



INSTITUTE FOR JUSTICE

**Testimony of Jaimie Cavanaugh in support of LD 1554**  
**Attorney, Institute for Justice**  
**Joint Committee on Health Coverage, Insurance and Financial Services**  
**May 1, 2023**

Dear Chair Bailey, Chair Perry, and Members of the Committee:

My name is Jaimie Cavanaugh and I'm an attorney with the Institute for Justice. I'm submitting this testimony in support of LD 1554.

The Institute for Justice (IJ) is a nonprofit, civil rights law firm dedicated to securing the foundations of a free society, which allow all Americans to pursue their dreams. As part of its mission, IJ has represented healthcare entrepreneurs who would like to offer innovative or lower-cost alternatives to available services but are stymied by certificate of need (CON) laws. For example, IJ sued Kentucky when it denied two immigrant entrepreneurs the opportunity to open a modest home health agency to offer language-appropriate care to the aging Nepali-speaking community in the Louisville area.<sup>1</sup> And IJ currently represents an ophthalmologist who wants to offer safe surgeries from his office.<sup>2</sup> Unfortunately, because the doctor has been unable to get a CON to use his own surgery center, he has been forced to perform surgeries at the local hospital, which adds thousands of dollars to the cost for his patients.

Aside from litigating the constitutionality of CON laws, IJ also researches these laws. In 2020, I put together a comprehensive survey of CON laws from across the country and reported on how states adjusted their CON laws in response to the pandemic.<sup>3</sup>

**The pandemic laid bare the existing problems with CON laws.** If CON laws actually created greater access to healthcare, as proponents argue, states would have needed more CON laws during the pandemic. But the exact opposite was true. Most states with CON programs in place were forced to quickly suspend their programs to allow hospitals to add beds and services, including Maine. Maine resorted to using emergency regulations, which required hospitals to apply for an emergency waiver to add beds or equipment during the pandemic. While some laud these rules as adequate given the circumstances, others might question why hospitals were forced to waste time with this paperwork at all during a healthcare emergency.

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<sup>1</sup> See <https://ij.org/case/kentucky-con/>.

<sup>2</sup> See <https://ij.org/case/north-carolina-con-ii/>.

<sup>3</sup> See Cavanaugh, *et al.*, *Conning the Competition: A Nationwide Survey of Certificate of Need Laws* (Aug. 2020) available at [https://ij.org/report/conning-the-competition/#:~:text=A%20Certificate%20Of%20Need%20\(CON,best%20to%20keep%20others%20out.](https://ij.org/report/conning-the-competition/#:~:text=A%20Certificate%20Of%20Need%20(CON,best%20to%20keep%20others%20out.)

And this problem wasn't limited to covid. As cases of RSV soared last fall, hospitals around the country filled up again and healthcare providers needed flexibility to respond to their patients' needs in real time.<sup>4</sup> This illustrates why doctors and patients, not bureaucrats, should decide when care is needed. Instead of waiting for the next emergency, you should take this opportunity to support CON repeal now.

Another key finding from my report is that **CON laws decrease access to healthcare in rural areas**.<sup>5</sup> Alabama,<sup>6</sup> Oregon<sup>7</sup>, Tennessee,<sup>8</sup> and Washington<sup>9</sup> are states with CON laws, however, they all exclude rural areas from their CON programs, presumably to encourage hospitals and other healthcare facilities to expand into rural areas. Florida also excluded rural areas from its CON program before it repealed the bulk of its CON laws in 2019.

Moreover, some of the country's most rural states have no CON laws at all. States like Idaho, North Dakota, South Dakota, and Wyoming don't burden their healthcare providers with CON laws. And rural states like Colorado, Utah, and Wyoming haven't had a single rural hospital closure since at least 2005 and none of these states have a CON program.<sup>10</sup> So it can't be that CON is necessary to preserve healthcare facilities in rural areas. Just the opposite, repealing CON will encourage expansion of facilities and services around the state.

**Many non-CON states are the same as Maine.** Some argue that non-CON states are different. In fact, I hear this argument in every state that is considering CON repeal: "We need CON here because we're different." But all kinds of states have functioning healthcare systems without CON laws. Nearly 40% of the nation's population live in a state without CON laws. If you're looking for a fellow democratically-controlled state, California is a non-CON state. If you're looking for rural states, states like Idaho, Utah, and Wyoming have no CON laws. Maine's only neighboring state, and fellow northeastern state, New Hampshire, also has no CON laws. New Hampshire repealed its CON program in 2016. And many states that maintain CON programs,

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<sup>4</sup> Hanna MacKay, *Two Michigan hospitals to add more beds on emergency basis amid RSV surge*, The Detroit News (Nov. 23, 2022) available at <https://www.detroitnews.com/story/news/local/michigan/2022/11/23/two-hospitals-add-more-beds-on-emergency-basis-amid-rsv-surge/69674623007/>; Susan K. Livio, *After holiday surge, N.J. pediatric hospital beds were 70% full with RSV, flu and COVID cases*, NJ.com (Dec. 8, 2022) available at <https://www.nj.com/healthfit/2022/12/after-holiday-surge-nj-pediatric-hospital-beds-were-70-full-with-rsv-flu-and-covid-cases.html>.

<sup>5</sup> Thomas Stratmann, *et al.*, *Public Health in Rural States: The Case against Certificate-of-Need Laws*, Mercatus Center George Mason University (Sept. 2020) attached hereto as Exhibit A.

<sup>6</sup> See Ala. Code § 22-21-263(a)(4)

<sup>7</sup> See Or. Rev. Stat. §§ 442.315(b), 442.347

<sup>8</sup> See Tenn. Code § 68-11-1626

<sup>9</sup> See Wash. Admin. Code § 246-310-042(1)

<sup>10</sup> See Map attached hereto as Exhibit B.

do so in very few categories. For example, Indiana, Ohio, and Montana only apply their CON laws to nursing homes/long-term care. Arizona only has CON for ambulances. These examples should make you feel confident that Maine can successfully repeal its CON laws.

**The research is not mixed; CON laws increase price, decrease quality, and decrease access to healthcare.** Proponents of CON laws try to argue that the research on CON laws is mixed or inconclusive. This is untrue. Review of the bulk of peer-reviewed literature on CON paints a clear picture. CON laws do not achieve any of their purported benefits. Quite the opposite, CON laws increase the cost of healthcare, both to government payors and to patients, decrease the quality of services, and decrease access to healthcare. In a study commissioned to aid the South Carolina legislature in considering CON repeal there, PH.D. economist, Matt Mitchell, reviewed over 90 peer-reviewed papers that studied CON laws and their effects.<sup>11</sup> He found that ten times as many studies concluded that CON is associated with higher costs. Only two studies found that CON increases access to care, while 33 found that CON limits access to care. Four times as many studies found that CON undermines the quality of care. And CON has not been shown to increase the amount of charity care that hospitals offer. Any researcher would tell you that these are not mixed results. The trend in the research is clear. CON laws are all downside.

**Many agencies of the federal government agree that states should repeal CON laws.** These agencies include: U.S. Department of Health and Human Services (HHS), U.S. Department of the Treasury (DOT), U.S. Department of Labor (DOL), Federal Trade Commission (FTC), and the Department of Justice (DOJ), Antitrust Division. In a 2018 report, HHS, DOT, and DOL concluded that “[s]tudies have found no empirical evidence that CON laws have restricted ‘over-investment.’ However, CON laws can restrict investments that would benefit consumers and lower costs in the long term and are likely to increase, rather than constrain, healthcare costs.”<sup>12</sup> The FTC and DOJ have been uniform in their criticism of CON<sup>13</sup> for decades and have offered testimony in support of states’ efforts to repeal CON.<sup>14</sup> Even Congress admitted that CON laws

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<sup>11</sup> Matthew D. Mitchell, PH.D., *South Carolina’s Certificate of Need Program: A Comprehensive Review of the Literature* (Mar. 2022) available at [https://palmettopromise.org/wp-content/uploads/2022/04/2022\\_Response-to-SC-LAC-report-PRINTED.pdf](https://palmettopromise.org/wp-content/uploads/2022/04/2022_Response-to-SC-LAC-report-PRINTED.pdf). Attached hereto as Exhibit C.

<sup>12</sup> U.S. Dep’t of Health and Human Servs., U.S. Dep’t of the Treasury, U.S. Dep’t of Labor, *Reforming America’s Healthcare System Through Choice and Competition*, 50 – 57 (2018) available at <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

<sup>13</sup> Fed. Trade Comm’n, Dep’t of Justice, *Improving Health Care: A Dose of Competition* (July 2004) available at <https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice>.

<sup>14</sup> See e.g., Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice Regarding Certificate-of-Need Laws and Alaska Senate Bill 62, Which Would Repeal Alaska’s CON Program (Apr. 12, 2017) available at <https://www.ftc.gov/legal-library/browse/advocacy-filings/joint-statement-federal-trade-commission-antitrust-division-us-department-justice-regarding>; Joint Statement of the Federal

failed to achieve their purpose by repealing the legislation that forced states to adopt CON laws in the first place.<sup>15</sup>

State government has noticed the problems with CON too. For example, North Carolina Treasurer, Dale Folwell, recently submitted a friend of the court brief in support of IJ's constitutional challenge to North Carolina's certificate of need laws.<sup>16</sup> Treasurer Folwell noted that rising healthcare costs posed a challenge to maintaining the solvency of the state's Teacher and State Employers Health Plan, which is funded in part by taxpayers. Repealing CON would decrease healthcare costs for the Plan, which had almost \$4 billion in expenditures in 2022.

Treasurer Folwell explained:

CON laws contribute to consolidated healthcare monopolies . . . by distorting market power in favor of large institutional hospitals. This illegal distortion of market power then results in higher prices, lower quality, and less availability of healthcare services. In turn, large institutional hospitals create incredible excess revenue while failing to earn their tax-exempt status through the provision of charity care and engage in business practices harmful to North Carolinians.

The same problems exist in Maine. Repealing CON is one way to begin correcting them. Repealing CON is the right thing to do for voters who are both users of the healthcare system and taxpayers.

Thank you for considering my testimony. I urge your support for LD 1554 and I'd be happy to answer follow up questions or further assist the Committee in any way.

Sincerely,



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Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250 (Jan. 11, 2016) available at <https://www.ftc.gov/legal-library/browse/advocacy-filings/joint-statement-federal-trade-commission-antitrust-division-us-department-justice-regarding>.

<sup>15</sup> Pub. L. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k– 300n-5), repealed, Pub. L. 99-660, § 701, 100 Stat. 3799 (1986).

<sup>16</sup> Attached hereto as Exhibit D.

# EXHIBIT A



## Public Health in Rural States: The Case against Certificate-of-Need Laws

*Thomas Stratmann, Matthew C. Baker, and Elise Amez-Droz*

September 2020

### **CERTIFICATE-OF-NEED LAWS ARTIFICIALLY RESTRICT PROVIDERS OF CARE IN RURAL AREAS**

Despite the advances of medicine of the past few decades, individuals in rural communities continue to face barriers to access to healthcare. While hospital consolidation and provider shortages present real challenges, an underrated barrier to access to care stems from legacy laws that were implemented almost 50 years ago: certificate-of-need (CON) laws. These laws exist in 37 states (including 12 of the country's 20 rural states) and put up artificial barriers to the provision of care by allowing regulators to decide whether new services are needed in a given geographic area. In practice, healthcare industry incumbents are heavily influential in the process and tend to block potential competitors from entering local markets. A new study by the Mercatus Center at George Mason University controls for social risk factors including race, education, and poverty status and finds that CON laws are associated with higher readmission rates and more emergency department (ED) visits among Medicare beneficiaries in rural areas.<sup>1</sup> CON laws in rural states are also associated with hundreds of dollars of additional expenditures and higher ambulance spending per Medicare beneficiary.

### **CON LAWS DO NOT ACHIEVE THEIR GOAL**

Since CON laws were first implemented, research has shown that they have never achieved their intended purpose of reducing or controlling healthcare spending.<sup>2</sup> State governments, with the help of local industry leaders, were to determine whether a new service was necessary

to meet the needs of the population, with the objective being to limit the number of available healthcare services to prevent overutilization. The federal government encouraged such efforts in the early 1970s by giving states subsidies for setting up CON laws. It did not take long for policymakers to realize that CON laws were not achieving their goal, and in 1986, the federal government removed the corresponding financial incentives.<sup>3</sup> Several states repealed their CON laws, but many did not. Today, 37 states have a CON program that applies to anywhere from 1 to 29 healthcare devices, facilities, and services.<sup>4</sup> Studies confirm what economic theory makes clear: all else being equal, restrictions on supply lead to increases in cost. Not only have CON laws backfired, but now ample evidence shows that CON laws have resulted in unintended side effects such as lower healthcare quality and restricted access to needed services, especially in rural states and counties.

**RURAL STATES WITH CON LAWS FARE WORSE**

The earlier-mentioned Mercatus Center study focuses on the country’s 20 rural states, 12 of which currently have CON laws.

**RURAL STATES WITH CON LAWS  
AS OF DECEMBER 31, 2015**

Alaska  
Arizona  
Arkansas  
Iowa  
Maine  
Mississippi  
Montana  
Nebraska  
Nevada  
Oklahoma  
Oregon  
Vermont

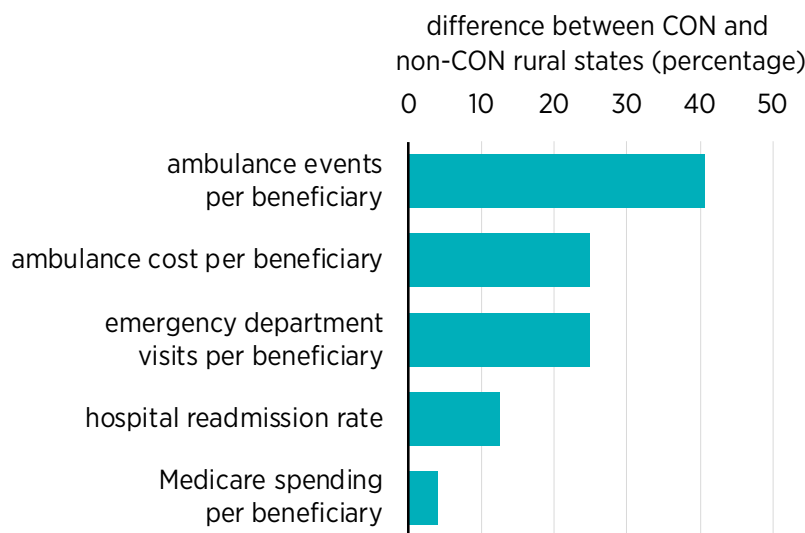
**RURAL STATES THAT HAVE  
REPEALED THEIR CON LAWS**

Colorado  
Idaho  
Kansas  
New Mexico  
North Dakota  
South Dakota  
Utah  
Wyoming

These states have varying socioeconomic characteristics that are associated with poor health outcomes. Still, when the researchers control for age, race, poverty status, and education, rural states with CON laws fare worse both in terms of health outcomes and healthcare spending than their non-CON counterparts (see figure 1).

Before controlling for the earlier-mentioned socioeconomic variables, CON states are associated with higher spending per Medicare beneficiary and higher readmission rates, more ED visits per 1,000 beneficiaries, and higher ambulance spending. The disparities remain when including those controls: CON rural states spend \$295 more per Medicare beneficiary and have 1.2 percentage point

**Figure 1.** Disadvantage for States with Certificate-of-Need Laws in Key Medicare Spending and Outcome Measures, 2015



Note: The CON state disadvantage is the difference in means between rural CON states and rural non-CON states for each measure.  
Source: Authors' calculations based on Centers for Medicare and Medicaid Services, "Public Use File" (dataset), Medicare Geographic Variation, 2016, [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV\\_PUF](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF).

higher readmission rates, 35.1 more ED visits per 1,000 beneficiaries, and \$2.54 higher ambulance spending per beneficiary than do non-CON rural states. These are common metrics of potentially preventable—and often wasteful—spending, often linked to limited access to care that could have better managed chronic conditions and prevented the need for acute care.

Far from helping states save money and provide much-needed services to Medicare beneficiaries, CON laws have the opposite effect in rural areas and lead to worse outcomes than in states that do not have CON restrictions. States that wish to direct dollars toward high-value care and enhance clinical outcomes should consider pursuing some of the following reforms.

### **STATES CAN SOLVE THE PROBLEM, AND THE FEDERAL GOVERNMENT CAN HELP**

The most straightforward and effective way of simultaneously improving health outcomes and reducing healthcare spending is for rural states to repeal CON laws. Attempts to do so have often been met with fierce political opposition, however, as incumbent hospitals and service providers act as powerful special interests. Therefore, we propose other pathways to gradually repeal CON laws.

#### **Partial Repeal of the Most Harmful CON Laws**

CON states often have CON requirements for various types of procedures and services. Legislators should consider the full list of CON requirements in their state and determine which ones



impose the heaviest burden on the state's residents.<sup>5</sup> For example, some CON laws are more likely to affect vulnerable patients, such as CON laws for drug and alcohol abuse treatment centers (found in 24 states), CON laws for psychiatric care facilities (found in 28 states), and CON laws for intermediate-care facilities for those with intellectual disabilities (found in 28 states). Certain CON requirements apply to services that are unlikely to be overprescribed, which means that those who seek to provide such services are not looking to build unnecessary capacity that will drive up costs. Examples include CON laws for neonatal intensive care units (found in 22 states), CON laws for burn care units (found in 14 states), and CON laws for hospice care facilities (found in 18 states). On similar grounds, other types of CON laws to consider removing are those that apply to inexpensive procedures and small investments, such as home healthcare services.<sup>6</sup>

**Phased Repeal through Sunset Clauses, Contingent Action, or Increases in Approval Rates**  
When immediate repeal is infeasible, CON law repeal can be spread over time via different policy strategies: sunset clauses, or automatic phase-out timelines, can be included in bills so that CON laws eventually expire. Three rural states, Idaho, Kansas, and Wyoming, added sunset clauses to their CON laws when the federal government removed its incentives for states in the late 1970s, and their CON programs subsequently expired. In 2012, New Hampshire approved a sunset effective 2015. Similarly, a CON state could make its CON laws contingent on policy decisions in neighboring states, so that its CON laws would go away should a neighboring state eliminate its CON laws also. Another route would be for states to mandate that CON boards approve a steadily growing share of CON applications, culminating with the approval of all applications, effectively amounting to a CON law repeal.<sup>7</sup>

#### Administrative Relief for CON Applicants

If the earlier-mentioned forms of repeal are infeasible, states with CON laws can make the process of obtaining a CON less onerous by reducing fees and simplifying reporting criteria. They can also improve applicants' odds of success by removing certain criteria, including nonduplication, utilization thresholds, and geographic requirements.<sup>8</sup>

#### Increased Transparency in the Approval Process

Applicants face a number of uncertainties when seeking a CON, including uncertainties regarding the amount of time the process will take and the total costs thereof. The outcome of the process may also be influenced by incumbents' efforts to challenge the application and by potential financial ties of CON board members to incumbent businesses. Transparency on all these fronts would minimize uncertainty and help applicants maximize their odds of approval.<sup>9</sup>

## Centers for Medicare and Medicaid Services Can Support Rural States' Efforts

Through the Center for Medicare and Medicaid Innovation, the Centers for Medicare and Medicaid Services has shown support for innovation in the delivery of high-quality healthcare services to Medicaid and Medicare beneficiaries. The presence of CON laws limits the number of services available to individuals in rural communities. Additionally, it also prevents providers from developing innovative services for patients by putting up high, artificial barriers to the provision of care. If spending differences are caused by CON laws, then the Centers for Medicare and Medicaid Services could reduce payments in states that have CON laws to give them incentives to scale down requirements.<sup>10</sup>

## CONCLUSION

Although the negative effects of CON laws have been well-known for decades, new evidence about their elevated effect on rural states adds urgency to the need to remove restraints on providers in areas with poor health outcomes and high healthcare spending. At stake for residents of rural areas is not only their contribution to healthcare spending but also their health and livelihood.

This policy brief summarizes a variety of options for policymakers wishing to remove regulatory barriers to the care on which rural residents depend—primarily suggesting a full repeal of CON laws but, in recognition of legislative and political hurdles, offering feasible alternative fixes.

## ABOUT THE AUTHORS

Thomas Stratmann is a senior research fellow at the Mercatus Center at George Mason University and professor of economics and law at George Mason University. His primary research interests are political economy, fiscal policy, law and economics, health economics, and experimental economics.

Matthew C. Baker is a PhD candidate at George Mason University and has worked for a hospital association as a health policy researcher for more than seven years. Matt currently holds an MS in agricultural and applied economics from Virginia Tech. His research areas include healthcare economics, healthcare quality measurement, and healthcare finance, especially Medicare payment policy.

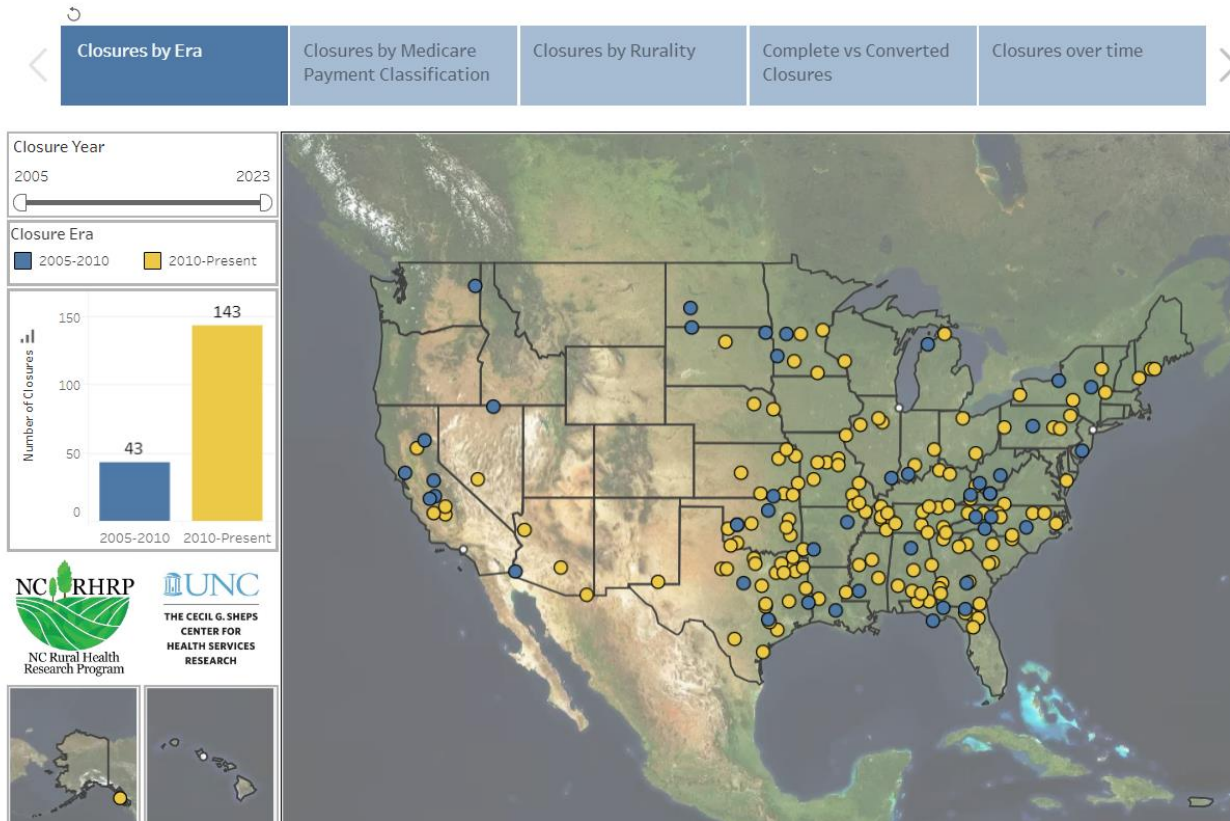
Elise Amez-Droz is the manager of the Open Health project at the Mercatus Center at George Mason University. Previously, she has worked as a market research analyst for a startup company in the pharmaceutical industry. She is a graduate of the Fuqua School of Business at Duke University.

