Certificate of Need (CON) Programs:

Stakeholder Views & Outcomes Research

Health Resources Board
October 24, 2013

Why Now?

- The Affordable Care Act (ACA) and Delaware's state healthcare innovation plan provide new opportunities to tackle Delaware's health care challenges and advance the Triple Aim of better care, better health, and lower costs

- Providers working to create linkages across the care continuum (even greater emphasis on efficiency)

- Payers developing new strategies to promote higher quality care at lower overall costs
  - Payment models incentivize provider consolidation and quality of care

Sharamitaro, A. & Sudhakaran, J. (2012). Certificate of Need (CON) Law Series Part IV: The Impact of the Affordable Care Act on CON. Health Capital Topics, 5, 1-3.

Why Now?

- An increase in the insured population (upwards of tens of millions of Americans)
- Shift toward “productive medicine”: patients receive the least amount of care at the point where it will produce the maximum health benefit
- Renewed emphasis on a proactive approach to health prevention, early intervention, community-based services, etc
- In instances where consolidation involves existing facilities, CON process may not be involved. But, for states with CON regulations involving capital expenditures, this will not be the case.
  - Nationally, CON programs will be an important piece of the puzzle → have the potential to moderate the speed with which ACA initiatives roll out across the U.S.

Why Now?

- Delaware is in the same boat as nearly 30 other states
  - Encouraged to evaluate / possibly revise current Certificate of Need (CON) / Certificate of Public Review (CPR) programs
  - An opportunity to better align CPR program with emerging health care goals in Delaware
  - Improve an existing health planning framework that works with payment incentives and other policy efforts to promote health system improvement
- Upcoming planned revision of Delaware's Health Resource Management Plan

CON Programs: A Timeline

- **1964:** New York is the first state to begin regulating hospital construction via the Metcalf-McCloskey Act; act specified that the state must provide "mandatory need determinations" before any hospital construction in NY
- **1968-1969:** Maryland, Rhode Island, California, and Connecticut adopt a similar certificate of need approach
- **1969-1972**: American Hospital Association (AHA) begins lobbies for federal CON legislation
- **1972:** Social Security Amendments of 1972 requires states to review hospital and medical facility capital expenditures exceeding $100,000; any change in bed capacity; or any substantial change in service
  - States allowed to deny reimbursements for expenditures "not meeting the state's health plan"

Smith, P. and Forgione, D. (2009). The Development of Certificate of Need Legislation. Journal of Health Care Finance, 36, 35-44.

CON Programs: A Timeline

- **1974:** Federal health planning programs and CON regulations officially enacted via the National Health Planning Resources Development Act (NHPRDA)
  - NHPRDA required all 50 states to establish oversight agencies to handle the submission of proposals for any major capital spending on health care resources (e.g., new construction, building expansions, new technology)
  - Guaranteed $1B federal funding for participatory states
- **1974-1982**: health care costs continue to rise nationwide despite 100% state participation in NHPRDA
- **1982:** Congress initiates a review of CON programs to determine if federal funding is still necessary

Smith, P. and Forgione, D. (2009). The Development of Certificate of Need Legislation. Journal of Health Care Finance, 36, 35-44.
National Conference of State Legislatures (NCSL), 2011

CON Programs: A Timeline

- **1982:** Congressional Budget Office (CBO) study does not offer a final recommendation, but reports that a number of problems with the current NHPRDA has limited the program's success in achieving cost savings
- **1983-1985:** Seven states (AZ, ID, KS, MN, NM, TX, and UT) abandon CON despite NHPRDA still in effect
- **1987**: NHPRDA repealed.
- **1987-1999:** CA, CO, IN, ND, PA, SD, and WY abandon CON
- Currently, 36 states (and D.C. and Puerto Rico) have CON programs. But, even in the 14 states that have repealed CON laws, some mechanisms remain in place to regulate health care costs and avoid duplication of services.

