

STRIVING FOR BETTER CARE:

A Review of Kentucky's
Certificate of Need Laws

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August 2023

 INSTITUTE
for JUSTICE



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EXECUTIVE SUMMARY

A certificate of need (CON) is a government mandated permission slip that a provider must get before opening a healthcare facility or adding new services. CON laws began as an experiment to reduce government expenditures on healthcare. The architects of CON laws thought that reducing the number of healthcare facilities would lower government spending on healthcare services. On some level, this might work; if there were no hospitals, there would be no healthcare spending. But if we assume that healthcare services provide value to patients, then reducing access to healthcare would likely be harmful, even if it does reduce spending. In fact, CON laws are more likely to *increase* healthcare costs because they limit supply and suppress competition. This drives up costs per service, which can increase overall spending, even if the amount of care that each person receives decreases.

As long as CON laws have existed, economists and health researchers have studied their effects. Decades of research confirm that CON laws fail to decrease spending and often increase it. They also limit access to care and likely undermine the quality of care.

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To better understand the existing data, we reviewed 128 papers that tested the effects of CON laws. These papers contained more than 400 tests. Some CON advocates claim that the data is mixed. This review of the literature ends the debate—89% of the tests show that CON laws lead to negative or neutral results, and negative results are five times (500%) more common than positive results. Many of these studies show that CON laws are bad for patients, bad for payors, bad for improving access to care (including rural care), bad for vulnerable populations, bad for mortality rates for common conditions, and bad for healthcare innovation.

CON laws force patients to accept a one-size-fits-all approach to healthcare. And those providers who dare disrupt the status quo are quickly squashed. Take Dipendra Tiwari and his business partner, Kishor Sapkota. In 2018, they decided to open a modest home health agency to help the sizable Nepali-speaking community in the Louisville area. Dipendra immigrated to the United States from Nepal in 2008. Here, in the land of opportunity, he earned an MBA and opened his own

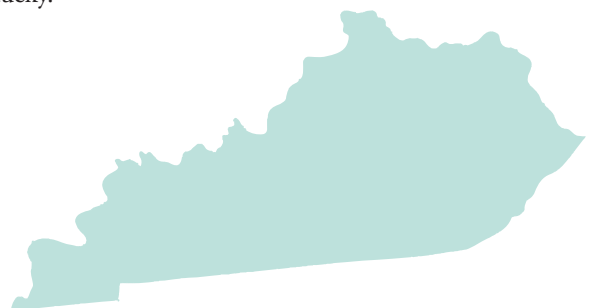
accounting practice. When he learned about Kentucky's CON laws, he was stunned. He never dreamed such a thing could exist in the United States.

Still, Dipendra and Kishor pressed forward. They named their agency Grace Home Care, because, in Dipendra's words, "the whole world is because of grace." He and Kishor submitted their CON application to the Cabinet for Health and Family Services. They estimated they'd serve a mere 30–45 patients in the first two years of operation. And they wouldn't be taking patients away from any existing home health agencies; they would be serving patients who couldn't find any care.

But the Cabinet denied Grace's application based on its rigid formula that said Jefferson County didn't need a new home health agency. The formula calculates "need" based on population and the number of patients that used home healthcare over the past two years. But looking backward is not a good way to estimate how many patients will need care in the future. And naturally, plugging numbers into a formula cannot account for real-world variables, like whether language-appropriate or culturally responsive care exists. The formula also ignores that people may be forgoing care because the available options don't meet their needs.

This fixed formula isn't the only part of the CON process that favors the status quo over innovation and competition. The CON application process allows existing providers to object when a new provider tries to open. In fact, opposition from a competitor during the CON application process decreases the chances of approval by nearly half. Baptist Health, a \$2 billion healthcare conglomerate in Louisville, opposed Dipendra and Kishor's application. Grace hardly stood a chance. Dipendra and Kishor's community continues to suffer.

In this report, we provide a deep dive into CON laws with a focus on Kentucky. We start by outlining the policy purposes of CON laws. Understanding the original intent behind CON makes it clear that many modern justifications are nothing more than *post hoc* rationalizations. Next, we walk through what facilities and services require a CON in Kentucky and how the application process works in practice. Anyone considering whether Kentucky's CON laws are still useful should get a feel for how they operate. Finally, we summarize the best available CON research. This report will arm readers with the tools necessary to improve healthcare outcomes in Kentucky.



KEY TAKEAWAYS

- **CON laws were designed to reduce the supply of hospitals and hospital beds.** Research confirms they have accomplished this. Patients in the average CON state have access to fewer hospitals, fewer ambulatory surgical centers (ASCs), fewer dialysis facilities, fewer imaging centers, and fewer rural hospitals per capita, among other things.
- **The rising tide of competition lifts all boats.** States without CON laws have more hospitals, more ASCs, more rural hospitals, and more rural ASCs per capita—dispelling the myth that hospitals close without cross-subsidization.
- **In fact, research finds that CON laws have no effect on cross-subsidization and do not increase charity care.**
- **CON laws have been studied extensively and 89% of academic tests find a bad or neutral outcome.** For every test associating CON laws with a “good” result, there are five that associate them with a “bad” result.
- **Critics worry that repealing CON laws will force rural and safety-net hospitals to close. But that hasn’t happened in the dozen states that have successfully repealed CON laws:**
 - One study found that four years after Pennsylvania repealed its CON laws, no hospital closures had been reported and incumbent hospitals were more profitable than new facilities.
 - Another study found that safety-net hospitals have higher profit margins in states without CON laws.
 - CON laws are not what keep rural hospitals from closing. Several states with zero CON laws, like CO, ID, UT, and WY, have had zero rural hospital closures since at least 2005.
 - And many states with CON laws exempt rural hospitals or rural facilities from their CON requirements: AL, IN, **KY**, MT, OH, OR, SC, TN, WA.
- **Kentucky’s CON application process advantages existing providers.** When incumbent providers opposed the applications of would-be competitors, approval rates fell by nearly half and the time until a final decision was extended by an average of five months. Many innovators give up without applying.
- **Research shows that states with CON laws were 27% more likely to run out of hospital beds during COVID-19 surges,** regardless of whether the states temporarily eased their CON laws during the pandemic or not.
- **Determining whether a service is “needed” (and thus whether a CON can be granted) in Kentucky depends on outdated, inelastic formulas.** These formulas rely on metrics like population and past usage, but ignore real, on-the-ground evidence of need.
- **Doctors and patients, not government officials, should decide when care is needed.** Twice in 2023, Governor Andy Beshear was forced to override CON regulations to address dangerously low access to healthcare—once for mental health services and again for ambulance services. It didn’t have to be like this. Providers filed CON applications to expand these services over the past few years, but the Cabinet denied them, leading to the present crisis.
- **The Federal Trade Commission and Antitrust Divisions of the Department of Justice have advocated for CON law repeal since the Reagan administration.** Their position has remained consistent across both Republican and Democratic administrations. Other agencies, like the U.S. Department of Health and Human Services, Department of Labor, and Department of the Treasury also agree.

In 2018, Dipendra Tiwari and his business partner Kishor Sapkota wanted to open a modest home health agency to serve Nepali speakers in Louisville, but Kentucky officials denied their CON application.



INTRODUCTION

A certificate of need (CON) is a government-mandated permission slip that is required before a provider can open a healthcare facility, acquire new equipment, or offer a new service. Without a CON, which can be difficult or sometimes impossible to get, new providers are locked out of the market. As a result, patients suffer. Kentucky adopted its first healthcare CON law in 1972. While 34 other states plus Washington D.C. also have CON laws today, these laws vary greatly among locales. States like Indiana, Montana, and Ohio apply CON laws only to nursing homes. Others, like Alabama, Kentucky, and New York, maintain more than 30 different CON

requirements for facilities, services, and equipment. Nearly 40% of Americans live in a state with only one or zero CON laws and about a third of the country lives in a state entirely free from healthcare CON laws.

This report does several things. We begin with a brief primer on the history of CON laws. Then, we offer a description of Kentucky's CON laws, followed by a summary of recent CON reforms. Next, we walk through the CON application process (spoiler: it's lengthy and expensive!). After that, we describe recent instances when CON laws were loosened or amended because they were harming public health. To wrap up this part

Without a CON, which can be difficult or sometimes impossible to get, new providers are locked out of the market. As a result, patients suffer.

In 2019, Dipendra and Kishor sued the Cabinet for Health and Family Services, arguing that the ban on their ability to open a home health agency prohibited them from exercising their constitutional right to earn a living.



of the report, we explain the trends in Kentucky's CON applications since 2019. For instance, an objection from an existing provider decreases the chance the Cabinet for Health and Family Services will approve a CON application by nearly half and almost doubles the time until a final decision.

Next, we dig into the academic research. Historically, some people have hesitated to reach a firm conclusion about whether CON laws produce positive or negative outcomes. True, some studies show that CON laws are harmful (they lead to diminished access, higher mortality rates, and higher costs). Others find that CON laws might provide limited benefits (they are associated with

We are hopeful that this report will spur practical healthcare solutions.

greater volume for incumbent providers, which can lead to better outcomes for certain procedures). To resolve this debate, we reviewed all the academic literature we could find—128 academic studies. The

results are alarming: CON laws harm patients, harm hospitals, harm communities, and harm payors. Indeed, 89% of the tests show that CON laws lead to bad or neutral outcomes.

Given our findings, the choice seems obvious. Repealing CON laws will create more opportunities for Kentuckians and will allow existing healthcare providers to better respond to their patients' needs. We are hopeful that this report will spur practical healthcare solutions.



OVERVIEW OF CERTIFICATE OF NEED

What Are CON Laws and Why Do CON Laws Exist?

A certificate of need (CON) is a government-mandated permission slip that is required before a firm can enter certain industries. In Kentucky, healthcare providers must get a CON before opening or expanding a healthcare facility, buying equipment, or offering new medical services. The Commonwealth's CON laws apply to more than 30 different services and technologies.¹

The original theory behind CON laws is attributed to Milton Roemer, a health researcher at UCLA in the 1950s. He suggested that any hospital bed that is built will be filled.² With this principle in mind, lawmakers thought that reducing the supply of healthcare facilities would reduce healthcare spending. For example, in 1964, when New York adopted the nation's first healthcare CON law,³ the New York Department of Health shared its belief that “[o]f the many factors contributing to the unnecessarily high costs of medical care, the construction of unnecessary and inadequate hospital beds is the most readily controlled.”⁴ Even then, CON laws were not without controversy. One person testified that existing healthcare planning councils were “controlled by the larger hospitals” and had already “attempted to prevent a smaller hospital from building.”⁵ CON laws would just exacerbate existing problems.

Other states followed New York, and CON laws rose to prominence in the 1970s. Likewise, Kentucky adopted its CON law in 1972.⁶ Then, in 1974, in an attempt to rein in federal healthcare spending, Congress enacted the National Health Planning and Resources Development Act (NHPDA).⁷ Through NHPDA, Congress threatened to withhold certain federal reimbursements from states that did not adopt CON laws. Every state except Louisiana complied. Apart from controlling costs, Congress hoped exercising this degree of central planning would ensure a more equitable

distribution of healthcare services and improve the quality of available services.

It is crucial to understand that at the time, the federal government reimbursed hospitals for their actual expenses.⁸ This is known as “cost-plus reimbursement.” This system incentivized “unchecked hospital spending,”⁹ because providers knew they would be reimbursed for the full costs of any services rendered. Thus, the government's concern for limiting the supply of hospitals was different than its concerns today. Now, providers are reimbursed on a fee-for-service

The true motivation for CON laws is gone, as is any justification for purposely limiting access to healthcare.

basis. Government payors reimburse providers based on a set fee schedule, regardless of a provider's actual expenses. The true motivation for CON laws is gone, as is any justification for purposely limiting access to healthcare.¹⁰

Even under cost-plus reimbursement, the experiment with CON laws failed. To its credit, Congress quickly recognized its mistake and repealed NHPDA in 1986.¹¹ A dozen states immediately eliminated their CON programs.

Modern CON laws vary greatly from state to state. Some states, like Indiana, Montana, Ohio, and (soon) South Carolina, apply CON laws only to nursing homes. Approximately 40% of Americans live in a state with only one or zero CON laws. Yet 31 states and Washington, D.C., apply CON laws to multiple facilities and services. States like Alabama, Hawaii, Kentucky, and New York are some of the worst offenders. Their statutes contain more than 30 unique CON requirements for healthcare facilities, equipment, and services.

Encouragingly, around 30% of Americans live in a state with no CON laws at all. States without CON laws are spread across the country and represent diverse populations. For example, California, Idaho, Pennsylvania, and Texas are all states that have repealed their CON laws.

1 See CON Laws in Kentucky at page 9 below.

2 Ann Marie Rhodes, *Antitrust and Health Planning Under the 1974 NHPDA Act*, 7 J. Corp. L. 311, 315 (1982).

3 Metcalf-McCloskey Act of 1964, 1964 N.Y. Laws 1883, available at <https://ij.org/wp-content/uploads/2023/07/Metcalf-McCloskey-1964.pdf>.

4 Letter from Andrew C. Fleck, Jr. to Sol Neil Corbin, Counsel to the Governor, “Assembly Intro.5019 – Senate Print 4584” (Apr. 3, 1964).

5 Letter from Guy H. Baldwin, Duane Lyman and Associates Architects to the Honorable Nelson D. Rockefeller, Governor of New York (Apr. 14, 1964).

6 An Act relating to the establishment of certificate of need, licensing and regulation of health facilities and health services, S.B. 283, ch. 149, K.R.S. §§ 216.415–.485, 216.990(2) (recodified §§ 216B.010 *et seq.* (1980)).

7 Pub. L. No. 93-641, 88 Stat. 2225 (codified at 42 U.S.C. §§ 300k–300n-6 (1982)), amended by Health Planning and Resources Development Amendments of 1979, Pub. L. No. 96-79, §§ 1-129, 93 Stat. 592 (codified at 42 U.S.C. §§ 300k–300t (1976 & Supp. 1981)).

8 Grace Bogart, *Iowans Need Change: The Case for Repeal of Iowa's Certificate of Need Law*, 45 J. Corp. L. 221, 232 (2019).

9 *Id.* at 232–33.

10 See Clark C. Havighurst, *Regulation of Health Facilities and Services by “Certificate of Need”*, 59 Va. L. Rev. 1143, 1157 (1973) (calling cost-plus reimbursement “[b]y far the most important factor[] occasioning entry and construction controls.”).

11 Pub. L. No. 99-660, § 701, 100 Stat. 3743, 3799 (1986).

CON Laws in Kentucky

Since 1972, when the General Assembly adopted Kentucky's first healthcare CON laws,¹² researchers have found evidence that CON laws fail to deter hospital investment.¹³ Yet, Kentucky has continued to expand its CON laws since the 1970s. Today, they apply to much more than just hospitals and their purposes have evolved. The following is the statement of legislative findings and purpose for Kentucky's CON program. This statement has remained fairly consistent since 1996:

The General Assembly finds that the licensure of health facilities and health services is a means to insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth. Therefore, it is the purpose of this chapter to fully authorize and empower the Cabinet for Health and Family Services to perform any certificate-of-need function and other statutory functions necessary to improve the quality and increase access to health-care facilities, services, and providers, and to create a cost-efficient health-care delivery system for the citizens of the Commonwealth.¹⁴

While these goals sound laudable, there's little evidence that CON laws have achieved them.¹⁵ As early as 1986, Congress recognized that CON laws failed to control costs.¹⁶ And the vast majority of academic literature establish that CON laws do the opposite of their stated purpose. Despite the evidence, the General Assembly and the Cabinet for Health and Family Services (Cabinet) have been reluctant to reform the Commonwealth's CON laws or regulations.

In 2013, in anticipation of changes to the healthcare landscape resulting from the Affordable Care Act (ACA),

the Commonwealth commissioned the Health Care Facility Capacity Report (Capacity Report) to determine whether Kentucky had an appropriate level of healthcare facilities and services.¹⁷ The Capacity Report estimated that utilization of outpatient services could increase by 6% and inpatient services could increase by 3% in response to the ACA.¹⁸ Access to mental health facilities was a particular concern given that Kentucky's "utilization of inpatient psychiatric care [was] about 50% higher than the national benchmark."¹⁹

The Capacity Report included several recommendations like eliminating the CON requirements for ambulatory surgical centers (ASCs), home health agencies, and imaging services like MRI and PET.²⁰ The Capacity Report noted that CON laws were leading to harm, such as causing existing ASCs to operate above capacity²¹ and discouraging home health agencies from opening in counties where service was needed.²² And, the Report found the CON program "may even be impeding competition."²³ Plus, CON laws were unnecessary for MRI and PET equipment because the market for "mature" "imaging technologies" "self-regulates."²⁴ Eliminating CON laws for imaging would mirror earlier decisions to discontinue CON for x-rays and CTs.²⁵

Unfortunately, the General Assembly never implemented these recommendations. A decade later, Kentucky's CON requirements for ASCs, home health agencies, and MRI and PET equipment remain; as do CON requirements for many other facilities, services, and types of equipment.

Three years after the Capacity Report came out—following its own internal study process—the Cabinet used its regulatory authority to make two minor changes. It reclassified adult day health programs and outpatient healthcare as eligible for the nonsubstantive application review process.²⁶ As explained below, nonsubstantive review is an accelerated CON application process. The Cabinet had originally proposed the same changes for ambulance services, chemical dependency treatment beds, and MRI, but succumbed to industry pressure and scrapped those plans.

In 2019, the General Assembly made some modest reforms to the CON program, including removing skilled nursing facilities, primary care centers, retail clinics, rehabilitation facilities, rural health clinics, and certain mobile services.²⁷ The

12 See 1972 CON Act, *supra* note 6.

13 Salkever, D. S., & Bice, T. W. (1976). The impact of certificate-of-need controls on hospital investment. *The Milbank Memorial Fund Quarterly. Health and Society*, 185–214. (They find, however, that CON laws had changed the composition of hospital investments.)

14 K.R.S. § 216B.010.

15 See The Findings in the Academic Research Are Clear: CON Laws Have Not Achieved Their Goals at page 18 below.

16 Patrick John McGinley, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a "Managed Competition" System*, 23 Fla. St. U. L. Rev. 141, 157–58 (1995).

17 Deloitte. (Dec. 2013). *The Commonwealth of Kentucky Health Care Facility Capacity Report*, available at <https://ij.org/wp-content/uploads/2023/07/KY-Deloitte-2013-Facilitystudy.pdf>.

18 *Id.* at 19.

19 *Id.* at 88.

20 *Id.* at 19.

21 See *id.* at 30–31.

22 *Id.* at 80.

23 *Id.* at 98; see also *id.* at 101 (noting that discontinuing CON for MRI and PT would mirror earlier decisions to discontinue CON for x-rays and CTs).

24 *Id.* at 101.

