

**RULES  
OF  
HEALTH SERVICES AND DEVELOPMENT AGENCY**

**CHAPTER 0720-11  
CERTIFICATE OF NEED PROGRAM – GENERAL CRITERIA**

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0720-11-.01 General Criteria for Certificate of Need

**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.

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- (3) 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 non-compliance 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;

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- (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

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- 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

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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 Re-Approval 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 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.
- (4) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The 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) 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;
  - (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.
- (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

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- 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) Contribution to the orderly development of health care facilities and/or services. The applicant should address 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.

**Authority:** T.C.A. §§ 4-5-201, et seq., 4-5-202, 68-11-1605, 68-11-1607, 68-11-1609, and 68-11-1633.

**Administrative History:** Original rule filed August 31, 2005; effective November 14, 2005. Emergency rule filed May 31, 2017; effective through November 27, 2017. The emergency rule expired November 28, 2017 and reverted to its previous status. Amendments filed October 24, 2017; effective January 22, 2018.