SPOTLIGHT REPORT

The Case Against CON: A law that prevents health care innovation

by Katherine Restrepo *posted on* June 2, 2015 *in* Health Care & Human Services, Law & Regulation

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What the healthcare industry needs is a strong dose of disruptive innovation — relaxing regulations that will increase provider competition, force downward pressure on costs, and enhance patient choice. CON ultimately picks who gets to compete within the health care sector. Reforming the law will by no means untangle the complexities of health care, but state lawmakers should capitalize on an opportunity to make one of the most highly regulated industries a little less heavy on the red tape and a little more patient friendly.

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Spotlight

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THE CASE AGAINST CON

A law that prevents health care innovation

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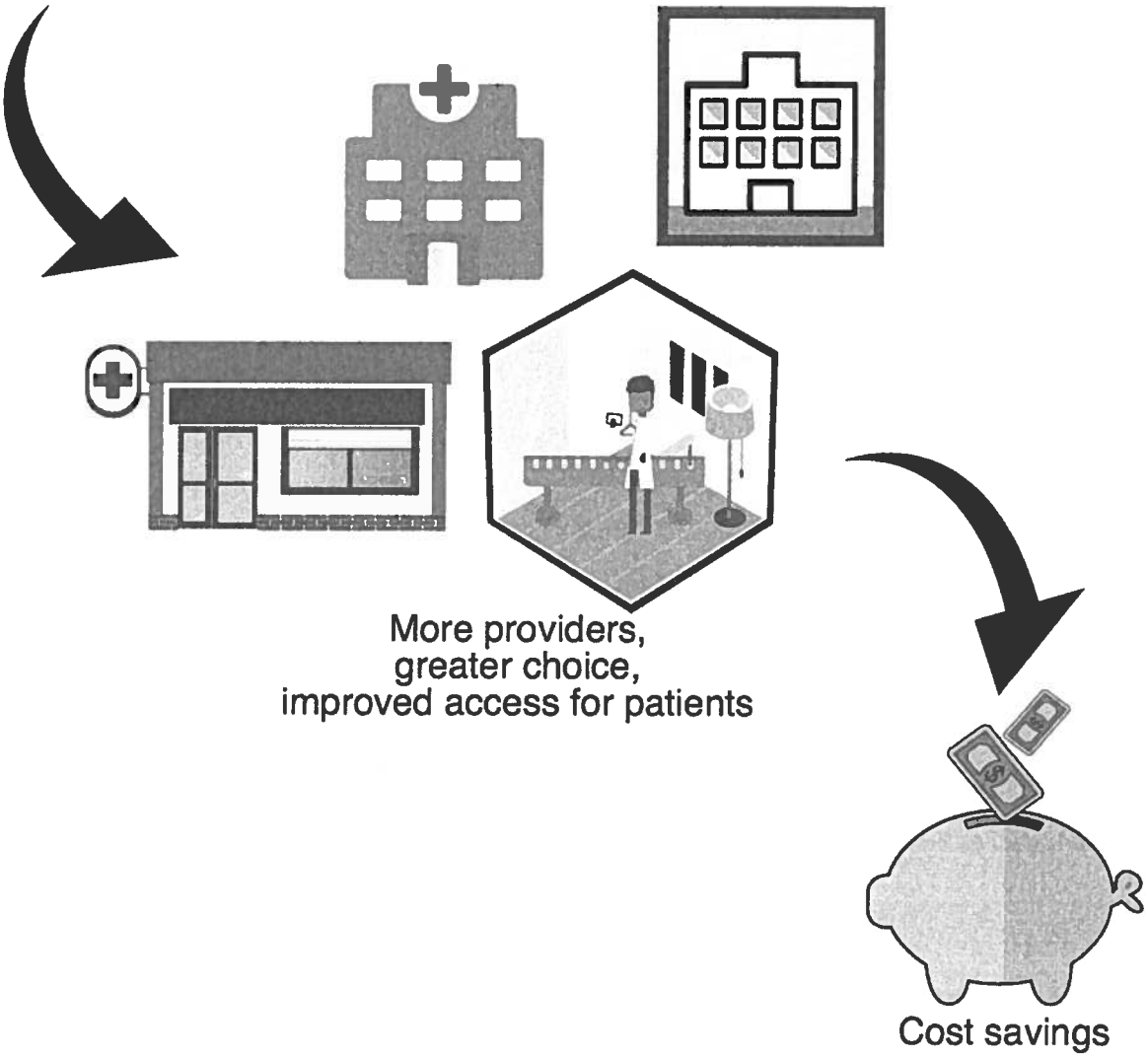
Repeal of CON laws



In the area of healthcare, today's political agenda focuses too much on reducing the number of uninsured and not enough on prescribing ways for patients to access less expensive services in alternative settings. One way legislators can increase the supply side of health care is to repeal North Carolina's Certificate of Need (CON) law.

