

**RULES
OF
HEALTH SERVICES AND DEVELOPMENT AGENCY**

**CHAPTER 0720-10
CERTIFICATE OF NEED PROGRAM – SCOPE AND PROCEDURES**

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0720-10-.01 PRIVATE PROFESSIONAL PRACTICE EXEMPTION.

- (1) Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied “exclusively as the professional practice office” of a medical doctor, osteopath, or dentist. Therefore, any person who seeks licensure as a health care institution as set forth in T.C.A. § 68-11-1602 must secure a certificate of need.
- (2) To establish or maintain a health care institution that does not require licensure, a certificate of need is required unless the place, building, or facility is occupied exclusively as the professional practice of a medical doctor, osteopathic doctor, or dentist. In determining whether the professional practice exemption is met, The Agency may consider all relevant factors, including but not limited to, form of facility ownership, types of service reimbursement sought and/or received, patient referral sources, advertising/marketing efforts, and whether the private practitioner retains complete responsibility for management and business control.
- (3) The “private professional practice” exemption has no application in regard to initiation of services, acquisition of major medical equipment, or other actions requiring a certificate of need. The applicability of the exemption, as defined above, is limited to the definition of a “health care institution.”

Authority: T.C.A. §§ 4-5-202, 68-11-1602, 68-11-1605, and 68-11-1607. **Administrative History:** Original rule filed August 31, 2005; effective November 14, 2005.

0720-10-.02 STANDARD PROCEDURES FOR CERTIFICATE OF NEED.

- (1) Application Form. Each application will be filed using standard application forms provided by The Agency. The applicant must provide all information requested in the application forms.
- (2) Letters of Intent.
 - (a) Each Letter of Intent shall be filed using standard forms provided by The Agency. The applicant must provide all information requested in the Letter of Intent form. The applicant must fully comply with all instructions contained in the Letter of Intent form provided by The Agency.
 - (b) Each Letter of Intent for home care organization applications shall also specify all counties in the proposed service area.
 - (c) Any Letter of Intent which contains insufficient information may be deemed void. The Letter of Intent may be refiled, but it is subject to the same requirements as an original Letter of Intent.

(Rule 0720-10-.02, continued)

- (d) Simultaneous with its filing with The Agency, the Letter of Intent shall be published for one day in a newspaper of general circulation in the county where the proposed project is to be located. The Letter of Intent shall be published in the Legal Notice section in a space which should be no smaller than four (4) column inches. Publication must be in the same form and format as the Publication of Intent form provided by The Agency.
1. For the purpose of these rules, “simultaneous” means that publication should, if possible, occur on the same day as filing. A day or two delay between filing and publication will not necessarily void the Letter of Intent, but both filing and publication must occur between the 1st and 10th day of the month preceding the beginning of the review cycle. If the last day for filing the Letter of Intent is a Saturday, Sunday or State holiday, filing must occur on the last preceding regular business day. If both filing and publication do not occur within the time period, the Letter of Intent will be null and void, and the applicant will be notified in writing.
 2. For the purpose of these rules, “newspaper of general circulation” means a publication with the following characteristics:
 - (i) Is regularly issued at least once a week;
 - (ii) Has a second class mailing privilege;
 - (iii) Includes a Legal Notice Section;
 - (iv) Is not fewer than four (4) pages in length;
 - (v) Has been published continuously during the immediately preceding one year period;
 - (vi) Is published for dissemination of news of general interest; and
 - (vii) Is circulated generally in the county in which it is published.
 3. In any county where a publication fully complying with this definition does not exist, the Executive director is authorized to determine appropriate publication to receive any required Letter of Intent. A newspaper which is engaged in the distribution of news of interest to a particular interest group or other limited group of citizens, is not a “newspaper of general circulation.”
 4. In the case of an application for or by a home care organization, the Letter of Intent shall be published in each county in which the agency will be licensed or in a regional newspaper which qualifies as a newspaper of general circulation in each county. In those cases where the Letter of Intent is published in more than one newspaper, the earliest date of publication shall be the date of publication for the purpose of determining the date for the timely filing of the application. Both the Letter of Intent and the application must specify the counties to be served.
- (3) Simultaneous Review. Those persons desiring simultaneous review for a certificate of need for which a Letter of Intent has been filed shall file a Letter of Intent with The Agency and the original applicant, and publish the Letter of Intent simultaneously in a newspaper of general circulation, as those terms are defined in sub-paragraph (2)(d), above, in the same county as the original applicant within ten (10) days after publication by the original applicant. The Executive director or his/her designee will determine whether applications are to be reviewed simultaneously.

