Independent Women's LAW CENTER

— LEGAL POLICY FOCUS —

Certificate-of-Need Laws

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EXECUTIVE SUMMARY

- Certificate-of-Need (CON) laws in 36 states require individuals who wish to expand or start a new healthcare business first to apply to state regulators and prove there is a "need" for their services.
- CON laws also allow *competitors* to object to a new or expanding business, effectively grating them a competitor's veto.
- CON regulations involve a litigation-like process that is time-consuming and expensive, often taking several years and up to hundreds of thousands of dollars in application and attorneys' fees.
- For example, it took five years and $175,000 before Progressive Radiology secured permission from CON regulators simply to purchase a second MRI machine.
- Certificate-of-Need Laws are barriers to entry that raise healthcare prices and hamstring the ability of states to deal with public health emergencies.
- During the coronavirus pandemic, many states temporarily waived CON law requirements in order to grant businesses the flexibility necessary to respond to the healthcare crisis.
- The Department of Justice and the Federal Trade Commission have both condemned Certificate-of-Need laws, concluding they "impede the efficient performance of the health care markets.... create barriers to entry and expansion to the detriment of health care competition and consumers ... undercut consumer choice, stifle innovation, and weaken markets' ability to contain health care costs."

MORE INFORMATION

What You Should Know

Ordinarily one is not required to seek the consent of government regulators, much less competitors, before starting a business in America. Yet that is precisely what Certificate-of-Need laws ("CON laws") in 36 states require when an individual wants to enter or expand into the healthcare sector.

For example, Philip Truesdale **started his own business** in Aberdeen, Ohio, with a single ambulance. He now owns seven. Truesdale's company transports patients who require non-emergency medical transportation because they need medical support while traveling, such as oxygen, dialysis, or a stretcher. Truesdale operates just miles from the Kentucky border, and often transports Ohio patients to healthcare facilities in Kentucky. Yet he cannot transport those same patients back to their home in Ohio because Kentucky's Certificate-of-Need statute prohibits Truesdale from originating trips in Kentucky or serving Kentucky residents.

CON law requirements kick in when an entrepreneur wishes to start (or expand) a healthcare business. She must first file a detailed application, which often includes financial information, proof of insurance, a description of the proposed business, and a filing fee of up to tens of thousands of dollars. Once the application has been filed, state regulators are required to notify all existing competitors and give them an opportunity to object. If an existing firm files an objection, the applicant must participate in a public hearing, where competitors are allowed to present evidence and cross-examine witnesses, in what has come to be known as "competitor's veto." In short the applicant must prove that there is a *need* for her services. Regulators normally consider a variety of vague factors such as necessity and the public interest in determining whether an applicant should recieve a certificate, granting wide discretion to state regulators.

> ***"Certificate-of-Need (CON) law requirements kick in when an entrepreneur wishes to start (or expand) a healthcare business."***

Why You Should Care

Certificate-of-Need Laws serve as protectionist barriers to entry that raise healthcare prices and hamstring the ability of states to deal with public health emergencies.

- **The Department of Justice and the Federal Trade Commission condemn Certificate-of-Need laws because they increase healthcare costs and impede competition.** After extensive investigation, the Department of Justice and the Federal Trade Commission **have both condemned** Certificate-of-Need laws, **concluding** they "impede the efficient performance of the health care markets." Worse, they "create barriers to entry and expansion to the detriment of health care competition and consumers … undercut consumer choice, stifle innovation, and weaken markets' ability to contain health care costs."

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- **Certificate-of-Need laws hamstring America's ability to deal with healthcare crises, like the coronavirus pandemic.** The coronavirus pandemic highlights the absurdity of allowing market participants to veto competition. Certificate-of-Need laws create expensive and time-consuming regulatory barriers to entry and impede the flexibility needed to respond to a healthcare emergency. Recognizing this, and in an effort to provide their healthcare sector with more flexibility to combat coronavirus, 22 states temporarily **suspended** their CON laws. Connecticut, Georgia, and New York, for example, waived Certificate-of-Need reviews for projects deemed necessary for responding to Covid-19.
- **Certificate-of-Need laws often raise healthcare costs, instead of minimizing them.** Defenders of Certificate-of-Need laws claim that they contain healthcare costs. In reality, CON laws often contribute to their rise. Because demand for healthcare services is generally price inelastic, meaning that people looking for healthcare are inclined to purchase it, no matter the cost, research has repeatedly shown that CON laws are likely to increase its price.

