Permission to Care: An Analysis of Certificate-of-Need Application Data in Seven States

Thomas Kimbrell and Kevin Schmidt, Americans for Prosperity Foundation

Abstract

Certificate of need (CON) laws require health care providers to obtain approval from the state before adding or expanding facilities, services, or equipment. Fifty years ago, lawmakers believed they could contain rising health care spending by preventing providers from offering redundant services in the same proximate area. A growing body of research finds that CON laws fail to reduce spending, improve access, or ensure quality in the health care industry; however, CON laws persist in many states. "Permission to Care" is a first-of-its-kind analysis of publicly available CON application data in seven states: Georgia, Iowa, Michigan, North Carolina, South Carolina, Virginia, and West Virginia. In sum, we find states denied billions in proposed health care provisions. For example, North Carolina denied $1.5 billion from January 2012–June 2022, Michigan denied $585 million from January 2018–February 2021, and Iowa denied $250 million from July 2016–February 2020. We also find evidence of the "competitor's veto." For example, although West Virginia has a low CON application denial rate, dozens of applications totaling $44 million in proposed capital expenditures were withdrawn over three years after competing providers filed opposition. Similarly, while only two percent of proposed capital expenditures were denied in South Carolina over three years, a quarter, valued at roughly $400 million, were withdrawn or appealed. We discuss our findings in the context of other empirical research and qualitative evidence to further illustrate the impact of CON on health care in each state.

Author Affiliation and Contact Information
Thomas Kimbrell
Research Analyst, Americans for Prosperity Foundation
tkimbrell@afphq.org

Kevin Schmidt
Director of Investigations, Americans for Prosperity Foundation
kschmidt@afphq.org

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Thomas Kimbrell and Kevin Schmidt

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(working paper)

1. Introduction

In this study, we attempt to measure the direct impact of certificate of need (CON) laws on health care investment in seven states: Georgia, Iowa, Michigan, North Carolina, South Carolina, Virginia, and West Virginia. CON laws require health care providers to obtain approval from the state before acquiring, replacing, or adding regulated facilities, services, or equipment. The specific facilities, services, and equipment regulated under CON vary from state to state, though considerable overlap exists. Table A1 shows the health care provisions regulated under CON in each state.[1]

Nearly 50 years ago, Congress passed the National Health Planning and Resources Development Act of 1974, which included a mandate that the states pass CON laws to receive certain federal health care funds.[2] Within a few years, nearly every state passed a CON law. At the time the bill was passed, health care costs were rising, and residents of many rural areas lacked access to care. Under the law, states were required to establish regulatory structures to plan their health care resources centrally. These state health system agencies were charged with identifying the state's health care needs and promoting the development of provisions in order to reduce costs and increase access to and quality of care.[3]

Naturally, the states we examine parrot Congress's purpose for their CON programs. Table 1 depicts each state's statement of purpose for their respective CON programs. All seven states

[1] Matthew D. Mitchell *et al.*, Mercatus Ctr., *The State of Certificate-of-Need Laws in 2020* (2020), *available at* https://www.mercatus.org/publication/con-laws-2020-about-update.
[2] National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (formerly codified at 42 U.S.C. §§ 300k–300n-5), *repealed by* Pub. L. No. 99-660, § 701, 100 Stat. 3743, 3799 (1986).
[3] *Id.*

assert that CON is intended to contain or control costs. Most include, either directly or indirectly, access and quality as considerations as well.

Table 1: Statement of Purpose for CON in Seven States

State	CON Purpose Statement
Georgia	The Certificate of Need (CON) program is intended to achieve three goals: (1) to measure and define need, (2) to control costs, and (3) to guarantee access to healthcare services.[4]
Iowa	It is the [State Health Facility C]ouncil's mandate to assure that growth and changes in the health care system occur in an orderly, cost-effective manner, and that the system is adequate and efficient.[5]
Michigan	Certificate of Need (CON) is a state regulatory program intended to balance the cost, quality, and access of Michigan's health care system. This is to ensure that needed services and facilities afford quality health care for the residents of the state.[6]
North Carolina	The fundamental premise of the CON law is that increasing health care costs may be controlled by governmental restrictions on the unnecessary duplication of medical facilities.[7]
South Carolina	The purpose of the Act is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public need and ensure high quality services are provided in health facilities in this State.[8]
Virginia	The program seeks to contain health care costs while ensuring financial viability and access to health care for all Virginia at a reasonable cost.[9]
West Virginia	The Health Care Authority's goals are to control health care costs, improve the quality and efficiency of the health care system, encourage collaboration and develop a system of health care delivery which makes health services available to all residents of the State. The Certificate of Need program is a regulatory element used to achieve these goals.[10]

