Pragmatic Approach to Health Law
Regulation and Administration:
Current CON Issues

Practical Issues in Health Law
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Objectives

- Historical Background on Health Care Planning Legislation and Regulation
- Brief overview of North Carolina's planning process and CON statute
- Impact of CON on access to health care and health care costs
- Case study—Good Hope Health System and Harnett County, NC

Historical Background

- 1974—National Health Planning and Resources Development Act, 42 U.S.C. §§300k-1-300k-3 (Repealed 1986)
- The NHRPDA authorized funds for state and local planning programs (excluding CON) if they met certain federal standards. By 1982, every state except Louisiana had a CON program modeled on the federal example. Louisiana had a Section 1122 program with similar coverage.
**Historical Background**

"I can finally lay to rest the Federal health planning authorities. I have sought their repeal since I assumed office. These authorities, while perhaps well-intentioned when enacted in the 1970's, have only served to insert the Federal government into a process that is best reserved to the marketplace."

—Ronald Reagan


President Reagan ended a 40-year national policy to improve geographic distribution to reduce medical waste to provide more economical services and to reduce excess capacity.

**North Carolina Planning Process and CON Statute**

- First CON was adopted by New York in 1964 and by 1974 26 states had CON laws.
- Chapter 1164 of 1971 Session Laws enacted first NC CON law to ensure that development is orderly, timely, economical, and without unnecessary duplication.
- Beginning in 1972, many states adopted Section 1122 programs that are a federally funded form of CON review for planning agency review and approval of Medicare and Medicaid reimbursement of capital expenditures for health care facilities.
- NC CON Law enacted in 1978, effective on January 1, 1979. The NC CON law has been amended numerous times since its enactment.

**North Carolina Planning Process and CON Statute**

NCGS 131E 175 Certificate of Need Statute: 
- Certificate of Need (CON) is the final written determination that a health service facility is needed to enhance the health and welfare of the citizens of this state.
- CON is used to provide a Mechanism for control of the supply of health services facilities and services in order to ensure availability of adequate health services in geographic areas and to prevent unnecessary duplication of these services.
- Enables awareness of the need for future facilities through an objective analysis of the impact of these facilities.
- Ensures public education and participation in the planning process.
- The general welfare and protection of health and safety of the people of this State requires that public health and welfare services be provided to enhance and maintain the quality and accessibility of services necessary for the health and safety of the people.
North Carolina Planning Process and CON Statute

- The State Medical Facilities Plan is developed by the NC Department of Health and Human Services through the NC Division of Health Service Regulation and the Medical Facilities Planning Section under the guidance of the State Health Coordinating Council.
- SHCC has 30 members and is chaired by Dan Myers, M.D. from Kinston, NC.
- Members include 5 from the 5 largest cities in NC.
- The 2009 Plan was recommended to Gov. Easley on Nov 3, 2008 and approved on December 29, 2008.
- The entire plan is 93 pages with appendices and can be accessed at:

- The major objective of the Plan 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.
- The Plan covers 12 specific areas, including acute care hospitals, operating rooms, inpatient rehabilitation facilities, nursing home facilities, etc.
- Basic principles guiding the decisions are:
  - Safety and Quality
  - Access to timely, clinically appropriate, and high-quality health care
  - Health Care Value—maximum health care benefits per dollar expended

Impact of CON on access to health care and health care costs

- Bottom line—CON statutes try to accomplish 3 things:
  - Over-capacity—Prevent unnecessary development of capacity that would likely result in higher costs to patients [see 131E-175 (4) and (7)]
  - Access—Increase the availability of services and facilities to residents that are underinsured or uninsured [see 131E-175 (2) and (3)]
  - Geographical distribution—Foster development of facilities across the state so that there is reasonable distribution and access for all of the state’s residents, particularly rural population [see 131E-175(3a)]
Impact of CON on access to health care and health care costs

Since the NHPRDA was repealed in 1987 states have been free to repeal their CON laws. Currently there are 36 states that still have CON laws on their books 22 years later. Would elimination of the CON laws lead to a significant increase in the number and availability of facilities and services? Many commentators point to the experience of Ohio which eliminated its CON statute in 1997 and allowed market forces to guide development of facilities and services in that state.