Background

Certificate-of-Need laws first began with state efforts to regulate railroad monopolies in the late 1800s. During the 1930s, these state laws were expanded to cover other industries. The federal government got involved in 1974, enacting **The National Health**

Planning and Resources Development Act of 1974, which withheld federal funds from states that failed to adopt Certificate of Need laws for healthcare facilities.

The NHPRDA was enacted in part due to unique economic circumstances facing the healthcare industry in the 1970s. During this time period, the federal government and private insurance reimbursed health care charges on a "cost-plus" basis, leading to fears of a medical arms race which would drive up costs. The theory behind these laws was that competition was economically wasteful and that state agencies were better situated to determine a community's needs than was the market. By the early 1980s, every state except Louisiana had CON laws on the books.

Cost-plus reimbursement policies subsequently changed, however, and in 1986, Congress repealed the NHPRDA. Fifteen states then repealed their CON laws, leaving 35 states and the District of Columbia with CON regulations governing their healthcare sectors.

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Con Law Anti-Competitive Behavior

Examples of the absurdity of CON laws abound:

- In 2010, **Georgia's Women's Surgical Center**, a state-of-the-art healthcare facility designed specifically for women, sought to add additional doctors and a second operating room. The center is Georgia's only fully accredited center performing all major and minor gynecological surgeries in an outpatient setting. It specializes in minimally invasive surgical techniques that avoid costly hospitalization. Georgia's Certificate-of-Need laws, however, prohibited the expansion. After seven years of expensive litigation, the Georgia Supreme Court **ultimately rejected** the Center's objections to Georgia's Certificate-of-Need laws.
- **Progressive Radiology** operates a radiology center in Northern Virginia. In 2003, the facility submitted a Certificate-of-Need application to add a second MRI machine. Virginia denied the application twice. It was only after five years and approximately $175,000 in expenses and attorneys' fees that Progressive Radiology was permitted to purchase a second MRI machine.
- Dr. Mark Baumel of **Colon Health Centers** sought to reduce preventable deaths from that cancer by partnering with gastroenterologists. According

to statistics, as many as 90 percent of colon-cancer deaths are preventable, but fewer than 50 percent of at-risk people get the proper screening. Thus, Dr. Baumel proposed a system of virtual colonoscopies whereby gastroenterologists would send electronic images to radiologists at Colon Health Centers. If there were abnormalities, the gastroenterologist could immediately perform a procedure without the need for a second appointment, shortening the time between diagnosis and treatment. After years of litigation, the Fourth Circuit ultimately rejected Dr. Baumel's challenge to Virginia's CON law.[1]

- Recognized as one of the top opthamologists in the nation, **Dr. Lee Birchansky** performs innovative, no-stitch cataract surgeries in Cedar Rapids, Iowa. He sought to open an outpatient eye surgery center next to his office to perform this procedure. Dr. Birchansky repeatedly sought approval from state Certificate-of-Need regulators but his application was denied four times. The local hospital, Mercy Medical Center, objected because their beds were only half full. Instead of building his own outpatient clinic, Iowa's CON laws have required him to perform these surgeries at his competitor's facilities. Meanwhile, Mercy used a loophole in Iowa's CON statute to open their own outpatient eye surgery clinic only four miles from Dr. Birchansky's office.
- **Korver ENT** owns a new medical facility in Orange City, Iowa. It explored plans to convert the lower level into an outpatient surgery center to perform tonsillectomies, sinus surgeries, and other outpatient ENT surgeries. Korver ultimately **decided not to go forward** with its business expansion because its business could not bear the time, expense, and uncertainty of Iowa's Certificate-of-Need process.
- Michael Ball had worked in the moving business for thirty-five years when he decided to open his own moving company. He applied for a Certificate-of-Need and no less than six moving companies filed protests, complaining that Ball's company would be "directly competitive" with their businesses and "dimin[ish]" their profits. At the hearing, the hearing officer concluded that Ball was fully qualified to operate a moving company but rejected his application because Ball had not proved that his moving company was needed.[2]
- **Dipendra Tiwari**, a native Nepali speaker, formed Grace Home Care and paid a $1,000 fee to submit a plan for a home health care agency catering to the Nepali refugee population in Louisville, Kentucky. Dipendra's future competitor—a $2 billion healthcare conglomerate objected, arguing there was no need for another

