JAMA | Original Investigation

Association of State Certificate of Need Regulation With Procedural Volume, Market Share, and Outcomes Among Medicare Beneficiaries

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IMPORTANCE Certificate of need laws provide state-level regulation of health system expenditure. These laws are intended to limit spending and control hospital expansion in order to prevent excess capacity and improve quality of care. Several states have recently introduced legislation to modify or repeal these regulations, as encouraged by executive order 13813, issued in October 2017 by the Trump administration.

OBJECTIVE To evaluate the difference in markers of hospital activity and quality by state certificate of need status. These markers include hospital procedural volume, hospital market share, county-level procedures per 10 000 persons, and patient-level postoperative outcomes.

DESIGN, SETTING, AND PARTICIPANTS A cross-sectional study involving Medicare beneficiaries aged 65 years or older who underwent 1 of the following 10 procedures from January 1, 2016, through November 30, 2018: total knee or hip arthroplasty, coronary artery bypass grafting, colectomy, ventral hernia repair, lower extremity vascular bypass, lung resection, pancreatic resection, cystectomy, or esophagectomy.

EXPOSURES State certificate of need regulation status as determined by data from the National Conference of State Legislatures.

MAIN OUTCOMES AND MEASURES Outcomes of interest included hospital procedural volume; hospital market share (range, 0-1; reflecting 0%-100% of market share); county-level procedures per 10 000 persons; and patient-level postoperative 30-day mortality, surgical site infection, and readmission.

RESULTS A total of 1 545 952 patients (58.0% women; median age 72 years; interquartile range, 68-77 years) at 3631 hospitals underwent 1 of the 10 operations. Of these patients, 468 236 (30.3%) underwent procedures in the 15 states without certificate of need regulations and 1 077 716 (69.7%) in the 35 states with certificate of need regulations. The total number of procedures ranged between 729 855 total knee arthroplasties (47.21%) and 4558 esophagectomies (0.29%). When comparing states without vs with certificate of need regulations, there were no significant differences in overall hospital procedural volume (median hospital procedure volume, 241 vs 272 operations per hospital for 3 years; absolute difference, 31; 95% CI, −27.64 to 89.64; $P = .30$). There were no statistically significant differences between states without vs with certificate of need regulations for 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 (median, 239.23 vs 205.41 operations per Medicare-eligible population in 3 years; absolute difference, 33.82; 95% CI, −84.08 to 16.43; $P = .19$); or 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 rate (9.69% vs 8.40%; OR, 0.80; 95% CI, 0.57 to 1.12; $P = .19$).

CONCLUSIONS AND RELEVANCE Among Medicare beneficiaries who underwent a range of surgical procedures from 2016 through 2018, there were no significant differences in markers of hospital volume or quality between states without vs with certificate of need laws. Policy makers should consider reevaluating whether the current approach to certificate of need regulation is achieving the intended objectives and whether those objectives should be updated.

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JAMA. 2020;324(20):2058-2068. doi:10.1001/jama.2020.21115

Certificate of need laws provide state-level regulation of health system spending by restricting unnecessary expenditures on hospital or service-line expansion. Currently, 35 states and the District of Columbia maintain some form of certificate of need regulation. Although the policy was intended to curb health care expenditure, it was thought to improve quality and access to care by ensuring local need for services, preventing the proliferation of hospitals in wealthier areas, reducing overuse of services, and limiting high-risk procedures to high-volume hospitals.[1-5] With the recent encouragement of the Trump administration under executive order 13813,[6] several states have renewed efforts to repeal their certificate of need regulations. Over the past 3 years, 12 states have introduced legislation to modify or repeal the regulation, with Florida repealing its law in 2019.[7]

The relationship between certificate of need status and patient outcomes is unclear.[1-4,8-11] The delivery of health care in the US has substantially changed since the association between certificate of need status and outcomes was originally studied, particularly in regard to health care quality measurement and improvement efforts.[12-14] Furthermore, despite known disparities in access to high-volume hospitals for vulnerable subgroups,[15] little is known about how certificate of need requirements might influence these disparities.

With several states working to scale back or eliminate the regulation, an updated evaluation of the clinical implications associated with repeal of certificate of need regulation is warranted. The objective of this study was to perform a contemporary evaluation of the association of certificate of need regulation status with procedural volume, market share, and postoperative outcomes across a broad range of surgical procedures.

Key Points

Question Is there an association between certificate of need laws, which regulate health system spending and expansion, and markers of hospital procedural activity and quality of care?

Findings In this cross-sectional study of 1 545 952 Medicare beneficiaries aged 65 years or older who underwent a broad range of hospital-based surgical procedures from January 1, 2016, through November 30, 2018, there were no significant differences found between states without and with certificate of need regulation for overall hospital procedural volume; hospital market share; county-level procedures per 10 000 persons; or risk-adjusted 30-day postoperative mortality, surgical site infection, or readmission.