Smith, P. and Forgione, D. (2009). The Development of Certificate of Need Legislation. Journal of Health Care Finance, 36, 35-44.
National Conference of State Legislatures (NCSL), 2011

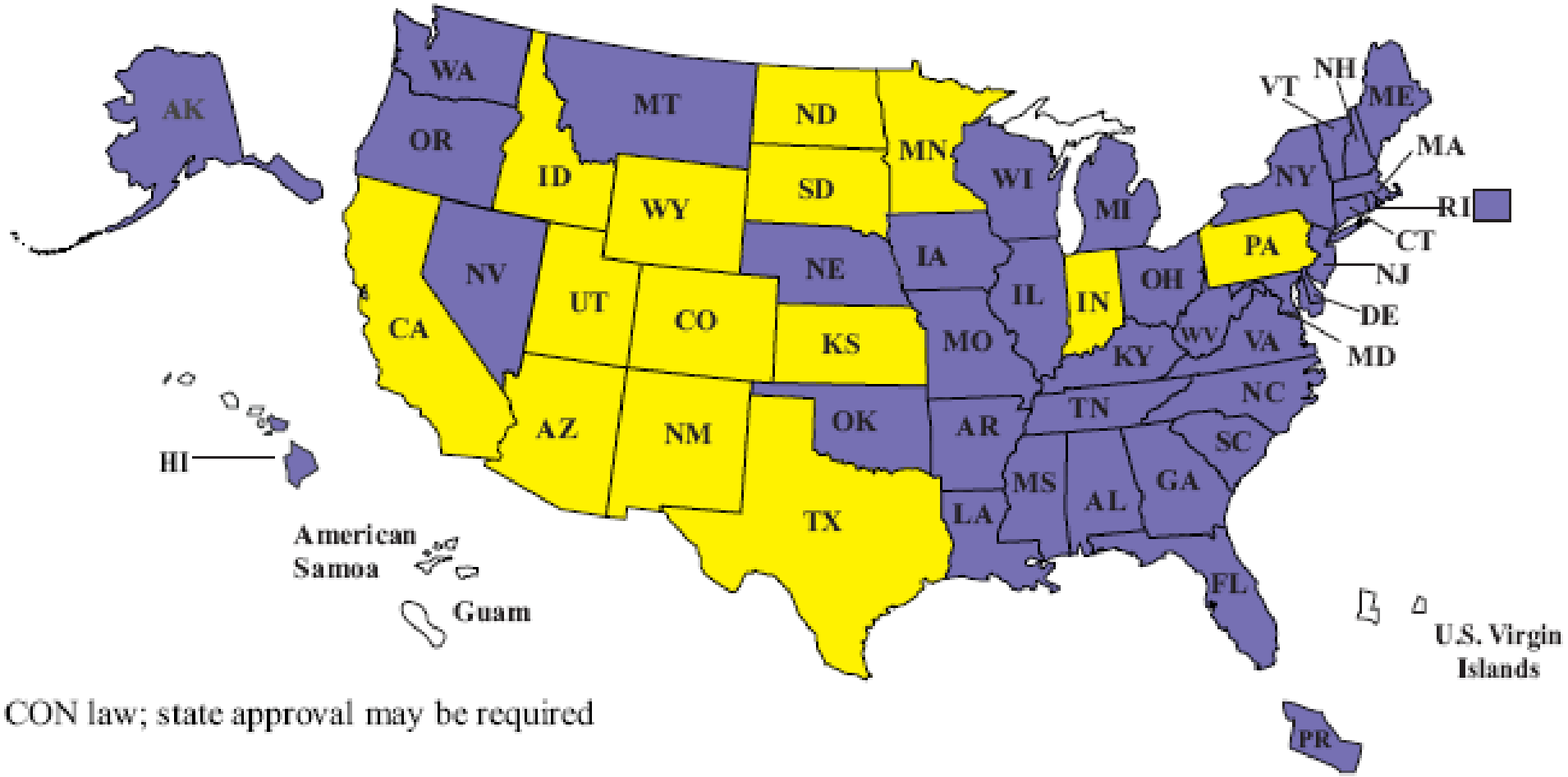
CON Programs: Delaware's Extended Timeline

- **1987:** Via Senate Bill 132, Delaware's state-only CON program was established under the Health Resources Management Council (HRMC)
- **1993:** Delaware's Joint Sunset Committee (JSC) sunset the HRMC, allowing a year to finalize business before 1994
- **1994:** House Bill 331 established the Delaware Health Resources Board (HRB) and issued a 1996 sunset date
- **1996:** Following an evaluation of the CON program by the Delaware Health Care Commission (DHCC), House Bill 640 was enacted which provided for the phase out of CON with a sunset date of 1999
- **1999:** Senate Bill 74 replaced CON with a Certificate of Public Review (CPR) and delayed the sunset date until 2002.

CON Programs: Delaware's Extended Timeline

- **2002:** Sunset provision was extended to 2005
- **2005:** Sunset date extended to 2009
- **2009:** Senate Bill 181 was signed into law, removing the sunset provision on the Delaware HRB Certificate of Public Review Process

State Certificate of Need (CON) Health Laws, 2010



CON law; state approval may be required

CON law repealed or not in effect.