## NOTES

1. Thomas Stratmann and Matthew Baker, “Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis” (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, July 2020).
2. Thomas Stratmann et al., “Certificate-of-Need Laws: Frequently Asked Questions,” Mercatus Center at George Mason University, August 29, 2017, <https://www.mercatus.org/publications/corporate-welfare/certificate-need-laws-frequently-asked-questions>.
3. Matthew D. Mitchell and Elise Amez-Droz, “How Certificate-of-Need Reform Can Increase Access to Higher-Quality, Lower-Cost Healthcare in Vermont” (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, February 2019).
4. Stratmann and Baker, “Examining Certificate-of-Need Laws.”
5. Thomas Stratmann et al., “Certificate-of-Need Laws: How CON Laws Affect Spending, Access, and Quality across the States,” Mercatus Center at George Mason University, August 29, 2017, <https://www.mercatus.org/publications/corporate-welfare/certificate-need-laws-how-con-laws-affect-spending-access-and-quality>.
6. Matthew D. Mitchell, Elise Amez-Droz, and Anna K. Parsons, “Phasing Out Certificate-of-Need Laws: A Menu of Options” (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, February 2020).
7. Mitchell, Amez-Droz, and Parsons, “Phasing Out Certificate-of-Need Laws.”
8. Mitchell, Amez-Droz, and Parsons.
9. Mitchell, Amez-Droz, and Parsons.
10. Mitchell, Amez-Droz, and Parsons.

# EXHIBIT B

## Rural Hospital Closures Maps, 2005 – Present



# EXHIBIT C



# **SOUTH CAROLINA'S CERTIFICATE OF NEED PROGRAM: A COMPREHENSIVE REVIEW OF THE LITERATURE**

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MARCH 2022



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P.O. Box 12676 Columbia, SC 29211 | 803-708-0673

# EXECUTIVE SUMMARY

## RESEARCH CONCLUSIONS ABOUT CERTIFICATE OF NEED

The research is conclusive. CON fails to achieve all of the reasons for its existence in the first place...



### DOES CON RESTRAIN **COST**?

No. Overwhelming number of studies confirm. Ten times as many studies find that CON is associated with **higher** costs than find it is associated with **lower** costs.

→ see pages **7-8**



### DOES CON ENSURE ADEQUATE **SUPPLY**? ENSURE RURAL ACCESS? ENCOURAGE ASCSs, MRIs?

No. Just **2** studies find that CON increases access to care while **33** find that it limits access.

→ see pages **8-9**



### DOES CON ENSURE MORE **CHARITY CARE**?

No. Recent (2021) Johns Hopkins study is freshest evidence.



### DOES CON PROMOTE HIGH **QUALITY**?

No. Nearly four times as many studies find that CON undermines quality of care than find that it enhances the quality of care.

→ see pages **9-10**



# INTRODUCTION

About four in ten Americans live in states with limited or no certificate of need requirements in health care. For several decades now, researchers have examined cost, access, and quality outcomes in these non-CON states, comparing them with outcomes in CON states. They have also studied changes in outcomes in states that have eased or eliminated their CON programs. A complete reading of this literature suggests that CON laws fail to achieve their stated goals. In fact, they likely undermine these goals by raising costs, limiting access, and diminishing the quality of care.

- Ten times as many studies find that CON is associated with higher costs than find it is associated with lower costs.
- Just two studies find that CON increases access to care while 33 find that it limits access.
- Nearly four times as many studies find that CON undermines quality of care than find that it enhances the quality of care.

— Matthew D. Mitchell, PhD



# TABLE OF CONTENTS

**I. LAC Findings Regarding South Carolina’s CON Program.....7**

**II. The Broader CON Literature.....7**

**A. Papers Assessing the Effect of CON on Costs and Efficiency.....7**

        Figure 1. Summarizing the CON and Cost Literature.....8

**B. Papers Assessing the Effect of CON on Access to Care .....8**

        Figure 2. Summarizing the CON and Access Literature.....9

**C. Papers Assessing the Effect of CON on the Quality of Care.....9**

        Figure 3. Summarizing the CON and Quality of Care Literature.....10

**III. Summary and Conclusion.....10**

**IV. Appendix.....11**

    Table 1. Studies Assessing the Effect of CON on Spending Per Service  
    (Costs, Prices, Charges, or Reimbursements).....11

    Table 2. Studies Assessing the Effect of CON on Spending Per Person  
    (Per Patient or Per Capita).....17

    Table 3. Studies Assessing the Effect of CON on Efficiency.....22

    Table 4. Studies Assessing the Effect of CON on Investment.....25

    Table 5. Studies Assessing the Effect of CON the Availability of and  
    Access to Services.....26

    Table 6. Studies Assessing the Effect of CON on Volume.....41

    Table 7. Studies Assessing the Effect of CON on Quality of Care.....52

**V. Endnotes.....69**



# I. LAC FINDINGS REGARDING SOUTH CAROLINA'S CON PROGRAM

Members of the South Carolina General Assembly recently asked the state's Legislative Audit Council (LAC) to review South Carolina's Certificate of Need (CON) program. In response, the LAC produced a report titled "A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program." The report offers a helpful and detailed look at a Certificate of Need program using information that only an agency like the LAC has access to. It also offers a short and incomplete review of the voluminous literature on CON, accounting for about one-fifth of the extant literature. While the 19 articles reviewed by the LAC may give a somewhat mixed impression of the regulation, a complete reading of the literature does not.

I commend the LAC for their detailed and helpful analysis of the South Carolina CON program. Among other findings, the LAC staff found that the state's CON program limits and delays the introduction of new services. For example, they found that the "CON process is greatly lengthened due to appeals to the Administrative Law Court (ALC) and courts of appeal. Additionally, we found that the CON process has deterred some providers from expanding services."<sup>1</sup> More specifically, they report that "appeals can extend the length of time of the CON application process by more than a year."<sup>2</sup> For example, they report that the average number of days between a CON decision and an ALC decision on ambulatory surgery facilities is **396** while the number of days between a CON decision and an ALC decision on emergency departments is **675**.<sup>3</sup>

The LAC found that most CON decisions in the state are not opposed. However, it also appears that opposition by incumbent providers is typically sufficient to kill a project. Among those applications that were approved, only **16%** were opposed by incumbent competitors, while among those that were denied, fully **78%** were opposed by competitors.<sup>4</sup> The LAC reports that "In one case, providers contesting the construction of an acute care hospital in Fort Mill exhausted their appeals in **February 2019**—nearly **13** years after DHEC issued a decision on the CON applications in **2006**. During that time, the populations of Fort Mill and nearby Tega Cay increased by **105%**."<sup>5</sup>

Regarding the role of incumbent providers, the LAC noted that:

*A DHEC official explained the largest number of complaints about the CON program stem from the appeals' timeline, and that the extended timeline is often a result of providers seeking to delay or stymie competition. Another DHEC official clarified most appeals litigation involved an approved project that another provider is challenging, and that it is generally existing providers challenging the decision to approve a new CON.*<sup>6</sup>

## II. THE BROADER CON LITERATURE

I have identified and read **93** peer-reviewed papers assessing the effects of CON laws on cost, access, quality, and other market conditions.<sup>7</sup> These papers compare outcomes in CON states with those in non-CON states. They also track outcomes over time to see what happens in states that repeal their CON laws or pare those laws back. These studies typically include observations spanning years, if not decades, and they employ regression analyses that control for possibly confounding factors such as local economic, demographic, and health conditions. Although my colleagues at the Mercatus Center and I have conducted several peer-reviewed studies, most of these papers are not authored by us.

The most common assessments in the literature address the effects of CON on **cost, access, and quality**. As I will show below, most studies find that CON raises costs and limits access to care. Moreover, **four** times as many studies find CON undermines quality than find that it enhances quality.

## A. PAPERS ASSESSING THE EFFECT OF CON ON COSTS AND EFFICIENCY

CON laws were initially intended to rein in healthcare spending,<sup>8</sup> and many people continue to support the regulations out of a belief that they reduce costs. There is little evidence that they do. Figure 1 presents an overview of the CON and cost literature. Of **40** tests designed to assess the effect of CON on costs, just **two** find that the regulation is associated with reduced costs. **Ten** times as many tests—**21** studies—find that CON is associated with higher spending or lower efficiency. While **17** studies reach mixed, insignificant, or inclusive results.

Studies measure costs and efficiency in different ways and it is helpful to present them in separate categories. Table 1 (see Appendix) summarizes the papers that assess the effect of CON on spending per service. **Seven** papers find CON is associated with higher spending per service. **Six** find mixed results. **Zero** papers conclude CON is clearly associated with lower spending per service.

Table 1 shows, for example, that reimbursement costs for coronary artery bypass grafts fell **2.8** percent in Ohio and **8.8** percent in Pennsylvania following repeal.<sup>9</sup> Hospital charges are **5.5** percent lower in repealing states **five** years after repeal.<sup>10</sup> Medicare reimbursements for total knee arthroplasty are **5** to **10** percent lower in non-CON states than in CON states.<sup>11</sup> Spinal surgery reimbursements fell faster in non-CON than in CON states (about **11** percent per year.<sup>12</sup>)

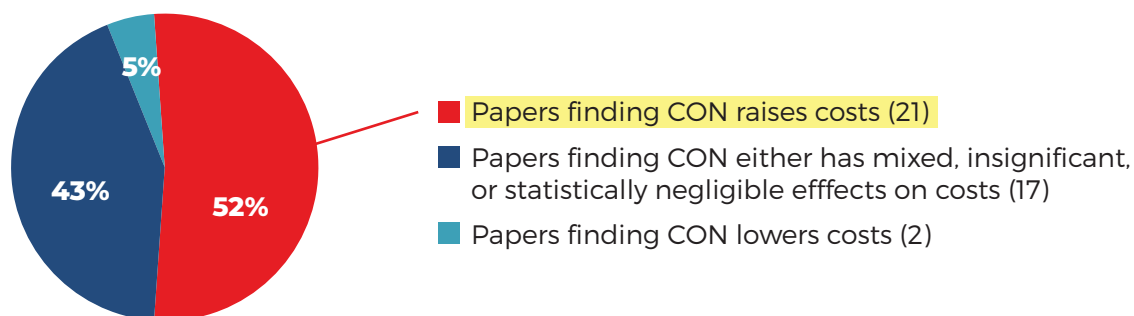
Among the negligible results shown in table 1, CON appears to have no effect on Medicaid nursing home reimbursement rates.<sup>13</sup> Nor does it seem to affect per diem Medicaid nursing home charges or per diem Medicaid long-term care charges.<sup>14</sup>

Table 2 summarizes the papers that assess the effect of CON on spending per person. **Eleven** papers find CON is associated with higher spending per person. **Seven** find mixed results. **Zero** papers conclude that CON is clearly associated with lower spending per person.

Table 2 shows that Medicaid community-based care expenditures per capita are higher in CON than in non-CON states.<sup>15</sup> Hospital expenditures per adjusted admission are higher in CON than in non-CON states.<sup>16</sup> And states that eliminate CON experience **5** percent reductions in real per capita health care spending.<sup>17</sup>

Table 3 summarizes the papers that assess the effect of CON on efficiency. **Two** find that CON is associated with reduced efficiency, **two** find it is associated with enhanced efficiency, and **three** find mixed results. Finally, table 4 summarizes the papers that assess the effect of CON on investment. **One** finds that CON is associated with more investment and the other reaches mixed conclusions.

### FIGURE 1. SUMMARIZING THE CON AND COST LITERATURE

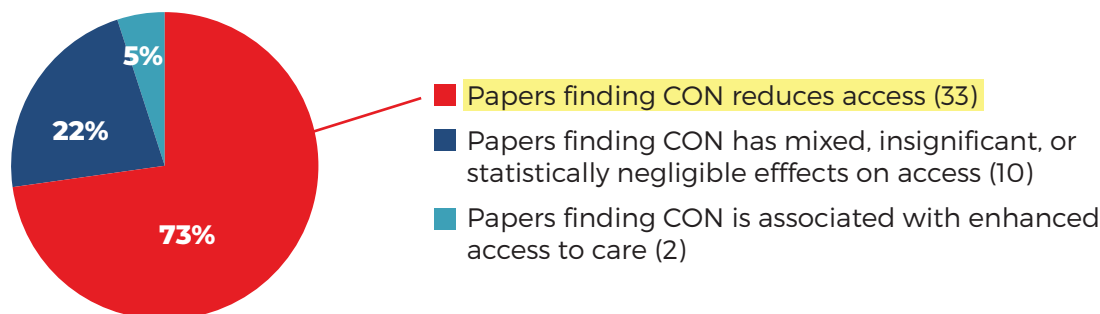


## B. PAPERS ASSESSING THE EFFECT OF CON ON ACCESS TO CARE

Figure 2 summarizes the literature assessing the effect of CON on access. Among **45** tests, a large majority—**73** percent—find that CON is associated with diminished access to care. **Ten** studies—**22** percent—find mixed or inconclusive results. And **two** studies associate CON with greater access to care.

The typical patient in a CON state has access to fewer hospitals,<sup>18</sup> hospice care facilities,<sup>19</sup> dialysis clinics,<sup>20</sup> cancer treatment facilities,<sup>21</sup> home health agencies,<sup>22</sup> psychiatric care facilities,<sup>23</sup> drug and substance abuse centers,<sup>24</sup> open-heart surgery programs,<sup>25</sup> revascularization programs,<sup>26</sup> and percutaneous coronary intervention programs.<sup>27</sup> Patients in these states have access to fewer hospital beds and are more likely to have been denied beds during the COVID-19 pandemic.<sup>28</sup> These patients have access to fewer medical imaging devices.<sup>29</sup> Patients in states with CON laws must travel longer distances for care,<sup>30</sup> are more likely to leave their state for care,<sup>31</sup> and must wait longer for care.<sup>32</sup> And whereas CON programs do not seem to increase charity care,<sup>33</sup> they do exacerbate Black-White disparities in the provision of care.<sup>34</sup>

**FIGURE 2. SUMMARIZING THE CON AND ACCESS LITERATURE**



There are **two** broad ways that the literature assesses the effect of CON on access to care. Some studies look at the effect of CON on the availability of services. These studies look to see if CON affects the number providers, the availability of certain services, distance to services, and wait times.

Table 5 lists the **twenty-eight** studies that assess the effect of CON on the availability of services. Of these, **26** find the regulation is associated with diminished access to services and **2** find mixed results. No study finds that CON is consistently associated with increased access to services.

Other studies look at the effect of CON on the total volume of services. These studies look to see if CON affects the volume of services offered. Table 6 lists the **seventeen** papers that assess the effect of CON on volume of care. Of these, **seven** find that CON is associated with a lower volume of care, **8** find mixed results, and **2** find that CON is associated with a higher volume of care.

## C. PAPERS ASSESSING THE EFFECT OF CON ON THE QUALITY OF CARE

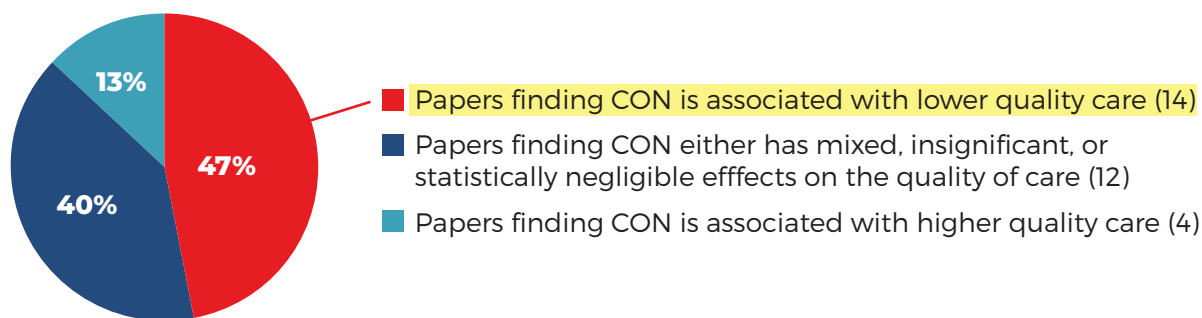
CON regulators typically do not assess provider quality when considering whether or not to grant a certificate. Still, the programs are often said to increase the quality of care by channeling more procedures through fewer providers, who then obtain greater proficiency through repetition.

Despite these assertions, about **four** times as many studies find that CON laws undermine quality than find that it enhances quality. In the typical CON state, patients experience higher mortality rates following heart attack, heart failure, and pneumonia.<sup>35</sup> They have higher readmission rates,<sup>36</sup> are more likely to die from postsurgery complications,<sup>37</sup> and are less likely to give their hospitals top ratings.<sup>38</sup> Nurs-

ing homes tend to get lower survey scores in CON states than in non-CON states,<sup>39</sup> and nursing home patients are more likely to be restrained in CON states than in non-CON states.<sup>40</sup> Home health agencies also receive lower scores in CON states than in non-CON states,<sup>41</sup> and home health agency clients are less likely to see improvements in mobility.<sup>42</sup> Finally, surgeries are more likely to be performed by lower-quality surgeons in CON states than in non-CON states.<sup>43</sup>

Figure 3 summarizes the **twenty-eight** studies that assess the effect of CON on the quality of care. **Fourteen** studies find that the regulation is associated with lower quality care, **12** obtain mixed results, and **4** studies find that CON is associated with higher quality care. Table 7 lists the studies in detail.

**FIGURE 3. SUMMARIZING THE CON AND QUALITY OF CARE LITERATURE**



## III. SUMMARY AND CONCLUSION

**Four in ten** Americans live in states with either no CON laws or very limited CON laws in health care (as I write, this number is growing because recent reforms in Florida and Montana are now taking effect).<sup>44</sup> In these states, providers may open new facilities or expand their services without first proving to a regulator that their community needs the service in question. These non-CON states include high- and low-income, urban and rural, and coastal and intracontinental communities. Policymakers in South Carolina can learn from the experience of patients in these states to see how CON laws affect spending, access, and quality of care. †

### LIFE AFTER CERTIFICATE OF NEED

Hospital executives and policymakers often worry about what would happen in their state if their CON laws were repealed. They need not worry. And they need not speculate. They can look to the experiences of Americans in non-CON states to see what is likely to happen. They can also look to the experiences of states that have eased or repealed these regulations. These experiences, documented in over 90 peer-reviewed studies, strongly suggest that patients in a state like South Carolina would gain greater access to higher-quality and lower-cost care if CON laws were to be eliminated.



## IV. APPENDIX

Papers often assess CON along multiple dimensions. When they do, the paper will appear in multiple tables and I will list all of the findings in the summary column, but underline the particular finding that is relevant for the specific table in which the summary appears.

**TABLE 1. STUDIES ASSESSING THE EFFECT OF CON ON SPENDING PER SERVICE (COSTS, PRICES, CHARGES, OR REIMBURSEMENTS)**

<b>A. PAPERS FINDING CON IS ASSOCIATED WITH HIGHER SPENDING PER SERVICE</b>			
No.	Paper	Summary	Quotes
1.	Keith B. Anderson and David I. Kass, "Certificate Of Need Regulation of Entry Into Home Health Care: A Multi-Product Cost Function Analysis" (Washington, D.C.: Federal Trade Commission, 1986).	They examined the effect of CON on economies of scale and cost in the home health care industry. They found: 1. <u>Costs were 2 percent higher in CON states relative to non-CON states.</u> 2. No substantial economies of scale in the home health industry overall, 3. Nor did they find a difference in economies of scale in CON and non-CON states.	"costs were higher in the presence of CON regulation. The estimated average increase in cost was about 2 percent.... We further suggest that the regulations may lead to price increases that cost consumers, health insurers, and government agencies upward to \$100 million per year in increased payments for home health services."
2.	Monica Noether, "Competition Among Hospitals," Journal of Health Economics 7, no. 3 (September 1988): 259–84.	CON increases the average price for specific disease categories such as congestive heart failure and pneumonia.	"CON's strongest effect is that it creates cost raising inefficiencies which are passed on in higher prices."
3.	Vivian Ho and Meei-Hsiang Ku-Goto, "State Deregulation and Medicare Costs for Acute Cardiac Care," Medical Care Research and Review 70, no. 2 (April 2013): 185–205.	Removing CON decreases the cost of coronary artery bypass grafts, but not for percutaneous coronary intervention. In Ohio, reimbursements fell 2.8 percent following repeal of CON and in Pennsylvania, they fell 8.8 percent following repeal.	"We found that states that dropped CON experienced lower costs per patient for coronary artery bypass grafts (CABG) but not for percutaneous coronary intervention (PCI)."

4.	James Bailey, “Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws,” Mercatus Working Paper (Arlington, VA: Mercatus Center at George Mason University, August 1, 2016).	Removing CON reduces hospital charges by 5.5% five years after repeal.	“CON repeal . . . is associated with . . . a statistically significant 1.1% reduction in average hospital charges per year (a 5.5% reduction for a mature CON repeal).”
5.	James A. Browne et al., “Certificate-of-Need State Laws and Total Knee Arthroplasty,” <i>The Journal of Arthroplasty</i> 33, no. 7 (July 1, 2018): 2020–24.	They examined the effect of CON on total knee arthroplasty (TKA) by comparing states with and without CON programs. They looked at 4 factors: <ol style="list-style-type: none"> <li>1. <u>Average Medicare reimbursements were 5% to 10% lower in non-CON states,</u></li> <li>2. CON was associated with lower TKA utilization per capita, but faster growth in utilization per capita.</li> <li>3. CON was associated with TKA in higher-volume hospitals,</li> <li>4. Examination of adverse events rates did not reveal any strong associations between any adverse outcome and CON status.</li> </ol>	“Average reimbursement (and thus Medicare spend) was 5% to 10% lower in non-CON states at all time points (P < .0001).”
6.	Chason Ziino, Abiram Bala, and Ivan Cheng, “Does ACDF Utilization and Reimbursement Change Based on Certificate of Need Status?,” <i>Clinical Spine Surgery</i> 33, no. 3 (April 2020): E92.	The paper looks at reimbursements for spinal surgery in CON and non-CON states, finding that reimbursements fell the most in non-CON outpatient settings (-11% compound annual growth) in non-CON states.	“Reimbursement decreased across all settings, with the most pronounced decrease in the non-CON outpatient setting with an adjusted CAGR of -11.0%.”