CON is a regulation that limits health care supply unless a specific "need" is determined by state bureaucrats. If medical providers have plans to build a new health care facility or expand an existing one, offer new services, or update major medical equipment, they must first ask permission from "The SHCC" (the State Health Coordinating Council) and then their competitors.[1]

History

Originally CON was a federal mandate for all states. Congress's intent behind enacting CON laws under the federal Health Planning Resources Development Act in 1974 was to cut down on health care cost inflation.[2] At that time, reimbursements for services were based on the costs of production, or a cost-plus system. Providers therefore had strong incentives to build and expand the capacity of health facilities.[3]

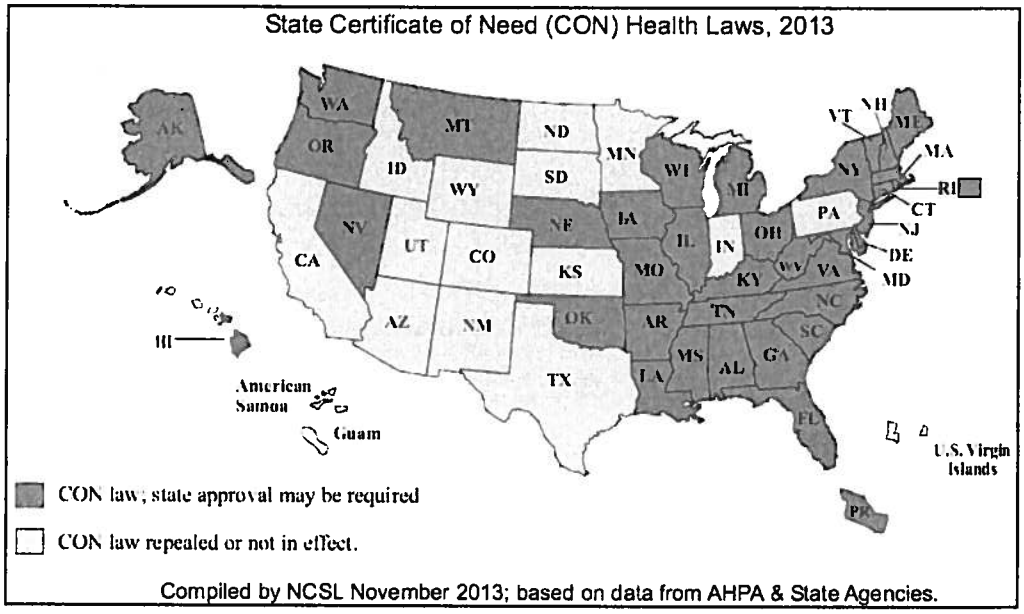
Yet once the reimbursement system shifted to fee-for-service, the feds repealed the CON mandate in 1987, citing that the program did not effectively restrain health care costs. Fifteen states have since scrapped their CON programs, while the approval and oversight process varies in remaining states.[4]

North Carolina CON

North Carolina burdens health care entrepreneurs with one of the most micromanaged CON programs in the nation, regulating 25 services that range from organ transplants to acute care hospital beds to ambulatory surgery centers (ASCs).[5]

Despite federal officials admitting to CON's inadequacies, the SHCC argues that centralized decision-making must remain in place to prevent duplicative services and an overinvestment in underused facilities that may yield low quality care. To this end, the 24 governor-appointed board members publish an annual Medical Facilities Plan,[6] a 450-page inventory that accounts for all types of entities and services offered across the state.

Granted, North Carolina did execute some reform in 2005, which allowed gastroenterologists to perform



1 North Carolina Division of Health Service Regulation: North Carolina State Health Coordinating Council. May 21, 2015. ncdhhs.gov/dhsr/ncshcc

2 Roy Cordato, "Certificate-of-Need Laws: It's Time For Repeal". Nov 28, 2005. johnlocke.org/research/show/policy%20reports/62

3 Jon Sanders, "Certified: The Need to Repeal CON; Counter to their intent, Certificate of Need laws raise health care costs". Oct. 24, 2013. johnlocke.org/research/show/spotlights/296

4 National Conference of State Legislatures, "Certificate of Need: State Health Laws And Programs". Jan. 2013. ncsl.org/research/health/con-certificate-of-need-state-laws.aspx

5 Ibid

6 North Carolina Division of Health Services Regulation: North Carolina State Medical Facilities Plan. March 2, 2015. ncdhhs.gov/dhsr/ncsmfp

Services regulated by North Carolina's CON law: How many other CON states also regulate them?	
Service regulated by CON in NC	**Number of other CON states (and DC) regulating it**
Acute Hospital Beds	27
Ambulatory Surgical Centers (ASC)	26
Burn Care	10
Cardiac Catheterization	25
Computed Tomography (CT) Scanners	12
Gamma Knives	14
Home Health	16
Hospice	17
Intermediate Care Facilities/Mental Retardation (ICF/MR)	21
Long Term Acute Care (LTAC)	27
Lithotripsy	14
Nursing Home Beds/Long Term Care Beds	36
Mobile Hi Technology (CT / MRI / PET, etc)	15
Magnetic Resonance Imaging (MRI) Scanners	18
Neo-Natal Intensive Care	22
Open Heart Surgery	24
Organ Transplants	20
Positron Emission Tomography (PET) Scanners	19
Psychiatric Services	25
Radiation Therapy	22
Rehabilitation	24
Renal Failure/Dialysis	11
Assisted Living & Residential Care Facilities	4
Subacute Services	12
Substance/Drug Abuse	18
Source: "Certificate of Need: State Health Laws and Programs," National Conference on State Legislatures, January 2011	

Key:

One-half or few other CON states regulate this service
One-third or fewer other CON states regulate this service

colonoscopies in their own endoscopy units.[7] Utilization of those services increased by 28 percent over four years, in part due to the state's baby boomer population, but overall Medicare savings still amounted to more than $224 million[8] within six years, since procedures performed in freestanding facilities are reimbursed at a lesser rate than those performed in full service hospitals.

