Examining Certificate-of-Need Laws in the Context of the Rural Health Crisis

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Abstract

To evaluate certificate-of-need (CON) laws in rural areas and their relationship with selected healthcare outcomes and with common measures of potentially avoidable spending, we regress county-level Medicare data and state-level all-patient spending and utilization data to compare healthcare outcomes and common measures of wasteful spending in rural states with and without CON laws. Results show that patients residing in counties restricted by CON laws spend more per Medicare beneficiary and have higher utilization rates in ambulance services, emergency departments, and readmissions, both before and after controlling for social risk factors such as race, education, and poverty status. These findings imply that policies countering CON restrictions may reverse the outcome gap for rural states in access to care, which in turn may reduce wasteful spending and utilization.

JEL codes: I180, I130

Keywords: Medicare, health outcomes, certificate of need, rural health, healthcare

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Thomas Stratmann and Matthew Baker

Rural areas in America are facing a health crisis[1] manifested in several diseases, including the current opioid epidemic. This crisis is rooted not just in patient sociodemographic factors but also in unique economic challenges for providers and uncertain political requirements for payers, all of which reduce access to healthcare and contribute to poor health outcomes in these communities. Since 2010, 128 rural hospitals have closed, and 700 more are at risk of closure.[2] Analysis cited by leading healthcare organizations reports that there are 15 percent fewer primary care physicians per capita in rural areas than in urban areas (that is, 68 per 100,000 people vs. 80 per 100,000 people).[3]

New construction of rural healthcare infrastructure or modification of existing infrastructure is either slow or nonexistent.[4] Reforming or improving the various regulations that affect healthcare infrastructure could provide a cost-effective way to address the structural underpinnings of the rural health crisis. Studies suggest that certificate-of-need (CON) laws are one example of a regulation that restricts higher-quality medical care.[5] CON laws require that facilities intending to increase bed and building capacity prove that the new services are

[1] John K. Iglehart, "The Challenging Quest to Improve Rural Health Care," *New England Journal of Medicine* 378, no. 5 (2018): 473–79.
[2] "170 Rural Hospital Closures: January 2005–Present (128 since 2010)," Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, April 13, 2020, http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.
[3] American Hospital Association, *Rural Report: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-Quality, Affordable Care*, 2019, 7.
[4] Jon M. Bailey, *The Top 10 Rural Issues for Health Care Reform* (Lyons, NE: Center for Rural Affairs, March 2009), 2.
[5] Robert L. Ohsfeldt and Pengxiang Li, "State Entry Regulation and Home Health Agency Quality Ratings," *Journal of Regulatory Economics* 53, no. 1 (2018): 1–19; Thomas Stratmann and David Wille, "Certificate-of-Need Laws and Hospital Quality" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016); Molly S. Myers and Kathleen M. Sheehan, "The Impact of Certificate of Need Laws on Emergency Department Wait Times," *Journal of Private Enterprise* 35, no. 1 (2020): 59–75.

"needed" by navigating a formal approval process to obtain written authorization from the state's health department. The process of gaining such authorization varies drastically from state to state. Since factors restricting access to high-quality care may exacerbate problems with excess spending faced by rural areas, we measure whether CON laws correlate with negative health outcomes in rural areas.

Residents of rural areas in the United States face unique challenges regarding access to healthcare, such as longer travel distances to providers. According to the Pew Research Center, the quarter of rural residents living farthest from a hospital reside an average of 34 minutes from the nearest hospital—over 80 percent more than the equivalent measure for urban Americans (19 minutes). The Pew study finds that 23 percent of rural Americans viewed their access to medical services as a problem, compared to 9 percent of urban Americans.[6] These limitations are exacerbated by restrictions on new medical services, restrictions that have an impact on rural communities that is difficult to fully measure.

In this analysis, we compare rural states with and without CON laws in terms of three characteristics that may independently or jointly contribute to the outcome of higher spending in Medicare and that are symptoms of issues affecting rural health: (1) level of competition, (2) access to healthcare, and (3) disease prevalence. We find that in counties restricted by CON laws healthcare expenses per Medicare beneficiary are higher, as are utilization rates of ambulance services, emergency departments, and readmissions. These findings hold true both before and after controlling for social risk factors such as race, education, and poverty status.

[6] Onyi Lam, Brian Broderick, and Skye Toor, "How Far Americans Live from the Closest Hospital Differs by Community Type," *Fact Tank* (Pew Research Center), December 12, 2018.

