REGULAR RULEMAKING

JUNE 30, 2021 DRAFT

RULES
OF
HEALTH SERVICES AND DEVELOPMENT AGENCY

CHAPTER 0720-08 - CONDUCT OF BUSINESS

0720-08-.01 COMMUNICATIONS.

(1) All documents, information, and written communications which are required to be filed with the Tennessee Health Services and Development Agency (hereinafter the "Agency") must be received at The Agency's business office located in Nashville, Tennessee, during normal business hours; or electronically pursuant to The Agency's instructions.

(2) The filing date of any document shall be the actual date of receipt in The Agency office or delivery electronically pursuant to The Agency's instructions. In the event the last appropriate filing date falls on a Saturday, Sunday, or legal holiday, such filing must occur on the business day immediately preceding.

(3) Such documents, information, and written communications shall not be sent by facsimile transmission. Any such documents, information, and written communications which are received by facsimile transmission will not be considered as having been "filed" with The Agency.

~~**0720-08-.02 CONFLICT OF INTEREST.**~~

~~(1) Definitions~~

~~(a) "Conflict of interest" means any matter before The Agency in which the member or employee of The Agency has a direct or indirect interest that is in conflict or gives the appearance of conflict with the discharge of the member's or employee's duties;~~

~~(b) "Direct interest" means a pecuniary interest in the persons involved in a matter before the Agency. This interest applies to The Agency member or employee, The Agency~~

~~member's or employee's relatives or an individual with whom or business as to which the member or employee has a pecuniary interest. For the purposes of this part, a relative is a spouse, parent, child, stepparent, stepchild, grandparent, grandchild, brother, sister, half-brother, half-sister, aunt, uncle, niece, or nephew by blood, marriage or adoption; and~~

~~(c) "Indirect interest" means a personal interest in the persons involved in a matter before the Agency that is in conflict or gives the appearance of conflict with the discharge of the Agency member's or employee's duties;~~

~~(2) All Agency members shall annually review and sign a statement acknowledging the statute, rules and policies concerning conflicts of interest.~~

~~(3) Any member, upon determining that a matter scheduled for consideration by The Agency results in a conflict with a direct interest, shall immediately notify the executive director and shall be recused from any deliberation of the matter, from making any recommendation, from testifying concerning the matter, or from voting on the matter. The member shall join the public during the proceedings.~~

~~(a) Any member with an indirect interest shall publicly acknowledge such interest.~~

~~(b) All members shall make every reasonable effort to avoid even the appearance of a conflict of interest. If a member is uncertain whether the relationship justifies recusal, the member shall follow the determination by the legal counsel for The Agency.~~

~~(c) A determination by The Agency or any court that a member of The Agency with a direct interest failed to provide notice and be recused from deliberations of the matter, from making any recommendation, from testifying concerning the matter, or from voting on the matter, shall result in the member's automatic termination from The Agency and the position shall be considered vacant. The member shall not be eligible for appointment to any agency, board or commission of the state for a period of two (2) years.~~

~~(d) The executive director, upon determining that a conflict exists for the executive director or any member of the staff, shall notify the chair of The Agency and take such action as the chair prescribes and pursuant to this part.~~

0720-08-.03 STAFF AND AGENCY DETERMINATIONS.

(1) Persons seeking information and/or guidance from The Agency or staff may receive such information and/or guidance by any of three methods: informal staff advice, staff determinations, or official Agency determinations.

(2) Staff Advice. Staff members may give advice or guidance orally or in writing when requested. Such informal staff advice is merely the personal opinion of the staff member, and does not represent the position of The Agency or any member thereof. Such advice is not binding on The Agency, and creates no precedent.

(3) Staff Determinations. A staff determination may be issued in writing, and signed by the executive director or general counsel. While a staff determination represents the considered position of staff, it does not necessarily represent the position of The Agency. A staff determination is not required to be officially adopted by The Agency, and creates no binding precedent on The Agency.

(a) When an inquiry is received which does not specifically request an official Agency determination, the executive director will determine whether the inquiry should be handled as a staff determination or as an Agency determination.

(4) Agency Determinations. An Agency determination represents a formal opinion of The Agency. Agency determinations are initially analyzed and drafted by staff, and presented to the full Agency during a regularly scheduled Agency meeting. The Agency may then adopt, reject, or modify staff's recommendation.

(a) Written requests for Agency determinations should be received by the last business day of the preceding month to be included on The Agency's agenda for that month. In the discretion of the executive director, the first inclusion of the request for determination on The Agency's agenda may be for the purpose of public notice; the request may then be placed on the agenda for the next succeeding Agency meeting for The Agency's consideration and decision. The executive director may waive the provisions of this subsection, and place the request for determination before The Agency for consideration on the first inclusion on the agenda.

(b) If the issue upon which a request for determination is based has been addressed by The Agency in prior determinations, or if the issue is otherwise not appropriate for a request for determination, staff will notify the person making the request and the request will not be placed on The Agency's agenda.