7.	<p>Olivia A. Schultz, Lewis Shi, and Michael Lee, "Assessing the Efficacy of Certificate of Need Laws Through Total Joint Arthroplasty," <i>Journal for Healthcare Quality: Official Publication of the National Association for Healthcare Quality</i> 43, no. 1 (February 1, 2021): e1–7.</p>	<p>They examined the effect of CON on total knee (TKA), hip (THA), and shoulder arthroplasty (TSA), finding:</p> <ol style="list-style-type: none"> <li>1. <u>TKA and TSA costs were higher in CON states than in non-CON states (and these results were statistically significant); THA costs were lower in CON states but these results were not statistically significant.</u></li> <li>2. CON is associated with a lower volume of procedures, though it was not statistically significant in the case of hip arthroplasty, and</li> <li>3. CON has no statistically significant effect on complications (deep vein thrombosis and pulmonary embolism)</li> </ol>	<p>"The average per-patient cost incurred on the day of TKA was \$34,265 in CON states and \$32,391 in non-CON states (p , .0001). Total hip arthroplasty was found to have a lower per-patient average cost in states with CON legislation—\$31,758 in CON states and \$32,245 comparatively. These results were not statistically significant (p 5 .3814). Conversely, the cost of TSA was higher in CON states at \$37,576 versus \$34,903 in non-CON states (p 5 .093).... The rate of TKA in patients diagnosed with arthritis in the knee was 12.3% (8,984/73,139) in CON states and 13.8% in non-CON states (6,612/47,744). Access was significantly greater in non-CON states (p , .0001). For THA, the rate was lower in CON states when compared with non-CON states with rates of 21.4% (4,843/22,608) and 21.9% (3,239/1,481), respectively; however, this difference was not statistically significant (p 5 .250). Similarly, TSA occurred at a decreased rate of 2.8% (683/24,675) in CON states compared with a rate of 3.2% (523/16,436) in non-CON states. This difference was statistically significant (p 5 .019).... The apparent nonsuperiority of CON states in achieving their purported goals may call into question the effectiveness of additional bureaucracy and regulation, suggesting a need for further examination.... One-year postoperatively, there were no significant differences in the rate of DVT [deep vein thrombosis] or PE [pulmonary embolism] after TKA, THA, or TSA in either study populations (p 5 .605, p 5 .713, p 5 .670)."</p>
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## B. PAPERS FINDING CON HAS MIXED, INSIGNIFICANT, OR NEGLIGIBLE EFFECTS ON SPENDING PER SERVICES

No.	Paper	Summary	Quotes
1.	Charlene Harrington et al., "The Effect of Certificate of Need and Moratoria Policy on Change in Nursing Home Beds in the United States," <i>Medical Care</i> 35, no. 6 (1997): 574–88.	In a two-stage least squares regression, they assess the effect of CON, and/or moratoria on the growth of nursing home beds and Medicaid nursing home reimbursement rates. They found: 1. <u>CON had no effect on Medicaid nursing home reimbursement rates.</u> 2. CON reduced growth of beds.	"States that had a certificate of need and/or moratorium did have significant reductions in the growth in nursing home beds but Medicaid nursing home reimbursement rates were not related to change in bed stock."
2.	David C. Grabowski, Robert L. Ohsfeldt, and Michael A. Morrissey, "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures," <i>Inquiry: A Journal of Medical Care Organization, Provision and Financing</i> 40, no. 2 (2003): 146–57.	CON repeal: 1. <u>Has no statistically significant effect on per diem Medicaid nursing home charges and</u> 2. <u>No effect on per diem Medicaid long-term-care charges.</u>	"The results . . . show that regulatory change did not have a statistically significant effect on either Medicaid payment rates or overall days."
3.	Abhinav Khanna et al., "Certificate of Need Programs, Intensity Modulated Radiation Therapy Use and the Cost of Prostate Cancer Care," <i>The Journal of Urology</i> 189, no. 1 (January 2013): 75–79.	The authors focus on intensity modulated radiation therapy. They find that: 1. <u>CON was not associated with any difference in cost growth</u> 2. CON was associated with greater growth in intensity modulated radiation therapy	"While the use of IMRT as a proportion of all definitive treatments for localized prostate cancer (ie radical prostatectomy, IMRT, 3D-CRT and brachytherapy) increased dramatically during the study period in CON Yes (2.3% of all treatments in 2002, 46.4% in 2008 to 2009) and CON No (11.3% of all treatments in 2002, 41.7% in 2008 to 2009) regions, greater growth of IMRT use was observed in CON Yes (slope 0.403) vs CON No (slope 0.241) regions in adjusted analyses (p 0.001).... Certificate of need programs were not effective in limiting intensity modulated radiation therapy use or attenuating prostate cancer health care costs. There remains an unmet need to control the rapid adoption of new, more expensive therapies for prostate cancer that have limited cost and comparative effectiveness data."

4.	James Bailey, Tom Hamami, and Daniel McCorry, "Certificate of Need Laws and Health Care Prices," Journal of Health Care Finance 43, no. 4 (2017).	They find that prices are higher in CON states relative to non-CON states, but the difference isn't statistically significant.	"We find that states with Certificate of Need laws have higher prices than states without Certificate of Need laws, but this difference is not statistically significant."
5.	Jourdan M. Cancienne et al., "Certificate-of-Need Programs Are Associated with a Reduced Incidence, Expenditure, and Rate of Complications with Respect to Knee Arthroscopy in the Medicare Population," HSS Journal: The Musculoskeletal Journal of Hospital for Special Surgery 16, no. Suppl 2 (December 2020): 264–71, <a href="https://doi.org/10.1007/s11420-019-09693-z">https://doi.org/10.1007/s11420-019-09693-z</a> .	<p>They examine the effect of CON on knee arthroscopy, assessing its effect on:</p> <ol style="list-style-type: none"> <li>1. <u>Charges and reimbursements: in t-tests without controls they found that charges (which are the prices set before any negotiation) were lower in CON states, while reimbursements (which are actual reimbursements) were not statistically significantly different.</u></li> <li>2. Total volume: total volume and growth in total volume was lower in CON states than in non-CON states.</li> <li>3. Volume within facilities: CON is associated with the presence of more high-volume facilities, and</li> <li>4. Quality: There were more ER visits within 30 days of operation and more infections within 6 months of operation in CON than in non-CON states; there were no differences in in-hospital deaths or readmissions within 30 days of the operation between CON and non-CON states.</li> </ol>	"Comparisons of charges and reimbursements were performed using Student's t tests.... CON states had significantly lower average per-patient charges for knee arthroscopy at all time points and overall compared with non-CON states (\$3719 and \$4769, respectively; $p < 0.001$ for all comparisons).... However, per-patient procedural reimbursements between CON and non-CON states were not statistically different (\$1790.36 and \$1813.09, respectively; $p = 0.429$ )."

6.	<p>Chason Ziino, Abiram Bala, and Ivan Cheng, "Utilization and Reimbursement Trends Based on Certificate of Need in Single-Level Cervical Discectomy," <i>The Journal of the American Academy of Orthopaedic Surgeons</i> 29, no. 10 (May 15, 2021): e518–22, <a href="https://doi.org/10.5435/JAAOS-D-19-00224">https://doi.org/10.5435/JAAOS-D-19-00224</a>.</p>	<p>They studied inpatient cervical discectomy in CON and non-CON states in inpatient and outpatient setting. It appears that they did not use any controls, however.</p> <p>Regarding reimbursements, they find:</p> <ol style="list-style-type: none"> <li>1. <u>In the inpatient setting, reimbursement was lower in non-CON states (\$1,128.40) than in the CON states (\$1,223.56). But reimbursements in the CON states were falling faster over time.</u></li> <li>2. <u>In the outpatient setting reimbursement was higher in Non-CON states (\$4,237.01) than in CON states (\$3,859.31) and reimbursements were growing in the non-CON states but falling in the CON states.</u></li> </ol> <p>Regarding access:</p> <ol style="list-style-type: none"> <li>3. In the inpatient setting, there were more patients in the CON setting than in the non-CON setting (657 compared with 231) and utilization of the procedure was growing faster in CON than in non-CON states but this does not appear to control for the larger population of CON states than non-CON states.</li> <li>4. Similarly, in the outpatient setting, there were more patients in the CON setting than in the non-CON setting (435 compared with 257) and utilization of the procedure was growing faster in CON than in non-CON states but again this does not appear to control for the larger population of CON states than non-CON states.</li> </ol>	<p>We analyzed a private payer and Medicare database from 2007 to 2015. All single-level cervical discectomies were selected then split into CON and non-CON states. Each group was then further split into inpatient and outpatient. Utilization and reimbursement were analyzed using the compound annual growth rate (CAGR), with reimbursement adjusted by the US Bureau of Labor Statistics Consumer Price Index. Results: We identified 1,580 single level cervical decompressions in our study period: 888 were done in the inpatient setting, whereas 692 were done in the outpatient setting. Adjusted reimbursement only increased in the non-CON outpatient setting, with a CAGR of 2.0%. All other settings had decreased reimbursement. Utilization increased across all four settings, with the highest growth seen in the CON outpatient setting, with a CAGR of 12.7%. The highest average reimbursement was in the non-CON outpatient setting at \$4,237.</p>
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**TABLE 2. STUDIES ASSESSING THE EFFECT OF CON ON SPENDING PER PERSON  
(PER PATIENT OR PER CAPITA)**

<b>A. PAPERS FINDING CON IS ASSOCIATED WITH HIGHER SPENDING PER PERSON</b>			
No.	Paper	Summary	Quotes
1.	Frank A. Sloan and Bruce Steinwald, "Effects of Regulation on Hospital Costs and Input Use," <i>The Journal of Law &amp; Economics</i> 23, no. 1 (1980): 81–109.	Comprehensive CON programs have no effect on hospital expenditures per patient day, while noncomprehensive programs increase hospital expenditures by 5 percent per patient day.	"The short-run effect of a mature, noncomprehensive program is to raise total expense per adjusted patient day by nearly 5 percent; the long-run effect is over twice this."
2.	Daniel Sherman, "The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis   Federal Trade Commission," Staff Report of the Bureau of Economics (Washington, D.C.: Federal Trade Commission, January 1988), <a href="https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs-economic-policy-analysis">https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs-economic-policy-analysis</a> .	He estimates the effects of CON on cost functions using a sample of 3708 hospitals using data from 1983-84. Though he uses the term costs, he is actually measuring operating expenditures. He finds that spending would fall by 1.4 percent if states relaxed CON.	"if states were to significantly relax the regulatory constraints hospitals face by doubling the threshold at which hospital expenditures were subject to CON review, total hospital costs would not increase, but rather would decline by 1.4 percent."
3.	Joyce A. Lanning, Michael A. Morrissey, and Robert L. Ohsfeldt, "Endogenous Hospital Regulation and Its Effects on Hospital and Non-Hospital Expenditures," <i>Journal of Regulatory Economics</i> 3, no. 2 (June 1991): 137–54.	They measure the effect of CON on hospital expenditures, finding that it is associated with 20.6 percent higher spending per capita.	"... the coefficient of CON is positive and statistically significant in all three expenditure equations. The most pronounced effect is on hospital expenditures, where CON appears to add 20.6 percent to per capita hospital expenditures in the long run. This is consistent with the view that CON programs act to protect inefficient hospitals from competition."
4.	John J. Antel, Robert L. Ohsfeldt, and Edmund R. Becker, "State Regulation and Hospital Costs," <i>The Review of Economics and Statistics</i> 77, no. 3 (1995): 416–22.	They find that CON increases per-day and per-admission hospital expenditures but has no relationship to per capita hospital expenditures.	"CON investment controls imply higher per day and per admission costs, but have no statistically significant effect on per capita cost."
5.	Nancy A. Miller, Charlene Harrington, and Elizabeth Goldstein, "Access to Community-Based Long-Term Care: Medicaid's Role," <i>Journal of Aging and Health</i> 14, no. 1 (February 2002): 138–59.	They find that CON increases per capita Medicaid community-based care expenditures.	"Use of a nursing home CON or combined CON/moratorium was associated with increased community-based care expenditures."

6.	Nancy A. Miller, Charlene Harrington, and Elizabeth Goldstein, "Access to Community-Based Long-Term Care: Medicaid's Role," <i>Journal of Aging and Health</i> 14, no. 1 (February 2002): 138–59.	They find CON laws increase hospital expenditures per adjusted admission.	"The results indicate that CON laws had a positive, statistically significant relationship to hospital costs per adjusted admission. . . .These findings suggest not only that CON do not really contain hospital costs, but may actually increase them by reducing competition."
7.	Patrick A. Rivers, Myron D. Fottler, and Jemima A. Frimpong, "The Effects of Certificate of Need Regulation on Hospital Costs," <i>Journal of Health Care Finance</i> 36, no. 4 (2010): 1–16.	They find that stringent CON programs increase hospital expenditures per admission.	"Implications from these results include the inability of CNR [CON] to contain HC [hospital costs] as assumed or expected, and the possibility that CNR [CON] may actually increase HC [hospital costs], while reducing competition."
8.	James Bailey and Tom Hamami, "Competition and Health-Care Spending: Theory and Application to Certificate of Need Laws," Working Paper (Philadelphia, PA: Federal Reserve Bank of Philadelphia, October 2019), <a href="http://www.philadelphiafed.org/the-economy/competition-and-health-care-spending-theory-and-application-to-certificate-of-need-laws">http://www.philadelphiafed.org/the-economy/competition-and-health-care-spending-theory-and-application-to-certificate-of-need-laws</a> .	CON causes spending on those with less than excellent health to be as much as 20% higher.	"Our own empirical work finds that CON increases overall per capita health spending by 10.5% but that this effect is quite heterogeneous. We find that CON has no significant effect on the spending of those with excellent health while increasing spending by the less healthy as much as 20.3%."
9.	James Bailey, "Can Health Spending Be Reined in through Supply Restraints? An Evaluation of Certificate-of-Need Laws," <i>Journal of Public Health</i> 27, no. 6 (December 1, 2019): 755–60, <a href="https://doi.org/10.1007/s10389-018-0998-1">https://doi.org/10.1007/s10389-018-0998-1</a>	States that eliminate CON experience 5 percent reductions in real per capita health care spending.	"Each year of CON repeal reduces total expenditures by a statistically significant 0.8%, so that after 5 years, total spending has fallen by 4% (Table 4). This result is driven by the fall in physician spending, which drops a statistically significant 1.4% per year, while hospital spending drops only a statistically insignificant 0.3%."



10	<p>Susan L. Ettner et al., “Certificate of Need and the Cost of Competition in <i>Home Healthcare Markets</i>,” <i>Home Health Care Services Quarterly</i> 39, no. 2 (June 2020): 51–64.</p>	<p>They examine the effects of home health agency CONs and nursing home CONs on home health agencies. They find that in states with home health agency CONs there are:</p> <ol style="list-style-type: none"> <li>1. <u>Lower per patient expenditures (they don't know if this is due to skimping or to economies of scale);</u></li> <li>2. <u>Higher expenditures per agency,</u></li> <li>3. <u>Higher expenditures per resident,</u></li> <li>4. Slightly fewer home health agencies per capita,</li> <li>5. Higher caseloads (volume) within agencies (this is what drives the higher expenditures per agency.</li> </ol>	<p>“We used 2010-16 Medicare Cost Reports for 10,737 freestanding home health agencies (HHAs) to examine the impact of home health (HH) and nursing home (NH) certificate-of-need (CON) laws on HHA caseload, total and per-patient variable costs. After adjusting for other HHA characteristics, total costs were higher in states with only HH CON laws (\$2,975,698), only NH CON laws (\$1,768,097), and both types of laws (\$3,511,277), compared with no CON laws (\$1,538,536). Higher costs were driven by caseloads, as CON reduced per-patient costs. Additional research is needed to distinguish whether this is due to skimping on quality vs. economies of scale.”</p>
11.	<p>Thomas Stratmann and Matthew Baker, “Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis,” Mercatus Working Paper (Arlington, VA: Mercatus Center at George Mason University, July 29, 2020), <a href="https://www.mercatus.org/publications/healthcare/examining-certificate-need-laws-context-rural-health-crisis">https://www.mercatus.org/publications/healthcare/examining-certificate-need-laws-context-rural-health-crisis</a>.</p>	<p>They examine the effect of CON on two measures of spending and two measures of quality (all four are indicators of “overutilization or waste”):</p> <ol style="list-style-type: none"> <li>1. <u>Medicare spending per rural beneficiary (they found this was \$295 higher in CON states than in non-CON states)</u></li> <li>2. <u>Ambulance spending per beneficiary (\$2.54 higher in CON states)</u></li> <li>3. Hospital readmission rates (1.2 percentage points higher in CON states)</li> <li>4. Emergency room visits per 1,000 beneficiaries (35.1 more emergency department visits per 1,000 beneficiaries in CON states),</li> </ol>	<p>“To evaluate certificate-of-need (CON) laws in rural areas and their relationship with selected healthcare outcomes and with common measures of potentially avoidable spending, we regress county-level Medicare data and state-level all-patient spending and utilization data to compare healthcare outcomes and common measures of wasteful spending in rural states with and without CON laws. Results show that patients residing in counties restricted by CON laws spend more per Medicare beneficiary and have higher utilization rates in ambulance services, emergency departments, and readmissions, both before and after controlling for social risk factors such as race, education, and poverty status.”... “In the version of the model with full controls and all counties in rural states, CON is associated with \$295 higher spending, 1.2 percentage points higher readmission, 35.1 more emergency department visits per 1,000 beneficiaries, and \$2.54 higher ambulance spending per beneficiary.”</p>

## B. PAPERS FINDING CON HAS MIXED, INSIGNIFICANT, OR NEGLIGIBLE EFFECTS ON SPENDING PER PERSON

No.	Paper	Summary	Quote
1.	Frank A. Sloan, "Regulation and the Rising Cost of Hospital Care," <i>The Review of Economics and Statistics</i> 63, no. 4 (November 1, 1981): 479–87.	CON has no effect on hospital expenditures per admission, per patient day, or per adjusted patient day.	"The certificate-of-need coefficients imply CON has had no impact on costs."
2.	Christopher J. Conover and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," <i>Journal of Health Politics, Policy and Law</i> 23, no. 3 (June 1, 1998): 455–81.	CON has no effect on total per capita health expenditures; there is no evidence of a surge in spending after repeal.	"Mature CON programs are associated with a modest (5 percent) long-term reduction in acute care spending per capita, but not with a significant reduction in total per capita spending. There is no evidence of a surge in acquisition of facilities or in costs following removal of CON regulations."
3.	Vivian Ho, "Does Certificate of Need Affect Cardiac Outcomes and Costs?," <i>International Journal of Health Care Finance and Economics</i> 6, no. 4 (March 6, 2007): 300–324.	<p>The study assesses the effect of CON on cardiac costs and outcomes. She finds:</p> <ol style="list-style-type: none"> <li>1. <u>While CON is associated with lower average costs per patient, it also seems to be associated with more procedures and this is enough to offset the savings from lower average costs;</u></li> <li>2. CON is associated with greater volume within hospitals,</li> <li>3. CON does not seem to be related to inpatient mortality.</li> </ol>	"This study compares mortality rates and costs for cardiac care in states with and without CON. CON appears to raise hospital procedure volume and lower the average cost of care. However, CON is associated with little reduction in inpatient mortality, and it may lead hospitals to operate on more patients than they would otherwise." "However, the presence of minimum volume standards may lead hospitals in CON states to increase the number of procedures performed relative to states without CON. The predicted increases in the total number of procedures performed (41% for PTCA and 18% for CABG in the year 2000) are large enough to offset any potential savings resulting from lower average costs per patient treated as a result of CON regulation. These results are consistent with past research which has found CON regulations do not restrain expenditure growth."

4.	Fred J. Hellinger, "The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis," <i>The American Journal of Managed Care</i> 15, no. 10 (October 2009): 737–44.	CON is associated with fewer hospital beds, which in turn are associated with slower growth in aggregate health expenditures per capita. But there is no direct relationship between CON and health expenditures per capita.	"Certificate-of-need programs did not have a direct effect on healthcare expenditures. . . . Certificate-of-need programs have limited the growth in the supply of hospital beds, and this has led to a slight reduction in the growth of healthcare expenditures."
5.	Momotazur Rahman et al., "The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures," <i>Medical Care Research and Review: MCRR</i> 73, no. 1 (February 2016): 85–105.	CON increases the growth in Medicare and Medicaid expenditures on nursing home care but decreases growth in home healthcare expenditures.	"Compared with states without CON laws, Medicare and Medicaid spending in states with CON laws grew faster for nursing home care and more slowly for home health care."
6.	Christopher J. Conover and Frank A. Sloan, "Evaluation of Certificate of Need in Michigan. Volume II: Technical Appendices" (Raleigh, NC: Duke University Center for Health Policy, Law and Management, 2003).	Dropping CON has 0% effect on all expenditures.	No quotes available.

7.	Daniel Polsky et al., “The Effect of Entry Regulation in the Health Care Sector: The Case of Home Health,” <i>Journal of Public Economics</i> 110 (February 2014): 1–14.	<p>They assess the effect of CON on home health agencies, using a research design that focuses on markets that straddle CON and non-CON states. They find that:</p> <ol style="list-style-type: none"> <li>1. <u>Medicare expenditures are not statistically significantly different between CON and non-CON states;</u></li> <li>2. Non-CON states have roughly twice as many home health agencies per Medicare beneficiary,</li> <li>3. CON states have 13.7 percent fewer home health admissions from hospitals;</li> <li>4. 60 day (total) readmission rates are 5% higher in CON states than in non-CON states, but the effect is not sustained.</li> <li>5. 60 day preventable readmission rates are 13 percent higher in CON states than in non-CON states, but the effect is not sustained.</li> <li>6. In CON states there are fewer home health visits, fewer visits per week, and a lower proportion of visits by skilled nurses, but the effects are small and not statistically significant;</li> <li>7. The Herfindahl Index in the home health market is approximately 1,000 points lower in non-CON states;</li> </ol>	“We find that CON states use home health less frequently, but system-wide rehospitalization rates, overall Medicare expenditures, and home health practice patterns are similar.”
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**TABLE 3. STUDIES ASSESSING THE EFFECT OF CON ON EFFICIENCY**

<b>A. PAPERS FINDING CON IS ASSOCIATED WITH LOWER EFFICIENCY</b>			
No.	Paper	Summary	Quote
1.	B. Kelly Eakin, “Allocative Inefficiency in the Production of Hospital Services,” <i>Southern Economic Journal</i> 58, no. 1 (1991): 240–48.	CON hospitals are less efficient than non-CON hospitals.	“... hospitals subject to CON regulations have a greater measure of allocative inefficiency by .88 to 1.03 percentage points.”

2.	Jomon A. Paul, Huan Ni, and Aniruddha Bagchi, "A Study of the Effects of Certificate of Need Law on Inpatient Occupancy Rates," <i>Service Science</i> 11, no. 1 (March 1, 2019): 1–15, <a href="https://doi.org/10.1287/serv.2018.0228">https://doi.org/10.1287/serv.2018.0228</a> .	States with CON laws have lower bed occupancy rates. The authors speculate that while CON reduces the number of beds, it may also shorten the length of patient stay and the net effect is to reduce the occupancy rate. Note that this is the opposite of the intention (which was to reduce unused capacity).	"From a theoretical standpoint, CON can lead to a reduction in the number of beds as well as in the number of inpatient days (possibly by shortening the length of patient stay). However, these two effects impact inpatient occupancy rate in opposite directions. We test empirically to find out which of these two effects dominate. In this study, we investigate the impact of CON and its stringency...on the inpatient occupancy rate using panel data, and we find that, on average, CON legislation reduces occupancy rate in inpatient units."
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## B. PAPERS FINDING CON HAS MIXED, INCONCLUSIVE, OR NEGLIGIBLE EFFECTS ON EFFICIENCY

No.	Paper	Summary	Quote
1.	Anderson and Kass, "Certificate Of Need Regulation of Entry Into Home Health Care: A Multi-Product Cost Function Analysis."	<p>They examined the effect of CON on economies of scale and cost in the home health care industry. They found:</p> <ol style="list-style-type: none"> <li>1. Costs were 2 percent higher in CON states relative to non-CON states.</li> <li>2. No substantial economies of scale in the home health industry overall,</li> <li>3. <u>Nor did they find a difference in economies of scale in CON and non-CON states.</u></li> </ol>	"We also examined whether unrealized scale economies were smaller where Certificate of Need regulations were imposed than where entry was unrestricted. We found no differences in the extent of economies in the two cases. Thus, we have no evidence that CON regulation contributes to efficiency in the realization of scale economies... there was no significant difference in the degree to which firms in CON regulated markets and firms in unregulated markets achieved these economies (of scale). We therefore again failed to find a 'public interest' justification for CON regulation."

2.	Chi-Chang Chen, "Estimating Nursing Home Cost and Production Functions: Application of Stochastic Frontier Models for the Analysis of Efficiency," ProQuest Dissertations and Theses (Ph.D., New Orleans, LA, Tulane University, 2005), <a href="http://www.proquest.com/docview/305399421/abstract/F9AE5D67757C4ACAPQ/1">http://www.proquest.com/docview/305399421/abstract/F9AE5D67757C4ACAPQ/1</a> .	CON is associated with greater cost efficiency, but diminished technical efficiency.	"Technical efficiency appeared to be lower for nursing homes operated in a state where CON or moratorium regulations were in place. This observation is consistent with prior studies and confirmed that while CON/moratorium regulations might improve state Medicaid budget deficit, reduced market competition resulted from the regulations offered no incentives for nursing homes to become more technical or cost efficient. However, results from this study showed that these regulations had a positive effect on cost efficiency. It was actually observed to reduce cost inefficiency."
3.	Laurie J. Bates, Kankana Mukherjee, and Rexford E. Santerre, "Market Structure and Technical Efficiency in the Hospital Services Industry: A DEA Approach," Medical Care Research and Review 63, no. 4 (August 2006): 499–524, <a href="https://doi.org/10.1177/1077558706288842">https://doi.org/10.1177/1077558706288842</a> .	CON hospitals are not any less efficient than non-CON hospitals.	"Evidence also implies that the presence of a state certificate-of-need law was not associated with a greater degree of inefficiency in the typical metropolitan hospital services industry."

