

900 KAR 6:065. Certificate of need application process.

RELATES TO: KRS 216B.015, 216B.040, 216B.062(1), 216B.085, 216B.095

STATUTORY AUTHORITY: KRS 194A.030(1)(c)4., 216B.040(2)(a)1

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the Cabinet for Health and Family Services to administer Kentucky's Certificate of Need Program and to promulgate administrative regulations as necessary for the program. This administrative regulation establishes the requirements necessary for the orderly administration of the certificate of need application, review, decision, and reconsideration process.

Section 1. Definitions.

- (1) "Cabinet" is defined by KRS 216B.015(6).
- (2) "Certificate of Need Newsletter" means the monthly newsletter that is published by the cabinet regarding certificate of need matters and is available on the Office of Inspector General, Division of Certificate of Need Web site at <https://chfs.ky.gov/agencies/os/oig/dcn>.
- (3) "Days" means calendar days, unless otherwise specified.
- (4) "Formal review" means the review of an application for certificate of need that is reviewed within ninety (90) days from the commencement of the review as provided by KRS 216B.062(1) and that is reviewed for compliance with the review criteria set forth at KRS 216B.040 and 900 KAR 6:070.
- (5) "Nonsubstantive review" is defined by KRS 216B.015(18).
- (6) "Owner" means a person as defined in KRS 216B.015(22) who is applying for the certificate of need and will become the licensee of the proposed health service or facility.
- (7) "Person" is defined by KRS 216B.015(22).
- (8) "Proposed service area" means the geographic area the applicant proposes to serve.
- (9) "Secretary" is defined by KRS 216B.015(26).
- (10) "Show cause hearing" means a hearing during which it is determined whether a person or entity has violated provisions of KRS Chapter 216B.

Section 2. Certificate of Need Application.

- (1) An applicant for a certificate of need shall file an application with the cabinet on the appropriate certificate of need application form: CON - Form 2A, CON - Form 2B, or CON - Form 2C, incorporated by reference in 900 KAR 6:055.
- (2) To file an application for certificate of need, the applicant shall file the appropriate certificate of need application form together with the prescribed fee set forth in 900 KAR 6:020 on or before the deadlines established by 900 KAR 6:060. The appropriate fee shall be received by the Division of Certificate of Need before an application may be deemed complete.
- (3)
 - (a) For the purpose of completing the application, neither the geographic area the applicant proposes to serve nor the health service area in which the project is proposed to be located shall include any area that is located outside of the Commonwealth of Kentucky.
 - (b) A person located and residing solely outside of the Commonwealth of Kentucky shall not qualify as an affected person for the purpose of opposing an application.
- (4) Formal or nonsubstantive review of an application for a certificate of need shall not begin until the application has been deemed complete by the cabinet.
- (5) The cabinet shall deem an application complete if the applicant has:
 - (a) Provided the cabinet with all of the information necessary to complete the application; or

- (b) Declined to submit the requested information and has requested that its application be reviewed as submitted.
- (6) Once an application has been deemed complete, the applicant shall not submit additional information regarding the application unless the information is introduced at a public hearing.
- (7) Once an application has been deemed complete, it shall not be amended to:
 - (a) Increase the scope of the project;
 - (b) Increase the amount of the capital expenditure;
 - (c) Expand the size of the proposed service area;
 - (d) Change the location of the health facility or health service; or
 - (e) Change the owner, unless the application involves a licensed health facility and a change of ownership with appropriate notice has occurred after the application was submitted.
- (8) An application that has been deemed complete may be amended at a public hearing to:
 - (a) Decrease the scope of the project;
 - (b) Decrease the amount of the capital expenditure; or
 - (c) Decrease the proposed service area.
- (9) An applicant that has had a certificate of need approved under the nonsubstantive review provisions of KRS 216B.095(3)(a) through (f) may request that the cabinet change the specific location to be designated on the certificate of need if:
 - (a) The facility has not yet been licensed;
 - (b) The location is within the county listed on the certificate of need application; and
 - (c) The applicant files a written request with the cabinet within 180 days of the date of issuance of the certificate of need. A request shall include the reason why the change is necessary.
- (10) An application that is not deemed complete within one (1) year from the date that it is filed shall expire and shall not be placed on public notice or reviewed for approval.

Section 3. Certificate of Need Review.

- (1) Prior to being reviewed for the approval or denial of a certificate of need, an application for certificate of need shall be reviewed for completeness pursuant to Section 4 of this administrative regulation.
- (2) Unless granted nonsubstantive review status under the criteria in 900 KAR 6:075, an application for a certificate of need shall be reviewed for approval or denial according to the formal review criteria set forth in 900 KAR 6:070.
- (3) If granted nonsubstantive review status under the criteria in 900 KAR 6:075, an application for a certificate of need shall be reviewed for approval or denial of the certificate of need according to the nonsubstantive review criteria set forth in 900 KAR 6:075.

