Unnecessary Certificate of Need Laws Limit Health Care

How certificate of need laws work?

Under a CON law regime, states require a certificate of need for a wide variety of expenditures, such as facility construction and modification, new medical procedures offered, and increased inpatient care beds.

CON laws were first passed in the 1960s by states hoping to slow health care price increases by limiting duplication and promoting consolidation of providers. CON programs require health care providers planning certain types of expansion to receive state approval, generally from the state’s health care agency or a designated CON commission. Such approval is required for a wide range of capital expenditures, including the construction of new hospitals, purchase of major medical technology, or provision of new medical procedures. Unlike other licensing laws, CON laws are generally not based on quantifiable criteria such as experience or education.

What effects do CON laws have on the cost of health care?

States with CON programs regulate on average 14 different medical services, devices, and procedures. According to data from the Kaiser Family Foundation, health care costs are 11 percent higher in CON states than in non-CON states. The study also found the greater the number of CON law restrictions, the higher the cost of health care. States requiring certificates of need on 10 or more services averaged per-capita health care costs 8 percent higher than the $6,837 average for states requiring certificates of need for fewer than 10 services.

Do CON laws improve or harm health care outcomes?

A 2016 study by Thomas Stratmann and David Wille of the Mercatus Center at George Mason University analyzed the effect of CON laws on specific metrics for nine quality indicators at 921 hospitals. The study reviewed data from 2011 to 2015 and found health care quality measures were significantly lower in CON states compared to states without CON laws.

The Mercatus results are alarming. Although proponents of CON laws claim they improve hospital quality by allowing existing providers to improve their skills and work in a limited number of hospitals, death rates were found to be frequently higher in CON states. “We find that mortality rates for pneumonia, heart failure, and heart attacks are significantly higher in hospitals in CON states relative to those in non-CON states,” wrote Stratmann and Wille.

One of the biggest discrepancies identified in the study is the difference in the rate of mortality resulting from complications in hospitals. In CON states, the mortality rate was about 5.5 percent higher than the average rate in non-CON states.

The stated goal of CON programs is to manage health care costs, yet research shows they actually increase costs for consumers by hindering competition and forcing providers to use older facilities and equipment. Mercatus found that CON laws reduce the availability of medical equipment and hospital beds. States with CON laws have 99 fewer hospital beds per 100,000 residents and a lower availability of MRI services, CT scanners, and optical and virtual colonoscopies.
Do CON laws help rural hospitals?

A common argument used in support of CON laws is the claim they help protect access to health care in rural communities by shielding hospitals from increased competition. In order to protect patient access to health care in rural communities, several states have moved to enact restrictive regulations on what health care experts call “hospital substitutes,” such as ambulatory surgical centers (ASC).

Some claim CON prevent what supporters call “cherry picking,” or “cream skimming,” a scenario whereby alternatives to hospitals such as ASCs will accept only the more-profitable and well-insured patients, leaving general hospitals with less-profitable and uninsured patients. CON advocates are concerned allowing open access to new markets to ASCs without regulatory barriers would increase cream skimming, harming the financial health of rural hospitals and potentially limiting access to health care services.

Currently, 26 states regulate the entry of hospital alternatives through their CON programs. In a study released in February 2016, Thomas Stratmann and Christopher Koopman of the Mercatus Center at George Mason University found states restricting entry and competition through a CON program had fewer total hospitals and fewer rural hospitals per capita. This is the opposite of the intended result. When controlling for certain demographics and year-specific effects, CON programs result in “30 percent fewer total hospitals per 100,000 state population and 30 percent fewer rural hospitals per 100,000 rural population,” wrote Stratmann and Koopman. “Moreover, we find 14 percent fewer total ASCs per 100,000 state population and 13 percent fewer rural ASCs per 100,000 rural population.”

The Mercatus study seems to suggest CON laws are not a silver bullet for protecting access to medical care in rural health care markets. These results are consistent with previous studies that show CON laws fail to achieve many of their stated goals and have instead reduced the availability of health care services.