Background

CON laws in the United States date back to 1964 in the state of New York. At that time, it was thought that healthcare costs were being driven by wasteful duplication of services. In 1974, Congress passed the National Health Planning and Resources Development Act, which threatened to remove federal funds from states that did not establish CON programs. Twelve years later, in 1986, the act was repealed after empirical criticisms, and in the subsequent years more than a dozen states removed their own CON laws from the books. At the time of this study, CON laws remain in 36 states and Washington, DC, while they have been repealed in 14 states.[7] Almost 40 percent of Americans live in states without CON laws restricting hospitals, ambulatory surgical centers, or other medical providers.[8]

Research regarding the impact of geography on access to care has shown that rurality has limited provider availability. One study demonstrates that CON laws in North Carolina are correlated with limited access to and availability of care in rural areas.[9] A separate study, of rural veterans seeking primary care, finds geographic distance to medical providers to be the "most important barrier."[10]

While policy suggestions intended to address the rural health crisis include federal expenditures for emergency air transport and stimulus payments to existing healthcare facilities, we consider CON repeal because it could provide a cost-effective, market-based alternative that would allow competitive forces to drive innovation within rural states. Decades' worth of

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[7] Matthew D. Mitchell, Elise Amez-Droz, and Anna K. Parsons, "Phasing Out Certificate-of-Need-Laws: A Menu of Options" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, February 2020).
[8] Mitchell, Amez-Droz, and Parsons, "Phasing Out Certificate-of-Need-Laws."
[9] Christopher Koopman and Thomas Stratmann, "Certificate-of-Need Laws and North Carolina: Rural Health Care, Medical Imaging, and Access" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, May 17, 2016).
[10] Colin Buzza et al., "Distance Is Relative: Unpacking a Principal Barrier in Rural Healthcare," *Journal of General Internal Medicine* 26, no. 2 (2011): 648–54.

research has questioned the value of CON laws for public health, but the current rural health crisis may provide the political will to finally modernize US public health policy by removing this barrier to healthcare infrastructure.

CON laws can be quite far-reaching: the National Conference of State Legislatures states that "Kentucky CON laws apply to over 24 different types of health care facilities while neighboring Ohio regulates only long-term care facilities."[11] According to the New York State Department of Health, New York's laws require regulatory approval for a variety of establishments and services,[12] including the following:

- Hospitals
- Nursing homes
- Diagnostic and treatment centers
- Ambulatory surgical centers
- Certified home health agencies
- Long-term healthcare programs
- Hospices, adult care facilities
- Adult day healthcare programs
- Some programs associated with various state offices

The process to apply for a certificate of need can be quite a long one in many places, requiring numerous steps and an extended period of time. For example, in Washington, DC, 13

[11] Jack Pitsor, "States Modernizing Certificate of Need Laws," *National Conference of State Legislatures* 27, no. 41 (December 6, 2019).
[12] "How to Determine If CON Submission Is Required," New York State Department of Health, last modified September 2019, https://www.health.ny.gov/facilities/cons/more_information/.

steps are required to apply for a CON.[13] While many of these steps are arduous, the public hearing section is of particular note. This is the stage at which potential competitors to the proposed new facility or service are given an opportunity to exercise what is often called a "competitor's veto."[14] Incumbents can argue before the regulatory body that the proposed facility should not be allowed to enter the market. Since new competition would decrease any business's market share, it should be unsurprising that incumbent businesses frequently seek to block new entrants.

The large burden involved in opening and expanding a medical facility tends to create what are, in effect, local monopolies in healthcare. The existence of CON laws in a state, therefore, determines whether the supply of medical services is driven by the market forces of supply and demand, or is also influenced by political forces such as lobbying or even by corruption.

A primary justification for CON laws was to reduce the risk of price increases owing to expensive duplication of services. These concerns originated at the time of CON implementation when Medicare services were reimbursed on a cost basis, rather than through the current prospective payment system.[15] Though many critics of CON laws claim that the laws no longer serve their intended purpose,[16] attempts to repeal them have nonetheless been met with an opposition that supports traditional controls on healthcare services.

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[13] "How to Obtain a Certificate of Need," DC Health (DC.gov), accessed July 4, 2020, https://dchealth.dc.gov/service/how-obtain-certificate-need.
[14] Anastasia Boden, "The 'Competitor's Veto' Is Killing Entrepreneurship—but That May End This Year," *The Hill*, April 8, 2019.
[15] Mark J. Botti, "Competition in Healthcare and Certificates of Need" (Testimony before a joint session of the Health and Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia, February 23, 2007).
[16] Maureen K. Ohlhausen, "Certificate of Need Laws: A Prescription for Higher Costs," *Antitrust* 30, no. 1 (2015): 50–54.