### C. PAPERS FINDING CON IS ASSOCIATED WITH GREATER EFFICIENCY

No.	Paper	Summary	Quote
1.	Gary D. Ferrier, Hervé Leleu, and Vivian Valdmanis, "The Impact of CON Regulation on Hospital Efficiency," Health Care Management Science 13, no. 1 (March 2010): 84–100.	CON hospitals are more efficient than non-CON hospitals.	"In general, we found that the hospital sector in states with active CON regulations performed better in terms of aggregate technical and mix efficiency, irrespective of the stringency or laxness of this oversight."

2.	Michael D. Rosko and Ryan L. Mutter, "The Association of Hospital Cost-Inefficiency With Certificate-of-Need Regulation," Medical Care Research and Review 71, no. 3 (January 22, 2014): 280–98.	CON hospitals are more efficient than non-CON hospitals.	"Average estimated cost-inefficiency was less in CON states (8.10%) than in non-CON states (12.46%)."
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**TABLE 4. STUDIES ASSESSING THE EFFECT OF CON ON INVESTMENT**

<b>A. PAPERS FINDING CON IS ASSOCIATED WITH MORE INVESTMENT</b>			
No.	Paper	Summary	Quote
1.	Fred J. Hellinger, "The Effect of Certificate-of-Need Legislation on Hospital Investment," Inquiry 13, no. 2 (1976): 187–93.	CON legislation induced hospitals to increase investments.	"The empirical results support the hypotheses that [CON] legislation has not significantly lowered hospital investment and that hospitals anticipated the effect of [CON] legislation by increasing investment in the period preceding the enactment of the legislation."
<b>B. PAPERS FINDING CON HAS MIXED, INSIGNIFICANT, OR NEGLIGIBLE EFFECTS ON INVESTMENT</b>			
No.	Paper	Summary	Quote
1.	David S. Salkever and Thomas W. Bice, "The Impact of Certificate-of-Need Controls on Hospital Investment," The Milbank Memorial Fund Quarterly. Health and Society 54, no. 2 (1976): 185–214.	CON does not decrease investment but does change its composition.	"CON did not reduce the total dollar volume of investment but altered its composition, retarding expansion in bed supplies but increasing investment in new services and equipment."

**TABLE 5. STUDIES ASSESSING THE EFFECT OF CON ON THE AVAILABILITY OF AND ACCESS TO SERVICES**

<b>A. PAPERS FINDING CON LIMITS ACCESS TO CARE</b>			
No.	Study	Summary	Quotes
1.	Paul L. Joskow, "The Effects of Competition and Regulation on Hospital Bed Supply and the Reservation Quality of the Hospital," <i>The Bell Journal of Economics</i> 11, no. 2 (1980): 421–47.	He assesses the effects of regulations on bed supply and the probability that a hospital will turn away patients. He finds that CON reduces bed supply by about 6 percent and makes it more likely that a hospital will turn away patients.	"For a hospital with an average daily census of 200, this implies that, on average, regulations of these types reduce the supply of beds by about 6 percent, other things equal."
2.	Jon M. Ford and David L. Kaserman, "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry," <i>Southern Economic Journal</i> 59, no. 4 (1993): 783–91, <a href="https://doi.org/10.2307/1059739">https://doi.org/10.2307/1059739</a> .	They assess the effect of CON on the number of dialysis clinics and stations, finding that it has limited new firm entry and total capacity.	"These results indicate that CON regulation has significantly retarded new firm entry and total capacity expansion in this industry, thereby restricting supply and fostering increased levels of industry concentration"
3.	Harrington et al., "The Effect of Certificate of Need and Moratoria Policy on Change in Nursing Home Beds in the United States."	In a two-stage least squares regression, they assess the effect of CON, and/or moratoria on the growth of nursing home beds and Medicaid nursing home reimbursement rates. They found: 1. CON had no effect on Medicaid nursing home reimbursement rates. 2. CON reduced growth of beds.	"States that had a certificate of need and/or moratorium did have significant reductions in the growth in nursing home beds but Medicaid nursing home reimbursement rates were not related to change in bed stock."



4.	J. L. Robinson et al., "Certificate of Need and the Quality of Cardiac Surgery," <i>American Journal of Medical Quality: The Official Journal of the American College of Medical Quality</i> 16, no. 5 (October 2001): 155–60.	<p>They examined the effect of CON elimination in PA (comparing it with NJ, which maintained CON):</p> <ol style="list-style-type: none"> <li>1. <u>On the number of open-heart surgery programs, which increased 25 percent following elimination of CON;</u></li> <li>2. The total volume of CABG surgeries which were unchanged following repeal,</li> <li>3. Provider volume, which shifted from programs that had been established before CON repeal to programs that were established after CON repeal, and</li> <li>4. Mortality rate, which was unchanged following repeal.</li> </ol>	"In the 3 years following the elimination of CON, the number of open-heart surgery programs increased 25%, yet there was no significant increase in the number of CABG surgeries performed. Quality, as measured by mortality rate, was not impacted by the real-location of the relatively stable CABG volume."
5.	Iona Popescu, Mary S. Vaughan-Sarrazin, and Gary E. Rosenthal, "Certificate of Need Regulations and Use of Coronary Revascularization After Acute Myocardial Infarction," <i>The Journal of the American Medical Association</i> 295, no. 18 (May 10, 2006): 2141–47.	<p>They studied access and quality outcomes in revascularization. They found that patients in CON states were:</p> <ol style="list-style-type: none"> <li>1. <u>Less likely to be admitted to hospitals offering revascularization,</u></li> <li>2. Less likely to undergo revascularization, and</li> <li>3. Had no difference in 30-day mortality rates relative to patients in non-CON states.</li> </ol>	"The 624,421 patients in states with certificate of need regulations were less likely to be admitted to hospitals with coronary revascularization services (321 573 [51.5%] vs 323 695 [62.8%]; $P < .001$ ) or to undergo revascularization at the admitting hospital (163 120 [26.1%] vs 163 877 [31.8%]; $P < .001$ ) than patients in states without certificates of need.... Patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with certificate of need regulations. However, differences in the availability and use of revascularization therapies were not associated with mortality."

6.	Vivian Ho et al., "Cardiac Certificate of Need Regulations and the Availability and Use of Revascularization Services," <i>American Heart Journal</i> 154, no. 4 (October 2007): 767–75.	<p>They study the association between cardiac CON regulations, availability of revascularization facilities, and revascularization rates, focusing on differences between the general population and the elderly and on differences between procedures (coronary artery bypass graft surgery (CABG) or a percutaneous coronary intervention (PCI)).</p> <p>They find that:</p> <ol style="list-style-type: none"> <li>1. <u>CON is associated with fewer hospitals offering CABG and PCI.</u></li> <li>2. CON has no effect on overall CABG utilization.</li> <li>3. CON is associated with 19.2 percent fewer PCIs per 1,000 elderly.</li> </ol>	<p>"Each year, the per capita number of hospitals performing CABG and PCI was higher in states without CON (3.7 per 100,000 elderly for CABG, 4.5 for PCI in 2002), compared with CON states (2.5 for CABG, 3.0 for PCI in 2002). Multivariate regressions that adjusted for market and population characteristics found no difference in CABG utilization rates between states with and without CON (<math>P = .7</math>). However, CON was associated with 19.2% fewer PCIs per 1000 elderly (<math>P = .01</math>), equivalent to 322,526 fewer PCIs for 1989 to 2002. Among most states that discontinued CON, the number of hospitals performing PCI rose in the mid 1990s, but there were no consistent trends in the number of hospitals performing CABG or in PCIs or CABGs per capita."</p>
7.	Marah N. Short, Thomas A. Aloia, and Vivian Ho, "Certificate of Need Regulations and the Availability and Use of Cancer Resections," <i>Annals of Surgical Oncology</i> 15, no. 7 (July 2008): 1837–45.	<p>They studied Medicare data on beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002.</p> <p>They found:</p> <ol style="list-style-type: none"> <li>1. <u>CON is associated with fewer hospitals per cancer incident for colectomy, rectal resection, and pulmonary lobectomy;</u></li> <li>2. CON has no effect on the number of procedures per cancer incident;</li> <li>3. CON was associated with greater hospital volume.</li> </ol>	<p>"The number of hospitals per cancer incident was lower in CON states versus non-CON states for colectomy (<math>P = .022</math>), rectal resection (<math>P = .026</math>), and pulmonary lobectomy (<math>P = .032</math>). Hospital volume was significantly higher in CON states versus non-CON states for colectomy (<math>P = .006</math>) and pulmonary lobectomy (<math>P = .043</math>). There were no differences between states with and without CON in the number of procedures per cancer incident."</p>

8.	Hellinger, "The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures."	<u>CON is associated with 10% fewer hospital beds</u> , which in turn is associated with slower growth in aggregate health expenditures per capita. But there is no direct relationship between CON and health expenditures per capita.	"Certificate-of-need laws have reduced the number of hospital beds by about 10%... Certificate-of-need programs did not have a direct effect on healthcare expenditures. . . . Certificate-of-need programs have limited the growth in the supply of hospital beds, and this has led to a slight reduction in the growth of health-care expenditures."
9.	Jonathan T. Kolstad, "Essays on Information, Competition and Quality in Health Care Provider Markets" (Ph.D. Dissertation, Boston, MA, Harvard University, 2009), <a href="https://healthpolicy.fas.harvard.edu/people/jonathan-kolstad">https://healthpolicy.fas.harvard.edu/people/jonathan-kolstad</a> .	He examined how the 1996 repeal of CON legislation in Pennsylvania affected the market for coronary artery bypass graft (CABG) surgery in the state, finding: 1. <u>The number of CABG facilities increased 46 percent and</u> 2. Surgeries were more likely to be performed by high quality surgeons.	"Within a few years after the repeal of CON legislation, the number of CABG facilities increased 46 percent. Consistent with theory, I show that entry led to a redistribution of surgeries from lower- to higher-quality surgeons. Under a reasonable set of assumptions, I find that the value of the improved outcomes due to this redistribution offset between 42 and 100 percent of the additional fixed costs incurred by new entrants." ... "about 11 additional patients per year survived CABG because of the share redistribution following CON repeal." The average CABG patient traveled 2.3 fewer miles following CON repeal."

10.	<p>Vivian Ho, Meei-Hsiang Ku-Goto, and James G Jollis, "Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON," Health Services Research 44, no. 2 Pt 1 (April 2009): 483–500, <a href="https://doi.org/10.1111/j.1475-6773.2008.00933.x">https://doi.org/10.1111/j.1475-6773.2008.00933.x</a>.</p>	<p>They use differences-in-differences regression analysis to compare states that dropped CON during the sample period with states that kept the regulation. They focused on coronary artery bypass graft surgery (CABG) and percutaneous coronary interventions (PCI). They found that in states that dropped CON:</p> <ol style="list-style-type: none"> <li>1. <u>The number of hospitals in the state performing CABG and PCI went up following repeal;</u></li> <li>2. Statewide procedural volume for CABG and PCI were unchanged;</li> <li>3. Mean hospital volume declined for both procedures, and</li> <li>4. Procedural CABG mortality declined after repeal, though the difference was not permanent</li> </ol>	<p>"States that dropped CON experienced lower CABG mortality rates relative to states that kept CON, although the differential is not permanent. No such mortality difference is found for PCI. Dropping CON is associated with more providers statewide and lower mean hospital volume for both CABG and PCI. However, statewide procedure counts remain the same.... We find no evidence that CON regulations are associated with higher quality CABG or PCI. Future research should examine whether the greater number of hospitals performing revascularization after CON removal raises expenditures due to the building of more facilities, or lowers expenditures due to enhanced price competition."</p>
11.	<p>David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, "Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery," American Economic Journal: Economic Policy 2, no. 1 (February 2010): 51–76.</p>	<p>They assess the 1996 repeal of CON in Pennsylvania on Coronary Artery Bypass Graft (CABG). They found:</p> <ol style="list-style-type: none"> <li>1. <u>Repeal of CON reduced travel distanced by 9 percent;</u></li> <li>2. There was no statistically significant effect on total volume following CON repeal;</li> <li>3. There were mixed results on scale; following CON repeal, fewer surgeries were performed by high-volume hospitals, but more were performed by high-volume surgeons.</li> <li>4. CON repeal led to a shift from standard quality to surgeons; and</li> <li>5. Incumbent hospital margins initially fell following repeal but these hospitals had regained profitability and were the most profitable by 2002.</li> </ol>	<p>Entry following CON repeal resulted in "a nine percent reduction in travel distance relative to the patient-weighted average travel distance prior to entry of 27 miles."</p>

12.	Mary S. Vaughan Sarrazin, Levent Bayman, and Peter Cram, "Trends during 1993-2004 in the Availability and Use of Revascularization after Acute Myocardial Infarction in Markets Affected by Certificate of Need Regulations," Medical Care Research and Review: MCRR 67, no. 2 (April 2010): 213-31, <a href="https://doi.org/10.1177/1077558709346565">https://doi.org/10.1177/1077558709346565</a> .	In a study design that exploits the fact that some markets cross boundaries between CON and non-CON states, they find: 1. <u>A greater increase in coronary artery bypass graft surgery programs in states that reduced CON regulation, and</u> 2. <u>No change in percutaneous coronary intervention (PCI) in states that reduced CON.</u>	"There was a greater rise in the number of CABG programs in markets with significant reduction in CON regulations during 1993-2004 compared with other markets, but CON reduction was not related to growth of PCI programs."
13.	Melissa D.A. Carlson et al., "Geographic Access to Hospice in the United States," Journal of Palliative Medicine 13, no. 11 (November 2010): 1331-38, <a href="https://doi.org/10.1089/jpm.2010.0209">https://doi.org/10.1089/jpm.2010.0209</a> .	This is a cross-sectional study of geographic access to U.S. hospices using multivariate logistic regression to identify gaps in hospice availability (measured by distance to hospice facilities) by community characteristics. CON was associated with longer travel distance to hospice care.	"Controlling for population density, the existence of CON policies was associated with more limited geographic access to hospice."
14.	Traci L Eichmann and Rexford E Santerre, "Do Hospital Chief Executive Officers Extract Rents from Certificate of Need Laws," Journal of Health Care Finance 37, no. 4 (January 1, 2011): 1-14.	They study the effects of CON on access and rents. They find CON is associated with 1. <u>12 percent fewer beds per capita,</u> 2. <u>48 percent fewer hospitals per capita, and</u> 3. <u>\$91,000 more in urban hospital CEO pay.</u>	"CON laws are shown to reduce the number of beds at the typical hospital by 12 percent, on average, and the number of hospitals per 100,000 persons by 48 percent. These reductions ultimately lead urban hospital CEOs in states with CON laws to extract economic rents of \$91,000 annually."

15.	<p>S. A. Lorch, P. Maheshwari, and O. Even-Shoshan, "The Impact of Certificate of Need Programs on Neonatal Intensive Care Units," <i>Journal of Perinatology: Official Journal of the California Perinatal Association</i> 32, no. 1 (January 2012): 39–44.</p>	<p>They studied NICU CONs. They found:</p> <ol style="list-style-type: none"> <li>1. <u>CON is associated with fewer units;</u></li> <li>2. <u>CON is associated with fewer beds;</u></li> <li>3. CON was unrelated to very low birth weight (VLBW) infant mortality and low birth weight (LBW) infant mortality.</li> <li>4. CON is associated with lower rates of all-infant mortality in states with a large metropolitan area.</li> </ol>	<p>"Absence of such programs was associated with more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and NICU beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation, and increased all-infant mortality rates in states with a large metropolitan area.... Mortality rates for VLBW or LBW infants were not significantly different between CON and non-CON states. However, for states with at least one large metropolitan area, states with CON legislation had significantly lower all infant mortality rates compared with states without CON legislation (0.54 fewer deaths/1000 births, 95% CI 0.02 to 1.06)."</p>
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16.	<p>Daniel Polsky et al., “The Effect of Entry Regulation in the Health Care Sector: The Case of Home Health,” <i>Journal of Public Economics</i> 110 (February 2014): 1–14. hospital readmission rates, and health care expenditures in states with and without Certificate of Need laws (CON</p>	<p>They assess the effect of CON on home health agencies, using a research design that focuses on markets that straddle CON and non-CON states. They find that:</p> <ol style="list-style-type: none"> <li>1. Medicare expenditures are not statistically significantly different between CON and non-CON states;</li> <li>2. <u>Non-CON states have roughly twice as many home health agencies per Medicare beneficiary.</u></li> <li>3. CON states have 13.7 percent fewer home health admissions from hospitals;</li> <li>4. 60 day (total) readmission rates are 5% higher in CON states than in non-CON states, but the effect is not sustained.</li> <li>5. 60 day readmission rates are 13 percent higher in CON states than in non-CON states, but the effect is not sustained.</li> <li>6. In CON states there are fewer home health visits, fewer visits per week, and a lower proportion of visits by skilled nurses, but the effects are small and not statistically significant;</li> <li>7. The Herfindahl Index in the home health market is approximately 1,000 points lower in non-CON states;</li> </ol>	<p>“We find that CON states use home health less frequently, but system-wide rehospitalization rates, overall Medicare expenditures, and home health practice patterns are similar.”</p>
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17.	<p>Thomas Stratmann and Jacob Russ, "Do Certificate-of-Need Laws Increase Indigent Care?," Working Paper (Arlington, VA: Mercatus Center at George Mason University, July 2014), <a href="http://mercatus.org/sites/default/files/Stratmann-Certificate-of-Need.pdf">http://mercatus.org/sites/default/files/Stratmann-Certificate-of-Need.pdf</a>.</p>	<p>They study the effects of CON on the supply of services and provision of services to indigent populations. They find:</p> <ol style="list-style-type: none"> <li>1. <u>CON programs are associated with 99 fewer hospitals per 100,000 people</u></li> <li>2. <u>Bed-specific CONs are associated with 131 fewer beds per 100,000 people</u></li> <li>3. <u>There are 4.7 fewer beds per 100,000 persons for each additional service covered by CON</u></li> <li>4. <u>CON programs reduce the number of hospitals with MRI machines by 1 to 2 hospitals per 500,000 people</u></li> <li>5. CON programs that require charitable care are uncorrelated with uncompensated care.</li> </ol>	<p>"Our evidence is consistent with previous studies in showing that CON programs are effective at restricting the supply of regulated medical services. It appears, however, that CON programs do not induce cross-subsidization.</p>
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18.	<p>Suhui Li and Avi Dor, “How Do Hospitals Respond to Market Entry? Evidence from a Deregulated Market for Cardiac Revascularization,” <i>Health Economics</i> 24, no. 8 (August 2015): 990–1008, <a href="https://doi.org/10.1002/hec.3079">https://doi.org/10.1002/hec.3079</a>.</p>	<p>Removal of CON was associated with:</p> <ol style="list-style-type: none"> <li>1. <u>A substantial increase in the number of hospitals performing cardiac revascularization procedures.</u></li> <li>2. An overall downward trend in CABG and an overall upward trend in the alternative procedure, PCI.</li> <li>3. Entry led to a significant increase in the likelihood of CABG, relative to trend, but it did not contribute to the increase in PCI after adjusting for patient traits, market characteristics, and area-specific trends.</li> <li>4. The probability of receiving PCI specifically at incumbent hospitals decreased with market entry, suggesting a volume shift from incumbents to entrants</li> <li>5. Entry shifted a disproportionate volume of low-severity patients from incumbent hospitals to entrants.</li> <li>6. Entry by new cardiac surgery centers tended to sort high-severity patients into the more invasive CABG procedure and low-severity patients into the less invasive PCI procedures, potentially improving quality of care.</li> </ol>	<p>“In this paper, we empirically examine the demand-augmenting, demand-redistribution, and risk-allocation effects of hospital entry by studying the cardiac revascularization markets in Pennsylvania, a state in which dynamic market entry occurred after repeal of CON in 1996. Results from interrupted time-series analyses indicate demand-augmenting effects for coronary artery bypass graft (CABG) and business-stealing effects for percutaneous coronary intervention (PCI) procedures: high entrant market share mitigated the declining incidence of CABG, but it had no significant effect on the rising trend in PCI use, among patients with coronary artery disease. We further find evidence that entry by new cardiac surgery centers tended to sort high-severity patients into the more invasive CABG procedure and low-severity patients into the less invasive PCI procedures. These findings underscore the importance of considering market-level strategic responses by hospitals when regulatory barriers are rescinded.”</p> <p>... “free entry improves the match between underlying medical risk and treatment intensity, potentially improving quality of care and hence being welfare enhancing.”</p>
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19.	<p>Thomas Stratmann and Christopher Koopman, "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community," Working Paper (Arlington, VA: Mercatus Center at George Mason University, February 18, 2016), <a href="http://mercatus.org/sites/default/files/Stratmann-Rural-Health-Care-v1.pdf">http://mercatus.org/sites/default/files/Stratmann-Rural-Health-Care-v1.pdf</a>.</p>	<p>They study the effect of CON on overall supply of services as well as rural supply of services. In particular, they find:</p> <ol style="list-style-type: none"> <li>1. <u>CON programs are associated with 30 percent fewer hospitals per 100,000 residents across the entire state.</u></li> <li>2. <u>ASC-specific CONs are correlated with 14 percent fewer total ASCs per 100,000 residents.</u></li> <li>3. CON programs are associated with 30 percent fewer rural hospitals per 100,000 rural residents.</li> <li>4. ASC-specific CONs are correlated with 13 percent fewer rural ASCs per 100,000 rural residents.</li> </ol>	<p>"We estimate that, when controlling for demographics and year-specific effects, the presence of a CON program is associated with 30 percent fewer total hospitals per 100,000 state population.... Moreover, we find 14 percent fewer total ASCs per 100,000 state population.... In particular, when controlling for demographics and year-specific effects, the presence of a CON program is associated with 30 percent (<math>1 - \exp(-.36)</math>) fewer rural hospitals per 100,000 rural population.... When controlling for demographics and year-specific effects, ASC-specific CON requirements are associated with 13 percent (<math>1 - \exp(-.135)</math>) fewer rural ASCs per 100,000 rural population</p>
20.	<p>Molly S. Myers and Kathleen M. Sheehan, "The Impact of Certificate of Need Laws on Emergency Department Wait Times," <i>Journal of Private Enterprise</i> 35, no. 1 (Spring 2020): 59–75.</p>	<p>They examine the effect of CON laws on wait times. They find CON programs:</p> <ol style="list-style-type: none"> <li>1. <u>Increase median wait times for medical examinations;</u></li> <li>2. <u>Increase wait times for pain medication administration;</u></li> <li>3. <u>Increase wait times for hospital admittance; and Increase wait times for hospital discharge.</u></li> </ol>	<p>"This paper empirically investigates how CON laws affect emergency department wait times and finds that CON laws have a statistically significant impact on increasing the median wait time for medical examination, pain medication administration, hospital admittance, and hospital discharge. These findings support the idea that movement toward a freer market for health care services through a reduction in CON laws could improve patient outcomes."</p>

21.	Matthew Mitchell, Thomas Stratmann, and James Bailey, "Raising the Bar: ICU Beds and Certificates of Need" (Arlington, VA: Mercatus Center at George Mason University, April 29, 2020), <a href="https://www.mercatus.org/publications/covid-19-crisis-response/raising-bar-icu-beds-and-certificates-need">https://www.mercatus.org/publications/covid-19-crisis-response/raising-bar-icu-beds-and-certificates-need</a> .	4. They studied the relationship between CON and projected ICU bed shortages over the course of the COVID-19 pandemic. They found that compared with non-CON states, in CON states, expected shortages were more than twice as likely and the shortages were about 9 times greater in per capita terms.	"We find that those states that require a CON for hospital beds are more than twice as likely to experience projected ICU bed shortages. On average, these states are expected to experience an ICU bed shortage of about 8,000 beds (about 9 beds per 10,000 residents). By contrast, states that do not require a CON for hospital beds are expected to experience an average shortage of about 114 ICU beds (about 1 bed per 10,000 residents). We also find that the temporary suspension of CON has no statistically significant relationship to ICU bed shortages."
22.	James B. Bailey, Thanh Lu, and Patrick Vogt, "Certificate of Need and Substance Use Treatment," SSRN Scholarly Paper (Rochester, NY: Social Science Research Network, December 29, 2020), <a href="https://doi.org/10.2139/ssrn.3757059">https://doi.org/10.2139/ssrn.3757059</a> .	They measure how CON affects the number of substance abuse facilities and beds per capita in a state, and the effect of CON on the forms of payment that treatment facilities accept. They find that CON reduces the acceptance of private insurance and Medicaid.	"CON has no statistically significant effect on the number of facilities, beds, or clients, and no significant effect on the acceptance of Medicare. However, it reduces the acceptance of private insurance by a statistically significant 1.85%, and the acceptance of Medicaid by a statistically significant 3.49%."