(Rule 0720-10-.02, continued)

- (a) The applicant seeking simultaneous review shall, at the time the Letter of Intent is filed with The Agency, also file a verified statement certifying it has complied with the procedural requirements for simultaneous review and evidence that the Notice was received by The Agency business office and the original applicant within ten (10) days after publication by the original applicant.
 - (b) In addition to the procedural requirements, the following factors may be considered by the Executive director in determining whether the applications are appropriate for simultaneous review:
 - 1. Similarity of services area.
 - 2. Similarity of location;
 - 3. Similarity of facilities; and
 - 4. Similarity of service to be provided.
 - (c) If, at the time an application is filed for simultaneous review, there is already another application filed for simultaneous review against the original application, the second application seeking simultaneous review may be simultaneously reviewed against both the original application and the other application seeking simultaneous review.
 - (d) The order in which applications filed for simultaneous review will be placed on the agenda will be determined by the order in which the Letters of Intent were received in The Agency office.
 - (e) Any application which is determined to not meet the criteria for a “simultaneous review” shall be null and void. The application may be re-filed for a subsequent review cycle, but is subject to the same requirements as an original application.
- (4) Applications.
- (a) All applications must be filed with The Agency within five (5) days after publication by the applicant, and must be accompanied by the filing fee. The date of filing shall be the actual date of receipt. If the last day for filing an application falls on a Saturday, Sunday, or State holiday, the application, to be timely, must be filed on the last preceding regular business day.
 - (b) Failure by the applicant to file an application within five (5) days after publication of the Letter of Intent in accordance with (a) above shall render the Letter of Intent, and hence the application, void.
 - (c) When an application is received at The Agency office, it must include an initial filing fee, as provided elsewhere in these rules. The filing fee is non-refundable, except as provided by T.C.A. § 68-11-1609. Review for completeness shall not begin prior to the receipt of the filing fee.
 - (d) Each application that is accompanied by the applicable filing fee will be reviewed for completeness by Agency staff.
 - 1. If it is deemed complete, The Agency will acknowledge receipt and notify the applicant that the review period will begin as of the date specified in the notification. Deeming complete means only that all questions and requests for information have been responded to in some reasonable manner. Deeming complete shall not be construed as validating the sufficiency of the information

(Rule 0720-10-.02, continued)

provided for the purposes of addressing the criteria under the applicable statutes, rules, and other guidelines.

2. If the application is incomplete, responses to requests for supplemental information by the staff must be completed by the applicant and filed at The Agency office within sixty (60) days of the written request by Agency staff. Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Resubmittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee.
- (e) An application for certificate of need shall not be amended in a substantive way by the applicant after being filed with The Agency. If the application is amended in a substantive manner varying from the Letter of Intent or the original application filed with The Agency, the application may be deemed void. This Rule does not prohibit correction of clerical errors in the application.
- (5) Examination Filing Fee.
 - (a) The amount of the initial fee shall be equal to \$5.75 per \$1,000 of the estimated capital expenditure involved, but in no case shall this fee be less than \$15,000 nor more than \$95,000.
 - (b) Any unpaid balance of litigation costs previously assessed against the applicant or any related entity of the applicant by the Tennessee Health Services and Development Agency may be offset against any filing fees paid. An application will not be deemed complete until the full filing fee, as well as such off set amounts, are paid in full.
 - (c) A final fee will be determined upon The Agency's receipt of the final project report. The amount of the final fee shall be the difference between the initial fee and the total fee based on actual final project costs, as such fee is calculated based on \$5.75 per \$1,000 of project costs, but in no case shall the total fee be less than \$15,000 nor more than \$95,000.
 - (6) Distribution of Applications. The Agency will promptly forward a copy of each application deemed complete to the Department of Health, or to the Department of Mental Health and Substance Abuse Services, or to the Department of Intellectual and Developmental Disabilities, and in doing so will fix the date on which the review process established by statute and these regulations will commence.
 - (7) Withdrawal of Applications. An application may be withdrawn at any time by the applicant.
 - (8) Beginning of the Review Cycle. The review cycle for each application shall begin on the first day of the appropriate month after the application has been deemed complete by the staff of The Agency.
 - (9) Reviewing Agencies' Actions on Applications.
 - (a) The Department of Health, or the Department of Mental Health and Substance Abuse Services, or the Department of Intellectual and Developmental Disabilities, shall within seven (7) days from the receipt of a completed application give notice to the Health Services and Development Agency of its receipt in writing. The appropriate reviewing agency shall expeditiously review all applications in a consistent manner and conduct such studies and inquiries thereon as may be determined necessary by the appropriate reviewing agency, by the Health Services and Development Agency's rules, or upon request of the Health Services and Development Agency, to enable it to make a report

(Rule 0720-10-.02, continued)

to the Health Services and Development Agency. Applicants must comply promptly with all reasonable requests made by the appropriate reviewing agency, for additional information for the purpose of this review. Copies of said studies and all correspondence related to the application shall be forwarded to the Health Services and Development Agency by the reviewing agency.