Meaning Policy makers should consider reevaluating whether certificate of need regulations are having their intended effect.

Methods

Data Source and Study Population

Because deidentified data were used for this research, this study was deemed excepted from human subject review by the Northwestern University institutional review board office. Data for this study came from the Centers for Medicare & Medicaid Services Limited Data Set (100% sample) inpatient files and enrollment files. Claims were included from patients aged 65 years or older who were admitted to an inpatient facility and had their procedure on or after January 1, 2016, and were discharged on or before November 30, 2018. Beneficiaries who underwent 1 of the following 10 procedures were included: total knee or hip arthroplasty, coronary artery bypass graft surgery, colectomy, ventral hernia repair, lower extremity bypass, lung resection, pancreatic resection, cystectomy, or esophagectomy. These operations represent a broad procedural mix, encompassing both low- and high-risk procedures. Procedures were identified by the *International Classification of Disease Procedure Codes, Tenth Revision* (eTable 1 in the Supplement).[16] The analysis was limited to patients who had Medicare fee-for-service coverage in the month of discharge and the month following discharge, underwent procedures at hospitals for which 2016 American Hospital Association Annual Survey data could be obtained, were located within the 50 United States and the District of Columbia, and were not newborns or admitted for trauma care. Facilities were only included that were identified by the survey as being a general medical and surgical, surgical, cancer, heart, or orthopedic hospital. County-level data were obtained from the Area Health Resources File, a data set maintained by the Health Resources and Services Administration, an agency of the US Department of Health and Human Services.

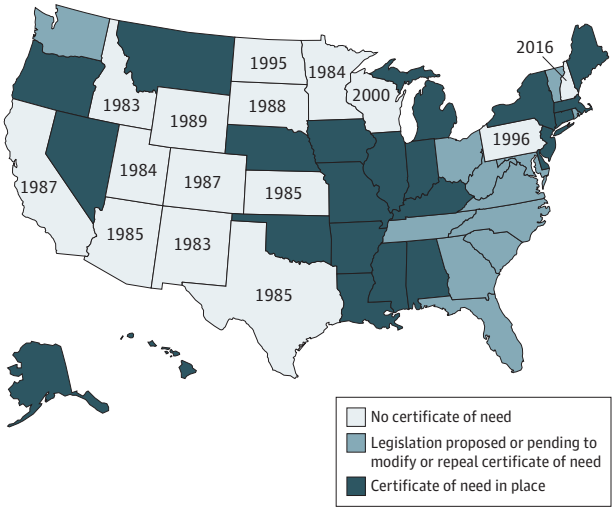
Exposure

Information regarding states' certificate of need status during the study period was acquired from the National Conference of State Legislatures.[7] Fifteen states had no regulation in place (**Figure**) and were grouped by regulation status. Although, Indiana had readopted the regulation in 2018, with a July 2019 effective date, we grouped it as a non-certificate of need regulation state because the effective date fell outside the included dates of this study. The remaining 35 states and the District of Columbia had continuous certificate of need regulations during the study period. Of the states with the regulation, 12 were trying to modify or repeal it (Florida, Georgia, Maryland, North Carolina, Ohio, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, Washington, West Virginia).[7]

Outcomes

Outcomes included hospital procedural volume, hospital market share, number of low-volume hospitals, county-level procedures per 10 000 persons, and postoperative outcomes. These outcomes were measured at the hospital level (volume, hospital market share within a county, and log-count of low-volume hospitals), market level (procedures per 10 000 persons in a county), and patient level (30-day postoperative outcomes). Hospital procedural volume was calculated based on claims data as a continuous variable. Hospital procedural volume was reported as the median of the distribution of case volumes among hospitals in each state. Hospital market share was defined as the percent of total procedures within a county-based market that were performed in a given hospital. For this

Figure. Certificate of Need Status by State From 2016-2018



The years presented represent the year the state repealed its certificate of need regulation. Prior to 1983, all states, except Louisiana, had enacted certificate of need legislation as part of the 1974 National Planning and Resources Development Act. Louisiana subsequently adopted certificate of need legislation in 1991.

analysis and similar to prior research, hospital market boundaries were defined by county.[2] Procedures per 10 000 Medicare-eligible persons were calculated by summing procedures within a county and dividing by the Medicare-eligible population within that county. This value was then multiplied by 10 000 to produce a value of procedures per 10 000 per county. Hospitals were defined as low volume if they were at or below the fifth percentile of procedure-specific volume.