[4] *Certificate of Need (CON)*, GA. DEP'T OF CMTY. HEALTH, https://dch.georgia.gov/divisionsoffices/office-health-planning/certificate-need-con (last visited Apr. 25, 2023).
[5] *Certificate of Need*, IOWA DEP'T OF HEALTH & HUMAN SERVS., https://hhs.iowa.gov/policy-and-workforce-services/cert-of-need (last visited Apr. 25, 2023).
[6] *Certificate of Need Commission*, GOV. GRETCHEN WHITMER, https://www.michigan.gov/whitmer/appointments/oma/all/1/certificate-of-need-commission (last visited Apr. 25, 2023).
[7] *Certificate of Need*, HEALTHCARE PLANNING & CERTIFICATE OF NEED SECTION, N.C. DIV. OF HEALTH SERV. REGULATION, https://info.ncdhhs.gov/dhsr/coneed/index.html (last visited Apr. 25, 2023).
[8] *Certificate of Need (CON)*, S.C. DEP'T OF HEALTH & HUMAN SERVS., https://scdhec.gov/healthcare-quality/certificate-need-con (last visited Apr. 25, 2023).
[9] *Certificate of Public Need Program*, VA. DEP'T OF HEALTH, https://www.vdh.virginia.gov/licensure-and-certification/the-certificate-of-public-need-program/ (last visited Apr. 25, 2023).
[10] *Certificate of Need*, W. VA. HEALTH CARE AUTH., https://hca.wv.gov/certificateofneed/Pages/default.aspx (last visited Apr. 25, 2023).

In practice, CON laws act as a barrier to entry to health care markets that artificially restricts the supply of health care provisions.[11] Indeed, the "unnecessary duplication of health resources" is an explicit goal of the National Health Planning and Resources Development Act.[12] Legislators believed that restricting the supply of health care would help contain costs and facilitate the efficient distribution of resources to expand access to care. However, a growing body of research indicates that CON laws have failed to achieve their stated goals and appear to be counterproductive.[13]

Numerous studies find that CON laws are associated with higher costs and higher spending.[14] Research also finds that health care spending decreases in the years following CON repeal.[15] Another study shows states with CON laws have fewer hospitals and ambulatory surgical centers per capita, even in rural areas, than states without CON, indicating that CON reduces access to care.[16] Further still, research has not established that states with CON laws have higher quality care than states without CON. At least one study suggests that CON is associated with lower-quality care.[17]

In 1986, Congress repealed the CON mandate after reforming how states were reimbursed for health care expenditures. Since then, 15 states have rescinded their CON laws; however, CON persists in 35 states and the District of Columbia. In recent years, several states have adopted

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[11] DEP'T OF HEALTH & HUMAN SERVS. ET AL., REFORMING AMERICA'S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION at 50 (2018), *available at* https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.

[12] National Health Planning and Resources Development Act § 1513, 88 Stat. at 2236.

[13] *See, e.g.*, Matthew D. Mitchell, *Certificate-of-Need Laws: How They Affect Healthcare Access, Quality, and Cost: What years of study reveals about the effectiveness of CON programs*, MERCATUS CTR. (May 21, 2021), https://www.mercatus.org/economic-insights/features/certificate-need-laws-how-they-affect-healthcare-access-quality-and-cost#2392643287-14222115 (last visited Apr. 27, 2023).

[14] *E.g.*, Matthew D. Mitchell, *Do Certificate-of-Need Laws Limit Spending?*, Mercatus Ctr. (Sept. 2016), *available at* https://www.mercatus.org/system/files/mercatus-mitchell-con-healthcare-spending-v1a.pdf.

[15] James Bailey, *Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws* (Mercatus Ctr., Working Paper, 2016), *available at* https://www.mercatus.org/research/working-papers/can-health-spending-be-reined-through-supply-constraints-evaluation.

[16] Thomas Stratmann & Christopher Koopman, *Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals* (Mercatus Ctr.,Working Paper, 2016) *available at* https://www.mercatus.org/research/working-papers/entry-regulation-and-rural-health-care-certificate-need-laws-ambulatory; *see* Thomas Stratmann & Matthew C. Baker, *Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans*, (Mercatus Ctr., Working Paper, 2016) *available at* https://www.mercatus.org/research/working-papers/are-certificate-need-laws-barriers-entry-how-they-affect-access-mri-ct-and.

