



**JOINT LEGISLATIVE OVERSIGHT COMMITTEE
ON HEALTH AND HUMAN SERVICES**

Overview of Certificate of Need Process

**Christopher G. Ullrich, M.D., FARC
Chair, State Health Coordinating Council**

**Emery E. Milliken
Department of Health and Human Services**

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Introduction

- Article 9 of Chapter 131E requires health care providers to obtain a certificate of need (CON) before developing new health service facilities, certain medical services or acquiring certain medical equipment.
- The Healthcare Planning and Certificate of Need (HPCON) Section in the Department of Health and Human Services' Division of Health Service Regulation (DHSR) administers the CON Law.
- Pursuant to G.S. 131E-177, the State Medical Facilities Plan (SMFP) is developed annually by the staff in the HPCON Section under the direction of the North Carolina State Health Coordinating Council (SHCC), a public advisory body.
- The SMFP includes the methodologies and data used in determining the need for additional facilities, services and medical equipment and the projected need.
- Health care providers submit CON applications proposing to develop the additional facilities, services or equipment determined to be needed.
- The CON applications are reviewed by the HPCON Section for conformity with the review criteria in the CON Law and rules adopted by DHSR and are approved or denied.

Role of NC DHHS in Administering the Certificate of Need Laws

- NC DHHS is designated as State Health Planning and Development Agency by G.S. 131E-177
- The Healthcare Planning and Certificate of Need (HPCON) Section, consisting of 20 FTEs, administers the Certificate of Need (CON) Law
- Powers and duties include:
 - Establish standards and criteria or plans required to carry out the provisions and purposes of the CON Law
 - Adopt, amend, or repeal rules
 - Develop policy, criteria and standards for health service facilities planning and develop a State Medical Facilities Plan
 - Grant, deny, or withdraw a CON
 - Collect fees

State Health Coordinating Council (SHCC): A Public Advisory Body

Major Functions

- Conducts meetings and holds public hearings to solicit and receive feedback from the public about regional concerns regarding medical facilities/equipment/services subject to CON and to receive recommendations related to health care planning**
- Based on data and public input, determines needs for health service facilities, health services and equipment**
- Prepares the annual State Medical Facilities Plan**

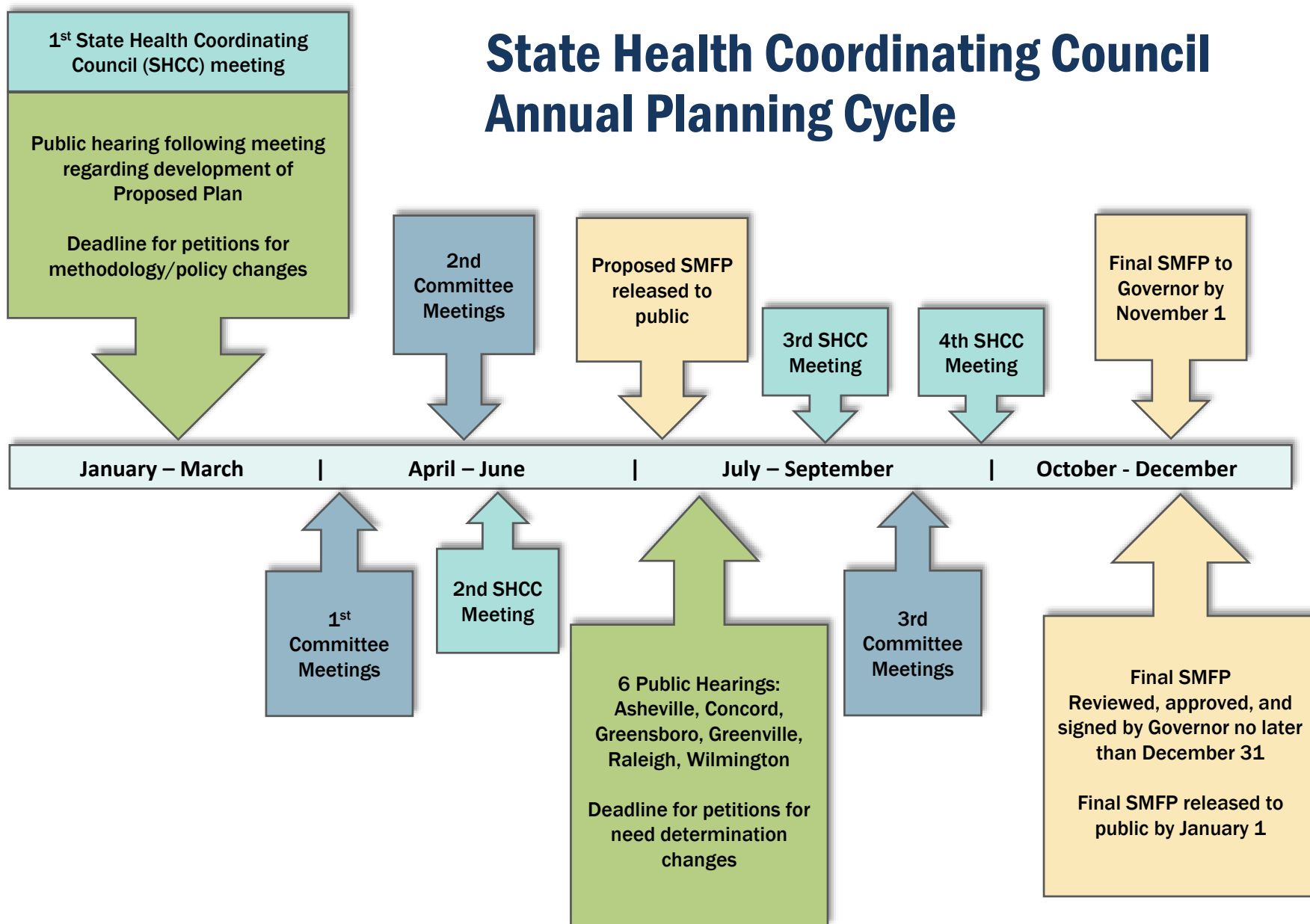
State Health Coordinating Council Members