Patient-level outcomes included 30-day mortality because most prior research on certificate of need laws examined this; surgical site infection was included as a specific outcome of surgical care: and readmission was included to capture a broad set of postoperative complications.[17] Mortality was defined as death within 30 days of a procedure. Surgical site infection included any wound infection identified by secondary diagnosis codes on the index claim or had occurred within 30 days of discharge based on inpatient claims (ie, the surgical site infection had to be serious enough to occur as an inpatient or require a readmission), and readmissions were defined as any admission within 30 days of the index discharge.[16,18-25]

Covariates

Patient-specific covariates were identified using claims files and included sex, age, race/ethnicity (White; Black; other, which includes Asian, Hispanic, North American Native, and a race/ethnicity that does not include White or Black; or unknown), procedure, year of procedure, type of admission (emergency, urgent, elective, unknown), source of admission (transfer, primary admission), and patient comorbidities. Patient comorbidities were identified using the *International Classification of Disease, Tenth Revision, Clinical Modification* system (eTable 2 in the Supplement) and combined to form a Charlson Comorbidity Index.[26,27] Hospital-specific covariates were identified using the American Hospital Association Annual Survey and included bed size, participation in a hospital network, accreditation by the Joint Commission, Member of the Council of Teaching Hospitals of the Association of American Medical Colleges, Core-Based Statistical Area (metropolitan, micropolitan, rural), and presence of an intensive care unit. Variables used in county-level analyses were obtained from the Area Health Resources File and included total nonfederal surgeons (those not employed by the federal government) in patient care, total surgical specialists, population, percent of persons aged 25 years or more with 4 or more years of college, the percent of the population in deep poverty, median household income, core-based statistical area type, and Medicare-eligible population.

Statistical Analysis

Patient and hospital characteristics in states without and with certificate of need regulation were summarized, and standardized mean differences were calculated. County characteristics were summarized using median values and interquartile range (IQR).

Certificate of need regulation was partly designed to encourage the concentration of procedures in smaller numbers of hospitals. Therefore, to examine whether hospital procedural volume and market share differed across states by certificate of need regulation status, unadjusted median regression models with robust standard errors to account for state-level clustering were estimated.[28] A set of median regression models with adjustment for hospital characteristics were also estimated to compare median procedure volume and market share. Whereas ordinary least-squares regression estimates the conditional mean of a distribution, median regression estimates the conditional quantile (ie, median). Median regression is less sensitive to the assumptions necessary for linear regression to be valid and is useful when outcomes may not be normally distributed such as occurs with some variables like procedure volume and health care cost.

To further explore associations of certificate of need regulation with hospital procedural volume, negative binomial regression models were estimated to assess whether the regulation was associated with the log count of low-volume hospitals after controlling for market characteristics—total number of nonfederal surgeons in patient care per 10 000 Medicare-eligible persons in a population in 2017; median household income in $10 000s in 2017; and core-based statistical area type, which include metropolitan (at least 1 urbanized area of >50 000 people), micropolitan (at least 1 urban cluster of >10 000 people but <50 000 people), and not a core-based statistical area type (areas that do not meet the previously noted criteria). Negative binomial models produce coefficients that represent the change in an independent variable on the log count of a dependent variable, in this case the count of low-volume hospitals. The negative binomial model interpretation of the coefficient is that of a change in independent variable on the log count of dependent variable. Similar to Poisson regression, negative binomial regression requires a dependent variable, which is an observed count.

However, negative binomial regression eases the restrictive assumption that the variance is equal to the mean (ie, assumption in Poisson regression). Because we used the negative binomial model (given the eased assumptions), we must interpret the output as the change in the independent variable on the log count of the dependent variable. If certificate of need regulation had concentrated procedures as they were intended to, there would be fewer low-volume hospitals in certificate of need states than in noncertificate of need states.

To explore whether certificate of need states were differentially successful in directing high-risk procedures away from low-volume hospitals, hospitals were categorized as low volume (at or below the fifth percentile for a given procedure category) and the proportion of high-risk procedures performed at these hospitals in states without and with certificate of need were compared using χ^2 tests adjusting for clustering at the state level. High-risk procedures were defined as esophagectomy, pancreatic resection, cystectomy, and lung resection.[16]

Certificate of need has also been thought to reduce overutilization. Therefore, to evaluate differences in procedure rates at individual hospitals between states without and with certificate of need laws, median procedure rates per 10 000 Medicare-eligible people were compared across states by regulation status using unadjusted median regression hypothesizing that if the regulation successfully reduced overutilization, states without certificate of need would have higher procedure rates per 10 000 Medicare-eligible people.

