

# Definitions

North Carolina General Statutes  
Certificate of Need Law

# When does an Operating Room require a Certificate of Need (CON)?

- “No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department ...” (emphasis added)
- What is a New Institutional Health Service?
  - Construction, development, or other establishment of new health service facility
  - Capital expenditure over \$2 million
  - Conversion of specialty ambulatory surgical program to multispecialty ambulatory surgical program or addition of a specialty to specialty ambulatory surgical program
  - Construction, development, establishment, increase in number, or relocation of OR or GI endoscopy room
  - Change in designation, in licensed health service facility, of OR to GI endoscopy room or change from GI endoscopy room to OR that results in a different number of each type of room than reflected on the license in effect as of January 1, 2005

# What types of licensed health service facilities have ORs?

- Hospitals
- Ambulatory Surgical Facilities (ASFs or ASCs)
  - “...a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. ... An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1c) of this section and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.”

# Ambulatory Surgical Program

- Ambulatory Surgical Program

- “...formal program for providing on a same-day basis those surgical procedures which require local, regional or general anesthesia and a period of post-operative observation to patients whose admission for more than 24 hours is determined, prior to surgery or gastrointestinal endoscopy, to be medically unnecessary.”

- Multispecialty Ambulatory Surgical Program

- “...a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.”

- Specialty Ambulatory Surgical Program

- “...a formal program for providing on a same-day basis surgical procedures for only the specialty areas identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need.”

# Hospital

- Hospital Licensure Law

- “...any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours.”

- CON Law

- “...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 injured, disabled, or sick persons. The term includes all facilities licensed pursuant to G.S. 131E-77 of the General Statutes, except long-term care hospitals.”

# 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.”
- What about GI Endoscopy Rooms?
  - “...a room used for the performance of 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.”
  - There is no methodology in the SMFP for GI Endoscopy Rooms
    - “The annual State Medical Facilities Plan shall not include policies or need determinations that limit the number of gastrointestinal endoscopy rooms that may be approved.” (emphasis added)

# Basic Principles

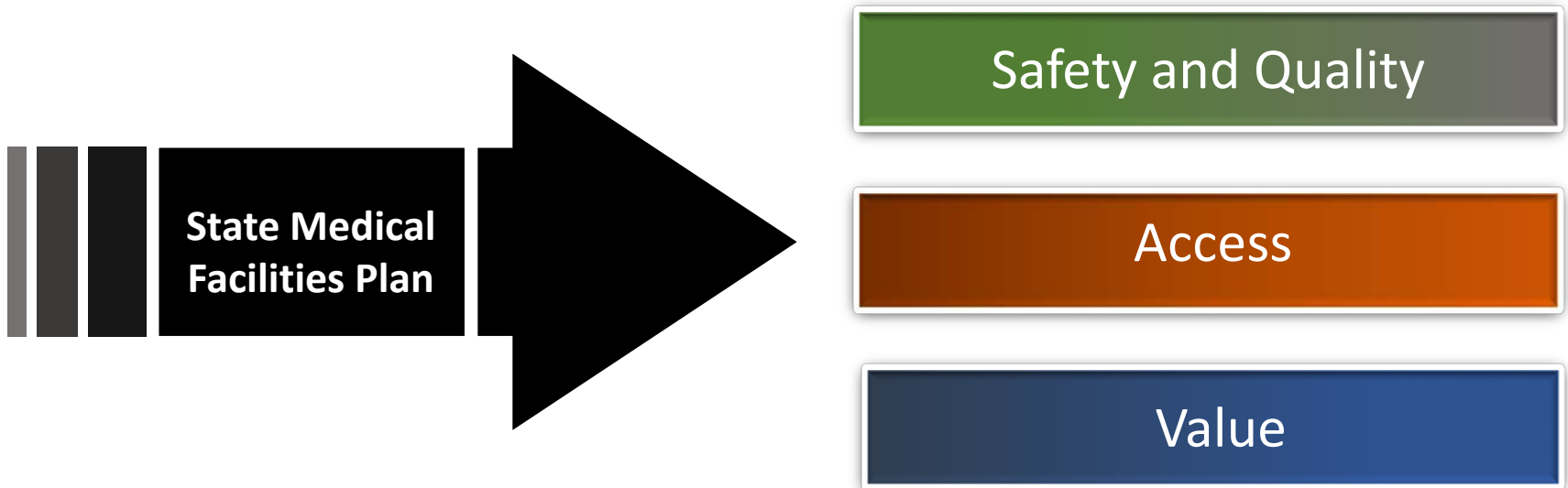
NC State Medical Facilities Plan

# Background

- Quality, Access, and Value Committee (QAV) was established in 2008 to review and rewrite the three Basic Principles
- Report and Recommendations from QAV were shared with SHCC
  - Gen 3 updated to be aligned with newly worded principles
  - Implement action plan for new Basic Principles
- Single Specialty Demonstration Project
  - Selection and evaluation included measureable criteria from each of the three basic principles
    - e.g. Requirements for payer mix, quality reporting, EHR