23.	<p>Susan L. Ettner et al., "Certificate of Need and the Cost of Competition in Home Healthcare Markets," <i>Home Health Care Services Quarterly</i> 39, no. 2 (June 2020): 51–64.</p>	<p>They examine the effects of home health agency CONs and nursing home CONs on home health agencies. They find that in states with home health agency CONs there are:</p> <ol style="list-style-type: none"> <li>5. Lower per patient expenditures (they don't know if this is due to skimping or to economies of scale);</li> <li>6. Higher expenditures per agency,</li> <li>7. Higher expenditures per resident,</li> <li>8. <u>Slightly fewer home health agencies per capita.</u></li> </ol> <p>Higher caseloads (volume) within agencies (this is what drives the higher expenditures per agency.</p>	<p>"We used 2010-16 Medicare Cost Reports for 10,737 freestanding home health agencies (HHAs) to examine the impact of home health (HH) and nursing home (NH) certificate-of-need (CON) laws on HHA caseload, total and per-patient variable costs. After adjusting for other HHA characteristics, total costs were higher in states with only HH CON laws (\$2,975,698), only NH CON laws (\$1,768,097), and both types of laws (\$3,511,277), compared with no CON laws (\$1,538,536). Higher costs were driven by caseloads, as CON reduced per-patient costs. Additional research is needed to distinguish whether this is due to skimping on quality vs. economies of scale."</p>
24.	<p>Matthew C. Baker and Thomas Stratmann, "Barriers to Entry in the Healthcare Markets: Winners and Losers from Certificate-of-Need Laws," <i>Socio-Economic Planning Sciences</i>, 2021, <a href="https://doi.org/10.1016/j.seps.2020.101007">https://doi.org/10.1016/j.seps.2020.101007</a>.</p>	<p>They examine the effect of medical imaging CONs on medical imaging providers. They find: CON laws are associated with 20 to 33 percent fewer providers; Residents of CON states are 3.4 to 5.3 percentage points more likely to travel out of state to obtain these services; CON laws are associated with 27-53 percent fewer scans by nonhospital providers per beneficiary, 23 to 70 percent fewer scans by new hospitals, and 6 to 21 percent more scans by holder hospitals</p>	<p>"Using Medicare claims data in 2013, we find that states with CON laws have 20 to 33% fewer providers, depending on the type of scanners to which the laws apply. As a result, residents of CON law states are 3.4–5.3 percentage points more likely to travel outside their home county to obtain imaging services than residents of non-CON states. In addition, there is a notable shift in the type of provider: CON laws are associated with 27–53% fewer scans by non-hospital providers per beneficiary, 23 to 70% fewer by new hospitals, but 6 to 21% more scans in older hospitals."</p>

25.	James Bailey and Eleanor Lewin, "Certificate of Need and Inpatient Psychiatric Services," <i>The Journal of Mental Health Policy and Economics</i> 24, no. 4 (December 1, 2021): 117–24.	<p>They examine the effect of psychiatric service CONs. They find that psychiatric service CONs:</p> <ol style="list-style-type: none"> <li>1. <u>Reduce the number of psychiatric hospitals by 20 percent;</u></li> <li>2. <u>Reduce the likelihood that a hospital will accept Medicare by 5.35 percentage points; and</u></li> <li>3. Reduce the number of psychiatric clients by 56 percent.</li> </ol>	<p>"We find that CON laws targeting psychiatric services are associated with a statistically significant 0.527 fewer psychiatric hospitals per million residents (20% fewer) and 2.19 fewer inpatient psychiatric clients per ten thousand residents (56% fewer). Psychiatric CON is also associated with psychiatric hospitals being 5.35 percentage points less likely to accept Medicare."</p>
26.	Matthew Mitchell and Thomas Stratmann, "The Economics of a Bed Shortage: Certificate-of-Need Regulation and Hospital Bed Utilization during the COVID-19 Pandemic," <i>Journal of Risk and Financial Management</i> 15, no. 1 (January 2022): 10, <a href="https://doi.org/10.3390/jrfm15010010">https://doi.org/10.3390/jrfm15010010</a> .	<p>They examine the effect of bed CON on statewide bed utilization rates and on individual hospital shortages. They find:</p> <ol style="list-style-type: none"> <li>1. States that require CONs for beds had 12 percent higher bed utilization rates;</li> <li>2. And 58 percent more days with more than 70% of their beds in use.</li> <li>3. Hospitals in these states were 27% more likely to run out of beds.</li> <li>4. States that relaxed these rules for COVID saw no difference in utilization rates or shortages.</li> </ol>	<p>We compare statewide bed utilization rates and hospital-level bed utilization rates in bed CON and non-bed CON states during the COVID-19 pandemic. Controlling for other possibly confounding factors, we find that states with bed CONs had 12 percent higher bed utilization rates and 58 percent more days in which more than 70 percent of their beds were used. Individual hospitals in bed CON states were 27 percent more likely to utilize all of their beds. States that relaxed CON requirements to make it easier for hospitals to meet the surge in demand did not experience any statistically significant decreases in bed utilization or number of days above 70 percent of capacity. Nor were hospitals in states that relaxed their CON requirements any less likely to use all their beds. Certificate-of-need laws seem to have exacerbated the risk of running out of beds during the COVID-19 pandemic. State efforts to relax these rules had little immediate effect on reducing this risk</p>

## B. PAPERS FINDING CON HAS MIXED, INSIGNIFICANT, OR NEGLIGIBLE EFFECTS ON ACCESS TO CARE

No.	Paper	Summary	Quotes
1.	Shihyun Noh and Catherine H. Brown, “Factors Associated with the Number of Substance Abuse Nonprofits in the U.S. States: Focusing on Medicaid Expansion, Certificate of Need, and Ownership,” <i>Nonprofit Policy Forum</i> 9, no. 2 (July 1, 2018), <a href="https://doi.org/10.1515/npf-2017-0010">https://doi.org/10.1515/npf-2017-0010</a> .	<ol style="list-style-type: none"> <li>1. CON laws are negatively associated with the number of nonprofit substance abuse facilities;</li> <li>2. But in states with both CON laws and Medicaid expansion, there were more nonprofit substance abuse facilities</li> </ol>	<p>“Certificate of Need (CON), that is, state regulation of new health services and facilities, can affect nonprofits’ responses to increased demand for substance abuse services. This study provides evidence that the number of nonprofit substance abuse facilities is negatively associated with state decisions to expand Medicaid and state regulation of new health services and facilities. However, in states with both Medicaid expansion and CON, the number of nonprofit substance abuse facilities tended to increase. In addition, evidence suggests that both nonprofit and for-profit substance abuse facilities are negatively influenced by Medicaid expansion and CON, but positively influenced by the interaction of Medicaid expansion and CON, government spending, racial diversity, median income, and uninsured rates.”</p>
2.	Joshua N. Herb et al., “Travel Time to Radiation Oncology Facilities in the United States and the Influence of Certificate of Need Policies,” <i>International Journal of Radiation Oncology, Biology, Physics</i> 109, no. 2 (February 1, 2021): 344–51.	<p>They measure the effect of CON on travel time to radiation oncology facilities, breaking down the effect by region. They find CON:</p> <ol style="list-style-type: none"> <li>1. Has no association with prolonged travel in the West;</li> <li>2. Is associated with lower odds of prolonged travel in both urban and rural tracts in the South;</li> <li>3. Is associated with increased odds of prolonged travel in both urban and rural tracts in the Midwest and Northeast.</li> </ol>	<p>“Presence of a CON law had no association with prolonged travel in the Western region, lower odds of prolonged travel in the Southern region for both rural and urban tracts, and higher likelihood of prolonged travel in the Midwest and Northeast Regions (Table 3) for both rural and urban tracts.”</p>

**TABLE 6. STUDIES ASSESSING THE EFFECT OF CON ON VOLUME**

<b>A. STUDIES FINDING CON IS ASSOCIATED WITH LIMITED VOLUME</b>			
No.	Paper	Summary	Quotes
1.	Iona Popescu, Mary S. Vaughan-Sarrazin, and Gary E. Rosenthal, "Certificate of Need Regulations and Use of Coronary Revascularization After Acute Myocardial Infarction," The Journal of the American Medical Association 295, no. 18 (May 10, 2006): 2141–47.	<p>They studied access and quality outcomes in revascularization. They found that patients in CON states were:</p> <ol style="list-style-type: none"> <li>1. Less likely to be admitted to hospitals offering revascularization,</li> <li>2. <u>Less likely to undergo revascularization, and</u></li> <li>3. Had no difference in 30-day mortality rates relative to patients in non-CON states.</li> </ol>	<p>"The 624,421 patients in states with certificate of need regulations were less likely to be admitted to hospitals with coronary revascularization services (321 573 [51.5%] vs 323 695 [62.8%]; <math>P&lt;.001</math>) or to undergo revascularization at the admitting hospital (163 120 [26.1%] vs 163 877 [31.8%]; <math>P&lt;.001</math>) than patients in states without certificates of need.... Patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with certificate of need regulations. However, differences in the availability and use of revascularization therapies were not associated with mortality."</p>
2.	Joseph S. Ross et al., "Certificate of Need Regulation and Cardiac Catheterization Appropriateness After Acute Myocardial Infarction," Circulation 115, no. 8 (February 27, 2007): 1012–19.	<p>They examine the effect of CON on the volume of cardiac catheterization after admission for acute myocardial infarction.</p> <p>In particular, however, they were interested in procedural volume under different levels of appropriateness (strongly, equivocally, or weakly indicated).</p> <p>While CON did not seem to decrease the volume of strongly-indicated catheterization, it did reduce the volume of equivocally and weakly indicated catheterization.</p> <p>Because their interest is both overall volume and rates of catheterization when it is not warranted, I am categorizing this in both the volume and the quality sections.</p>	<p>"After stratification by appropriateness, CON regulation was not associated with a significantly lower rate of catheterization among 63,823 patients with strong indications (49.9% versus 50.3%; adjusted RR 0.94, 95% confidence interval 0.86 to 1.02, <math>P0.17</math>). However, CON regulation was associated with significantly lower rates of catheterization among 65,077 patients with equivocal indication (45.0% versus 46.0%; adjusted RR 0.88, 95% confidence interval 0.78 to 1.00, <math>P0.05</math>) and among 8,379 patients with weak indications (19.8% versus 21.8%; adjusted RR 0.84, 95% confidence interval 0.71 to 0.98, <math>P0.04</math>). Associations were weakened substantially after adjustment for hospital coronary artery bypass graft surgery or cardiac catheterization capability."</p>

3.	<p>Daniel Polsky et al., “The Effect of Entry Regulation in the Health Care Sector: The Case of Home Health,” <i>Journal of Public Economics</i> 110 (February 2014): 1–14.</p>	<p>They assess the effect of CON on home health agencies, using a research design that focuses on markets that straddle CON and non-CON states. They find that:</p> <ol style="list-style-type: none"> <li>1. Medicare expenditures are not statistically significantly different between CON and non-CON states;</li> <li>2. Non-CON states have roughly twice as many home health agencies per Medicare beneficiary,</li> <li>3. <u>CON states have 13.7 percent fewer home health admissions from hospitals;</u></li> <li>4. 60 day (total) readmission rates are 5% higher in CON states than in non-CON states, but the effect is not sustained.</li> <li>5. 60 day readmission rates are 13 percent higher in CON states than in non-CON states, but the effect is not sustained.</li> <li>6. In CON states there are fewer home health visits, fewer visits per week, and a lower proportion of visits by skilled nurses, but the effects are small and not statistically significant;</li> <li>7. The Herfindahl Index in the home health market is approximately 1,000 points lower in non-CON states;</li> </ol>	<p>“We find that CON states use home health less frequently, but system-wide rehospitalization rates, overall Medicare expenditures, and home health practice patterns are similar.”</p>
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4.	Aaron J. Casp et al., “Certificate-of-Need State Laws and Total Hip Arthroplasty,” <i>The Journal of Arthroplasty</i> 34, no. 3 (March 2019): 401–7.	<p>They study the effect of CON on total hip arthroplasty. They find:</p> <ol style="list-style-type: none"> <li>1. CON is associated with a <u>lower volume of total hip arthroplasty.</u></li> <li>2. CON is associated with care in high-volume hospitals.</li> <li>3. No difference in postoperative complications.</li> </ol>	<p>“The per capita incidence of THA was higher in non-CON states than CON states at each time period and overall (<math>P &lt; .0001</math>). However, the rate of change in THA incidence over the time period was higher in CON states (1.0 per 10,000 per year) compared to non-CON states (0.68 per 10,000 per year) although not statistically significant. Length of stay was higher and a higher percentage of patients received care in high-volume hospitals in CON states (both <math>P &lt; .0001</math>). No meaningful differences in postoperative complications were found.”</p>
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5.	<p>Olivia A. Schultz, Lewis Shi, and Michael Lee, "Assessing the Efficacy of Certificate of Need Laws Through Total Joint Arthroplasty," <i>Journal for Healthcare Quality: Official Publication of the National Association for Healthcare Quality</i> 43, no. 1 (February 1, 2021): e1–7.</p>	<p>They examined the effect of CON on total knee, hip, and shoulder arthroplasty, finding:</p> <ol style="list-style-type: none"> <li>4. CON has no effect on the cost per procedure,</li> <li>5. <u>CON is associated with a lower volume of procedures, though it was not statistically significant in the case of hip arthroplasty, and</u></li> <li>6. CON has no statistically significant effect on complications (deep vein thrombosis and pulmonary embolism)</li> </ol>	<p>"The rate of TKA in patients diagnosed with arthritis in the knee was 12.3% (8,984/73,139) in CON states and 13.8% in non-CON states (6,612/47,744). Access was significantly greater in non-CON states (p , .0001). For THA, the rate was lower in CON states when compared with non-CON states with rates of 21.4% (4,843/22,608) and 21.9% (3,239/1,481), respectively; however, this difference was not statistically significant (p 5 .250). Similarly, TSA occurred at a decreased rate of 2.8% (683/24,675) in CON states compared with a rate of 3.2% (523/16,436) in non-CON states. This difference was statistically significant (p 5 .019).... The apparent nonsuperiority of CON states in achieving their purported goals may call into question the effectiveness of additional bureaucracy and regulation, suggesting a need for further examination.... One-year postoperatively, there were no significant differences in the rate of DVT [deep vein thrombosis] or PE [pulmonary embolism] after TKA, THA, or TSA in either study populations (p 5 .605, p 5 .713, p 5 .670)."</p>
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6.	Cancienne et al., “Certificate-of-Need Programs Are Associated with a Reduced Incidence, Expenditure, and Rate of Complications with Respect to Knee Arthroscopy in the Medicare Population.”	<p>They examine the effect of CON on knee arthroscopy, assessing its effect on:</p> <ol style="list-style-type: none"> <li>1. Charges and reimbursements: in t-tests without controls they found that charges (which are the prices set before any negotiation) were lower in CON states, while reimbursements (which are actual reimbursements) were not statistically significantly different.</li> <li>2. <u>Total volume: total volume and growth in total volume was lower in CON states than in non-CON states.</u></li> <li>3. Volume within facilities: CON is associated with the presence of more high-volume facilities, and</li> <li>4. Quality: There were more ER visits within 30 days of operation and more infections within 6 months of operation in CON than in non-CON states; there were no differences in in-hospital deaths or readmissions within 30 days of the operation between CON and non-CON states.</li> </ol>	<p>“the incidence of knee arthroscopy was significantly lower in CON states compared with non-CON states (<math>p &lt; 0.0001</math>). In addition, the rate of decrease in the incidence of knee arthroscopy over the period studied was significantly greater in CON states compared with non-CON states (<math>p &lt; 0.006</math>).”</p>
7.	James Bailey and Eleanor Lewin, “Certificate of Need and Inpatient Psychiatric Services,” Social Science Research Network working paper, 2021.	<p>They examine the effect of psychiatric service CONs. They find that psychiatric service CONs:</p> <ol style="list-style-type: none"> <li>1. Reduce the number of psychiatric hospitals by 20 percent,</li> <li>2. Reduce the likelihood that a hospital will accept Medicare by 5.35 percentage points; and</li> <li>3. <u>Reduce the number of psychiatric clients by 56 percent.</u></li> </ol>	<p>“We find that CON laws targeting psychiatric services are associated with a statistically significant 0.527 fewer psychiatric hospitals per million residents (20% fewer) and 2.19 fewer inpatient psychiatric clients per ten thousand residents (56% fewer). Psychiatric CON is also associated with psychiatric hospitals being 5.35 percentage points less likely to accept Medicare.”</p>

## B. PAPERS FINDING CON HAS MIXED, INSIGNIFICANT, OR NEGLIGIBLE EFFECTS ON VOLUME OF CARE

No.	Paper	Summary	Quotes
1.	Cutler, Huckman, and Kolstad, "Input Constraints and the Efficiency of	<p>They assess the 1996 repeal of CON in Pennsylvania on Coronary Artery Bypass Graft (CABG). They found:</p> <ol style="list-style-type: none"> <li>1. Repeal of CON reduced travel distanced by 9 percent;</li> <li>2. <u>There was no statistically significant effect on total volume following CON repeal;</u></li> <li>3. There were mixed results on scale; following CON repeal, fewer surgeries were performed by high-volume hospitals, but more were performed by high-volume surgeons.</li> <li>4. CON repeal led to a shift from standard quality to high-quality surgeons; and</li> <li>5. Incumbent hospital margins initially fell following repeal but these hospitals had regained profitability and were the most profitable by 2002.</li> </ol>	<p>"Relating CABG volume to a post-1996 indicator, state indicator variables, and a post-1996 Pennsylvania-specific indicator yields a coefficient on the differential impact in Pennsylvania after 1996 of -417 (standard error=2,234). In addition to being statistically insignificant, the estimated value of this coefficient is actually negative suggesting, if anything, a slightly greater decline in total CABG volume following the repeal of CON."</p>
2.	J. L. Robinson et al., "Certificate of Need and the Quality of Cardiac Surgery," <i>American Journal of Medical Quality: The Official Journal of the American College of Medical Quality</i> 16, no. 5 (October 2001): 155–60.	<p>They examined the effect of CON elimination in PA (comparing it with NJ, which maintained CON):</p> <ol style="list-style-type: none"> <li>1. On the number of open-heart surgery programs, which increased 25 percent following elimination of CON;</li> <li>2. <u>The total volume of CABG surgeries which were unchanged following repeal,</u></li> <li>3. Provider volume, which shifted from programs that had been established before CON repeal to programs that were established after CON repeal, and</li> <li>4. Mortality rate, which was unchanged following repeal.</li> </ol>	<p>"In the 3 years following the elimination of CON, the number of open-heart surgery programs increased 25%, yet there was no significant increase in the number of CABG surgeries performed. Quality, as measured by mortality rate, was not impacted by the real-location of the relatively stable CABG volume."</p>

3.	Vivian Ho et al., "Cardiac Certificate of Need Regulations and the Availability and Use of Revascularization Services," <i>American Heart Journal</i> 154, no. 4 (October 2007): 767–75.	<p>They study the association between cardiac CON regulations, availability of revascularization facilities, and revascularization rates, focusing on differences between the general population and the elderly and on differences between procedures (coronary artery bypass graft surgery (CABG) or a percutaneous coronary intervention (PCI)). They find that:</p> <ol style="list-style-type: none"> <li>1. CON is associated with fewer hospitals offering CABG and PCI,</li> <li>2. <u>CON has no effect on overall CABG utilization.</u></li> <li>3. CON is associated with 19.2 percent fewer PCIs per 1,000 elderly.</li> </ol>	<p>"Each year, the per capita number of hospitals performing CABG and PCI was higher in states without CON (3.7 per 100,000 elderly for CABG, 4.5 for PCI in 2002), compared with CON states (2.5 for CABG, 3.0 for PCI in 2002). Multivariate regressions that adjusted for market and population characteristics found no difference in CABG utilization rates between states with and without CON (<math>P = .7</math>). However, CON was associated with 19.2% fewer PCIs per 1000 elderly (<math>P = .01</math>), equivalent to 322,526 fewer PCIs for 1989 to 2002. Among most states that discontinued CON, the number of hospitals performing PCI rose in the mid 1990s, but there were no consistent trends in the number of hospitals performing CABG or in PCIs or CABGs per capita."</p>
4.	Marah N. Short, Thomas A. Aloia, and Vivian Ho, "Certificate of Need Regulations and the Availability and Use of Cancer Resections," <i>Annals of Surgical Oncology</i> 15, no. 7 (July 2008): 1837–45.	<p>They studied Medicare data on beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002.</p> <p>They found:</p> <ol style="list-style-type: none"> <li>1. CON is associated with fewer hospitals per cancer incident for colectomy, rectal resection, and pulmonary lobectomy;</li> <li>2. <u>CON has no effect on the number of procedures per cancer incident;</u></li> <li>3. CON was associated with greater hospital volume.</li> </ol>	<p>"The number of hospitals per cancer incident was lower in CON states versus non-CON states for colectomy (<math>P = .022</math>), rectal resection (<math>P = .026</math>), and pulmonary lobectomy (<math>P = .032</math>). Hospital volume was significantly higher in CON states versus non-CON states for colectomy (<math>P = .006</math>) and pulmonary lobectomy (<math>P = .043</math>). There were no differences between states with and without CON in the number of procedures per cancer incident."</p>

5.	Ho, Ku-Goto, and Jollis, "Certificate of Need (CON) for Cardiac Care."	<p>They use differences-in-differences regression analysis to compare states that dropped CON during the sample period with states that kept the regulation. They focused on coronary artery bypass graft surgery (CABG) and percutaneous coronary interventions (PCI). They found that in states that dropped CON:</p> <ol style="list-style-type: none"> <li>1. The number of hospitals in the state performing CABG and PCI went up following repeal;</li> <li>2. <u>Statewide procedural volume for CABG and PCI were unchanged;</u></li> <li>3. Mean hospital volume declined for both procedures, and</li> <li>4. Procedural CABG mortality declined after repeal, though the difference was not permanent</li> </ol>	<p>"States that dropped CON experienced lower CABG mortality rates relative to states that kept CON, although the differential is not permanent. No such mortality difference is found for PCI. Dropping CON is associated with more providers statewide and lower mean hospital volume for both CABG and PCI. However, statewide procedure counts remain the same.... We find no evidence that CON regulations are associated with higher quality CABG or PCI. Future research should examine whether the greater number of hospitals performing revascularization after CON removal raises expenditures due to the building of more facilities, or lowers expenditures due to enhanced price competition."</p>
6.	Elana C. Fric-Shamji and Mohammed F. Shamji, "Effect of US State Certificate of Need Regulation of Operating Rooms on Surgical Resident Training," Clinical and Investigative Medicine. Medecine Clinique Et Experimentale 33, no. 2 (April 1, 2010): E78.	<p>They evaluate the mean per capita rates of 26 diverse surgical procedures in 21 CON and 5 non-CON states between 2004 and 2006. The proportion of procedures performed in teaching facilities was also assessed. They found no significant difference in procedural rates between CON and non-CON states.</p>	<p>"States with CON laws did not differ significantly in procedural rates for any of the investigated surgical procedures; however, such regulation was associated with different trends in teaching center caseload, depending on the type of procedure. Complex procedures, such as Whipple operations (<math>p = 0.14</math>) or resection of acoustic neuroma (<math>p = 0.37</math>), underwent no redistribution. Conversely, common procedures that might have previously been performed in private settings, such as total hip replacement (<math>p = 0.003</math>) or mastectomy (<math>p = 0.01</math>), did occur more commonly in teaching facilities under CON regulation."</p>

7.	Browne et al., “Certificate-of-Need State Laws and Total Knee Arthroplasty.”	<p>They examined the effect of CON on total knee arthroplasty (TKA) by comparing states with and without CON programs. They looked at 4 factors:</p> <ol style="list-style-type: none"> <li>1. Average Medicare reimbursements were 5% to 10% lower in non-CON states,</li> <li>2. <u>CON was associated with lower TKA utilization per capita, but faster growth in utilization per capita.</u></li> <li>3. CON was associated with TKA in higher-volume hospitals,</li> <li>4. Examination of adverse events rates did not reveal any strong associations between any adverse outcome and CON status.</li> </ol>	“Although CON status was associated with lower per capita utilization of TKA, the annual incidence of TKA appears to have increased over time more rapidly in states with CON laws compared with non-CON states.”
8.	Tarik K. Yuce et al., “Association of State Certificate of Need Regulation With Procedural Volume, Market Share, and Outcomes Among Medicare Beneficiaries,” JAMA 324, no. 20 (November 24, 2020): 2058, <a href="https://doi.org/10.1001/jama.2020.21115">https://doi.org/10.1001/jama.2020.21115</a> .	<p>The assess the effect of CON on measures of volume and of quality. They found:</p> <ol style="list-style-type: none"> <li>1. <u>No significant difference between CON and non-CON states in county-level procedures per 10,000 persons.</u></li> <li>2. No significant difference between CON and non-CON states for hospital procedural volume,</li> <li>3. No difference in hospital market share,</li> <li>4. No difference in risk-adjusted 30-day postoperative mortality,</li> <li>5. No difference in surgical cite infection, and</li> <li>6. No difference in readmission</li> </ol>	“there were no significant differences found between states without and with certificate of need regulation for overall hospital procedural volume; hospital market share; county-level procedures per 10 000 persons; or risk-adjusted 30-day postoperative mortality, surgical site infection, or readmission.... Policy makers should consider reevaluating whether the current approach to certificate of need regulation is achieving the intended objectives and whether those objectives should be updated.”

