Certificates of Need

Executive Summary

In 1974, the U.S. Congress passed a provision under the Public Health Service Act (PHSA) requiring states to establish State Health Planning and Development Agencies to design a state health plan and administer the Certificate of Need (CON) programs. CONs provide state governments the approval and coordination framework to determine what services are needed in various communities, and when a service is deemed excessive (e.g., too high in cost, or too underutilized). Since the late 1980's, 15 states have repealed or scaled back their certificate of need laws. While Missouri law currently dictates 14 areas of oversight (MO Rev. Stat. XII § 197.300-366) recent legislation has been proposed to scale back or repeal these laws (HB 1616, SB 727, and SB 890 from the 2022 Legislative Session).

Highlights

- Hospitals and long-term care facilities apply (with fee) for Certificates of Need with state regulatory bodies when seeking to add new services (e.g. specialty treatment centers, increased bed capacity at elderly homes).
- The applications for certificates take into account the local community need, and can be costly, adding costs to the consumer's bill.
- The effect of CONs on reducing the overall long-term healthcare costs to the consumer are minimal, and CONs can be moderately detrimental to healthcare quality outcomes depending on the measurement used.
- States with CON laws can see losses in available services/instruments if a neighboring state has deregulated their CON laws and draws demand out-of-state.

Limitations

- Measures of healthcare quality can vary, affecting the relationships studied between certificate of need laws and quality of care.
- While lower immediate costs are realized when certificates of need are repealed, overall higher healthcare spending may negate the positive results of repealing a CON law.
- Studies are mixed regarding the market effect of CONs; some report that CONs stifle the entry of innovative services/facilities, while others indicate that CONs have an anti-trust effect and prevent existing facilities from obtaining exclusive market control.

Research Background

Definition and Purpose of Certificates of Need

Certificates of Need (CONs) are documents required by state laws that allow for the approval of spending for projects at certain health care facilities or expanding of a service by demonstrating

a local need.[1,2] Activities that may necessitate review during a CON application include the opening of a new hospital or care facility, changes in bed capacity, replacement of major medical equipment, renovations or modernizations of a facility, changes in management/ownership, or cost overruns on previously approved projects.[2]

The concept was introduced federally in the 1974 National Health Planning and Resources Development Act, which sought to manage the amount of healthcare resources available in an area and rising healthcare prices.[3] The law thus gave policymakers the ability to mitigate potential overuse of health care services.[3] Applications were then assigned to State Health Planning and Development Agencies when a healthcare provider sought to provide new services or facilities.[3] The agencies determine whether the service was needed in an area and if there was a sufficient number of providers for the service.[3] These laws were often aimed at limiting adjacent/nearby hospitals from investing in and duplicating specialty services in effort to control costs that are passed on to patients, and focus on the quality of care.[4] However, in 1986 the federal CON mandate was repealed, leaving a mix of states who have retained those laws or repealed them (Figure 1).[3]

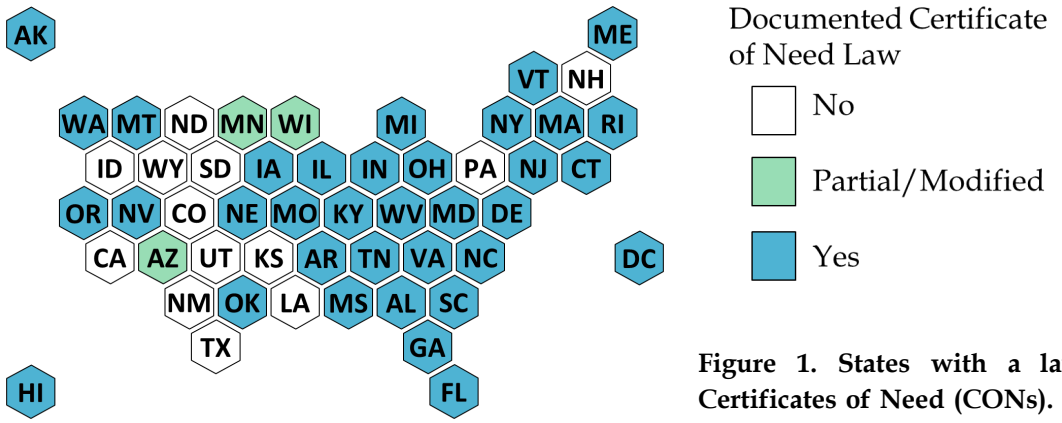

Figure 1. States with a law requiring Certificates of Need (CONs). Map of states (represented as hexagons) with colors related to whether a state has a CON law (blue) or whether the state has laws that are similar to a CON requirement. Map made with PresentationGo.com with data from the National Conference of State Legislatures.[1]

Important factors that are often considered during a CON application may include: 1) demonstrated need in the community; 2) availability of effective or low-cost alternative services; 3) availability of funds for a new proposed project; 4) how the proposed project fits within the public health planning process; 5) Long-term financial feasibility for a new project; 6) prior experience and success in administering the health care service; 7) consideration for critically underserved populations, such as rural, elderly, low-income populations.[3]

Effects of Certificate of Need Laws

CON applications can be costly, and those fees can often be passed on to the consumer in higher prices.[6] Two policy studies have shown that CON programs are associated with a slight reduction in costs to the consumer for brief illnesses, while also showing slight increases in hospital profits, higher total healthcare spending, and increased healthcare prices.[5,6] One of

these studies found no evidence of increased costs for up to seven years after the federal CON mandate was repealed and CON regulations were removed.[5]

