CERTIFICATE OF NEED PROGRAM REVIEW

An overview of select states' CON programs



Jessica Schaeffer-Helmecki & Hillary Style
Office of Health Care Access

July 2016



OVERVIEW

States Reviewed:

- Maryland
- Vermont
- Rhode Island
- Hawaii
- Massachusetts
- North Carolina
- Michigan
- New Jersey

Selected based on:

- "robustness" of the program
- unique features
- availability of information, and/or
- comparability toConnecticut



Where are CON programs housed?

Most CON programs are located within other states' version of DPH. However, some are separate, essentially quasipublic entities:

- State Health Planning & Development Agency (HI)
- Dept. of Public Health, Determination of Need Program (MA)
- Green Mountain Care Board, previously Division of Health Care Administration, Banking, Insurance, Securities (VT)
- Department of Health and Human Services (MI)
- Health Care Commission (MD)
- Division of Health Services Regulation (NC)
- Health Systems Policy Regulation (RI)
- Department of Public Health, Certificate of Need and Facility Licensing (NJ)



➤ What is the process for review?

Most states' application processes are generally similar to CT's:

- Application many states request a Letter of Intent prior to filing (CT previously did)
- Agency reviews and requests any necessary additional information –
 many speak informally to suggest modifications to make the application
 more "approvable"; NC will deny any incomplete applications
- Hearings VT has a public hearing on every application; most states have some form of public hearings or allow submission of written public comments.
- Decision either made by agency head (Commissioner or Director) or by a panel of appointed experts
- Appeal or Review usually to superior court; parties with standing to appeal vary



- > Who is the final decision maker?
 - Panels (MD, VT)
 - Director/Agency Commissioner although Director/Commissioner may ultimately sign decisions, often do so with the advice of a panel of appointed experts (NC, MA, HI, RI, NJ, MI)
 - Administrative judge(s) RI holds "administrative hearings" for hospital conversions before an administrative judge; some documents are deemed confidential and not made part of the public record (NJ limited situations)



➤ What is considered?

Criteria vary widely dependent upon what services and facilities a state regulates. Broadly, states tend to review:

- Public need
- Financial stability
- Other existing providers including any opportunities to coordinate
- Construction (costs, funding, design, energy efficiency)
- Relationship to state plan / need calculations
- Quality of care



Please refer to state-specific fact sheets for each state's statutory criteria

➤ What is reviewed?

The particulars of what is reviewed by each state varies. The common facilities and actions reviewed, though, are:

- Major medical equipment
- Capital expenditures above a certain threshold
- Nursing homes
- Transfers of ownership of hospitals
- Establishing or expanding a hospital service

More rarely:

- Terminations
- Reductions in services



Please refer to state-specific fact sheets for each state's reviewed services, actions and facilities

> Are any types of applications "weighted"?

- CT does not weight applications per se, however, more attention and resources are directed to proposals for services in which the market is saturated or competitive
- RI has in the past issued requests for proposals but has not done so recently
- NC conducts a yearly survey to determine need for various types of hospital beds, operating rooms, medical equipment, home health offices and other services requiring CON approval; will only accept applications for which there is an identified unmet need.



> Are any types of applications "weighted"? (cont'd)

 HI provides the following rubric "grading" applications based on whether statutory criteria are met:

	CRITERIA	NET	MET	COMMENTS
RELATIONSHIP TO THE STATE PLAN	Relationship of the proposal to the state health services and lacilities plan.			
NEED AND ACCESSIBILITY	2. The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular the elderty, low income persons, racial and ethnic minorities, women, persons with disabilities, and other underserved groups are likely to have access to those services. 3. In the case of a reduction, elimination, or relocation of a facility or service: A. the need that the population presently served has for the service; B. the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements; and C. the effect of the reduction, elimination, or relocation of the service on the ability of the elderly, low income persons, racial and ethnic minorities, women, persons with disabilities and other underserved groups to obtain needed health care.			
QUALITY OF SERVICE/CARE	 The applicant's compliance with federal and state licensure and certification requirements. The quality of the health care services proposed. In the case of existing health services or facilities, the quality of care provided by those facilities in the past. 			
COST AND FINANCES	7. The probable impact of the proposal on the overall costs of health services to the community. 8. The probable impact of the proposal on the costs of and charges for providing health services by the applicant. 9. The immediate and long-term financial feasibility of the proposal.			
RELATIONSHIP TO THE EXISTING HEALTHCARE SYSTEM	The relationship of the proposal to the existing health care system of the area. The availability of less costly or more effective alternative methods of provioling services.			
AVAILABILITY OF RESOURCES	12. The availability of resources (including health personnet, management personnet, and funds for capital and operating needs) for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the Hawai'i Health Performance Plan, H2P2, (state health services and facilities plan).	**		