[17] Thomas Stratmann & David Wille, Certificate-of-Need Laws and Hospital Quality (Mercatus Ctr., Working Paper, 2016) *available at* https://www.mercatus.org/system/files/mercatus-stratmann-wille-con-hospital-quality-v1.pdf.

piecemeal reforms to ease CON's regulatory burdens. For example, Tennessee exempted several services from CON in a reform bill signed in 2021,[18] Montana reformed its CON law in 2021 to regulate only long-term care facilities,[19] Florida eliminated CON requirements for numerous services in 2019,[20] and New Hampshire legislation from 2012 phased out the state's CON program in 2016.[21]

In states with CON, the state health agency or a CON board typically determines the state's need for health care. Health care providers must apply to these regulatory bodies and obtain a certificate of need to offer or expand services, establish new facilities, or deploy medical equipment. Most states allow competing health care providers to intervene in the process and object to others' applications. Furthermore, many CON states provide for judicial review of CON decisions. "Affected parties" can administratively challenge CON decisions and litigate them in court. These systems create a "competitor's veto" that acts as an additional barrier to entry on top of the approval process.[22]

In this study, we measure the direct impact of CON laws on health care investment in seven states. To our knowledge, this type of analysis has not been conducted previously.[23] We do so by collecting and analyzing publicly available CON application data. In sum, we find states denied billions in proposed health care provisions. We also find evidence of the "competitor's veto." For example, although relatively few CON applications in West Virginia were denied over three years, twice as many applications, totaling $44 million in proposed capital expenditures, were withdrawn after competing providers filed opposition. Similarly, while only two percent of proposed capital expenditures were denied in South Carolina over three years, 25 percent, roughly $400 million, were withdrawn or appealed.

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[18] Tennessee Health Services and Planning Act of 2021, Tenn. Pub. Ch. No. 557, HB 948/SB1281, *available at* https://publications.tnsosfiles.com/acts/112/pub/pc0557.pdf.
[19] Mont. HB 231 (2021), *available at* https://leg.mt.gov/bills/2021/billpdf/HB0231.pdf.
[20] Fla. CS/HB 21 (2019), *available at* https://www.flsenate.gov/Committees/billsummaries/2019/html/2068.
[21] N.W. Ch. 264, HB 1553 (2012), *available at* https://legiscan.com/NH/text/HB1553/id/657133/New_Hampshire-2012-HB1553-Chaptered.html.
[22] ANASTASIA BODEN & ANGELA C. ERIKSON, PAC. LEGAL FOUND., COMPETITOR'S VETO: A ROADBLOCK TO NEW BUSINESS (2021), *available at* https://pacificlegal.org/wp-content/uploads/2021/01/con-law-report.pdf.
[23] The authors have previously published some of the findings and content of this paper in a series of reports. *See generally Permission to Care*, AMS. FOR PROSPERITY, https://americansforprosperity.org/permission-to-care/ (last visited Apr. 27, 2023). Other recent studies have also analyzed CON application data. *E.g.*, CHRISTOPHER DENSON & MATTHEW MITCHELL, GA. PUB. POLICY FOUND., ECONOMIC REPORT ON GEORGIA'S CERTIFICATE OF NEED PROGRAM (Apr. 2023), *available at* https://georgiapolicy.org/wp-content/uploads/2023/04/CON-report.pdf; RON SHULTIS ET AL., BEACON CTR. OF TENN., OLD REGULATIONS, BUREAUCRACY, AND PROTECTIONISM: HOW GOVERNMENT REDUCES ACCESS TO HEALTHCARE THROUGH CERTIFICATE-OF-NEED LAWS (2022), *available at* http://www.beacontn.org/wp-content/uploads/2023/01/CON-Report-Final.pdf.

The actual cost of CON laws is much greater than the sum of proposed expenditures reflected in denied CON applications. CON laws appear to increase the time it takes health care providers to develop and deploy new provisions.[24] There are also unseen costs: a latent supply of health care which CON precludes. That is, health care services providers would otherwise offer, but for which they never apply for a CON.

2. Data

To conduct our study, we collect publicly available CON application data in seven states: Georgia, Iowa, Michigan, North Carolina, South Carolina, Virginia, and West Virginia. The CON application data is collected manually and programmatically from each state's respective CON websites.[25] Due to varying availability and accessibility of data across states, the time periods included in each state sample differ. Table 3 depicts the date ranges for the data included in each state.