Literature Review

Since the first implementation of CON laws in New York, scholars have been studying the laws' effects on a variety of metrics, including the cost of care, the dispersion of technology, health outcomes, and availability of hospital services. Despite the good intentions behind the laws, "the majority of studies fail to establish any definitive link between CON laws and lower unit costs."[17] This is consistent with economic theory since, ceteris paribus, restricting the quantity of a good or service *increases* the price consumers pay, by making the good or service more scarce relative to its demand.

Various studies have found differing results from CON laws that have been enacted, and multiple studies have found that CON laws have had no effect on costs, or even that they may increase them. A 1994 paper by John A. Nyman studies the effects of CON laws on nursing home prices, finding that the price of private nursing home care was increased because of these laws, pushing people onto Medicaid sooner, and thus likely increasing overall costs as well.[18] Additionally, 2016 research by Mercatus scholar James Bailey shows no margins on which CON laws have decreased costs, and argues that they may have increased costs for doctors and hospitals, especially in Medicare.[19] As early as 1976, David Salkever and Thomas Bice found that spending on beds (which are covered by CON laws) was simply shifted to other aspects of healthcare such as new services and equipment, and that overall costs did not decrease.[20]

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[17] Ohlhausen, "Certificate of Need Laws."
[18] John A. Nyman, "The Effects of Market Concentration and Excess Demand on the Price on Nursing Home Care," *Journal of Industrial Economics* 42, no. 2 (1994): 193–204.
[19] James Bailey, "Can Health Spending Be Reined In through Supply Restraints? An Evaluation of Certificate-of-Need Laws," *Journal of Public Health* 27 (2019): 755–60.
[20] David S. Salkever and Thomas W. Bice, "The Impact of Certificate-of-Need Controls on Hospital Investment," *Milbank Memorial Fund Quarterly: Health and Society* 54, no. 2 (1976): 185–214.

Studies analyzing the effect of CON law severity on medical costs have shown mixed results. For example, one study found that although there was no increase in costs associated with all CON laws, some of the more stringent CON laws may have had the effect of raising healthcare costs.[21]

Studies that have found modest evidence for a decrease in costs in CON states typically come with caveats. A study published in 1998 showed a 5 percent reduction in acute care spending, along with no reduction in per capita healthcare spending and no change in quality.[22] This study did identify, however, an increased cost per day per admission to the hospital, as well as increased hospital profits.

Costs are one vital factor in medicine—but so are outcomes. A study on mortality by Bailey found no reduction in all-cause mortality with the implementation of CON laws. Instead, the study reported an increase, though this increase was not statistically significant.[23] Researchers Vivian Ho, Meei-Hsiang Ku-Goto, and James Jollis found similar results in their 2009 research on cardiac care. The authors did not find evidence that CON laws increased the quality of care. They did, however, note that after CON laws were dropped, mortality for coronary artery bypass surgery dropped for four years, but not permanently.[24]

In a study on quality of care, one of us (Thomas Stratmann, writing with David Wille) found that mortality rates are higher at hospitals in states with CON laws than in states without.[25]

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[21] Patrick A. Rivers, Myron D. Fottler, and Jemima A. Frimpong, "The Effects of Certificate of Need Regulation on Hospital Costs," *Journal of Healthcare Finance and Economics* 6, no. 4 (2006): 300–324.
[22] Christopher J. Conover and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," *Journal of Health Politics, Policy and Law* 23, no. 3 (1998): 455–81.
[23] James Bailey, "The Effect of Certificate of Need Laws on All-Cause Mortality," *Health Services Research* 53, no. 1 (2016): 49–62.
[24] Vivian Ho, Meei-Hsiang Ku-Goto, and James G. Jollis, "Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON," *Health Services Research* 44, no. 2, part 1 (2009): 483–500.
[25] Stratmann and Wille, "Certificate-of-Need Laws and Hospital Quality."

Specifically, we found a 2.5 to 5 percent higher-than-average mortality rate for discharged patients with pneumonia, heart failure, and heart attack.