Section 4. Completeness Review.

- (1) Fifteen (15) days after the deadline for filing an application in the appropriate batching cycle, the cabinet shall conduct an initial review to determine if the application is complete for formal review or nonsubstantive review requested pursuant to KRS 216B.095(3)(a) through (f).
- (2) If the cabinet finds that the application for formal review is complete, the cabinet shall:
 - (a) Notify the applicant in writing within one (1) day that the application has been deemed complete and that review of the application for the approval or denial of a certificate of need shall begin upon public notice being given; and
 - (b) Give public notice in the next appropriate Certificate of Need Newsletter, pursuant to the timetable set forth in 900 KAR 6:060, that review of the application for approval

or denial of a certificate of need has begun.

(3) If the cabinet finds that the application for nonsubstantive review is complete, the cabinet shall notify the applicant in writing within ten (10) days that the application has been deemed complete and that review of the application for the approval or denial of a certificate of need shall begin upon public notice being given.

(4) A decision to grant or deny nonsubstantive review status shall be made within ten (10) days of the date the applicant is notified that the application has been deemed complete.

(5) The cabinet shall give public notice for applications granted nonsubstantive review status under the provisions of KRS 216B.095(3)(a) through (f) in the next appropriate Certificate of Need Newsletter, pursuant to the timetable set forth in 900 KAR 6:060, that status has been granted and that review of the application for approval or denial of a certificate of need has begun.

(6) If the cabinet finds that the application is incomplete, the cabinet shall:

(a) Provide the applicant with written notice of the information necessary to complete the application; and

(b) Notify the applicant that the cabinet shall not deem the application complete unless within fifteen (15) days of the date of the cabinet's request for additional information:

1. The applicant submits the information necessary to complete the application by the date specified in the request; or
2. The applicant requests in writing that the cabinet review its application as submitted.

(7) If, upon the receipt of the additional information requested, the cabinet finds that the application for formal review is complete, the cabinet shall:

(a) Notify the applicant in writing that:

1. The application for formal review has been deemed complete; and
2. Review of the application for the approval or denial of a certificate of need shall begin upon public notice being given; and

(b) Give public notice in the next appropriate Certificate of Need Newsletter, pursuant to the timetable set forth in 900 KAR 6:060, that review of the application for approval or denial of a certificate of need has begun.

(8) If, upon the receipt of the additional information requested, the cabinet finds that an application for nonsubstantive review is complete, the cabinet shall:

(a) Notify the applicant in writing that:

1. The application has been deemed complete;
2. Review of the application for the approval or denial of a certificate of need shall begin upon public notice being given; and
3. A decision to grant or deny nonsubstantive review status shall be made within ten (10) days of the date that the application was deemed complete; and

(b) Give public notice in the next appropriate Certificate of Need Newsletter, pursuant to the timetable set forth in 900 KAR 6:060, for an application granted nonsubstantive review status under the provisions of KRS 216B.095(3)(a) through (f) that status has been granted and that review of the application for approval or denial of a certificate of need has begun.

(9) If the information submitted in response to the cabinet's request for additional information is insufficient to complete the application, the cabinet shall:

(a) Request the information necessary to complete the application; and

(b) Inform the applicant that the application shall not be deemed complete and shall not be placed on public notice until:

1. The applicant submits the information necessary to complete the application; or
2. The applicant requests in writing that its application be reviewed as submitted.

(10) Once an application has been deemed complete, an applicant shall not submit additional information to be made part of the public record unless:

- (a) The information is introduced at a public hearing;
- (b) For a deferred application for formal review, the additional information is submitted at least twenty (20) days prior to the date that the deferred application is placed on public notice; or
- (c) For a deferred application for nonsubstantive review, the additional information is submitted at least ten (10) days prior to the date that the deferred application is placed on public notice.

(11) A determination that an application is complete shall:

- (a) Indicate that the application is sufficiently complete to be reviewed for approval or disapproval;
- (b) Not be determinative of the accuracy of, or weight to be given to, the information contained in the application; and
- (c) Not imply that the application has met the review criteria for approval.

Section 5. Notice of Decision.

(1) The cabinet shall notify the applicant and any party to the proceeding of the final action on a certificate of need application within three (3) days.

(2) Notification of approval shall be in writing and shall include:

- (a) Verification that the review criteria for approval have been met;
- (b) Specification of any terms or conditions limiting a certificate of need approval, including limitations regarding certain services or patients. This specification shall be listed on the facility or service's certificate of need and license;
- (c) Notice of appeal rights; and
- (d) The amount of capital expenditure authorized, if applicable.

(3) Written notification of disapproval shall include:

- (a) The reason for the disapproval; and
- (b) Notice of appeal rights.