To investigate whether there were differential odds of the indicators for the quality of care, 30-day postoperative mortality, 30-day postoperative surgical site infection, or 30-day readmission for patients undergoing surgery by state certificate of need status, a series of multivariable logistic regression models were estimated with adjustment for patient and hospital characteristics. Models were estimated with robust clustered standard errors to account for state-level clustering. Primary analyses were completed with all 10 procedures pooled together. Adjusted analyses were then repeated for each individual procedure in order to identify procedure types that may be sensitive to certificate of need regulation.

To explore whether certificate of need regulation may have had any differential association with outcomes for certain vulnerable subgroups,[29-34] multivariable logistic regression models were reestimated to include interactions between certificate of need status and race/ethnicity (White [reference], Black, other), age (65-69 [reference], 70-74, 75-79, ≥80 years), severity of illness (Charlson Comorbidity Index, 0 [reference], 1, ≥2), and dual eligibility status (none [reference], state buy-in for Medicare Parts A and B in the month of discharge and the month after). As with other vulnerable subgroups, race/ethnicity was included in this analysis given previous documentation of disparities in outcomes.[33] Patient race/ethnicity was obtained from Medicare inpatient claims data (unknown, White, Black, other, Asian, Hispanic, North American Native).

Sensitivity analyses were undertaken to evaluate the robustness of the results. First, to ensure results were not driven by the large proportion of low-risk orthopedic cases within the cohort, analyses were repeated excluding total hip and total knee arthroplasty. Second, analyses were repeated by placing the 12 states working to repeal the legislation in the cohort of states that did not have a certificate of need regulation. As an extension, this sensitivity analysis was repeated excluding those 12 states altogether. Third, analyses of the quality markers of 30-day mortality, surgical site infection, and readmission were repeated with adjustment for hospital procedural volume in pooled and procedure-specific models. Fourth, procedures per 10 000 Medicare-eligible persons were recalculated with markets defined by hospital referral regions rather than by counties. Sensitivity analyses are further discussed in the eMethods of the Supplement.

All analyses adjusted for state-level clustering because certificate of need regulation is governed by state policy and clustering at lower levels (eg, hospital or county) would potentially underestimate similarity between hospitals and/or counties within a state facing the same regulatory environment.[35] The threshold used for statistical significance was $P < .05$. We have denoted P values that remain significant after Bonferroni correction for 11 tests in procedure-stratified analyses, for which $P < .05$ was lowered to $P < .005$. All statistical analyses were 2-sided. Because of the potential for type I error due to multiple comparisons, findings of all analyses should be interpreted as exploratory. Statistical analysis was performed using STATA version 15.1.

Results

Study Population

A total of 1 545 952 patients met the inclusion criteria (eTable 3 in the Supplement). Of these, 729 855 patients (47.21%) underwent total knee arthroplasties; 421 939 (27.29%), total hip arthroplasties; 126 813 (8.20%), colectomies; 127 672 (8.26%), coronary artery bypass graft surgeries; 54 063 (3.50%), ventral hernia repairs; 31 231 (2.02%), lower extremity bypasses; 27 461 (1.78%), lung resections; 13 497 (0.87%), pancreas resections; 8863 (0.57%), cystectomies, and 4558 (0.29%) esophagectomies. A total of 468 236 patients (30.29%) underwent procedures in the 15 states without certificate of need regulations and 1 077 716 (69.71%) in the 35 states and the District of Colombia with the regulation.

Hospitals in states without certificate of need regulation were more frequently small (<100 beds, 44.98% vs 39.66%), had fewer intensive care units (79.78% vs 88.19%), and were less often accredited by the Joint Commission (70.73% vs 74.38%) than hospitals in states with certificate of need regulation. Patient, hospital, and county characteristics are further summarized in **Table 1**. Standardized mean differences are reported in eTable 4 in the Supplement.

Hospital Procedural Volume, Hospital Market Share, Procedures per 10 000 Persons

No significant difference in overall hospital-level procedural volumes existed between states without vs states with certificate of need regulation status (median hospital procedure volume 241 vs 272 procedures per hospital for 3 years, absolute

Table 1. Patient, Hospital, and County Characteristics in States With and Without Certificate of Need Regulation

	No certificate of need (n = 468 236)	Certificate of need (n = 1 077 716)
No. of states	15	35[a]
Patient characteristics, %		
Sex		
Men	42.43	41.76
Women	57.57	58.24
Age, y[b]		
65-69	33.36	32.63
70-74	28.51	28.94
75-79	20.54	20.93
≥80	17.58	17.50
Race[c]		
White	90.69	89.71
Black	2.85	6.12
Other/unknown	6.46	4.17
Procedures		
Total knee arthroplasty	48.64	46.59
Total hip arthroplasty	27.57	27.17
Coronary artery bypass graft	7.65	8.52
Colectomy	7.68	8.43
Ventral hernia repair	3.43	3.52
Lower extremity bypass	1.76	2.13
Lung resection	1.55	1.87
Pancreatic resection	0.85	0.88
Cystectomy	0.58	0.57
Esophagectomy	0.28	0.30
Year of procedure		
2016	34.68	35.16
2017	35.47	35.34
2018	29.85	29.50
Type of admission[d]		
Emergency	7.02	8.41
Urgent	5.70	6.05
Elective	87.28	85.53
Source of admission		
Transferred from other facility	2.75	3.10
Primary admission	97.25	96.90
Charlson Comorbidity Index[e]		
0	46.36	43.55
1	23.14	23.58
≥2	30.50	32.87

