Overview of North Carolina Certificate of Need Law

Prepared by Research Division Staff

North Carolina State Health Coordinating Council

North Carolina State Health Coordinating Council

- **Establishment and Membership:**
  - Originally established by Executive Order No. XIX signed by Gov. Holshouser on June 1, 1976.
  - Directs the development of the annual State Medical Facilities Plan, which prescribes the policies and methodologies used in determining need for new health care facilities and services in North Carolina. G.S. 131E-177.

Establishment and Membership continued:

Current Council created by Executive Order No. 139 by Gov. Mike Easley on March 3, 2008. Provides for 29 members appointed by the Governor:

- 1 member from the academic medical centers
- 1 member from the area health education centers
- 2 members from business and industry (at least one individual representing small business and one representing large business)
- 1 member from the health insurance industry
- 1 member from the N.C. Association of County Commissioners
- 1 member from the N.C. Health Care Facilities Association
- 1 member from the N.C. Hospital Association
- 1 member from the N.C. Association for Home Care
- 1 member from the N.C. Association of Long-Term Care Facilities
- 1 member from the N.C. Association of Local Health Directors
- 1 member from the N.C. Medical Society
- 1 member from the N.C. House of Representatives
- 1 member from the N.C. Senate
- 1 member from the U.S. Department of Veterans Affairs (non-voting)
- 14 at-large members to represent other health professional associations and to ensure regional representation

Current SHCC Members

Member	Representing	From
William Wainwright, Chairman	N.C. House of Representative	Havelock
Donald Beaver	Health Care Facilities Association	Hickory
Bill Bedsole	At-Large	Washington
Greg Beier	At-Large	Winston-Salem
Don Bradley, MD	Health Insurance Industry	Durham
Richard Bruch, MD	N.C. Medical Society	Durham
Vacant	At-Large	
Dennis Clements, III, MD	Academic Medical Centers	Durham
Johnnie Farmer	County Commissioners Association	Aulander
Anthony Foriest	N.C. Senate	Graham
Sandra Greene, DrPH	At-Large	Chapel Hill
Ted Griffin	Business and Industry	Durham
Harold Hart	Business and Industry	Siler City
Laurence Hinsdale	At-Large	Concord
Daniel Hoffman	Department of Veterans Affairs	Durham
John Holt, Jr., MD	At-Large	Raleigh
Eric Janis, MD	At-Large	Smithfield
Brenda Latham-Sadler, MD	At-Large	Winston-Salem
Leslie Marshall, MD	At-Large	Raleigh
Frances Mauney	At-Large	Durham
Zach Miller	Long-Term Care Facilities Association	Wilmington
Jerry Parks	Association of Local Health Directors	Edenton
Prashant Patel, MD	At-Large	Cary
Thomas Pulliam, MD	At-Large	Winston-Salem
Pam Tidwell	Home Care Association	Asheville
Deborah Teasley, PhD	Area Health Education Centers	Fayetteville
Christopher Ullrich, MD	At-Large	Charlotte
Zane Walsh, MD	At-Large	Fayetteville
John Young	N.C. Hospital Association	Kings Mountain

- Next meeting September 28, 2011, on the Dorothea Dix Campus at the Brown Building, Conference Room 104, beginning at 10:00 a.m.

North Carolina State Health Coordinating Council

- Members serve 3-year staggered terms so that the terms of approximately 1/3 of the members expire in a single calendar year.
- Chair and Vice-Chair appointed by Governor for 2-year terms.

State Medical Facilities Plan

State Medical Facilities Plan

- **What is it?**
  - An annual document containing policies and methodologies used in determining need for new health care facilities and services in North Carolina.
  - Developed by the North Carolina Department of Health and Human Services, Division of Health Services Regulation, under the direction of the North Carolina State Health Coordinating Council.
  - Must be approved by the Governor.
  - Each Plan takes effect on January 1st and expires on December 31st.

State Medical Facilities Plan

- **What is it?**
  - The purpose of the Plan is to make an overall needs assessment.
  - Major objective is to provide individuals, institutions, state and local government agencies, and community leadership with policies and projections of need to guide local planning for specific health care facilities and services.