We construct separate databases for each state in the study. For some states, like West Virginia, we include whether the application received opposition from affected parties. And for other states, like Georgia, North Carolina, and South Carolina, we include whether the decision to approve or deny the CON application was appealed.[26]

Table 3 reports our findings. "N" is the number of CON applications, and "Proposed Investment" is the sum of the estimated cost reported on CON applications. The date range of the data reflects the earliest and latest date in the sample that a decision to approve or deny a CON application was issued.

In sum, we find states denied billions in proposed health care provisions: North Carolina denied $1.5 billion from January 2012–June 2022, Georgia denied $700 million from February 2010–November 2022, Michigan denied $585 million from January 2018–February 2021, and Iowa denied $250 million from July 2016–February 2020. The rate of applications denied ranges from 3 percent

[24] DENSON & MITCHELL, *supra* note 23.
[25] *See supra* notes 4–10; *see also Certificate of Need*, Mich. Dep't of Health & Human Servs., https://www.michigan.gov/mdhhs/doing-business/providers/certificateofneed (last visited Apr. 25, 2023).. .
[26] We collect additional data that is beyond the scope of this paper. For example, Mercatus's "CON Laws in 2020" includes a taxonomy of services regulated under CON in each state. *See* Mitchell *et al.*, *supra* note 1. For some states, Mercatus's taxonomy was used to categorize each application by service. For states where application data included the location of the proposed project, we incorporated the Federal Office of Rural Health Policy's eligible zip codes data to classify the project as rural or non-rural. *See Federal Office of Rural Health Policy (FORHP) Data Files*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/rural-health/about-us/what-is-rural/data-files (last visited Apr. 27, 2023).

to 14 percent, and the amount of proposed investment denied ranges from one-tenth of a percent to 45 percent. Except for proposed investment in Iowa, denial rates are low relative to approvals.

However, the amount of proposed investment denied or withdrawn does not represent the total amount of health care investment forgone under CON regimes. There is a latent supply of health care that does not appear in CON applications. We expect several factors, including restrictive need calculations, threat of competitor opposition, and high costs, have a chilling effect on CON applications, which we explore in the next section.

Table 2: CON Application Decisions

State	Approved		Denied		Withdrawn		
	N	Proposed Investment	N	Proposed Investment	N	Proposed Investment	Decision Date Range
Georgia	596 (79%)	$12,748,093,597 (93%)	92 (12%)	$690,009,391 (5%)	71 (9%)	$298,560,761 (2%)	Sep 10, 2010– Dec 9, 2022
Iowa	66 (6%)	275,908,560 (%52)	4 (6%)	$237,100,000 (45%)	-	-	July 2016– Feb 2020
Michigan	423* (91%)	$4,842,704,435* (88%)	31 (5%)	585,029,607 (10%)	25 (4%)	$127,857,114 (2%)	Jan 5, 2018– Feb 27, 2021
North Carolina	1,435 (86%)	$7,611,820,158 (84%)	229 (14%)	$1,476,515,050 (16%)	2 (0.1%)	$3,817,154 (0.04%)	Jan 10, 2012– June 30, 2022
South Carolina	279 (94%)	$1,635,187,719 (97%)	8 (3%)	$30,976,410 (2%)	9 (3%)	$22,918,623 (1%)	Feb 28, 2018– Feb 22, 2021
Virginia	236 (92%)	$1,893,570,432 (94%)	21 (8%)	$117,187,949 (6%)	-	-	Jan 2016– Dec 2021
West Virginia	181 (78%)	$1,034,104,623 (95%)	10 (4%)	$936,000 ($0.1%)	40 (17%)	$53,440,832 (5%)	Jan 17, 2017– Aug 16, 2021

*Includes conditional approvals.

3. The Competitor's Veto and CON's Unseen Costs

In many states, incumbent care providers intervene in the CON process to prevent competing providers from entering the market. In some states, they can do so at the beginning of the process by influencing how the state determines the need for additional health care provisions. In most CON states, except Michigan, competing providers can oppose others' CON applications during the application process. Finally, competing providers can challenge CON decisions administratively and in state courts. Taken together, these conditions arm incumbent care providers with a "competitor's veto."[27]

[27] BODEN & ERIKSON, *supra* note 22.