A1995 study of the adoption of hemodialysis technologies found that adoption rates are slowed by CON laws and that these slower adoption rates prevent improvements in quality care.[26] Contrary to this finding, a study on radiotherapy technologies by Bruce Jacobs and his coauthors showed no effect of CON laws on the rate of technological adoption.[27] However, this study did note another matter of interest: CON laws may have sheltered institutions using particular radiotherapy technologies from competition, "thereby providing unwarranted economic advantages to those institutions approved to provide services."[28]

The effect of CON laws on medical providers' market power has been explored elsewhere also. In 1993, Ford and Kaserman found that CON laws prevented new entry into the dialysis industry and prevented the expansion of incumbents to the point that current providers have increased market power and increased profits.[29] Additionally, the authors note that CON laws slow the expansion of dialysis facilities' capacity and the opening of new facilities, which leads to a decreased quality of care (as is typical in monopolized industries) and increased mortality.

Increased market power was also noted in the Sloan and Conover paper (discussed earlier). It should not come as a surprise that hospitals in states with CON laws enjoy concentrated market power and increased profits. Limiting the competitors' ability to enter a market moves incumbents closer to a monopoly position, allowing individual hospitals to

[26] Steven B. Caudill, Jon M. Ford, and David L. Kaserman, "Certificate-of-Need Regulation and the Diffusion of Innovations: A Random Coefficient Model," *Journal of Applied Econometrics* 10, no. 1 (1995): 73–78.
[27] Bruce Jacobs et al., "Certificate of Need Regulations and the Diffusion of Intensity-Modulated Radiotherapy," *Urology* 80, no. 5 (2012): 1015–20.
[28] Jacobs et al., "Certificate of Need Regulations."
[29] Jon M. Ford and David L. Kaserman, "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry," *Southern Economic Journal* 59, no. 4 (1993): 783–91.

exercise greater control over the prices they offer and thus their profit margin, especially in an industry with demand as inelastic as it is in the healthcare industry.

Research from Matthew Mitchell at the Mercatus Center at George Mason University has uncovered negative results of CON laws on multiple margins of healthcare provision, such as the number of many provider types (hospitals, ambulatory surgical centers, rural hospitals, ambulatory surgical centers, hospice care facilities, and dialysis clinics) as well as hospital beds per capita, the quantity of imaging services, the distance to medical care, and racial disparities in medical care.[30]

A 1991 study found that CON regulations increase inefficiency.[31] Eakin's study also notes greater inefficiency in hospitals with larger market shares. He concludes that "competition may increase efficiency in the production of hospital services, while regulations that restrict entry may result in more inefficiency."[32]

Lastly, there is evidence that CON laws restrict healthcare access in rural areas by restricting the number of hospitals per capita. In a 2016 study, one of us (Stratmann, with Christopher Koopman) shows that, on a per capita basis, states with CON laws have 30 percent fewer hospitals, 30 percent fewer rural hospitals, 14 percent fewer ambulatory surgical centers, and 13 percent fewer rural ambulatory surgical centers.[33]

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[30] Matthew D. Mitchell, "First, Do No Harm: Three Ways That Policymakers Can Make It Easier for Healthcare Professionals to Do Their Jobs" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, March 24, 2020).
[31] B. Kelly Eakin, "Allocative Inefficiency in the Production of Hospital Services," *Southern Economic Journal* 58, no. 1 (1991): 240–48.
[32] Eakin, "Allocative Inefficiency."
[33] Thomas Stratmann and Christopher Koopman, "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, February 2016).

Methods

Recent major healthcare legislation identified 20 rural states on the basis of current population densities collected from the 2010 census.[34] Because we are studying population-based outcomes (and thus service-specific CON measures are less relevant), and to avoid arbitrary delineations, we use a binary CON indicator for whether a CON law for any facility or service is present in the state. Twelve of the states identified as rural had CON laws as of December 31, 2015: Alaska, Arizona, Arkansas, Iowa, Maine, Mississippi, Montana, Nebraska, Nevada, Oklahoma, Oregon, and Vermont. The other eight had repealed them before 1995: Colorado, Idaho, Kansas, New Mexico, North Dakota, South Dakota, Utah, and Wyoming.

Although this analysis examines a cross-section of geographic characteristics rather than trends over time, the timeframe of the data was chosen to allow ample time for the relationship between CON laws and outcomes to take effect, since all non-CON states had maintained their status for no less than 20 years by 2015. (Arizona, which has an approval program for ambulatory services and ambulances, is grouped with other CON states—as it is classified in other publications[35]—because the program is similar to CON and targets services relevant to this study.[36]) Comparisons of the two groups of states on several relevant public health measures demonstrate the varying impact of CON laws and programs and point to possible policy solutions for the Centers for Medicare and Medicaid Services (CMS), state governments, and other health policy decision makers.