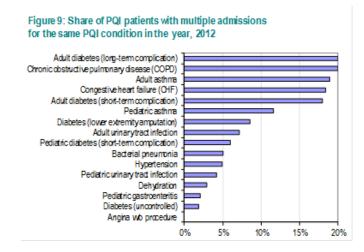
➤ What data is collected by OHCA?

- Inpatient discharge data
- Ambulatory surgery data
- Aggregate data from hospitals on scans, endoscopies, ER visits and hospital clinic data

Would benefit from: all-payer claims data

Primary insurer's Prevention Quality Indicators (PCI) total charges and hospitalizations, 2012

Payer	Total charges	Change in total charges, 2008-2012	PQI Hospitalizations	PQI % of all hospitalizations
Medicare/				
other federal	\$810,414,699	14%	28,180	17%
Medicaid	\$260,130,521	26%	8,032	9%
Private	\$258,579,213	1%	7,740	6%
Uninsured ¹	\$16,258,387	-14%	785	10%
Total	\$1,345,382,820	13%	44,737	11%



DATABOOK, Preventable Hospitalizations in Connecticut: A Reassessment of Access to Community Health Services 2008 - 2012



What data is collected by other states?

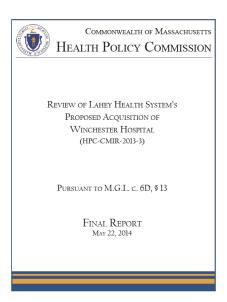
- Annual Survey (MI) collects yearly statistical data from every CON-covered service provider. Data collected is dependent upon type of service. May include volume, patient days of care, number of procedures performed and/or staffing levels, among others
- State census data (MI) in order to calculate specific need for a particular service or facility
- Inpatient discharge data (MI, NY)
- All-payer claims data (MA, MD)
- Acute Hospital Case Mix (MA*) including hospital inpatient discharge data, outpatient observation data, emergency department database, hospital readmission rates

^{*} MA collects extensive data in areas of Quality, Health Care Costs and Payments, Insurance Access, and Health System Performance. Visit www.chiamass.gov for a comprehensive overview.



> Do other states conduct market impact studies?

- CT: for certain hospital transfers of ownership
- RI: for mergers of hospital systems; conducted by a consultant
- MA hires consultant to conduct a cost of market impact review who works with CON staff (available at http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/material-change-notices-cost-and-market-impact-reviews/hpc-cost-and-market-impact-reviews.html)





> Do other states incorporate quality measures into analysis?

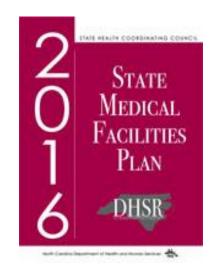
- MD: incorporates into <u>rate setting</u>; collects data including mortality rates, patient services, readmission rates, administrative claims data, infection incidents, patient complaints
- RI: reviews quality measures as part of hospital transfers of ownership analysis as it is tied to <u>licensing</u>
- NJ: does not review specific metrics; <u>consumer complaints</u>, however, are considered during licensing process
- NC: looks at any violations or civil penalties levied against <u>other</u>
 <u>facilities</u> owned or operated by the applicant



STATE HIGHLIGHTS

North Carolina

- Planning State Medical Facilities Plan is developed annually by the State Health Coordinating Council. The plan contains detailed methodology for calculating bed need for a range of services. Applications are reviewed in light of the need determined using the calculations provided by the plan.
- Regulations specific and tailored to address each reviewed area (i.e. cardiac cath, burn center, etc.).
- Enforcement Can assess a civil penalty up to \$20,000 per incident per service. Penalty standard, "knowingly offers a new service without a CON" is low enough to be applied and effective.
- Staff is assigned to counties develop expertise in the needs of the specific community and can consider health care need holistically