25 *Id.*

26 Emily Whelan Parento, *Certificate of Need in the Post-Affordable Care Act Era*, 105 Ky. L. J. 201, 250–51 (2017).

27 Ky. H.B. 444 (2019).

2019 amendments also increased the expenditure minimums that trigger CON requirements in some cases. The most recent expenditure minimum available on the Cabinet Division of Certificate of Need’s website at the time of publication was \$3,740,706.00, effective December 1, 2022.²⁸

As of July 2023, Kentucky requires a CON for the following services and technologies:

1. Acute care hospital beds
2. Adult day health
3. Ambulance providers
4. Birth centers
5. Cardiac catheterization, freestanding or mobile
6. Chemical dependency treatment programs or beds
7. Comprehensive physical rehabilitation beds
8. Freestanding ASCs
9. Freestanding emergency departments
10. Home health agencies
11. Hospice services, residential or facilities, if provided by a non-hospice entity
12. Hospitals
13. Hospital beds
14. Intermediate care facilities (ICFs)
15. ICFs for individuals with intellectual or developmental disabilities
16. Long term care beds
17. Megavoltage radiation equipment, freestanding or mobile
18. MRI equipment, freestanding or mobile
19. New technological developments
20. Nursing homes
21. Nursing home beds
22. Open heart surgery
23. Organ transplantation
24. Personal care homes
25. PET equipment, freestanding or mobile
26. Prescribed pediatric extended care facilities
27. Private duty nursing facilities
28. Program of all-inclusive care for the elderly if it includes a CON service
29. Psychiatric hospital beds
30. Psychiatric residential treatment facilities levels I and II
31. Relocating a facility or replacing existing equipment
32. Special care neonatal beds

Note that the list includes services that are unlikely to be over-prescribed, such as birth centers and neonatal units.

It also includes services like home healthcare and hospice care that are often thought of as low-cost alternatives to other modes of care. Finally, the list includes services in high demand that cater to vulnerable or underserved populations like psychiatric care and chemical dependency treatment.

In 2019, while the General Assembly was modifying the law, Dipendra and Kishor sued the Cabinet, arguing that the ban on their ability to open a home health agency prohibited them from exercising their constitutional right to earn a living.²⁹ At the outset of the case, the district court rejected the defendants’ motions to dismiss. In describing the potential problems with CON laws, the court asked what “if Michigan had told Henry Ford he couldn’t build a Model T because the market had enough Buicks[?]”³⁰ Or what if the government decided there was “no need for iPhones (2007) because of Blackberries (1999)[?]”³¹ Ultimately, the court allowed the case to proceed because “[a]s important as innovation-through-competition has been to those industries, it’s arguably even more important in healthcare, where the stakes are life and death.”³²

After two more years of litigation, Dipendra and Kishor lost their case under the government-friendly rational basis test. On appeal, Chief Judge Jeffrey Sutton of the 6th U.S. Circuit Court of Appeals confirmed that the rational basis test requires judges to uphold “silly,” “unjust,” “unfair,” “unwise,” “stupid,” “ineffective,” and “incorrigibly foolish” laws.³³ Judge Sutton also noted:

- “Since 1987, the federal government—across different agencies and ideologically diverse administrations—continues to advocate against [CON] laws, noting their tendency to increase costs while decreasing access and quality of care . . . [P]ublic defenders of such laws are a shrinking minority.”³⁴
- “[T]he judgment that [CON laws were] a failed experiment has the ring of truth to it. Were we Kentucky legislators ourselves, we would be inclined to think that certificate-of-need laws should be the exception, not the rule, and perhaps have outlived their own needs.”³⁵

In 2023, the General Assembly adopted HB 334, which makes it easier for existing intermediate care facilities for individuals with intellectual disabilities (ICF/ID) to get CONs to add beds. This legislation was an attempt to address the existing seven-to-ten-year waitlist for a bed in an ICF/ID.

28 See K.R.S. § 216B.130; 900 K.A.R. 6:030; Cabinet for Health and Family Services, 2022 Annual Adjustment to the Expenditure Minimums Required by KRS 216B.130, available at <https://ij.org/wp-content/uploads/2023/07/2022-expend.-min.pdf>.

29 Co-author Jaimie Cavanaugh represented Dipendra and Kishor in this case, as did her employer the Institute for Justice. The Kentucky Hospital Association intervened as a defendant in the action to defend the CON laws. More information is available here: <https://ij.org/case/kentucky-con/>.

30 *Tiwari v. Friedlander*, No. 3:19-CV-884-JRW-CHL, 2020 WL 4745772, at *1 (W.D. Ky. Aug. 14, 2020) (“*Tiwari I*”).

31 *Id.* at *1.

32 *Id.* at *2.

33 *Tiwari v. Friedlander*, 26 F.4th 355, 361, 365 (6th Cir. 2022) (“*Tiwari II*”); *id.* at 363 (“Kentucky’s certificate-of-need law passes [the rational-basis test], perhaps with a low grade but with a pass all the same.”) (overruling *Tiwari I*).

34 *Tiwari II*, 26 F.4th at 365.

35 *Id.*

The State of Certificate of Need Laws Around the Country

In 2018, the U.S. Department of Health and Human Services, Department of the Treasury, and Department of Labor published a report providing:

Studies 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.³⁶

The Federal Trade Commission (FTC) and the Antitrust Division of the U.S. Department of Justice (DOJ) have held the same position for decades.³⁷ In testimony submitted in support of a 2016 South Carolina bill to repeal CON laws, the two agencies described “decades” of FTC studies beginning in the late 1980s showing that CON laws lead to higher healthcare costs.³⁸ Federal agencies have publicly supported CON repeal across both Republican and Democratic administrations.³⁹

At the state level, most of Kentucky’s neighboring states have recently enacted reforms:

- In 1999, Indiana repealed its CON program. In 2018, it reenacted CON for nursing homes only.
- In 2012, Ohio repealed most of its CON laws. Since then, Ohio has regulated only long-term care homes.⁴⁰
- In 2021, Tennessee overhauled its CON laws by:
 - exempting mental health hospitals and psychiatric services from CON;
 - allowing critical access hospitals to reopen without CON;
 - easing requirements to re-open a closed hospital;
 - relaxing the requirements for adding nursing home beds or opening home health agencies;
 - imposing a one-year expiration on all CONs;
 - and updating the CON application process.
- In 2023, West Virginia amended its CON laws to eliminate CON for birth centers and allow existing hospitals to add services without a CON.

Many states recognize that applying CON laws to rural hospitals hurts communities. That is why states including

Alabama, Oregon, Tennessee, and Washington exempt rural hospitals from their CON laws. Kentucky exempts rural clinics from its CON laws.

Other recent CON reforms of note include:

- In 2019, Florida repealed most of its CON requirements. CON remains in place for nursing homes, hospice, and intermediate care facilities for the developmentally disabled.
- In 2021, Montana repealed its entire CON program except for nursing homes.
- In 2022, North Carolina State Treasurer, Dale Folwell, an elected official, filed an amicus brief with the North Carolina Supreme Court arguing that:

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.⁴¹

- In 2023, Connecticut repealed its birth center CON law.
- In 2023, North Carolina overhauled its CON laws by:
 - exempting psychiatric and chemical dependency treatment facilities;
 - increasing expenditure minimums that trigger CON review; and
 - repealing CON requirements for ASCs and MRIs in counties with more than 125,000 people.
- In 2023, South Carolina repealed its entire CON program, except for nursing homes.⁴²

36 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 (2019) (citations omitted), available at <https://ij.org/wp-content/uploads/2023/07/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

37 Joint Statement of the Antitrust Division of the FTC and the Antitrust Division of the DOJ on Certificate-of-Need Laws and South Carolina House Bill 3250 (Jan. 11, 2016), available at <https://ij.org/wp-content/uploads/2023/07/FTC-DOJ-SC-2016.pdf>.

38 *Id.* at 2–3.

39 See also U.S. Department of Health and Human Services, U.S. Department of the Treasury, U.S. Department of Labor, *Improving Health Care A Dose of Competition*, ch. 8, 1–6 (July 2004).

40 See Ohio Am. Sub. H.B. 487 (2012).

41 Brief of Amicus Curiae Treasurer Dale R. Folwell, CPA at 12, *Singleton v. N.C. Dep’t of Health & Hum. Servs.*, No. COA21-558 (N.C. Aug. 15, 2022), available at <https://ij.org/wp-content/uploads/2023/07/NC-Treasurer-Amicus-Brief.pdf>.

42 South Carolina’s CON for hospitals will sunset on January 1, 2027. S.C. Code § 44-7-160(C).

HOW DO I GET A CERTIFICATE OF NEED?

Applying for a Certificate of Need

Formal Review

Navigating the CON application process can feel like a never-ending maze. Not only is the process lengthy and expensive, an applicant often must overcome a competitor's objections to stand a chance at receiving a CON. To offer any services covered by Kentucky's CON laws (see list on page 10), you need to start by putting together an application. In theory, you fill out a form, submit it to the Cabinet for Health and Family Services (Cabinet), and wait for a decision.

Sounds straightforward, right? But nothing about CON is that simple. The formal CON application process involves nine steps and often requires a hearing akin to a full-blown trial. To stand any chance at getting a CON, you will have to hire attorneys and consultants and can be forced to wait months or years before you get a final decision. In the meantime, you'll be in limbo, not knowing whether you can open your business. There is also a faster process, called "nonsubstantive review." Let's walk through the application process.

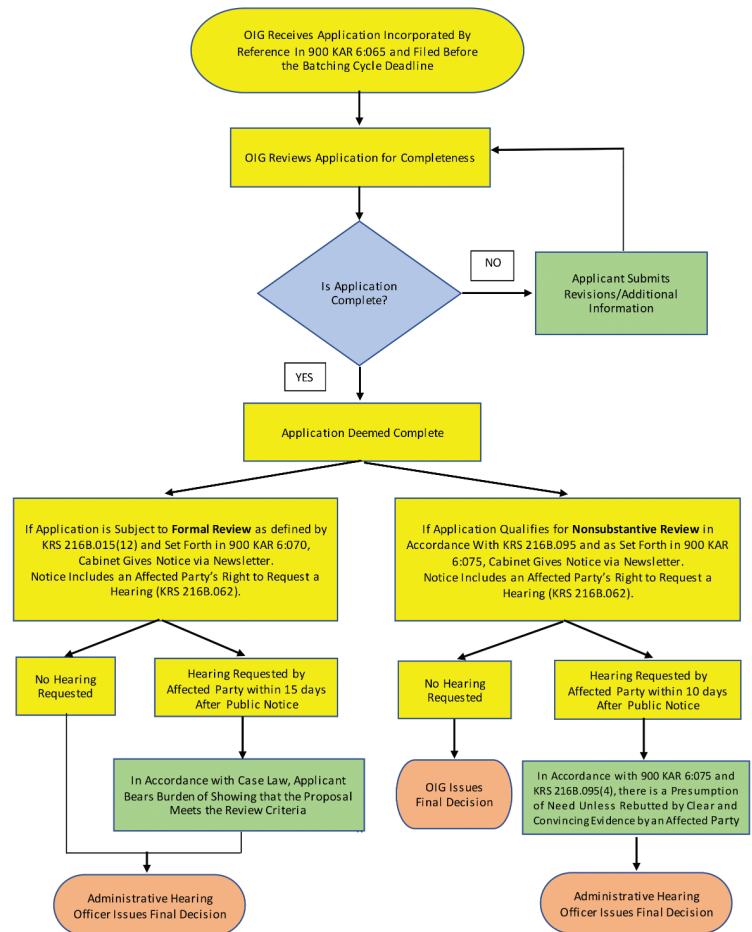
First, you need to determine if you're requesting substantive (formal) review or nonsubstantive review. The Office of the Inspector General provided this dizzying flow chart⁴³ in an attempt to clarify the process:

Let's say you want to open a home health agency. That requires formal review, so your application must satisfy these five review criterion: (1) consistency with the State Health Plan (SHP)⁴⁴; (2) need and accessibility; (3) interrelationships and linkages; (4) costs, economic feasibility, and resource availability; and (5) quality of care.⁴⁵ The first criteria (consistency with the SHP) is often the most strictly construed, but even if your application is inconsistent with the SHP, the reviewer still makes findings about the rest of the criteria.

Second, you check the SHP, a document that the Cabinet publishes every three years.⁴⁶ The Cabinet is supposed to update it annually and it must be approved by the Governor.⁴⁷ The SHP is available to download on the Cabinet's website. A CON application often lives or dies with the SHP because it contains formulas or other assessments that determine whether a facility or service is "needed." These formulas vary depending on the proposed facility or service. If the formulas in the SHP don't show a "need" for your service in your geographic area, the Cabinet cannot approve your CON application.⁴⁸

For example, a home health agency can open in a county only if the formula shows that at least 250 new patients need home health services. The Cabinet calculates need like this⁴⁹:

Figure 1. Certificate of Need (CON) Application Review Flowchart



43 Kentucky's Certificate of Need (CON) Program Emergency Medical Services Task Force 2 (Aug. 16, 2022), available at <https://ij.org/wp-content/uploads/2023/07/KY-CON-Task-Force-Aug.-16-2022.pdf>.

44 See e.g., Emergency – 2023 Update to the State Health Plan (Mar. 2023), available at <https://ij.org/wp-content/uploads/2023/07/March-2023-Updated-KY-SHP.pdf>.

45 See K.R.S. § 216B.040(2)(a)2.

46 K.R.S. § 216B.015(28).

47 *Id.*

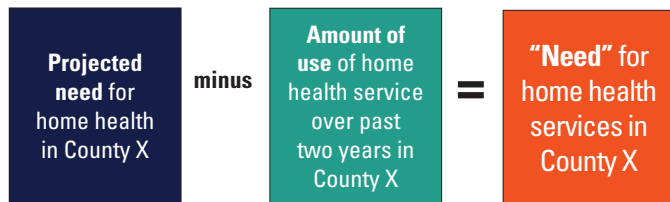
48 Although it is futile to submit a CON application when the SHP does not show a "need" for a particular facility or service, applicants sometimes try anyway. See CON Laws During Recent Public Health Emergencies at page 15 below; Executive Summary at page 4 above (explaining Dipendra and Kishor's attempt to get a CON to serve patients lacking home health services in the Louisville area).

49 See SHP, *supra* note 44, at 34 (explaining how projected need and average number of unduplicated patients are calculated). There are different formulas for different facilities and services.

First, determine the number of people in given age groups (e.g., ages 65–74 or 75–84) who used home healthcare (averaged over the last two years). These are base rates that the Cabinet considers the “right” **amount of use**.

Next, for each county, multiply the statewide age-group rates by the projected population for the SHP year and add results together. This produces an estimate of how many people per county “should” be using home health services. This is **projected need**.

Finally, subtract the amount of use from the projected need to determine each county’s “**need**” for home health services.⁵⁰



Applying this formula is mandatory for new entrants. Even if you collected sworn statements from 250 individuals unable to find adequate service, it would be immaterial. The Cabinet would still find that your application was inconsistent with the SHP.

But, of course, every rule has an exception. Unsurprisingly, the exception advantages incumbents. Incumbent home health agencies can expand when need reaches 125 new patients.⁵¹ Thus, existing home health agencies can easily prevent new home health agencies from opening by expanding before need reaches 250, permanently shutting any competition out of the market.

In reality, trusting past usage to predict future need is risky. The 2013 Capacity Report aptly noted the flaw in relying on past usage as a baseline,⁵² citing nursing homes as an example:

If patients are not admitted to nursing facilities in the first place because of capacity constraints, then baseline utilization data may underestimate actual demand for nursing services (unmet demand is not captured). Future projections could correspondingly under-represent demand. This consideration applies particularly to health services that operate at or close to capacity today.⁵³

Moreover, existing providers have an incentive to game the formula. A newcomer’s application is more likely to be denied if existing facilities are operating under capacity. Knowing this, incumbent providers may have an incentive to keep beds unfilled or appointments open despite CON’s goal of preventing the underutilization of care.

Third, assuming the SHP reflects that a need exists, you will

start on your application. This often involves paying an attorney and/or consultant to help with formal documents. These experts will know how the application process works, do statistical analyses to show that there’s a lack of care, help you make financial projections, and otherwise help you with your business plans. Lawyers can be hard to come by for new providers. When Dipendra and Kishor searched for one in Louisville, every lawyer they called represented a health system, or had in the past, and therefore had a conflict of interest. Remember, even if there is a need according to the SHP, your application still needs to comply with the four remaining review criteria:

1. **Need and accessibility.** In essence, you have to prove need a second time. This might require a consultant to prove the need for your service using different metrics than the SHP formula. And proving accessibility can be a catch-22. Services in a rural area might be needed and not opposed by an existing agency, but they might not be considered accessible. By contrast, services in an urban area would be more accessible but attract opposition from existing providers who will argue enough service exists.
2. **Interrelationships and linkages.** Basically, you must show that you are connected to existing healthcare infrastructure. You might collect letters from future potential employees and potential providers/facilities that would refer patients to your home health agency. You might even get letters from future patients. This criterion favors existing providers. They’re already linked to existing healthcare facilities and networks and have no incentive to support new providers.
3. **Costs and economic feasibility.** Here, you need to disclose your finances to show your project is economically feasible. The Cabinet wants to see how much it will cost you to open, your projected revenue in the first couple of years, and how much capital you can invest. If you have any backers or partners, the Cabinet will want to know that too. Again, you may need a consultant, accountant, or other expert to help you prepare this part of your application.
4. **Quality of care.** Finally, you must attest that you will offer high-quality care. Although this sounds like the most important criterion, the Cabinet never follows up on the assertions in a provider’s application after issuing a CON. That’s part of the licensing and inspection process managed by the Cabinet’s Office of Inspector General Healthcare Division. CON laws are not a tool to ensure the quality of healthcare services. And it’s very unlikely the Cabinet would deny a CON application based on quality concerns alone.

50 The population and number of users of a service are provided by the Cabinet. See e.g., 2022 Home Health Need, available at <https://ij.org/wp-content/uploads/2023/07/2022HomeHealthNeed.pdf>.

51 SHP, *supra* note 44, at 34–35; see also *Tiwari I*, 2020 WL 4745772, at *4 (“[T]he deck is stacked against start-ups because of incumbents’ successful ‘rent-seeking’ with the ‘rents’ referring to monopoly profits.”).

52 See, e.g., *Tiwari I*, 2020 WL 4745772, at *11 (“Patients are more than numbers you plug in a formula. Old or young, rich or poor, English-speaking or Nepali-speaking, each patient is unique.”).

53 Capacity Report, *supra* note 17, at 75.

Fourth, after paying your advisors to help prepare your application, you're finally ready to file. Keep your checkbook out—the filing fees range from \$1,000 to \$25,000 depending on the cost of your project.⁵⁴ Be aware, the Cabinet will keep your application fee even if it does not approve your application. From 2019 through May 2023, the Cabinet collected over \$2 million in filing fees.