Powerful stakeholders like the North Carolina Hospital Association have successfully blocked many legislative reform initiatives, since nonprofit health systems generally leverage CON to their advantage. After all, what law better protects their fortresses from potential competitors who could possibly provide more innovative services at a fraction of the cost? As Paul Starr notes in his Pulitzer-Prize-winning book, "The Social Transformation of American Medicine,"

> *The interest of state legislators was plainly cost control. However, the main inspiration for certificate-of-need came from the American Hospital Association and its state affiliates. The hospitals, anxious to avoid other forms of control, stood to benefit from the limits on competition that this sort of regulation would create. Opposed were profit making hospitals and nursing homes and some state medical societies, which objected to anyone but doctors regulating medical services.*[9]

7 North Carolina General Assembly Legislative Research Commission: Report on Committee on Market Based Solutions and Elimination of Anti-Competitive Practices in Health Care. Pp 12-13. April 15, 2014. ncleg.net/documentsites/committees/BCCI-6610/April%2015,%202014/DRAFT%20Report%20of%20Committee%20on%20Market%20Based%20Solutions%20and%20Elimination%20of%20Anticompetitive%20Practices%20in%20Healthcare%20to%20LRC.pdf

8 David J French, MBA, MHA, Strategic Healthcare Consultants, material presented to the North Carolina General Assembly on Sept. 27, 2012. ncleg.net/documentsites/committees/HSCCONPRH1/09-27-12/09-27-2012%20Presentation%20(3)%202005%20Change%20in%20the%20CON%20Law%20for%20GI%20Endoscopy%20Procedure%20Rooms.pdf

9 Paul Starr, "The Social Transformation of American Medicine: The rise of a sovereign profession and the making of a vast industry," pp 398-399. 1982.

Basic economics teaches that restricting the supply of health care services, as with anything else, keeps costs artificially high. Hospitals acknowledge this but claim that CON laws help them remain financially afloat.

Moreover, in North Carolina, having a CON is the ultimate bulwark against competition. For health care entities to receive a facility fee reimbursement from Medicare and Medicaid, they must be licensed, which means acquiring a certificate of need. CON supporters argue that with CON in place, hospitals are able to shift more costs onto private coverage patients, offsetting total uncompensated care and ostensibly providing better access to indigent care. However, a report published by the Mercatus Center concludes that better metrics are needed to determine whether CON laws directly correlate with health systems providing more indigent care.[10]

Hospitals also declare that health care is an exception to principles of supply and demand because the price-controlling government has had a strong presence since Medicaid and Medicare were introduced in 1965. Because of this, there is no free-market in health care.

To that point, the Hospital Association is correct. But does that mean that an already overwhelming and unpredictable regulatory environment needs additional oversight in the form of CON or that attempts to free the market should be resisted?

An Inefficient System

The purpose of CON regulation is to effectively manage health care infrastructure so that it meets patient needs. However, the law's regulatory structure is outdated and flawed.

It can take years for any medical provider or health system seeking to offer new services to receive a stamp of approval from the SHCC. And that's just half the battle. Other groups filing competing applications will likely contest the state's granted certification. Even parties *unaffiliated* with the application can appeal the state's decision. If that happens, the Office of Administrative Hearings (OAH) reviews the CON proposal and must make a decision within *270 days*. If the CON party is not satisfied with that ruling, an appeal can be made to the NC Supreme Court.[11]

These appeals may come from any provider offering comparable services, not just providers that vie for a specific certificate. For example, Triangle Orthopedic Associates (TOA), North Carolina's largest private orthopedic practice, and Duke University Health System filed competing applications for a fixed MRI machine in 2004. TOA ended up winning the bid. While Duke did not petition against the decision, a separate company, Alliance Imaging, did.[12] It had previously provided MRI services to TOA and feared the loss of business that would result if TOA procured its own machine.

Gaming CON

Additionally, once a certificate of need is secured, incumbent providers have the ability to take advantage of a gaping loophole[13] that enables them to artificially lower the "need" for operating rooms as determined by the State Medical Facilities Plan.

In November 2012, Surgical Care Affiliates filed a legal challenge to the state's Department of Health and Human Services (DHHS), alleging that procedure rooms should not be defined as sub par to operating rooms. Prior to *Surgical Care Affiliates vs DHHS*, procedure rooms differed from operating rooms due to factors such as smaller square footage, lower ceiling height, or having to pump medical gasses into the room from outside. Less invasive procedures were conducted in these settings. However, since DHHS settled the lawsuit, procedure rooms can now be built to the same standards as operating rooms.