0720-08-.04 ACCESS TO AGENCY RECORDS.

(1) Public Inspection. All public records of The Agency are available for inspection during normal business hours in accordance with reasonable office policies.

(2) Copies. Upon a request for records under Tennessee's Public Records Act, Tenn. Code Ann. § 10-7-501 et seq., The Agency shall assess charges for the copying and labor based on the most current version of the Schedule of Reasonable Charges, issued by the Office of Open Records Counsel. Should any charge assessed under this rule total ten dollars ($10.00) or less, The Agency shall waive the charge and provide the requested documents without payment. The Executive Director, or his or her designee, may reduce any part of the charges calculated under these rules upon a written determination that such a reduction would be in the best interests of the public.

(3) Audio Recordings of meetings of The Agency are available for review and duplication. For each audio tape or disc to be duplicated, the person requesting the duplication shall pay a fee of fifteen dollars ($15.00).

0720-08-.05 CONDUCTING AGENCY MEETINGS.

(1) The Agency will hold regularly scheduled, public meetings to consider applications for certificates of need, and to conduct other business.

(2) Meetings of The Agency will be under the direction of the Chair, or in the Chair's absence or at his/her request, the Vice-Chair or other designated member as determined by the Chair. The meetings will be conducted in accordance with Robert's Rules of Order, except where otherwise provided by rule or statute.

(3) All motions for the approval or disapproval of certificates of need and for Agency Determinations will be determined by roll call vote. Except where otherwise provided by rule or by statute, matters other than the approval or disapproval of a certificate of need and Agency Determinations may, at the discretion of the Chair or acting Chair, be determined by voice vote.

(a) Any Agency member present and voting on a matter which has been determined by a voice vote may request that a roll call vote be taken. In the event such a request is made, a roll call vote will be taken. No additional debate or discussion will be allowed on the matter, unless otherwise appropriate under applicable rules of parliamentary procedure.

(b) Conditions placed upon the granting of a certificate of need should be included in the motion for approval, or an amendment thereto, and determined in accordance with these rules.

~~**0720-08-.06 BEGINNING OF REVIEW CYCLES.**~~

~~Review cycles shall begin on the first day of each month.~~

CHAPTER 0720-09 - DEFINITIONS

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

~~(1) "Adult psychiatric" means inpatient mental health services provided to patients 18 years of age and over.~~

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

(3) "Ambulatory surgical treatment center" is as defined in T.C.A., Title 68 § 68-11-201~~, Chapter 11, Part 2~~.

(4) "Capital expenditure" in relation to a proposed establishment of, modification, renovation, or addition to a health care institution, means an expenditure by or on behalf of a health care institution which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance. Any series of expenditures, each less than the threshold, but which when taken together are in excess of the threshold, directed toward the accomplishment of a single goal or project, requires a certificate of need. Any series of related expenditures made over a twelve (12) month period will be presumed to be a single project.

(a) Establishment, modifications, additions, or renovations. In calculating the capital expenditure for establishment, modifications, additions, or renovations, "capital expenditure" is the amount per construction bid or total amount of invoices for the single project excluding major medical equipment.

(b) Equipment. The cost of all medical equipment, whether fixed or moveable, 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, 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 payment, whichever is greater.

(5) "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.

(6) "Change of location" means a change of the specific location of an existing institution, facility, service, or piece of major medical equipment, in part or in its entirety. The following activities involving a home care organization are a change of location of a health care institution, and require a certificate of need unless exempted pursuant to TCA § 68-11-1607(a)(4):

(a) The addition of one or more counties to the licensed service-area of a home care organization.~~;~~

~~(b) The change of location of a parent office to a different county.~~

~~(7) "Child and adolescent psychiatric" means inpatient mental health services provided to patients under 18 years of age.~~

(8) "Executive director" means the chief administrative officer of The Agency and the appointing authority, exercising general supervision over all persons employed by The Agency, as defined in T.C.A. § 68-11-1606.

(9) "Expiration date" is the date ~~upon~~ by which activity authorized by a certificate of need ~~expires and becomes null and void~~must be implemented. The expiration date may be established by statute, by rule, or by order of The Agency.

(10) "Home health service" is as defined in T.C.A. § 68-11-201~~Title 68, Chapter 11, Part 2~~.

(11) "Hospital" is as defined in T.C.A. § 68-11-201~~Title 68, Chapter 11, Part 2~~.

(12) "Intellectual disability institutional habilitation facility" means a facility which offers on a regular basis health related services to individuals with intellectual disabilities who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but, because of physical or mental condition require residential care and services (more than room and board) and involves health related care under the supervision of a physician. Such a facility also offers an intensive program of habilitative services, as licensed by the Department of Intellectual and Developmental Disabilities.

(13) "Long-term categories" includes nursing home services, regardless of the length of stay, and any other health service which is intended or reasonably expected to result in an average length of stay of 2l days or longer.