- (b) Within sixty (60) days (or thirty (30) days where the application is on the consent calendar), of the date fixed by The Health Services and Development Agency pursuant to Rule 0720-10-.03(4), the reviewing agency shall file its official written report with The Health Services and Development Agency. A copy of this report shall be forwarded by the reviewing agency to the applicant, and to any other person requesting one.
- (10) Reviewing Agency's Report to The Health Services and Development Agency. The reviewing agency's report shall address at a minimum each of the applicable criteria for certificate of need set forth in the statutes, rules, and the state health plan. The reviewing agency shall clearly set forth any planning methodologies, data bases, and resource materials utilized in making its findings. The reviewing agency may include other information it deems appropriate and informative. The report shall address the following:
- (a) The applicant's compliance with the criteria found in Agency Rules 0720-11;
 - (b) A verification of the methodologies provided by the applicant to meet the criteria specified in (a), as well as identification of any additional methodologies that would further clarify compliance with the criteria;
 - (c) An assessment of the applicant's compliance with any applicable Guidelines for Growth; and
 - (d) An analysis of any information received from the Division of TennCare as to the previous, current and proposed TennCare participation or non-participation of the applicant and any affiliate(s) involved with the project.
- (11) An applicant may provide written supporting information to its application during the review cycle. Further, the applicant will have the right to respond in writing to the report made by the reviewing agency. The reviewing agency and the Health Services and Development Agency shall receive a copy of the applicant's response to the agency's report not less than ten (10) days prior to the Health Services and Development Agency meeting.
- (12) Holder of certificate of need. A certificate of need will normally be issued to the person to whom the license for the health care institution is or will be issued; if not a health care institution as defined in T.C.A. § 68-11-1602, then a certificate of need will normally be issued to the person who will provide the service.

Authority: T.C.A. §§ 4-5-201, et seq., 4-5-202, 68-11-1605, 68-11-1606, 68-11-1607, 68-11-1608, 68-11-1609, and 2016 Tenn. Pub. Acts Ch. 1043. **Administrative History:** Original rule filed August 31, 2005; effective November 14, 2005. Emergency rule filed July 1, 2016; effective through December 28, 2016. The emergency rule expired on December 29, 2016 and reverted back to its previous status. Amendments filed November 15, 2016; effective February 13, 2017. Rule was previously numbered 0720-10-.03, but was renumbered 0720-10-.02 with the deletion of the original rule 0720-10-.02 filed October 24, 2017; effective January 22, 2018. Amendments filed October 24, 2017; effective January 22, 2018.

0720-10-.03 EMERGENCY CERTIFICATE OF NEED.

- (1) Where an unforeseen event necessitates action of a type requiring a certificate of need and the public health, safety, or welfare would be unavoidably jeopardized by compliance with the

(Rule 0720-10-.03, continued)

standard procedures for application and granting of a certificate of need, The Agency may issue an emergency certificate of need.

- (2) An emergency certificate of need may be issued upon request of the applicant when the Executive director and officers of The Agency concur, after consultation with the appropriate reviewing agency. Prior to an emergency certificate of need being granted, the applicant must publish notice of the application in a newspaper of general circulation, and Agency members must be notified by Agency staff of the request.
- (3) A decision regarding whether to issue an emergency certificate of need will be considered at the next regularly scheduled Agency meeting unless the applicant's request is necessitated by an event that has rendered its facility, equipment or service inoperable. In such case, The Agency's Chair and Vice-Chair may act immediately to consider the application for an emergency certificate of need.
- (4) Said certificate is valid for a period not to exceed one hundred twenty (120) days: when the applicant has applied for a certificate of need under standard Agency procedures, an extension of the emergency certificate of need may be granted.

Authority: T.C.A. §§ 4-5-201, et seq., 4-5-202, 68-11-1605, and 2016 Tenn. Pub. Acts Ch. 1043.

Administrative History: Original rule filed August 31, 2005; effective November 14, 2005. Rule was previously numbered 0720-10-.04, but was renumbered 0720-10-.03 with the deletion of the original rule 0720-10-.02 filed October 24, 2017; effective January 22, 2018. Amendments filed October 24, 2017; effective January 22, 2018.