Fifth, the Cabinet will review your application and either ask for additional information or formally confirm that your application is complete.⁵⁵ Then, the Cabinet publishes your application in its monthly CON Newsletter. The Newsletter notifies your competition that you've applied for a CON. This step is mandatory. There may be delays, though, because the Cabinet publishes home health agency CON applications only in February, May, August, and November.⁵⁶ Different types of CON applications are published in different months.

Sixth, now the real fun begins. Once the Cabinet publishes the Newsletter with information about your application, any “affected person” has 15 days to intervene in the review process and request a hearing.⁵⁷ In theory, a future user of your home health agency is an “affected person” and could request a hearing. In practice, that never happens because consumers don't oppose access to more care. Only potential competitors intervene to oppose your application. They often drop their objections, however, if you agree not to directly compete with their territory.⁵⁸

Although the hearing is before an administrative agency and not in a court, you need to be represented by an attorney and prepare like you would for a full-blown trial. You will appear before a hearing officer who acts like a judge. Your opposition is often a large healthcare system with the resources to stretch the application process out in hopes that you will give up. And it works. Some applicants decide they don't want to deal with the headache of a hearing, or simply can't afford to keep paying an attorney, and walk away at this point.

Before the hearing, the parties (including your would-be competitors) may engage in discovery, subpoena witnesses, and file dispositive motions.⁵⁹ At the hearing, each party is allowed to present its case; make an opening statement; call witnesses; cross-examine opposing witnesses; offer documentary evidence into the record; and make a closing statement.⁶⁰ The burden is on you to prove that you satisfy all five review criteria. Your

opponents will argue that they are already providing enough care and that if the Cabinet grants your application, it will hurt their bottom lines.

Seventh, after the hearing concludes, the hearing officer will consider the evidence and issue a final order approving or disapproving your application. This entire process can last months or sometimes over a year. If they feel their application will be denied, some applicants choose to withdraw their applications at this point.

Eighth, you get a final order! Let's say the hearing officer grants your CON application. You might think you can go open your home health agency. But wait; any affected person can appeal this order as long as they were a party during the administrative hearing. The affected person can request reconsideration from the Cabinet and/or appeal the order to the Franklin Circuit Court.⁶¹ And as with any other judicial decision, the losing party can appeal from the Circuit Court's decision. If the Cabinet does not approve your CON application, you have the same rights to appeal.

The appeal process will add years to your timeline and put the status of your CON in jeopardy. You are not allowed to open your agency while appeals are pending.

Ninth, if you are lucky enough to avoid the appeal process, you can begin taking steps toward opening. You must submit progress reports to the Cabinet every six months until you become operational. Otherwise, the Cabinet can revoke your CON.⁶²

This process is not for the faint of heart. It's clear why many entrepreneurs give up without applying or simply avoid states with CON laws altogether. As a result, Kentucky has missed out on countless healthcare providers and innovations that are enjoyed in other parts of the country. The CON process can't be the best way to ensure access to affordable, quality healthcare services in the Bluegrass State.

Nonsubstantive Review

The nonsubstantive review process moves faster. Certain services like adult day care, transferring acute care hospital beds between facilities with one owner, hospital-owned freestanding emergency departments, and private duty nursing agencies are eligible for nonsubstantive review.⁶³ Under this process, there is “a presumption that the facility or service

⁵⁴ 900 K.A.R. 6:020 § 1.

⁵⁵ This and the steps moving forward are subject to specific deadlines. See CON Batching Cycle Timetable – March 2023, available at <https://ij.org/wp-content/uploads/2023/07/KY-March-2023-batching-cycle-chart.pdf>.

⁵⁶ 900 K.A.R. 6:060 § 2(b).

⁵⁷ See K.R.S. § 216B.015(3) (defining “affected persons” as “the applicant; any person residing within the geographic area served or to be served by the applicant; any person who regularly uses health facilities within that geographic area; health facilities located in the health service area in which the project is proposed to be located which provide services similar to the services of the facility under review; health facilities which, prior to receipt by the agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future; and the cabinet and third-party payors who reimburse health facilities for services in the health service area in which the project is proposed to be located[.]”).

⁵⁸ See CON Laws During Recent Public Health Emergencies at page 15 below (noting that nearly 60% of ambulance CON applications in Kentucky from 2009 through 2022 were granted after affected persons dropped their objections in exchange for the applicant agreeing to decrease the size of its service area).

⁵⁹ K.R.S. § 216B.085; 900 K.A.R. 6:090 § 3.

⁶⁰ 900 K.A.R. 6:090 § 3.

⁶¹ See K.R.S. § 216B.115.

⁶² See K.R.S. § 216B.086; 900 K.A.R. 6:100.

⁶³ See CON Task Force, *supra* note 43, at 3.

is needed and a presumption that the facility or service is consistent with the [SHP].⁶⁴ There's no relying on population projections or worrying about need formulas. Although there are a few requirements for different facilities and services,⁶⁵ they are not subjective in the way that the review criteria like interrelationships and linkages or economic feasibility are during formal review. If you meet the requirements under nonsubstantive review, it's very likely the Cabinet will approve your application.⁶⁶

Affected persons can still request a hearing, but under nonsubstantive review, the burden flips. Here, the Cabinet will approve an application unless the affected person can prove that a need for the facility or service does not exist by clear and convincing evidence.

If your application for nonsubstantive review is not approved, you have three options. One, you can go through the formal review process. Two, you can request that the Cabinet reconsider the nonsubstantive review decision. Three, you can appeal the decision to the Franklin Circuit Court.⁶⁷

CON Laws During Recent Public Health Emergencies

As you might imagine, going through the cumbersome CON application process just described would be a disaster during a public health emergency. Since 2020, Kentucky's CON laws have been adjusted three different times to keep up with demand from public health emergencies, exposing how inflexible and potentially harmful CON laws are.

First, in March 2020, the COVID-19 pandemic forced the Cabinet to allow providers to expand facilities without seeking a CON. Under normal circumstances, adding hospital beds would require formal review by the Cabinet—which can take months or years. Under the Cabinet's relaxed CON guidelines, providers were allowed to take actions that would normally require a CON as long as they notified the Cabinet.⁶⁸ Even under this system, filing paperwork with the Cabinet is the last thing hospitals should have been worrying about while trying to increase access to healthcare during a global pandemic.

Kentucky was hardly alone. Between 2020 and 2022, at least 24 other states with CON laws also recognized that CON laws were a barrier to care. These states also suspended or modified their CON programs. If CON laws somehow provide access to *more* healthcare, as proponents argue, why were most states with CON laws forced to relax them during the pandemic?

Other CON proponents argue that CON laws weren't a barrier during pandemic surges precisely because states were quick to waive or loosen CON requirements. But patients in states with CON laws entered the pandemic with fewer hospitals per capita, which disadvantaged them:

- Hospitals in states with CON laws were 27% more likely to run out of hospital beds. There was no difference in this figure between states that relaxed their CON requirements during the pandemic and those that did not.⁶⁹
- One estimate predicted that ICU bed shortages would be nine times greater per capita in CON states compared to states without CON laws.⁷⁰

And the emergency suspensions were only temporary. In Kentucky and elsewhere, once the official state of emergency ended, providers were required to surrender the extra beds and equipment they had acquired. This undoubtedly deterred some providers from expanding at all.

Outside the pandemic, in March 2023, Governor Andy Beshear was forced to issue an emergency regulation to update the SHP “to ease the urgent mental health crisis by promoting greater access to psychiatric care across Kentucky.”⁷¹ Recall that the Capacity Report, published in 2013, identified this problem.⁷² Despite the Capacity Report's clear warning, no one addressed the problem until it was too late and emergency regulations were necessary.

Without CON laws, Kentucky might have kept pace with the demand for psychiatric services. Instead, Governor Beshear's statement of emergency reads:

There is an ongoing mental health crisis across the nation, and hospitals report that the proportion of emergency department visits due to mental health issues has increased markedly during the last few years. The expansion of inpatient behavioral health services throughout the state, including rural areas, will enhance immediate access to resources for at-risk mental health patients of such acuity that they need inpatient services and stabilization. This amendment is needed . . . to help promote access to inpatient psychiatric healthcare.⁷³

Despite the seriousness of the problem, the amended regulation is narrow. It permits existing hospitals to

64 900 K.A.R. 6:075E.

65 See 900 K.A.R. 6:075E.

66 See, e.g., Survey of Recent CON Applications at page 17 below.

67 900 K.A.R. 6:075E § 2(14); K.R.S. § 216B.115.

68 Cavanaugh, J., et al., (2020) Conning the Competition: A Nationwide Survey of Certificate of Need Laws. *Institute for Justice*, 69, available at <https://ij.org/report/conning-the-competition/>.

69 Mitchell, M., & Stratmann, T. (2021). 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(1), 10.

70 Mitchell, M. D., Stratmann, T., & Bailey, J. B. (April 2020). *Raising the Bar: ICU Beds and Certificates of Need*. (Policy Brief) *Mercatus Center at George Mason University*. <https://www.mercatus.org/publications/covid-19-crisis-response/raising-bar-icu-beds-and-certificates-need>.

71 See Statement of Emergency 900 K.A.R. 6:075E (Mar. 15, 2023), available at <https://ij.org/wp-content/uploads/2023/07/Beshear-Mental-Health-Emergency-Order.pdf>.

72 Capacity Report, *supra* note 17, at 88.

73 Statement of Emergency, *supra* note 71, at 68.

apply to convert no more than 25 hospital beds to adult psychiatric care beds under nonsubstantive review, but only if the hospital's current occupancy rates are less than 70%.⁷⁴ The emergency regulation does not accommodate adolescent beds or new psychiatric facilities. Plus, providers could still face opposition if they file an application under this emergency regulation.

This could have been avoided. In 2021, a Louisville hospital filed a CON application to do almost exactly what this emergency regulation proposes but was stopped by Kentucky's CON laws. On October 27, 2021, Mary & Elizabeth Hospital (ME) applied to convert 33 of its 298 licensed acute care beds to adult psychiatric beds. Its application noted that Baptist Health had recently closed its psychiatric care unit, eliminating 22 local psychiatric beds. Apart from Baptist's closure, ME explained that it had been forced to send many patients to Our Lady of the Peace Hospital for psychiatric care following their treatment for medical issues. If it had more psychiatric beds, ME could have treated those patients in one place.

ME was trying to be proactive and increase access to care before the number of psychiatric beds dipped dangerously low. Yet the Cabinet hearing officer denied ME's application because the SHP didn't show a need for more beds. According to the SHP formula, the metro area's 1.2 million residents needed a mere 185 adult psychiatric beds. The Cabinet documented 337 licensed adult psychiatric care beds in the region at the time.⁷⁵ And math is math. Because 337 exceeds 185, the hearing officer couldn't approve the application. It didn't matter that ME reported only 66 medical psychiatric beds were actually operational in the region. As the final order casually notes, "revisions to the SHP methodology may indeed be warranted."⁷⁶

The situation is troubling because it could have been avoided and tragic for the patients who missed out on needed psychiatric services.

If Kentucky officials had approved those 33 psychiatric beds in 2021, fewer people would have suffered without treatment, sat in ER beds for longer than necessary, or been forced to leave Kentucky to seek care.

CON laws prevent healthcare providers from scaling up in response to warnings about inadequate access to care. Ultimately, patients pay the price.

Just two months later, in May 2023, Governor Beshear approved a second emergency regulation to address the lack of ambulance services in the Commonwealth.⁷⁷ The regulation provides:

There is an ongoing shortage of ambulance services available across the Commonwealth due to financial demands and workforce shortages. Under current regulations, a new ambulance service would be required to apply for a certificate of need before it could begin operation, which is a lengthy process that can take six (6) months to a year . . . This will allow an ambulance provider to quickly begin serving an area where continuous ambulance services have ceased without waiting months to obtain a certificate of need.⁷⁸

Notably, the regulation acknowledges that providers often have to wait months to get a CON. As with access to psychiatric beds, it didn't have to be this way. Since 2021, at least 11 ambulance CON applications have been disapproved by the Cabinet. Those are 11 providers that could have been alleviating this shortage.

Opposition from affected persons is especially forceful for ambulance CON applications. After reviewing 32 CON applications to provide Class I Ambulance Service submitted from 2009 through 2022, we found that the Cabinet granted nearly 90% of unopposed applications, yet it granted only 13% of opposed applications. In 13 instances (57%), the Cabinet approved opposed applications only after the applicant agreed to serve a smaller geographic area so competitors would withdraw their objections.

Despite the difficulty in getting a CON to operate an ambulance in Kentucky, the lack of access to medical transport throughout the Commonwealth has been well documented. For instance, one report from 2018 found that urban counties in Kentucky had 25% fewer ambulance providers than other states in the region.⁷⁹

These examples show the devastating effects of artificially limiting the supply of healthcare services. Even outside the pandemic, CON laws are harmful. CON laws prevent healthcare providers from scaling up in response to warnings about inadequate access to care. Ultimately, patients pay the price.

⁷⁴ See SHP, *supra* note 44, at 23–24.

⁷⁵ There are an additional 289 beds allocated to the Central State Hospital and the Kentucky Correctional Psychiatric Center, but these are not available for the general population to seek treatment on their own.

⁷⁶ Final Order, *U of L Health-Louisville, Inc. d/b/a Mary & Elizabeth Hospital*, CON Application # 056-06-106(26), Case No. HSAHB CON 21-035 (Mar. 16, 2022), available at <https://ij.org/wp-content/uploads/2023/07/ME-final-order.pdf>.

⁷⁷ 900 K.A.R. 6:080E (approved by Office of Inspector General May 10, 2023), available at <https://ij.org/wp-content/uploads/2023/07/900-KAR-6-080E.pdf>.

⁷⁸ *Id.*

⁷⁹ See *Kentucky takes steps to address lack of adequate ambulance service in 6 counties*, THE LANE REPORT (Oct. 10, 2018), <https://www.lanereport.com/106541/2018/10/kentucky-takes-steps-to-address-lack-of-adequate-ambulance-service-in-6-counties/>; see also *Truesdell v. Friedlander*, No. 22-5808 (6th Cir. filed Sept. 13, 2022) (ambulance provider appealing denial of dismissal of constitutional challenge to Kentucky's CON law).

Figure 2. Approval Rate

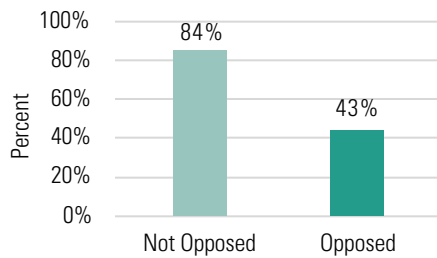
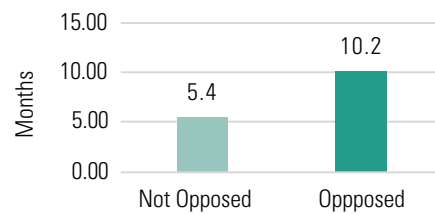


Figure 3. Wait Time for a Decision



Survey of Recent CON Applications

To learn more about the application process, we reviewed every CON application submitted in Kentucky that received a final decision from January 1, 2019 through May 19, 2023.⁸⁰ We counted approvals, disapprovals, withdrawals, revocations, and voided applications, while we excluded deferrals and applications that remained pending at the time of review. In total, we reviewed 262 complete applications. The vast majority—76% of the applications—came from existing providers. Only 24% of the applications were from providers not already operating in Kentucky. The Cabinet approved 227 (86.6%) of the applications it received. But that doesn't tell the whole story.

Of the 262 applications, 164 (63%) were complete applications for nonsubstantive review. The most common type of nonsubstantive application was for adult day healthcare centers. Recall that under nonsubstantive review, the applicant does not bear the burden of proving need; need is presumed. The Cabinet approved all but seven of these applications—an approval rate of 96 percent. These can essentially be thought of as non-CON cases.

In contrast, the Cabinet received 98 complete applications for substantive (formal) review. In these cases, the Cabinet must assess need. The Cabinet approved 70 applications (71%).

Neither the applicant's status as an incumbent provider nor the size of the investment were statistically significantly

related to the odds of approval. As expected, opposition *did* statistically significantly reduce the chances of approval and delayed the approval process. As shown in Figure 2 above, the approval rate for unopposed substantive review applications was 84% but was nearly cut in half, to 43%, for opposed applications.

Opposed applications also took significantly longer to receive a final decision. Among unopposed applications, the wait time averaged 5.4 months. That time nearly doubled, to an average of 10.2 months for opposed applications.⁸¹ Figure 3 shows this delay. As far as we can tell, all opposed parties were would-be competitors.

While it's good news that most applications—even most substantive review applications—were approved during this time period, the analysis suggests that incumbent providers use the contested application process to block and delay competitors from offering services that patients need.

Between 2019 and 2023, CON laws denied Kentuckians access to psychiatric services, acute hospital services, skilled nursing facilities, ground ambulances, and more. We believe the number of providers that abandon their plans without applying for a CON is high, especially in light of the SHP's strict need formulas.

We believe the number of providers that abandon their plans without applying for a CON is high, especially in light of the SHP's strict need formulas.

80 The data set we reviewed was given to us by the Cabinet in response to an Open Records Act request and is also publicly available through the CON Application Search tool on the Cabinet's website: <https://prd.webapps.chfs.ky.gov/cononline/SearchApplication.aspx>.

81 Among all applications, it appears that wait times have declined in recent years from seven months in 2019 to just over three months in 2022.

The Findings in the Academic Research Are Clear: CON Laws Have Not Achieved Their Goals

Co-author, Matthew Mitchell,⁸² has identified and classified every original, peer-reviewed, empirical analysis of healthcare CON laws over the last five decades.⁸³ In a forthcoming publication, he will provide an exhaustive analysis of the studies. In this section, we provide a condensed version of his findings. While the bulk of the publications reviewed are academic, this analysis also includes a handful of academic-quality studies by government agencies such as the Federal Trade Commission.

Few policy experiments have been as thoroughly examined as CON laws. The review identifies 128 separate papers that contain 423 unique tests.⁸⁴ The bulk of these tests address the stated goals of CON laws: access, quality, and costs. There were also tests assessing the effects of CON laws on underserved populations, competition, provider volume, profits, and other miscellaneous outcomes such as CEO pay.⁸⁵ Though the analysis makes no judgments on the quality of the empirical tests contained in the papers, limiting the analysis to peer-reviewed material ensures a minimum quality threshold.

The following sections highlight some of the major findings. Figure 4 below shows that among 389 tests with an identifiable result, a slight majority (205 tests) associate CON laws with a “bad” outcome. These bad outcomes include higher spending, lower quality, harm to underserved populations, diminished access, or less competition. The next most common result (140 tests) is a neutral or insignificant result. A mere 44 tests (11%) associate CON laws with a “good” outcome like less spending,

greater access, or higher quality. In other words, for every one test that associates CON laws with a good outcome, there are nearly five tests that associate it with a bad outcome.