Representing	Number of Seats
Academic Medical Centers	1
Business and Industry (Large)	1
Business and Industry (Small)	1
County Government (Rural)	1
County Government (Urban)	1
Health Insurance Industry	1
Home Care Facilities	1
Hospice	1
Hospitals	1
NC House of Representatives	1
NC Senate	1
Nursing Homes	1
Physician	1
Local Health Director	1
At-Large	11
Total	25

State Health Coordinating Council (cont.)

- The entire State Health Coordinating Council (SHCC) meets quarterly
- There are three standing committees
 - Acute Care Services
 - Long-term Behavioral Health Services
 - Technology and Equipment
- Each member serves on one of the three committees
- Each committee meets three times per year
- Work Groups, consisting of members of the SHCC and the public, are created to work on a specific “need methodology”
- “Need methodology” is the process of collecting data about the supply and utilization of facilities and services that are subject to CON and applying policies and projections to determine future needs which are documented annually in the State Medical Facilities Plan
 - Data driven and patient-centric by design
- Interested Parties meetings are held to discuss a specific issue
- All meetings are open to the public

State Health Coordinating Council Annual Planning Cycle



State Health Coordinating Council

Public Hearings and Petitions

- Development of the State Medical Facilities Plan (SMFP) is a transparent process with numerous opportunities for public input
- Public Hearings
 - A public hearing is held in Raleigh following the first meeting of the full State Health Coordinating Council in March to hear comments on the need methodologies and policies in the SMFP
 - Six public hearings are held in July at different locations across the state to receive comments on the contents of the Proposed SMFP
- Petitions
 - Spring Petitions

Spring petitions provide an opportunity for any member of the public to recommend changes to need methodologies or policies that would have a statewide effect
 - Summer Petitions

Summer petitions provide an opportunity for any member of the public to request an adjusted need determination based on the unique or special attributes of a service area that differ from those based on application of the standard need methodology

Petitions (cont.)

Year	Number of Spring Petitions	Number of Spring Petitions Approved (1)	Number of Summer Petitions	Number of Summer Petitions Approved
2015	6	1	12	6
2016	3	0	12	6
2017	2	0	17	12
2018	2	0	7	4
2019	3	1	14	7

1) Some petitions are granted in part. However, unless the petition is granted in full, it is not included in the number of approved petitions.