(continued)

Table 1. Patient, Hospital, and County Characteristics in States With and Without Certificate of Need Regulation (continued)

	No certificate of need (n = 468 236)	Certificate of need (n = 1 077 716)
Hospital characteristics, %		
No. of hospitals	1305	2326
Bed size		
<100	44.98	39.66
100-299	37.39	38.19
≥300	17.62	22.15
Participant in hospital network[f]	37.79	49.97
Joint Commission accreditation[g]	70.73	74.38
Member of Council of Teaching Hospitals	4.90	7.05
Core-based statistical area type[h]		
Metro	68.97	66.42
Micro	17.78	18.83
Rural	13.26	14.75
Intensive care unit	79.78	88.19
County characteristics, median (IQR)		
No. of counties	564	1290
Population estimate in 10 000s	4.58 (2.10-14.25)	5.37 (2.70-13.26)
Population in deep poverty, %[i]	55 (41-71)	66 (49-84)
Total surgical specialists/population in 10 000s	2.51 (1.37-4.21)	2.51 (1.32-4.37)
>25 y with >4 y of college/population in 10 000s	1485.22 (1181.30-1928.50)	1416.28 (1104.29-1893.75)
Median household income in $10 000s	5.34 (4.73-6.16)	5.04 (4.35-5.86)

Abbreviation: AAMC, Association of American Medical Colleges; AHA, American Hospital Association; IQR, interquartile range.

[a] Includes the District of Columbia.

[b] At the patient level, data were complete for variables in the analysis with the exception of 2: patient age (number missing, 47 801 [3.04%]) and whether a hospital has an intensive care unit (number of patient observations with missing data, 158 262 [10.06% in patient-level data]). All analyses were carried out on complete cases. Categories may not add to 100% due to rounding.

[c] Patient race determined using Medicare claims data. Other includes Asian, Hispanic, North American Native, as well as a race/ethnicity that does not include White or Black.

[d] Type of admission determined using Medicare claims data. See the Methods section for definitions.

[e] The Charlson Comorbidity Index represents a weighted comorbidity score (0, no comorbidities; higher scores, increased comorbidities, increased likelihood of mortality, or higher resource use; range, 0-33).

[f] Hospital network is defined by the AHA as either a multihospital or diversified single-hospital system.

[g] The proportion of hospitals that are not Joint Commission accredited may be accredited by an alternative organization.

[h] See the Methods section for US geographic area definitions.

[i] Deep poverty is defined as living with income lower than half of one's poverty threshold.

difference, 31; 95% CI, −27.64 to 89.64; P = .30; **Table 2**). Evaluation of procedure-specific hospital procedural volume yielded significantly lower median volumes in states without than states with certificate of need regulation for coronary artery bypass graft surgery (median, 84 vs 136 procedures per hospital for 3 years; absolute difference, 52; 95% CI, 26.26-77.75; P < .001); colectomy (median, 21 vs 31 procedures per hospital for 3 years; absolute difference, 10; 95% CI, 4.14-15.86; P = .001); lower extremity bypass (median, 11 vs 17 procedures per hospital for 3 years; absolute difference, 6; 95% CI, 2.57-9.43; P < .001); lung resection (median, 9 vs 14 procedures per hospital for 3 years; absolute difference, 5; 95% CI, 1.68-8.32; P = .003); and esophagectomy (median, 2 vs 3 procedures per hospital for 3 years; absolute difference, 1; 95% CI, 0.60-1.41; P < .001).

