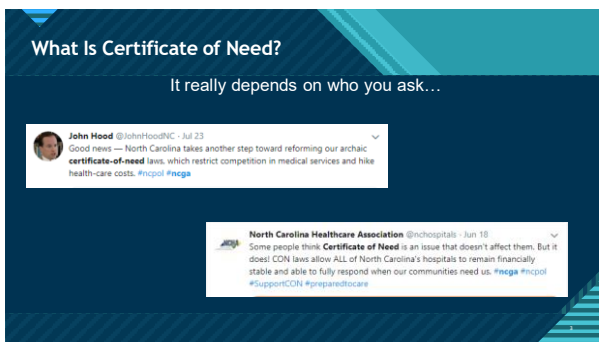




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Certificate of Need in a Nutshell

- Certificate of Need (CON) is a mechanism to define the need for new healthcare facilities and services, with the goal of controlling costs by preventing unnecessary duplication of facilities.
- CON laws are found in Article 9 of Chapter 131E of the North Carolina General Statutes (G.S. 131E-175 through G.S. 131E-191.1).
- CON regulations are found in Subchapter 14C of Chapter 10A of the North Carolina Administrative Code. (10A NCAC 14C.0101 through 10A NCAC 14C.4006).
- The CON program in North Carolina is administered by the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation, Department of Health and Human Services.

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Hill-Burton Act of 1946

- Provided federal grants to modernize hospitals that had become obsolete due to a lack of capital investment throughout the Great Depression and World War II.
- Funds were provided to local health planning councils charged with determining the need for hospital facilities.
- New hospitals were required to submit plans to the State for approval prior to the start of construction.

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Comprehensive Health Planning Act of 1966

- Provided funding for state and local health planning councils.
- Health planning councils were to assess the comprehensive health needs of each area and plan for the coordination and development of new services.
- Funding was available for health staffing and services, not just facility construction.

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National Health Planning and Resource Development Act of 1972

- NHRPDA established the first CON requirements.
- Required states to create local health service agencies, designate a State Health Planning and Development agency, and create a State Health Coordinating Council to carry out the planning function consistent with federal requirements.
- Proposed projects had to be consistent with a state's health plan to be approved for construction or implementation.
- States that complied with the federal regulations got priority in funding.
- Intent was to assure a proper distribution of health care facilities and services throughout a state and to control health care costs by eliminating the unnecessary duplication of such facilities and services.

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North Carolina CON

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North Carolina CON

- G.S. 131E-176(3) defines "Certificate of Need" to mean "a written order which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project."
- Under G.S. 131E-181, a CON is valid only for the defined scope, physical location, and person named in the application, and it cannot be assigned except as provided by law.
- CON law prohibits health care providers from acquiring or adding to their facilities and equipment, except in specified circumstances, without the prior approval of the Department of Health and Human Services. Prior approval is also required for the initiation of certain medical services.

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CON Requirements: G.S. 131E-178

- A CON must be obtained before:
 - Developing or offering a "new institutional health service."
 - Acquiring a health service or facility if the acquisition would have been considered development of a new institutional health service.
 - Making a capital expenditure in excess of \$2,000,000.

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"New Institutional Health Service"

G.S. 131E-178(16) lists the things that are considered "new institutional health services":

- Establishment of a new health service facility
- Any change in bed capacity
- Offering dialysis or home health services (under certain conditions)
- A change in a project previously approved for a CON if the change is made before the project has been completed for one year
- Bone marrow transplant services
- Burn intensive care services
- Cardiac catheterization services (under some circumstances)
- Neonatal intensive care services
- Open-heart surgery centers
- Solid organ transplant services
- Air ambulance equipment
- Gamma knives
- Heart-lung bypass machines
- Linear accelerators
- Lithotriptors
- MRI machines
- PET scanners
- Simulators
- Establishment of a hospice, hospice inpatient, or hospice residential care facility
- Relocation of an existing health service facility
- Increase in the number of operating rooms or gastrointestinal endoscopy rooms in an existing healthcare facility

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CON Exemptions: G.S. 131E-184

- New Institutional Health Service exemptions:
 - Infrastructure improvements like parking and HVAC
 - Replacement equipment
 - Improvements necessary to comply with state or federal regulations
- Capital expenditures in excess of \$2,000,000 are exempt in certain circumstances:
 - Expanding an existing nursing home, adult care facility, or ICF without a change in bed capacity.
 - Replacement of equipment with an existing CON on the main campus of a healthcare facility.
 - Replacing, renovating, or expanding an existing healthcare facility with a CON, so long as bed capacity does not change.
- Conversion of beds from acute care to psychiatric care.
- Legacy medical facilities.

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CON Process

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Application: G.S. 131E-182

- A complete application must be filed.
- A non-refundable fee of \$5,000, plus .3% of the amount by which the capital expenditure exceeds \$1,000,000, must accompany the application.
- Maximum fee is \$50,000.

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Review Process: G.S. 131E-185

- Review must be completed within 90 days.
- The review period can be extended for an additional 60 days if DHHS requests.
- Anyone can file comments on the application within the first 30 days of review.
- A public hearing is conducted if more than one applicant applies for the CON, if the application is for an expenditure of more than \$5,000,000, or if an "affected party" requests a hearing.
- "Affected party" is defined statutorily and includes:
 - The applicant
 - Anyone residing in the service area
 - Anyone regularly receiving care in the service area
 - Anyone who provides similar healthcare services in the service area

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Review Criteria: G.S. 131E-183

- Compliance with SMFP.
- Identification of population to be served.
- Demonstration that the project is cost-effective.
- Existence of sufficient capital to complete the project and sufficient manpower to staff the completed project.
- No unnecessary duplication of services.
- The needs of HMOs, the elderly, medically underserved groups, and healthcare professional training programs in the area must be met.
- Description of expected competitive effects on similar healthcare services in the area.

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Decision: G.S. 131E-186

- Decision must be announced within 90 or 150 days, depending on whether the review was extended.
- Decision can be approval, approval with conditions, or denial.
- DHHS must provide written findings on which the decision was based.

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Appeal: G.S. 131E-188

- Any affected person can petition for a contested case hearing of the decision within 30 days.
- The contested case hearing is in front of an administrative law judge.
- The ALJ must issue final decision within 270 days of the contested case petition being filed.
- Any party to the contested case can appeal to the Court of Appeals within 30 days of the ALJ's decision being filed.

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