State Medical Facilities Plan

- **What's in it?**

10A NCAC 14C .0103 STATE MEDICAL FACILITIES PLAN

(a) The North Carolina State Medical Facilities Plan contains the following information:

(1) inventory of certain categories of inpatient and outpatient health care facilities, including number of beds and utilization of beds;

(2) type of services provided by each category of health care facility;

(3) projections of need for acute care hospitals (including rehabilitation services), long-term care facilities (including nursing homes, home health agencies, and hospice inpatient facilities), mental health facilities and end stage renal dialysis services for various geographical areas of the state;

(4) statement of policies related to acute care facilities, rehabilitation services, long-term care, psychiatric facilities, chemical dependency facilities, and facilities for intermediate care for the mentally retarded, which are used with other criteria contained in this Subchapter and in G.S. 131E-183 and need projections to determine whether applications proposing additional beds and services of these types may be approved under the certificate of need program; and

(5) the certificate of need review schedule and description of review categories.

State Medical Facilities Plan

- **What is it?**
  - Determination of need is based primarily on population growth and demographics.
  - The projections of need for the various facilities and services are used in conjunction with other statutes and rules in reviewing certificate of need applications for establishment, expansion, or conversion of health care facilities and services.

State Medical Facilities Plan

- **What is it?**
  - Projections of need are provided for the following types of facilities:
    - acute care hospitals
    - operating rooms
    - inpatient rehabilitation facilities
    - technology services
    - nursing care facilities
    - adult care home beds
    - Medicare-certified home health agencies
    - end-stage renal disease dialysis facilities
    - hospice home care and hospice inpatient beds
    - psychiatric hospital units and specialty hospitals
    - substance abuse hospital units, specialty hospitals, and residential facilities
    - intermediate care facilities for mentally retarded persons

State Medical Facilities Plan

- **Basic Principles Governing Plan Development**
  - **The Department of Health and Human Services is designated under G.S. 131E-177 as the State Health Planning and Development Agency for the State of North Carolina.**

State Medical Facilities Plan

- Import 131E-177 GARDS

State Medical Facilities Plan

- ***Approved 2011 Plan***
  - Promote cost-effective approaches
  - Expand health care services to the medically underserved
  - Encourage quality health care services
- ***Proposed 2012 Plan***
  - Safety and Quality Basic Principle
  - Access Basic Principle
  - Value Basic Principle

State Medical Facilities Plan

- **What is it?**
  - Methodologies are driven by utilization and demographics.
  - As utilization changes, and as the population grows and ages, methodologies may change.
  - Consideration is given to county needs as well as the prevention of unnecessary duplication of health resources in an area.

State Medical Facilities Plan

- **What is it?**
- Import 131E-183 from GARDS

State Medical Facilities Plan

It should be noted that the State Plan does not necessarily cover all services and equipment regulated under Certificate of Need.

State Medical Facilities Plan

Although DHHS is involved in making determinations of need for services and facilities in the Plan, DHHS does not necessarily participate in the reimbursement of the cost of care of patients using services and facilities developed in response to this need.

State Medical Facilities Plan

- "Need Determinations" and, where appropriate, "Certificate of Need Application Due Dates" are listed in each service area chapter.
- Includes background information on the North Carolina State Health Coordinating Council and on the annual planning cycle, and contains general policies related to implementing the planning cycle.
- Chapters dealing with specific facility/service categories contain summaries of the supply and the utilization of each type of facility or service, a description of changes in the projection method and policies from the previous planning year, a description of the projection method, and other data relevant to the projections of need.

State Health Planning Process

State Health Planning Process

- Throughout the development of the North Carolina State Medical Facilities Plan there are opportunities for public review and comment.
- The process starts in the spring. A general public hearing is held to discuss methodologies as to how to project need determinations.

State Health Planning Process

- A public hearing is held in the winter to receive comments and petitions for changes in basic policies and methodologies for projecting need.
- Sections of the plan, including the policies and methods for projecting need, are developed with the assistance of committees of the North Carolina State Health Coordinating Council. The committees submit their recommendations to the Council for approval.

State Health Planning Process

- A proposed plan is assembled and made available to the public.
- Public hearings on the proposed plan are held throughout the state in early summer.
- Comments and petitions received during this public hearing period are considered by the council and, upon incorporation of all changes approved by the Council, a recommended proposed plan is presented to the Governor for review and approval.
- With the Governor's approval, the State Medical Facilities Plan becomes the official document for health facility and health service planning in North Carolina for the specified calendar year.

State Health Planning Process

- After the Plan has been signed by the Governor, it will be amended only as necessary to correct errors or to respond to statutory changes, amounts of legislative appropriations, or judicial decisions.
- Public hearings will be conducted on proposed amendments and the Council will recommend any changes deemed necessary and appropriate for the Governor's approval.
- Thereafter, petitions may be submitted to revise the next State Medical Facilities Plan, to change basic policies and methodologies, or to make adjustments to need determinations.

