

Revisiting States' Experience With Certificate of Need

Vivian Ho, PhD

Many states enforce certificate of need regulations that require hospitals to obtain approval from a designated state agency before opening new facilities, adding capacity, or offering particular complex, costly services, such as heart transplants. Yet at least 9 states took steps in 2019 to modify their certificate of need rules, often because those laws are viewed as ineffective in controlling overutilization or improving quality.^{1,2} As Yuce and colleagues³ observed in this issue of *JAMA*, most of the literature examining the association between certificate of need and measures of utilization and patient outcomes is more than a decade old, and advances in quality measurement and improvement warrant the updated analysis that these authors undertook.

Yuce et al analyzed claims for 1 545 952 Medicare beneficiaries who received 1 of 10 types of surgeries from 2016 through 2018 to compare the experience of patients treated in states with vs without hospital certificate of need regulations, including 468 236 (30.3%) in 15 states vs 1 077 716 (69.7%) in 35 states and the District of Columbia. In this comparison, they found no significant differences between states without vs with the regulation in adjusted overall median hospital procedural volume (241 vs 272 procedures per hospital for 3 years; absolute difference, 31; 95% CI, -27.64 to 89.64, $P = .30$); median hospital market share (median, 28% vs 52%, absolute difference, 24%; 95% CI, -5% to 55%; $P = .11$); procedure rates per 10 000 Medicare eligible population per capita (median, 239.23 vs 205.41 operations per Medicare-eligible population for 3 years, absolute difference, 33.82; 95% CI, -84.08 to 16.43; $P = .19$); or the number of low-volume hospitals (defined as at or below the fifth percentile of procedure-specific volume). With respect to patient outcomes, there were no significant differences in the adjusted odds of 30-day mortality (1.17% vs 1.33%, odds ratio [OR], 1.04; 95% CI, 0.93 to 1.16; $P = .52$), surgical site infection (1.24% vs 1.25%; OR, 0.93; 95% CI, 0.83 to 1.04; $P = .21$), or readmission (9.69% vs 8.40%; OR, 0.80; 95% CI, 0.57 to 1.12; $P = .19$).

The study by Yuce et al has several strengths, including the analysis of recent data, examination of a wide range of common low- and high-risk procedures, and the use of 3 different measures of patient outcomes. However, the study also has limitations to consider. The analysis was cross-sectional and compared states with and without a certificate of need in 2016 through 2018 rather than examining the experience of states that had previously repealed the legislation. If states that chose to maintain the regulation differ systematically from those that discontinued it in terms of factors that may influence quality such as health care system organi-

zation, then the estimates from this study may not be a valid predictor of outcomes for states that choose to repeal the measure in the future. The map of states with and without the regulations Yuce and colleagues presented in the article reveals that certificate of need is much more prevalent among eastern states than western states. Another map from the American Hospital Association shows that, except for the western coastal states, the density of community hospitals in the eastern part of the country is much greater than in the west.⁴ If hospital coverage of eastern coast states is already more comprehensive, then potential entrants to health care markets may not consider building new hospitals even if certificate of need regulation is discontinued.

In addition, the study only included patients who had Medicare fee-for-service coverage. Therefore, surgical patients with Medicare Advantage insurance were excluded from the hospital volume counts. Average state Medicare Advantage enrollment was 34% in the US in 2018, but there was wide variation by state. In 7 states, more than 40% of Medicare beneficiaries were enrolled in Medicare Advantage, whereas in 16 states, less than 20% were enrolled.⁵ Measurement error with volume, market share, or the number of low-volume hospitals as the dependent variable could lead to larger error variance when estimating the association between these variables and certificate of need, which would reduce the chance of finding a significant association between these 2 factors.

In a related previous study, Polsky et al⁶ examined Medicare claims data from 4 448 479 hospital discharges resulting in 522 232 home health visits in 2006 to examine the association of the regulation of home health agencies with home health use and rehospitalizations. To address concerns regarding selection effects and certificate of need status, their regressions included hospital referral region-fixed effects (0/1 indicators for each hospital referral region). By doing so, the coefficient for the certificate of need variable measured the association of certificate of need within hospital referral regions overlapping state borders where one state had the regulation and another did not. Within-regional comparisons of the associations between certificate of need and health-related outcomes or utilization are less subject to concerns regarding confounding from unobservable factors. Polsky et al found that adjusted discharge rates to home health were 1.6 percentage points lower in states with than states without certificate of need home health regulations. However, hospital readmission rates (a measure of quality) were similar.