10 Thomas Stratmann and Jacob W. Russ, "Do Certificate of Need Laws Increase Indigent Care?" July 2014. mercatus.org/sites/default/files/Stratmann-Certificate-of-Need.pdf

11 North Carolina Division of Health Service Regulation: Healthcare Planning and Certificate of Need Section. April 2, 2013. ncdhhs.gov/dhsr/coneed/overview.html

12 Richard Bruch, MD: John Locke Foundation Shaftesbury Society Luncheon. Oct 13, 2014. jlf.streamhammer.com/speakers/richardbruch101314.mp4

13 Dan Way, "Physicians Remain Unhappy With Certificate of Need Reforms: Doc group says hospitals still have unfair advantage in adding facilities." May 9, 2013. carolinajournal.com/exclusives/display_exclusive.html?id=10140 and Steve W. Keene, North Carolina Medical Society, material presented to the Committee on Market Based Solutions and Elimination of Anti-Competitive Practices In Health Care. Feb 18, 2014. ncleg.net/documentsites/committees/BCCI-6610/February%2018,%202014/Keene%2002-18-14.pdf

What's important to note here is that procedure rooms are not regulated under CON. As a result, health systems now have a strong incentive to add more full-blown procedure rooms while completely bypassing the obstacle to gain state approval for more operating rooms. And because surgeries performed within procedure rooms are not accounted for within the State Medical Facilities Plan, it appears on paper that there is a low demand for more operating rooms, when the reality could be quite the contrary.

There is insufficient data to determine how many surgeries are being performed in procedure rooms, but Surgical Care Affiliates' legal win is certainly benefiting the status quo and only makes it more difficult for new market entrants.[14] This doesn't mean that North Carolina's Division of Health Services Regulation (DHSR) – an arm of the state Department of Health and Human Services – should regulate procedure rooms. Rather, operating rooms should also be removed from onerous CON regulations.

Reforming North Carolina's CON law

Both the House and Senate in North Carolina are pushing to make changes to CON.

The Senate has filed Senate Bill 702 to fully dismantle both CON and Certificate of Public Advantage (COPA).[15] Under COPA, Mission Health, a dominant hospital system located in Western North Carolina, has the ability to be a monopoly and remain immune from any intervention by the Federal Trade Commission so long as the state exercises regulatory oversight,[16] including a margin cap along with cost caps limited to inpatient and outpatient services.

Naturally, however, stakeholders find ways around rules. A 2011 economic analysis prepared by Charles River Associates in Washington, D.C., highlights how Mission Health has the ability to use the margin cap to its advantage:[17]

> *The Margin Cap also creates an incentive for MHS to lower its margin by paying higher-than-normal prices for its inputs. This might take the form of MHS being willing to pay more than others in competitive bidding for hospitals, for empty land on which to build new facilities, or to outbid rivals when purchasing physician practices.*

Meanwhile, House Bill 200 takes a more piecemeal approach by exempting the following services from CON review:[18]

- Diagnostic centers
- Some ambulatory surgical facilities
- Gastrointestinal endoscopy rooms
- Psychiatric hospitals
- Operating rooms

Legislative Action

At present, the NC House is considering legislation to address the concerns outlined above. The most contentious provision in House Bill 200: Amend Certificate of Need Laws involves multi-specialty ambulatory surgery centers (ASCs). Hospitals fear that if more provider-led surgery centers were to break ground, these facilities could take away their most lucrative outpatient service lines,[19] which they rely on to cover the losses incurred from providing required indigent care. Declining margins could put at risk hospitals' mission of meeting the health care needs of their surrounding communities.

Last year, North Carolina hospitals reported $1.8 billion in uncompensated care,[20] but the latest data from the

14 Dan Way, "Certificate of Need Law Under Microscope: Hospitals, surgeons square off in battle on regulating new facilities," Feb. 25, 2013 carolinajournal.com/exclusives/display_exclusive.html?id=9930

15 Senate Bill 702: Repeal CON and COPA Laws. Filed March 26, 2015. ncleg.net/gascripts/BillLookUp/BillLookUp.pl?Session=2015&BillID=S702