Helpful Resources

- The 2012 Proposed State Medical Facilities Plan is online at: http://www.ncdhhs.gov/dhsr/ncsmfp/2012/prop2012snfp.pdf
- Information on civil rights under Hill-Burton can be found at: http://www.hhs.gov/ocr/civilrights/understanding/Hill-Burton/index.html
- Publications relating to the North Carolina Medical Facilities Plan can be found online at: http://www.ncdhhs.gov/dhsr/mfp/publications.html
- Information on the purposes of the N. C. Division of Health Service Regulation, including links to information Certificate of Need, legislative actions, declaratory rulings, and rules and regulations, can be found at: http://www.ncdhhs.gov/dhsr/

North Carolina's Certificate of Need Program

Overview

- Certificate of need (CON) is the regulatory system through which the State determined need for certain medical facilities, services, and equipment is allocated among providers and throughout the state.

- NCGS 131E-176(3): A Certificate of Need is 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.

North Carolina's Certificate of Need Program

- CON law prohibits health care providers from acquiring, replacing, 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.
- A CON is valid only for the defined scope, physical location, and person named in the application and cannot be assigned except as provided by law. G.S. 131E-181.

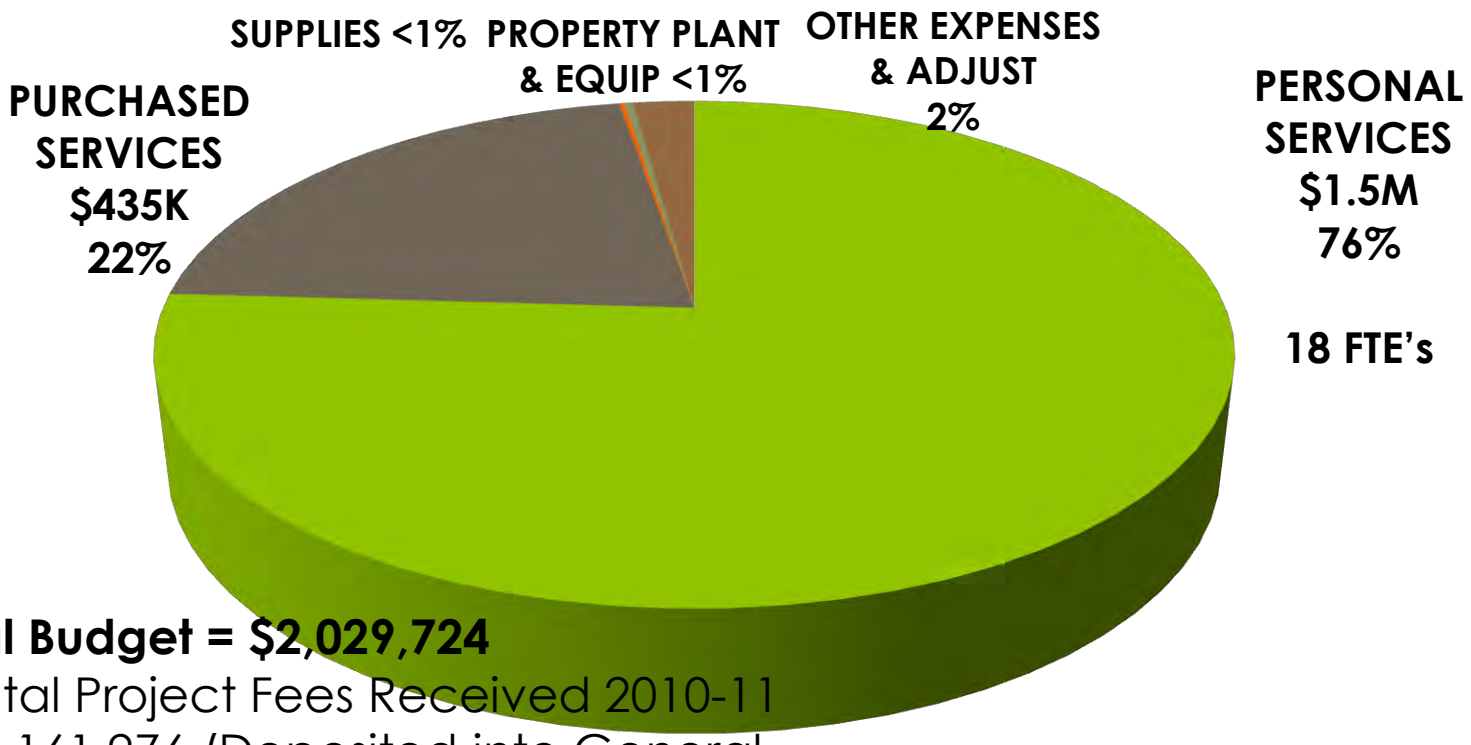
North Carolina's Certificate of Need Program