# Basic Principles Governing the Development



# Chapter 6

## Operating Room Methodology

# Step 1: Delineation of Service Areas (Table 6A, Column A)

- Occurs every 3 years
    - Last done for 2017 SMFP
  - Definition of Service Area:
    - Single County = County with at least 1 licensed facility that has at least 1 OR
    - Multicounty =
      1. 2 or more counties, in which a county with no licensed ORs is grouped with the county that serves the largest proportion of its surgical patients
- OR**
2. A county with no licensed ORs is split between 2 counties with an OR if at least 35% of the patients in the county with no ORs receive surgical services in each of the 2 counties with an OR

# Data Sources

- Office of State Budget and Management
  - State Demographer
  - County-level population estimates
- License Renewal Applications (LRA)
  - Hospital and Ambulatory Surgical Facility
  - Information is identical from both types of facilities
  - Self-report data
  - Verify inventory against Acute and Home Care Licensure's Master Facility File
- Track Certificate of Need and Licensure actions

# Start with the Inventory (Table 6A)

- Information is obtained for each facility
- Accumulated to County/Service Area for Totals

		CASES		OPERATING ROOMS			EXCLUDED ORs		ADJUSTMENTS		
Service Area	Facility	IP Cases (-C-sec)	Amb Cases	IP	Amb	Shared	C-Section	Tr/Burn	CON	CONS-C-Section	Total Rooms in Planning Inventory
R	ASC	0	950	0	2	0	0	0	0	0	2
R	Hosp	1466	3280	1	0	3	-1	0	0	0	3
<b>R</b>	<b>Total</b>	<b>1466</b>	<b>4230</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>-1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>

# Step 2. Estimate Total Surgery Hours for Previous Year (Table 6B)

<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>
	Inpatient			Outpatient			Total
Service Area	Cases	Standard Case Time	Estimated Hours	Cases	Standard Case Time	Estimated Hours	Hours
R	1466	3	4398	4230	1.5	6345	10743

# Step 3. Project Future OR Requirements, Based on Growth of OR Hours (Table 6B)

<b>A</b>	<b>I</b>	<b>J</b>	<b>K</b>	<b>L</b>
Service Area	Growth Factor 2015-2019 (Population Change Rate )	2019 Projected Surgical Hours	Standard Hours per OR per year (80% utilization assumed)	Projected ORs Needed in 2019
R	11.3%	11957	1872	<b>6.39</b>
		<i>H * I</i>		<i>J/K</i>

$$\frac{2019 \text{ est pop} - 2015 \text{ est pop}}{2015 \text{ est pop}}$$

$$\frac{159,000 - 142,853}{142,853}$$

$$10743 \times 1.113$$

$$9 \text{ hours/day, } 260 \text{ days/year, times } 80\%$$

$$(9 \times 260 \times .8) = 1872$$

$$11956 \div 1872$$

# Steps 4 & 5. Planning Inventory & Need Determination

A	L	M	N	O	P	Q	R	S	T	U
		All ORs			Excluded		CON			
Service Area	ORs Needed in 2019	IP	Amb	Shared	Ded. C-Sec	1 OR for each Level I/II Tr Ctr & Burn Unit	+ or - CONs issued, prev need, etc.	Adj Planning Inv	2019 OR Deficit or Surplus (Surplus shows as a <b>MINUS</b> )	Need for New ORs
R	<b>6.39</b>	1	2	3	-1	0	0	<b>5</b>	<b>1.39</b>	<b>2</b>

6.39 - 5 = 1.39

Rooms in Service Area	Fractional Deficit Value	Projected Need
More than 10	>= .50	Amount of deficit, rounded up
6-10	>= .30	Amount of deficit, rounded up
5 or fewer	>= .20	Amount of deficit, rounded up



# Certificate of Need Process

- Need methodology in SMFP shows a need for one or more additional ORs in a service area.
- CON schedules a review in Chapter 6 of the SMFP.
- CON applications are due on the 15<sup>th</sup> of the month prior to the month the review begins (they always begin on the 1<sup>st</sup> day of the month).
- Applications are frequently competitive; CON receives multiple applications proposing to develop the additional operating rooms.
- Number of ORs in need determination is a determinative limit on the number of ORs that may be approved.
- CON has 90 days to review the applications against the statutory and regulatory review criteria or rules.
- The current rules for operating rooms are based on the current methodology, including the assumptions used in that methodology. The rules may need to be changed depending on what changes, if any, are made to the operating room methodology.
- CON may extend the review an additional 60 days for a total of no more than 150 days.

# After the Decision

- Once a decision is mailed to the applicants, the 30-day appeal period begins.
- If there is no appeal, the certificate may be issued.
- If there is an appeal
  - Administrative Law Judge (ALJ) has 270 days to make his or her decision.
  - The ALJ's decision may be appealed to the N.C. Court of Appeals. They have no time limit for making their decision.
  - Decisions made by the N.C. Court of Appeals may be appealed to the N.C. Supreme Court. They also have no time limit for making their decision.

# After the CON is Issued

- The certificate holder is required to make a good faith effort to develop the facility or additional ORs in a timely manner consistent with the representations made in the certificate of need application
- The certificate holder is required to submit periodic progress reports.