State Medical Facilities Plan

- Developed by DHHS and the State Health Coordinating Council pursuant to G.S. 131E-176(25)
- Includes need methodologies for determining the need for additional:

Acute Care Hospital Beds

Hospice Services (Home Care and Inpatient Beds)

Operating Rooms

Psychiatric Inpatient Services

Burn Intensive Care Services

Substance Use Disorder (Inpatient and Residential Services)

Transplantation Services

Intermediate Care Facilities for Individuals with Intellectual Disabilities

Inpatient Rehabilitation Services

Cardiac Catheterization Equipment

End-stage Renal Disease Dialysis Facilities

Linear Accelerators

Nursing Care Facilities

Lithotriptors

Adult Care Facilities

Magnetic Resonance Imaging (MRI) Scanners

Medicare-certified Home Health Agencies

Positron Emission Tomography (PET) Scanners

Health Service Facilities Subject to CON Review

- Hospitals
- Ambulatory Surgical Facilities
- Inpatient Rehabilitation Facilities
- Nursing Homes
- Adult Care Homes (seven or more beds)
- Medicare-certified Home Health Agencies
- Hospice Home Care Agencies
- Hospice Inpatient Facilities
- Hospice Residential Facilities
- Kidney Disease Treatment Centers (Outpatient Dialysis Facilities)
- Psychiatric Hospitals
- Chemical Dependency Treatment (Substance Use Disorder) Facilities
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Diagnostic Centers *

*Any facility where the cost of diagnostic equipment costing \$10,000 or more exceeds \$500,000

Activities Subject to CON Review Pursuant to G.S. 131E-178(a) and – 176(16)

- Constructing or developing a new health service facility
- Spending more than \$2,000,000 on a health service or health service facility
- Increasing the number of beds, dialysis stations or operating rooms
- Relocating beds, dialysis stations or operating rooms from one facility or campus to another
- Offering bone marrow and solid organ transplantation services, burn intensive care services, cardiac catheterization services, neonatal intensive care services, and open-heart surgery services
- Acquiring cardiac catheterization equipment, gamma knife, heart-lung bypass machine, linear accelerator, lithotripter, MRI scanner, PET scanner and simulators
- Acquiring major medical equipment (i.e., equipment that costs more than \$750,000)

CON Review Cycle

- **Application Submitted** – Submitted on the 15th of the month before the review begins
- **Review Begins** – On the 1st of the month; there are 11 reviews a year
- **Public Comment Period** – Anyone may submit written comments during the 1st 30 days of the review
- **Public Hearing** – If required, will be held within 20 days after the end of the public comment period
- **Agency Decision** – No later than 150 days from the 1st day of the review
- **Appeal Period** – 30 days from the day after the decision is issued
- **Appeal to the Office of Administrative Hearings** – The administrative law judge (ALJ) has 270 days to issue a final decision
- **Appeal to the Court of Appeals** – The ALJ's final decision may be appealed to the Court of Appeals
- **CON Issued** – 30 days after the decision if not appealed or per ALJ or Court of Appeals ruling

CON Data for Calendar Years 2015-2019

Calendar Year	Total Number of Applications Received	Number of Applications Included in a Competitive Review (1)	Total Capital Cost	Total Fees Collected (2)	Total Number of Decisions (3)	Number of Approvals	Number of Decisions Appealed
2015	121	7	\$602,282,840	\$1,493,008	121	116	11
2016	166	26	\$684,422,056	\$2,027,233	165	149	27
2017	161	21	\$734,355,958	\$1,967,666	158	141	22
2018	203	37	\$1,143,532,915	\$2,855,115	200	186	28
2019 (4)	186	29	\$1,030,127,677	\$2,261,390	145	137	9

- 1) A competitive review occurs when two or more applications are received for review in the same review period for the same health service in the same service area and the approval of one application requires the denial of another application.
- 2) Application fees are collected in accordance with G.S. 131E-182(c) and credited to the General Fund.
- 3) The number of decisions may be less than the number of applications received because of applications withdrawn without review.
- 4) As of February 3, 2020, a decision has been issued for 145 of the 186 applications received in 2019. The remaining applications are being reviewed consistent with the statutory timeframes.

North Carolina Compared to Other States

- 1) 36 states have a CON Law (1)
- 2) As many as 30 different types of services are subject to CON review (1)
- 3) Ohio regulates only 1 service, nursing homes (1)
- 4) South Carolina regulates 20 services (1)
- 5) North Carolina regulates the same 20 services as South Carolina, plus 8 services not regulated by South Carolina (1)
- 6) The dollar threshold for capital expenditures varies by state but it is the same in North and South Carolina (\$2,000,000) (1)
- 7) North Carolina's CON process is transparent and includes a public advisory body and numerous opportunities for public input

- 1) 2016 CON Matrix by State Rated by Regulated Service, Review Thresholds and Relative Scope