- CON Regulations are found in Article 9 of Chapter 131E of the NC General Statutes. G.S. 131E-175 – G.S. 131E-191.1.
- Certificate of Need Regulations are found in Subchapter 14C of Chapter 10A of the NC Administrative Code. (10A NCAC 14C.0101 through 10A NCAC 14C.4006)

North Carolina's Certificate of Need Program

- The CON Section (the "agency") is located in the Division of Health Services Regulation within Department of Health and Human Services.
- Data from the Department shows that the Certificate of Need Section receives an average of 217 applications for review each year.
- The CON program is primarily receipts funded.

North Carolina's Certificate of Need Program



Total Budget = $2,029,724

Acutal Project Fees Received 2010-11 = $2,161,276 (Deposited into General

North Carolina's Certificate of Need Program

History

- North Carolina first adopted a CON law in 1971.
- The 1971 law was found unconstitutional by the NC Supreme Court. In re Certificate of Need for Aston Park Hospital, Inc. 282 NC 542 (1973).
- The basis for the decision was that the statutory program deprived individuals of the right to use private property without due process of law.
- Legislature repealed the act shortly thereafter.

North Carolina's Certificate of Need Program

Current CON Law

- Enacted in 1977.
- Included extensive findings of fact including:
- "(7) That the general welfare and protection of lives, health, and property of the people of the State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria..."
- The NC Supreme Court has upheld the constitutionality of the current CON law.

Certificate of Need in NC

- **Requirement of Certificate of Need**

  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 a "new institutional health service if purchased."
  - Capital expenditure of $2 million or more

Certificate of Need in NC

Developing or offering a
"new institutional health service"

- Construction, development, or other establishment of a new health service facility

Certificate of Need in NC

- **Health Service Facilities Regulated by CON:**
  - Acute care hospitals
  - Inpatient psychiatric hospitals
  - Inpatient rehabilitation hospitals
  - Nursing homes
  - Kidney disease treatment centers
  - Intermediate care facilities for the mentally retarded
  - Certified home health agencies
  - Chemical dependency treatment facilities
  - Diagnostic centers
  - Hospice programs
  - Hospice inpatient facilities
  - Hospice residential care facilities
  - Ambulatory surgical facilities
  - Adult care homes
  - Long-term care hospitals

Certificate of Need in NC

Acute Care Hospitals*

- Hospital: A public or private institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of the injured, disabled, or sick persons, except long-term care hospitals. NCGS 131E-176(13)
- The State Medical Facilities Plan uses the term Acute Care Hospital to distinguish from long-term care hospital. As of Spring 2011, there are 114 licensed acute care hospitals for a total of 20,699 licensed acute care beds.

Certificate of Need in NC

Long-term Care Hospitals*

- Long-term care hospital: A hospital that has been classified as a long-term care hospital by the Centers for Medicare and Medicaid Services, pursuant to 42 C.F.R. § 412. NCGS 131E-176(14k)
  - Meets Medicare's conditions of participation for acute care hospitals
  - Average stay of more than 25 days
- 2010 data indicates there are 9 licensed long-term care hospitals with a total of 424 beds.

Certificate of Need in NC

Adult Care Homes*

- Adult care home: a licensed facility with seven or more beds that provides residential care for aged or disabled persons whose principal need is a home which provides the supervision and personal care appropriate to their age and disability and for whom medical care is only occasional or incidental. NCGS 1313E-176(1)
- Services are founds in adult care homes, nursing homes, and hospitals.

Certificate of Need in NC

Adult Care Homes (continued)

- 41,809 licensed beds
- 996 licensing pending beds
- 530 beds with previous need determinations for which a CON has not been issued

Certificate of Need in NC

Home Health Agencies*

- Home health agency: A private organization or public agency which furnishes or offers to furnish home health services. NSGS 131E-176(12)
  - 211 Medicare-certified home health agencies

Certificate of Need in NC

Hospice Programs*

- Hospice: Any coordinated program of home care with provision for inpatient care for terminally ill patients and their families. A hospice program of care provides palliative and supportive medical to meet needs of patients and their families, which are experienced during the final stages of terminal illness and during dying and bereavement. NCGS 131E-176(13a)

- 257 hospice facilities
  - 35 hospice inpatient facilities with 323 beds
  - 26 hospice residential facilities with 177 beds