(4) An identical application for certificate of need that is disapproved shall not be refiled for a period of twelve (12) months from the original date of filing, absent a change in circumstances.

Section 6. Deferral of an Application.

(1)

(a) Except as described in paragraph (b) of this subsection, an applicant may defer review of an application a maximum of two (2) times by notifying the cabinet in writing of its intent to defer review.

(b) An applicant shall not defer review of an application filed pursuant to 900 KAR 6:080 to alleviate an emergency circumstance.

(c)

1. If the application has been granted nonsubstantive review status under the provisions of KRS 216B.095(3)(a) through (f), the notice to defer shall be filed pursuant to 900 KAR 6:090 no later than five (5) days prior to the date that the decision is due on the application unless a hearing has been scheduled.

2. If a hearing has been scheduled, the notice to defer shall be filed pursuant to 900 KAR 6:090 no later than six (6) days prior to the date of the hearing.

(d)

1. If the application is being reviewed under formal review, the notice to defer shall be filed pursuant to 900 KAR 6:090 no later than ten (10) days prior to the date that the decision is due on the application unless a hearing has been scheduled.

2. If a hearing has been scheduled, the notice to defer shall be filed pursuant to 900 KAR 6:090 no later than eight (8) days prior to the date of the hearing.

- (e) If a hearing has been scheduled, the applicant shall also notify all parties to the proceedings in writing of the applicant's intent to defer the application.
- (2) If a notice to defer an application for formal review is filed, the application shall be deferred to the next regular batching cycle and shall be placed on public notice pursuant to the timetables set forth in 900 KAR 6:060.
- (3) If an application for formal review is deferred, an applicant may update its application by providing additional information to the cabinet at least twenty (20) days prior to the date that the deferred application is placed on public notice.
- (4) If a notice to defer an application that has been granted nonsubstantive review is filed, the application shall be deferred and shall be placed on public notice in the Certificate of Need Newsletter published the next calendar month following the date the request was received.
- (5) If an application for nonsubstantive review is deferred, an applicant may update its application by providing additional information to the cabinet at least ten (10) days prior to the date that the deferred application is placed on public notice.
- (6) In order for a hearing to be held on a deferred application, a hearing shall be requested by either the applicant or an affected person within:
 - (a) Ten (10) days of the deferred application being placed on public notice if the application has been granted nonsubstantive review status; or
 - (b) Fifteen (15) days of the deferred application being placed on public notice if the application is being reviewed under the provision of formal review.

Section 7. Withdrawal of an Application.

- (1) An applicant may withdraw an application for certificate of need by notifying the cabinet in writing of the decision to withdraw the application prior to the entry of a decision to deny or approve the application.
- (2) If a hearing has been scheduled or held on the application, the applicant shall also notify all parties to the proceedings in writing of the applicant's decision to withdraw the application.

Section 8. Location of New and Replacement Facilities. A certificate of need approved for the establishment of a new facility or the replacement of an existing facility shall be valid only for the location stated on the certificate.

Section 9. Requests for Reconsideration.

- (1) A request for reconsideration shall be filed, pursuant to 900 KAR 6:090, within fifteen (15) days of the date of the notice of the cabinet's final decision relating to:
 - (a) Approval or disapproval of an application for a certificate of need;
 - (b) An advisory opinion entered after a public hearing;
 - (c) Revocation of a certificate of need; or
 - (d) A show cause hearing conducted in accordance with 900 KAR 6:090.
- (2) A copy of the request for reconsideration shall be served by the requester on all parties to the proceedings.
- (3) A party to the proceedings shall have seven (7) days from the date of service of the request for reconsideration to file a response to the request with the cabinet.
- (4) If a hearing was held pursuant to subsection (1)(a), (b), or (c) of this section, the hearing officer that presided over the hearing shall enter a decision to grant or deny a request for reconsideration within thirty (30) days of the request being filed.
- (5) If a hearing was held pursuant to subsection (1)(d) of this section, the secretary shall enter a decision to grant or deny a request for reconsideration within thirty (30) days of the request being filed.
- (6) If reconsideration is granted, the hearing shall be held by the cabinet in accordance with the applicable provisions of 900 KAR 6:090, Section 3 or 4, within thirty (30) days

of the date of the decision to grant reconsideration, and a final decision shall be entered by the cabinet no later than thirty (30) days following the conclusion of the hearing.

(7) If reconsideration is granted on the grounds that a public hearing was not held pursuant to KRS 216B.085, the applicant shall have the right to waive the reconsideration hearing if the deficiencies in the application can be adequately corrected by submission of written documentation.

(36 Ky.R. 233; 805; eff. 10-21-2009; 41 Ky.R. 633; 1381; 1557; eff. 2-5-2015; 43 Ky.R. 1306, 1567; eff. 3-31-2017; 47 Ky.R. 1687, 2592; eff. 6-16-2021.)