenty-four months after the issuance of an order granting the certificate, which order is not subject to further appeal.

(a) For the purpose of this rule, "to obligate" means:

(i) For a project that primarily involves construction and is to be financed through external borrowing of funds, to secure financial commitment for the stated purpose of developing the project and commence construction that continues uninterrupted except for interruptions or delays that are unavoidable due to reason's beyond the person's control, including labor strikes, natural disasters, material shortages, or comparable events.

(ii) For a project that primarily involves construction and is to be financed internally, to receive formal approval from the holder's board of directors or trustees, or other governing authority to commit specified funds for the implementation of the project and commence construction that continues uninterrupted except for unavoidable interruptions or delay due to reason's beyond the person's control, including labor strikes, natural disasters, material shortages, or comparable events

(iii) For a project that involves no capital expenditure or only minor renovations to existing structures, to provide the long-term care service by the means specified in the approved application for the certificate.

(iv) For a project that primarily involves leasing a building or space that requires only minor renovations to the existing space, to execute a lease and provide the long-term care service by the means specified in the approved application for the certificate.

- (v) For a project that primarily involves leasing a building or space that has not been constructed or requires substantial renovations to existing space, to commence construction for the purpose of implementing the reviewable activity that continues uninterrupted except for interruptions or delays that are unavoidable due to reasons beyond the person's control, including labor strikes, natural disasters, material shortages, or comparable events.

- (b) For the purposes of this rule, "commence construction" means:
 - (i) For a project involving construction, the placement of any structural foundation element that becomes an integral part of the structure. A structural foundation element includes, but is not limited to, footings, piers, grade beams and infrastructure items such as pilings and caissons. The acts of surveying, staking, soil testing, demolition of existing structures, delivery of materials, establishment or connection of utility services, elimination or removal of a safety or sanitary hazard from the site and site preparation, including site grading, site filling or clearing, are not considered commencement of construction.

 - (ii) For projects involving exclusively renovations to an existing structure, the modification or removal of an integral part of the structure or portion thereof. Such modification or removal includes, but is not limited to, the modification or removal of walls and ceilings, large surface replastering, major plumbing projects, and window replacement. Minor repair and maintenance activities that minimally disrupt building components, such as minor electrical or plumbing activities, are not considered commencement of construction.

- (c) For the purpose of this rule, "provide the long-term care service" means, in the case of a project that affects the number of long-term care beds at an existing long-term care facility, to obtain a license or certification specifying the appropriate bed capacity.

- (d) The twenty-four month period specified in paragraph (A)(1) of this rule shall not be extended by any means, including the granting of a subsequent or replacement certificate of need.

- (2) After obligating, maintain reasonable progress towards completion of the project. Reasonable progress includes, but is not limited to:

- (a) When the holder maintains uninterrupted progress except for delays that are unavoidable due to reasons beyond the holder's control; or
 - (b) When the holder provides reasonable assurance that it will provide the long-term care service specified in the approved application for the certificate by the projected completion date approved by the director.
- (3) Submit all documents required by paragraph (B) of this rule for monitoring implementation of the reviewable activity in a timely manner.
- (4) Not transfer the certificate, within the meaning of section 3702.523 of the Revised Code.
- (5) Conduct the reviewable activity in substantial accordance with the approved application. A reviewable activity shall not be determined to be not in substantial accordance with the certificate of need solely because of either of the following:
 - (a) A decrease in bed capacity; or
 - (b) 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.
- (6) Conduct the reviewable activity at the site specified in the approved application.
- (7) Not expend more than one hundred ten per cent of the maximum capital expenditure stated in the certificate.
 - (a) A civil monetary penalty may be imposed upon a holder if the more than one hundred ten per cent of the maximum capital expenditure stated in the certificate is expended.
 - (b) The penalty imposed shall equal the amount of the application fee paid for the approved certificate of need plus an amount equal to the expenditure overrun above one hundred and ten percent of the maximum capital expenditure stated in the certificate multiplied by 0.015.
 - (c) The director shall notify the holder of the certificate of need of the penalty proposed under this paragraph by certified mail.

- (d) The holder of the certificate of need may appeal to the director in writing within thirty days of the date the director mailed the notice of the penalty in accordance with Chapter 119. of the Revised Code.
 - (e) The holder of the certificate of need may choose to pay the penalty proposed under this paragraph within thirty days of the date the director mailed the notice in lieu of an appeal.
- (B) The director shall monitor project implementation activities by holders of certificates of need. The director's monitoring shall include but shall not be limited to review of documentation submitted by holders. Each holder shall submit the following:
- (1) Progress reports, on forms provided by the director, not less than six months after obligating the project and every six months thereafter until the project is complete. The holder shall submit progress reports more frequently if requested by the director;
 - (2) An affidavit of substantial completion of the project, on a form provided by the director, upon project completion;
 - (3) Architectural drawings or design development drawings, when appropriate to the nature of the activity and when requested by the director;
 - (4) Written documentation of obligating the project, which shall be submitted to the director not later than the earlier of thirty days after obligating or five days after the twenty-four month period expires. Documentation of obligation may include, but shall not be limited to, design drawings, a statement by the general contractor attesting to the date construction commenced, a building permit issued by the building authority having jurisdiction, approval to commit the specified funds for implementation of the approved project from a board of directors or trustees or other governing authority, construction contracts, purchase or lease contracts for the building, zoning approvals, evidence of site acquisition, or secured financial agreements, licensure, certification, or registration of the long-term care beds;
 - (5) Timely notification of any delay and request for approval of any changes to the projected completion date; and
 - (6) Any other documents relevant to project implementation, upon request by the director.

3701-12-18

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- (C) The director may issue and enforce, in the manner provided in section 119.09 of the Revised Code, subpoenas and subpoenas duces tecum to compel a person to testify and produce documents relevant to the director's monitoring of the approved project. The director or the director's representative may visit sites where the activities are or will be conducted.
- (D) The director shall send a notice to the holder of the certificate that states whether or not the holder has obligated the approved project. The director shall send the notice by certified mail to the holder not later than fifteen days after the director receives the obligation documentation or fifteen days after the twenty-four month period expires, whichever is later.
- (E) If a holder fails to obligate the approved project, the certificate of need expires regardless of whether the director has sent notice pursuant to paragraph (D) of this rule or not. No further action is required by the director. Expiration of a certificate of need does not constitute a withdrawal and the procedure provided in paragraph (F) of this rule for a withdrawal does not apply. A determination by the director that a certificate of need has expired is final and not appealable under Chapter 119. of the Revised Code.
- (F) The director may withdraw a certificate of need for failure to comply with the requirements for maintaining the validity of the certificate established by this rule or any other rule of this chapter or because the application or supplemental information contained material, false or misleading statements or knowing omissions of material information. In withdrawing a certificate, the director shall use the following procedures:
 - (1) At least thirty days before withdrawing the certificate, the director shall notify the holder of the proposed withdrawal by certified mail. The notice shall include the reasons for the proposed action and a statement that the holder may respond to the proposal in writing within thirty days after the mailing of the notice of the proposed withdrawal.
 - (2) Before withdrawing the certificate, the director shall consider any information timely filed by the holder and may consider any other information that the director considers appropriate.
 - (3) The director shall notify the holder of the withdrawal of the certificate or the decision not to withdraw the certificate by certified mail within ninety days after the mailing of the notice of the proposed withdrawal. The notice of withdrawal shall specify the reasons for the withdrawal, citations of relevant provisions of the Revised Code and the Administrative Code and a

description of the right to appeal the withdrawal, in accordance with Chapter 119. and section 3702.60 of the Revised Code.

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.