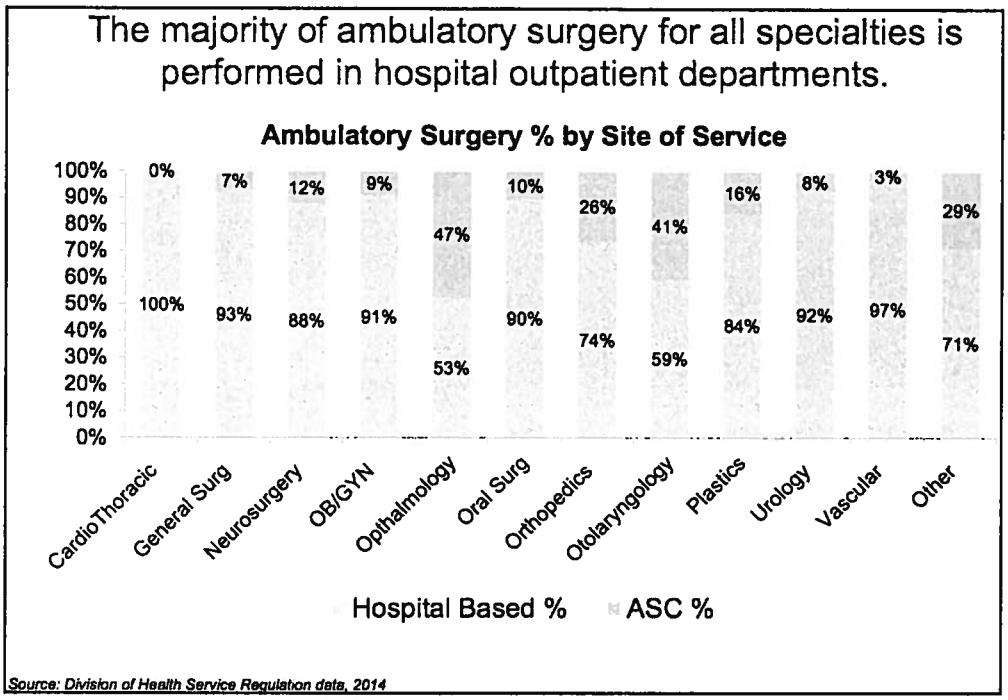
16 Jon Sanders, "Beyond CON: North Carolina's Certificate of Public Advantage," May 13, 2014. johnlocke.org/newsletters/research/2014-05-13-nglv9f70iil84hg0liq0bfrga1-regulation-update.html

17 Gregory S. Vistnes, Ph.D., "An Economic Analysis of the Certificate of Public Advantage (COPA) Agreement Between the State of North Carolina and Mission Health," Charles River Associates. Washington, DC. Feb. 10, 2011.

18 House Bill 200: Amend Certificate of Need Laws. Filed March 10, 2015. ncleg.net/Sessions/2015/Bills/House/PDF/H200v0.pdf

19 Jason deBruyn, "Changing Face of Surgeries" Triangle Business Journal. Aug. 8, 2014. bizjournals.com/triangle/print-edition/2014/08/08/changing-face-of-surgeries.html?page=all

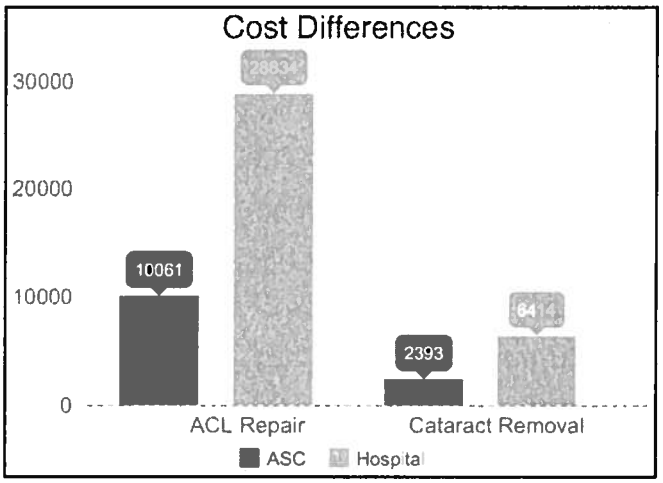
20 William Mahone, "Why Certificate of Need laws are important to NC health care" Op-Ed in News & Observer. March 17,2015.



Department of Revenue also shows they were granted over $227 million in sales tax exemptions.[21] The deal community hospitals have with the federal government is that exemptions from sales, property, and income taxes require hospitals to care for any patient who walks through their doors, regardless of their ability to pay.

What hospitals don't mention is that relaxing CON deals a huge break to patients, as independent ASCs are typically reimbursed by Medicare 45 to 60 percent less[22] for the same procedure compared to those being performed in a hospital outpatient setting. Since Medicare approved reimbursement for free standing centers back in 1982,[23] there has been a strong shift to outpatient surgical care. And, thanks to technological innovations, more surgeries are minimally invasive and can be safely performed in these focused facilities. Today, over 70 percent of the 635,000 annual surgeries in North Carolina are performed in outpatient settings, and 70 percent of these surgeries are conducted in the highest cost hospital systems, as seen in the table left.[24]

The chart below compares average charges for an ACL repair and a cataract removal — two of the most common outpatient surgeries— in two sample cities. These figures are taken from Blue Cross and Blue Shield of North Carolina's publicly accessible cost estimator tool.[25]