Yuce et al conducted a sensitivity analysis using the hospital referral region as the unit of analysis with the median

procedure rate as the dependent variable (see eTable 11E in the Supplement of the article). However, the authors split hospital referral regions that overlap state borders into 2 different state-specific observations. To measure within-hospital referral region associations of procedure volume with certificate of need regulation, the hospital would need to be used as the unit of observation to enable comparisons among hospitals within the same hospital referral region that were vs not subject to state certificate of need regulations.

Yuce et al³ acknowledge that there is variation in the scope and implementation of the regulation between states that is unaccounted for in their analysis. Certificate of need programs often regulate many facilities and services besides hospitals including long-term care, outpatient surgery centers, purchases of major medical equipment, and transplant services. Of the 35 states in the analysis by Yuce et al that maintain the law, only 28 explicitly regulate general hospitals. Of these states, only 27 regulate changes in bed capacity.⁷ Arizona, Minnesota, and Wisconsin do not officially operate a certificate of need program, but they maintain several approval processes that function similarly to certificate of need.² A comparison of states that explicitly regulate hospitals with this legislation with states without the legislation or with states that have certificate of need-like regulations for hospitals may have yielded different results.

Despite some methodological concerns, the findings by Yuce et al that certificate of need was not associated with better patient outcomes are generally consistent with previous studies. A report from 2009 found that removal of cardiac certificate of need regulations by 7 states between 1989 and 2002 was not associated with worse outcomes for patients who had undergone coronary artery bypass graft surgery or percutaneous coronary intervention.⁸ Certificate of need regulations for home health agencies were not associated with fewer rehospitalizations for Medicare patients.⁶ In addition, as the authors note, certificate of need laws have not been associated with significant differences in all-cause mortality.⁹

Yuce et al did not explicitly test whether certificate of need was associated with fewer hospitals per capita or with lower spending, which was one of the original motivations for the certificate of need regulation. Past research has found that more hospitals performed coronary bypass graft surgery and percutaneous coronary intervention in states in which certificate of need regulations involving cardiac procedures and services were removed.⁸ States without certificate of need for home health agencies have roughly twice as many of these facilities per Medicare beneficiary than states that do not.⁶ However, previous studies from 2013 and 2014 found that certificate of need has not been associated with lower Medicare

spending per patient for cardiac care or overall Medicare spending for home health agencies.^{6,10}

In addition, Yuce et al found a significantly higher median procedure volume for states with certificate of need for 5 of the 10 specific procedures that they examined (coronary artery bypass graft surgery, colectomy, lower extremity bypass, lung resection, and esophagectomy). This finding is not surprising, given that the regulations explicitly specify minimum procedure volumes for only 1 of these procedures, coronary artery bypass graft surgery. Certificate of need may be too blunt a tool for attaining volumes that are sufficiently high to be clinically beneficial for a limited set of complex operations. The authors report median volumes in states with certificate of need of only 14, 6, and 3, respectively, for these procedures (Table 2 in the article). Moreover, restricting the number of hospitals in a market to attain minimum volume standards for a limited number of operations ignores the potential advantage of having more hospitals and beds to treat other conditions.

More recently, certificate of need has been effective in slowing the proliferation of freestanding emergency departments, which have been associated with higher emergency spending per capita,¹¹ and higher prices for conditions and procedures comparable with those delivered at urgent care centers.¹² Twenty-four states require a certificate of need before a freestanding emergency department can be opened. Of the 32 states with freestanding emergency departments, those with certificate of need requirements have significantly fewer of these facilities per capita.¹³ However, states could instead develop licensing requirements without certificate of need to regulate entry of freestanding emergency departments.

The study by Yuce et al in this issue of *JAMA* provides an important updated analysis that confirms previous studies that have found little or no benefit of certificate of need regulations for improving patient outcomes through higher hospital procedure volume or controlling hospital utilization. Based on these findings, states should consider repealing these regulations. Not only have the rules been ineffective for improving patient welfare, a recent federal report documents the negative influence of certificate of need on hospital market competition.¹⁴ Instead, states may improve patient welfare more by addressing hospital market consolidation. Hospital market concentration has been associated with higher prices in multiple studies,¹⁵ and hospital mergers have been shown to be detrimental to quality of care.¹⁶ Certificate of need only regulates individual facilities; the regulations do not address the increasing size and power of hospital systems. As the health care delivery landscape evolves, policy makers must adapt quickly and decisively to preserve quality of care and affordability for patients.