(14) "Mental health hospital" means a public or private hospital or facility or part of a hospital or facility equipped to provide inpatient care and treatment for persons with mental illness or serious emotional disturbance, as licensed by the Department of Mental Health and Substance Abuse Services.

(15) "Neonatal intensive care unit" means a special care unit staffed and equipped to provide professional intensive treatment for the care of newborns with severe or complicated illnesses and/or high-risk newborn infants, staffed by a neonatologist and specialized nurses and in which bassinets are used as licensed beds.

(16) "Not directly related to patient care" may include the following types of single, isolated expenditures:

(a) Telephone systems;

(b) Non-clinical data processing systems;

(c) Heating and/or air conditioning systems;

(d) Energy conservation devices;

(e) Parking facilities;

(f) Roof repairs;

(g) Medical office buildings;

(h) Warehouses; and

(i) Cafeterias.

(17) "Nursing home" is as defined in T.C.A. § 68-11-201~~Title 68. Chapter 11, Part 2~~.

(18) "Outpatient diagnostic center" is as defined in T.C.A. § 68-11-201~~Title 68, Chapter 11, Part 2~~.

(19) "Person" where the context requires, may refer to any natural person, legal entity, facility, or institution, as defined in T.C.A. § 68-11-1602.

~~(20) "Recuperation center" is as defined in T.C.A. Title 68, Chapter 11, Part 2.~~

(21) "Residential hospice" is as defined in T.C.A. § 68-11-201~~Title 68. Chapter 11, Part 2~~.

(22) "Service area" means the county or counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide services and in which the majority of its service recipients reside.

(23) "Substantive amendment" as used in T.C.A. § 68-11-1607 means any amendment which has the effect of increasing the number of beds, square footage, cost, or other elements which are reasonably considered in the discretion of The Agency to be integral components of the application. A reduction of the above referenced components may be considered a substantive amendment if the amendment and supporting documentation are not received by the staff and Agency in a timely manner, necessary to allow The Agency to make an informed decision. Nothing in this rule shall be interpreted as limiting The Agency's authority to approve or deny all or part of any given application.

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

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."

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.

(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~~ between the sixteenth day and last day of the month of~~after~~ publication by the original applicant. The Executive director or his/her designee will determine whether applications are to be reviewed simultaneously.

(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 between the sixteenth day and last day of the month of~~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 and filing fees may be filed at any time after the filing of the Letter of Intent, and must be filed with The Agency ~~within five (5) days~~no later than the first day of the month after publication by the applicant~~, and must be accompanied by the filing fee~~. If the application and filing fee have not been received by The Agency by the first day of the month after publication by the applicant, then the application may not enter the review cycle on the fifteenth day of that month. 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 no later than the first day of the month ~~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 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 first 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~~2.25 per $1,000 of the estimated capital expenditure involved, but in no case shall this fee be less than $~~15,000~~3,000 nor more than $~~95,000~~45,000.

(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~~2.25 per $1,000 of project costs, but in no case shall the total fee be less than $3,000 ~~15,000~~ nor more than $45,000~~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 for comment~~, 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~~ fifteenth day of the appropriate month after the application has been deemed complete by the staff of The Agency.

(9) ~~Reviewing Agencies' Actions~~Staff Reports 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 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~~ At the end of the review cycle, Agency staff shall make public ~~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~~report shall clearly set forth any planning methodologies, data bases, and resource materials utilized in making its findings. The ~~reviewing agency~~report may include other information the executive director ~~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~~ five (5~~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.

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 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 submit any written documentation requested by the Executive Director~~; 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, and Executive Director 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.

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, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must

appear to be necessary to provide needed health care in the area to be served, provide health care that meets appropriate quality standards, and demonstrate that the effects attributed to competition or duplication would be positive for the consumers.

(3) If opposition is stated in writing prior to the application being formally considered by the agency then the application must be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties. ~~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.

(4~~5~~) ~~Any application which remains on the consent calendar will be individually considered and voted upon by The Agency.~~Applications on the Consent Calendar will be considered and voted upon by The Agency by a single roll-call vote for the entire Consent Calendar, unless an Agency member or the executive director request otherwise for specific applications.

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 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~~;~~

~~(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~~ thirty (~~1~~30) percent increase or decrease shall be presumed substantive, though there will be instances where changes greater than ~~ten~~ thirty (~~10~~30) percent would not be substantive and instances where changes less than ~~ten~~ thirty (~~10~~30) percent would be substantive, depending upon the totality of the circumstances. In no event will any change in cost of less than $~~10,000~~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 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.

(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.

(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.

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 seventy-five percent (75%) 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. The executive director must notify the agency of any exemption granted pursuant to this subdivision (a)(4)(A);

(2) The executive director will issue the exemption only upon receipt of a completed application for the exemption 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 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 to be made by The Agency. The independent review and verification must be applied to, but not necessarily be limited to, applicant-provided information as to any other 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 20 days prior to issuing an exemption;

(3) Opposition to an exemption application may be presented, subject to the same requirements of T.C.A., Title 68 § 68-11-1609(g).