1 *Colon Health Centers of America, LLC v. Hazel*, 813 F.3d 145 (4th Cir. 2016).

2 Timothy Sandefur, *State "Competitor's Veto" Laws and the Right to Earn a Living: Some Paths to Federal Reform*, 38 HARVARD JLPP 1009, 1038-39 (2014).

home health agency. Despite the thousands of Nepali-speaking refugees who have settled in Louisville, the state refused to grant Dipendra a Certificate-of-Need. Dipendra is currently challenging Kentucky's CON requirement.

Myths About Certificate Of Need Laws

States have continued to hang on to Certificate-of-Need laws even without federal incentives based on the prevalence of certain myths about the role CON laws play in regulating healthcare quality, access, and costs.

MYTH #1—Certificate-of-Need laws reduce the cost of healthcare services.

A. In 1974, Congress was concerned with inflation in the healthcare sector and encouraged states to adopt Certificate-of-Need laws in the hope such laws would rein in healthcare spending. Many states that continue to enforce CON laws today similarly rationalize these statutes by the stated purpose of containing healthcare costs. **New York**, for example, relies on its CON laws to "limit" health care costs.

B. The cost-limiting purpose of Certificate-of-Need laws is at odds with basic economic theory. When regulation reduces the supply of a product, like healthcare services, Economics 101 suggests that the per-unit price of that product will *increase*. As **the Fourth Circuit Court of Appeals** put it, "barriers to entry like CON programs may reduce competition and thereby allow entrenched incumbents to exert market power and charge inefficiently high prices."

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C. Empirical evidence bears these economic predictions out. Evidence establishes that CON laws—far from reducing healthcare costs—often increase those costs. According to the **Department of Justice and the Federal Trade Commission**, CON laws have "generally failed in their intended purpose of containing costs." Rather, the **best empirical evidence** shows that CON laws have "no effect or actually increase[] both hospital spending per capita and total spending per capita." And **research from the Mercatus Center** suggests that CON laws have the unintended consequence of raising spending by 3-4% overall and 7% for Medicare.[3]

3 Certain medical services are elective and thus elastic, such as plastic surgery. Further, services purchased through Medicaid are more elastic as Medicaid sets reimbursement rates. The Mercatus Center thus found that CON laws would be more likely to reduce spending by Medicaid.

Myth #2—Certificate-of-Need laws increase healthcare access for rural communities.

A. The National Health Planning and Resources Development Act identified rural access to healthcare as a priority, and modern-day supporters of CON laws continue to argue that CON regulations help increase access to health care in rural communities. But there is no evidence that CON laws increase access for people living in rural areas and studies establish that CON laws decrease the number of hospitals overall, including in rural communities. **Recent research** shows that states with CON regulations have 30% fewer hospitals per 100,000 residents, including in less-populated areas. Rural states also had 13% fewer ambulatory surgical centers. Further, people who live in CON states must drive further to access healthcare than people who live in non-CON states.

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MYTH #3—CON programs increase the quality of healthcare offered.

A. CON regulations do not normally assess the quality of a provider's service, instead these regulations focus on whether there is an economic need for these services. Still some of those who favor CON regulation claim that these regulations cause practitioners to become more specialized and thus proficient. **New York** for example cites the delivery of "high quality health care" as a goal of its CON laws.