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[34] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (December 13, 2016).
[35] Thomas Stratmann et al., "Certificate-of-Need Laws: Arizona," part of the web project "Certificate-of-Need Laws: How CON Laws Affect Spending, Access, and Quality across the States," Mercatus Center at George Mason University, August 29, 2017, https://www.mercatus.org/publications/certificate-need-laws-arizona.
[36] "Ground Ambulance Program—Certificate of Necessity (CON) Holders," Arizona Department of Health Services, Emergency Medical Services & Trauma System, accessed July 4, 2020, https://www.azdhs.gov /preparedness/emergency-medical-services-trauma-system/index.php#ambulance-ground-program-con.

Using metrics selected on the basis of public health priorities, we compare overall and specific costs of healthcare services, incidences and charges for high-value services, and access to healthcare in CON states and non-CON states, using the data described below. The data collected for this study are state- and county-level data for the most recent year available from a variety of sources. Medicare utilization information is obtained from CMS.[37] All-payer 2015 utilization data for stroke and heart attack (also known as acute myocardial infarction) are obtained from the Agency for Healthcare Research and Quality.[38] (The all-payer data are not available for some states, including five rural states: Alaska, Idaho, Mississippi, Montana, and South Dakota.) Demographic information, including race and poverty status, are derived from the US Census Bureau's American Community Survey and the Small Area Income and Poverty Estimates program.[39] While rural states are defined as detailed earlier, rural counties are defined as counties classified by the United States Department of Agriculture rural urban continuum codes as nonmetropolitan (codes 4 through 9).

We use ordinary least squares regressions with White-Huber robust standard errors at the state and county level to estimate the relationships among spending, outcomes, and CON regulations in rural states. The regression takes the following form:

$$Y_{ij} = \beta_0 + \beta_1(CON\ law)_i + \boldsymbol{\gamma X}_{ij} + \varepsilon_{ij},$$

where *Y* represents one of four outcomes or spending measures, one for each model, listed below for county *i* in state *j*. The vector ***X*** includes the county's average age, the percentage of the population that is not non-Hispanic white, the percentage of the population below the poverty

[37] Centers for Medicare and Medicaid Services, "Geographic Variation Public Use File" (dataset), 2015, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF.
[38] Agency for Healthcare Research and Quality, "HCUPnet: Healthcare Cost and Utilization Project" (database), accessed July 18, 2018, https://hcupnet.ahrq.gov/.
[39] US Census Bureau, Small Area Income and Poverty Estimates (database), 2015.

line, and the percentage of adults with a bachelor's degree. For each outcome or spending measure, we specify one version of the model with control variables in $\boldsymbol{X}$ and one without, both for all counties in the rural states and for only rural counties in the rural states. The four outcome or spending measures are defined as follows: (1) total standardized Medicare spending per capita, (2) readmission rate, (3) emergency department (ED) visits per 1,000 beneficiaries, and (4) standardized ambulance costs per beneficiary. Because each measure is associated with overutilization or waste, which we hypothesize is a consequence of limited access to care, we predict positive coefficients on β_1 across models and specifications.

Medicare spending and ambulance costs are standardized to adjust for geographic differences in cost of living. Regressions use all observations for which we have complete data. At the county level, we have complete data for 1,014 out of a total of 1,018 counties in rural states. At the state level, all states have complete data except that data from the Agency for Healthcare Research and Quality are not available for some states, as noted earlier. In the county-level regressions, the CON indicator variable and the rural indicator variable are state-level variables, while control variables are measured at the same level as the outcomes in the corresponding regression at the county and state levels. For the county-level regressions, standard errors are clustered at the state level.

Results

Eight of the ten highest-spending rural states by Medicare spending per beneficiary are states with CON laws (see table 1). Ambulance spending, emergency department utilization, and readmission rates tend to be higher in CON states with high Medicare spending.