(4) The exemption determination shall be made at a time and place to be posted on The Agency's website, no sooner than 20 days after the notice is posted.

(4) A relocation exemption granted by the executive director is subject to Agency review as provided by law.

0720-10-.07 EXEMPTION FROM VOIDING OF A CERTIFICATE OF NEED AND ANY ACTIVITY AUTHORIZED BY THE CERTIFICATE OF NEED

(1) The Agency may issue a temporary exemption to subdivision to the voiding of a certificate of need and any activity authorized by the certificate of need upon finding that sufficient cause for the temporary cessation of the activity has been presented to the agency along with a plan to resume the activity in the future;

(2) Any person seeking a temporary exemption must file an application for the exemption prior to the month of The Agency's meeting where the request is to be considered;

(3) The application must include reasons for the temporary cessation of the activity, a detailed plan to resume the activity, and an estimated date for resumption of the activity;

(4) Opposition to an exemption request may be presented, subject to the same requirements of T.C.A., Title 68 § 68-11-1609(g).

(5) Any temporary exemption issued by The Agency must expire at a date certain;

(6) An additional temporary exemption may be requested prior to the expiration of a temporary exemption;

(7) There is no limit on the number of temporary exemptions that may be issued by The Agency upon finding that sufficient cause for the temporary cessation of the activity has been presented to the agency along with a plan to resume the activity in the future.

0720-10-.08 TRANSFER OF A CERTIFICATE OF NEED

(1) The Agency may approve the transfer of a certificate of need after the agency determines that the new holder of the certificate of need would provide health care that meets appropriate quality standards, and that the transfer would 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;

(2) The Agency will consider a written request with supporting evidence at the first Agency meeting occurring two (2) weeks after the executive director has deemed the submission complete. The executive director's deeming the written submission complete shall not be considered to be a determination that the statutory requirements for approval have been satisfied. The executive director may make a recommendation for approval or denial of the request.

0720-10-.09 STANDARD PROCEDURES FOR OPPOSITION TO CERTIFICATE OF NEED APPLICATIONS

(1) Any healthcare institution wishing to oppose a certificate of need application must file a written objection with The Agency specifying reasons why one (1) or more of the criteria of subsection TCA 68-11-1609(b) are not satisfied. The reasons should be specified in sufficient detail to inform the applicant and The Agency of all arguments in advance of the meeting at which the application is to be considered.

(2) Any healthcare institution wishing to oppose a certificate of need application must serve a copy to the contact person for the applicant, not later than fifteen (15) days before the agency meeting at which the application is originally scheduled.

0720-10-.10 STANDARD PROCEDURE FOR SUBMISSION OF VISUAL AIDS TO BE USED AT AGENCY MEETINGS

Copies of all visual aids must be submitted to Agency staff no later than the Friday prior to the Agency's meeting at which the visual aids will be used. Visual aids not submitted in compliance may not be used at the meeting.

CHAPTER 0720-11

CERTIFICATE OF NEED PROGRAM – GENERAL CRITERIA

0720-11-.01 GENERAL CRITERIA FOR CERTIFICATE OF NEED.

The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

(1) Need. The health care needed in the area to be served may be evaluated upon the following factors:

(a) The relationship of the proposal to any existing applicable plans;

(b) The population served by the proposal;

(c) The existing or certified services or institutions in the area;

(d) The reasonableness of the service area;

(e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, TennCare participants, and low-income groups;

(f) Comparison of utilization/occupancy trends and services offered by other area providers;

(g) The extent to which Medicare, Medicaid, TennCare, medically indigent, charity care patients and low income patients will be served by the project. In determining whether this criteria is met, the Agency shall consider how the applicant has assessed that providers of services which will operate in conjunction with the project will also meet these needs.

~~(2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:~~

~~(a) Whether adequate funds are available to the applicant to complete the project;~~

~~(b) The reasonableness of the proposed project costs;~~

~~(c) Anticipated revenue from the proposed project and the impact on existing patient charges;~~

~~(d) Participation in state/federal revenue programs~~;

~~(e) Alternatives considered; and~~

~~(f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.~~

(~~3~~2) Quality. Whether the proposal will provide health care that meets appropriate quality standards may be evaluated upon the following factors:

(a) Whether the applicant commits to maintaining staffing comparable to the staffing chart presented in its CON application;

(b) Whether the applicant will obtain and maintain all applicable state licenses in good standing;

(c) Whether the applicant will obtain and maintain TennCare and Medicare certification(s), if participation in such programs was indicated in the application;

(d) Whether an existing healthcare institution applying for a CON has maintained substantial compliance with applicable federal and state regulation for the three years prior to the CON application. In the event of non-compliance, the nature of noncompliance and corrective action shall be considered;

(e) Whether an existing health care institution applying for a CON has been decertified within the prior three years. This provision shall not apply if a new, unrelated owner applies for a CON related to a previously decertified facility;

(f) Whether the applicant will participate, within 2 years of implementation of the project, in self-assessment and external assessment against nationally available benchmark data to accurately assess its level of performance in relation to established standards and to implement ways to continuously improve.