0720-10-.04 CONSENT CALENDAR.

- (1) Each meeting's agenda will be available for both a consent calendar and a regular calendar.
- (2) In order to be placed on the consent calendar, the application must not be opposed by anyone having legal standing to oppose the application, and the executive director must determine that the application appears to meet the established criteria for granting a certificate of need. Public notice of all applications intended to be placed on the consent calendar will be given.
- (3) As to all applications which are placed on the consent calendar, the reviewing agency shall file its official report with The Agency within thirty (30) days of the beginning of the applicable review cycle.
- (4) If opposition by anyone having legal standing to oppose the application is stated in writing prior to the application being formally considered by The Agency, it will be taken off the consent calendar and placed on the next regular agenda. Any member of The Agency may state opposition to the application being heard on the consent calendar, and if reasonable grounds for such opposition are given, the application will be removed from the consent calendar and placed on the next regular agenda.
 - (a) For purposes of this rule, the "next regular agenda" means the next regular calendar to be considered at the same meeting.
- (5) Any application which remains on the consent calendar will be individually considered and voted upon by The Agency.

Authority: T.C.A. §§ 4-5-201, et seq., 4-5-202, 68-11-1605, 68-11-1606, 68-11-1608, and 2016 Tenn. Pub. Acts Ch. 1043. **Administrative History:** Original rule filed August 31, 2005; effective November 14, 2005. Rule was previously numbered 0720-10-.05, but was renumbered 0720-10-.04 with the deletion of the original rule 0720-10-.02 filed October 24, 2017; effective January 22, 2018. Amendments filed October 24, 2017; effective January 22, 2018.

0720-10-.05 EXPIRATION, REVOCATION, AND MODIFICATION OF ISSUED CERTIFICATES.

- (1) Prolonged certification periods and extensions of expiration dates of certificates are disfavored. Any request for a prolonged certification period must be clearly set forth in the application in order to be considered. A request for an extension of the expiration date must be made in writing to The Agency and filed prior to the first day of the month in which the request is to be considered by The Agency, and will be processed in accordance with policies established by staff.
- (2) Prolonged certification period. A prolonged certification period will be granted only where exceptional circumstances are shown to exist which make completion of the project within the time limits prescribed by statute unachievable using all reasonable means.
- (3) Extension of expiration date may be granted due to unforeseen occurrences. All requests for extension of the expiration date must be filed at The Agency's office and be accompanied by a filing fee. The filing fee shall be an amount which bears the same ratio to the initial examination fee submitted with the application, as the requested extension of time bears to the original certification period.
- (4) Extension of expiration date due to appeal. In the event of a proper and timely appeal of The Agency's decision to grant a certificate of need, the certification period will be automatically extended, and the expiration date will be automatically stayed, during the pendency of the appeal.
 - (a) The time period of the extension/stay will be equal to the period of time beginning with the date the petition is received at The Agency's office, and ending with the effective date of the decision of the appellate court of last resort, or the expiration of the time period available for seeking further appellate review (where such appellate review is not sought), whichever occurs first.
 - (b) At the conclusion of the appellate process, as described in subparagraph (4)(a) above, a revised certificate of need, reflecting the new expiration date, may be issued upon request of the certificate holder.
- (5) The Agency will conduct an annual review of progress of each project for which a certificate of need has been granted. The certificate holder shall timely respond to staff requests for information in connection with such progress reviews, and otherwise cooperate with staff in such progress reviews. As part of this progress review, the certificate holder shall submit to The Agency a copy of any signed agreements with TennCare managed care organizations executed after the date the certificate of need was granted, or a status update on any pending negotiations with such entities, within six (6) months after issuance of the certificate of need, and again at twelve (12) months. The certificate holder must show that it is making substantial and timely progress in implementing the project. In the absence of such a showing, The Agency may initiate proceedings to revoke the certificate of need.
- (6) Special corrections and revised certificates. Any issued certificate of need containing typographical errors or requiring similar clerical changes on its face, should be reported by the certificate holder and/or may be recalled by The Agency or staff. In the event of such non-substantive changes, or technical errors or omissions the executive director may issue a "revised" certificate in correct form. The certificate holder shall surrender the original certificate prior to its reissuance in corrected form.
 - (a) Examples of errors and omissions and other nonsubstantive changes which may be made through a revised certificate include:
 1. A typographical error;

(Rule 0720-10-.05, continued)