Table 1. Ranking of Rural States by Standardized Medicare Costs and Utilization, 2015

		State rank (darkest shading = highest utilization and spending)			
		Primary measure		Secondary measures	
Rural state	CON	Standardized Medicare spending per beneficiary	Ambulance standardized cost per Medicare beneficiary	emergency department visits per 1,000 Medicare beneficiaries	Medicare readmission rate
Mississippi	yes	$10,660	$128	854	18.5%
Oklahoma	yes	$10,131	$136	767	16.7%
Kansas	no	$9,385	$108	659	16.1%
Nevada	yes	$9,292	$124	622	18.5%
Arkansas	yes	$9,133	$134	698	17.7%
Nebraska	yes	$8,964	$93	548	15.6%
Arizona	yes	$8,622	$112	572	16.1%
Utah	no	$8,576	$68	561	12.7%
Maine	yes	$8,230	$148	809	16.7%
Iowa	yes	$8,211	$84	654	15.7%
North Dakota	no	$8,194	$88	595	14.8%
Colorado	no	$8,101	$89	623	14.6%
South Dakota	no	$8,088	$96	508	14.4%
Idaho	no	$7,965	$91	621	13.0%
Wyoming	no	$7,584	$98	599	14.5%
New Mexico	no	$7,536	$151	616	15.8%
Vermont	yes	$7,411	$127	676	16.4%
Montana	yes	$7,279	$84	560	14.1%
Oregon	yes	$7,242	$118	615	15.3%
Alaska	yes	$6,791	$189	577	14.3%

Note: CON = certificate of need. Readmissions are measured within 30 days of an acute hospital stay during 2015. Darker shading represents higher levels of utilization and spending—the hospital with the highest rate is shaded darkest, and the hospital with the lowest rate is shaded white. The list is sorted according to overall spending and flagged by CON status.
Source: Centers for Medicare and Medicaid Services, "Geographic Variation Public Use File" (dataset), 2015, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF.

Table 2 confirms that rural states, on average, exhibit a range of higher spending and utilization figures in CON states compared to non-CON states, including Medicare spending per beneficiary (3.9%), readmission (12.4%), ambulance utilization (40.6%), emergency department utilization (24.8%), and utilization for treatment of stroke (27.3%) and acute myocardial

infarction (30.2%). These data also show that social risk factors differ between rural CON and rural non-CON states, validating the need for an adjusted comparison across states that properly accounts for risk factors in our regression model.

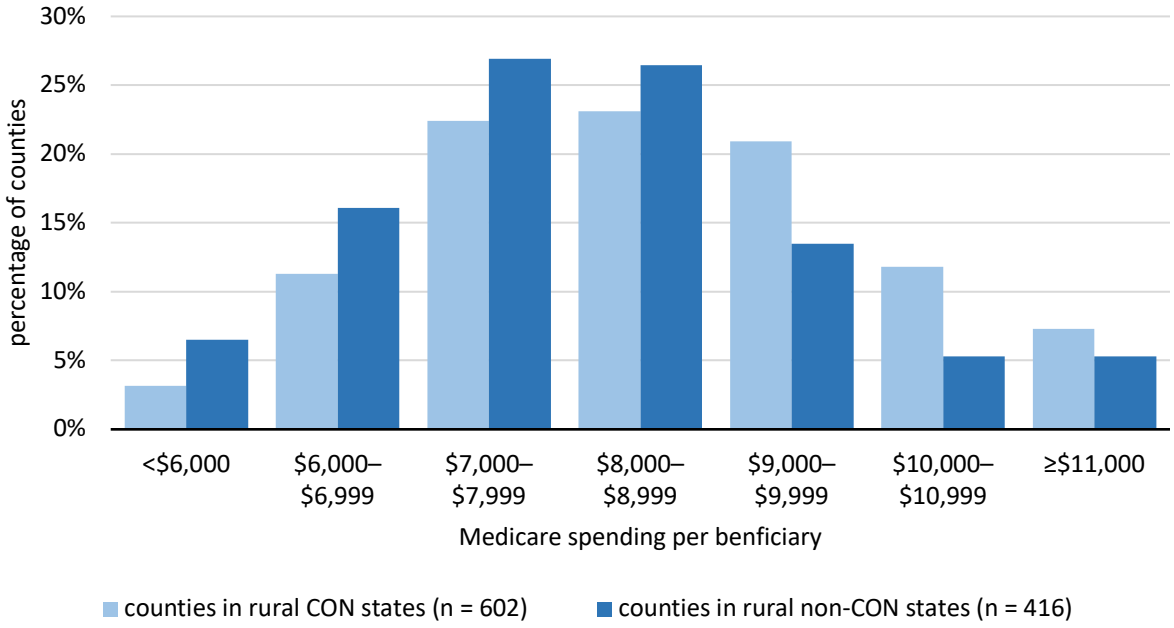
Table 2. Baseline Characteristics in Rural States by Certificate-of-Need (CON) Status, 2015