Available at https://www2.ncdhhs.gov/dhsr/ncsmfp/2016/2 016smfp.pdf



STATE HIGHLIGHTS

Michigan

Data Collection

- Conducts an annual survey collecting data for every CON-regulated service in the state.
 Data differs from service to service, including elements such as volume, staffing, and number of patient days of care.
- Inpatient database with statistical data used by Michigan State University for demographic research and analysis, which provides basis for review standards set by the Standard Advisory Committees (SACs)

Certificate of Need Commission

- Establishes review standards and methodology rather than considering actual applications
- Eleven members appointed by the Governor from stakeholder groups
- Standards are reviewed every 3 years or as needed
- The Commission sets up work groups or Standard Advisory Committees; 2/3 of members must be experts in the field for which they are reviewing standards.
- SACs take into account population health, utilization and projections.
- CON analysts apply SAC methodology to quantify actual need in a particular area.



STATE HIGHLIGHTS

Maryland

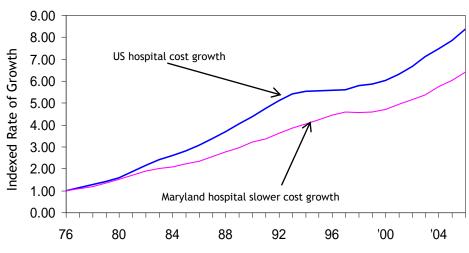
Rate Setting

- Rates apply to: hospitals; all payers equally
- Set by: Health Services Cost Review Commission (separate from CON)
- Goal: ensure benefits of hospital consolidation are realized while avoiding unnecessary increases in costs to consumers/payers

Process:

- "Global budget" setting revenues for each hospital established
- Hospitals permitted add-on rate to cover uncompensated care
- Potential add'l revenue allotment based on quality assessment
- If volume decreases, hospital may raise rates to maintain its global budget
- Adjustments may be made for inflation, population growth and market shifts

"Bending the Curve" Growth in Hospital Costs per case (MD vs. US)



- 1976: Maryland Cost per case was 25% ABOVE the US average
- 2010: Maryland Hospital cost per case 3% BELOW the US average

MD Health Services Cost Review Commission Maryland All-Payer Hospital Payment System Presentation (2013).



> Batching

periodically accepting applications of the same or similar type at a pre-determined time (e.g., imaging equipment in January and June); applications reviewed "competitively."

- Allows best proposal to be selected rather than the first submitted
- Analysts can compare similar applications concurrently
- Applicants have incentive to provide additional insight about other applications before OHCA
- More predictable review cycle, potentially facilitating faster reviews
- Fosters competition



> Panels

members are generally appointed by the Governor for set terms and are related to the health-care industry (doctors, nurses, public health professors, large equipment experts, economists, insurance and hospital representatives)

- **Voting Panels** have discretion to approve or deny applications, generally after a public hearing or meeting that is open to the public
- Advisory Panels make recommendations to the CON director or Commissioner
- Standard-setting are tasked with establishing the criteria by which applications are judged; in Michigan, commission creates the statistical formulas applied to a population to determine if a need exists for the facility or service



> Panels (cont'd)

- Helps ensure political and industry stakeholder buy-in
- Provides technical expertise to assist agency decisions
- Can pull in topic-experts as needed to reflect changes in health care landscape
- May reduce appearances of bias
- > States using panels (almost all states have one form or another)
 - Advisory: MA, RI, HI
 - Voting: VT, MD, NJ (however Deputy Commissioner signs), HI (panel makes determination and if Director opts to do otherwise there is an automatic hearing to reconsider),
 - Standard Setting: NJ, MI, NC



Penalties

OHCA's statutes do currently contain a penalty provision (\$1k/day authority); however, must show a "willful" violation of the statute. Proving a willful intent is prohibitively stringent.