ARTICLE INFORMATION

Author Affiliations: Department of Economics, Rice University, Houston, Texas; Department of Medicine, Baylor College of Medicine, Houston, Texas.

Corresponding Author: Vivian Ho, PhD, Department of Economics, Rice University, 6100 Main St, MS 22, Houston, TX 77005 (vho@rice.edu).

Conflict of Interest Disclosures: Dr Ho reported serving as an expert consultant in 2020 for

Arnall Golden Gregory LLP, which is representing a nonprofit hospital in Georgia that is contesting a certificate of need application by an affiliate to open a freestanding emergency department in the same market.

REFERENCES

1. Pitsor J. States modernizing certificate of need laws. National Conference of State Legislatures LegisBrief. Published December 2019. Accessed October 14, 2020. <https://www.ncsl.org/research/health/states-modernizing-certificate-of-need-laws.aspx>
2. CON-certificate of need state laws. National Conference of State Legislatures. Posted December 1, 2019. Accessed October 13, 2020. https://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#State_Legislative_Actions
3. Yuce TK, Chung JW, Barnard C, Bilimoria KY. Association of state certificate of need regulation and procedural volume, market share, and outcomes among Medicare beneficiaries. *JAMA*. Published November 24, 2020. doi:10.1001/jama.2020.21115
4. Fast facts on US hospitals 2020. American Hospital Association. Updated March 2020. Accessed October 13, 2020. <https://www.aha.org/statistics/fast-facts-us-hospitals>
5. Medicare advantage enrollees as a percent of total Medicare population. The Henry J. Kaiser Family Foundation. Published 2018. Accessed October 13, 2020. <https://www.kff.org/medicare/state-indicator/enrollees-as-a-of-total-medicare-population/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Overall%22,%22sort%22:%22desc%22%7D>
6. Polsky D, David G, Yang J, Kinoshian B, Werner R. The effect of entry regulation in the health care sector: the case of home health. *J Public Econ*. 2014; 110:1-14. doi:10.1016/j.jpubeco.2013.11.003
7. Butler J, Rakotoniaina A, Fournier D. 50-state scan shows diversity of state certificate-of-need laws. National Academy for State Health Policy. Published May 22, 2020. Accessed October 13, 2020. <https://www.nashp.org/50-state-scan-shows-diversity-of-state-certificate-of-need-laws/>
8. Ho V, Ku-Goto M-H, Jollis JG. Certificate of need (CON) for cardiac care: controversy over the contributions of CON. *Health Serv Res*. 2009;44(2 pt 1):483-500.
9. Bailey J. The effect of certificate of need laws on all-cause mortality. *Health Serv Res*. 2018;53(1):49-62. doi:10.1111/1475-6773.12619
10. Ho V, Ku-Goto M-H. State deregulation and Medicare costs for acute cardiac care. *Med Care Res Rev*. 2013;70(2):185-205. doi:10.1177/1077558712459681
11. Ho V, Xu Y, Akhter M. Freestanding emergency department entry and market-level spending on emergency care. *Acad Emerg Med*. 2019;26(11):1221-1231. doi:10.1111/acem.13848
12. Ho V, Metcalfe L, Dark C, et al. Comparing utilization and costs of care in freestanding emergency departments, hospital emergency departments, and urgent care centers. *Ann Emerg Med*. 2017;70(6):846-857.e3. doi:10.1016/j.annemergmed.2016.12.006
13. Gutierrez C, Lindor RA, Baker O, Cutler D, Schuur JD. State regulation of freestanding emergency departments varies widely, affecting location, growth, and services provided. *Health Aff (Millwood)*. 2016;35(10):1857-1866. doi:10.1377/hlthaff.2016.0412
14. Azar AM, Mnuchin ST, Acosta A. *Reforming America's Healthcare System Through Choice and Competition*. US Dept of Health and Human Services; 2018. Accessed October 2020. <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>
15. Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit*. 2015;53(2):235-284. doi:10.1257/jel.53.2.235
16. Beaulieu ND, Dafny LS, Landon BE, Dalton JB, Kuye I, McWilliams JM. Changes in quality of care after hospital mergers and acquisitions. *N Engl J Med*. 2020;382(1):51-59. doi:10.1056/NEJMsa1901383