Undoubtedly, the amount of healthcare CON precludes in a state is greater than the sum of proposed health care investment reflected on CON applications denied or withdrawn during a given time. We expect there is a latent supply of health care for which providers have not applied to offer because of the high barriers to entry CON presents. The literature supports such a claim. Studies have found CON is associated with fewer hospitals and ambulatory surgical centers per capita as well as lower utilization of non-hospital providers of medical imaging services.[28] Patients in CON states also travel further and are more likely to cross state lines to obtain care.[29] In this section, we analyze qualitative and quantitative evidence of the effect of the competitor's veto and the unseen costs of CON.

3.1. Restrictive Need Calculations

CON states typically publish state health plans or other planning documents which set forth the unmet need for regulated health care facilities, services, and equipment. Health care providers know a CON application will almost certainly be denied if the state has not predetermined a need for the proposed project. In fact, Michigan requires applicants to certify that the state has determined a need for their proposed service before the state will even accept the application.

In Michigan, North Carolina, and South Carolina, industry insiders affiliated with incumbent care providers serve on the states' respective health care planning authorities, where they have significant sway over the state's need determinations. These committee members are incentivized to protect their affiliate providers from new competition through restrictive need determinations.

In North Carolina, the State Health Coordinating Council (NCSHCC) determines the state's need for health care facilities and services. Each year, the NCSHCC prepares the State Medical Facilities Plan, which includes the need determination methodologies for most facilities and services regulated under CON. Our analysis of Council members found that at least 15 of the 25 current members are employed or affiliated with health care providers regulated by the Council.[30]

To the south, incumbent providers hold four of the 14 seats on the South Carolina Health Planning Committee, which provides advice to the South Carolina Department of Health and

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[28] *See* Stratmann & Koopman, *supra* note 16; *see also* Stratmann & Baker, *supra* note 16.
[29] *See* Melissa D.A. Carlson *et al.*, *Geographic Access to Hospice in the United States*, 13(11) J. OF PALLIATIVE MED. 1331, 1331–1338 (Nov. 2010); *See also* Stratmann & Baker, *supra* note 16.
[30] Analysis of the North Carolina State Health Coordinating Council members' affiliations was conducted in November 2022.

Environmental Control on the state's health plan.[31] The South Carolina State Health Plan is the central planning document for services regulated under the CON program.

In the Great Lakes State, the Michigan Department of Health and Human Services ("MDHHS") and the Michigan Certificate of Need Commission administer the CON program. The Commission is an eleven-member board responsible for developing, approving, or revising the state's CON Review Standards. MDHHS uses the standards to issue CON decisions. At least eight of the Commission members are affiliated with incumbent care providers.[32]

Our review of these state planning documents finds evidence of their often arbitrary and restrictive nature. The following two case studies illustrate this point and provide a peek at the latent supply of health care CON precludes.

3.1.1. NICU Need in South Carolina

The South Carolina Health Planning Committee determined that the need for neonatal intensive care bassinets is less than the neonatal mortality rate. According to the South Carolina Department of Health and Environmental Control (SCDHEC), the neonatal mortality rate in South Carolina in 2019 was 4.5 deaths per 1,000 live births.[33] The 2020 South Carolina Health Plan calculates the need for neonatal intensive care at a rate of 3.25 bassinets per 1,000 live births.[34] The disparity is even more significant in minority communities. The infant mortality rate among non-white mothers is 7.5 deaths per 1,000 live births[35]—2.3 times greater than the SCDHEC need calculation. Additionally, 94.5 infants per 1,000 live births are admitted to neonatal intensive care units (NICU).[36] That means the actual NICU utilization rate is 30 times greater than the state-determined rate used to calculate the need for NICU beds.

More than 1,000 babies are born in the Palmetto State every week (the common denominator for the NICU need-determination and the neonatal mortality rate is 1,000 live births).[37]

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[31] Analysis of the South Carolina Health Planning Committee was conducted in November 2022.
[32] *See Certificate of Need Commission*, *supra* note 6.
[33] S.C. DEP'T OF HEALTH & ENVTL. CONTROL, INFANT MORTALITY & SELECTED BIRTH CHARACTERISTICS: 2019 SOUTH CAROLINA RESIDENCE DATA (Oct. 2020), *available at* https://scdhec.gov/sites/default/files/Library/CR-012142.pdf.
[34] S.C. DEP'T OF HEALTH & ENVTL. CONTROL, 2020 SOUTH CAROLINA HEALTH PLAN (Mar. 2020), *available at* https://scdhec.gov/sites/default/files/media/document/2020_South_Carolina_Health_Plan-June_12_2020_0.pdf.
[35] INFANT MORTALITY, *supra* note 33.
[36] Braley Dodson, *Why have South Carolina's NICU rates doubled?*, WBTW NEWS13 (March 7, 2022), https://www.wbtw.com/news/pee-dee/marlboro-county/why-have-south-carolinas-nicu-rates-doubled/.
[37] INFANT MORTALITY, *supra* note 33.