How do CON laws effect competition?

In addition to the effect on health care outcomes and prices, CON laws also give undue influence to competitors during vetting processes. When a health care company applies to enter a new market, competitors often use the CON process to block potential competition. As a result, CON laws raise the price of medical care by preventing new medical providers from competing with existing hospitals.

Even worse, CON laws create what is essentially a “competitor’s veto” of new market entrants. A 2011 report from the National Institute for Health Care Reform confirmed the same problem exists in Connecticut, Georgia, Illinois, Michigan, South Carolina, and Washington. According to the report, “In five of the six states studied – all except Michigan – the CON approval process can be highly subjective and tends to be influenced heavily by political relationships rather than policy objectives.”
How do CON laws impact health care innovation?

CON laws are outdated and obtrusive regulations that retard health care innovations. Although most CON law disputes involve the construction or expansion of physical facilities, they also apply to new treatments and services provided by clinics and hospitals. A recent example of a major health care treatment being slowed by CON occurred in 2019 in Michigan, where a controversy emerged over a vote to impose new accreditation requirements for health care providers seeking to offer new immunotherapy cancer treatments.

These promising treatments work within the body’s immune system to attack and kill cancer cells. At the center of the debate is a process known as Chimeric Antigen Receptors Therapy (CAR-T) where t-cells within the immune system are bio-engineered to attack cancer cells. Under Michigan’s CON rules, hospitals seeking to provide CAR-T services would have to go through an additional accreditation process via the Foundation for the Accreditation of Cellular Therapy. This is in addition to the lengthy and costly CON approval process.

Anna Parsons, a policy coordinator with the American Legislative Exchange Council, told Reason.com, “the safe administration of CAR T-cell therapy does not require hospitals to make new capital investments—which is the only time CON laws should apply. Literally any FDA-certified hospital should be capable of offering these treatments, since all the high-tech bioengineering is done at other locations. The only thing that happens at the hospital is a simple blood transfusion.”

These new rules were proposed at the urging of the University of Michigan Health System (UMHS), the state’s largest hospital system. UMHS officials claim the measures are necessary to ensure patient safety. Although CAR-T is still under development for most types of cancers, it has been approved for children suffering from leukemia and for adults with advanced lymphoma.

Conclusion

Like all industries, when the U.S. health care system has improved, it’s been because of competition and innovations born in the free market, not because of government regulation. If health care providers have the means to expand and innovate, they should be encouraged to do so. Unfortunately, far too many states unnecessarily limit the expansion of health care providers and services because of outdated and unnecessary CON laws, which lack transparency and political accountability.

Ideally, all states should repeal burdensome and unnecessary CON laws, which would benefit all health care consumers and providers.
Additional Resources

**Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals**

Thomas Stratmann and Christopher Koopman of the Mercatus Center at George Mason University evaluate the impact of CON regulations related to ambulatory surgical centers (ASC) on the availability of rural health care. Their research shows despite the expressed goal of ensuring that rural populations have improved access to health care, CON states have fewer hospitals and ASCs on average—and fewer in rural areas—than states without CON regulations.

**The Great Healthcare CON**
http://fee.org/the_freeman/detail/the-great-healthcare-con

Jordan Bruneau of the Foundation for Economic Education finds CON laws raise health care prices and reduce availability. He advises, “Rather than pinning our hopes on grand plans to overhaul the system, we should first look at where we can make changes on the margin that would move us in the right direction. Abolishing CON laws – a barrier to entry that drives up price, restricts access, and is maintained by cronyism – would be a great place to start.”

**Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans**
https://www.heartland.org/policy-documents/are-certificate-need-laws-barriers-entry-how-they-affect-access-mri-ct-and-pet-scan

A study published in January 2016 from the Mercatus Center at George Mason University examines how CON regulations affect the availability of imaging services provided by hospitals and other medical providers. The results show CON regulations adversely impact non-hospital providers; hospitals largely remain unaffected. The study also shows residents of CON states are more likely to travel out of state to obtain imaging services than residents of non-CON states.

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