Together, 345 out of 389 tests find that CON laws are associated with either an insignificant or bad outcome. That’s 89 percent. Economists and health researchers become increasingly confident in an outcome when many tests point in the same direction. There’s no contest here. This decisive result confirms that CON laws are not achieving their intended goals and have outlived their utility.⁸⁶

These findings are consistent with standard economic theory, confirming CON laws operate as economists predict. CON laws are barriers to entry that protect incumbent providers from competition, increase costs, and limit access to care. Worse, the one thing protectionism should accomplish—enhancing the profits of incumbent providers—may not even occur in the long run (although it might in the short run).⁸⁷ CON laws, then, are all downside.

CON Laws Decrease Access to Health Care

Access is the most-studied effect of CON laws. By design, CON regulations limit the supply of facilities, technology, and investment. Thus, it seems intuitive that they would reduce the availability of services. Yet, vexingly, one purpose of Kentucky’s CON laws is to “increase access to health-care facilities, services, and providers.”⁸⁸ The authors of this legislation evidently believed that by limiting the supply of certain services and procedures, they could increase the supply in other areas.

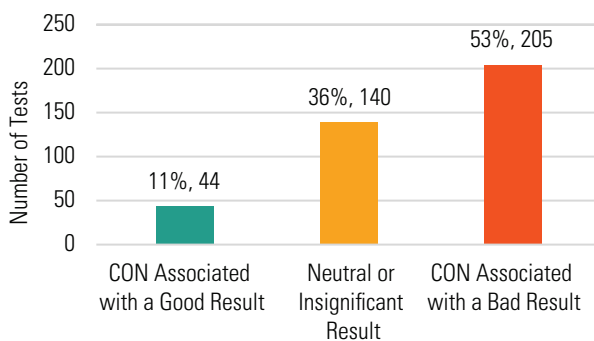
The data suggest otherwise. A total of 170 tests examine whether CON laws impede or enhance access to care, and 153 (or 90%) find that CON laws impede access to care or have a neutral or insignificant effect on access. For every test associating CON laws with increased access, there are more than five associating it with diminished access. The weight of the evidence is undeniable.

These tests largely fall into two categories: “availability tests” and “utilizations tests.”

Availability Tests

Availability tests assess how easy it is for patients to obtain care. They measure things like the number of providers or services per capita, or the units of technology per capita. Other availability tests assess how far patients must travel to find care, while still others assess how long they must wait once they get there. In total, there have been 80 tests assessing the effect of

Figure 4. Summary of Tests with an Obvious Normative Implication



82 See About the Authors for Mitchell’s biography at page 42 below.

83 No studies published after June 30, 2023 are included in this review.

84 Due to the nature of some tests, some results are counted in more than one category. For example, if a paper finds that CON laws encourage an unwarranted treatment, it is associated with both greater utilization of a procedure and lower quality.

85 Some of these studies did not contribute to this analysis because their findings were outside the scope of this report. They are still reported in the Appendix.

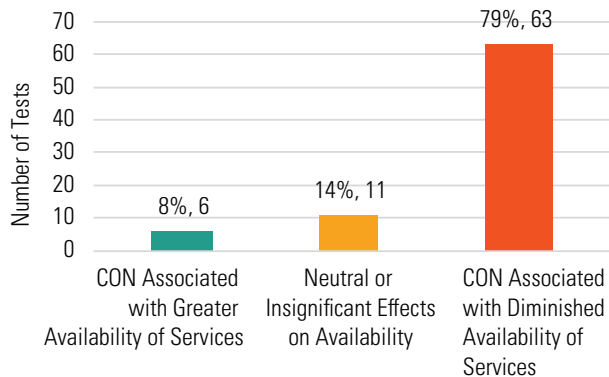
86 Citations and brief descriptions of each study are available in the Appendix. Note that there are a few studies listed in the Appendix that are not reflected in this report because they tested CON indirectly or addressed topics like CEO pay or competition that we did not include in this analysis.

87 See Sloan, F. A. (1981). Regulation and the rising cost of hospital care. *The Review of Economics and Statistics*, 63(4), 479–487. <https://doi.org/10.2307/1935842>; Dobson, A., et al. (2007). An Evaluation of Illinois’ Certificate of Need Program. <https://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf>; Cutler, D. M., Huckman, R. S., & Kolstad, J. T. (2010). Input constraints and the efficiency of entry: Lessons from cardiac surgery. *American Economic Journal: Economic Policy*, 2(1), 51–76.

88 K.R.S. § 216B.010.

CON laws on the availability of care. As shown in Figure 5, 79% of these tests associate CON laws with diminished availability of care, while just 8% associate them with increased availability.

Figure 5. Tests Assessing the Effect of CON on Availability of Services



Among other things, researchers find that patients in states with CON laws have:

- 30–48% fewer hospitals,⁸⁹
- 30% fewer rural hospitals and 13% fewer rural ambulatory surgical centers,⁹⁰
- 25% fewer open-heart surgery programs,⁹¹
- 20% fewer psychiatric care facilities,⁹² and
- Fewer dialysis clinics and reduced capacity at existing clinics.⁹³

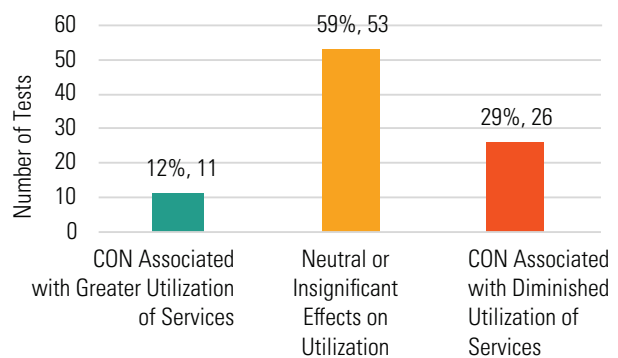
Several studies also associate CON laws with fewer hospital beds.⁹⁴ For example, one study finds that each additional service covered by CON reduces the number of hospital beds per 100,000 persons by 4.7%.⁹⁵ And, patients in states with CON laws have access to fewer medical imaging devices,⁹⁶ must wait longer for care,⁹⁷ must travel farther for care,⁹⁸ and are more likely to leave their state for care.⁹⁹

Utilization Tests

Another way to measure access is to look at the actual utilization of services. Here, the theoretical effect of CON laws is less clear because patients will often seek care even if it is costly or inconvenient. It is also possible that CON laws could increase utilization of certain services by suppressing utilization of other services. For example, if a condition can be treated by either procedure A or procedure B, but procedure A is limited by a CON, we would expect to see the number of users of procedure A decrease and the number of users of procedure B increase.

We have identified 90 tests that measure whether CON laws affect the utilization of healthcare services. Of these, 79 tests find either no significant relationship or a negative relationship between CON laws and utilization of services. Only 11 tests associate CON with greater utilization of services. Thus, there is little support for the proposition that CON laws increase the utilization of care.

Figure 6. Tests Assessing the Effect of CON on Utilization of Services



89 Stratmann and Koopman estimate 30% fewer while Eichmann and Santerre estimate 48% fewer. Stratmann, T., & Koopman, C. (February 2016). Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals. (Working Paper). *Mercatus Center at George Mason University*. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3191476; Eichmann, T. L., & Santerre, R. E. (2011). Do hospital chief executive officers extract rents from Certificate of Need laws?. *Journal of Health Care Finance*, 37(4), 1–14.

90 Stratmann & Koopman, *supra* note 89.

91 Robinson, J. L., *et al.* (2001). Certificate of need and the quality of cardiac surgery. *American Journal of Medical Quality*, 16(5), 155–160.

92 Bailey, J., & Lewin, E. (2021). Certificate of Need and Inpatient Psychiatric Services. *The Journal of Mental Health Policy and Economics*, 24(4), 117–124.

93 Ford, J. M., & Kaserer, D. L. (1993). Certificate-of-need regulation and entry: Evidence from the dialysis industry. *Southern Economic Journal*, 59(4), 783–791. <https://doi.org/10.2307/1059739>.

94 Joskow, P. L. (1980). The effects of competition and regulation on hospital bed supply and the reservation quality of the hospital. *The Bell Journal of Economics*, 11(2), 421–447; Anderson, K. B. (1991). Regulation, market structure, and hospital costs: comment. *Southern Economic Journal*, 58(2), 528–534. <https://doi.org/10.2307/1060194>; Eichmann, & Santerre, *supra* note 89.

95 Stratmann, T., & Russ, J. (July 2014). *Do Certificate-of-Need Laws Increase Indigent Care?* (Working Paper No. 14-20). *Mercatus Center at George Mason University*. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3211637.

96 *Id.*

97 Myers, M. S., & Sheehan, K. M. (2020). The impact of certificate of need laws on emergency department wait times. *Journal of Private Enterprise*, 35(1), 59–75.

98 Carlson, M. D., *et al.* (2010). Geographic access to hospice in the United States. *Journal of Palliative Medicine*, 13(11), 1331–1338. <https://doi.org/10.1089/jpm.2010.0209>.

99 Baker, M. C., & Stratmann, T. (2021). Barriers to entry in the healthcare markets: Winners and Losers from Certificate-of-Need Laws. *Socio-Economic Planning Sciences*, 77, 101007. <https://doi.org/10.1016/j.seps.2020.101007>.

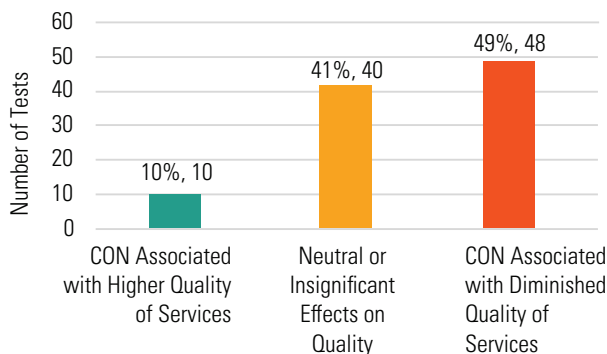
CON Laws Contribute to Lower Quality Care and Worse Healthcare Outcomes

Another legislative purpose for CON laws is to improve the quality of healthcare.¹⁰⁰ Yet CON laws only serve an initial gatekeeping function. While applicants may attest that they will offer quality services during the application process, the Cabinet does not follow up on quality concerns. Instead, quality requirements in Kentucky are monitored and enforced by the Office of Inspector General, Division of Health Care under its facility licensure authority.¹⁰¹

It's unsurprising then that the overwhelming majority of the existing tests show that CON laws lead to worse care or have neutral/insignificant effects on quality. Of 98 tests, only ten associate CON laws with improved quality.

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Figure 7. Tests Assessing the Effect of CON on Quality of Care



States with CON laws have:

- Higher mortality rates for heart attack, heart failure, and pneumonia,¹⁰²
- Higher mortality rates for natural death, septicemia, diabetes, chronic lower respiratory disease, influenza or pneumonia, Alzheimer's, and COVID-19,¹⁰³
- Higher readmission rates following heart attack, heart failure, and pneumonia,¹⁰⁴ and
- Lower nursing staff-to-patient ratios and greater use of physical force in nursing homes.¹⁰⁵

States without CON laws have an estimated 5.7% fewer deaths from post-surgical complications due to the mortality rates highlighted above.

Overwhelming Evidence Shows that CON Laws Lead to Higher Health Care Spending

CON Laws Increase Spending Per Service

Another primary legislative purpose behind Kentucky's CON program is to deliver "cost-efficient" healthcare services.¹⁰⁶ Yet standard economic theory and common-sense dictate that reducing the supply of healthcare will have the opposite effect. As supply decreases, costs and prices typically increase.

There is no doubt that healthcare is a highly regulated market with many distortions (hidden pricing, third-party payment, etc.). Even so, there's no reason to believe that restricting supply (another distortion) will decrease per-service spending. Instead, supply restrictions—even in regulated and distorted markets—tend to increase spending per service.¹⁰⁷ Additionally, because of their anti-competitive properties, CON laws seem likely to permit some degree of monopoly pricing power. This too, is likely to increase spending per service.¹⁰⁸ The data bear this out: the findings in the CON literature are predictable. Restricting the supply of healthcare does not decrease costs.

100 See K.R.S. § 216B.010 (authorizing the Cabinet to perform CON functions to "improve the quality" of healthcare).

101 See K.R.S. § 216B.042.

102 Stratmann, T. (2022). The Effects of Certificate-of-Need Laws on the Quality of Hospital Medical Services. *Journal of Risk and Financial Management*, 15(6), 272. <https://doi.org/10.3390/jrfm15060272>; Chiu, K. (2021). The impact of certificate of need laws on heart attack mortality: Evidence from county borders. *Journal of Health Economics*, 79, 102518. <https://doi.org/10.2139/ssrn.3678714>.

103 Choudhury, A., Ghosh, S., & Plemmons, A. (2022). Certificate of Need Laws and Health Care Use during the COVID-19 pandemic. *Journal of Risk and Financial Management*, 15(2), 76. <https://doi.org/10.3390/jrfm15020076>.

104 Stratmann, *supra* note 102.

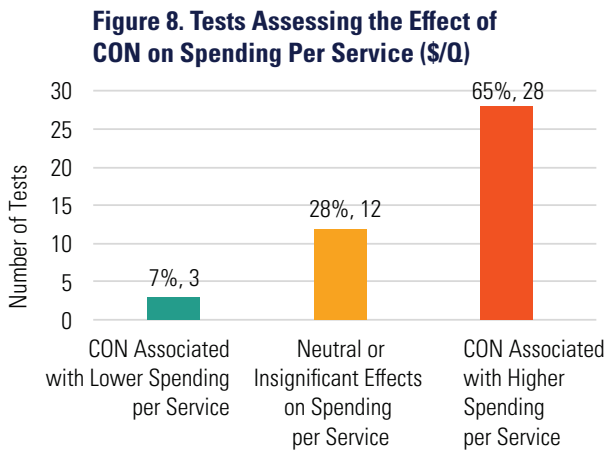
105 Zinn, J. S. (1994). Market competition and the quality of nursing home care. *Journal of Health Politics, Policy and Law*, 19(3), 555–582. <https://doi.org/10.1215/03616878-19-3-555>.

106 See K.R.S. § 216B.010.

107 As economists Jon Ford and David Kasserman explained nearly three decades ago, "the economic effect [of a CON requirement] is to shift the supply curve of the affected service back to the left," and "the effect of such supply shifts is to raise . . . [the] equilibrium price." Ford & Kasserman, *supra* note 93.

108 See *Tiwari I*, 2020 WL 4745772, at *2 (Noting "four decades of academic and government studies saying Certificate of Need laws accomplish nothing more than protecting monopolies held by incumbent companies.")

Figure 8 shows that among 43 tests, 28 (65%) tests find that CON laws are linked to higher spending per service, while a mere three tests (7%) associate them with lower spending per service.



To take just a few examples:

- CON laws are associated with 10% higher variable costs in general acute hospitals,¹⁰⁹
- Hospital charges in states without CON laws are 5.5% lower five years after repeal,¹¹⁰
- In Ohio, reimbursements for coronary artery bypass grafts fell 2.8% following repeal of CON laws; in Pennsylvania, they fell 8.8% following repeal,¹¹¹
- Acute care costs rise with the rigor of the CON program from the most resource-intensive diagnoses,¹¹²
- CON laws are associated with higher Medicaid costs for home health services,¹¹³ and
- There is some evidence that CON is associated with higher Medicaid long-term care costs.¹¹⁴

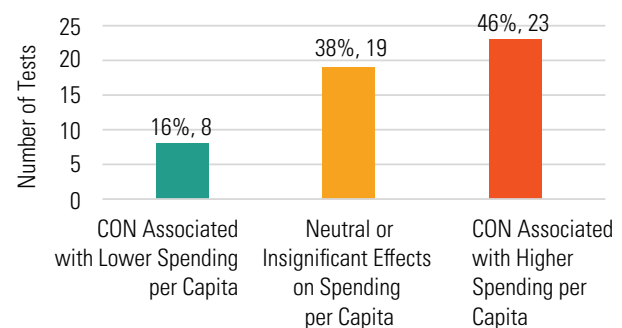
CON Laws Increase Spending Per Patient

Though economic theory offers little reason to expect CON laws to decrease spending per service, it might—as we explained at the outset of this paper—decrease spending per person or per patient. The logic is straightforward: the total amount spent per person is equal to the number of services that the person obtains, multiplied by the amount spent per service. Since CON laws are likely to decrease the number of services that people obtain while increasing the amount spent per service, its effect on total spending is theoretically ambiguous.

A CON program might, for example, lead to zero spending if it eliminated all healthcare resources (though undoubtedly this would not be socially optimal). Even this theoretical possibility, however, is unlikely. This is because healthcare services are generally found to be inelastically demanded; that is, patients will seek them out regardless of price or distance.¹¹⁵

Here again, the real-world experience (shown in Figure 9) reflects standard economic theory. Among 50 tests assessing the effects of CON laws on spending per person, 46% find that CON laws are linked to higher spending per capita while only 16% associate it with lower spending per capita.

Figure 9. Tests Assessing the Effect of CON on Spending Per Capita (\$/Capita)



109 Anderson, K. B., *supra* note 47.

110 Bailey, J. B. (August 2016). *Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws*. (Working Paper). Mercatus Center at George Mason University. <https://mercatus.org/research/working-papers/can-health-spending-be-reined-through-supply-constraints-evaluation>.

111 Ho, V., & Ku-Goto, M. H. (2013). State deregulation and Medicare costs for acute cardiac care. *Medical Care Research and Review*, 70(2), 185–205. <https://doi.org/10.1177/1077558712459681>.

112 Custer, W. S., *et al.* (2006). Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program. https://scholarworks.gsu.edu/cgi/viewcontent.cgi?article1017&context=ghpc_reports.

113 *Id.*

114 *Id.*

115 Ringel, J. S., *et al.* (2002). The elasticity of demand for health care: a review of the literature and its application to the military health system. *National Defense Research Institute and Rand Health*. https://www.rand.org/pubs/monograph_reports/MR1355.html.

Among these tests, researchers find:

- Hospital expenditures are 20.6% higher per capita in states with CON laws,¹¹⁶
- Stringent CON programs increase hospital expenditures per admission,¹¹⁷ and
- Nursing home CONs are associated with higher expenditures per resident,¹¹⁸

CON Laws Increase Government Healthcare Expenditures

Increased spending translates to government payors too.