Certificate of Need in NC

End-stage Renal Disease (ESRD) Facilities*

- Kidney disease treatment center: A facility that is certified as an end-stage renal disease facility by the Centers for Medicare and Medicaid Services,, pursuant to 42 C.F.R. § 405. NCGS 131E-176(14e)
  - Renal transplantation center
  - Renal dialysis center
  - Renal dialysis facility
  - Self dialysis unit
  - Special purpose renal dialysis facility

- 168 ESRD centers that are certified and operational
- 214 CONs are issued for more centers but they are not yet certified

Certificate of Need in NC

Substance Abuse Inpatient and Residential Services* (Chemical Dependency Treatment Beds)

- Chemical dependency treatment facility: A facility, or unit in a facility, which is engaged in providing 24-hour a day treatment for chemical dependency or substance abuse. NCGS 131E-176(5a)

  - 3 state-owned Alcohol and Drug Abuse Treatment Centers (ADATCs) have 240 beds
    - Julian F. Keith ADATC – Black Mountain, NC
    - R. J. Blackley ADATC – Butner, NC
    - Walter B. Jones ADATC – Greenville, NC
  - 17 non-state owned in specialty and acute care hospitals
  - 15 residential treatment facilities
  - 658 beds
  - Beds specifically for detoxification are not included.

Certificate of Need in NC

Intermediate Care Facilities for Mentally Retarded*(ICF/MR)

- Intermediate care facility for the mentally retarded: Licensed facilities providing health and habilitative services for persons with mental retardation, autism, cerebral palsy, epilepsy or related conditions.
  NCGS 131E-176(13a)
  - ICF/MR is a category of group home under the federal-state Medicaid program.
  - 5,084 certified beds

Certificate of Need in NC

Also regulated by CON as a "new institutional health service"

- Operating Rooms
- Gastrointestinal Endoscopy Rooms

Certificate of Need in NC

Operating Rooms*

- Operating room: A room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room. NCGS 131E-176(18c)

- Ambulatory surgical facility: A facility designed for the provision of a specialty or multispecialty ambulatory surgical program.. An ambulatory surgical facility may only admit patients for a period of less than 24 hours. NCGS 131E-176(1b)

  - 161 dedicated inpatient surgery rooms
  - 292 dedicated ambulatory surgical facility rooms
  - 869 shared operating rooms.

Certificate of Need in NC

Gastrointestinal Endoscopy Rooms*

- Session Law 2005-36 removed GI endoscopy rooms from the definition of operating room.

- Gastrointestinal endoscopy room: A room used for procedures that require the insertion of a flexible endoscope into a gastrointestinal orifice to visualize the gastrointestinal lining and adjacent organs for diagnostic or therapeutic purposes. NCGS 131E-176(7d)

- 444 GI Endoscopy rooms

Certificate of Need in NC

Also regulated by CON as a "new institutional health service"

- Bone marrow transplantation
- Burn intensive care services
- Neonatal intensive care services
- Open-heart surgery services
- Cardiac catheterization services

Certificate of Need in NC

Bone Marrow Transplantation Services*

- Bone marrow transplantation: The process of infusing bone marrow into persons with diseases to stimulate the production of blood cells. NCGS 131E-176(2a)

- Two Types:
  - Allogeneic (donor)
  - Autologous (self)

- 593 transplants were performed in FY 2009-2010. Allogeneic bone marrow transplants are limited to the 5 Academic Medical Center Teaching Hospitals.

Certificate of Need in NC

Burn Intensive Care Services*

- Burn intensive care services: Services provided in a unit designed to care for patients who have been severely burned. NCGS 131E-176(2b)
- Currently there are 2 burn intensive care service centers:
  - NC Baptist Hospital
  - UNC Hospital
- Total of 29 burn unit beds

Certificate of Need in NC

Cardiac Catheterization Services*

- Cardiac catheterization services: Procedures, excluding pulmonary angiography procedures, in which a catheter is introduced into a vein or artery and threaded through the circulatory system into the heart specifically to diagnose abnormalities in the motion, contraction, and blood flow of the moving heart or to perform surgical therapeutic interventions to restore, repair, or reconstruct the coronary blood vessels of the heart. NCGS 131E-176(2g)

  - 51 hospitals
  - 3 cardiac diagnostic centers (outpatient facilities)
  - 12 mobile cardiac units

Certificate of Need in NC

Neonatal Intensive Care Services

- Neonatal intensive care services: Services provided by a health service facility to high-risk newborn infants who require constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care. NCGS 131E-176(15b)

Certificate of Need in NC

Open-heart Surgery Services*

- Open-heart surgery services: Tthe provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects. NCGS 131E-176(18b)

- 22 hospitals provide open-heart surgery services
- 72 heart-lung bypass machines

Certificate of Need in NC

Solid Organ Transplantation Services*

- Solid organ transplantation services: Surgical procedures and the interrelated medical services that accompany the surgery to remove an organ from a patient and surgically implant an organ from a donor. NCGS 131E-176(24d)

- Performed only at the 5 Academic Medical Center Teaching Hospitals.