1. This may include accreditation by any organization approved by Centers for Medicare and Medicaid Services (CMS) and other nationally recognized programs. The Joint Commission or its successor, for example, would be acceptable if applicable. Other acceptable accrediting organizations may include, but are not limited to, the following:

(i) Those having the same accrediting standards as the licensed hospital of which it will be a department, for a Freestanding Emergency Department;

(ii) Accreditation Association for Ambulatory Health Care, and where applicable, American Association for Accreditation of Ambulatory Surgical Facilities, for Ambulatory Surgical Treatment Center projects;

(iii) Commission on Accreditation of Rehabilitation Facilities (CARF), for Comprehensive Inpatient Rehabilitation Services and Inpatient Psychiatric projects;

(iv) American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority, for Megavoltage Radiation Therapy projects;

(v) American College of Radiology, for Positron Emission Tomography, Magnetic Resonance Imaging and Outpatient Diagnostic Center projects;

(vi) Community Health Accreditation Program, Inc., Accreditation Commission for Health Care, or another accrediting body with deeming authority for hospice services from CMS or state licensing survey, and/or other third party quality oversight organization, for Hospice projects;

(vii) Behavioral Health Care accreditation by the Joint Commission for Nonresidential Substitution Based Treatment Center, for Opiate Addiction projects;

(viii) American Society of Transplantation or Scientific Registry of Transplant Recipients, for Organ Transplant projects;

(ix) Joint Commission or another appropriate accrediting authority recognized by CMS, or other nationally recognized accrediting organization, for a Cardiac Catheterization project that is not required by law to be licensed by the Department of Health;

(x) Participation in the National Cardiovascular Data Registry, for any Cardiac Catheterization project;

(xi) Participation in the National Burn Repository, for Burn Unit projects;

(xii) Community Health Accreditation Program, Inc., Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS and participation in the Medicare Quality Initiatives, Outcome and Assessment Information Set, and Home Health Compare, or other nationally recognized accrediting organization, for Home Health projects;

(xiii) Participation in the National Palliative Care Registry, for Hospice projects; and

(xiv) As an alternative to the provision of third party accreditation information, applicants may provide information on any other state, federal, or national quality improvement initiatives, for Nursing Home projects.

(g) For Ambulatory Surgical Treatment Center projects, whether the applicant has estimated the number of physicians by specialty expected to utilize the facility, developed criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel, and documented the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.

(h) For Cardiac Catheterization projects:

1. Whether the applicant has documented a plan to monitor the quality of its cardiac catheterization program, including but not limited to, program outcomes and efficiencies;

2. Whether the applicant has agreed to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee; and

3. Whether the applicant will staff and maintain at least one cardiologist who has performed 75 cases annually averaged over the previous 5 years (for an adult program), and 50 cases annually averaged over the previous 5 years (for a pediatric program).

(i) For Open Heart projects:

1. Whether the applicant will staff with the number of cardiac surgeons who will perform the volume of cases consistent with the State Health Plan (annual average of the previous 2 years), and whether the applicant will maintain this volume in the future;

2. Whether the applicant will staff and maintain at least one surgeon with 5 years of experience; and

3. Whether the applicant will participate in a data reporting, quality improvement, outcome monitoring, and external assessment system that benchmarks outcomes based on national norms (demonstrated active participation in the STS National Database is expected and shall be considered evidence of meeting this standard);

(j) For Comprehensive Inpatient Rehabilitation Services projects, whether the applicant will have a board-certified physiatrist on staff (preferred);

(k) For Home Health projects, whether the applicant has documented its existing or proposed plan for quality data reporting, quality improvement, and an outcome and process monitoring system;

(l) For Hospice projects, whether the applicant has documented its existing or proposed plan for quality data reporting, quality improvement, and an outcome and process monitoring system;

(m) For Megavoltage Radiation Therapy projects, whether the applicant has demonstrated that it will meet the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority;

(n) For Neonatal Intensive Care Unit projects, whether the applicant has documented its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems; whether the applicant has documented the intention and ability to comply with the staffing guidelines and qualifications set forth by the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities; and whether the applicant will participate in the Tennessee Initiative for Perinatal Quality Care (TIPQC);

(o) For Nursing Home projects, whether the applicant has documented its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems, including in particular details on its Quality Assurance and Performance Improvement program;

(p) For Inpatient Psychiatric projects:

1. Whether the applicant has demonstrated appropriate accommodations for patients (e.g., for seclusion/restraint of patients who present management problems and children who need quiet space; proper sleeping and bathing arrangements for all patients), adequate staffing (i.e., that each unit will be staffed with at least two direct patient care staff, one of which shall be a nurse, at all times), and how the proposed staffing plan will lead to quality care of the patient population served by the project;

2. Whether the applicant has documented its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems; and

3. Whether an applicant that owns or administers other psychiatric facilities has provided information on satisfactory surveys and quality improvement programs at those facilities.