Compiled by NCSL June 2010; based on data from AHPA

Regulated Services (2010)	Number of States
Nursing Home Beds/Long Term Care Beds	37
Acute Hospital Beds	28
Long Term Acute Care (LTAC)	28
Ambulatory Surgical Centers (ASC)	27
Cardiac Catheterization	26
Psychiatric Services	26
Open Heart Surgery	25
Rehabilitation	25
Neo-Natal Intensive Care	23
Radiation Therapy	23
Intermediate Care Facilities/Mental Retardation (ICF/MR)	22
Organ Transplants	21
Positron Emission Tomography (PET) Scanners	20
Magnetic Resonance Imaging (MRI) Scanners	19
Substance/Drug Abuse	19
Home Health	18
Hospice	18
Mobile Hi Technology (CT / MRI / PET, etc)	16
Gamma Knives	15
Lithotripsy	15
Obstetrics Services	15
Computed Tomography (CT) Scanners	13
Subacute Services	13
Renal Failure/Dialysis	12
Swing Beds	12
Burn Care	11
Air Ambulance	6
Assisted Living & Residential Care Facilities	5
Ultra-Sound	4
Medical Office Buildings	2
Ambulance Services, Ground	1

Bolded *service categories represent those regulated via Delaware's CPR process.*

CON Programs: Basic Intent

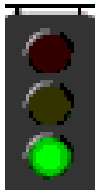
- CON programs aimed at restraining health care costs and allowing coordinated planning of new services and construction based on a genuine need in a community

- Basic underlying assumption: excess health care capacity directly results in health care price inflation.
  - When facilities cannot meet their quotas, fixed costs must be met through higher charges for services rendered.

- CON programs intended to dovetail with other health care cost control measures
  - Stark Law Regulations: limits on physician referrals to facilities in which they or a family member have a financial interest
  - Precertification by insurers to make sure treatment requests are necessary
  - Prepayment of covered services
  - Fixed payments for defined services (Diagnostic-Related Groups (DRGs))
  - Providing patients with information about costs of treatments and quality of care at competing facilities

National Conference of State Legislatures (NCSL), 2011

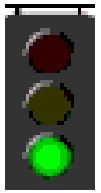
CON Programs: Supporters' Views



- Health care is not a typical economic product for which usual market forces apply
  - Patients don't "shop" for health care services the way they do for other commodities
- Facilities are insensitive to market effects on price and require a regulatory approach based on public interest
- CON programs help distribute care to disadvantaged populations or geographic areas that may be ignored by new and existing medical centers
  - Especially safety net hospitals and rural communities
  - Require provision of charity care or have applicants address the potential impact on existing safety net hospitals

National Conference of State Legislatures (NCSL), 2011

CON Programs: Supporters' Views



- CON programs consider public policy concerns beyond simple licensure
  - Michigan: only facilities able to perform cardiothoracic surgery are allowed to do interventional catheterization procedures. Assures patients that emergency complications could be managed with immediate surgery, if necessary.
- Removal of CON will lead to a proliferation of "low-volume" facilities, which some view as providing lower-quality care
- Removal of CON will favor for-profit hospitals which may be less willing to provide indigent care

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CON Programs: Opponents' Views

- By restricting new construction, CON programs may reduce competition between facilities, thus keeping prices high
- Joint report issued by the Federal Trade Commission and the Department of Justice (2004):
  - *"CON programs can actually drive up prices by fostering anticompetitive barriers to entry"*
- Anticipated/potential changes in payment systems (including Medicare) make external regulatory controls unnecessary
- CON programs may be less necessary as payers move toward reimbursement systems that reward efficiency
- Competitive success has been demonstrated in the areas of pharmaceuticals, urgent care centers, and elective surgeries

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CON Programs: Opponents' Views

- CON programs are not consistently administered (both within and across states)
- Health facility development should be left to each institution based on their unique economics
- CONs sometimes granted on the basis of political influence, institutional prestige, etc.
- System-wide shift toward *"empowering consumer choice in healthcare markets"*

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National Conference of State Legislatures (NCSL), 2011

Quantitative CON Research:

What are the Measurable Impacts of CON?

Health Resources Board
October 24, 2013

(Relatively Scant) Quantitative-Based Literature Review

1. Granderson, G. (2011). The impacts of hospital alliance membership, alliance size, and repealing certificate of need regulation, on the cost efficiency of non-profit hospitals. *Managerial and Decision Economics, 32*, 159-173.