Given the deliberative nature of CON applications, the ability for healthcare facilities to rapidly surge physical capacity during an emergency (like the COVID-19 pandemic) may also be constrained. One study found that states that required a CON for increased hospital beds had a higher percentage (7.6% more) of its beds in use during the pandemic given the lower supply of total beds.[7]

Another study has shown a consequential decrease in the quality of care, particularly in cardiac surgery, mortality, and dialysis care, in states that have more rigorous CON laws.[8] This may be attributable to limitations on lower-quality, but plentiful substitutes in terms of long-term care facilities, and lack of access in states where minimum hospital services still do not provide enough coverage.[8] Another study on patients aged 65 years and older found no significant difference in the quality of care between states that require CONs and those that do not.[4] However, an important caveat to these studies is that measures used to assess quality of care can vary significantly (e.g., measures may include readmission and mortality rates, quality and process-of-care indicators, and voluntary patient-experience surveys). For example, one study found that while measures such as readmission from a pulmonary embolism and mortality from heart attack is slightly lower or unchanged in CON states, the mortality rate after a patient is discharged from pneumonia or heart failure treatment is higher.[9] As a result, CON studies may show little-to-no effect on healthcare quality or substantially lower healthcare quality, depending on the measure used.[9]

While CONs have been cited as barriers to entry, competition, and innovative facilities,[10] one policy analysis concluded that CONs may provide a "pro-competitive"anti-trust effect, primarily by preventing established hospital systems from expanding their own capacity for specialized services and consolidating marketplace options.[11] Some states (such as Florida, Georgia, North Carolina, and Virginia) even require that CON applications consider whether the new service fosters competition.[11] Further, CONs may promote cost-efficiencies and dampen the incentive for high-profit, costly services to enter the marketplace.[12]

However, given the mosaic of state-level CON laws, states without CON requirements may have a "draining" effect on resources in more regulated neighboring states (of Missouri's neighboring states, only Kansas has no CON laws). Certain services are unlikely to respond to CON regulation of an individual service by relocating, while others are more flexible and can easily set up new operations by simply moving machinery.[13] One study on the availability of high-cost and easily movable magnetic resonance imaging (MRI) devices in counties in the U.S. that border states without a CON law found that 6.4 fewer MRIs per million people were available in CON-requiring counties that border unregulated states.[13]

State Level Legislation

Currently, 35 states and the District of Columbia require CONs (or similarly modified types of documentation) for any expanded medical facility services, including neighboring Nebraska,

Iowa, Oklahoma, Kentucky, and Arkansas (Figure 1). In Missouri, the law (sections § 197.300 through 197.366) states that any hospital, long-term or residential care facility (LTC), assisted living, or skilled nursing facility is required to file with the Missouri Department of Health and Senior Services' volunteer Health Facilities Review Committee for a CON in a given area.[2] Fourteen CON structures exist in Missouri, regulating specific activities like development or acquisition of a new health care facility, pre-development project costs exceeding $150,000, changing or relocating the licensed bed capacity of a health care facility by more than 10%, and offering a new health service (excluding home health services) that was not offered in the last 12 months.[1] A full listing of regulated activities is provided in Table 1.[9] In fiscal year 2021, Missouri health care facilities sought to approve new services totaling $278,752,835, of which approximately $143,119,831 was approved in November 2021.[14]

Healthcare activities regulated in Missouri		
Acute Hospital Beds	Cardiac Catheterization	Computed Tomography Scanners
Gamma Knives	Lithotripsy	Positron Emission Tomography Scanners
Mobile Hi-Technology	Radiation Therapy	Nursing & Long Term Care Beds
Long Term Acute Care	Rehabilitation	Magnetic Resonance Imaging Scanners
Assisted Living & Residence Care Facilities		

Table 1. Activities requiring a CON application in Missouri.[9]

Several states have either eliminated or scaled back their CON laws. Reasons for scaling back these laws have included 1) a need for increased access of services for vulnerable populations (e.g., those dealing with substance use disorders), 2) lack of need to regulate services that do not get overprescribed, 3) lack of need to regulate already low-cost options, 4) lack of need to regulate low-cost hospital investments, 5) delays to applications and lack of competition, and 6) both state regulatory costs and compliance costs from healthcare providers.[15]

The process for repeal may include a 1) *Full Repeal,* a complete removal of CON laws; 2) a *Partial Repeal,* where CON requirements are eliminated for certain services or technologies; 3) *Phased Repeal,* where CON laws are eliminated in stages or gradually over a given period of time with automatic end dates; and 4) a *Contingent Repeal,* where the repeal of CON laws is dependent on whether neighboring states have also made changes to the law.[15] Additionally, other actions that do not involve a direct repeal of CON regulations may include *Administrative Relief*, where states reduce burdens caused by the CON rules, such as reduced fees and simplified application and reporting requirements; and a *Modification of Criteria*, where CON application requirements are eased based on whether a facility duplicates an existing service nearby or whether an existing service is under-utilized.[15]

Legislation (HB 1616, SB 727, and SB 890) that repeals or modifies the existing certificate of need laws, including by mandating Medicare and insurance reimbursements of expenditures at long

term care facilities without CON approval, has been proposed in the Missouri 2022 legislative session .

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