### C. PAPERS THAT FIND CON IS ASSOCIATED WITH HIGHER VOLUME

No.	Paper	Summary	Quotes
1.	Abhinav Khanna et al., “Certificate of Need Programs, Intensity Modulated Radiation Therapy Use and the Cost of Prostate Cancer Care,” <i>The Journal of Urology</i> 189, no. 1 (January 2013): 75–79.	<p>The authors focus on intensity modulated radiation therapy. They find that:</p> <ol style="list-style-type: none"> <li>1. CON was not associated with any difference in cost growth</li> <li>2. <u>CON was associated with greater growth in intensity modulated radiation therapy</u></li> </ol>	<p>“While the use of IMRT as a proportion of all definitive treatments for localized prostate cancer (ie radical prostatectomy, IMRT, 3D-CRT and brachytherapy) increased dramatically during the study period in CON Yes (2.3% of all treatments in 2002, 46.4% in 2008 to 2009) and CON No (11.3% of all treatments in 2002, 41.7% in 2008 to 2009) regions, greater growth of IMRT use was observed in CON Yes (slope 0.403) vs CON No (slope 0.241) regions in adjusted analyses (p 0.001).... Certificate of need programs were not effective in limiting intensity modulated radiation therapy use or attenuating prostate cancer health care costs. There remains an unmet need to control the rapid adoption of new, more expensive therapies for prostate cancer that have limited cost and comparative effectiveness data.”</p>



2.	Ziino, Bala, and Cheng, "Utilization and Reimbursement Trends Based on Certificate of Need in Single-Level Cervical Discectomy."	<p>They studied inpatient cervical discectomy in CON and non-CON states in inpatient and outpatient setting. It appears that they did not use any controls, however.</p> <p>Regarding reimbursements, they find:</p> <ol style="list-style-type: none"> <li>1. In the inpatient setting, reimbursement was lower in non-CON states (\$1,128.40) than in the CON states (\$1,223.56). But reimbursements in the CON states were falling faster over time.</li> <li>2. In the outpatient setting reimbursement was higher in Non-CON states (\$4,237.01) than in CON states (\$3,859.31) and reimbursements were growing in the non-CON states but falling in the CON states.</li> </ol> <p>Regarding access:</p> <ol style="list-style-type: none"> <li>3. <u>In the inpatient setting, there were more patients in the CON setting than in the non-CON setting (657 compared with 231) and utilization of the procedure was growing faster in CON than in non-CON states but this does not appear to control for the larger population of CON states than non-CON states.</u></li> <li>4. <u>Similarly, in the outpatient setting, there were more patients in the CON setting than in the non-CON setting (435 compared with 257) and utilization of the procedure was growing faster in CON than in non-CON states but again this does not appear to control for the larger population of CON states than non-CON states.</u></li> </ol>	<p>We analyzed a private payer and Medicare database from 2007 to 2015. All single-level cervical discectomies were selected then split into CON and non-CON states. Each group was then further split into inpatient and outpatient. Utilization and reimbursement were analyzed using the compound annual growth rate (CAGR), with reimbursement adjusted by the US Bureau of Labor Statistics Consumer Price Index. Results: We identified 1,580 single level cervical decompressions in our study period: 888 were done in the inpatient setting, whereas 692 were done in the outpatient setting. Adjusted reimbursement only increased in the non-CON outpatient setting, with a CAGR of 2.0%. All other settings had decreased reimbursement. Utilization increased across all four settings, with the highest growth seen in the CON outpatient setting, with a CAGR of 12.7%. The highest average reimbursement was in the non-CON outpatient setting at \$4,237.</p>
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**TABLE 7. STUDIES ASSESSING THE EFFECT OF CON ON QUALITY OF CARE**

<b>A. PAPERS THAT FIND CON IS ASSOCIATED WITH LOWER QUALITY CARE</b>			
No.	Paper	Summary	Quotes
1.	S. M. Shortell and E. F. Hughes, "The Effects of Regulation, Competition, and Ownership on Mortality Rates Among Hospital Inpatients," <i>The New England Journal of Medicine</i> 318, no. 17 (April 28, 1988): 1100–1107, <a href="https://doi.org/10.1056/NEJM198804283181705">https://doi.org/10.1056/NEJM198804283181705</a> .	They examined the effect of CON (among other factors) on hospital quality, finding that the ratio of actual to predicted mortality rates among Medicare patients were 5 to 6 percent higher in state with stringent CON regulation.	"Hospitals in states with the most stringent procedures for reviewing applications for Certificate of Need had ratios of actual to predicted death rates that were 5 to 6 percent higher than those of hospitals with less stringent certificate-of-need procedures (p0.05)."
2.	J. S. Zinn, "Market Competition and the Quality of Nursing Home Care," <i>Journal of Health Politics, Policy and Law</i> 19, no. 3 (1994): 555–82.	She examined the determinants of nursing home quality. One of her explanatory variables was nursing home construction moratoria. She found these to be associated with lower RN staffing ratios and greater use of physical restraint.	"In markets where a moratorium on nursing home bed construction erects a barrier to new competitors, RN staffing tends to be lower and prevalence rates higher. The association is significant for the use of physical restraints and RN staffing level."
3.	Ho, Ku-Goto, and Jollis, "Certificate of Need (CON) for Cardiac Care."	<p>They use difference-in-difference regression analysis to compare states that dropped CON during the sample period with states that kept the regulation. They focused on coronary artery bypass graft surgery (CABG) and percutaneous coronary interventions (PCI). They found that in states that dropped CON:</p> <ol style="list-style-type: none"> <li>1. The number of hospitals in the state performing CABG and PCI went up following repeal;</li> <li>2. Statewide procedural volume for CABG and PCI were unchanged;</li> <li>3. Mean hospital volume declined for both procedures, and</li> <li>4. <u>Procedural CABG mortality declined after repeal, though the difference was not permanent</u></li> </ol>	"States that dropped CON experienced lower CABG mortality rates relative to states that kept CON, although the differential is not permanent. No such mortality difference is found for PCI. Dropping CON is associated with more providers statewide and lower mean hospital volume for both CABG and PCI. However, statewide procedure counts remain the same.... We find no evidence that CON regulations are associated with higher quality CABG or PCI. Future research should examine whether the greater number of hospitals performing revascularization after CON removal raises expenditures due to the building of more facilities, or lowers expenditures due to enhanced price competition."

4.	Kolstad, “Essays on Information, Competition and Quality in Health Care Provider Markets.”	<p>He examined how the 1996 repeal of CON legislation in Pennsylvania affected the market for coronary artery bypass graft (CABG) surgery in the state, finding:</p> <ol style="list-style-type: none"> <li>1. The number of CABG facilities increased 46 percent and</li> <li>2. <u>Surgeries were more likely to be performed by high quality surgeons.</u></li> </ol>	<p>“Within a few years after the repeal of CON legislation, the number of CABG facilities increased 46 percent. Consistent with theory, I show that entry led to a redistribution of surgeries from lower- to higher-quality surgeons. Under a reasonable set of assumptions, I find that the value of the improved outcomes due to this redistribution offset between 42 and 100 percent of the additional fixed costs incurred by new entrants.” ... “about 11 additional patients per year survived CABG because of the share redistribution following CON repeal.” The average CABG patient traveled 2.3 fewer miles following CON repeal.”</p>
5.	Cutler, Huckman, and Kolstad, “Input Constraints and the Efficiency of Entry.”	<p>They assess the 1996 repeal of CON in Pennsylvania on Coronary Artery Bypass Graft (CABG). They found:</p> <ol style="list-style-type: none"> <li>1. Repeal of CON reduced travel distanced by 9 percent;</li> <li>2. There was no statistically significant effect on total volume following CON repeal;</li> <li>3. There were mixed results on scale; following CON repeal, fewer surgeries were performed by high-volume hospitals, but more were performed by high-volume surgeons.</li> <li>4. <u>CON repeal led to a shift from standard quality to high-quality surgeons; and</u></li> <li>5. Incumbent hospital margins initially fell following repeal but these hospitals had regained profitability and were the most profitable by 2002.</li> </ol>	<p>“The reallocation associated with entry is thus equivalent to a 53 percent increase (relative to the mean) in share for high-quality surgeons in markets with positive entrant share less than 10 percent and a 44 percent increase for the same surgeons in markets with entrant share between 10 and 20 percent.”</p>

6.	<p>Aaron D. Falchook and Ronald C. Chen, "Association Between Certificate of Need Legislation and Radiation Therapy Use Among Elderly Patients With Early Cancers," <i>International Journal of Radiation Oncology, Biology, Physics</i> 91, no. 2 (February 1, 2015): 448–50, <a href="https://doi.org/10.1016/j.ijrobp.2014.10.033">https://doi.org/10.1016/j.ijrobp.2014.10.033</a>.</p>	<p>They examined utilization of radiation therapy when it is not warranted in CON and non-CON states, concluding that there is greater use of this treatment on elderly patients who may not need it in CON than in non-CON states.</p>	<p>High quality cancer care includes reducing overtreatment, a well-recognized problem for elderly patients with ductal carcinoma in situ (Stage 0) or Stage 1 breast cancer and low-risk prostate cancer. The federal Health Planning Resources Development Act of 1974 led to implementation of CON programs in multiple states. The stated purpose of CON is to facilitate coordinated health care services to reduce overall medical costs. We examined whether CON is associated with less radiotherapy (RT) use in elderly patients with Stage 0-1 breast cancer, and low-risk prostate cancer. <b>Methods:</b> We compared RT use in 6 Surveillance, Epidemiology and End Results (SEER) states with CON for radiotherapy vs. 6 states without CON for 1) men 65 years and older with low-risk prostate cancer, 2) women 70 years and older with Stage 0-1 breast cancer after lumpectomy. In both clinical scenarios, the use of RT is controversial. Patients diagnosed from 2004-2011 were included. <b>Results:</b> 40,267 men and 24,385 women were included. Radiotherapy use was higher in CON states: prostate cancer (64.3 vs. 56.0%, <math>p&lt;.001</math>), and breast cancer (59.5% vs. 53.6%, <math>p&lt;.001</math>) overall, and for each year studied (Table). RT use decreased from 2004 to 2011, but remains persistently higher in states with CON programs. On multivariate analysis controlling for age, race, stage and year, CON was associated with higher use in both prostate cancer (OR 1.46, <math>p&lt;.001</math>) and breast cancer (OR 1.35, <math>p&lt;.001</math>). <b>Conclusions:</b> There is more RT use in CON states for elderly patients who may not need this treatment for Stage 0-1 breast cancer and low-risk prostate cancer. This suggests that CON programs may not be effective in reducing overtreatment, an important quality of care issue in oncology.</p>
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7.	Li and Dor, "How Do Hospitals Respond to Market Entry?"	<p>Removal of CON was associated with:</p> <ol style="list-style-type: none"> <li>1. A substantial increase in the number of hospitals performing cardiac revascularization procedures,</li> <li>2. An overall downward trend in CABG and an overall upward trend in the alternative procedure, PCI.</li> <li>3. Entry led to a significant increase in the likelihood of CABG, relative to trend, but it did not contribute to the increase in PCI after adjusting for patient traits, market characteristics, and area-specific trends.</li> <li>4. The probability of receiving PCI specifically at incumbent hospitals decreased with market entry, suggesting a volume shift from incumbents to entrants</li> <li>5. Entry shifted a disproportionate volume of low-severity patients from incumbent hospitals to entrants.</li> <li>6. <u>Entry by new cardiac surgery centers tended to sort high-severity patients into the more invasive CABG procedure and low-severity patients into the less invasive PCI procedures, potentially improving quality of care.</u></li> </ol>	<p>"In this paper, we empirically examine the demand-augmenting, demand-redistribution, and risk-allocation effects of hospital entry by studying the cardiac revascularization markets in Pennsylvania, a state in which dynamic market entry occurred after repeal of CON in 1996. Results from interrupted time-series analyses indicate demand-augmenting effects for coronary artery bypass graft (CABG) and business-stealing effects for percutaneous coronary intervention (PCI) procedures: high entrant market share mitigated the declining incidence of CABG, but it had no significant effect on the rising trend in PCI use, among patients with coronary artery disease. We further find evidence that entry by new cardiac surgery centers tended to sort high-severity patients into the more invasive CABG procedure and low-severity patients into the less invasive PCI procedures. These findings underscore the importance of considering market-level strategic responses by hospitals when regulatory barriers are rescinded."</p> <p>... "free entry improves the match between underlying medical risk and treatment intensity, potentially improving quality of care and hence being welfare enhancing."</p>
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8.	<p>Thomas Stratmann and David Wille, "Certificate of Need Laws and Hospital Quality," Mercatus Working Paper (Arlington, VA: Mercatus Center at George Mason University, September 2016).</p>	<p>The study the effect of CON 9 measures of hospital quality:</p> <ol style="list-style-type: none"> <li>1. Death among surgical inpatients with serious treatable complications</li> <li>2. Postoperative pulmonary embolism or deep vein thrombosis</li> <li>3. Percent of patients giving their hospital a 9 or 10 overall rating</li> <li>4. Pneumonia readmission rate</li> <li>5. Pneumonia mortality rate</li> <li>6. Heart failure readmission rate</li> <li>7. Heart failure mortality rate</li> <li>8. Heart attack readmission rate</li> <li>9. Heart attack mortality rate</li> </ol> <p>Hospitals in CON states performed worse than those in non-CON states in 8 of the 9 categories, the exception being postoperative pulmonary embolism.</p>	<p>"Analyzing nine quality indicators and estimating the effect of CON laws on the basis of only how hospital quality varies within the same healthcare market, we find no evidence that CON laws increase the quality of care. Instead, we find evidence consistent with the hypothesis that limiting entry results in lower hospital quality."</p>
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9.	Robert L. Ohsfeldt and Pengxiang Li, "State Entry Regulation and Home Health Agency Quality Ratings," <i>Journal of Regulatory Economics</i> 53, no. 1 (2018): 1–19.	<p>They examine the effect of CON on home health agency quality ratings from the Centers for Medicare and Medicaid Services (CMS). They find that:</p> <ol style="list-style-type: none"> <li>1. HHAs in CON states were about 58% less likely to be rated as High quality ( <math>p &lt; .01</math>).</li> <li>2. HHAs in CON states also were about 30% more likely to be rated as "Medium" quality compared to HHAs in states without CON for HHAs.</li> </ol>	<p>"We assessed the impact of state CON programs for HHAs, and for potential substitute service providers, on quality ratings for HHAs. HHA quality ratings were obtained from the Home Health Compare database developed by the Centers for Medicare and Medicaid Services (CMS) for the last quarter of 2010 through the last quarter of 2013. The HHA-level data were augmented with county-level area characteristics for each HHA in the CMS database. An ordered logit model was used to estimate the association between state CON restrictions and Low, Medium, and High quality categories, adjusted for HHA and area characteristics. The results indicated that HHAs in states with CON for HHAs were less likely to have High quality ratings, and more likely to have Medium quality ratings, compared to agencies in states without CON for home health....</p> <p>26.1% of HHAs in states without CON for HHAs were rated in the High quality category, compared to 10.8% of HHAs in states with CON for HHAs. Thus, HHAs in CON states were about 58% less likely to be rated as High quality ( <math>p &lt; .01</math> ). HHAs in CON states also were about 30% more likely to be rated as "Medium" quality compared to HHAs in states without CON for HHAs.</p>
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10.	Stratmann and Baker, "Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis."	<p>They examine the effect of CON on two measures of spending and two measures of quality (all four are indicators of "overutilization or waste"):</p> <ol style="list-style-type: none"> <li>1. Medicare spending per rural beneficiary (they found this was \$295 higher in CON states than in non-CON states)</li> <li>2. Ambulance spending per beneficiary (\$2.54 higher in CON states)</li> <li>3. <u>Hospital readmission rates (1.2 percentage points higher in CON states)</u></li> <li>4. <u>Emergency room visits per 1,000 beneficiaries (35.1 more emergency department visits per 1,000 beneficiaries in CON states),</u></li> </ol>	<p>"To evaluate certificate-of-need (CON) laws in rural areas and their relationship with selected healthcare outcomes and with common measures of potentially avoidable spending, we regress county-level Medicare data and state-level all-patient spending and utilization data to compare healthcare outcomes and common measures of wasteful spending in rural states with and without CON laws. Results show that patients residing in counties restricted by CON laws spend more per Medicare beneficiary and have higher utilization rates in ambulance services, emergency departments, and readmissions, both before and after controlling for social risk factors such as race, education, and poverty status."... "In the version of the model with full controls and all counties in rural states, CON is associated with \$295 higher spending, 1.2 percentage points higher readmission, 35.1 more emergency department visits per 1,000 beneficiaries, and \$2.54 higher ambulance spending per beneficiary."</p>
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11.	Bingxiao Wu et al., “Entry Regulation and the Effect of Public Reporting: Evidence from Home Health Compare,” <i>Health Economics</i> 28, no. 4 (April 2019): 492–516.	<p>They assess the effect of CON regulation on several measures of quality, using a cross-border design to control for endogeneity. They find that CON is uniformly associated with worse outcomes including:</p> <ol style="list-style-type: none"> <li>1. patients perform worse on functional improvement measures (bathing, ambulating, transferring to bed, managing oral medication, and less pain interfering with activity) and</li> <li>2. They are more likely to be admitted to the ER and</li> <li>3. More likely to be admitted to an acute care hospital.</li> </ol>	<p>“We find that home health agencies in non-CON states improved quality under public reporting significantly more than agencies in CON states. Because home health care is a labor-intensive and capital-light industry, the state CON law is a major barrier for new firms to enter.... Overall, quality improvement is more pronounced in non-CON states than in CON states, and the results are robust across different specifications. The increase in the reported functional improvement score was 1.4 percentage points higher in non-CON states than in CON states. This corresponds to a 2.9% further increase from the pre-HHC average level of the functional status improvement rate (0.49). Similar effects are observed for the reduction of emergency department visit and hospitalization rate, as well as the increase in unreported functional improvement score.”</p>
12.	Bichaka Fayissa et al., “Certificate-Of-Need Regulation and Healthcare Service Quality: Evidence from the Nursing Home Industry,” <i>Healthcare (Basel, Switzerland)</i> 8, no. 4 (October 23, 2020): E423, <a href="https://doi.org/10.3390/healthcare8040423">https://doi.org/10.3390/healthcare8040423</a> .	<p>In an IV study, they find that CON is associated with:</p> <ol style="list-style-type: none"> <li>1. <u>18 to 24 percent lower nursing home survey scores computed by healthcare professionals, and</u></li> <li>2. <u>The substitution of lower-quality certified nursing assistance care for higher-quality licensed practical nurse care</u></li> </ol>	<p>“Instrumental variables results indicate that health survey scores for nursing homes that are computed by healthcare professionals are about 18–24% lower, depending on the type of nursing home under consideration, in states with CON regulation. We also find that the presence of CON regulation leads to a substitution of lower-quality certified nursing assistant care for higher-quality licensed practical nurse care, regardless of the type of nursing home under consideration.”</p>

13.	Sriparna Ghosh, Agnitra Roy Choudhury, and Alicia Plemmons, "Certificate-of-Need Laws and Healthcare Utilization During COVID-19 Pandemic," SSRN Scholarly Paper (Rochester, NY: Social Science Research Network, July 29, 2020), <a href="https://doi.org/10.2139/ssrn.3663547">https://doi.org/10.2139/ssrn.3663547</a>	They examined the relationship between CON and mortality associated with illnesses that require similar medical equipment as COVID. They find that: 1. There are higher mortality rates in CON states than in non-CON states; and 2. States with high healthcare utilization that reformed their CON laws during the pandemic saw lower mortality rates resulting from natural death, septicemia, diabetes, chronic lower respiratory disease, influenza or pneumonia, Alzheimer's, and COVID.	"Our investigation primarily focuses on mortality caused by COVID and non-COVID related reasons, and in understanding how these laws affect access to healthcare for illnesses that might require similar medical equipment. Our baseline results suggest that mortality rates are higher in states with CON laws relative to that in states without any CON laws. Furthermore, states with high healthcare utilization due to COVID that reformed their CON laws during the pandemic saw a significant reduction in mortality resulting from natural death, Septicemia, Diabetes, Chronic Lower Respiratory Disease, Influenza or Pneumonia, and Alzheimer's Disease in addition to reduction in COVID deaths."
14.	Kevin Chiu, "The Impact of Certificate of Need Laws on Heart Attack Mortality: Evidence from County Borders," <i>Journal of Health Economics</i> , 2021, <a href="https://doi.org/10.2139/ssrn.3678714">https://doi.org/10.2139/ssrn.3678714</a> .	He uses a cross-border discontinuity design to study the effect of CON on heart attack mortality. He finds that it is associated with 6 to 10 percent higher mortality three years after enactment.	"To estimate the net effect of CON regulations, I use a border discontinuity design to measure within-regional heart attack mortality spanning 1968 to 1982. I estimate that CON regulations led to an increase in heart attack deaths, by 6%-10%, three years after the policy was enacted."

## B. PAPERS FINDING CON HAS MIXED, INSIGNIFICANT, OR NEGLIGIBLE EFFECTS ON QUALITY OF CARE

No.	Paper	Summary	Quotes
1.	J. L. Robinson et al., "Certificate of Need and the Quality of Cardiac Surgery," <i>American Journal of Medical Quality: The Official Journal of the American College of Medical Quality</i> 16, no. 5 (October 2001): 155–60.	They examined the effect of CON elimination in PA (comparing it with NJ, which maintained CON): 1. On the number of open-heart surgery programs, which increased 25 percent following elimination of CON; 2. The total volume of CABG surgeries which were unchanged following repeal, 3. Provider volume, which shifted from programs that had been established before CON repeal to programs that were established after CON repeal, and 4. <u>Mortality rate, which was unchanged following repeal.</u>	"In the 3 years following the elimination of CON, the number of open-heart surgery programs increased 25%, yet there was no significant increase in the number of CABG surgeries performed. Quality, as measured by mortality rate, was not impacted by the real-location of the relatively stable CABG volume."