B. Economic theory suggests the opposite—that competition often drives an increase in quality. A **recent study** by the Mercatus Center, for example, found that states with CON laws tended to receive "lower-quality services." Moreover, as illustrated by the CON regulation examples above, CON laws can operate to bar the entry of new firms or new technologies that provide innovative services as well as new and more cost-effective treatments. As the Department of Justice has concluded, CON laws stifle innovation and create barriers to entry to the detriment of consumers.

MYTH #4—Certificate-of-Need laws ensure services are aligned with community needs.

A. Some policy makers **claim** that CON laws help to ensure services are properly aligned with community needs. By their nature, however, CON laws are barriers

to entry, they thus serve as a one-way ratchet, restricting supply. It can take years and tens of thousands of dollars to obtain a Certificate-of-Need.

B. A **comprehensive study** of the effect of CON programs on the supply of medical equipment found that such regulation diminishes supply. The **study found** that controlling for demographics and other variables, CON states have, on average, 99 fewer hospital beds per 100,000 people than States without these regulations.

MYTH #5—Health care is a "special" good to which normal economic forces do not apply.

A. Some proponents of CON laws argue that the healthcare market is special. **According to a representative** of the American Health Planning Association, "[c]ompetition in health care is … very different" than in other markets. In 1974, insurance was reimbursed on a cost-plus basis, and, in passing the 1974 Health Planning Act, Congress appears to have shared the view that the healthcare sector was plagued by market failures.

B. While the healthcare market is undeniably complex, basic supply and demand can **still describe** most of the market. CON laws shift the supply curve left—leading to a lower quantity produced at any given price. Because the demand for healthcare is relatively inelastic, **research** shows that "CON laws are likely to increase total spending." Further, because many patients have insurance, this makes it **even more likely** that patient demand is inelastic and thus that CON regulations will result in increased spending on the regulated healthcare service. (By increasing co-pays and deductibles or denying procedures insurance companies can raise the elasticity of demand.) **Research from the Mercatus Center** suggests that CON laws have the unintended consequence of raising spending by 3-4% overall and 7% for Medicare.

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Arguments Against Certificate-of-Need Laws

1. The Original Cost-Control Rationale No Longer Applies—CON laws were enacted under particular market and regulatory conditions that no longer exist today. The National Health Planning and Resources Development Act of 1974 was enacted in part due to insurance **reimbursement programs** which provided reimbursements on a "cost-plus" basis, leading to inflationary concerns. These reimbursement policies have

changed, and in 1986, Congress repealed The National Health Planning and Resources Development Act of 1974.

Further, during the early 1930s, the time in which CON laws were fashionable, so was the economic theory of "destructive competition." This theory posits that unregulated competition is "dangerously inefficient" because "of the lag time between a spike in demand and the increase in supply."[4] Economists now largely recognize that supply and demand are the best mechanism for determining output levels, that free competition produces efficient outcomes, and that inefficiencies caused by government attempts to regulate market entry cause their own inefficiencies.[5]

It is simply unrealistic to expect government regulators to look into their crystal ball and predict future needs for medical services. Take Starbucks, for example. There were millions of coffee shops in the United States in 1992, and the company would have had a hard time establishing that a new chain was "necessary."[6] And yet, the market clearly had room for a new coffee shop—at least one with the attributes of Starbucks.

"It is simply unrealistic to expect government regulators to look into their crystal ball and predict future needs for medical services."

2. CON Laws Encourage Anti-Competitive Behavior—Certificate-of-Need laws enable existing businesses tools to impede competition for self-interested reasons.[7] Existing firms can use their right to protest an application to increase the cost of entry on a new market participant. Incumbents have exploited the CON regulatory process to stop or delay new competition. When an incumbent business objects, potential competitors must divert funds from investment in healthcare facilities to legal, consulting, and lobbying expenditures. Thus, the Anti-Trust Division of DOJ and the FTC **found** that incumbents use CON regulations "to forestall competitors from entering an incumbent's market."