newsobserver.com/opinion/op-ed/article15115157.html

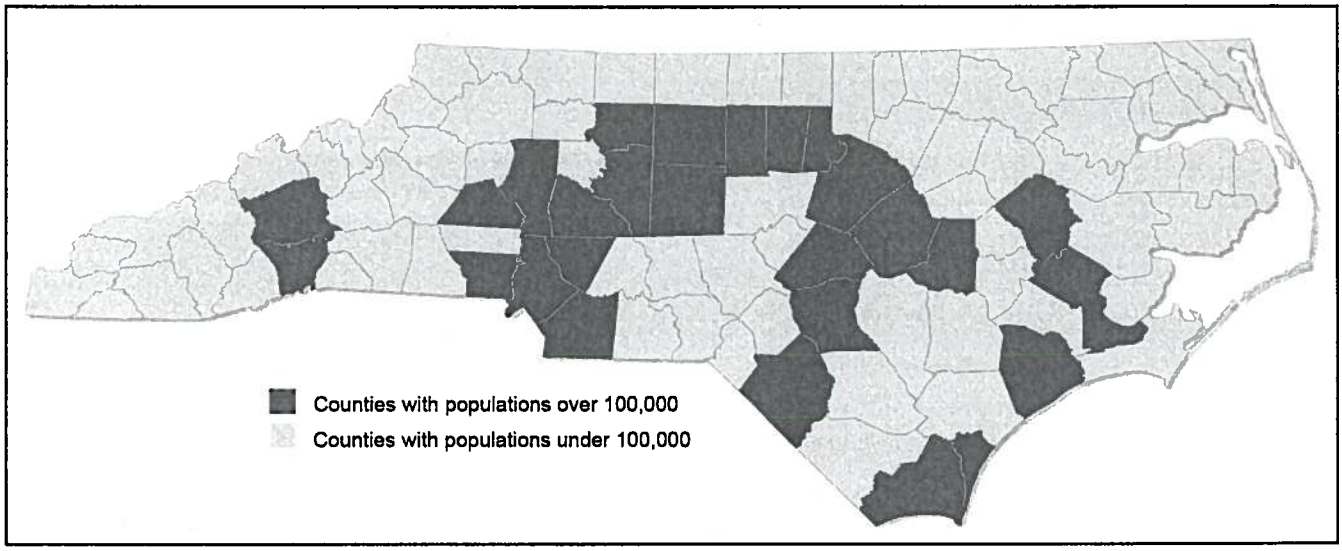
21 North Carolina Department Of Revenue: Table 35 B: Sales And Use Tax Refunds Issued To Nonprofit Entity Claimants: Annual Refunds Of $100,001 Or More By Type Of Claimant By Fiscal Year. dor.state.nc.us/publications/abstract/2013/table_35b.pdf

22 Brittany La Couture, "Ambulatory Surgical Centers and Medicare" American Action Forum. Aug. 5, 2014. americanactionforum.org/insights/ambulatory-surgical-centers-and-medicare

23 Daniel R. Levinson, Inspector General for the Department of Health and Human Services, "Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates For Ambulatory Surgical Center-Approved Procedures To Ambulatory Surgical Center Payment Rates. oig.hhs.gov/oas/reports/region5/51200020.pdf

24 Carolinas HealthCare System Powerpoint: "Impact of CON Regulations On Health Care Costs." Slide 11 data derived from the Division of Health Services Regulation. 2014.

25 Some of the list prices do not include the reimbursed charges for anesthesia, drugs, medical supplies, or other professional fees for some procedures. Prices may also vary depending on location, case complexity, and patient health status. Blue Cross and Blue Shield of North Carolina: Estimate Your Health Care Costs. bcbsnc.com/content/providersearch/treatments/index.htm#/



No doubt, outpatient surgery is big business for hospitals. Novant Health's surgery center operates on a 26 percent profit margin. Rex Healthcare, a subsidiary of UNC, projects an impressive 40 percent profit margin for its developing surgery center.[26] According to Guy David, Associate Professor of Healthcare Management at the University of Pennsylvania's Wharton School of Business, ambulatory care currently accounts for roughly 60 percent of hospital revenue, up from just 10-15 percent in the 1990s.[27]

Under HB 200, any new ASC, whether provider-led or under hospital ownership, would be required to provide 7 percent charity care. In other words, ASCs need to demonstrate that the combined value of surgery cases provided to charity care patients plus Medicaid patients is equivalent to at least 7 percent of patient revenue. (The value of these cases is based on what Medicare would reimburse.) Aside from three physician-led single-specialty ASCs having to comply by the 7 percent rule as part of a demonstration project that began in 2010,[28] there is currently not a uniform formula for licensed hospitals in North Carolina to comply with in order to maintain their sales tax, property tax, and income tax-exempt, nonprofit status.[29]

The bill also prohibits construction in counties with populations of fewer than 100,000 people unless the project is approved as a joint venture with a neighboring health system. Rural hospital advocates argue that this concession is necessary to protect suffering community hospitals, but what it ultimately means is that patients in 73 of the 100 counties in the state are unlikely to enjoy better access to more affordable health care.[30]

Rural Health Care

Proponents of CON argue that it helps preserve health care infrastructure, especially in rural areas. They contend, for example, that repealing the law could lead to a greater concentration of ambulatory surgery centers (ASCs) in more urbanized areas, which would attract more rural patients and put community hospitals at risk.