(q) For Freestanding Emergency Department projects, whether the applicant has demonstrated that it will be accredited with the Joint Commission or other applicable accrediting agency, subject to the same accrediting standards as the licensed hospital with which it is associated;

(r) For Organ Transplant projects, whether the applicant has demonstrated that it will achieve and maintain institutional membership in the national Organ Procurement and Transportation Network (OPTN), currently operating as the United Network for Organ Sharing (UNOS), within one year of program initiation; additionally, the applicant shall comply with CMS regulations set forth by 42 CFR Parts 405, 482, and 498, Medicare Program; Hospital Conditions of Participation: Requirements for Approval and ReApproval of Transplant Centers To Perform Organ Transplants; and

(s) For Relocation and/or Replacement of Health Care Institution projects:

1. For hospital projects, Acute Care Bed Need Services measures are applicable; and

2. For all other healthcare institutions, applicable facility and/or service specific measures are applicable.

(t) ~~HSDA~~ The Agency will notify the applicant and any applicable licensing agency if any volume or quality measure has not been met.

(u) Within one month of notification the applicant must submit a corrective action plan and must report on the progress of the plan within one year of that submission.

(43) The effects attributed to competition or duplication would be positive for the consumers~~Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services~~. The the effects attributed to competition or duplication would be positive for the consumers~~contribution which the proposed project will make to the orderly development of an adequate and effective health care system~~ may be evaluated upon the following factors:

(a) Participation in TennCare, medicare and other federal and state reimbursement programs; participation in other insurance plans; and charity care.~~The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);~~

(b) ~~The positive or negative effects attributed to duplication or competition~~Access to quality, low-cost healthcare services;

(c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;~~ and~~

(d) Whether the applicant commits to maintaining an actual payor mix that is comparable to the payor mix projected in its CON application, particularly as it relates to Medicare, TennCare/Medicaid, Charity Care, and the Medically Indigent~~.~~; and

(e) The impact upon patient charges.

(5) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site, The Agency may consider, in addition to the foregoing factors, the following factors:

(a) Need. The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change to the proposed new site.

~~(b) Economic factors. The applicant should show that the project can be economically accomplished and maintained at the proposed new site.~~

(c) Quality of Health Care to be provided. The applicant should show the quality of health care to be provided will be served at least as well as at the original site.

(d) The effects attributed to competition or duplication would be positive for the consumers. ~~Contribution to the orderly development of health care facilities and/or services~~ The applicant should address the effects attributed to competition or duplication would be positive for the consumers.~~any potential delays that would be caused by the proposed change of site, and show that any such delays~~

~~are outweighed by the benefit that will be gained from the change of site by the population to be served~~.

(6) Certificate of need conditions. In accordance with T.C.A. § 68-11-1609, The Agency, in its discretion, may place such conditions upon a certificate of need it deems appropriate and enforceable to meet the applicable criteria as defined in statute and in these rules.

CHAPTER 0720-12

CERTIFICATE OF NEED PROGRAM – APPLICATION, DISCLOSURE OF INFORMATION AND REPORTING REQUIREMENTS

0720-12-.01 STANDARD APPLICATION.

(1) Application for a certificate of need shall be made on form(s) provided by The Agency. The applicant must provide all information requested in the application forms. The information which may be required in the application form(s) includes, but is not necessarily limited to, the following:

(a) Facility identification, including legal interests and status, operator and owners;

(b) Detailed project description;

(c) Detailed project cost data;

~~(d) Detailed disclosure of anticipated financing mechanism;~~

(e) Project operating costs and revenues, patient charges, and occupancy rate;

(f) Information on whether the proposed project will provide health care that meets appropriate quality standards;

(g) Information on the project's relationship to public needs and the existing health service system; and

(h) A copy of any signed agreement between the applicant and TennCare managed care organizations; if a signed agreement has not been executed prior to The Agency's consideration of the application, the applicant shall provide a list of any such organizations with whom the applicant is negotiating, or a statement that the applicant does not intend to contract with any TennCare managed care organization(s).

(2) The accuracy of the information provided must be attested to by the responsible party or his agent in a notarized statement. Providing false, incorrect, misleading, or fraudulent information is grounds for revocation of the certificate of need.

0720-12-.02 REPORT OF BED INCREASES NOT REQUIRING A CERTIFICATE OF NEED.

(1) Any rehabilitation facility, ~~mental health hospital~~ nursing home or hospital which is increasing the number of its licensed beds without the necessity of obtaining a certificate of need, as provided by law, shall report such activity on forms provided by The Agency.