Impact of CON on access to health care and health care costs—Ohio

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>New CON after 1997</th>
<th>Old CON 1993</th>
<th>Net Change</th>
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<tr>
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<td>155</td>
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<td>ER</td>
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<tr>
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<td>84</td>
<td>152</td>
<td>68</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>27</td>
<td>407</td>
<td>380</td>
</tr>
</tbody>
</table>

Includes facilities and services under CON.
Impact of CON on access to health care and health care costs—Ford Study

- Ford Motor Co. studied health care costs in 5 states—Indiana, Ohio, Kentucky, Michigan, and Missouri.
- Indiana and Ohio, which eliminated CON coverage for most services, consistently had the highest relative costs.
- Michigan, with a CON program since 1972 covering a wide range of services, consistently had among the lowest relative costs.
- Kentucky and Missouri, which also had CON programs covering a wide range of services, also had low relative costs.
- Study found a correlation between CON review and lower costs across a range of different services, including impatient and outpatient.

Impact of CON on access to health care and health care costs

- Would a significant increase in the supply of services and facilities lead to a significant increase in utilization?
- Absent CON, how could reasonable geographic access be assured?
- Absent CON, how could we assure the willingness and ability of hospitals and other providers to provide services for underserved people?

NC Case Study—Good Hope Hospital and Harnett County

- Good Hope Hospital in Erwin, NC was constructed in 1913.
- GHH licensed for 72 beds (29 psych and 43 general acute), 2 ORs & 1 endoscopy procedure room.
- April 2001 filed CON application for replacement facility in Erwin.
- July 2001 CON granted with conditions:
  - set aside certain existing equipment
  - add another operating room
  - must have 34 general acute beds, and 17 psych beds
  - get approval for patient design
  - had merger other option
- August 2001 GHH filed contested case, settled in December with 3 ORs.
- Major discussion with Nash-Johnson Regional Hospital broke down.
- July 2002 Medical Care Commission denied GHH’s request to proceed using funding from HUB.
NC Case Study—Good Hope Hospital and Harnett County

In June 2003, the General Healthcare System, a joint venture with a large hospital management company managing over 50 hospitals, applied for CON placement in a new facility. The application was approved to address the need for a new private capital partner and a new location for the facility.

In July 2003, the public hearing was held, and BURL and Central Carolina Hospital opposed the application. In September 2003, CON was denied, and GHHS filed a petition for a contested case hearing.

In contested case hearing for 17 days in May-June 2004, GHHS was not exempt from CON filing requirements.

In August 2003, GHHS gave notice to the Agency that it was acquiring a facility and that replacement was required. 131 G. 184 provides for exemption for various circumstances, including renovation needed to meet licensure requirements to comply with accreditation or certification requirements to receive reimbursement under Medicare and other governmental plans, to replace or repair facilities destroyed or damaged by accident or natural disaster, etc.

In December, the Agency ruled that GHHS was not exempt from CON filing requirements.

In January 2004, GHHS filed a declaratory judgment action in Superior Court. In January 2005, it was dismissed and ultimately upheld by the Court of Appeals in January 2006 and the NC Supreme Court.

November 2004, Governor Easley sent memo with the 2005 State Medical Facilities Plan which he approved, with two exceptions.

Under circumstances exist in Harnett County that a new hospital containing not more than 50 acute care beds is needed in the central part of the county. The CON process to build the new hospital should be open to any applicant and filed in the cycle that begins on October 1, 2005.

The successful applicant for a CON to develop the new hospital should be required to assure it will not develop or replace acute care beds or operating rooms in Harnett County and to withdraw any other pending applications or legal actions concerning the development or replacement of such beds or rooms.
NC Case Study—Good Hope Hospital and Harnett County

- August 2005: DHHS filed a new CON application in response to 30-day determination issued by the Governor in the 2005 SML, that also a rehearing of its 2003 application with supplemental information.
- Harnett Health System, a part-owner of Holly Johnson
- Harnett County, and WakeMed also filed for CON in August 2005.
- January 2006: the Agency approved Harnett Health.
- All parties appealed and Town of Lillington intervened.
- November 2006: ALJ ruled to uphold Agency's decision.
- January 2008: the NC Board of Appeals affirmed, and RA's Superior Court upheld.
- $46 million facility for WakeMed was under construction in 2009.

NC Case Study—Good Hope Hospital and Harnett County—Conclusions

- Financial considerations are still a significant driver, both in reality and in the application for a CON—there are still significant market forces at work.
- Local considerations are extremely important—politics plays a large role.
- Legal challenges can have a huge impact in delaying projects that are badly needed.
- Restrictions on the ability to build facilities does result in the availability of services to persons with no or limited coverage—otherwise private imaging centers, ambulatory surgery and outpatient facilities would have been developed in Harnett County.