2.	Vivian Ho, "Certificate of Need, Volume, and Percutaneous Transluminal Coronary Angioplasty Outcomes," American Heart Journal 147, no. 3 (March 2004): 442–48.	<p>She compares Florida, where there is a CON for percutaneous transluminal coronary angioplasty (PTCA) with California, where there is no such CON. She finds: s</p> <ol style="list-style-type: none"> <li>1. CON is associated with higher in-hospital volume for PTCA</li> <li>2. <u>There is a positive relationship between PTCA volume and mortality outcomes (though note that she does not directly study the relationship between CON and PTCA mortality outcomes).</u></li> </ol>	"Florida CON laws were associated with higher average PTCA volumes relative to California hospitals, where no such laws exist. Because a higher PTCA volume was associated with moderately better outcomes, CON may be marginally effective in improving outcomes for PTCA."
3.	Iona Popescu, Mary S. Vaughan-Sarrazin, and Gary E. Rosenthal, "Certificate of Need Regulations and Use of Coronary Revascularization After Acute Myocardial Infarction," The Journal of the American Medical Association 295, no. 18 (May 10, 2006): 2141–47.	<p>They studied access and quality outcomes in revascularization. They found that patients in CON states:</p> <ol style="list-style-type: none"> <li>3. Were less likely to be admitted to hospitals offering revascularization,</li> <li>4. Were less likely to undergo revascularization, and</li> <li>5. <u>Had no difference in 30-day mortality rates relative to patients in non-CON states.</u></li> </ol>	"The 624,421 patients in states with certificate of need regulations were less likely to be admitted to hospitals with coronary revascularization services (321 573 [51.5%] vs 323 695 [62.8%]; $P<.001$ ) or to undergo revascularization at the admitting hospital (163 120 [26.1%] vs 163 877 [31.8%]; $P<.001$ ) than patients in states without certificates of need.... Patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with certificate of need regulations. However, differences in the availability and use of revascularization therapies were not associated with mortality."
4.	Verdi J. DiSesa et al., "Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery: An Analysis Using the Society of Thoracic Surgeons' National Cardiac Surgery Database," Circulation 114, no. 20 (November 14, 2006): 2122–29.	<p>They study CON, volume, and mortality in coronary artery bypass grafting (CABG). They find:</p> <ol style="list-style-type: none"> <li>1. CON is positively associated with CABG volume within hospitals, and</li> <li>2. <u>There is no direct relationship between CON and mortality.</u></li> </ol>	"CON states have significantly higher hospital CABG surgery volumes but similar mortality compared with non-CON states. CON regulation alone is not a sufficient mechanism to ensure quality of care for CABG surgery."

5.	Vivian Ho, "Does Certificate of Need Affect Cardiac Outcomes and Costs?," <i>International Journal of Health Care Finance and Economics</i> 6, no. 4 (March 6, 2007): 300–324.	<p>The study assesses the effect of CON on cardiac costs and outcomes. She finds:</p> <ol style="list-style-type: none"> <li>1. While CON is associated with lower average costs per patient, it also seems to be associated with more procedures and this is enough to offset the savings from lower average costs;</li> <li>2. CON is associated with greater volume within hospitals,</li> <li>3. <u>CON does not seem to be related to inpatient mortality.</u></li> </ol>	<p>"This study compares mortality rates and costs for cardiac care in states with and without CON. CON appears to raise hospital procedure volume and lower the average cost of care. However, CON is associated with little reduction in inpatient mortality, and it may lead hospitals to operate on more patients than they would otherwise." "However, the presence of minimum volume standards may lead hospitals in CON states to increase the number of procedures performed relative to states without CON. The predicted increases in the total number of procedures performed (41% for PTCA and 18% for CABG in the year 2000) are large enough to offset any potential savings resulting from lower average costs per patient treated as a result of CON regulation. These results are consistent with past research which has found CON regulations do not restrain expenditure growth."</p>
6.	S. A. Lorch, P. Maheshwari, and O. Even-Shoshan, "The Impact of Certificate of Need Programs on Neonatal Intensive Care Units," <i>Journal of Perinatology: Official Journal of the California Perinatal Association</i> 32, no. 1 (January 2012): 39–44.	<p>They studied NICU CONs. They found:</p> <ol style="list-style-type: none"> <li>1. CON is associated with fewer units;</li> <li>2. CON is associated with fewer beds;</li> <li>3. <u>CON was unrelated to very low birth weight (VLBW) infant mortality and low birth weight (LBW) infant mortality.</u></li> <li>4. CON is associated with lower rates of all-infant mortality in states with a large metropolitan area.</li> </ol>	<p>"Absence of such programs was associated with more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and NICU beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation, and increased all-infant mortality rates in states with a large metropolitan area.... Mortality rates for VLBW or LBW infants were not significantly different between CON and non-CON states. However, for states with at least one large metropolitan area, states with CON legislation had significantly lower all infant mortality rates compared with states without CON legislation (0.54 fewer deaths/1000 births, 95% CI 0.02 to 1.06)."</p>

7.	<p>Daniel Polsky et al., “The Effect of Entry Regulation in the Health Care Sector: The Case of Home Health,” <i>Journal of Public Economics</i> 110 (February 2014): 1–14.</p>	<p>They assess the effect of CON on home health agencies, using a research design that focuses on markets that straddle CON and non-CON states. They find that:</p> <ol style="list-style-type: none"> <li>1. Medicare expenditures are not statistically significantly different between CON and non-CON states;</li> <li>2. Non-CON states have roughly twice as many home health agencies per Medicare beneficiary,</li> <li>3. CON states have 13.7 percent fewer home health admissions from hospitals;</li> <li>4. <u>60 day (total) readmission rates are 5% higher in CON states than in non-CON states, but the effect is not sustained.</u></li> <li>5. <u>60 day readmission rates are 13 percent higher in CON states than in non-CON states, but the effect is not sustained.</u></li> <li>6. <u>In CON states there are fewer home health visits, fewer visits per week, and a lower proportion of visits by skilled nurses, but the effects are small and not statistically significant;</u></li> <li>7. The Herfindahl Index in the home health market is approximately 1,000 points lower in non-CON states;</li> </ol>	<p>“We find that CON states use home health less frequently, but system-wide rehospitalization rates, overall Medicare expenditures, and home health practice patterns are similar.”</p>
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8.	Browne et al., "Certificate-of-Need State Laws and Total Knee Arthroplasty."	<p>They examined the effect of CON on total knee arthroplasty (TKA) by comparing states with and without CON programs. They looked at 4 factors:</p> <ol style="list-style-type: none"> <li>1. Average Medicare reimbursements were 5% to 10% lower in non-CON states,</li> <li>2. CON was associated with lower TKA utilization per capita, but faster growth in utilization per capita.</li> <li>3. CON was associated with TKA in higher-volume hospitals,</li> <li>4. <u>Examination of adverse events rates did not reveal any strong associations between any adverse outcome and CON status.</u></li> </ol>	"Examination of adverse events rates did not reveal any strong associations between any adverse outcome and CON status."
9.	James Bailey, "The Effect of Certificate of Need Laws on All-Cause Mortality," <i>Health Services Research</i> 53, no. 1 (February 2018): 49–62.	He uses fixed- and random-effects regressions to test how the scope of state Certificate of Need laws affects all-cause mortality within US counties. Though he finds a positive relationship between CON laws and all-cause mortality, the results are not statistically significant.	"Certificate of Need laws have no statistically significant effect on all-cause mortality. Point estimates indicate that if they have any effect, they are more likely to increase mortality than decrease it."
10.	Aaron J. Casp et al., "Certificate-of-Need State Laws and Total Hip Arthroplasty," <i>The Journal of Arthroplasty</i> 34, no. 3 (March 2019): 401–7.	<p>They study the effect of CON on total hip arthroplasty. They find:</p> <ol style="list-style-type: none"> <li>1. CON is associated with a lower volume of total hip arthroplasty.</li> <li>2. CON is associated with care in high-volume hospitals.</li> <li>3. <u>No difference in postoperative complications between CON and non-CON states.</u></li> </ol>	"The per capita incidence of THA was higher in non-CON states than CON states at each time period and overall ( $P < .0001$ ). However, the rate of change in THA incidence over the time period was higher in CON states (1.0 per 10,000 per year) compared to non-CON states (0.68 per 10,000 per year) although not statistically significant. Length of stay was higher and a higher percentage of patients received care in high-volume hospitals in CON states (both $P < .0001$ ). No meaningful differences in postoperative complications were found."

11.	Yuce et al., “Association of State Certificate of Need Regulation With Procedural Volume, Market Share, and Outcomes Among Medicare Beneficiaries.”	<p>The assess the effect of CON on measures of volume and of quality. They found:</p> <ol style="list-style-type: none"> <li>1. No difference in county-level procedures per 10,000 persons,</li> <li>2. No significant difference between CON and non-CON states for hospital procedural volume,</li> <li>3. No difference in hospital market share,</li> <li>4. <u>No difference in risk-adjusted 30-day postoperative mortality,</u></li> <li>5. <u>No difference in surgical cite infection, and</u></li> <li>6. <u>No difference in readmission</u></li> </ol>	<p>“there were no significant differences found between states without and with certificate of need regulation for overall hospital procedural volume; hospital market share; county-level procedures per 10 000 persons; or risk-adjusted 30-day postoperative mortality, surgical site infection, or readmission.... Policy makers should consider reevaluating whether the current approach to certificate of need regulation is achieving the intended objectives and whether those objectives should be updated.”</p>
12.	Olivia A. Schultz, Lewis Shi, and Michael Lee, “Assessing the Efficacy of Certificate of Need Laws Through Total Joint Arthroplasty,” Journal for Healthcare Quality: Official Publication of the National Association for Healthcare Quality 43, no. 1 (February 1, 2021): e1–7.	<p>They examined the effect of CON on total knee, hip, and shoulder arthroplasty, finding:</p> <ol style="list-style-type: none"> <li>7. CON has no effect on the cost per procedure,</li> <li>8. CON is associated with a lower volume of procedures, though it was not statistically significant in the case of hip arthroplasty, and</li> <li>9. <u>CON has no statistically significant effect on complications (deep vein thrombosis and pulmonary embolism)</u></li> </ol>	<p>“The rate of TKA in patients diagnosed with arthritis in the knee was 12.3% (8,984/73,139) in CON states and 13.8% in non-CON states (6,612/47,744). Access was significantly greater in non-CON states (p , .0001). For THA, the rate was lower in CON states when compared with non-CON states with rates of 21.4% (4,843/22,608) and 21.9% (3,239/1,481), respectively; however, this difference was not statistically significant (p 5 .250). Similarly, TSA occurred at a decreased rate of 2.8% (683/24,675) in CON states compared with a rate of 3.2% (523/16,436) in non-CON states. This difference was statistically significant (p 5 .019).... The apparent nonsuperiority of CON states in achieving their purported goals may call into question the effectiveness of additional bureaucracy and regulation, suggesting a need for further examination.... One-year postoperatively, there were no significant differences in the rate of DVT [deep vein thrombosis] or PE [pulmonary embolism] after TKA, THA, or TSA in either study populations (p 5 .605, p 5 .713, p 5 .670).”</p>

## C. PAPERS FINDING CON IS ASSOCIATED WITH HIGHER QUALITY CARE

No.	Paper	Summary	Quotes
1.	Mary S. Vaughan-Sarrazin et al., "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States with and without Certificate of Need Regulation," <i>JAMA</i> 288, no. 15 (October 16, 2002): 1859-66.	<p>They assess the effect of CON on coronary artery bypass graft (CABG) surgery, finding:</p> <ol style="list-style-type: none"> <li>1. Mean annual hospital volume is lower in states without CON.</li> <li>2. More patients undergo CABG surgery in low-volume hospitals in states without CON, and</li> <li>3. <u>Mortality following CABG is higher in states without CON.</u></li> </ol>	<p>"Unadjusted mortality was 5.1% in states without certificate of need regulation compared with 4.4% in states with continuous regulation, and 4.3% in states with intermittent certificate of need regulation (P&lt;.001 for each comparison). Adjusting for demographic and clinical factors, mortality remained higher in states without certificate of need regulation compared with states with continuous certificate of need regulation (odds ratio [OR], 1.22; 95% confidence interval [CI], 1.15-1.28; P&lt;.001). Using the same groups for comparison, the mean annual hospital volume for CABG surgery was 84% lower in states without certificate of need regulation (104 vs 191; P&lt;.001) and more patients underwent CABG surgery in low-volume hospitals (&lt;100 procedures annually) (30% vs 10% for states with continuous certificate of need programs; P&lt;.001). Following the repeal of certificate of need regulation in states categorized as intermittent, the percentage of patients undergoing CABG surgery in low-volume hospitals tripled."</p>



2.	Joseph S. Ross et al., "Certificate of Need Regulation and Cardiac Catheterization Appropriateness After Acute Myocardial Infarction," <i>Circulation</i> 115, no. 8 (February 27, 2007): 1012–19.	<p>They examine the effect of CON on the volume of cardiac catheterization after admission for acute myocardial infarction.</p> <p>In particular, however, they were interested in procedural volume under different levels of appropriateness (strongly, equivocally, or weakly indicated).</p> <p>While CON did not seem to decrease the volume of strongly-indicated catheterization, it did reduce the volume of equivocally and weakly indicated catheterization.</p> <p>Because their interest is both overall volume and rates of catheterization when it is not warranted, I am categorizing this in both the volume and the quality sections.</p>	<p>"After stratification by appropriateness, CON regulation was not associated with a significantly lower rate of catheterization among 63,823 patients with strong indications (49.9% versus 50.3%; adjusted RR 0.94, 95% confidence interval 0.86 to 1.02, P0.17). However, CON regulation was associated with significantly lower rates of catheterization among 65,077 patients with equivocal indication (45.0% versus 46.0%; adjusted RR 0.88, 95% confidence interval 0.78 to 1.00, P0.05) and among 8,379 patients with weak indications (19.8% versus 21.8%; adjusted RR 0.84, 95% confidence interval 0.71 to 0.98, P0.04). Associations were weakened substantially after adjustment for hospital coronary artery bypass graft surgery or cardiac catheterization capability."</p>
3.	S. A. Lorch, P. Maheshwari, and O. Even-Shoshan, "The Impact of Certificate of Need Programs on Neonatal Intensive Care Units," <i>Journal of Perinatology: Official Journal of the California Perinatal Association</i> 32, no. 1 (January 2012): 39–44.	<p>They studied NICU CONs. They found:</p> <ol style="list-style-type: none"> <li>1. CON is associated with fewer units;</li> <li>2. CON is associated with fewer beds;</li> <li>3. CON was unrelated to very low birth weight (VLBW) infant mortality and low birth weight (LBW) infant mortality.</li> <li>4. <u>CON is associated with lower rates of all-infant mortality in states with a large metropolitan area.</u></li> </ol>	<p>"Absence of such programs was associated with more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and NICU beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation, and increased all-infant mortality rates in states with a large metropolitan area.... Mortality rates for VLBW or LBW infants were not significantly different between CON and non-CON states. However, for states with at least one large metropolitan area, states with CON legislation had significantly lower all infant mortality rates compared with states without CON legislation (0.54 fewer deaths/1000 births, 95% CI 0.02 to 1.06)."</p>

4.	Cancienne et al., “Certificate-of-Need Programs Are Associated with a Reduced Incidence, Expenditure, and Rate of Complications with Respect to Knee Arthroscopy in the Medicare Population.”	<p>They examine the effect of CON on knee arthroscopy, assessing its effect on:</p> <ol style="list-style-type: none"> <li>1. Charges and reimbursements: in t-tests without controls they found that charges (which are the prices set before any negotiation) were lower in CON states, while reimbursements (which are actual reimbursements) were not statistically significantly different.</li> <li>2. Total volume: total volume and growth in total volume was lower in CON states than in non-CON states.</li> <li>3. Volume within facilities: CON is associated with the presence of more high-volume facilities, and</li> <li>4. <u>Quality: There were more ER visits within 30 days of operation and more infections within 6 months of operation in non-CON than in CON states; there were no differences in in-hospital deaths or readmissions within 30 days of the operation between CON and non-CON states.</u></li> </ol>	<p>“Finally, the incidence of ER visits within 30 days and infection within 6 months of surgery was significantly higher in non-CON states than that in CON states (<math>p &lt; 0.001</math> and <math>p = 0.005</math>, respectively) (Table 1). There was no significant difference in the incidence of in-hospital deaths and readmissions within 30 days of surgery between CON and non-CON states.”</p>
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# ENDNOTES

- <sup>1</sup> South Carolina General Assembly Legislative Audit Council, "A Review of the S.C. Department Of Health And Environmental Control Certificate Of Need Program" (Columbia, South Carolina, February 2022), 45.
- <sup>2</sup> South Carolina General Assembly Legislative Audit Council, 48.
- <sup>3</sup> South Carolina General Assembly Legislative Audit Council, 49.
- <sup>4</sup> South Carolina General Assembly Legislative Audit Council, 57–58.
- <sup>5</sup> South Carolina General Assembly Legislative Audit Council, 52.
- <sup>6</sup> South Carolina General Assembly Legislative Audit Council, 56.
- <sup>7</sup> In a forthcoming review of the literature, I intend to add more categories and more papers that look at the effects of CON on other factors such as hospital profitability and volume of care within hospitals.
- <sup>8</sup> "National Health Planning and Resources Development Act of 1974," Pub. L. No. 93–641, 88 U.S.C. 2225 (1975), <https://www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg2225.pdf>.
- <sup>9</sup> Vivian Ho and Meei-Hsiang Ku-Goto, "State Deregulation and Medicare Costs for Acute Cardiac Care," *Medical Care Research and Review: MCRR* 70, no. 2 (April 2013): 185–205, <https://doi.org/10.1177/1077558712459681>.
- <sup>10</sup> James Bailey, "Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws," *Mercatus Working Paper* (Arlington, VA: Mercatus Center at George Mason University, August 1, 2016), <https://www.mercatus.org/publications/certificate-need/can-health-spending-be-reined-through-supply-constraints-evaluation>.
- <sup>11</sup> James A. Browne et al., "Certificate-of-Need State Laws and Total Knee Arthroplasty," *The Journal of Arthroplasty* 33, no. 7 (July 1, 2018): 2020–24.
- <sup>12</sup> Chason Ziino, Abiram Bala, and Ivan Cheng, "Does ACDF Utilization and Reimbursement Change Based on Certificate of Need Status?," *Clinical Spine Surgery* 33, no. 3 (April 2020): E92, <https://doi.org/10.1097/BSD.0000000000000914>.
- <sup>13</sup> Charlene Harrington et al., "The Effect of Certificate of Need and Moratoria Policy on Change in Nursing Home Beds in the United States," *Medical Care* 35, no. 6 (1997): 574–88.
- <sup>14</sup> David C. Grabowski, Robert L. Ohsfeldt, and Michael A. Morrissey, "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures," *Inquiry: A Journal of Medical Care Organization, Provision and Financing* 40, no. 2 (2003): 146–57.
- <sup>15</sup> Nancy A. Miller, Charlene Harrington, and Elizabeth Goldstein, "Access to Community-Based Long-Term Care: Medicaid's Role," *Journal of Aging and Health* 14, no. 1 (February 2002): 138–59.
- <sup>16</sup> Patrick A. Rivers, Myron D. Fottler, and Mustafa Zeedan Younis, "Does Certificate of Need Really Contain Hospital Costs in the United States?," *Health Education Journal* 66, no. 3 (September 1, 2007): 229–44, <https://doi.org/10.1177/0017896907080127>.
- <sup>17</sup> James Bailey, "Can Health Spending Be Reined in through Supply Restraints? An Evaluation of Certificate-of-Need Laws," *Journal of Public Health* 27, no. 6 (December 1, 2019): 755–60, <https://doi.org/10.1007/s10389-018-0998-1>.
- <sup>18</sup> Traci L. Eichmann and Rexford E. Santerre, "Do Hospital Chief Executive Officers Extract Rents from Certificate of Need Laws," *Journal of Health Care Finance* 37, no. 4 (2011): 1–14; Thomas Stratmann and Jacob Russ, "Do Certificate-of-Need Laws Increase Indigent Care?" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, July 2014); Thomas Stratmann and Christopher Koopman, "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, February 2016).
- <sup>19</sup> Melissa D. A. Carlson et al., "Geographic Access to Hospice in the United States," *Journal of Palliative Medicine* 13, no. 11 (2010): 1331–38.
- <sup>20</sup> Jon M. Ford and David L. Kaserman, "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry," *Southern Economic Journal* 59, no. 4 (1993): 783–91.
- <sup>21</sup> Marah N. Short, Thomas A. Aloia, and Vivian Ho, "Certificate of Need Regulations and the Availability and Use of Cancer Resections," *Annals of Surgical Oncology* 15, no. 7 (July 2008): 1837–45.
- <sup>22</sup> Daniel Polsky et al., "The Effect of Entry Regulation in the Health Care Sector: The Case of Home Health," *Journal of Public Economics* 110 (2014): 1–14; Susan L. Ettner et al., "Certificate of Need and the Cost of Competition in Home Healthcare Markets," *Home Health Care Services Quarterly* 39, no. 2 (2020): 51–64.

- <sup>23</sup> James B. Bailey and Eleanor Lewin, "Certificate of Need and Inpatient Psychiatric Services," *Journal of Mental Health Policy and Economics* 24, no. 4 (2021): 117-24.
- <sup>24</sup> James B. Bailey, Thanh Lu, and Patrick Vogt, "Certificate of Need and Substance Use Treatment" (working paper, December 29, 2020).
- <sup>25</sup> Jamie L. Robinson et al., "Certificate of Need and the Quality of Cardiac Surgery," *American Journal of Medical Quality* 16, no. 5 (2001): 155-60.
- <sup>26</sup> Iona Popescu, Mary S. Vaughan-Sarrazin, and Gary E. Rosenthal, "Certificate of Need Regulations and Use of Coronary Revascularization after Acute Myocardial Infarction," *Journal of the American Medical Association* 295, no. 18 (2006): 2141-47; Vivian Ho et al., "Cardiac Certificate of Need Regulations and the Availability and Use of Revascularization Services," *American Heart Journal* 154, no. 4 (2007): 767-75; Vivian Ho, Meei-Hsiang Ku-Goto, and James G. Jollis, "Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON," *Health Services Research* 44, no. 2 (2009): 483-500; Jonathan T. Kolstad, "Essays on Information, Competition and Quality in Health Care Provider Markets" (PhD diss., Harvard University, 2009), <https://healthpolicy.fas.harvard.edu/people/jonathan-kolstad>; Mary S. Vaughan-Sarrazin, Levent Bayman, and Peter Cram, "Trends during 1993-2004 in the Availability and Use of Revascularization after Acute Myocardial Infarction in Markets Affected by Certificate of Need Regulations," *Medical Care Research and Review* 67, no. 2 (2010): 213-31; David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, "Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery," *American Economic Journal: Economic Policy* 2, no. 1 (2010): 51-76.
- <sup>27</sup> Ho et al., "Cardiac Certificate of Need Regulations."
- <sup>28</sup> Paul L. Joskow, "The Effects of Competition and Regulation on Hospital Bed Supply and the Reservation Quality of the Hospital," *Bell Journal of Economics* 11, no. 2 (1980): 421-47; Charlene Harrington et al., "The Effect of Certificate of Need and Moratoria Policy on Change in Nursing Home Beds in the United States," *Medical Care* 35, no. 6 (1997): 574-88; Fred J. Hellinger, "The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis," *American Journal of Managed Care* 15, no. 10 (2009): 737-44; Eichmann and Santerre, "Do Hospital Chief Executive Officers Extract Rents?"; S. A. Lorch, P. Maheshwari, and O. Even-Shoshan, "The Impact of Certificate of Need Programs on Neonatal Intensive Care Units," *Journal of Perinatology: Official Journal of the California Perinatal Association* 32, no. 1 (2012): 39-44; Stratmann and Russ, "Do Certificate-of-Need Laws Increase Indigent Care?"; Matthew D. Mitchell and Thomas Stratmann, "The Economics of a Bed Shortage: Certificate-of-Need Regulation and Hospital Bed Utilization during the COVID-19 Pandemic," *Journal of Risk and Financial Management* 15, no. 1 (2022): 10.
- <sup>29</sup> Stratmann and Russ, "Do Certificate-of-Need Laws Increase Indigent Care?"; Matthew C. Baker and Thomas Stratmann, "Barriers to Entry in the Healthcare Markets: Winners and Losers from Certificate-of-Need Laws," *Socio-Economic Planning Sciences* 77 (2021): 101007.
- <sup>30</sup> Cutler, Huckman, and Kolstad, "Input Constraints and the Efficiency of Entry"; Carlson et al., "Geographic Access to Hospice in the United States."
- <sup>31</sup> Baker and Stratmann, "Barriers to Entry in the Healthcare Markets."
- <sup>32</sup> Molly S. Myers and Kathleen M. Sheehan, "The Impact of Certificate of Need Laws on Emergency Department Wait Times," *Journal of Private Enterprise* 35, no. 1 (2020): 59-75.
- <sup>33</sup> Stratmann and Russ, "Do Certificate-of-Need Laws Increase Indigent Care?"
- <sup>34</sup> Joel C. Cantor et al., "Reducing Racial Disparities in Coronary Angiography," *Health Affairs* 28, no. 5 (2009): 1521-31; Derek DeLia et al., "Effects of Regulation and Competition on Health Care Disparities: The Case of Cardiac Angiography in New Jersey," *Journal of Health Politics, Policy, and Law* 34, no. 1 (2009): 63-91.
- <sup>35</sup> Thomas Stratmann and David Wille, "Certificate of Need Laws and Hospital Quality" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016).
- <sup>36</sup> Polsky et al., "The Effect of Entry Regulation in the Health Care Sector"; Stratmann and Wille, "Certificate of Need Laws and Hospital Quality"; Thomas Stratmann and Matthew C. Baker, "Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, July 2020).
- <sup>37</sup> Stratmann and Wille, "Certificate of Need Laws and Hospital Quality."
- <sup>38</sup> Stratmann and Wille.
- <sup>39</sup> Bichaka Fayissa et al., "Certificate-Of-Need Regulation and Healthcare Service Quality: Evidence from the Nursing Home Industry," *Healthcare* 8, no. 4 (2020): E423.
- <sup>40</sup> Jacqueline S. Zinn, "Market Competition and the Quality of Nursing Home Care," *Journal of Health Politics, Policy, and Law* 19, no. 3 (1994): 555-82.
- <sup>41</sup> Robert L. Ohsfeldt and Pengxiang Li, "State Entry Regulation and Home Health Agency Quality Ratings," *Journal of Regulatory Economics* 53, no. 1 (2018): 1-19.

