

CHAPTER 0720-09

0720-09-.01 DEFINITIONS. The following terms shall have the following meanings.

(1) ~~"Agency" means the Tennessee Health Services and Development Agency.~~

(21) "Ambulatory surgical treatment center" is as defined in T.C.A. § 68-11-201.

(32) "Capital expenditure" in relation to a project, means any series of expenditures by or on behalf of an applicant which, under generally accepted accounting principles, is directed toward the accomplishment of the project.

(a) "Capital expenditure" includes the amount per construction bid or total amount of invoices for the single project.

(b) "Capital expenditure" includes the cost of all medical equipment, whether fixed or moveable, and is considered in calculating the amount of the examination fee. The cost for such fixed and moveable equipment includes, but is not necessarily limited to all costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purpose applied for. Such costs specifically include, but are not limited to, the following:

1. Maintenance agreements, covering the expected useful life of the equipment;
2. Federal, state and local taxes, and other government assessments; and
3. Installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding.

If the acquisition is by lease, the cost is either the fair market value of the equipment or the total amount of lease payments for the initial term of the lease, whichever is greater.

(c) Lease, loan, or gift. In calculating the value of a lease, loan, or gift, the "cost" is the fair market value of the above-described expenditures. In the case of a lease, the cost is the fair market value of the lease or the total amount of the lease payments for the initial term of the lease, whichever is greater.

(43) "Certification period" means the period of time beginning on the date of issuance of a certificate of need and ending on the expiration date of a certificate of need, as established by statute, rule, or order of the Agency.

(54) "Change of location" means a change of the specific location of an existing institution, facility, or service.

(5) ~~"Commission" means the Health Facilities Commission.~~

...

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.~~

(32) 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.

(43) 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.

(54) 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.

(65) 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 nonsubstantive 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;
2. A change in the "doing business as" name of an institution or facility;
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.

(76) 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 thirty (30) percent increase or decrease shall be presumed substantive, though there will be instances where changes greater than thirty (30) percent would not be substantive and instances where changes less than thirty (30) percent would be substantive, depending upon the totality of the circumstances. In no event will any change in cost of less than \$100,000 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 constitute the transfer of a certificate of need, and will render the certificate null and void, as provided in T.C.A. § 68-11-1618.

In addition to the circumstances constituting a change of ownership ("change of control") as specified in T.C.A. § 68-11-1618, 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.

(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 or exemption is required.

(87) 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 between the first day and the fifteenth day of the month preceeding the agency meeting at which the request will be initially scheduled for consideration. 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.

...

#### 0720-10-.06 EXEMPTION FROM CERTIFICATE OF NEED FOR RELOCATION OF HEALTH CARE INSTITUTIONS OR SERVICES.

(1) The Executive Director may issue an exemption for the relocation of existing healthcare institutions and approved services when the Executive Director determines that:

(a) At least ~~seventyninety~~-five percent (~~75~~<sup>95</sup>%) of patients to be served are reasonably expected to

reside in the same zip codes as the existing patient population; ~~and~~

(b) The relocation will not reduce access to consumers, particularly those in underserved communities; those who are uninsured or underinsured; women and racial and ethnic minorities; TennCare or medicaid recipients; and low income groups; ~~and~~

(c) The payor mix will not include an increase in commercial insurance.

(2) The Executive Director will issue the exemption only upon receipt of a completed exemption application on forms provided by the Agency and proof of publication of notice of the application in a newspaper of general circulation in both the county of the existing facility or service and the county where the service or facility is to be relocated;

(a) Prior to deeming an application complete, the Executive Director shall ensure Agency staff's independent review and verification of information submitted to the Agency in applications, presentations, or otherwise. The purpose of the independent review and verification is to ensure that the information is accurate, complete, comprehensive, timely, and relevant to the decision. The independent review and verification must be applied to, but not necessarily be limited to, applicant-provided information as to any critical information submitted or requested concerning an application; and staff examinations of data sources, data input, data processing, and data output, and

verification of critical information;

(b) The application, supporting documentation and staff review must be posted on the Agency's website no later than 21 days prior to issuing an exemption;

(3) Opposition to an exemption application must be filed with the Agency no later than 15 days after the application, supporting documentation and staff review have been posted; any opposition must be limited to the basis for review detailed in 0720-10-.06(1)(a) and (1)(b).

(4) The exemption determination shall be made at a time and place to be posted on the Agency's website, no sooner than 21 days after the notice is posted.

(5) A relocation exemption granted by the Executive Director is subject to Agency review as provided by law.

...

#### 0720-12-.05 ANNUAL REPORT CONCERNING APPROPRIATE QUALITY MEASURES.

For every certificate of need issued after July 1, 2016, reporting shall be made to the Health Services and Development Agency each **of the first three years** on the anniversary date of implementation of the certificate of need, on forms prescribed by the Agency. Reporting shall include an assessment of each applicable quality standard and shall include results of any surveys or disciplinary actions by state licensing agencies, payors, or CMS, which are relevant to the health care institution or service authorized by the certificate of need. The existence and results of any remedial action, including any plan of correction, shall also be provided, unless the information is considered confidential under state or federal law. Reporting may be made for the entire health care institution, relevant department, service, equipment or beds, rather than

segregating the portion authorized by the particular certificate of need; reporting for the portion authorized by the particular certificate of need is preferred if the data is easily segregated and doing so would not be unduly burdensome or costly to the provider.

...

#### 0720-12-.07 REPORTS CONCERNING ACTIVITY IN ECONOMICALLY DISTRESSED COUNTIES.

(1) Reporting shall be made to the Health Services and Development Agency on forms provided by the Agency by any person ~~who~~ that establishes a health care institution or initiates any service specified in T.C.A. § 68-11-1607(a)(3) pursuant to the exemption provided in T.C.A. § 68-11-1607(q) within ninety (90) days of initiation of the exempted activity.

(2) Any person ~~who~~ that provides positron emission tomography services or magnetic resonance imaging services pursuant to T.C.A. § 68-11-1607(q) must be accredited by The Joint Commission or the American College of Radiology in the modalities provided by that person and submit proof of the accreditation to the Agency within two (2) years of the initiation of service.

**(3) A person that provides a service other than positron emission tomography services or magnetic resonance imaging, or establishes a healthcare institution shall submit proof of**

accreditation by an appropriate external peer-review organization for the service or facility to the agency within two (2) years of the date of initiation of service or licensure of the healthcare institution.

...

0720-13-.02 CONTESTED CASES BEFORE ADMINISTRATIVE JUDGES SITTING ALONE.

...

(2) In all cases, whether heard by an Administrative Judge sitting alone, or by the full Agency, the petitioner and other parties, with the exception of (A) a party that is a certificate of need holder, if the agency's decision to approve the certificate of need application is being appealed in the contested case, and (B) the Agency,~~with the exception of the Agency~~ shall bear the cost for all court reporters and transcriptions, and charges billed to the Agency for the Administrative Judge's work/time; in a contested case where the petition is dismissed, whether voluntarily or involuntarily, the petitioning party or parties shall be considered a "losing party" under T.C.A. § 68-11-1610. The original transcript and one copy of the transcript for each member of the Agency shall be provided to the Agency by the other parties, if the case is to be reviewed by the full Agency.

...