Without consideration for clustering at the state level, the difference in overall hospital market share was significantly different (absolute difference, 24%; 95% CI, 0.18-0.32; P < .001); however, there were no statistically significant differences in overall hospital market share between states without vs with certificate of need regulation when clustering at the state level was adjusted for in the model (median, 28% vs 52%; range, 0-1; reflecting 0%-100% of market share; absolute difference, 24%; 95% CI, −5% to 55%, P = .11; Table 2). Similarly, procedure-specific market share did not significantly differ between states without vs with certificate of need regulation. Following adjustment for hospital characteristics, there were no statistically significant differences in overall median hospital procedural volume between states with vs without certificate of need regulations (coefficient, 7.5; 95% CI, −41.19 to 56.19; P = .76) or median market share (coefficient, 0.01; 95% CI, −0.03 to 0.05; P = .65; eTable 5 in the Supplement). Further exploration of the adjusted association between certificate of need regulation and the log count of low-volume hospitals demonstrated that certificate of need regulation was not significantly associated with having fewer low-volume hospitals for all procedures pooled (coefficient, −0.28; 95% CI, −0.67 to 0.11; P = .15; eTable 6 in the Supplement). Significant differences in the log count of low-volume hospitals were noted for 3 of the 10 examined procedures individually (ie, certificate of need regulation associated with fewer low-volume hospitals): colectomy (coefficient, −0.59; 95% CI, −0.90 to −0.28; P < .001), ventral hernia repair (coefficient, −0.50; 95% CI, −0.77 to −0.23;

Table 2. Median Hospital Procedural Volume and Market Share by State Certificate of Need Status (2016-2018)

	No. of hospitals	Median operations per hospital for 3 y (95%CI)		Absolute difference (95% CI)	*P* value [a]
		No certificate of need	Certificate of need		
Procedure[b]					
Overall	3631	241 (211.51 to 270.49)	272 (221.32 to 322.68)	31 (−27.64 to 89.64)	.30
Total knee arthroplasty	3315	133 (115.53 to 150.47)	153 (132.87 to 173.13)	20 (−6.65 to 46.66)	.14
Total hip arthroplasty	3255	68 (56.98 to 79.03)	86 (73.41 to 98.59)	18 (1.26 to 34.74)	.04
Coronary artery bypass graft	1133	84 (66.90 to 101.10)	136 (116.76 to 155.24)	52 (26.26 to 77.75)	<.001[c]
Colectomy	3304	21 (17.37 to 24.63)	31 (26.40 to 35.60)	10 (4.14 to 15.86)	.001 [c]
Ventral hernia repair	3202	12 (9.78 to 14.22)	15 (12.36 to 17.64)	3 (−0.45 to 6.45)	.09
Lower extremity bypass	1784	11 (8.23 to 13.7)	17 (14.97 to 19.03)	6 (2.57 to 9.43)	.001 [c]
Lung resection	1498	9 (6.61 to 11.39)	14 (11.69 to 16.31)	5 (1.68 to 8.32)	.003 [c]
Pancreatic resection	905	4 (3.34 to 4.66)	6 (4.67 to 7.33)	2 (0.51 to 3.49)	.01
Cystectomy	948	3 (2.03 to 3.97)	4 (3.44 to 4.56)	1 (−0.12 to 2.12)	.08
Esophagectomy	854	2 (1.72 to 2.28)	3 (2.71 to 3.29)	1 (0.60 to 1.41)	<.001 [c]
		Median percent market share (95%CI)			
Hospital market share[d]					
Overall	3631	28 (7 to 49)	52 (31 to 73)	24 (−5 to 55)	.11
Total knee arthroplasty	3315	26 (7 to 46)	52 (33 to 71)	26 (−2 to 53)	.07
Total hip arthroplasty	3255	25 (6 to 45)	49 (31 to 69)	24 (−3 to 51)	.08
Coronary artery bypass graft	1133	26 (12 to 40)	44 (34 to 54)	18 (1 to 36)	.04
Colectomy	3304	31 (8 to 54)	53 (31 to 74)	22 (−10 to 53)	.18
Ventral hernia repair	3202	30 (6 to 55)	50 (31 to 69)	20 (−11 to 51)	.20
Lower extremity bypass	1784	18 (4 to 32)	33 (23 to 44)	15 (−2 to 33)	.09
Lung resection	1498	20 (7 to 34)	37 (27 to 46)	17 (−1 to 33)	.06
Pancreatic resection	905	30 (9 to 52)	46 (36 to 55)	16 (−8 to 39)	.21
Cystectomy	948	35 (13 to 56)	50 (35 to 65)	15 (−11 to 42)	.25
Esophagectomy	854	43 (23 to 63)	50 (37 to 63)	7 (−17 to 31)	.56

[a] 95% CIs and *P* values for difference in medians obtained from median regression model regressing hospital market volume on certificate of need vs no certificate of need state indicator, with robust SEs to account for state-level clustering.

[b] The number of hospitals that have performed at least 1 of the procedures listed.

[c] Significant after Bonferroni correction for 11 comparisons (*P* < .05 lowered to *P* < .005).

[d] Hospital market share defined as the percent of total procedures within a county-based market that were performed in a given hospital. The number of hospitals that have performed at least 1 of the procedures listed.