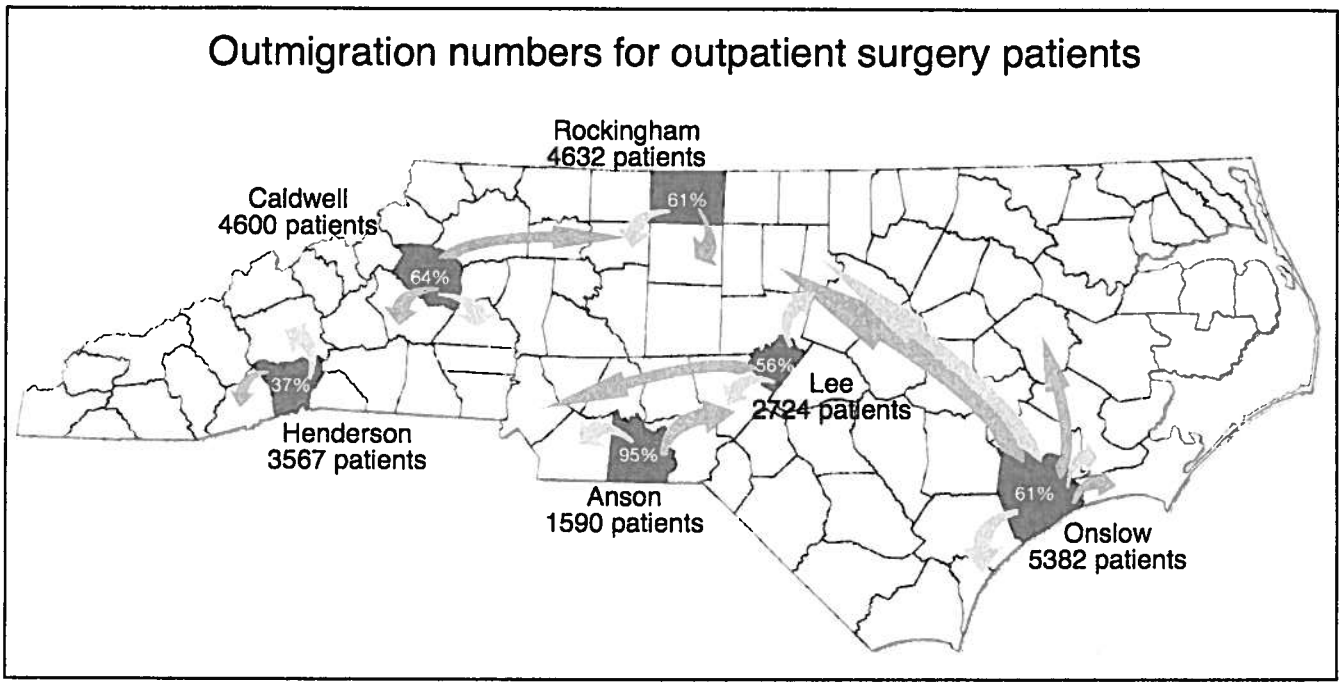
26 Jason deBruyn, "Changing Face of Surgeries" Triangle Business Journal. Aug. 8, 2014. bizjournals.com/triangle/print-edition/2014/08/08/changing-face-of-surgeries.html?page=all

27 Beth Kutscher, "Outpatient care takes the inside track: Ambulatory services continue to account for a growing share of systems' revenue, as they work to bring care closer to the customer." Modern Healthcare. August 4, 2012. modernhealthcare.com/article/20120804/MAGAZINE/308049929

28 Department of Health and Human Services. 2015 State Medical Facilities Plan. p 97. Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project ncdhhs.gov/dhsr/ncsmfp/2015/2015smfp.pdf

29 David J French, MBA, MHA, Strategic Healthcare Consultants, material presented to the North Carolina General Assembly Committee on Market Based Solutions and Elimination of Anti-Competitive Practices in Health Care. Feb. 18, 2014. ncleg.net/documentsites/committees/BCCI-6610/February%2018,%202014/PowerPoint%20Charity%20Care%20and%20ASC%20CON%20Limitation%202_17_14.pdf

30 Office of State Budget and Management 2014 Provisional County Population Estimates – Ranked by Size. osbm.state.nc.us/ncosbm/facts_and_figures/socioeconomic_data/population_estimates/demog/countygrowth_bysize_2014.html



But to the extent that market forces can operate under CON, patients are already migrating to access ambulatory surgical care outside of their counties of residence. While CON is supposed to effectively allocate health care resources across different geographic areas within North Carolina, the graph above illustrates a different story.

The six highlighted counties represent mostly rural areas of the state and do not have any existing free standing ASCs.[31]

Anson County, with a population of roughly 26,000, may not have sufficient volume to support a free standing ASC, but it does have a high outpatient migration rate of 95 percent.[32] A majority of these patients are forgoing care at Anson County Hospital and are instead seeking outpatient surgery treatment at the Carolinas Medical Center's hospital outpatient department. Others are traveling to free standing ASCs such as the Eye Surgery Center of the Carolinas in Moore County.

Meanwhile, Onslow County's population size of 194,000 holds promise for a viable ambulatory surgery center that could help offset its 61 percent patient migration rate to six different counties. Patients are traveling from 40 miles to either the Surgery Center of Morehead City or Carteret General Hospital in New Hanover County up to 140 miles to the University of North Carolina Medical Center in Orange County.