- Negligent Standard OHCA has proposed lowering the standard to require a showing of negligence-or a failure to exercise reasonable care--in obtaining a CON or complying with a CON condition
- No Showing of Intent / "Strict Liability" several states do not require any showing of intent and any violations of the statute may be subject to penalties; however, there tends to be some discretion in pursuing fines or penalties and states tend to try to work with parties to resolve the issues



Penalties (cont'd)

- Makes statute more enforceable
- Levels the playing field, such that parties who consistently comply with the law are not at a disadvantage

>States that enforce penalties:

- NC: strict liability, \$20k per "incident" of violation
- MI: can issue compliance order, civil fine or propose corrective action
- VT: can additionally bar other state agencies from issuing licenses to health care facility that fails to acquire a CON
- CT: must receive CON before being issued a license by DPH



> Expedited Review

shortened review period; generally limited to less complex types of applications that are not particularly contentious. Often require a higher application fee

- Agency discretion Applicants submit a request and analysts review the request in light of the current workload; if approved, the analyst and applicant work together to set a schedule
- Abbreviated decisions shorter decisions allow for a faster review time
- "On Call" informal conversation between applicant and agency;
 agency accommodates to best of ability (current method used in CT)
- Mandatory expedited review certain types of applications automatically expedited



> Expedited Review (cont'd)

- Applicants able to implement projects more quickly
- Enables agency to focus resources on more complex applications
 (however additional resources would be necessary to facilitate a large number of expedited applications; additionally it may be difficult to predict which applications will be contentious and necessitate closer review)

> States with expedited review:

- VT: applicants submit request for expedited review, agency may grant under certain circumstances; no public hearing
- NC: expedited for non-competitive reviews under capital threshold and no public hearing requested
- MI: applicant submits a request, may grant at election of analysts depending on case load and complexity of application; determine a mutually agreeable deadline
- RI, NJ: if granted, application bypasses review board and goes directly to deputy commissioner (decision maker)



▶ Standards/Definition Setting

Applications are reviewed in light of specific proscribed standards; may be used to proactively plan health care services or to set minimum standards of care or use (i.e., staffing levels or utilization). CT has proposed definitions in regulation (e.g., clear public need)

- In regulation legislature gives authority to the state to establish definitions and/or standards in their regs
- State health plan often uses methodology incorporating population predictions and utilization data to establish need for a service in a particular area
- By Panel/Commission appointed body sets the standards or, alternatively, establishes or reviews the formula by which need is calculated



> Standards/Definition Setting (cont'd)

- More consistent and predictable reviews of applications
- Less subjective interpretation of statutory language
- Facilitates a more proactive planning process
- Able to more easily respond to changing health care needs

>States with standards/definitions . . .

- In regulation: NC (extremely detailed and specific), HI
- In state plan: NC (sets methodology for need analysis), MD, VT
- Established by panel or commission: MI
- CT's standards for imaging, cardiac services and ambulatory surgery can be found in the Statewide Health Care Facilities and Services Plan (http://www.ct.gov/dph/lib/dph/ohca/publications/2012/ohcastatewide_facilities_and_services.pdf)



▶ Incorporation of Public Health Initiatives

Method by which to encourage health care providers to address public health concerns and priorities through the CON program

- Agreed Settlements tie approval of profitable services to needed but unprofitable services, such as new training programs, Hep C treatment or specialty services for indigent peoples
- Percentage of fees used for local health initiatives in addition to application fee, requires percentage of capital costs to be set aside to establish a program in conjunction with a local health office
- Issuing request for proposals unmet need is identified and CON program announces it will begin accepting applications for that service; may or may not offer financial incentive to develop



- > Incorporation of Public Health Initiatives (cont'd)
 - More proactive addressing of beneficial but unprofitable services
 - Links larger health care providers to needs of the local community
 - >States incorporating public health initiatives through. . .
 - Agreed Settlements: RI
 - Percentage of fees: MA
 - RFPs: NJ (issues "call for service" in response to finding a need for a certain type of bed; offers yearly stipend to the facility that receives the CON)



SUMMARY OF FINDINGS

- Most states house their CON programs within the health department and use CON as a planning tool to align the health care industry with the needs of the public
- 7 of the 8 survey states batch at least some types of applications
- Maryland is currently the sole state that sets all payer rates; however other states have contacted Maryland to learn about its program
- 8 out of 8 survey states have at least an advisory panel
- Michigan and Maryland have most thorough data collection
- Most states engage in proactive health facility planning





Connecticut Department of Public Health