These costs are ultimately borne by taxpayers. Consider:

- Medicare spending per rural beneficiary is \$295 higher in states with CON laws than in states without,¹¹⁹
- Medicare reimbursements for total knee arthroplasty are 5 to 10% lower in states without CON laws,¹²⁰ and
- CON laws are associated with higher per-capita Medicaid community-based care expenditures.¹²¹

There is No Evidence That CON Laws Lead to Better Care for Underserved Populations

Some argue that even if healthcare costs are higher in states with CON laws, it is necessary to protect hospitals, especially safety-net hospitals, from closing. This rationale contradicts the cost-efficiency rationale for CON laws, which posits that CON is needed to limit healthcare spending. Instead, the cross-subsidy rationale admits that CON laws are likely to lead to more spending—and higher profits for incumbent providers—but then contends that these profits will be diverted to care for the needy.

We found no studies that supported this theory. Ten tests assess the effect of CON laws on underserved populations. Eight of those tests associate CON laws with diminished care for underserved populations, while two tests find neutral or insignificant effects. No tests associate CON with positive effects on underserved populations. The findings of these tests include:

- Substance abuse centers in states with CON laws are less likely to accept Medicaid patients,¹²²
- Uninsured patients are more likely to pay out of pocket in states with CON laws,¹²³
- A large black-white disparity in the availability of coronary angiographies disappeared when the procedure was exempted from CON requirements,¹²⁴ and
- There is no evidence of cross-subsidization and no evidence that CON laws increase charity care.¹²⁵

In fact, two studies suggest safety-net hospitals might be more stable in states *without* CON laws:

- Safety-net hospitals in states without CON laws had higher margins than safety-net hospitals in states with CON laws,¹²⁶ and
- Denied CON applications could have harmed the financial stability of safety net hospitals (though this was not a direct test of CON).¹²⁷

Together, the majority of the literature finds that CON laws are cost neutral or negatively impact cost. And there is no evidence that CON positively impacts charity care.

116 Rivers, P. A., Fottler, M. D., & Younis, M. Z. (2007). Does certificate of need really contain hospital costs in the United States?. *Health Education Journal*, 66(3), 229–244. <https://doi.org/10.1177/0017896907080127>.

117 Rivers, P. A., Fottler, M. D., & Frimpong, J. A. (2010). The Effects of Certificate of Need Regulation on Hospital Costs. *Journal of Health Care Finance*, 36(4), 1–16.

118 Ettner, S. L., et al. (2020). Certificate of need and the cost of competition in home healthcare markets. *Home Health Care Services Quarterly*, 39(2), 51–64. <https://doi.org/10.1080/01621424.2020.1728464>.

119 Stratmann, T., & Baker, M. (2020). *Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis*. (Working Paper) *Mercatus Center at George Mason University*. <https://www.mercatus.org/publications/healthcare/examining-certificate-need-laws-context-rural-health-crisis>.

120 When a good is inelastically demanded, a supply restriction will tend to increase total spending. For further details, see Mitchell, M. D. (2016). Do Certificate-of-Need Laws Limit Spending?. *Mercatus Center at Georgia Washington University*. <https://www.mercatus.org/system/files/mercatus-mitchell-con-healthcare-spending-v3.pdf>; Bailey, J. (2018). The effect of certificate of need laws on all-cause mortality. *Health Services Research*, 53(1), 49–62; Bailey, J., Hamami, T., & McCorry, D. (2016). Certificate of need laws and health care prices. *Journal of Health Care Finance*, 43(4); Ringel et al., *supra* note 115.

121 Miller, N. A., Harrington, C., & Goldstein, E. (2002). Access to community-based long-term care: Medicaid's role. *Journal of Aging and Health*, 14(1), 138–159. <https://doi.org/10.1177/089826430201400108>.

122 Bailey, J. B., Lu, T., & Vogt, P. (2022). Certificate-of-need laws and substance use treatment. *Substance Abuse Treatment Prevention and Policy*, 17, 38. <https://doi.org/10.1186/s13011-022-00469-z>.

123 Custer, *supra* note 112.

124 Cantor, J. C., et al. (2009). Reducing racial disparities in coronary angiography. *Health Affairs*, 28(5), 1521–1531. <https://doi.org/10.1377/hlthaff.28.5.1521>; DeLia, D., et al. (2009). 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(1), 63–91. <https://doi.org/10.1215/03616878-2008-992>.

125 Stratmann, T., & Russ, J., *supra* note 95.

126 Dobson, A., *supra* note 87.

127 Mendelson, D. N., & Arnold, J. (1993). Certificate of need revisited. *Spectrum (Lexington, Ky)*, 66(1), 36–44.

CONCLUSION

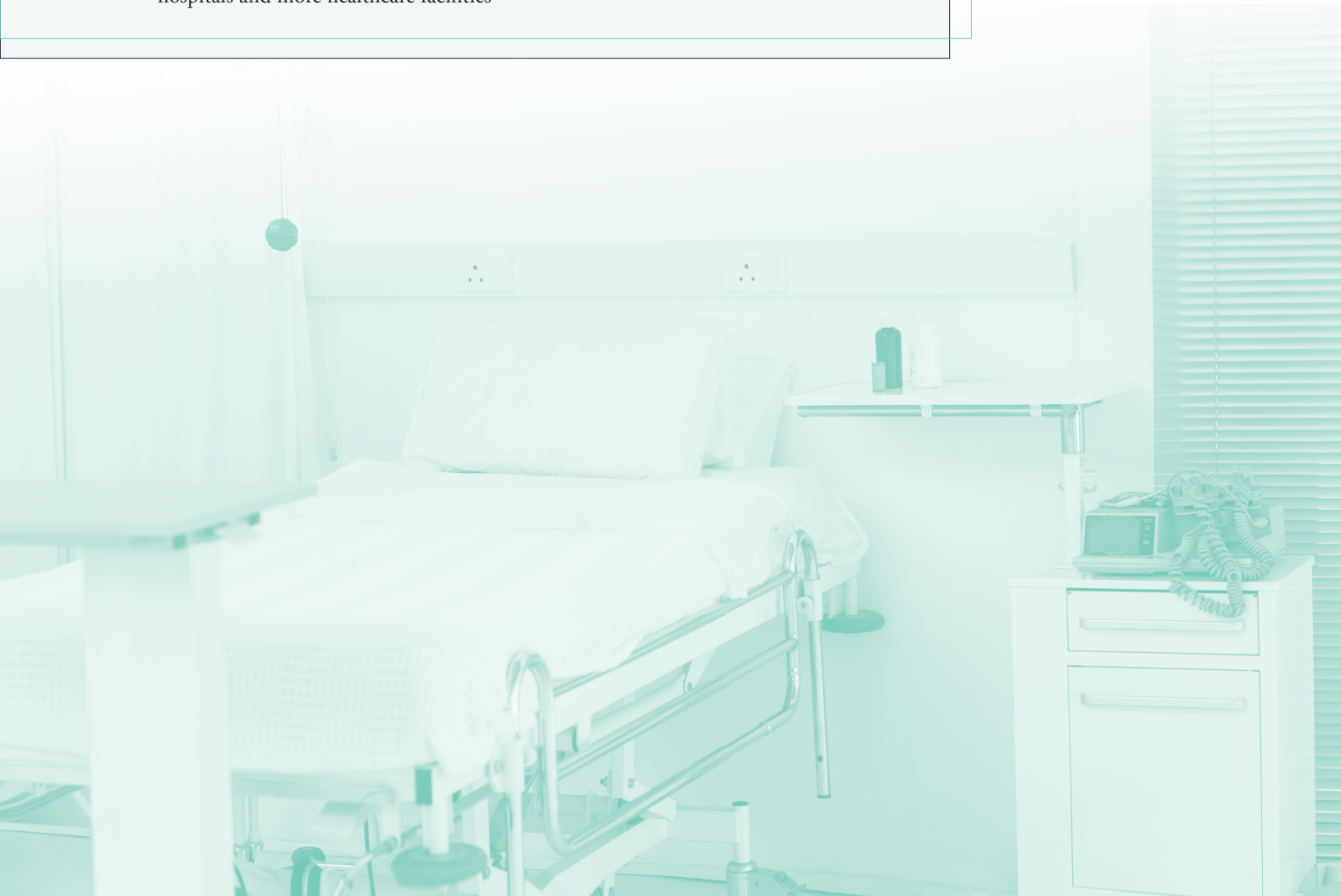
The stated purpose of Kentucky's CON program is to "improve the quality and increase access to health-care facilities, services, and providers, and to create a cost-efficient health-care delivery system for the citizens of the Commonwealth." Five decades of research show that CON laws have not delivered on this promise.

Instead, incumbent providers use CON laws to block and delay their competitors from entering the market. And more broadly, exhaustive research shows that patients in states with CON laws have less access to care, the quality of the care is diminished, and that the costs of care are higher.

Some states repealed CON decades ago. Today, those states have more hospitals and more healthcare facilities

per capita. Nationwide, states are recognizing that the gamble on CON laws has not paid off. Kentucky's neighbors—Indiana and Ohio—repealed every CON law, except for nursing homes, many years ago. Other neighboring states—Tennessee and West Virginia—enacted recent reforms to give residents greater access to healthcare. And still others, like South Carolina and Montana, have said enough is enough. They repealed nearly all of their CON programs. The message is clear. To improve healthcare conditions in Kentucky, lawmakers should rethink CON.

To improve healthcare conditions in Kentucky, lawmakers should rethink CON.



APPENDIX

Appendix of Certificate of Need (CON) Studies¹²⁸

Paper	Summary
Hellinger, F. J. (1976). The effect of certificate-of-need legislation on hospital investment. <i>Inquiry</i> , 13(2), 187–193.	CON legislation induced hospitals to increase investments before CON took effect. He interprets this as a bad result. We code it as positive since it did increase access (in the short run).
Salkever, D. S., & Bice, T. W. (1976). The impact of certificate-of-need controls on hospital investment. <i>The Milbank Memorial Fund Quarterly. Health and Society</i> , 54(2), 185–214.	CON does not decrease investment but does change its composition.
Salkever, D. S., & Bice, T. W. (1979). <i>Hospital certificate-of-need controls: Impact on investment, costs, and use</i> . American Enterprise Institute. https://www.aei.org/research-products/book/hospital-certificate-of-need-controls-impact-on-investment-costs-and-use/ .	They assess the effect of CON on a cross section, time series data set that covers all states from 1968 to 1972. They find that CON is associated with: 1) At best, a modest reduction in total spending per capita; 2) A small increase in average inpatient cost per inpatient day; and 3) Reduced inpatient days per capita.
Joskow, P. L. (1980). 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(2), 421–447.	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% and makes it more likely that a hospital will turn away patients.
Sloan, F. A., & Steinwald, B. (1980). Effects of regulation on hospital costs and input use. <i>The Journal of Law and Economics</i> , 23(1), 81–109.	Comprehensive CON programs have no effect on hospital expenditures per patient day, while noncomprehensive programs increase hospital expenditures by 5% per patient day.
Sloan, F. A. (1981). Regulation and the rising cost of hospital care. <i>The Review of Economics and Statistics</i> , 63(4), 479–487. https://doi.org/10.2307/1935842 .	He studies the effects of both mature and new CON regulations on hospital costs and profits. His data is drawn from the 48 contiguous states, plus DC, over the years 1963-1978. His measures of cost are total hospital expense per admission, per adjusted admission, per patient day, and per adjusted patient day. His measure of profit is the ratio of total revenue to total expense. He finds: 1) Total expense per admission was lower in the years after CON was implemented for part of the period studied; 2) Expense per adjusted admission was not statistically significantly different after CON was implemented; 3) Expense per patient day was not statistically significantly different after CON was implemented; 4) Expense per adjusted patient day was not statistically significantly different after CON was implemented; and 5) Profits were lower after CON was implemented.

128 This Appendix contains the certificate of need studies that Dr. Matthew Mitchell has identified and reviewed through June 30, 2023. A few of the studies that appear in this Appendix are not reflected in the report's analysis because they tested CON indirectly or addressed topics like CEO pay or competition.

<p>Coelen, C., & Sullivan, D. (1981). An analysis of the effects of prospective reimbursement programs on hospital expenditures. <i>Health Care Financing Review</i>, 2(3), 1–40.</p>	<p>They use data from a sample of approximately 2700 community hospitals in the U.S. from 1969 to 1978 to estimate the effects of prospective reimbursement programs on hospital expenditures per patient day, per admission, and per capita. Though their primary interest is in prospective reimbursement programs, they also included CON as a covariate. They find no evidence that CON reduces spending per patient day, per admission, or per capita and some evidence that it increases expenditures. And in about half the states they find evidence that it is associated with higher spending per patient day, per admission, and per capita.</p>
<p>Cromwell, J., & Kanak, J. R. (1982). The effects of prospective reimbursement programs on hospital adoption and service sharing. <i>Health Care Financing Review</i>, 4(2), 67–88. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4191291/.</p>	<p>Their primary focus is on prospective reimbursement programs and their effect on the diffusion of services, but they use CON as a control variable and find that it has no effect on the diffusion of services.</p>
<p>Eastaugh, S. R. (1982). The effectiveness of community-based hospital planning: some recent evidence. <i>Applied Economics</i>, 14(5), 475–490. https://doi.org/10.1080/00036848200000043.</p>	<p>He assesses the effects of CON on change in plant assets, change in beds, and change in plant assets per bed during the 1975-1979 period. His data are from 50 states, and his measure of CON is the percentage of the 1975-1979 period in which a CON program was in effect in each state. He finds CON has:</p> <ol style="list-style-type: none"> 1) A marginally significant, positive effect on change in plant assets (percentage and log), which he interprets as a negative result; 2) No statistically significant effect on change in beds (percentage and log), which he interprets as a negative result; and 3) Significant, positive effect on change in plant assets per bed (percentage and log), which he interprets as a negative result.
<p>Sloan, F. A. (1983). Rate regulation as a strategy for hospital cost control: evidence from the last decade. <i>The Milbank Memorial Fund Quarterly. Health and Society</i>, 61(2), 195–221. https://doi.org/10.2307/3349905.</p>	<p>His primary interest is the effect of rate regulation on hospital costs, but he includes CON as a control. His data is drawn from the 48 contiguous states, plus DC, over the years 1963-1980. His measures of spending are total hospital expense per admission, per “adjusted” admission (adjusted for hospital outpatient activity), per patient day, per adjusted patient day, and per length of stay. He finds no evidence that CON reduces spending per patient.</p>
<p>Lee, A. J., Birnbaum, H., & Bishop, C. (1983). How nursing homes behave: A multi-equation model of nursing home behavior. <i>Social Science & Medicine</i>, 17(23), 1897–1906. https://doi.org/10.1016/0277-9536(83)90167-3.</p>	<p>The paper assesses the effect of various policies on nursing home behavior using the 1973 National Nursing Home Survey. Of relevance here, they find that CON is associated with:</p> <ol style="list-style-type: none"> 1) Higher operating costs per patient day and 2) Higher average annual occupancy.
<p>Ashby J. L., Jr. (1984). The impact of hospital regulatory programs on per capita costs, utilization, and capital investment. <i>Inquiry</i>, 21(1), 45–59.</p>	<p>He assesses the effect of CON and other regulatory programs on five outcomes. His unit of analysis is each state in each year from 1971- 1977. He finds that:</p> <ol style="list-style-type: none"> 1) CON is associated with statistically significant positive growth in hospital costs per capita; 2) CON has no statistically significant effect on percentage change in average length of stay; 3) CON has no statistically significant effect on percentage change in total admissions per capita; and 4) CON has no statistically significant effect on percentage change in plant assets.
<p>Gertler, Paul J., (October 1985). <i>A Latent Variable Model of Quality Determination</i>. (Working Paper). <i>Nat'l Bureau of Economic Research</i>. https://www.nber.org/papers/w1750.</p>	<p>He finds that under a binding CON capacity constraint, increases in Medicaid rates are associated with lower quality in New York state nursing home facilities.</p>

<p>Anderson, K. B., & Kass, D. I. (1986). <i>Certificate of need regulation of Entry Into Home Health Care: A Multi-product Cost Function Analysis, an Economic Policy Analysis</i>. Federal Trade Commission. https://www.ftc.gov/sites/default/files/documents/reports/certificate-need-regulation-entry-home-health-care/231954.pdf.</p>	<p>They examined the effect of CON on economies of scale and cost in the home health care industry. They find:</p> <ol style="list-style-type: none"> 1) Costs were 2% higher in CON states relative to non-CON states; 2) No substantial economies of scale in the home health industry overall; and 3) No difference in economies of scale in CON and non-CON states.
<p>Noether, M. (1988) Competition among hospitals, <i>Journal of Health Economics</i> 7(3), 259–284.</p>	<p>CON increases the average price and expense for several disease categories including:</p> <ol style="list-style-type: none"> 1) Diabetes mellitus; 2) Cataract surgery; 3) Acute myocardial infarction; 4) Congestive heart failure; 5) Acute, cerebrovascular disease; 6) Pneumonia; 7) Other respiratory system disease; 8) Inguinal hernia; 9) Diverticula of intestine; 10) Hyperplasia of prostate; and 11) Fracture of neck and femur.
<p>Sherman, D. (1988). <i>The effect of state certificate-of-need laws on hospital costs: An economic policy analysis</i>. Bureau of Economics, Federal Trade Commission. https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs-economic-policy-analysis.</p>	<p>He estimates the effects of CON on cost functions using a sample of 3708 hospitals using 1983-1984 data. Though he uses the term costs, he is actually measuring operating expenditures. He finds that spending would fall by 1.4% if states relaxed CON by raising the thresholds at which it is applied.</p>
<p>Shortell, S. M., & Hughes, E. F. (1988). The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. <i>New England Journal of Medicine</i>, 318(17), 1100–1107. https://doi.org/10.1056/NEJM198804283181705.</p>	<p>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% higher in state with stringent CON regulation.</p>
<p>Mayo, J. W., & McFarland, D. A. (1989). Regulation, market structure, and hospital costs. <i>Southern Economic Journal</i>, 55(3), 559–569. https://doi.org/10.2307/1059572.</p>	<p>They study the effect of variation in CON approval in different service areas of Tennessee on the number of beds, finding it is associated with fewer beds. They also find that larger hospital size is associated with more spending and infer that CON is associated with lower average spending per patient day, though they don't directly measure it.</p>
<p>Anderson, K. B. (1991). Regulation, market structure, and hospital costs: comment. <i>Southern Economic Journal</i>, 58(2), 528–534. https://doi.org/10.2307/1060194.</p>	<p>This is a reply to Mayo and McFarland's 1989 paper. Anderson estimates the effects of CON (and the number of years CON has been in effect) on average variable costs among 2,069 general acute hospitals with 100 or more beds. He uses CON age as a measure of CON stringency under the theory that "the effect should increase the longer the regulation has been around." He applies the equation linearly and multiplied by the number of beds to see if CON has a different effect on large hospitals. He finds:</p> <ol style="list-style-type: none"> 1) CON is associated with 10% higher variable costs and 2) CON is associated with greater probability of a hospital having 100 or fewer beds.
<p>Eakin, B. K. (1991). Allocative inefficiency in the production of hospital services. <i>Southern Economic Journal</i>, 58(1), 240–248. https://doi.org/10.2307/1060045.</p>	<p>CON hospitals are less efficient than non-CON hospitals.</p>
<p>Lanning, J. A., Morrisey, M. A., & Ohsfeldt, R. L. (1991). Endogenous hospital regulation and its effects on hospital and non-hospital expenditures. <i>Journal of Regulatory Economics</i>, 3, 137–154. https://doi.org/10.1007/BF00140955.</p>	<p>They measure the effect of CON on hospital expenditures, finding that it is associated with 20.6% higher spending per capita.</p>