P < .001), and lower extremity bypass (coefficient, −0.35; 95% CI, −0.56 to −0.14; *P* = .001).

There were no statistically significant differences in median county-level procedure rates per 10 000 Medicare-eligible population in states without vs with certificate of need regulation overall (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; **Table 3**) or after Bonferroni correction for any of the 10 individual procedures. Further evaluation of the distribution of high-risk procedures indicated that there was no significant difference in the proportion of high-risk procedures performed at low-volume centers in states without vs with certificate of need regulation for lung resection (0.5% vs 0.4%; *P* = .06), pancreatic resection (1.2% vs 1.2%; *P* = .99); cystectomy (2.7% vs 1.8%, *P* = .19); esophagectomy (5.9% vs 4.6%, *P* = .28; eFigure in the Supplement).

Postoperative Outcomes

There were no significant differences in unadjusted 30-day rates of overall mortality (1.17% vs 1.33%, *P* = .12), surgical site infection (1.24% vs 1.25%, *P* = .98), or readmission (9.70% vs 8.40%, *P* = .24) in states without vs with certificate of need regulation (eTable 7 in the Supplement). Following adjustment for patient and hospital characteristics, there were no significant differences between states without vs with certificate of need for the odds of death within 30 days of a procedure (1.17% vs 1.33%; OR, 1.04; 95% CI, 0.93-1.16; *P* = .52), developing a surgical site infection within 30 days (1.24% vs 1.25%; OR, 0.93; 95% CI, 0.83-1.04; *P* = .21), or 30-day readmission (9.69% vs 8.40%; OR, 0.80; 95% CI, 0.57-1.12; *P* = .19; **Table 4**; eTable 8 in the Supplement). These findings remained consistent across all procedures when examined individually (eTable 9 in Supplement).

Further evaluation of the association between certificate of need regulation and postoperative outcomes among subgroups, including racial/ethnic minorities (eg, Black), older patients, patients with several comorbidities, and patients with dual eligibility yielded no statistically significant differences in 30-day mortality, surgical site infection, or readmission (eTable 10 in the Supplement).

Sensitivity Analyses

Several sensitivity analyses yielded findings that were consistent with the primary analyses, including (1) exclusion of the

Table 3. Evaluation of County-Level Procedure Rates per 10 000 Medicare-Eligible Population by Certificate of Need Status[a,b]

	No. of counties	Median procedures per Medicare-eligible people for 3 y (95%CI)		Absolute difference (95% CI)	*P* value[c]
		No certificate of need	Certificate of need		
Overall[d]	1854	239.23 (194.25 to 284.22)	205.41 (182.99 to 227.82)	33.82 (−84.08 to 16.43)	.19
Total knee arthroplasty	1661	154.76 (124.26 to 185.27)	122.91 (108.74 to 137.08)	31.85 (−65.596 to 1.783)	.06
Total hip arthroplasty	1620	75.35 (60.99 to 89.65)	58.59 (52.17 to 65.01)	16.76 (−32.44 to 1.04)	.04
Coronary artery bypass graft surgery	527	38.38 (27.41 to 49.35)	49.86 (40.22 to 59.51)	11.48 (−3.12 to 26.09)	.12
Colectomy	1720	18.35 (16.48 to 20.22)	22.05 (20.07 to 24.02)	3.70 (0.98 to 6.42)	.01
Ventral hernia repair	1628	9.80 (8.40 to 11.21)	10.06 (9.04 to 11.08)	0.26 (−1.48 to 1.99)	.77
Lower extremity bypass	765	6.85 (5.22 to 8.49)	8.84 (7.25 to 10.43)	1.99 (−0.29 to 4.27)	.09
Lung resection	664	4.80 (3.62 to 5.98)	6.67 (5.42 to 7.92)	1.87 (0.15 to 3.59)	.03
Pancreatic resection	432	1.72 (1.24 to 2.19)	2.09 (1.53 to 2.65)	0.37 (−0.37 to 1.11)	.32
Cystectomy	479	1.16 (0.75 to 1.58)	1.66 (1.40 to 1.92)	0.50 (0.003 to 0.99)	.05
Esophagectomy	449	0.93 (0.53 to 1.34)	0.99 (0.81 to 1.17)	0.06 (−0.39 to 0.50)	.81

[a] Procedures per 10 000 Medicare-eligible persons within a county were calculated by summing procedures performed within each county, dividing that value by the Medicare-eligible population within the county and multiplying by 10 000.

[b] Medicare-eligible population data were obtained from the Area Health Resources File, are based on information from the State County Penetration Data for Medicare Advantage Files, and includes those who are enrolled in either Medicare part A or part B.

[c] 95% CIs and *P* values for difference in medians obtained from median regression model with robust standard errors to account for state-level clustering.