2. A change in the name of an institution or facility;
 - (i) This refers only to a change in the “doing business as” name, not to a change of ownership. Any change of ownership occurring prior to licensure of a proposed new health care institution is covered in paragraph eight (8) of this rule.
 - (ii) A change of ownership of a health care institution occurring within two years of initial licensure requires notice to The Agency, but no revised or modified certificate of need will be issued.
 3. An extension of the expiration date due to a completed appeal; and
 4. Other non-substantive changes as approved by the executive director;
- (b) Except for changing the expiration date due to a completed appeal as provided above, a revised certificate pursuant to this subdivision shall not be construed as extending the expiration date.
- (7) Modifications and/or addendums to issued certificates. In the event a certificate holder wishes to make substantive changes relating to the scope, cost, or duration of the project, written request must be made to, and formally approved by, The Agency in its discretion. If approved, such changes may be reflected in either the issuance of a modified certificate of need, or by the issuance of an addendum to the original certificate. If the request is denied, The Agency's decision is final, and no appeal shall be allowed.
- (a) Changes included within the provisions of this subdivision may include, but are not limited to, cost increases or decreases, downscaling or increasing the scope or square footage of a project, requests for an extension of the expiration date and changes of ownership where allowed by law and Agency rules. Generally, such changes resulting in either a ten (10) percent increase or decrease shall be presumed substantive, though there will be instances where changes greater than ten (10) percent would not be substantive and instances where changes less than ten (10) percent would be substantive, depending upon the totality of the circumstances. In no event will any change in cost of less than \$10,000 be deemed a substantive cost modification. In no event will any change which would independently require a certificate of need be considered for a modification or addendum. Multiple requests for modifications of a certificate of need, and such other modifications which in the discretion of The Agency would have significantly impacted public participation in The Agency's consideration of the original application, may be considered by The Agency as requiring a separate certificate of need.
1. Certain changes of ownership (“change of control”), prior to licensure constitutes the transfer of a certificate of need, and will render the certificate null and void, as provided in T.C.A. § 68-11-1620.

In addition to the circumstances constituting a change of ownership (“change of control”) as specified in T.C.A. § 68-11-1620, the termination of interest of over 50% of the membership of a non-profit corporation constitutes a change of ownership/change of control. If the change is made from a non-profit, membership corporation to a non-profit, non-membership corporation, there is no change of control if the boards of directors of the corporations are interlocking to the extent that there is no actual change of control of the corporate powers of the corporation which will hold the certificate of need.

(Rule 0720-10-.05, continued)

- (b) Any certificate holder seeking a modification or addendum must make a formal request in writing to The Agency, in accordance with policies adopted by The Agency staff. Such written request must be accompanied by the appropriate supporting documentation justifying the requested modification. Simultaneously with the submission of such written request, the certificate holder shall also file written notice with all parties who sought simultaneous review, filed competing applications, or who opposed the original application. Where an extension of the expiration date is sought, the request must be accompanied by the fee referred to elsewhere in this rule.
 - (c) A change of site may not be approved through a modification or addendum; a separate certificate of need is required.
- (8) Any certificate holder seeking the removal of a condition which was placed on the certificate of need may make an application in writing to The Agency, in accordance with policies adopted by The Agency staff. At the time it makes such written application with The Agency, the certificate holder shall also file written notice with all parties who sought simultaneous review, filed competing applications, or who opposed the original application, and shall publish notice thereof in a newspaper of general circulation. In order to show “good cause” for removing a condition, the certificate holder has the burden of showing that circumstances have significantly changed, which necessitate the removal of the condition. Mere disagreement or dissatisfaction with the condition will normally not be considered to be good cause for removing the condition.
- (a) Application to The Agency for the addition of a specialty to an issued certificate that is limited to either a single specialty or specific multiple specialties shall be made by the filing of a new certificate of need application form.
 - (b) Application to The Agency for the addition of therapeutic cardiac catheterization to an issued certificate that is limited to diagnostic cardiac catheterization shall be made by the filing of a new certificate of need application.

Authority: T.C.A. §§ 4-5-201, et seq., 4-5-202, 68-11-1605, 68-1-1606, 68-1-1607, 68-11-1609, 68-11-1611, 68-11-1620, and 2016 Tenn. Pub. Acts Ch. 1043. **Administrative History:** Original rule filed August 31, 2005; effective November 14, 2005. Rule was previously numbered 0720-10-.06, but was renumbered 0720-10-.05 with the deletion of the original rule 0720-10-.02 filed October 24, 2017; effective January 22, 2018. Amendments filed October 24, 2017; effective January 22, 2018.