# EXHIBIT D

No. \_\_\_\_\_

TENTH DISTRICT

SUPREME COURT OF NORTH CAROLINA

\*\*\*\*\*

JAY SINGLETON, D.O. and )  
SINGLETON VISION CENTER, PA, )

Plaintiff-Appellants, )

v )

NORTH CAROLINA DEPARTMENT )  
OF HEALTH AND HUMAN )  
SERVICES; ROY COOPER, Governor of )  
the State of North Carolina, in his )  
official capacity; MANDY COHEN, )  
North Carolina Secretary of Health and )  
Human Services, in her official capacity; )  
PHIL BERGER, President Pro Tempore )  
of the North Carolina Senate, in his )  
official capacity; and TIM MOORE, )  
Speaker of the North Carolina House of )  
Representatives, in his official capacity, )

Defendant-Appellees. )

From Wake County  
No. COA21-558

\*\*\*\*\*

MOTION BY TREASURER DALE R.  
FOLWELL, CPA, FOR LEAVE TO FILE  
A BRIEF AS AMICUS CURIAE

\*\*\*\*\*

TO THE HONORABLE SUPREME COURT OF NORTH CAROLINA:

Treasurer Dale R. Folwell, CPA, respectfully seeks leave pursuant Rule 28(i) of the North Carolina Rules of Appellate Procedure to file an amicus curiae brief in support of Plaintiffs' Petition for Discretionary Review. The proposed amicus curiae brief is attached as Exhibit A.

NATURE OF APPLICANT'S INTEREST

As keeper of the public purse, Treasurer Folwell is also a fiduciary for the North Carolina State Health Plan for Teachers and State Employees (Plan) pursuant to N.C.G.S. § 135-48.2 (2021). Consisting of almost 750,000 members, including active and retired members, the Plan is one of the largest purchasers of healthcare in North Carolina. In the most recent fiscal year ending in June of 2022, the Plan had almost \$4 billion in expenditures, the vast majority of which are associated with medical and pharmacy claims. Thus, as a fiduciary, Treasurer Folwell is concerned for the continued solvency of the Plan, which is funded in part by taxpayers. In addition, as chairman of the Local Government Commission, Treasurer Folwell is often tasked with evaluating certain financing proposals for various healthcare entities.

### WHY AN AMICUS CURIAE BRIEF IS DESIRABLE

In their complaint, Plaintiffs assert an as-applied challenge against the Certificate of Need (CON) law, N.C.G.S. § 131E-175, *et seq.* Such a challenge, by its nature, is limited to the factual circumstances of this case. The proposed brief provides a view of the significant public interest in this case from Treasurer Folwell's broader perspective.

### ISSUES OF LAW TO BE ADDRESSED

The proposed brief would address the following issue:

(1) Whether the subject matter of this appeal has significant public interest such that discretionary review is appropriate under N.C.G.S. § 7A-31(c) (2021)?

### POSITION OF AMICUS CURIAE

Treasurer Folwell holds the position that whether the CON law violates Article I, Sections 19, 32, and 34 of the North Carolina Constitution is an issue of significant public interest. CON laws create insurmountable barriers to entry that shield existing institutional healthcare providers from competition. In turn, the accessibility, quality, and affordability of healthcare decreases while profits dramatically increase, to the detriment of North Carolinians. This Court previously



recognized that the North Carolina Constitution protects North Carolinians against these harms. Whether it continues to do so is an issue of significant public interest.

### CONCLUSION

Treasurer Folwell respectfully requests this motion for leave be allowed and the proposed amicus curiae brief attached hereto be accepted for consideration by the Supreme Court of North Carolina.

This, the 15th day of August, 2022.

DEPARTMENT OF THE STATE  
TREASURER

/s/ J. Benjamin Garner

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EXHIBIT A

No. \_\_\_\_\_

TENTH DISTRICT

SUPREME COURT OF NORTH CAROLINA

\*\*\*\*\*

JAY SINGLETON, D.O. and )  
SINGLETON VISION CENTER, PA, )

Plaintiff-Appellants, )

v )

NORTH CAROLINA DEPARTMENT )  
OF HEALTH AND HUMAN )  
SERVICES; ROY COOPER, Governor of )  
the State of North Carolina, in his )  
official capacity; MANDY COHEN, )  
North Carolina Secretary of Health and )  
Human Services, in her official capacity; )  
PHIL BERGER, President Pro Tempore )  
of the North Carolina Senate, in his )  
official capacity; and TIM MOORE, )  
Speaker of the North Carolina House of )  
Representatives, in his official capacity, )

Defendant-Appellees. )

From Wake County  
No. COA21-558

\*\*\*\*\*

BRIEF OF AMICUS CURIAE TREASURER  
DALE R. FOLWELL, CPA

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**INDEX**

TABLE OF AUTHORITIES .....	iii
INTRODUCTION .....	2
ARGUMENT .....	3
CONCLUSION .....	12
CERTIFICATE OF SERVICE	

## TABLE OF AUTHORITIES

## CASES

<i>Cheryl Lloyd Humphrey Land Inv. Co., LLC v. Resco Prods., Inc.</i> , 377 N.C. 384, 2021-NCSC-56 .....	3
<i>In re Certificate of Need for Aston Park Hosp., Inc.</i> , 282 N.C. 542 (1973) .....	10, 11

## CONSTITUTIONAL PROVISIONS

N.C. Const. art. I, § 19 .....	2, 10
N.C. Const. art. I, § 32 .....	2, 10
N.C. Const. art. I, § 34 .....	2, 10

## STATUTES AND COURT RULES

N.C.G.S. § 7A-31(c) (2021) .....	3, 12
N.C.G.S. § 131E-175, <i>et seq.</i> (2021) .....	3, 6
N.C.G.S. § 135-48.2(a) (2021) .....	8

## PUBLIC AND SESSION LAWS

National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5) .....	4
Pub. L. No. 99-660, § 701, 100 Stat. 3799 (1986) .....	4
Act of July 27, 1971, ch. 1164, 1971 N.C. Sess. L. 1715 .....	3–4



## EXECUTIVE ORDERS

Exec. Order. No. 130 (April 8, 2020) .....	6
--	---

## OTHER AUTHORITIES

Barak D. Richman, <i>Concentration in Health Care Markets: Chronic Problems and Better Solutions</i> , American Enter. Inst. (June 2012) .....	6
Christopher Rowland, <i>The unintended consequences of the \$178 billion bailout to keep hospitals and doctors afloat</i> , Washington Post (June 22, 2022), <a href="https://www.washingtonpost.com/business/2022/06/22/covid-hospital-relief-fund/">https://www.washingtonpost.com/business/2022/06/22/covid-hospital-relief-fund/</a> .....	7
Matthew D. Mitchell, <i>Certificate-of-Need Laws: Are They Achieving Their Goals?</i> , Mercatus Center (April 2017) .....	3, 4, 5, 6
Matthew D. Mitchell and Christopher Koopman, <i>40 Years of Certificate-of-Need Laws Across America</i> , Mercatus Center (Sep. 27, 2016), <a href="https://www.mercatus.org/publications/corporate-welfare/40-years-certificate-need-laws-across-america">https://www.mercatus.org/publications/corporate-welfare/40-years-certificate-need-laws-across-america</a> .....	5
Maureen K. Ohlhausen, <i>Certificate of Need Laws: A Prescription for Higher Costs</i> , 30 Antitrust 50 (2015) .....	3
N.C. State Health Plan and Johns Hopkins Bloomberg Sch. of Pub. Health, <i>N.C. Hosps.: Charity Care Report</i> (Oct. 27, 2021) .....	7–8
N.C. State Health Plan and Rice Univ. Baker Inst. for Pub. Pol’y, <i>N.C. Nonprofit Hospitals Bill the Poor</i> 1 (Jan. 26, 2022) .....	8
Office of the State Controller, <i>State of North Carolina: Annual Comprehensive Financial Report</i> (June 30, 2021) .....	9

Patrick John McGinley, <i>Reconsidering Certificate of Need Laws in a “Managed Competition” System</i> , 23 Fla. St. U. L. Rev. 141 (1995) .....	4
Press Release, Federal Trade Commission and Department of Justice, <i>Fed. Trade Comm’n, Dep’t of Just. Issue Joint Statement on Certificate-of-Need Laws in Illinois</i> (Sept. 12, 2008) .....	4–5
Steve Riley, <i>Dale Folwell Battles the Health Care ‘Cartel’</i> , The Assembly (Feb. 3, 2022), <a href="https://www.theassemblync.com/long-form/dale-folwell-battles-the-health-care-cartel/">https://www.theassemblync.com/long-form/dale-folwell -battles-the-health-care-cartel/</a> .....	7

No. \_\_\_\_\_

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Plaintiff-Appellants, )

vs. )

NORTH CAROLINA DEPARTMENT )  
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SERVICES; ROY COOPER, Governor of )  
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official capacity; MANDY COHEN, )  
North Carolina Secretary of Health and )  
Human Services, in her official capacity; )  
PHIL BERGER, President Pro Tempore )  
of the North Carolina Senate, in his )  
official capacity; and TIM MOORE, )  
Speaker of the North Carolina House of )  
Representatives, in his official capacity, )

Defendant-Appellees. )

From Wake County  
No. COA21-558

\*\*\*\*\*

BRIEF OF AMICUS CURIAE TREASURER  
DALE R. FOLWELL, CPA

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## INTRODUCTION

The issue at the heart of this case—whether North Carolina’s Certificate of Need law violates Article I, Sections 19, 32, and 34 of the North Carolina Constitution—is of significant public interest due to the harmful effects that illegal healthcare monopolies enabled by this law inflict on North Carolinians. In theory, some argued, Certificate of Need laws would increase accessibility, quality, and affordability of healthcare services. In practice, however, Certificate of Need laws erect insurmountable regulatory barriers wielded by existing institutional healthcare entities to exclude others from entering the market.

Thus, Certificate of Need laws contribute to the creation of highly consolidated healthcare monopolies. In turn, these monopolies decrease the accessibility, quality, and affordability of healthcare while dramatically increasing their prices and excess revenues, all at the expense of North Carolinians. Determining whether the Certificate of Need law runs afoul of the North Carolina Constitution’s protections against these types of harmful monopolies and special privileges is an issue of significant public interest justifying this Court’s review.<sup>1</sup>

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<sup>1</sup> No person or entity other than amicus curiae or amicus curiae’s counsel wrote any part of this brief or contributed any money to support the briefs preparation. *See* N.C. R. App. P. 28(i)(2).

## ARGUMENT

Under Section 7A-31(c), this Court may grant discretionary review when “[t]he subject matter of the appeal has significant public interest.” N.C.G.S. § 7A-31(c)(1) (2021). For the following reasons, the subject matter of this appeal is of significant interest to the public such that discretionary review is appropriate in this case.<sup>2</sup>

When Medicare and Medicaid were first implemented, the programs reimbursed medical providers for services based on actual cost, creating incentives for providers to increase healthcare costs. Maureen K. Ohlhausen, *Certificate of Need Laws: A Prescription for Higher Costs*, 30 Antitrust 50, 51 (2015); R. at 17, ¶ 44–48.<sup>3</sup> In an attempt to tamp down these costs, states started passing Certificate of Need (CON) laws, beginning with New York in 1964. Matthew D. Mitchell, *Certificate-of-Need Laws: Are They Achieving Their Goals?*, Mercatus Center 1 (April 2017). In 1971, North Carolina passed its own CON law, now codified at N.C.G.S. § 131E-175, *et seq.* See Act of July 27, 1971, ch. 1164, 1971 N.C.

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<sup>2</sup> This brief argues that the Supreme Court’s review of this case is proper under N.C.G.S. § 7A-31(c)(1) (2021). This brief expresses no opinion, favorable or unfavorable, as to whether this Court should retain Plaintiffs’ notice of appeal based upon a substantial constitutional question or whether review is proper under N.C.G.S. § 7A-31(c)(2)–(3) (2021).

<sup>3</sup> Because this case involves the trial court’s grant of Defendants’ motion to dismiss, this Court on review takes the allegations of Plaintiffs’ complaint as true. See *Cheryl Lloyd Humphrey Land Inv. Co., LLC v. Resco Prods., Inc.*, 377 N.C. 384, 2021-NCSC-56, ¶ 2.

Sess. L. 1715. Believing CON laws would help control public health expenditures, Congress enacted the National Health Planning and Resources Development Act (NHPDA) of 1974 to mandate that states pass CON laws. Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), *repealed by* Pub. L. No. 99-660, § 701, 100 Stat. 3799 (1986). Apart from Louisiana, every state passed a CON law by the early 1980s. Mitchell, *supra*, at 1.

In 1984, however, “Congress restructured the Medicare and Medicaid reimbursement system to a fee-for-service model,” thus eliminating the key rationale for CON laws. R. at 10, ¶ 51. Congress then repealed the NHPDA in 1986 because it “failed to reduce the nation’s aggregate health care costs, and it was beginning to produce detrimental effects in local communities.” Patrick John McGinley, *Reconsidering Certificate of Need Laws in a “Managed Competition” System*, 23 Fla. St. U. L. Rev. 141, 157 (1995). In 2008, the Federal Trade Commission and the United States Department of Justice stated that CON laws “undercut consumer choice, stifle innovation and weaken markets’ ability to contain health care costs.” Press Release, Federal Trade Commission and Department of Justice, *Fed. Trade Comm’n, Dep’t of Just. Issue Joint*

*Statement on Certificate-of-Need Laws in Illinois* (Sept. 12, 2008). Since the repeal of the NHPRDA, fifteen states have repealed their CON laws due to “higher healthcare prices and higher overall healthcare spending.” Matthew D. Mitchell and Christopher Koopman, *40 Years of Certificate-of-Need Laws Across America*, Mercatus Center (Sep. 27, 2016), <https://www.mercatus.org/publications/corporate-welfare/40-years-certificate-need-laws-across-america>.

Research shows that “by limiting supply and undermining competition, CON laws may undercut” the aims originally used by legislators to justify the laws. Matthew D. Mitchell, *Certificate-of-Need Laws: Are They Achieving Their Goals?*, Mercatus Center 1–2 (April 2017). Notably, “[t]he process for obtaining a CON can take years and tens or even hundreds of thousands of dollars.” *Id.* at 2. These high costs are generally a barrier to market entry, including for ambulatory surgical centers such as Plaintiff Singleton Vision Center (Center). *Id.* Because existing providers are shielded from competition, the availability of healthcare resources is restricted—states with CON laws “have about 99 fewer hospital beds per 100,000 people than states without these regulations.” Moreover, states with CON laws have “[thirty] percent

fewer *rural* hospitals per 100,000 residents compared with non-CON states.” *Id.* To maintain this barrier, existing healthcare institutions are willing to

inflict economic harm by spending heavily to sustain current monopoly barriers. . . . This is especially true for health care monopolists because so many are maintained with legal and regulatory barriers [such as] certificate of need laws . . . . Thus, health care monopolists are willing to spend heavily . . . on legal and political resources that impede competition. This contrasts starkly with the narrative in which we reward monopolies (with monopoly profits) for their investing in the ‘superior skill, foresight, and industry’ that creates social value.

Barak D. Richman, *Concentration in Health Care Markets: Chronic Problems and Better Solutions*, American Enter. Inst. 6 (June 2012) (footnote omitted).

Despite Congress’ repeal of the NHPRDA and these negative effects, North Carolina’s CON law remains in force to the detriment of North Carolinians. *See* N.C.G.S. § 131E-175, *et seq.* (2021). Our state’s lack of hospital capacity was a contributing factor to Governor Cooper’s decision to suspend the CON law during the COVID-19 pandemic. *See* Exec. Order. No. 130 (April 8, 2020). Moreover, the CON law is contributing to a rapid consolidation of our state’s major hospital



systems. See Steve Riley, *Dale Folwell Battles the Health Care ‘Cartel’*, The Assembly (Feb. 3, 2022), <https://www.theassemblync.com/long-form/dale-folwell-battles-the-health-care-cartel/> (“In the past decade in North Carolina, Atrium Health acquired Carolinas Medical Center and Wake Forest Baptist. Novant purchased New Hanover Regional Medical Center. And HCA bought Mission Hospital in Asheville.”).

While receiving tax breaks worth hundreds of millions of dollars, these consolidating entities are reaping incredible excess revenues. UNC Hospitals had \$516 million in excess revenue during the most recent fiscal year. Riley, *supra*. Duke University Health System had \$450 million in excess revenues in 2018 and \$430 million in 2019, both at a margin of greater than ten percent. *Id.* In 2020, Atrium Health, headquartered in Charlotte, had excess revenues of more than \$1 billion, *see id.*, while receiving \$617 million in federal COVID-19 relief funds, *see* Christopher Rowland, *The unintended consequences of the \$178 billion bailout to keep hospitals and doctors afloat*, Washington Post (June 22, 2022), <https://www.washingtonpost.com/business/2022/06/22/covid-hospital-relief-fund/>. North Carolina hospitals have been “more than three times more profitable than the national average.” N.C. State

Health Plan and Johns Hopkins Bloomberg Sch. of Pub. Health, *N.C. Hosps.: Charity Care Report* (Oct. 27, 2021).

While gaining these excess revenues, these consolidating entities are also able to engage in practices that harm North Carolinians. Despite their tax-exempt status, large reserves, and significant profits, many of our state’s institutional hospitals fail to provide sufficient levels of charity care. *Id.* at 3. Instead, these hospitals charge patients who qualify for charity care amounts they cannot afford. N.C. State Health Plan and Rice Univ. Baker Inst. for Pub. Pol’y, *N.C. Nonprofit Hosps. Bill the Poor* 1 (Jan. 26, 2022). In efforts to collect this money, institutional hospitals “have sued patients, garnished their tax returns, damaged their credit and encouraged them to open medical credit cards charging interest rates as high as 11.25% after the first year.” *Id.* at 3.

In addition, rising healthcare costs due in part to the CON law also impact state employees, along with taxpayers, through the North Carolina State Health Plan for Teachers and State Employees (Plan). Pursuant to statute, “[t]he State Treasurer . . . shall carry out [his] duties and responsibilities as [a] fiduciar[y] for the Plan.” N.C.G.S. § 135-48.2(a) (2021). The Plan consists of almost 750,000 members, including active

and retired teachers and state employees, along with their dependents. In the 2012–2013 fiscal year, the Plan’s expenditures were approximately \$2.7 billion dollars, the vast majority of which are associated with medical and pharmacy claims. In the most recent fiscal year, ending June 30, 2022, the Plan incurred almost \$4 billion in expenditures. Thus, over the past decade, the Plan’s annual expenditures have grown by approximately \$1.3 billion.

Rising healthcare costs thus pose a challenge to maintaining the solvency of the Plan and are a liability to taxpayers, who support the Plan through appropriations from the General Assembly. These appropriations grow at approximately four percent per year, but the Plan’s costs continue to grow at approximately seven percent per year. Moreover, the Plan faces a \$33.5 billion liability for retiree healthcare costs, with only \$2.6 billion set aside from the General Assembly to cover that liability. *See* Office of the State Controller, *State of North Carolina: Annual Comprehensive Financial Report* 235 (June 30, 2021). Thus, the healthcare monopolies maintained in part by the CON law are harming North Carolinians as consumers of healthcare and also as taxpayers.

Understanding that the CON law contributes to harmful monopolies, this Court previously held that the CON law violates the North Carolina Constitution. *See In re Certificate of Need for Aston Park Hosp., Inc.*, 282 N.C. 542, 551 (1973). In *Aston Park*, a private company was precluded from building a new hospital with “the sole reason for such prohibition being that, in the opinion of the [Medical Care] Commission, there are now in the area hospitals with bed capacity sufficient to meet the needs of the population.” *Id.* at 548. This Court found no “reasonable relation between the denial of the right of a person, association or corporation to construct and operate upon his or its own property, with his or its own funds, an adequately staffed and equipped hospital and the promotion of the public health.” *Id.* at 551.

Thus, this Court held that the CON law was “a deprivation of liberty without due process of law, in violation” of Article I, Section 19 of the North Carolina Constitution. *Id.* at 551. In addition, this Court held that “[s]uch requirement establishes a monopoly in the existing hospitals contrary to the provisions of Article I, [Section] 34 . . . and is a grant to them of exclusive privileges forbidden by Article I, [Section] 32.” *Id.* In so holding, the Court noted that the North Carolina Constitution does not

“permit the legislature to grant to the Medical Care Commission authority to exclude [the new hospital] from this field of service in order to protect existing hospitals from competition otherwise legitimate.” *Id.* at 552.

This Court’s concerns in *Aston Park* are evident in this case as well. Plaintiff Dr. Singleton desires to perform operations at the Center, which meets the licensure requirements to do so. R. at 12, ¶ 11; 15, ¶ 27–30. Under the current CON law, however, Dr. Singleton may only perform an “incidental” number of surgeries at the Center. R. at 12, ¶ 11; 15, ¶ 31. For example, Dr. Singleton charges \$1,800 to patients whose cataract surgeries are performed at the Center. R. at 14, ¶ 23. The remainder of Dr. Singleton’s surgeries must be performed at the nearby hospital, CarolinaEast, which charges \$6,000 for the facility fee alone. *Id.* Obtaining a CON allowing Dr. Singleton to perform surgeries at the Center may take years and cost him hundreds of thousands of dollars. R. at 22–23, ¶ 73–74; 24, ¶ 87. Adding to the difficulty, CarolinaEast, with its operating budget of more than \$1 billion, R. at 27, ¶ 101, has stated they will oppose Dr. Singleton’s request for a CON, R. at 30, ¶ 118. Thus, Dr. Singleton is precluded from performing surgeries at the Center, for

no reason other than the State has determined, through the CON regulatory scheme, that patients do not “need” those surgeries.

### CONCLUSION

CON laws contribute to consolidated healthcare monopolies in North Carolina by distorting market power in favor of large institutional hospitals. This illegal distortion of market power then results in higher prices, lower quality, and less availability of healthcare services. In turn, large institutional hospitals create incredible excess revenue while failing to earn their tax-exempt status through the provision of charity care and engage in business practices harmful to North Carolinians. This Court has previously determined that the North Carolina Constitution protects North Carolinians against these harms. Whether the North Carolina Constitution continues to do so is a matter of significant public interest. Accordingly, discretionary review is proper in this case under Section 7A-31(c) and this Court should grant Plaintiffs’ petition.

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TREASURER

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