Certificate of Need in NC

Equipment regulated by CON as a "new institutional health service"

- Air ambulance
- Cardiac catheterization equipment
- Gamma knife
- Heart-lung bypass machine
- Linear accelerator
- Lithotripter
- MRI
- PET scanner
- Simulator
- Mobile medical equipment not in use prior to 1993
- Major medical equipment

Certificate of Need in NC

Air Ambulance

- Air ambulance: Aircraft used to provide air transport of sick or injured persons between destinations within the State. NCGS 131E-176(1a)
  - 7 helicopter
  - 3 fixed wing
- FAA laws preempt; however CON still regulates air ambulances in terms of quality of care and requirements that they affiliate and are approved by local emergency management agencies

Certificate of Need in NC

Gamma Knife*

- Gamma knife: Equipment which emits photon beams from a stationary radioactive cobalt source to treat lesions deep within the brain and is one type of stereotactic radiosurgery. NCGS 131E-176(7c)

- Uses radiation to perform brain surgery without opening the skull.

  - Wake Forest Baptist Hospital
  - Pitt County Memorial Hospital

Certificate of Need in NC

Linear Accelerator*

- Linear accelerator: A machine used to produce ionizing radiation in excess of 1,000,000 electron volts in the form of a beam of electrons or photons to treat cancer patients. NCGS 131E-176(14g)
- Used in the treatment of cancer - destroying cells with ionizing radiation
  - 2010 date shows 20 linear accelerators in 15 locations
  - More have a certificate of need in hand or for which there is a prior year need determination

Certificate of Need in NC

Lithotripter*

- Lithotripter: Extra-corporeal shock wave technology used to treat persons with kidney stones and gallstones. NCGS 131E-176(14i)
  - FY 2009-2010: 14 lithotripsy unites operated by 8 providers.
  - One fixed unit and 13 mobile units

Certificate of Need in NC

Magnetic Resonance Imaging Scanner (MRI)*

- Magnetic resonance imaging scanner: Medical imaging equipment that uses nuclear magnetic resonance.
NCGS 131E-176(14m)

- Mobile MRI: a scanner and transporting equipment that is moved at least weekly to provide services at two or more host facilities.

  - Fixed: 231 MRI scanners
  - Fixed equivalent (mobile): 263.53

Certificate of Need in NC

Positron Emission Tomography Scanner (PET)*

- Positron emission tomography scanner: Equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures. NCGS 131E-176(19a)
- Typically used in cancer diagnostics.
- Mobile PET: Scanner and its transporting equipment that is moved to provide services at two or more host facilities.
  - Fixed: 27
  - Mobile: 2 (one in East and one in West)

Certificate of Need in NC

Major Medical Equipment

- Major medical equipment: Costs more than seven hundred fifty thousand dollars ($750,000).
- The costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the equipment operational is included. The capital expenditure for the equipment is the fair market value of the equipment or the cost of the equipment, whichever is greater. NSGS 131E-176(14o)

Certificate of Need in NC

Also regulated by CON as a "new institutional health service"

- Change in bed capacity
  - Relocation of health service facility beds or dialysis stations
  - Change of heath service facility beds from one category to another
  - Increase in dialysis stations or health service facility beds
- Conversion of non-health care beds to health care beds

Certificate of Need in NC

Also regulated by CON as a "new institutional health service"

- Change in project
  - Cost overrun of 15%
  - Addition of a health service
- Opening of an additional office by existing home health agency or hospice
- Relocation of a facility from one service area to another
- Conversion of specialty ambulatory surgical program

Certificate of Need in NC

Exceptions to CON process

(NCGS 131E-184)

- Include:
  - Parking
  - Heating and cooling systems
  - Elevators
  - Replacement Equipment
  - Conversion of semi-private rooms to private rooms
  - Elimination or prevention of imminent safety hazards

Certificate of Need in NC

Changes from Session Law 1993-7

- Definition of "new institutional health services" expanded:
  - Pre-1993: Regulated health services expenditures by health service facilities only
  - S.L. 1993-7: Regulates health service expenditures by **any person**

North Carolina's Certificate of Need Program

Review Schedules

- Review schedules for CON are established in the State Medical Facilities Plan each year.
- Schedules groups health services by review categories and health service areas. Similar proposals in the same area can be reviewed competitively.
- Review categories run from A to M and include:
  - Category A – proposals submitted by acute care hospitals.
  - Category B – increase in nursing care or adult home beds.
  - Category C – new psychiatric facilities and new beds in existing facilities.