Rural state averages	12 CON states	8 non-CON states	Difference
Medicare outcome measures			
Medicare spending per beneficiary	$8,497	$8,178	3.9%
Hospital readmission rate	16.3%	14.5%	12.4%
Ambulance events per beneficiary	262	187	40.6%
Ambulance cost per beneficiary	$123	$99	24.8%
Emergency department visits per 100 beneficiaries	663	598	24.8%
Medicare risk variables			
Average age (Medicare beneficiaries)	71.2	71.6	−0.6%
Percentage any race besides non-Hispanic white	17.8%	11.5%	55.1%
Poverty percentage	14.8%	13.1%	12.5%
Percentage with a bachelor's degree	27.1%	29.1%	−6.8%
Other outcome measures			
Strokes per 1,000 population	1.7	1.4	27.3%
AMI cases per 1,000 population	2.0	1.6	30.2%
Other measure			
Hospitals per 100,000 population	1.48	1.71	−13.4%

Sources: Medicare outcome measures and risk variables are from the Centers for Medicare and Medicaid Services, "Geographic Variation Public Use File" (dataset), 2016, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF. Other outcome measures include all-payer patients and are derived from the Agency for Healthcare Research and Quality, "HCUPnet: Healthcare Cost and Utilization Project" (database), accessed July 18, 2018, https://hcupnet.ahrq.gov/#setup. The tool excludes five states: Alaska, Idaho, Mississippi, Montana, and South Dakota. Hospital counts are from the Centers for Medicare and Medicaid Services, "Provider of Services Current File" (dataset), 2016, accessed July 18, 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/POS2016.

Figure 1 demonstrates that differences in spending in CON and non-CON states persist across all spending levels. Not only do CON states have fewer low-spending counties, they also have more high-spending hospitals beginning at $9,000 per beneficiary, and a spending distribution that is flatter overall. This comparison shows that the breadth of the relationship between spending and CON is not limited to certain spending ranges, but rather exists throughout spending levels in a state.

Figure 1. Distribution of Medicare Spending per County, 2015



Note: CON = certificate of need.
Source: Centers for Medicare and Medicaid Services, "Geographic Variation Public Use File" (dataset), 2015, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF.

The results of our regression quantify the relationship between CON and healthcare spending and utilization both before and after controlling for relevant demographic characteristics (see table 3). Although the CON difference is reduced when adjusting for variables of social risk, the estimates for CON laws remain positive for all four outcomes. In the version of the model with full controls and all counties in rural states, CON is associated with $295 higher spending, 1.2 percentage points higher readmission, 35.1 more emergency department visits per 1,000 beneficiaries, and $2.54 higher ambulance spending per beneficiary. Comparing the inclusion of all counties in rural states to only rural counties in rural states reveals that most counties in rural states are themselves rural, and the magnitude of the CON relationship is similar in both definitions of rurality.

Table 3. Regression Results Comparing Spending among Rural States before and after Controlling for Patient Characteristics, 2015

Size of CON difference in county-level regression (std. errors)	Model number	All counties in rural states		Rural counties in rural states	
		Without control variables	Including control variables for age, race, education, and poverty	Without control variables	Including control variables for age, race, education, and poverty
Number of observations		1,018	1,014	807	803
Dependent variable					
Total standardized Medicare spending per capita ($)	(1)	494 (99)	295 (96)	488 (117)	254 (112)
Readmission rate (%)	(2)	1.7 (0.2)	1.2 (0.2)	1.7 (0.2)	1.1 (0.2)
Emergency department visits per 1,000 beneficiaries	(3)	76.7 (9.6)	35.1 (8.9)	74.4 (11.3)	23.7 (10.5)
Standardized ambulance costs per beneficiary ($)	(4)	14.4 (16.5)	2.5 (6.1)	11.5 (8.0)	1.9 (7.6)

Note: CON = certificate of need. Each value is the result of a separate regression. Values in parenthesis are standard errors. Readmissions are measured within 30 days of an acute hospital stay during 2015. Model 2 excludes observations without complete control variable information. Rural counties are defined by the United States Department of Agriculture's Rural-Urban Continuum Codes classification as nonmetropolitan.
Source: Centers for Medicare and Medicaid Services, "Geographic Variation Public Use File" (dataset), 2015, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF.

Discussion

We find that rural states with CON laws spend more per Medicare beneficiary after accounting for county-level factors and social risk factors. The excess spending is associated with measures of utilization, implying that there is a mechanism by which CON laws may increase spending and access for Medicare beneficiaries.