2. Ferrier, G., Leleu, H., Valdmanis, V. (2010). The impact of CON regulation on hospital efficiency. *Health Care Management Science, 13*, 84-100.

3. Ho, V. (2006). Does certificate of need affect cardiac outcomes and costs? *International Journal of Health Care Finance and Economics, 6*, 300-324.

4. Conover, C. & Sloan, F. (1998). Does removing certificate-of-need regulations lead to a surge in health care spending? *Journal of Health Politics, Policy, and Law, 23*, 455-481.

5. Eakin, B. (1991). Allocative inefficiency in the production of hospital services. *Southern Economic Journal, 58*, 240-248.

6. Mayo, J. & McFarland, D. (1989). Regulation, market structure, and hospital costs. Southern Economic Journal, 55, 559-569.

7. Sloan, F. & Steinwald, B. (1980). Effects of regulation on hospital costs and input use. *Journal of Law and Economics, 23*, 81-109.

(Relatively Scant) Quantitative-Based Literature Review

- All focus primarily cost and quality outcomes in **acute care** and **ambulatory surgery**
  - Some measure impact on **total per capita health care spending** at the state level
  - But none focus on LTC cost and quality outcomes
  - Questions about the availability of LTC cost and quality data

- Existing research (7 main studies + a handful of lesser-known studies) spans a nearly 35-year time period
- Contradictory findings → few obvious conclusions

1. The impacts of hospital alliance membership, alliance size, and repealing certificate of need regulation, on the cost efficiency of non-profit hospitals. Granderson, G. (2011). *Managerial and Decision Economics, 32*, 159-173.

- **Findings:** On average, **repealing** state CON programs contributed to a statistically significant ($\alpha = 0.10$) **improvement in hospital cost efficiency**

2. The Impact of CON regulation on hospital efficiency. Ferrier, G., Leleu, H., & Valdmanis, V. (2010). *Health Care Management Science, 13*, 84-100.

- **Findings:** Hospitals operating in states where CON regulation was active had **higher average technical and structural efficiency scores** than hospitals operating in in states that did not have CON programs

- However, when hospital efficiency scores were aggregated to the **state level,** the presence of CON programs **did not contribute to an improvement in scale efficiency**

3. Does certificate of need affect cardiac outcomes and cost? Ho, V. (2006). *International Journal of Health Care Finance and Economics, 6,* 300-324.

- **Findings:** CON states demonstrated **higher hospital procedure volume** and **lower average cost of care**

4. Does removing certificate-of-need regulations lead to a surge in health care spending? Conover, C. & Sloan, F. (1998). *Journal of Health Politics, Policy, and Law, 23,* 455-481.

- **Findings:** Mature CON programs (those >2 years post-implementation) had a statistically significant ($\alpha = 0.05$) **negative impact** on acute care spending
  - Long-term 5% reduction in per capita acute care expenditures (also includes ambulatory care)

- CON laws had **no effect** on total personal health expenditures per capita

5. Allocative inefficiency in the production of hospital services. Eakin, B. (1991). *Southern Economic Journal, 58,* 240-248.

- **Findings:** Hospitals in CON states had **higher levels of allocative inefficiency** compared to those in non-CON states

6. Regulation, market structure, and hospital costs. Mayo, J. & McFarland, D. (1989). *Southern Economic Journal, 55,* 559-569.

- **Findings:** CON regulation was associated with **lower total hospital costs as well as lower cost per patient day**

7. Effects of regulation on hospital costs and input use. Sloan, F. & Steinwald, B. (1980). *Journal of Law and Economics, 23,* 81-109.

- **Findings** States with comprehensive CON programs (defined as requiring applications for service expansion and a threshold for reviewing equipment purchases under $100,000) had **no statistically significant impact on hospital costs**

(Relatively Scant) Quantitative-Based Literature Review

1. Granderson, G. (2011).

2. Ferrier, G., Leleu, H., Valdmanis, V. (2010).

3. Ho, V. (2006).

4. Conover, C. & Sloan, F. (1998).

5. Eakin, B. (1991).

6. Mayo, J. & McFarland, D. (1989).

7. Sloan, F. & Steinwald, B. (1980).

Qualitative CON Research:

What Do the Stakeholders Have to Say?

Health Resources Board
October 24, 2013

Health Care Certificate-of-Need Laws: Policy or Politics?