North Carolina's Certificate of Need Program

- Insert proposed 2012 review schedule.

North Carolina's Certificate of Need Program

- Insert HSA map

North Carolina's Certificate of Need Program

Application Process

- G.S. 131E-182
- Applications, including the filing fee, must be received by 5:30p on the 15th day of the month prior to the beginning of the scheduled review period.
- Applications:
  - Must be deemed complete by the first day of the scheduled review period.
  - May not be amended. However, after the review begins, the analyst may request additional information.
- Minimum application fee is $5,000. Maximum $50,000.

North Carolina's Certificate of Need Program

Review Process

- G.S. 131E-185
- Time limit for review is 90 days. May be (and usually is) extended an additional 60 days.
- Any person may file written comments about an application under review during first 30 days.
- Within 20 days of the close of the written comment period, the Department must hold a public hearing in the health service area if one or more of the following apply:
  - The review is competitive.
  - The project involves expenditures of $5 million or more.
  - A written request for a public hearing is received from an "affected party".
  - Agency determines a hearing is in the public interest.

North Carolina's Certificate of Need Program

Expedited Reviews

- G.S. 131E-176(7b)
- Applicant may file a petition for an expedited review. Department may allow if:
  - Review is not competitive
  - Project expenditures are < $5 million.
  - No request for a public hearing is received during the 30 day written comment period.
  - Agency determines the public interest does not require a public hearing.

North Carolina's Certificate of Need Program

Review Criteria

- G.S. 131E-183
- Applications are reviewed against statutory criteria and standards for particular health service facilities and health services established in the rules.
  - A proposed project must be consistent with the policies and need determinations set forth in the State Medical Facilities Plan.
  - The population to be serve must be identified:
    - Applicant must demonstrate the need that the population identified has for the proposed services.
    - Must demonstrate the extent to which all residents will have access, including low income persons, minorities, elderly, and other underserved groups.

North Carolina's Certificate of Need Program

Review Criteria: (continued)

- Projects involving reduction/elimination/relocation of services must demonstrate that the needs of the population presently served will be adequately met and the effect on underserved groups to obtain health care.
- If alternative methods exist to meet the need, the applicant must demonstrate that the proposal is the least costly or most effective alternative.
- Financial and operational projections must show availability of funds and financial feasibility of the project.

North Carolina's Certificate of Need Program

Review Criteria: (continued)

- Applicant must demonstrate that the project will not result in the unnecessary duplication of health services or health service facilities.
- Applicant must show the availability of resources such as health manpower.
- Applicant must demonstrate that the ancillary and support services will be available.
- Applicants proposing to serve a substantial number of persons outside the health service area or adjacent areas must document the special needs and circumstances to warrant the service.
- The application shall show that the design, means, and cost are the most reasonable alternative and will not unduly increase health care costs by the applicant/provider.

North Carolina's Certificate of Need Program

Review Criteria (continued)

- Applicant must demonstrate the contribution of the proposed service in meeting the health care needs of the elderly, medically underserved, and Medicare-Medicaid recipients.
- Current use of applicants existing services.
- Past performance in meeting obligations.
- Existence of any civil rights access complaints against the applicant.

North Carolina's Certificate of Need Program

Review Criteria (continued)

- Offer by applicant of a range of means by which a person will have access.
- Applicant shall demonstrate the proposed health services will accommodate the clinical needs of the health care professional training programs in the area.
- Applicant must demonstrate the expected effects of the proposed services on competition in the proposed service area.

North Carolina's Certificate of Need Program

Decision and Issuance of CON:

- G.S. 131E-186/131E-187
- Decision to approve, approve with conditions, or deny an application should issue within statutory time frame (90-150 days).
- The Department must provide written notice of all findings and conclusions that are the basis for the decision within 5 business days of the decision.
- The CON shall issue within 35 days of the decision if there has been no request for a contested case hearing.

North Carolina's Certificate of Need Program

Appeals:

- G.S. 131E-188
- Petition for a contested case hearing must be filed within 30 days of the Department's decision.
- May be filed by any "affected person".
- Includes applicants, persons living in the service area or geographic area, providing similar services in the service area, and third party payers who reimburse facilities in the service area.
- Petitioner must file a bond equal to 5% of the cost of the project. No < $5,000, No > $50,000.
- Approved applicant may file against bond if petition for contested case deemed frivolous or filed to delay.