(2) Any rehabilitation facility, nursing home ~~mental health hospital~~ or hospital reporting such increases must provide all information requested in the form(s). Information required to be provided by the forms may include, but not be limited to, the following:

(a) Facility identification;

(b) Date of most recent prior increase in number of licensed beds not requiring a certificate of need, number of beds increased, and type of beds;

(c) Number of licensed beds prior to the request;

(d) Number of beds being increased, by licensure category; and

(e) Anticipated date of licensure/certification.

~~**0720-12-.03 REPORT OF CHANGE OF OWNERSHIP OF LICENSED INSTITUTIONS.**~~

~~(1) Notice of a change of ownership of a health care institution, occurring within two years of the date of initial licensure, must be reported to The Agency in writing. Any person reporting such a change of ownership must provide all information requested by The Agency. Such information which may be required may include, but not be limited to, the following:~~

~~(a) Identification of the current owner of the health care institution;~~

~~(b) Identification of the proposed new owner of the health care institution;~~

~~(c) Identification of the health care institution, the ownership of which is proposed to be transferred; and,~~

~~(d) The effective date of the proposed change of ownership.~~

0720-12-.04 REGISTRATION OF EQUIPMENT.

(1) Ownership of computerized axial tomographers, magnetic resonance imagers, linear accelerators, positron emission tomography, and any other piece of equipment specified by law, must be made on forms provided by The Agency within ninety (90) days of acquisition of the equipment.

(2) The person registering such equipment must provide all information requested in the form(s) provided by Agency staff. Information which may be required by the form(s) may include, but not be limited to, the following:

(a) Identification of the owner of such equipment;

(b) The location of the equipment, including facility identification;

(c) Whether the acquisition is by purchase, lease, or otherwise;

(d) The date of delivery of the equipment; and

(e) The expected useful life of the equipment.

(3) All such equipment shall be filed on an annual inventory survey developed by Agency staff. The survey shall include, but not be limited to, the identification of the equipment and utilization data

according to source of payment. The survey shall be filed no later than thirty (30) days following the end of each state fiscal year. The Agency is authorized to impose a penalty not to exceed fifty dollars ($50) for each day the filing of the survey is late.

0720-12-.045 ANNUAL REPORTS CONCERNING MAGNETIC RESONANCE IMAGING SERVICES.

Any person who provides magnetic resonance imaging services shall file an annual report each year with The Agency ~~concerning adult and pediatric patients~~ that details the mix of payors by percentage of cases for the prior calendar year for its patients, including private pay, private insurance, uncompensated care, charity care, Medicare, and Medicaid. These reports shall be filed on forms provided by The Agency, shall indicate whether magnetic resonance imaging services will be provided to a patient who is fourteen (14) years of age or younger on more than five (5) occasions per year, and shall be due as provided by law.

0720-12-.056 ANNUAL REPORT CONCERNING ~~CONTINUED NEED AND~~ APPROPRIATE QUALITY MEASURES.

(1) For every certificate of need issued after July 1, 2016, reporting shall be made to the Health Services and Development Agency each year 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 ~~volume and~~ 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-.06 REPORTS CONCERNING OUTPATIENT DIAGNOSTIC CENTERS

For every certificate of need issued for the after July 1, 2016 for the establishment of an outpatient diagnostic center, reporting shall be made to the Health Services and Development Agency within two (2) years after the date of receiving a certificate of need as to whether the outpatient diagnostic center has become accredited by the American College of Radiology in the modalities provided by that facility.

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 establishes a healthcare institution or initiates any service specified in TCA 68-11-1607(a)(3) pursuant to the exemption provided in TCA 68-11-1607(q) within ninety (90) days of initiation of the exempted activity.

(2) Any person who provides positron emission tomography services or magnetic resonance imaging services pursuant to TCA 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.

0720-12-.08 REPORTS CONCERNING ~~ACCREDIDATION~~ACCREDITATION OF HOME HEALTH AGENCIES OPERATING PURSUANT TO CERTIFICATE OF NEED EXEMPTIONS

Reporting shall be made to the Health Services and Development Agency within two (2) years of the licensure of the home health agency, on forms prescribed by the Agency, by each home health agency established pursuant to a certificate of need exemption in TCA 68-11-1607(r) or TCA 68-11-1607(s). Reporting shall include whether the home health agency has been accredited, and if so, by which accrediting organization.

0720-12-.09 REPORTS CONCERNING ~~ACCREDIDATION~~ACCREDITATION OF POSITRON EMISSION TOMOGRAPHY PROVIDERS OPERATING PURSUANT TO CERTIFICATE OF NEED EXEMPTIONS

A provider of positron emission tomography established without a certificate of need pursuant to TCA 68-11-1607(u) must become accredited by the American College of Radiology and provide to the agency proof of the accreditation within two (2) years of the date of licensure.

0720-12-10 REPORTS CONCERNING HEALTH CARE SERVICES

(1) A person who performs the following actions shall file an annual report as described in this subsection with the Agency:

(A) Cardiac catheterization;

(B) Open heart surgery;

(C) Organ transplantation;

(D) Operation of a burn unit;

(E) Operation of a neonatal intensive care unit;

(F) Provision of home health services; or

(G) Provision of hospice services.