There are some limitations with the approach we took to our analysis. First, using a cross-sectional approach when comparing rural states by CON status limits the comparison to one year's difference. However, CON laws in different states were enacted and repealed at different times, meaning that some states have had more time to adapt to the new laws than others.

Second, CON status is treated as a binary designation that merely indicates whether a state has any CON law or similar program, which may not accurately reflect the various types and numbers of CON laws in each state. These varying regulations may have different effects on competition and ultimately on Medicare spending. Previous studies explored state CON status classification further by considering the number of CON laws per state or by weighting CON laws by relevance to an outcome measure of interest.[40] Third, Medicare spending aggregated at the state level may be biased because CON status for a state may impact rural and urban counties differently compared to non-CON states.

The size of the relationship between outcomes and CON laws in rural states is large, and was robust to the inclusion of sociodemographic controls and the definition of rurality. The CON difference in spending displayed in table 1 shows that the difference occurs in many states that exhibit high spending, and is not heavily driven by the presence of outliers. States such as Mississippi and Oklahoma are the most appropriate for CON reform among rural states, on the basis of their high levels of utilization and spending measures, as well as their poor performance on several health metrics (see table 1). Since repeal of these laws at the state level is contentious and states have done little to reform CON laws in recent years, CMS and other health agencies may address the problems of CON through other means.

Special funding and regulatory waivers have been made available in previous years for rural states. Model demonstrations through the Center for Medicare and Medicaid Innovation, grant programs such as the Rural Community Hospital Demonstration, and rural health emergency funding may alleviate the lack of competition in our identified states. The May 2018

[40] Thomas Stratmann and Jacob W. Russ, "Do Certificate-of-Need Laws Increase Indigent Care?" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, July 2014); Bailey, "Effect of Certificate of Need Laws on All-Cause Mortality."

release of the CMS Rural Health Strategy seeks to address the unique economics of providing healthcare in rural America by reducing regulations that limit access to care.[41] CMS could coordinate its priorities for improvement of rural healthcare access with Congress or individual states to enable long-term investments in health infrastructure. If spending differences are causally linked to CON, then CMS could introduce payment reductions to providers in states with CON laws to correct for the existence of CON barriers to innovation.

Current political initiatives supporting competition in healthcare provide a window of opportunity for legislative action to improve rural health. The current presidential administration's priorities of reducing regulation, addressing the health crisis in rural America, and simplifying the market for healthcare services in an expanding economy require that policymakers consider the impacts of certificate-of-need reform.

Policy Recommendations

Given the negative correlation between CON laws and outcomes, fully repealing CON legislation may help to bridge the gap, represented by 13 percent fewer hospitals per capita, that can be observed between states with and without CON laws. It may also help to lower the rates of per capita medical spending observed in rural states with CON laws, closing the gap between these states and those without CON laws.

However, in many jurisdictions, wholesale repeal may be politically unfeasible given the incentives of incumbents to keep their market power. Matthew Mitchell, Elise Amez-Droz, and Anna Parsons at the Mercatus Center have laid out a series of steps that can be taken, short of

[41] Centers for Medicare and Medicaid Services, *CMS Rural Health Strategy*, 2018, https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.

full repeal.[42] These steps include partial repeal of the most egregious CON laws, phased repeal, providing administrative relief to those applying for approval in states that retain CON laws, and other actions. Partial repeal could address CON laws that harm vulnerable populations. It could also allow policymakers to target specific procedures that are not likely to be overprescribed. Finally, partial repeal could remove restrictions on low-cost care or small investments. Phased repeals may take a variety of forms as well, including sunset clauses, temporary CON repeal, or increasing the rate of approvals. Administrative relief could reduce the cost of CON requirements for applicants merely by reducing application fees and simplifying reporting criteria. States could also limit the criteria required by the CON application, removing requirements to show nonduplication or utilization and removing geographic requirements.

Mitchell, Amez-Droz, and Parsons also note several other methods that can be used to lessen the negative impacts of CON laws. For instance, a state could pass a repeal measure that is contingent on political factors such as neighboring states also repealing their own CON laws. States could also mandate increased transparency about data such as approval rates, which applications are opposed by incumbent providers, the financial ties of CON board members (including incumbent providers' donations), compliance costs, and who on the CON board already works in the industry (and is thus a vested interest).

Reducing the regulatory burden on healthcare providers attempting to care for underserved rural communities can encourage growth and innovation that targets these populations, potentially increasing access to healthcare and lowering per capita costs.

[42] Mitchell, Amez-Droz, and Parsons, "Phasing Out Certificate-of-Need-Laws."