Approximately 95 of those babies born each week will need intensive care. According to the March of Dimes, the average stay for infants admitted to special care nurseries is 13.2 days.[38] According to the 2020 South Carolina Health Plan, there were 147 total intensive care bassinets in the state.[39] With 190 infants admitted to NICU every two weeks, who stay for an average of two weeks, it is easy to see how the state need-determinations artificially limit hospitals' NICU capacity.

SCDHEC plans perinatal care at the regional level. Only certain hospitals in each of the five perinatal care regions can add intensive care bassinets. Our analysis finds that NICU utilization for perinatal care in Regions I, II, and III were 120%, 95%, and 99%, respectively. However, in the South Carolina Health Plan, the Health Planning Committee includes intermediate care bassinets, which are not regulated under CON, to calculate neonatal care utilization rates for the respective perinatal care regions. Doing so obscures the actual intensive care utilization rates, making the need appear less dire. For instance, by including unregulated intermediate care bassinets, SCDHEC reports the utilization of neonatal special care units in Region I as 65 percent, even though the actual intensive bassinets utilization is 120 percent.[40]

3.1.2. Nursing Home Need in Michigan

In Michigan, a so-called "error" in the state-determined methodology for calculating the need for nursing home beds generated CON application data that provides us with a glimpse at the latent supply of health care CON precludes. In late 2019, the Michigan Department of Health and Human Services (MDHHS) projected a need for nearly 3,000 additional nursing home beds.[41] Our analysis of the CON application data finds health care providers submitted dozens of CON applications in December 2019 and January 2020 to build new nursing homes or add beds to existing nursing homes. In sum, we find MDHHS received CON applications to add at least 3,299 nursing home beds, estimated at over $630 million in new investment. However, at the urging of incumbent providers, the Michigan CON Commission—which is partly comprised of incumbent providers—reduced the projected need for beds tenfold.[42] According to our analysis, three-fourths of the applications were subsequently denied or withdrawn. We find MDHHS approved just 376

[38] MARCH OF DIMES & NAT'L PERINATAL INFO. CTR., SPECIAL CARE NURSERY ADMISSIONS (2011).
[39] SOUTH CAROLINA HEALTH PLAN, *supra* note 34.
[40] SOUTH CAROLINA HEALTH PLAN, *supra* note 34 at 35.
[41] *See* Mark Sanchez, *Rule change brings flood of nursing home proposals*, MIBIZ (Mar. 15, 2020), *available at* https://mibiz.com/sections/health-care/rule-change-brings-flood-of-nursing-home-proposals.
[42] *Id.*

new nursing home beds, 11 percent of the total applied for. This disparity suggests that CON artificially restricts the supply of nursing beds below equilibrium in Michigan.

3.2. Competitor's Veto Adds Costs and Delays

In all the states in our sample, except Michigan, competing health care providers, often called "affected parties," can oppose others' CON applications. Competitor opposition can significantly lengthen the approval process. Depending on the state, affected parties can file opposition comments or request a hearing. Figure A1 depicts the South Carolina CON application and appeal process, which is typical of the states in our sample.

A recent analysis of Georgia CON applications conducted by the Georgia Public Policy Foundation and Matthew Mitchell, Senior Research Fellow at the Knee Center for the Study of Occupational Regulation at West Virginia University, found that competitor opposition increased the time to decision by 520 days, and that each additional party opposed adds another 129 days.[43] The study also found that competitor opposition increased the chances an application is denied to 50 percent, and that "each additional party opposed . . . increases the odds of denial by about 11 percent."[44]

Like most states with CON, the states in our sample also allow affected parties to appeal CON application decisions in administrative bodies and state courts. Litigation of CON decisions can further draw out the CON process to extraordinary lengths of time. In two recently resolved cases in South Carolina, legal challenges to CON decisions delayed the openings of two much-needed hospitals by over a decade.[45] At the time of our analysis, two approved certificates of need for NICU bassinets in South Carolina are being appealed. Two competing providers each applied to add six intensive care bassinets. SCDHEC approved both applications in 2021; however, both facilities filed legal challenges opposing SCDHEC's decision to approve the other's application.