Yee, T., Stark, L., Bond, A., & Carrier, E. (2011).
National Institute for Health Care Reform, Research Brief, Number 4.

- 6 states selected for study based on the following criteria:
  - Regulations in all categories of CON spending (hospital, ASC, LTC, etc.); recent changes in CON legislation; recent evaluation of CON process; and/or current events in the media involving CON issues.
  - 6 states = Connecticut, Georgia, Illinois, Michigan, South Carolina, Washington

- Telephone interviews with 42 representatives of state agencies, hospitals, physician groups, medical societies, hospital associations, payers, consultants, attorneys, and policy groups that work directly with their state's CON program

- National Institute for Health Care Reform:
  - *"A 501(c)(3) nonprofit, nonpartisan organization established by the International Union, UAW; Chrysler Group LLC; Ford Motor Company; and General Motors to conduct health policy research and analysis to improve the organization, financing and delivery of health care in the U.S."*

  - *"The Institute does not take policy positions, and similar to HSC, strives to be an honest broker of information and a reliable resource for decision makers on all sides of the critical issues facing the U.S. health care system."*

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Viewpoint A: CON Agency Experiences

- CON authorities face intense scrutiny
- Basic function of CON boards is to process and review CON applications, but many report "being caught in the competitive crossfire" (appeals, public hearings, court battles)
- Challenges to the CON process more often involve providers contesting approvals of competitors' applications (as opposed to providers appealing their own denied applications)
- High CON approval rate: across the 6 states, CON approval rate ranged from 88%-96% (FY 2009)
  - Does not necessarily indicate a lenient CON process (rather, applicants becoming more savvy of their state's CON process)
- Difficulty in evaluating applications (staffing and funding difficulties)

Health Care Certificate-of-Need Laws: Policy or Politics?

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Viewpoint B: Hospital Experiences

- Hospitals typically view CON programs positively
- Use the process to protect existing market share (geographic or service line) and block competitors, but find the process difficult if they are trying to enter a market
- Cited tracking CON applications as a way to “keep tabs” on competitor hospitals
- Smaller, community hospitals tended to view CON process as an unlevel playing field (often lack financial resources to go through sometimes decade-long court battles with larger hospitals)
- Hospitals have a “love-hate relationship” with the CON process, but ultimately support the process; they see it as a tool to block physician-owned facilities

Health Care Certificate-of-Need Laws: Policy or Politics?

Yee, T., Stark, L., Bond, A., & Carrier, E. (2011).
National Institute for Health Care Reform, Research Brief, Number 4.

Viewpoint C: Physician Experiences

- Most physicians interested in establishing for-profit facilities viewed CONs as overly restrictive
- Many supported repeal of the regulations entirely; cited as the #1 barrier to market entry
- Even among physicians who successfully obtained a CON, many supported repeal because of added-on restrictions
- CONs can act as barriers to innovation (obtaining a CON for new technology make take >18 months, delaying patients from being treated with the most-advanced equipment)
- Some physicians noted that these innovation delays negatively affect the ability to recruit top-tier specialist physicians to a geographic region

Health Care Certificate-of-Need Laws: Policy or Politics?

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National Institute for Health Care Reform, Research Brief, Number 4.

Strategic Approaches to CON Applications

- Respondents from all 6 states reported using public relations and marketing campaigns for large applications. Many have in-house strategic planning teams; others hire consultants and attorneys with significant CON experience.
- Hospital respondent: “While it is not supposed to be based on public opinion, the public plays a big role. They can write letters and talk to senators.”
- All states have had CON appeal battles go on for years; sometimes providers appealed decisions to the highest authority in the state (the state supreme court)
- In Michigan, two hospitals independently and successfully circumvented the CON process by convincing the state legislature to override a CON denial

Health Care Certificate-of-Need Laws: Policy or Politics?

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National Institute for Health Care Reform, Research Brief, Number 4.