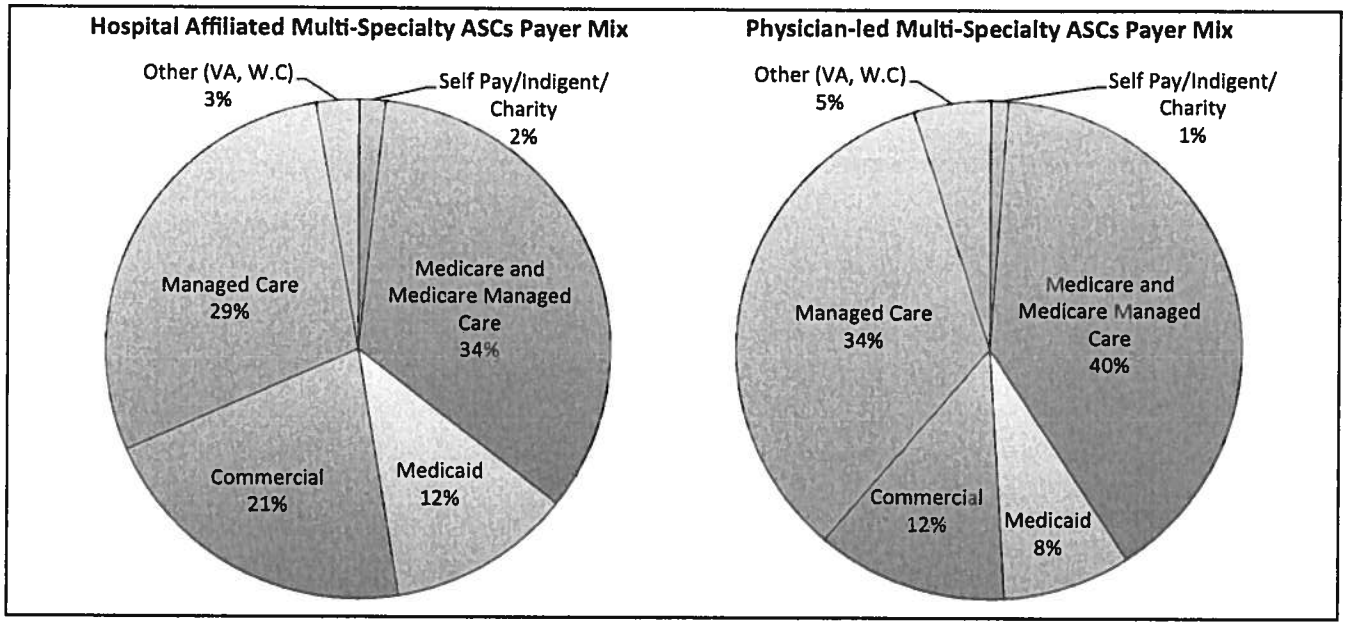
If the market itself determines a demand for more ASCs, not only will this enhance patient access, but it will also enable patients to enjoy lower health care costs. Let's not forget what's best for the patient.

Rural health care infrastructure is fragile, but evidence suggests that CON is not stabilizing medical access in these areas. Other factors have led to the decline of rural health care, such as demographic pressures placed on these programs in regions that have higher percentages of elderly and uninsured.[33]

31 The data on the above outpatient surgery patient migration patterns was collected from 2014 hospital and ASC license renewal applications. These applications must be submitted annually to the Division of Health Service Regulation, an arm of the state's Department of Health and Human Services. With this data, the Division documents a statewide inventory of the varying types of health care entities, assets, equipment, and services offered. As previously mentioned, this inventory is used to calculate what health care resources are "needed" and is published in the annual state medical facilities plan. It should be noted that the number of outpatient surgery cases is self-reported.

32 Dan Way, "Politics Battles Principles in CON Debate: Hospitals don't want competition, and conservative lawmakers hear about it" Carolina Journal Online. May 28, 2015. carolinajournal.com/articles/display_story.html?id=12085

33 Melanie Evans, "Hospitals face closures as 'a new day in health care' dawns," Modern Healthcare. Feb. 21, 2015. modernhealthcare.com/article/20150221/MAGAZINE/302219988\ and Nathan T. Washburn and Karen



Reforming or repealing Certificate of Need will *not* compromise patient access to care. If we look at the existing multi-specialty ASCs, payer mix is comparable. Ten ASCs are wholly under physician ownership, while 17 are hospital affiliated.[34]

Conclusion

What the healthcare industry needs is a strong dose of disruptive innovation[35] — relaxing regulations that will increase provider competition, force downward pressure on costs, and enhance patient choice. CON ultimately picks who gets to compete within the health care sector. Reforming the law will by no means untangle the complexities of health care, but state lawmakers should capitalize on an opportunity to make one of the most highly regulated industries a little less heavy on the red tape and a little more patient friendly.

A. Brown, "The Decline of the Rural American Hospital and How to Reverse it." Harvard Business Review. Jan. 30, 2015.

34 The charts below illustrate average payer percentages based on data from 2014 license renewal applications submitted to the Division of Health Service Regulation.

35 Clayton M. Christensen, Richard M.J. Bohmer, John Kenagy, "Will Disruptive Innovations Cure Health Care?" Harvard Business Review. Sept-Oct 2000 Issue. hbr.org/2000/09/will-disruptive-innovations-cure-health-care