In 2018, the West Virginia University Cancer Institute announced its intent to launch "LUCAS," a mobile lung cancer screening program for the "42 West Virginia counties that do not

[43] DENSON & MITCHELL, *supra* note 24 at 14.
[44] *Id.* at 13.
[45] *See* Eric Boehm, *It Took More Than 15 Years for a South Carolina Hospital To Get Permission To Be Built*, REASON (Oct. 8, 2021), https://reason.com/2021/10/08/it-took-more-than-15-years-for-a-south-carolina-hospital-to-get-permission-to-be-built/.

currently have access to a Medicare-certified lung cancer screening provider."[46] LUCAS offers charity care to patients who cannot afford to pay for screening.[47] The HCA granted a CON for the project in 2019 over two competitors' objections. One competitor then appealed the decision. Ultimately, the Circuit Court of Kanawha County affirmed the CON in March 2022,[48] but not before the CON process delayed the project's launch for years.

In North Carolina, the 2018 State Medical Facilities Plan identified a need for one mobile PET scanner.[49] Four providers applied for the CON. Mobile PET Scanner providers in North Carolina must secure letters of support from incumbent providers that agree to act as host sites.[50] After the North Carolina Department of Health and Human Services (NCDHHS) awarded one applicant the CON, another appealed. Court records show one of the "losing" applicants approached providers who agreed to support the "winning" applicant and pressured them to rescind their support.[51] Ultimately, the Court of Appeals of North Carolina affirmed NCDHHS' decision in July 2021;[52] however, deployment of the mobile PET scanner was delayed for more than two years.

These examples are not exceptional. Our analysis of Georgia CON data finds rival providers are currently contesting a dozen CON approvals, delaying approximately $269 million in already-approved health care investment. Another $43 million in denied CON applications is also being appealed. Similarly, in North Carolina, we find competing providers appealing approximately $423 million in approved CON applications. In South Carolina, CON applications for roughly $400 million, 23 percent of the total proposed investment in the sample, were withdrawn or appealed.

Competitor opposition during the CON application process and post-decision litigation greatly increases the costs of obtaining a CON. Costs can balloon in the hundreds of thousands of dollars.[53] We expect these costs have a chilling effect on CON applications and deter providers from

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[46] *Mobile lung cancer screening program to assist in early detection*, W.VA. UNIV. (Jul. 18, 2018), https://medicine.wvu.edu/News/Story?headline=mobile-lung-cancer-screening-program-to-assist-in-early-detection.
[47] *LUCAS*, W.VA. UNIV. CANCER INST., https://cancer.wvumedicine.org/about-us/programs/mobile-cancer-screening-program/lucas/ (last visited Apr. 25, 2023).
[48] Final Order, *Charleston Area Med. Ctr. v. W. Va. Health Care Auth.*, No. 19-AA-166 (Cir. Ct. Kanawha Cty. Mar. 15, 2022), available at https://bit.ly/3OxGKGQ.
[49] N.C. DEP'T OF HEALTH & HUMAN SERVS., 2018 STATE MEDICAL FACILITIES PLAN (Jan. 2018), *available at* https://info.ncdhhs.gov/dhsr/ncsmfp/2018/2018smfp.pdf.
[50] 10A N.C. ADMIN. CODE 14C.3701.(5) (2019).
[51] *Mobile Imaging Partners of N.C. v. N.C. Dep't of Health & Human Servs.*, 862 S.E.2d 217 (N.C. Ct. App. 2021).
[52] *Id.*
[53] *See*, *e.g.*, Regina Conley, *Certificate of Need: The Cost of the Process*, CIVITAS INST. (Sept. 16, 2011), https://www.nccivitas.org/2011/certificate-of-need-the-cost-of-the-process/; *see also North Carolina CONs Patients:*

pursuing a CON to offer services they otherwise would. In 2006, for example, a hospital in West Virginia agreed to a consent decree with the Antitrust Division of the U.S. Department of Justice after threatening to oppose a competing hospital's CON application to dissuade them from expanding services.[54] The judgment enjoined the offending provider from engaging in further anticompetitive behavior. The previous year, a similar case also resolved with two other West Virginia hospitals entering into a consent decree with the Antitrust Division, preventing them from prohibiting or restricting other providers from obtaining a CON.[55]

We find evidence of this deterring effect in the West Virginia CON application data, where four times as many applications have been withdrawn as denied.[56] From 2017–2020, applicants withdrew at least 20 CON applications totaling $43.7 million in proposed capital expenditures after rival providers filed opposition.

