

STATE: **NORTH CAROLINA, Dept. of Health and Human Services**

WEBSITE: <https://www2.ncdhhs.gov/DHSR/coneed/index.html>

Criteria	Description	Source
What facilities or equipment reviewed (i.e., urgent care, insurance companies)	<ol style="list-style-type: none"> 1. Develop <ol style="list-style-type: none"> a. Acute Care Hospitals b. Inpatient Psychiatric Facilities c. Substance Abuse Facilities (but not detox only facilities) d. Nursing Homes e. Adult Care Homes (7 or more beds) f. Kidney Disease Treatment Centers g. Intermediate Care for "Mentally Retarded" Facilities h. Inpatient Rehabilitation Facilities i. Home Health Agency Offices j. Hospice Home Care Offices k. Diagnostic Centers l. Ambulatory Surgical Facilities 2. Upgrading or expanding existing health service w/ cap expenditures above certain amount 	www2.ncdhhs.gov/dhsr/coned/index.html
What actions reviewed (i.e., substantive vs terminations)	<ol style="list-style-type: none"> 1. Establish new health service facility 2. "Capital expenditure" by any person for health service in excess of \$2 million 3. "Change in bed capacity" 4. New dialysis or home health service 5. Change in previously approved project capital costs of 15%+ 6. Offering: bone marrow or organ transplant, burn care, NICU, cardiac cath 7. Acq of equipment: cardiac cath equip, gamma knife, heart-lung bypass, LinAc, Lithotripter, MRI, PET or Simulator 8. Acq of health service facility from a health maintenance organization 9. Conversion of non-health care beds to health care beds 10. Construction/est of hospice 11. Opening of an add'l office by existing home health agency or hospice 12. Acq major med equip (\$750k incl study, renovations etc.) 13. Relocation of health service facility from one service area to another 14. Furnishing mobile medical equipment to any person 15. Operating or Endoscopy room: construction, development, relocation, increase in no. of 16. Change in designation from OR to endoscopy room and vice versa 	G.S. 131E 176(16)
Exceptions	Institutional health service used for research only	

Decisions	<p>2015:</p> <ul style="list-style-type: none"> • 122 Conditional Approvals • 7 Denials • 1 Withdrawal <p>2014:</p> <ul style="list-style-type: none"> • 129 Approvals • 22 Denials • 2 Withdrawals <p>2013:</p> <ul style="list-style-type: none"> • 118 Approvals • 26 Denials • 1 Withdrawal 	Phone Interview
Hospitals, systems and population	<p>127 Hospitals including specialty and long term care. Most are part of a network/system.</p> <p>Population: 10,042,802</p>	Phone Interview
What are the criteria considered & how defined (i.e., "clear public need")	<ul style="list-style-type: none"> • Consistent with applicable policies and need determinations in the State Medical Facilities Plan which is update annually by the State Health Coordinating Council. The SMFPsets max # of beds by category, ORs, med equip, home health offices and other services requiring CON approval. Whether consistent with the Plan • Identify the population to be served, demonstrate the need that population has for the project and demonstrate the extent to which low income, racial and ethnic minorities, women, handicapped persons, elderly and other underserved groups will have access to the project • If reduction or elimination of service: needs of pop currently being served met adequately • Financial and operational projections • No unnecessary duplication • Availability of resources incl health manpower and management personnel (i.e., staffing) • Provision of necessary ancillary and support services;, Coordination w/ existing health care system • "An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals" • Special needs of health maintenance organizations will be fulfilled (6 considerations) • Construction projects must demonstrate least expensive alternative and will not unduly increase costs of health services to public • Contribution of proposal to care for medically underserved groups • Will accommodate the clinical needs of health professional training programs • Expected effects on competition in proposed service area • Quality of care has been provided in past 	G.S. 131E-183

	Regulations are <i>incredibly</i> specific and tailored to address each reviewed area (i.e., cardiac cath, burn center, etc.)	
Application fee	\$5,000 and .3% of capital expenditure proposed up to \$50,000	
Decision maker (i.e., review panel, Deputy/Commissioner)	Secretary of Health and Human Services – delegated to the Healthcare Planning and Certificate of Need Section in the Division of Health Service Regulation	
Use of Experts	State Health Coordinating Council develops the State Medical Facilities Plan. The State Health Coordinating Council is made up of doctors and other experts from the state health field. They are appointed by the Governor and are an advisory body. The Governor must approve the plan each year.	https://www2.ncdhs.gov/DHSR/ncshcc/index.html
Scheduling/Timeline (i.e., batching? expedited, etc.)	<ul style="list-style-type: none"> • Review schedules set in “State Medical Facilities Plan”- applications for similar proposals in same service area reviewed together • Competitive Review – approval of one application = denial of another • Expedited review, <i>may</i> approve applicant’s request for if: <ul style="list-style-type: none"> - not competitive review - capital expenditure = <\$5 million - no request for public hearing w/ time frame (either by department or public) • 90 days for initial review generally; public may submit written comment during first 30 	G.S. 131E-182 G.S. 131E-176(7b)
Public Hearings (i.e., initiating)	Mandatory when: review is competitive, proposal will cost \$5 million +, written request by an “affected party” (applicant, individual residing or regularly using health facilities w/ service area, provider of similar services . . . basically <i>anyone</i>)	G.S. 131E-185
Appeal	<p>“any affected person may file petition for contested case hearing with Office of Admin Hearings” and administrative law judge makes ruling</p> <p>Competitors can appeal approvals of competitive applications. They have to be able to prove prejudice or error.</p>	Phone Interview
Planning	A State Medical Facilities Plan is developed every year. The plan sets the methodology for different types of bed need. If an unmet need is found, applications are accepted to fill that need the following year. These applications are scheduled and may be competitive. The methodology is also used when evaluating other CON applications to determine if there is enough need to support the service.	Phone Interview
Enforcement	<p>Section may withdraw CON if applicant/holder fails to develop and operate the service consistent with representations made in the application or w/ any conditions the Section placed on the CON</p> <p>Review all records of which pertain to construction, acquisition activities, staffing or costs and charges for patient care, staffing record and utilization statistics</p> <p>Assessment of civil penalty (knowingly offers new service w/o CON or violates terms of CON): up to \$20,000/time service is provided in violation</p> <p>The Office of the Attorney General can get involved if fines are appealed or not paid.</p>	G.S. 131E-189 G.S. 131E-190 10a NCAC 14D.0500, .0501 Phone Interview

Quality of Care	Statewide analysis is part of their criteria. They have to look at the quality of care at other similar health services owned, operated or managed by the applicant or a related entity.	Phone Interview
Data	Data comes from licensing renewal applications and Truven billing data for acute care beds. There are also transparency regulations that allow them access to outpatient data.	Phone Interview
Rate Setting	No rate setting	Phone Interview
Other	Staff are assigned counties but may review applications from any county	