Improving CON Processes

- Unanimous agreement among respondents: CON process is far from perfect and requires continual evaluation and adjustment
  - Michigan: appointed CON commission evaluates the review standards on a three-year rotating schedule and has the authority to recommend revisions
- Effort to reduce paperwork and burden on CON authorities to review applications (e-filing systems increase efficiency and transparency)
- Strengthen state health planning: inadequate information to estimate changes in population and demand for services weakens CON programs

State-Initiated CON Evaluations

Health Resources Board
October 24, 2013

State-Initiated CON Evaluations

- States continue to investigate their unique CON history, considering amendments, complete overhauls, or even repeal of their current CON programs
  - New York (2012)*
  - Connecticut (2012)*
  - New Jersey (2008)
  - Illinois (2007)
  - Georgia (2006)
  - Washington (1999)
- Delaware completed its own CON evaluation in **1996** and a second CPR evaluation in **2008**

State-Initiated CON Evaluations

- **New York** (2012)*: http://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf
- **Connecticut** (2012)*: http://www.ct.gov/dph/lib/dph/ohca/publications/2012/ohcastatewide_facilities_and_services.pdf
- **New Jersey** (2008): http://www.nj.gov/health/rhc/finalreport/documents/entire_finalreport.pdf
- **Illinois** (2007): http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf
- **Georgia** (2006): http://dch.georgia.gov/sites/dch.georgia.gov/files/imported/vgn/images/portal/cit_1210/61/51/72484934FINAL_Georgia_CON_Commission_Report.pdf
- **Washington** (1999): http://www.leg.wa.gov/JLARC/AuditAndStudyReports/1999/Documents/99-1.pdf

State-Initiated CON Evaluations: Washington (1999)

- Joint Legislative Audit and Review Committee contracted with the Health Policy Analysis Program of the University of Washington's School of Public Health

- Study examined effects of CON and its possible repeal on cost, quality, and accessibility for the following 5 services:
  A. Hospitals
  B. Ambulatory surgery centers
  C. Kidney dialysis centers
  D. Home health services
  E. Hospice

- Nursing homes were excluded from the study

State-Initiated CON Evaluations: Washington (1999)

- **Methods:**

A. **Literature Review**

B. **Analyses of repealed-CON States**

C. **Focus Groups**
   - Five focus groups comprised of Washington State service providers in the aforementioned service areas

D. **Key Informants**
   - Interviews with 10 experts with specialized knowledge of Washington's CON program; informants represented consumer, business, labor, academic, and government perspectives

E. **Advisory Group**
   - Consisting of representatives of stakeholder organizations

F. **Peer Review**
   - Two national expert peer reviewers with divergent views of health sector regulation

State-Initiated CON Evaluations: Washington (1999)

- Three policy options proposed

1. **Reform the Program:**

- Reassess program goals in context of current health care system
- Establish a system for CON to be more responsive to changes in the health care system
- Strengthen state monitoring of quality, access, and charity care/unreimbursed community services

2. **Repeal the Program:**

- Re-evaluate state health policy goals / identify other means of attaining these goals
- Strengthen data collection and monitoring programs to oversee costs, quality, access, and community benefits

3. **Conduct Additional Economic Analyses**

- Initiate an economic study to provide greater understanding of the effects of CON
- Study would model the simulated impacts should WA CON program be repealed
- Estimated cost for proposed study: $200,000 - $300,000

State-Initiated CON Evaluations: Delaware (1996 & 2008)

- **1996:** Cost Containment Committee authored *Evaluation of Certificate of Need and Other Health Planning Mechanisms*
  - DHCC recommended eliminating the CON program in gradual phases
  - Sufficient evidence did not exist to demonstrate that CON contained costs
  - Effort to eliminate CON failed (hospital association lobbied for its continuation) *(2012 JSC Report (HRB))*
  - As an alternative, legislation was passed to change CON into the CPR program (threshold for review changed from $750K to $5.8M)

State-Initiated CON Evaluations: Delaware (1996 & 2008)

- **2008:** *Delaware Certificate of Public Review Policy Options Review*
  - If CPR is discontinued, other mechanisms for assuring consumer access to health care services
  - If CPR is continued, consider extending CPR to services (as opposed to facilities and technology)
  - More staff and/or funding to develop analytic reports, methodology, other activities
  - Increase application filing fees to cover the operations of the program
  - Consider revising timelines and deadlines to enable the Board to meet quarterly instead of monthly
  - Consider amending the governing statute to reduce the number of people serving on the HRB
  - Clarify specific instances that qualify as conflicts of interest for Board members (uncertainty)

Why Now?

- The Affordable Care Act (ACA) and Delaware's state healthcare innovation plan provide brand new opportunities to tackle Delaware's health care challenges and advance the Triple Aim of better care, better health, and lower costs
- Providers working to create linkages across the care continuum
- Payers developing new strategies to promote higher quality care at lower overall costs (link payment to quality)
- Delaware is in the same boat as nearly 30 other states
  - Encouraged to evaluate / possibly revise current Certificate of Need (CON) / Certificate of Public Review (CPR) programs
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END