4. Conclusion

CON acts as a regulatory barrier to entry to health care markets. Originally intended to contain costs of and ensure access to health care, research indicates CON fails to achieve these goals. Here, we analyzed CON application data to measure the impact of CON on health care investment in seven states. The states in our sample denied few CON applications relative to those approved, though the absolute value of the proposed investment denied is not insignificant. On top of that, CON precludes more health care investment than just the provisions on denied CON applications. CON leaves latent an unknown supply of health care. Industry gatekeeping, threat of competitor opposition, and high costs conspire to deter providers from applying for a CON or completing the application process. This effect can be large. In the case of nursing home beds in Michigan, the data show a latent marginal supply at least ten times larger than the CON-restricted marginal supply. In West Virginia, the proposed investment withdrawn after competitors filed opposition is more than 43 times larger than the proposed investment denied.

Our study raises new questions and avenues for further research. For example, a qualitative study could shed light about the impact of the competitor's veto and fear of litigation costs by

Outdated Law Prevents Doctor From Providing Transparently Priced, Low-Cost MRI Scans, INST. FOR JUSTICE, https://ij.org/case/north-carolina-con/ (last visited Apr. 27, 2023).

[54] *United States v. Charleston Area Med. Ctr., Inc.*, No. 2:06-0091 (S.D. W.Va. 2006).

[55] *United States v. Bluefield Reg'l Med. Ctr., Inc.*, No. 1:05-0234 (S.D. W.Va. 2005).

[56] Some CON applications in the West Virginia sample were withdrawn reason unrelated to competitor opposition, *e.g.*, errors in paperwork.

interviewing health care providers, current or former executives, and current or former agency staff about the CON process in their state. On the quantitative side, our research approach could be replicated in the over twenty states with CON laws we did not include in our sample. Finally, there is a gap in understanding how states decide to calculate need determinations.

Appendix

Table A1. Services Regulated Under CON

Regulated Services	GA	IA	MI	NC	SC	VA	WV
Ambulatory Surgical Centers	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Assisted Living & Residential Care Facilities	No	No	No	Yes	No	No	No
Burn Care	No	No	No	Yes	No	No	No
Cardiac Catheterization	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Computed Tomography (CT) Scanners	Yes	Yes	Yes	Yes	No	Yes	Yes
Gamma Knives	Yes	Yes	No	Yes	Yes	Yes	No
Home Health	Yes	No	No	Yes	Yes	No	Yes
Hospice	No	No	No	Yes	Yes	Yes	Yes
Hospital Beds (Acute, General, Med-Surg, etc.)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hypodermic Syringes and Needles	No	No	No	No	No	No	No
Intermediate Care Facilities (ICFs) for Individuals with Intellectual Disabilities	Yes	Yes	No	Yes	Yes	Yes	Yes
Linear Accelerator Radiology	Yes	No	Yes	Yes	Yes	No	Yes
Lithotripsy	Yes	No	Yes	Yes	No	Yes	No
Long-Term Acute Care (LTAC)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Magnetic Resonance Imaging (MRI) Scanners	Yes	Yes	Yes	Yes	No	Yes	Yes
Magnetic source imaging (MSI) scanners	No	No	No	No	No	No	No
Medical office buildings	No	No	No	No	No	No	No

Regulated Services	GA	IA	MI	NC	SC	VA	WV
Mobile Hi Technology (CT/MRI/PET, etc.)	Yes	Yes	Yes	Yes	No	Yes	Yes
Neonatal Intensive Care	Yes	No	Yes	Yes	Yes	Yes	Yes
New Hospitals or Hospital-Sized Investments	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nursing Home Beds/Long-Term Care Beds	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Obstetrics Services	Yes	Yes	No	No	Yes	Yes	Yes
Open-Heart Surgery	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Organ Transplants	No	Yes	Yes	Yes	No	Yes	Yes
Positron Emission Tomography (PET) Scanners	Yes	Yes	Yes	Yes	No	Yes	Yes
Psychiatric Services	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Radiation Therapy	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rehabilitation	Yes	No	No	Yes	Yes	Yes	Yes
Renal Failure/Dialysis	No	No	No	Yes	No	No	Yes
Subacute Services	No	No	No	No	No	No	No
Substance/Drug Abuse	Yes	No	No	Yes	Yes	Yes	Yes
Swing Beds	No	No	Yes	No	No	No	No
Ultrasound	No	No	No	No	No	No	Yes
Air Ambulance	No	No	Yes	Yes	No	No	No
Ground Ambulance	No	No	No	No	No	No	No

Source: Mitchell et al., *supra* note 1.

Figure A1. South Carolina CON Process