(2) The annual report must be submitted on or before September 30th of each year, with the first filing being required no sooner than September 30, 2022.

(3) The annual report must be submitted in a manner and on forms prescribed by the agency, and must include utilization data according to source of payment and zip codes of patient origin.

CHAPTER 0720-13

RULES OF PROCEDURE FOR HEARING CONTESTED CASES

0720-13-.01 GENERAL PROCEDURES FOR CONTESTED CASES.

(1) Except as otherwise provided herein, all contested cases before The Agency will be conducted in accordance with T.C.A. §§ 4-5-301 et seq., 68-11-1610, with these Rules, and with the Rules of the Secretary of State Chapter 1360-04-01.

(2) Eligibility to appeal. Any person with legal standing, and who meets the requirements of T.C.A. § 68-11-1610 may petition The Agency for a contested case hearing to appeal the grant or denial of a certificate of need.

(3) Filing of petitions. Petitions for contested case hearings must be filed with The Agency ~~in triplicate~~ pursuant to Rule 0720-08-.01 of the Health Services and Development Agency, and must be ~~received at~~filed with The Agency ~~offices~~ within fifteen (15) days of the date of The Agency's meeting at which the action which is the subject of the petition took place. Simultaneous with filing, the petitioner shall serve copies of the petition on all other parties in the matter. The petitioner shall have the burden of proving, by a preponderance of the evidence, that a certificate of need should be granted or should be denied.

(4) Intervention. Any person with legal standing and who meets the requirements of T.C.A. § 4-5-310 may file a petition for intervention in a contested case.

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

(1) With the exception of declaratory orders referenced below, all petitions for a contested case hearing shall routinely be referred to the Administrative Procedures Division, Department of State for hearing by an Administrative Judge sitting alone on behalf of The Agency. The Agency retains the right, however, to hear any particular contested case on its own behalf.

(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 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.

(3) Unless agreed otherwise by the parties, at the beginning of all contested case hearings, Agency counsel shall provide a summary of what the case is about, description of the project, and introduce into evidence the application, the reviewing agency's report and the staff Summary, and the minutes of The Agency reflecting the action that was taken before The Agency. In no event 0shall this provision mean that The Agency is a neutral party in contested cases, or that its counsel represents the interests of any party other than The Agency.

(4) In all cases, whether heard by an Administrative Judge sitting alone, or by the full Agency, the party petitioning for such hearing shall present its case first, unless the parties agree otherwise.

0720-13-.03 AGENCY REVIEW OF INITIAL ORDERS.

(1) An Initial Order issued by an Administrative Judge, sitting alone, may be reviewed by The Agency pursuant to T.C.A §§ 4-5-301, et seq., ~~68-11-1610,~~ these Rules, and the Rules of the Secretary of State Chapter 1360-04-01. Such review shall be limited to reviewing legal conclusions in the Initial Order. The Agency may, in its discretion, decline to exercise any review of an Initial Order issued by an Administrative Judge, in which event the Initial Order issued by an Administrative Judge shall become a Final Order as provided by the Administrative Procedures Act.

(2) In such a review proceeding, The Agency's review is strictly limited to the record which was developed before the Administrative Judge. No additional evidence is to be received or considered by The Agency.

(3) Such a review proceeding is in the nature of appellate review. Each party will be given the opportunity to file a brief which should specify what action the party maintains The Agency should take on the Initial Order. The Agency may place reasonable page limitations on such briefs.

(4) In such a review proceeding, each party will normally be limited to oral argument of thirty (30) minutes in length, including rebuttal.

(5) At the conclusion of the review proceeding The Agency may decide that the Initial Order should be adopted in its entirety, or it may make such modifications to the Initial Order as it deems appropriate.

(a) Alternatively, The Agency may take the matter under advisement, and subsequently reconvene, after reasonable notice to the parties, to hold its public deliberations and to render a Final Order.

0720-13-.04 DECLARATORY ORDERS.

(1) Any affected person may petition The Agency for a declaratory order, as provided in T.C.A. §4-5-223, as to the interpretation, validity, or applicability of a statute or rule within the primary jurisdiction of The Agency. Such petition shall be filed with The Agency in triplicate, and must specifically identify the statute or rule at issue, and the nature of the ruling sought.

(2) A petition for declaratory order is viewed as primarily involving questions of law and statutory or rule interpretation. The parties should strive to limit the amount of evidence presented, and to stipulate the facts to the extent possible.

(3) In the event the petition for declaratory order arises out of The Agency's action on a specific project or issue, the petition for declaratory order shall be filed within thirty (30) days of the date of The Agency meeting at which the action at issue was taken.

(4) No person may file a petition for declaratory order as to any action or issue which is the subject of a pending or completed contested case proceeding involving the same person.