Mayo, J. W., & McFarland, D. A. (1991). Regulation, market structure, and hospital costs: reply. <i>Southern Economic Journal</i> , 58(2), 535-538. https://doi.org/10.2307/1060195 .	This is a reply to Anderson's (1991) critique of their 1989 paper. Anderson worried CON might constrain hospitals on one dimension (say beds), but then cause them to substitute into other areas of spending (say labor). They tested this possibility and found mixed results. In a larger panel dataset, they found support for Anderson's concern (CON increases spending), while in a 1984 cross-section they found support for their initial (implied) conclusion (CON decreases spending).
Swan, J., & Harrington, C. (1991). Certificate of need and nursing home bed capacity in states. <i>Journal of Health and Social Policy</i> , 2(2), 87-105. https://doi.org/10.1300/j045v02n02_06 .	They assess the effect of nursing home CONs on nursing home bed stock using cross-section, time-series data (1981-1984). They find: 1) Nursing home CONs constrain the bed stock and 2) The greater the dollar amount of CON approvals per aged population (a measure of CON stringency), the greater the bed stock.
Campbell, E. S., & Ahern, M. W. (1993). Have procompetitive changes altered hospital provision of indigent care?. <i>Health Economics</i> , 2(3), 281-289. https://doi.org/10.1002/hec.4730020311 .	Private nonprofit hospitals that are more profitable offer more uncompensated care. This suggests the possibility of a quid pro quo, but they do not actually test CON.
Campbell, E. S., & Fournier, G. M. (1993). Certificate-of-need deregulation and indigent hospital care. <i>Journal of Health Politics, Policy and Law</i> , 18(4), 905-925. https://doi.org/10.1215/03616878-18-4-905 .	Not a direct test of CON, they find that CONs are more likely to be awarded to hospitals that provide more indigent care.
Ford, J. M., & Kaserman, D. L. (1993). Certificate-of-need regulation and entry: Evidence from the dialysis industry. <i>Southern Economic Journal</i> , 59(4), 783-791. https://doi.org/10.2307/1059739 .	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.
Mendelson, D. N., & Arnold, J. (1993). Certificate of need revisited. <i>Spectrum (Lexington, Ky.)</i> , 66(1), 36-44.	They find that Ohio denied CON applications that could have had adverse effects on the financial viability of safety net hospitals, but it was not a direct test of CON.
Nyman, J. A. (1994). The effects of market concentration and excess demand on the price of nursing home care. <i>The Journal of Industrial Economics</i> , 42(2), 193-204. https://doi.org/10.2307/2950490 .	He doesn't directly test CON, but rather tests the effect of market concentration and excess demand on nursing home prices. Since CON is likely to make both matters worse, he concludes that CON likely undermines its goals.
Zinn, J. S. (1994). Market competition and the quality of nursing home care. <i>Journal of Health Politics, Policy and Law</i> , 19(3), 555-582. https://doi.org/10.1215/03616878-19-3-555 .	She examined the determinants of nursing home quality. One of her explanatory variables was nursing home construction moratoria. She finds these to be associated with lower RN staffing ratios and greater use of physical restraint.
Antel, J. J., Ohsfeldt, R. L., & Becker, E. R. (1995). State regulation and hospital costs. <i>The Review of Economics and Statistics</i> , 77(3), 416-422. https://doi.org/10.2307/2109904 .	They find that CON increases per-day and per-admission hospital expenditures but has no relationship to per capita hospital expenditures.
Caudill, S. B., Ford, J. M., & Kaserman, D. L. (1995). Certificate-of-need regulation and the diffusion of innovations: a random coefficient model. <i>Journal of Applied Econometrics</i> , 10(1), 73-78.	They examine the effect of CON on the diffusion of hemodialysis an effective and practical treatment for chronic renal failure. Their data span 50 states and 14 years. They find that CON regulation slows the spread of hemodialysis.
Fournier, G. M., & Campbell, E. S. (1997). Indigent care as quid pro quo in hospital regulation. <i>Review of Economics and Statistics</i> , 79(4), 669-673. https://doi.org/10.1162/003465397557088 .	They find that Florida awarded CON licenses to hospitals providing more care to the poor, though they don't directly test whether CON increases indigent care.
Harrington, <i>et al.</i> (1997). The effect of certificate of need and moratoria policy on change in nursing home beds in the United States. <i>Medical Care</i> , 35(8), 574-588.	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 find: 1) CON had no effect on Medicaid nursing home reimbursement rates and 2) CON reduced growth of beds.
Conover, C. J., & Sloan, F. A. (1998). Does removing certificate-of-need regulations lead to a surge in health care spending?. <i>Journal of Health Politics, Policy and Law</i> , 23(3), 455-481. https://doi.org/10.1215/03616878-23-3-455 .	CON has no effect on total per capita health expenditures; there is no evidence of a surge in spending after repeal.

<p>D'anno, T., Succi, M., & Alexander, J. A. (2000). The role of institutional and market forces in divergent organizational change. <i>Administrative Science Quarterly</i>, 45(4), 679–703. https://doi.org/10.2307/2667016.</p>	<p>They study the market and institutional determinants of radical organizational change in rural hospitals. In particular, they study the factors that make a rural hospital likely to change to provide other types of services. They find that stronger CON regulation makes a rural hospital 8% less likely to change.</p>
<p>Robinson, J. L., et al. (2001). Certificate of need and the quality of cardiac surgery. <i>American Journal of Medical Quality</i>, 16(5), 155–160.</p>	<p>They examined the effect of CON elimination in PA (comparing it with NJ, which maintained CON) on:</p> <ol style="list-style-type: none"> 1) The number of open-heart surgery programs, which increased 25% 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) Mortality rate, which was unchanged following repeal.
<p>Miller, N. A., Harrington, C., & Goldstein, E. (2002). Access to community-based long-term care: Medicaid's role. <i>Journal of Aging and Health</i>, 14(1), 138–159. https://doi.org/10.1177/089826430201400108.</p>	<p>They find that CON increases per capita Medicaid community-based care expenditures.</p>
<p>Vaughan-Sarrazin, M. S., et al. (2002). Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulation. <i>JAMA</i>, 288(15), 1859–1866.</p>	<p>They assess the effect of CON on coronary artery bypass graft (CABG) surgery, finding:</p> <ol style="list-style-type: none"> 1) Mean annual hospital volume is lower in states without CON; 2) More patients undergo CABG surgery in low-volume hospitals in states without CON; and 3) Mortality following CABG is higher in states without CON.
<p>Grabowski, D. C., Ohsfeldt, R. L., & Morrissey, M. A. (2003). The effects of CON repeal on Medicaid nursing home and long-term care expenditures. <i>INQUIRY: The Journal of Health Care Organization, Provision, and Financing</i>, 40(2), 146–157. https://doi.org/10.5034/inquiryjrnl_40.2.146.</p>	<p>CON repeal:</p> <ol style="list-style-type: none"> 1) Has no statistically significant effect on per diem Medicaid nursing home charges; 2) No effect on per diem Medicaid long-term-care charges; and 3) No effect on days.
<p>Gulley, O. D., & Santerre, R. E. (2003). The Effect of Public Policies on Nursing Home Care in the United States. <i>Eastern Economic Journal</i>, 29(1), 93–104.</p>	<p>They look at the effects of several public policies on nursing home residents and nursing home beds per person 65 years old and older. Their data are from a cross-section of counties in 1991. Their measure of CON is the number of years in which a CON law has been in effect. They find that in states where CON has been in effect for longer:</p> <ol style="list-style-type: none"> 1) There are fewer nursing home beds per persons 65 years old and older, but the effect is not statistically significant and 2) There are fewer nursing home patients per persons 65 and older, but this effect is also statistically insignificant.
<p>Conover, C. J., & Sloan, F. A. (2003). Evaluation of Certificate of Need in Michigan. <i>Volume II: Technical appendices</i>. Raleigh, NC: Duke University Center for Health Policy, Law and Management.</p>	<p>Repealing CON has 0% effect on all expenditures.</p>
<p>Teske, P., & Chard, R. (2004). Hospital Certificates-of-Need. Regulation in the States, <i>Brookings Institute</i>, 125–132. https://epdf.pub/regulation-in-the-states.html.</p>	<p>This study examines several political factors to determine the likelihood of a state retaining CON regulation. They find that the following factors are associated with CON regulation:</p> <ol style="list-style-type: none"> 1) Democrats in upper and lower houses; 2) Higher hospital costs; 3) More affluent and better-educated citizens; 4) Fewer physicians; and 5) A variable measuring hospital interests: the number of hospital industry-related interest groups active in a particular state multiplied by their average political action committee spending; They find this to be significantly associated with retention of CON, but legislative party makeup is more important.

<p>Ho, V. (2004). Certificate of need, volume, and percutaneous transluminal coronary angioplasty outcomes. <i>American Heart Journal</i>, 147(3), 442–448.</p>	<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:</p> <ol style="list-style-type: none"> 1) CON is associated with higher in-hospital volume for PTCA and 2) 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).
<p>Chen, C. C. (2005). <i>Estimating nursing home cost and production functions: Application of stochastic frontier models for the analysis of efficiency</i> [Doctoral dissertation, Tulane University], ProQuest Dissertations & Theses Global. http://www.proquest.com/docview/305399421/abstract/F9AE5D67757C4ACAPQ/1.</p>	<p>Nursing home CONs are associated with greater cost efficiency but diminished technical efficiency.</p>
<p>Bates, L. J., Mukherjee, K., & Santerre, R. E. (2006). Market structure and technical efficiency in the hospital services industry: a DEA approach. <i>Medical Care Research and Review</i>, 63(4), 499–524. https://doi.org/10.1177/1077558706288842.</p>	<p>CON hospitals are not any less efficient than non-CON hospitals.</p>
<p>Custer, W. S., et al. (2006). Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program. https://scholarworks.gsu.edu/cgi/viewcontent.cgi?article=1017&context=ghpc_reports.</p>	<p>They use a cross-border design to study the effect of CON in hospital markets. This allows them to control for unobservable factors. They also used interviews and public information to develop an index measuring CON rigor based on fees, administrative requirements, reviewability, appeals, and administrative complexity. They assess the effects of CON on acute care, long term care, and home health markets. They find:</p> <ol style="list-style-type: none"> 1) CON is associated with higher private inpatient acute care costs; 2) Acute care costs rise with the rigor of the CON program for the most resource-intensive acute care diagnoses; 3) Some evidence that CON is associated with higher Medicaid costs for home health services; 4) Weak evidence that CON is associated with higher private long term care costs; 5) Weak evidence that CON is associated higher Medicaid long term care costs; 6) Some evidence that CON is associated with higher per-capita costs for home health services; 7) CON is associated with fewer hospitals; 8) CON is associated with fewer hospital beds; 9) CON is associated with fewer home health agencies per 1000 residents; 10) CON is associated with fewer Medicare beneficiaries receiving home health services; 11) There is no significant relationship between the percentage of hospital admissions that are self-pay, though when controlling for the number of uninsured and family income, CON is positively related to self-pay admission per uninsured; 12) There is no apparent difference in acute care quality in CON and non-CON markets; 13) In long term care, CON is associated with better quality on two measures but worse quality on six measures; 14) In home health markets, they find no evidence that CON affects any of 10 outcome measures of quality; 15) They find that acute care markets are less competitive when CON is rigorous; and 16) CON is associated with lower levels of competition in home health agency markets.

<p>DiSesa, V. J., <i>et al.</i> (2006). Contemporary impact of state certificate-of-need regulations for cardiac surgery: an analysis using the Society of Thoracic Surgeons' National Cardiac Surgery Database. <i>Circulation</i>, 114(20), 2122–2129.</p>	<p>They study CON, volume, and mortality in coronary artery bypass grafting (CABG). They find:</p> <ol style="list-style-type: none"> 1) CON is positively associated with CABG volume within hospitals and 2) There is no direct relationship between CON and mortality.
<p>Ho, V. (2006). Does certificate of need affect cardiac outcomes and costs?. <i>International Journal of Health Care Finance and Economics</i>, 6, 300–324.</p>	<p>The study assesses the effect of CON on cardiac costs and outcomes. She finds:</p> <ol style="list-style-type: none"> 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; 2) CON is associated with greater volume within hospitals; and 3) CON does not seem to be related to inpatient mortality.
<p>Popescu, I., Vaughan-Sarrazin, M. S., & Rosenthal, G. E. (2006). Certificate of need regulations and use of coronary revascularization after acute myocardial infarction. <i>Jama</i>, 295(18), 2141–2147.</p>	<p>They study access and quality outcomes in revascularization. They find that patients in CON states:</p> <ol style="list-style-type: none"> 1) Were less likely to be admitted to hospitals offering revascularization; 2) Were less likely to undergo revascularization; and 3) Had no difference in 30-day mortality rates relative to patients in non-CON states.
<p>Dobson, A., <i>et al.</i> (2007). An Evaluation of Illinois' Certificate of Need Program. https://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf.</p>	<p>They find that safety-net hospitals in non-CON states had higher margins than those in CON states.</p>
<p>Ho, V., <i>et al.</i> (2007). Cardiac certificate of need regulations and the availability and use of revascularization services. <i>American Heart Journal</i>, 154(4), 767–775.</p>	<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:</p> <ol style="list-style-type: none"> 1) CON is associated with fewer hospitals offering CABG and PCI; 2) CON has no effect on overall CABG utilization; and 3) CON is associated with 19.2% fewer PCIs per 1,000 elderly.
<p>Rivers, P. A., Fottler, M. D., & Younis, M. Z. (2007). Does certificate of need really contain hospital costs in the United States?. <i>Health Education Journal</i>, 66(3), 229–244. https://doi.org/10.1177/0017896907080127.</p>	<p>They find CON laws increase hospital expenditures per adjusted admission.</p>
<p>Ross, J. S., <i>et al.</i> (2007). Certificate of need regulation and cardiac catheterization appropriateness after acute myocardial infarction. <i>Circulation</i>, 115(8), 1012–1019.</p>	<p>They examine the effect of CON on the volume of cardiac catheterization after admission for acute myocardial infarction. In particular, however, they were interested in procedural volume under different levels of appropriateness (strongly, equivocally, or weakly indicated). While CON did not seem to decrease the volume of strongly-indicated catheterization, it did reduce the volume of equivocally and weakly indicated catheterization. Because their interest is both overall volume and rates of catheterization when it is not warranted, I categorize in both the volume and the quality sections.</p>
<p>Taylor Jr, D. H., <i>et al.</i> (2007). What length of hospice use maximizes reduction in medical expenditures near death in the US Medicare program?. <i>Social Science & Medicine</i>, 65(7), 1466–1478. https://doi.org/10.1016/j.socscimed.2007.05.028.</p>	<p>Hospices are associated with savings of about \$2,309 per user. Conover and Bailey use this to figure that “each hospice foregone in a market area represents \$230,000 in potential annual savings lost.” See Conover, C. J., & Bailey, J. (2020). Certificate of need laws: a systematic review and cost-effectiveness analysis. <i>BMC Health Services Research</i>, 20, 748. https://doi.org/10.1186/s12913-020-05563-1.</p>

<p>Short, M. N., Aloia, T. A., & Ho, V. (2008). Certificate of need regulations and the availability and use of cancer resections. <i>Annals of surgical oncology</i>, 15, 1837–1845.</p>	<p>They study Medicare data on beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002. They find:</p> <ol style="list-style-type: none"> 1) CON is associated with fewer hospitals per cancer incident for colectomy, rectal resection, and pulmonary lobectomy; 2) CON has no effect on the number of procedures per cancer incident; and 3) CON was associated with greater hospital volume.
<p>Zhang, L. (2008). <i>Uncompensated care provision and the economic behavior of hospitals: The influence of the regulatory environment</i>. Georgia Institute of Technology and Georgia State University. http://scholarworks.gsu.edu/pmap_diss/19.</p>	<p>He examined the effect of three regulatory policies—CON laws, uncompensated care pools, and community benefit requirement laws. CON is associated with small increases in uninsured admissions, though the results were small (0.07%) and not statistically significant when he attempted to control for endogeneity. Furthermore, he finds that in the presence of all three policies, the number of uninsured admissions by nonprofit hospitals fell.</p>
<p>Cantor, J. C., et al. (2009). Reducing racial disparities in coronary angiography. <i>Health Affairs</i>, 28(5), 1521–1531. https://doi.org/10.1377/hlthaff.28.5.1521.</p>	<p>The authors study a 1996 New Jersey reform that created a pilot program to license additional hospitals to perform coronary angiography. They find that a large black-white disparity disappeared after the reform.</p>
<p>DeLia, D., et al. (2009). Effects of regulation and competition on health care disparities: the case of cardiac angiography in New Jersey. <i>Journal of Health Politics, Policy and Law</i>, 34(1), 63–91. https://doi.org/10.1215/03616878-2008-992.</p>	<p>This builds off of the authors’ previous study, confirming the result (the reforms eliminated the black-white disparity) using additional techniques (weighting ZIP codes by the number of black and white residents). They also study the mechanism by which the disparity was eliminated, finding that incumbent hospitals served more black patients as new entrants cut into their market share for white patients.</p>
<p>Garmon, C. (2009). Hospital competition and charity care. <i>Forum for Health Economics & Policy</i>, 12(1). https://doi.org/10.2202/1558-9544.1130.</p>	<p>This is not a direct test of CON. Instead, he tests whether hospital competition is associated with more or less charity care. He finds no evidence that increased competition reduces charity care. Furthermore, he finds some evidence that reduced competition leads to higher prices for uninsured patients.</p>
<p>Hellinger, F. J. (2009). The effect of certificate-of-need laws on hospital beds and healthcare expenditures: an empirical analysis. <i>American Journal of Managed Care</i>, 15(10), 737–744.</p>	<p>CON is associated with fewer hospital beds, which in turn are associated with slower growth in aggregate health expenditures per capita. There is no direct relationship between CON and health expenditures per capita.</p>
<p>Ho, V., Ku-Goto, M. H., & Jollis, J. G. (2009). Certificate of need (CON) for cardiac care: controversy over the contributions of CON. <i>Health services research</i>, 4(2p1), 483–500. https://doi.org/10.1111/j.1475-6773.2008.00933.x.</p>	<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 find that in states that dropped CON:</p> <ol style="list-style-type: none"> 1) The number of hospitals in the state performing CABG and PCI went up following repeal; 2) Statewide procedural volume for CABG and PCI were unchanged; 3) Mean hospital volume declined for both procedures; and 4) Procedural CABG mortality declined after repeal, though the difference was not permanent.
<p>Kolstad, J. T. (2009). <i>Essays on information, competition and quality in health care provider markets</i>. Harvard University. https://healthpolicy.fas.harvard.edu/people/jonathan-kolstad.</p>	<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"> 1) The number of CABG facilities increased 46% and 2) Surgeries were more likely to be performed by high-quality surgeons.