CON laws also tip their hand in favor of existing businesses, allocating to new businesses the burden of proving the necessity of their proposed service. This makes certificates difficult to obtain and has the effect of shielding existing businesses from

4 Sandefur, *supra* at 1026.
5 *Id.*
6 *Id.*
7 *Id.* at 1010.

new competition. As Judge Richard Posner describes, in order to enter a market, a firm must convince a state agency of its necessity, which requires "a formal submission, substantial legal and related expenses, and a delay often of years—all before the firm may commence operations."[8] The "costs and delay are alone enough to discourage many prospective entrants."[9] Further, the "procedural gauntlet," Judge Posner continues, is particularly costly in the CON-law context because success is at best uncertain.[10]

Public choice theory suggests that incumbent businesses are most likely to engage in anticompetitive behavior when the cost of the exclusionary conduct (here, filing a protest) is minimal and the burden it imposes on a potential rival is great—precisely the regulatory framework embodied in CON regulations.[11]

CON laws, Judge Posner has gone so far as to write, "may perpetuate monopoly."[12] They limit "greatly the growth of competition in the regulated industries."[13] In short, CON laws encourage anticompetitive behavior. As DOJ and the FTC have both concluded, CON programs "pose serious anti-competitive risks."

3. CON Laws Increase HealthCare Costs—According to the Antitrust Division of DOJ and the FTC, "Certificate-of-Need laws impede the efficient performance of healthcare markets." By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers. They "undercut consumer choice, stifle innovation, and weaken markets' ability to contain healthcare costs." **According to DOJ and the FTC**, "Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anti-competitive barriers to entry." In fact, **research** suggests that CON laws have the unintended consequence of raising healthcare spending by 3-4% overall and Medicare spending by 7%.

> *"By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers."*

8 Richard A. Posner, *Natural Monopoly and Its Regulation*, 21 STAN. L. REV. 548, 612 (1969).
9 *Id.*
10 *Id.*
11 Sandefur, *supra* at 1035.
12 Posner, *supra* at 612.
13 *Id.*

4. Certificate-of-Need Laws Harm States Ability To Meet Healthcare Crises— Certificate-of-Need laws create expensive and time-consuming regulatory barriers to entry and impede the flexibility needed to respond to a healthcare emergency. Recognizing this, and in an effort to provide their healthcare sector with more flexibility to combat coronavirus, 22 states **suspended** their CON laws in response to COVID-19. These barriers to entry have no grounding in health or safety and serve only to delay and make market entry more costly—such regulations have no place in ordinary circumstances and directly impede the ability of states to respond quickly to healthcare emergencies.

> *"Certificate-of-Need laws create expensive and time-consuming regulatory barriers to entry and impede the flexibility needed to respond to a healthcare emergency."*

What We Can Do

While some federal courts have held Certificate-of-Need laws invalid,[14] others have concluded that plaintiffs should seek relief from the legislature.[15] As the Fourth Circuit put it, the arguments made by plaintiffs challenging Virginia's CON laws "might be more persuasively made before the Virginia General Assembly, not a panel of unelected judges."[16] In order to give states the flexibility they need to deal with healthcare crises and to bring down the cost of entry and ultimately the cost of healthcare services, Americans should encourage individual legislatures and city governments to repeal CON regulations on the healthcare industry.

Conclusion

In *New State Ice. Co v. Liebmann*, the United States Supreme Court noted that a CON law regulating the ice-making business created a state-established monopoly: "The aim is not to encourage competition, but to prevent it; not to regulate the business, but to preclude persons from engaging in it."[17] These sorts of protectionist regulations have no more place in the healthcare industry than they do in the ice-making industry. It is time for courts and legislators to recognize that these outdated regulations based on debunked economic theories need to go.

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14 *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 573 (4th Cir. 2005); *Walgreen Co. v. Rullan*, 405 F.3d 50, 59 (1st Cir. 2005); *Medigen of Kentucky, Inc. v. Public Serv. Comm'n of West Virginia*, 985 F.2d 164, 167 (4th Cir. 1993); *Bruner v. Zawacki*, 997 F. Supp. 2d 691, 700 (E.D. Ky. 2014).

15 *Colon Health Centers of America, LLC v. Hazel*, 813 F.3d 145 (4th Cir. 2016).

16 *Id.*

17 *New State Ice Co. v. Liebmann*, 285 U.S. 262, 279 (1932).