North Carolina's Certificate of Need Program

Timetable for Appeals:

- G.S. 131E-188
- Appointment of ALJ – 15d after petition filed.
- Completion of discovery – 90d after assignment of ALJ.
- Hearing – w/n 45d of completion of discovery.
- AlJ decision – w/n 75d after hearing.
- Deadlines may be extended for discovery through ALJ decision to a total of 270d from filing petition.
- Effective January 1, 2012, the ALJ makes the final decision in a contested case. S.L. 2001-398.

North Carolina's Certificate of Need Program

Court of Appeals:

- G.S. 131E-188(b) and (b1)
- Appeal from the decision of the ALJ is to the Court of Appeals.
- Taken w/n 30 days of receipt of the final decision.
- Bond must be posted with the Clerk of the Court of Appeals. Amount of bond ranges from $5,000 to $50,000.
- If the Court of Appeals finds that the appeal was frivolous or filed to delay, the Court shall remand the case to the Superior Court for a hearing on the bond and shall award the CON holder reasonable attorneys' fees and costs incurred in the appellate action.

North Carolina's Certificate of Need Program

Exemptions from review:

- G.S. 131E-184
- New institutional health services are exempt from CON review if required to:
  - Eliminate or prevent an imminent safety hazard.
  - Comply with State licensure standards.
  - Comply with accreditation or certification standards necessary for reimbursement under Medicare/Medicaid.
  - Provide data processing equipment.

North Carolina's Certificate of Need Program

Exemptions from review: (continued)

- Provide parking, hvac, elevators, or other basic plant or mechanical improvements.
- Repair or replacement of facilities after accidents or natural disasters.
- Replacement of nonhealth service facilities.
- Provide replacement equipment.
- Acquire an existing health service facility including equipment owned by that facility.
- Develop or acquire a physician office building.

North Carolina's Certificate of Need Program

Capital expenditures of > $2million are exempt where:

- The expenditure involves an existing nursing home, adult care home, or intermediate care facility for the mentally retarded, that is renovating or replacing the facility on the same site and there is no change in bed capacity or addition of a health service facility or new institutional health service; and

- The expenditure will be used for conversion of semiprivate to private rooms, providing homelike residential dining areas, or renovating or expanding residential living or common areas.

North Carolina's Certificate of Need Program

Other Exemptions:

- G.S. 131E-184(c) provides an exemption from CON review of any conversion of existing acute care beds to psychiatric beds if:
  - The hospital seeking the conversion has a contract with the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services and one or more Area Mental Health Authorities to provide psychiatric beds to patients referred by the contracting agencies.
  - The total number of beds converted shall not exceed twice the number of beds under the contract.

North Carolina's Certificate of Need Program

- G.S. 131E-184 (d) provides an exemption from review for the construction and operation of a new chemical dependency or substance abuse facility for the purpose of providing such inpatient services solely to inmates of the Department of Correction.
- If such facility provides services to members of the general public as well as inmates, only the portion of the facility serving inmates is exempt from review.

North Carolina's Certificate of Need Program

- G.S. 131E-179 allows the agency to exempt a health service facility from CON review for a new institutional health service to be used solely for research purposes.
- The health service facility must file notice of intent with the agency and the agency must find:
  - The new service will not affect the charges of the facility for other medical or patient care services other than those included in the research.
  - The new service will not substantially change bed capacity or the medical and other patient care services.
- The health service facility shall not charge patients for the use of the service exempted from CON review.(Without first obtaining a CON).

North Carolina's Certificate of Need Program

Progress Reports/Withdrawal of CON:

- G.S. 131E-189
- A CON will a timetable for the holder to complete a project or make a service available.
- Periodic reports are required on the progress in meeting the established timetable.
- Failure to make good faith efforts to meet the timetable may result in the CON being withdrawn.
- Failure to develop a service in a manner consistent with the representations in a CON application or the conditions imposed on its issuance may result in a withdrawal of the CON.
- A CON may be immediately withdrawn if the holder transfers ownership or control of the facility, project or CON before completion of the project.

North Carolina's Certificate of Need Program

Enforcement and Sanctions:

- G.S. 131E-190
- Offering a new institutional health service without first obtaining a CON may result in:
- Withholding of Medicare and Medicaid funding for the reimbursement of capital and operating expenses relating to the new institutional health service.
- Revocation or suspension of licenses.
- Civil penalties of not more than $20,000 for failure to obtain a CON or to conform to the conditions of a CON. A violation occurs each time the service is offered.
- Injunctive relief requiring the holder of the CON to materially comply with the representations in the holder's application.