<p>Tynan, A., <i>et al.</i> (2009). <i>General hospitals, specialty hospitals and financially vulnerable patients</i>. Center for Studying Health System Change.</p>	<p>Not a direct test of CON, they find that general hospitals are able to cope with the entry of specialty hospitals with little change in the provision of care for financially vulnerable patients. The analysis was done in three markets with established specialty hospitals—Indianapolis, IN, Phoenix, AZ, and Little Rock, AR.</p>
<p>Carlson, M. D., <i>et al.</i> (2010). Geographic access to hospice in the United States. <i>Journal of Palliative Medicine</i>, 13(11), 1331–1338. https://doi.org/10.1089/jpm.2010.0209.</p>	<p>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.</p>
<p>Cutler, D. M., Huckman, R. S., & Kolstad, J. T. (2010). Input constraints and the efficiency of entry: Lessons from cardiac surgery. <i>American Economic Journal: Economic Policy</i>, 2(1), 51–76.</p>	<p>They assess the 1996 repeal of CON in Pennsylvania on coronary artery bypass graft. They find:</p> <ol style="list-style-type: none"> 1) Repeal of CON reduced travel distance by 9%; 2) There was no statistically significant effect on total volume following CON repeal; 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; 4) CON repeal led to a shift from standard quality to high-quality surgeons; and 5) Incumbent hospital margins initially fell following repeal but these hospitals had regained profitability and were the most profitable by 2002.
<p>Ferrier, G. D., Leleu, H., & Valdmanis, V. G. (2010). The impact of CON regulation on hospital efficiency. <i>Health Care Management Science</i>, 13, 84–100.</p>	<p>CON hospitals are more efficient than non-CON hospitals.</p>
<p>Rivers, P. A., Fottler, M. D., & Frimpong, J. A. (2010). The Effects of Certificate of Need Regulation on Hospital Costs. <i>Journal of Health Care Finance</i>, 36(4), 1–16.</p>	<p>They find that stringent CON programs increase hospital expenditures per admission.</p>
<p>Shamji, E. C., & Shamji, M. F. (2010). Effect of US State Certificate of Need regulation of operating rooms on surgical resident training. <i>Clinical and Investigative Medicine</i>, E78–E84.</p>	<p>They evaluate the mean per capita rates of 26 diverse surgical procedures in 21 CON and five non-CON states between 2004 and 2006. The proportion of procedures performed in teaching facilities was also assessed. They find no significant difference in procedural rates between CON and non-CON states.</p>
<p>Vaughan Sarrazin, M. S., Bayman, L., & Cram, P. (2010). Trends during 1993-2004 in the availability and use of revascularization after acute myocardial infarction in markets affected by certificate of need regulations. <i>Medical care research and review</i>, 67(2), 213–231. https://doi.org/10.1177/1077558709346565.</p>	<p>In a study design that exploits the fact that some markets cross boundaries between CON and non-CON states, they find:</p> <ol style="list-style-type: none"> 1) A greater increase in coronary artery bypass graft surgery programs in states that reduced CON regulation and 2) No change in percutaneous coronary intervention programs in states that reduced CON.
<p>Eichmann, T. L., & Santerre, R. E. (2011). Do hospital chief executive officers extract rents from Certificate of Need laws?. <i>Journal of Health Care Finance</i>, 37(4), 1–14.</p>	<p>They study the effects of CON on access and rents. They find CON is associated with:</p> <ol style="list-style-type: none"> 1) 12% fewer beds per capita; 2) 48% fewer hospitals per capita; and 3) \$91,000 more in urban hospital CEO pay.
<p>Granderson, G. (2011). The impacts of hospital alliance membership, alliance size, and repealing certificate of need regulation, on the cost efficiency of non-profit hospitals. <i>Managerial and Decision Economics</i>, 32(3), 159–173. https://doi.org/10.1002/mde.1524.</p>	<p>He studies the effect of hospital alliance membership, alliance size, and CON on hospital cost efficiency among 144 urban Midwest hospitals from 1996 to 1999. He finds that repeal of CON resulted in greater hospital efficiency, as measured by a stochastic cost frontier.</p>
<p>Jacobs, B. L., <i>et al.</i> (2012). Certificate of Need Regulations and the Diffusion of Intensity-Modulated Radiotherapy. <i>Urology</i>, 80(5), 1015–1020. https://doi.org/10.1016/j.urology.2012.07.042.</p>	<p>They examine whether CON reduces the use of a questionably-warranted procedure, radiotherapy, for prostate cancer. They find no difference in the use of the procedure in CON and non-CON health service areas. In fact, in HSAs with high-stringency CONs, they find greater use of the procedure.</p>

<p>Lorch, S. A., Maheshwari, P., & Even-Shoshan, O. (2012). The impact of certificate of need programs on neonatal intensive care units. <i>Journal of Perinatology</i>, 32(1), 39–44.</p>	<p>They study NICU CONs. They find:</p> <ol style="list-style-type: none"> 1) CON is associated with fewer units; 2) CON is associated with fewer beds; 3) CON was unrelated to very low birth weight, infant mortality, and low birth weight infant mortality; and 4) CON is associated with lower rates of all-infant mortality in states with a large metropolitan area.
<p>Nelson, C., <i>et al.</i> (2012). Certificate of Need (CON) Status and its Impact on Overtreatment of Low-risk Prostate Cancer in the Elderly. <i>International Journal of Radiation Oncology, Biology, Physics</i>, 84(3), S123–S124. https://doi.org/10.1016/j.ijrobp.2012.07.121.</p>	<p>They examine whether CON reduces the use of a questionably-warranted procedure, definitive intensity modulated radiation therapy (IMRT), among 155,379 men between 2004 and 2007. They find no evidence that limits the use of the procedure.</p>
<p>Delamater, P. L., <i>et al.</i> (2013). Do more hospital beds lead to higher hospitalization rates? A spatial examination of Roemer's law. <i>PloS One</i>, 8(2), e54900. https://doi.org/10.1371/journal.pone.0054900.</p>	<p>Not a direct test of CON, this is an assessment of Roemer's Law—the idea that a built hospital bed tends to be filled. They find evidence for the theory.</p>
<p>Ho, V., & Ku-Goto, M. H. (2013). State deregulation and Medicare costs for acute cardiac care. <i>Medical Care Research and Review</i>, 70(2), 185–205. https://doi.org/10.1177/1077558712459681.</p>	<p>Removing CON decreases the cost of coronary artery bypass grafts, but not for percutaneous coronary intervention. In Ohio, reimbursements fell 2.8% following repeal of CON and in Pennsylvania, they fell 8.8% following repeal.</p>
<p>Jacobs, B. L., <i>et al.</i> (2013). Certificate of need legislation and the dissemination of robotic surgery for prostate cancer. <i>The Journal of Urology</i>, 189(1), 80–85. https://doi.org/10.1016/j.juro.2012.08.185.</p>	<p>They study whether CON restrains the use of a questionable procedure—robotic prostatectomy. They find that CON stringency had no effect on the use of the procedure.</p>
<p>Lu-Yao, G. L., <i>et al.</i> (2013). Certificate of need and use of IMRT in elderly patients with low-risk prostate cancer, <i>Journal of Clinical Oncology</i>, 31(6, Suppl.), S204. https://doi.org/10.1200/jco.2013.31.6_suppl.204.</p>	<p>They study whether CON limits the use of IMRT (intensity modulated radiation therapy) in a population that would likely benefit from it the least: older or debilitated men with low-risk prostate cancer. They find that CON laws actually encourage the procedure.</p>
<p>Khanna, A., <i>et al.</i> (2013). Certificate of need programs, intensity modulated radiation therapy use and the cost of prostate cancer care. <i>The Journal of Urology</i>, 189(1), 75–79. https://doi.org/10.1016/j.juro.2012.08.181.</p>	<p>The authors focus on intensity modulated radiation therapy. They find:</p> <ol style="list-style-type: none"> 1) CON is not associated with any difference in cost growth and 2) CON is associated with greater growth in intensity modulated radiation therapy, which is an expensive and no more effective treatment, so they interpret this as a negative quality result.
<p>Paul, J. A., Ni, H., & Bagchi, A. (2014). Effect of certificate of need law on emergency department length of stay. <i>The Journal of Emergency Medicine</i>, 47(4), 453–461. https://doi.org/10.1016/j.jemermed.2014.04.027.</p>	<p>They study the effect of CON and CON stringency on the length of stay in emergency room departments. They find that CON is associated with shorter ED stays, which they interpret as quality-enhancing, though it is not clear why this is definitely a good thing. More stringent CON regulation undermines the effect.</p>
<p>Polsky, D., <i>et al.</i> (2014). The effect of entry regulation in the health care sector: The case of home health. <i>Journal of Public Economics</i>, 110, 1–14. https://doi.org/10.1016/j.jpubeco.2013.11.003.</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:</p> <ol style="list-style-type: none"> 1) Medicare expenditures are not statistically significantly different between CON and non-CON states; 2) Non-CON states have roughly twice as many home health agencies per Medicare beneficiary; 3) CON states have 13.7% fewer home health admissions from hospitals; 4) 60 day (total) readmission rates are 5% higher in CON states than in non-CON states, though the effect is not sustained; 5) 60 day preventable readmission rates are 13% higher in CON states than in non-CON states, though the effect is not sustained; 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; and 7) The Herfindahl Index in the home health market is approximately 1,000 points lower in non-CON states.

<p>Rosko, M. D., & Mutter, R. L. (2014). The association of hospital cost-inefficiency with certificate-of-need regulation. <i>Medical Care Research and Review</i>, 71(3), 280–298. https://doi.org/10.1177/1077558713519167.</p>	<p>CON hospitals are more efficient than non-CON hospitals.</p>
<p>Stratmann, T., & Russ, J. (July 2014). <i>Do Certificate-of-Need Laws Increase Indigent Care?</i>. (Working Paper No. 14-20). <i>Mercatus Center at George Mason University</i>. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3211637.</p>	<p>They study the effects of CON on the supply of services and provision of services to indigent populations. They find: 1) CON programs are associated with 99 fewer hospital beds per 100,000 people; 2) Bed-specific CONs are associated with 131 fewer beds per 100,000 people; 3) There are 4.7 fewer beds per 100,000 persons for each additional service covered by CON; 4) CON programs reduce the number of hospitals with MRI machines by 1 to 2 hospitals per 500,000 people; and 5) CON programs that require charitable care are uncorrelated with uncompensated care.</p>
<p>Chui, P. W., <i>et al.</i> (2015). Association of state certificate of need regulations with the appropriateness of PCI procedures. <i>Circulation</i>, 132(Suppl_3), A18805. https://doi.org/10.1161/circ.132.suppl_3.18805.</p>	<p>To see if CON limits the use of inappropriate percutaneous coronary interventions, they looked at the share of procedures considered appropriate, uncertain, or inappropriate in CON and non-CON states. They find that states with CON have a lower proportion of inappropriate PCIs, but the differences were small.</p>
<p>Falchook, A. D., & Chen, R. C. (2015). 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(2), 448–450. https://doi.org/10.1016/j.ijrobp.2014.10.033.</p>	<p>They examined utilization of radiation therapy when it is not warranted in CON and non-CON states, concluding that in CON states there is greater use of this treatment on elderly patients who may not need it.</p>
<p>Horwitz, J. R., & Polsky, D. (2015). Cross border effects of state health technology regulation. <i>American Journal of Health Economics</i>, 1(1), 101–123. https://doi.org/10.1162/ajhe_a_00005.</p>	<p>They use a cross-border design to estimate the effect of CON on MRI machines. They find that in a CON county that borders a non-CON county there are 6.4 fewer MRIs per million people.</p>
<p>Li, S., & Dor, A. (2015). How do hospitals respond to market entry? Evidence from a deregulated market for cardiac revascularization. <i>Health economics</i>, 24(8), 990–1008. https://doi.org/10.1002/hec.3079.</p>	<p>Removal of CON is associated with: 1) A substantial increase in the number of hospitals performing cardiac revascularization procedures; 2) An overall downward trend in coronary artery bypass graft (CABG) and an overall upward trend in the alternative procedure, percutaneous coronary intervention (PCI); 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; 4) The probability of receiving PCI specifically at incumbent hospitals decreased with market entry, suggesting a volume shift from incumbents to entrants; 5) Entry shifted a disproportionate volume of low-severity patients from incumbent hospitals to entrants; and 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.</p>
<p>Bailey, J. B. (August 2016). <i>Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws</i>. (Working Paper). <i>Mercatus Center at George Mason University</i>. https://mercatus.org/research/working-papers/can-health-spending-be-reined-through-supply-constraints-evaluation.</p>	<p>Removing CON reduces hospital charges by 5.5% five years after repeal.</p>
<p>Bailey, J., Hamami, T., & McCorry, D. (2016). Certificate of need laws and health care prices. <i>Journal of Health Care Finance</i>, 43(4).</p>	<p>They find that prices are higher in CON states relative to non-CON states, but the difference isn't statistically significant.</p>

<p>Kim, S., <i>et al.</i> (2016). Does certificate of need minimize intensity modulated radiation therapy use in patients with low risk prostate cancer?. <i>Urology Practice</i>, 3(5), 342–348. https://doi.org/10.1016/j.urpr.2015.09.001.</p>	<p>They study the effect of CON laws on the use of intensity modulated radiation therapy when it is not warranted. They find that the therapy was actually used more often in CON states than in non-CON states, concluding that it failed to achieve its goal.</p>
<p>Rahman, M., <i>et al</i> (2016). The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures. <i>Medical Care Research and Review</i>, 73(1), 85–105.</p>	<p>CON increases the growth in Medicare and Medicaid expenditures on nursing home care but decreases growth in home healthcare expenditures.</p>
<p>Stratmann, T., & Koopman, C. (February 2016). <i>Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals</i>. (Working Paper). <i>Mercatus Center at George Mason University</i>. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3191476.</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"> 1) CON programs are associated with 30% fewer hospitals per 100,000 residents across the entire state; 2) Ambulatory surgical center (ASC)-specific CONs are correlated with 14% fewer total ASCs per 100,000 residents; 3) CON programs are associated with 30% fewer rural hospitals per 100,000 rural residents; 4) ASC-specific CONs are correlated with 13% fewer rural ASCs per 100,000 rural residents.
<p>Ni, H., Paul, J. A., & Bagchi, A. (2017). Effect of certificate of need law on the intensity of competition: the market for emergency care. <i>Socio-Economic Planning Sciences</i>, 60, 34–48. https://doi.org/10.1016/j.seps.2017.02.002.</p>	<p>They assess the effect of CON on market concentration (as measured by the Herfindahl–Hirschman Index (HHI)). They measure CON two ways—using a simple binary measure and a stringency measure based on the dollar threshold at which investments are subject to review. They use two-stage least square regression to address concerns of endogeneity. Their (somewhat dubious) IVs in the binary tests are an index of science and technology and the unemployment rate, and in the stringency model, they are the CPI and the unemployment rate. They find that CON laws are associated with greater competition, concluding that they serve as a sort of anti-trust tool.</p>
<p>Perry, B. J. (2017). Certificate of Need Regulation and Hospital Behavior: Evidence from MRIs in North Carolina. <i>Available at SSRN 3225741</i>. https://doi.org/10.2139/ssrn.3225741.</p>	<p>Service areas in North Carolina are allocated a new machine when the number of MRI procedures performed in the area crosses a predetermined threshold. He compares service areas that are just below the threshold to areas just above the threshold to see the effect of a binding CON constraint. He finds:</p> <ol style="list-style-type: none"> 1) By limiting the use of scanners, CON laws reduce spending on patients with low back pain by about \$400 in the first month of diagnosis; 2) CON limits the number of MRI scanners in an area—when an area is allowed to obtain a scanner, they almost always do; 3) Providers get around this constraint, to some degree, by utilizing unregulated mobile scanners; 4) Patients in a region constrained by CON receive 34% fewer scans in the first month after diagnosis; 5) Medicare patients are disproportionately crowded out by CON; their fraction of MRIs performed jumps 10 percentage points after CON approval; and 6) CON seems to limit cancer patient access to scans, but not musculoskeletal disorder patient access to scans.
<p>Stratmann, T., & Monaghan, S. (August 2017). <i>The effect of interest group pressure on favorable regulatory decisions: the case of certificate-of-need laws</i>. (Working Paper) <i>Mercatus Center at George Mason University</i>. https://www.mercatus.org/research/working-papers/effect-interest-group-pressure-favorable-regulatory-decisions.</p>	<p>They examine the link between PAC contributions by applicants and the likelihood of CON approval in three states. They find:</p> <ol style="list-style-type: none"> 1) The approval rate in Georgia is 57%, the approval rate in Michigan is 77%, and the approval rate in Virginia is 51% and 2) A 1% increase in contributions by an applicant firm increases the odds of approval by 6.7% in Georgia, 1.8% in Michigan, and 3.6% in Virginia.

<p>Bailey, J. (2018). The effect of certificate of need laws on all-cause mortality. <i>Health Services Research</i>, 53(1), 49–62. https://doi.org/10.1111/1475-6773.12619.</p>	<p>He uses fixed- and random-effects regressions to test how the scope of state CON 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.</p>
<p>Browne, J. A., et al. (2018). Certificate-of-need state laws and total knee arthroplasty. <i>The Journal of Arthroplasty</i>, 33(7), 2020–2024. https://doi.org/10.1016/j.arth.2018.01.063.</p>	<p>They examined the effect of CON on total knee arthroplasty (TKA) by comparing states with and without CON programs. They look at four factors and find:</p> <ol style="list-style-type: none"> 1) Average Medicare reimbursements were 5% to 10% lower in non-CON states; 2) CON was associated with lower TKA utilization per capita, but faster growth in utilization per capita; 3) CON was associated with TKA in higher-volume hospitals; and 4) Examination of adverse events rates did not reveal any strong associations between any adverse outcome and CON status.
<p>Noh, S., & Brown, C. H. (2018). Factors associated with the number of substance abuse nonprofits in the US states: focusing on Medicaid expansion, certificate of need, and ownership. <i>Nonprofit Policy Forum</i>, 9(2), 20170010. https://doi.org/10.1515/npf-2017-0010.</p>	<p>They study the effects of CON on substance abuse facilities, finding:</p> <ol style="list-style-type: none"> 1) CON laws are negatively associated with the number of nonprofit substance abuse facilities and 2) In states with both CON laws and Medicaid expansion, the number of nonprofit substance abuse facilities tended to increase.
<p>Ohsfeldt, R. L., & Li, P. (2018). State entry regulation and home health agency quality ratings. <i>Journal of Regulatory Economics</i>, 53, 1–19. https://doi.org/10.1007/s11149-018-9351-4.</p>	<p>They examine the effect of CON on home health agency (HHA) quality ratings from the Centers for Medicare and Medicaid Services. They find:</p> <ol style="list-style-type: none"> 1) HHAs in CON states were about 58% less likely to be rated as high quality ($p < .01$) and 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.
<p>Bailey, J. (2019). Can health spending be reined in through supply restraints? An evaluation of certificate-of-need laws. <i>Journal of Public Health</i>, 27, 755–760. https://doi.org/10.1007/s10389-018-0998-1.</p>	<p>States that eliminate CON experience 4% reductions in real per capita health care spending.</p>
<p>Casp, A. J., et al. (2019). Certificate-of-need State Laws and Total Hip Arthroplasty. <i>The Journal of Arthroplasty</i>, 34(3), 401–407. https://doi.org/10.1016/j.arth.2018.11.038.</p>	<p>They study the effect of CON on total hip arthroplasty. They find CON is associated with:</p> <ol style="list-style-type: none"> 1) Lower volume of total hip arthroplasty; 2) Care in high-volume hospitals; and 3) No difference in postoperative complications between CON and non-CON states.
<p>Paul, J. A., Ni, H., & Bagchi, A. (2019). A Study of the Effects of Certificate of Need Law on Inpatient Occupancy Rates. <i>Service Science</i>, 11(1), 1–15. https://doi.org/10.1287/serv.2018.0228.</p>	<p>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).</p>
<p>Paul, J. A., Ni, H., & Bagchi, A. (2019). Does certificate of need law enhance competition in inpatient care market? An empirical analysis. <i>Health Economics, Policy and Law</i>, 14(3), 400–420. https://doi.org/10.1017/S1744133117000184.</p>	<p>They study the effect of CON on market concentration, as measured by a normalized Herfindahl–Hirschman Index (HHI) built using inpatient volume data of acute care hospitals in each health referral region (HRR). They find that CON is associated with less market concentration.</p>
<p>Wu, B., et al. (2019). Entry regulation and the effect of public reporting: Evidence from Home Health Compare. <i>Health Economics</i>, 28(4), 492–516.</p>	<p>They assess the effect of CON regulation on several measures of quality in home health care, 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"> 1) Patients perform worse on functional improvement measures (bathing, ambulating, transferring to bed, managing oral medication, and less pain interfering with activity); 2) Patients are more likely to be admitted to the ER; and 3) Patients are more likely to be admitted to an acute care hospital.

<p>Averett, S. L., Terrizzi, S., & Wang, Y. (2019). Taking the CON out of Pennsylvania: Did hip/knee replacement patients benefit? A retrospective analysis. <i>Health Policy and Technology</i>, 8(4), 349–355. https://doi.org/10.1016/j.hlpt.2019.09.006.</p>	<p>They analyze the effects of the expiration of Pennsylvania’s CON law on hip and knee replacement surgeries. They assess the effect of deregulation on one measure of cost per service (charges) and four measures of quality. They find that deregulation had:</p> <ol style="list-style-type: none"> 1) No effect on total charges; 2) Increased the length of stay; 3) No effect on hospital acquired infections; and 4) Decreased mortality.
<p>Chui, P. W., <i>et al.</i> (2019). Association of statewide certificate of need regulations with percutaneous coronary intervention appropriateness and outcomes. <i>Journal of the American Heart Association</i>, 8(2), e010373. https://doi.org/10.1161/JAHA.118.010373.</p>	<p>Like their 2015 paper, this one assesses whether CON limits inappropriate percutaneous coronary interventions. Again, they find a small but economically insignificant effect.</p>
<p>Malik, A. T., <i>et al.</i> (2019). Certificate-of-Need state laws and elective posterior lumbar fusions: A Medicare trends, costs and outcomes analysis. <i>The Spine Journal</i>, 19(9), S45. https://doi.org/10.1016/j.spinee.2019.05.106.</p>	<p>The examined the effect of CON on elective posterior lumbar fusions (PLFs) from 2005 to 2014, finding:</p> <ol style="list-style-type: none"> 1) Average 90-day reimbursements were slightly higher (1.4% higher) in non-CON states (\$22,115 vs. \$21,802) 2) CON laws are associated with lower per capita utilization of PLFs; 3) CON laws are associated with more high-volume facilities; 4) CON laws are not associated with significant reduction in 90-day readmissions; 5) CON laws are not associated with significant reduction in 90-day complications.
<p>Cancienne, J. M., <i>et al.</i> (2020). Certificate-of-Need Programs Are Associated with a Reduced Incidence, Expenditure, and Rate of Complications with Respect to Knee Arthroscopy in the Medicare Population. <i>The Musculoskeletal Journal of Hospital for Special Surgery</i>, 16(2 Suppl.), 264–271. https://doi.org/10.1007/s11420-019-09693-z.</p>	<p>They examine the effect of CON on knee arthroscopy, assessing its effect on:</p> <ol style="list-style-type: none"> 1) Charges and reimbursements: in t-tests without controls they find that charges (which are the prices set before any negotiation) were lower in CON states, while reimbursements (which are actual payments) were not statistically significantly different; 2) Total volume: total volume and growth in total volume was lower in CON states than in non-CON states; 3) Volume within facilities: CON is associated with the presence of more high-volume facilities; and 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.
<p>Ettner, S. L., <i>et al.</i> (2020). Certificate of need and the cost of competition in home healthcare markets. <i>Home Health Care Services Quarterly</i>, 39(2), 51–64. https://doi.org/10.1080/01621424.2020.1728464.</p>	<p>They examine the effects of home health agency (HHA) CONs and nursing home CONs on home health agencies. They find that in states with HHA CONs there are:</p> <ol style="list-style-type: none"> 1) Lower per patient expenditures (they don’t know if this is due to skimping or to economies of scale); 2) Higher expenditures per agency; 3) Higher expenditures per resident; 4) Slightly fewer home health agencies per capita; and 5) Higher caseloads (volume) within agencies (this is what drives the higher expenditures per agency).
<p>Fayissa, B., <i>et al.</i> (2020). Certificate-of-need Regulation and Healthcare Service Quality: Evidence from the Nursing Home Industry. <i>Healthcare</i> 8(4), 423. https://doi.org/10.3390/healthcare8040423.</p>	<p>In an IV study, they find that CON is associated with:</p> <ol style="list-style-type: none"> 1) 18 to 24% lower nursing home survey scores computed by healthcare professionals and 2) The substitution of lower-quality certified nursing assistance care for higher-quality licensed practical nurse care.

<p>Mitchell, M. D., Stratmann, T., & Bailey, J. B. (April 2020). <i>Raising the Bar: ICU Beds and Certificates of Need</i>. (Policy Brief) <i>Mercatus Center at George Mason University</i>. https://www.mercatus.org/publications/covid-19-crisis-response/raising-bar-icu-beds-and-certificates-need.</p>	<p>They study the relationship between CON and projected ICU bed shortages over the course of the COVID-19 pandemic. They find that compared with non-CON states, in CON states, expected shortages were more than twice as likely and the shortages were about nine times greater in per capita terms.</p>
<p>Myers, M. S., & Sheehan, K. M. (2020). The impact of certificate of need laws on emergency department wait times. <i>Journal of Private Enterprise</i>, 35(1), 59–75.</p>	<p>They examine the effect of CON laws on wait times. They find CON programs increase:</p> <ol style="list-style-type: none"> 1) Median wait times for medical examinations; 2) Wait times for pain medication administration; 3) Wait times for hospital admittance; and 4) Wait times for hospital discharge.
<p>Sridharan, M., <i>et al.</i> (2020). Certificate-of-Need State Laws and Elective Posterior Lumbar Fusions: Is It Time to Repeal the Mandate?. <i>World Neurosurgery</i>, 144, e495–e499. https://doi.org/10.1016/j.wneu.2020.08.201.</p>	<p>They examined the effect of CON on elective posterior lumbar fusions (PLFs) from 2005 to 2014, finding:</p> <ol style="list-style-type: none"> 1) Average 90-day reimbursements were slightly higher (1.4% higher) in non-CON states (\$22,115 vs \$21,802); 2) CON laws are associated with lower per capita utilization of PLFs; 3) CON laws are associated with more high-volume facilities; 4) CON laws are not associated with significant reduction in 90-day readmissions; and 5) CON laws are not associated with significant reduction in 90-day complications.
<p>Stratmann, T., & Baker, M. (July 2020). <i>Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis</i>. (Working Paper) <i>Mercatus Center at George Mason University</i>. https://www.mercatus.org/publications/healthcare/examining-certificate-need-laws-context-rural-health-crisis.</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"> 1) Medicare spending per rural beneficiary (they find this was \$295 higher in CON states than in non-CON states); 2) Ambulance spending per beneficiary (\$2.54 higher in CON states); 3) Hospital readmission rates (1.2 percentage points higher in CON states); and 4) Emergency room visits per 1,000 beneficiaries (35.1 more emergency department visits per 1,000 beneficiaries in CON states).
<p>Yuce, T. K., <i>et al.</i> (2020). Association of state certificate of need regulation with procedural volume, market share, and outcomes among Medicare beneficiaries. <i>JAMA</i>, 24(20), 2058–2068. https://doi.org/10.1001/jama.2020.21115.</p>	<p>They assess the effect of CON on measures of volume and of quality. They find:</p> <ol style="list-style-type: none"> 1) No significant difference between CON and non-CON states in county-level procedures per 10,000 persons; 2) No significant difference between CON and non-CON states for hospital procedural volume; 3) No difference in hospital market share; 4) No difference in risk-adjusted 30-day postoperative mortality; 5) No difference in surgical site infection; and 6) No difference in readmission.
<p>Ziino, C., Bala, A., & Cheng, I. (2020). Does ACDF Utilization and Reimbursement Change Based on Certificate of Need Status?. <i>Clinical Spine Surgery</i>, 33(3), E92–E95. https://doi.org/10.1097/BSD.0000000000000914.</p>	<p>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.</p>

<p>Ziino, C., Bala, A., & Cheng, I. (2020). Does certificate-of-need status impact lumbar microdecompression reimbursement and utilization? A retrospective database review. <i>Current Orthopaedic Practice</i>, 31(1), 85–89. https://doi.org/10.1097/BCO.0000000000000828.</p>	<p>They examined the effect of CON in lumbar microdecompressions in both in-patient and out-patient settings, focusing on growth in utilization of the procedure over time and changes in reimbursement over time. These were simple comparisons, not regressions with controls. They find:</p> <ol style="list-style-type: none"> 1) CON status did not affect overall reimbursement rates (“The ability of outpatient surgery to lower costs may, in fact, be more powerful than CON programs.”) and 2) Utilization of the procedure increased more in CON states than in non-CON states.
<p>Bailey, J., & Lewin, E. (2021). Certificate of Need and Inpatient Psychiatric Services. <i>The Journal of Mental Health Policy and Economics</i>, 24(4), 117–124.</p>	<p>They examine the effect of psychiatric service CONs. They find that psychiatric service CONs:</p> <ol style="list-style-type: none"> 1) Reduce the number of psychiatric hospitals by 20%; 2) Reduce the likelihood that a hospital will accept Medicare by 5.35 percentage points; and 3) Reduce the number of psychiatric clients per capita by 56%.
<p>Baker, M. C., & Stratmann, T. (2021). Barriers to entry in the healthcare markets: Winners and Losers from Certificate-of-Need Laws. <i>Socio-Economic Planning Sciences</i>, 77, 101007. https://doi.org/10.1016/j.seps.2020.101007.</p>	<p>They examine the effect of medical imaging CONs on medical imaging providers. They find:</p> <ol style="list-style-type: none"> 1) CON laws are associated with 20 to 33% fewer providers; 2) Residents of CON states are 3.4 to 5.3 percentage points more likely to travel out of state to obtain these services; and 3) CON laws are associated with 27 to 53% fewer scans by nonhospital providers per beneficiary; 4) CON laws are associated with 23 to 70% fewer scans by new hospitals; and 5) CON laws are associated with 6 to 21% more scans by older hospitals.
<p>Chiu, K. (2021). The impact of certificate of need laws on heart attack mortality: Evidence from county borders. <i>Journal of Health Economics</i>, 79, 102518. https://doi.org/10.2139/ssrn.3678714.</p>	<p>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% higher mortality three years after enactment.</p>
<p>Herb, J. N., <i>et al.</i> (2021). 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(2), 344–351. https://doi.org/10.1016/j.ijrobp.2020.08.059.</p>	<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"> 1) Has no association with prolonged travel in the West; 2) Is associated with lower odds of prolonged travel in both urban and rural tracts in the South; and 3) Is associated with increased odds of prolonged travel in both urban and rural tracts in the Midwest and Northeast.
<p>Mitchell, M., & Stratmann, T. (2021). 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(1), 10. https://doi.org/10.3390/jrfm15010010.</p>	<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"> 1) States that require CONs for beds had 12% higher bed utilization rates; 2) Those states had 58% more days with more than 70% of their beds in use; 3) Hospitals in these states were 27% more likely to run out of beds; and 4) States that relaxed these rules for COVID saw no difference in utilization rates or shortages.

<p>Schultz, O. A., Shi, L., & Lee, M. (2021). Assessing the Efficacy of Certificate of Need Laws Through Total Joint Arthroplasty. <i>The Journal for Healthcare Quality</i>, 43(1), e1–e7. https://doi.org/10.1097/JHQ.0000000000000286.</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"> 1) TKA and TSA costs were higher in CON states than in non-CON states (and these results were statistically significant); 2) THA costs were lower in CON states but these results were not statistically significant; 3) CON is associated with a lower volume of TKA and TSA procedures, though it was not statistically significant for THA; and 4) CON has no statistically significant effect on complications (deep vein thrombosis and pulmonary embolism).
<p>Ziino, C., Bala, A., & Cheng, I. (2021). Utilization and Reimbursement Trends Based on Certificate of Need in Single-Level Cervical Discectomy. <i>Journal of the American Academy of Orthopaedic Surgeons</i>, 29(10), e518–e522.</p>	<p>They study inpatient cervical discectomy in CON and non-CON states in inpatient and outpatient settings. It appears that they did not use any controls, however. Regarding reimbursements, they find:</p> <ol style="list-style-type: none"> 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; 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 non-CON states but falling in the CON states. <p>Regarding access:</p> <ol style="list-style-type: none"> 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; and 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 (again this does not appear to control for the larger population of CON states than non-CON states).
<p>Bailey, J. B., Lu, T., & Vogt, P. (2022). Certificate-of-need laws and substance use treatment. <i>Substance Abuse Treatment Prevention and Policy</i>, 17, 38. https://doi.org/10.1186/s13011-022-00469-z.</p>	<p>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 but has no statistically significant effect on the number of facilities, beds, or clients and no significant effect on the acceptance of Medicare or Medicaid.</p>
<p>Choudhury, A., Ghosh, S., & Plemmons, A. (2022). Certificate of Need Laws and Health Care Use during the COVID-19 pandemic. <i>Journal of Risk and Financial Management</i>, 15(2), 76. https://doi.org/10.3390/jrfm15020076.</p>	<p>They examined the relationship between CON and mortality associated with illnesses that require similar medical equipment as COVID-19. They find:</p> <ol style="list-style-type: none"> 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-19.

<p>Stratmann, T. (2022). The Effects of Certificate-of-Need Laws on the Quality of Hospital Medical Services. <i>Journal of Risk and Financial Management</i>, 15(6), 272. https://doi.org/10.3390/jrfm15060272.</p>	<p>He studies the effect of CON on nine measures of hospital quality:</p> <ol style="list-style-type: none"> 1) Death among surgical inpatients with serious treatable complications; 2) Postoperative pulmonary embolism or deep vein thrombosis; 3) Percent of patients giving their hospital a 9 or 10 overall rating; 4) Pneumonia readmission rate; 5) Pneumonia mortality rate; 6) Heart failure readmission rate; 7) Heart failure mortality rate; 8) Heart attack readmission rate; and 9) Heart attack mortality rate. <p>Hospitals in CON states performed worse than those in non-CON states in eight of the nine categories, the exception being postoperative pulmonary embolism.</p>
<p>Bailey, J., & Hamami, T. (2023). Competition and health-care spending: Theory and application to Certificate of Need laws. <i>Contemporary Economic Policy</i>, 41(1), 128–145. https://doi.org/10.1111/coep.12584.</p>	<p>CON causes spending on those with less than excellent health to be as much as 20% higher, though it has no statistically significant effect on spending on those in good health.</p>
<p>Gaines, A. G., & Cagle, J. G. (2023). Associations Between Certificate of Need Policies and Hospice Quality Outcomes. <i>American Journal of Hospice and Palliative Medicine</i>, 10499091231180613. Advance online publication. https://doi.org/10.1177/10499091231180613.</p>	<p>They study the effects of CON laws in a cross-sectional analysis of hospice quality outcomes using the hospice item set metric (HIS) developed by the Centers for Medicare and Medicaid Services. Controlling for ownership and size, they find hospice CON states had higher HIS ratings than those from non-CON states along four dimensions:</p> <ol style="list-style-type: none"> 1) Beliefs and values addressed ($\beta = .05$, $P = .009$); 2) Pain assessment ($\beta = .05$, $P = .009$); 3) Dyspnea treatment ($\beta = .08$, $P < .001$); and 4) The composite measure ($\beta = .09$, $P < .001$). <p>They also find that along four additional measures the differences were statistically insignificant ($P > .05$):</p> <ol style="list-style-type: none"> 1) Treatment preferences; 2) Pain screening; 3) Dyspnea screening; and 4) Opioid bowel treatment.

ABOUT THE AUTHORS



Jaimie Cavanaugh is an attorney with the Institute for Justice. She has litigated a constitutional challenge to Kentucky's certificate of need (CON) laws and played a key role in the near full repeal of South Carolina's CON laws in 2023. In 2020, Cavanaugh was lead author of the report *Conning the Competition, A Nationwide Survey of Certificate of Need Laws*. Her experience in this area has established her as a national policy expert. She routinely advises legislators as they consider repealing CON laws. Her work has appeared in *The Wall Street Journal*, *USA Today*, *NBC News*, *Medscape*, and others. She also works to end government-imposed barriers to economic liberty and infringement of private property. Cavanaugh earned her JD from the University of Colorado and her BA from the University of Michigan.



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