[d] Analyses included counties with nonzero procedures of a particular category. No differences remained significant at the $P < .005$ level or after adjusting for 11 tests using the Bonferroni method (lower $P < .05$ to $P < .005$).

Table 4. Comparison of Risk-Adjusted Patient-level Outcomes Including All Evaluated Procedures by State Certificate of Need Status[a]

	Rate (95% CI), %				
	No certificate of need	Certificate of need	Absolute difference (95% CI)	OR (95% CI)	*P* value
Mortality	1.17 (0.24 to 2.10)	1.33 (0.77 to 1.89)	0.16 (−0.93 to 1.25)	1.04 (0.93 to 1.16)	.52
Surgical site infection[b]	1.24 (0.45 to 2.04)	1.25 (0.80 to 1.70)	0.01 (−0.92 to 0.92)	0.93 (0.83 to 1.04)	.21
Readmission[c]	9.69 (5.96 to 13.43)	8.40 (6.42 to 10.38)	1.29 (−5.52 to 2.93)	0.80 (0.57 to 1.12)	.19

Abbreviations: ICU, intensive care unit; OR, odds ratio.

[a] A total of 1 391 134 observations had complete data in regression estimation samples. Therefore, the calculation includes 1 391 134 observations across all procedures and all hospitals. Logistic regression models adjusting for procedure type, procedure year, gender, age, race, type of admission, Charlson Index, dual eligibility status, source of admission, bed size, participation in hospital network, accreditation by the Joint Commission, member of the Council of Teaching Hospitals of the Association of American Medical Colleges, area type, and presence of an intensive care unit.

[b] Surgical site infections are limited to those during the index inpatient stay or requiring rehospitalization.

[c] Readmission was defined as admission to the hospital in the 30 days following the procedure. This did not include observation stays (ie, <24 hours).

large proportion of orthopedic procedures; (2) repeat analysis with the states working to repeal certificate of need regulation included in the noncertificate of need cohort; (3) analysis with the states working to repeal certificate of need regulation excluded; (4) adjustment for differences in hospital procedural volume when evaluating mortality, surgical site infection, or readmission; and (5) evaluation of procedure rates with markets defined by hospital referral regions (eTable 11 in the Supplement). The lone exception was the evaluation of mortality following pancreatic resection with adjustment for hospital procedural volume: following adjustment, states with certificate of need regulation had statistically significantly higher odds of mortality (OR, 1.61; 95% CI, 1.23-2.10; $P < .001$).

Discussion

In this cross-sectional study of a national cohort involving patients aged 65 years or older who underwent a wide range of surgical procedures from 2016 through 2018, no statistically significant differences existed in markers of hospital capacity and quality by state certificate of need status. Given that certificate of need laws are intended to limit spending and overexpansion to avoid excess capacity and improve quality, the findings of this study suggest that certificate of need regulations may not be having their intended effect.

To our knowledge, this study reports the first evaluation of certificate of need (1) in a contemporary era of heightened and incentivized quality consciousness, (2) across a broad set of surgical procedures, (3) with a focus on procedural concentration and clinical outcomes, and (4) with attention to potential differential disparities among subgroups. The current literature regarding the clinical implications of certificate of need remains limited. Most prior studies were based on data that are 2 decades old, have focused on cardiac procedures, and examined limited outcomes such as mortality and hospital procedural volume.[2-4,10,11,36-38] Less is known regarding the effect of certificate of need on clinical outcomes (eg, surgical site infection, readmission) or the concentration of cases within states. One study, evaluating

all-cause mortality within the general US population from 1992 through 2011, found no significant difference by state status, with point estimates suggesting that states with certificate of need regulation had higher all-cause mortality.[8] However, all-cause mortality within the general population is a broad measure that is likely affected by many factors besides certificate of need regulation. Given the lack of contemporary studies on this topic, the current study serves as an updated and expanded assessment of the association between certificate of need regulation and quality at a time when several states, encouraged by the Trump administration, have increased efforts to repeal or scale back certificate of need.

By limiting the number of hospitals for specific services, certificate of need regulations aim to concentrate procedures in a smaller number of facilities and increase procedural volume. Therefore, under the regulation, hospitals should have greater procedural volumes and market share, there should be fewer low-volume hospitals, and patients undergoing complex procedures should be less likely to receive care at low-volume hospitals. The current study suggests that although there were no significant differences in overall hospital procedural volume, hospitals in states with the regulation had significantly higher median hospital procedural volume for 5 of 10 specific procedures. Furthermore, certificate of need regulation was associated with states having significantly fewer low-volume hospitals performing 3 of 10 procedures: colectomy, ventral hernia repair, and lower extremity bypass.

In the initial market share analysis, there was statistically significantly greater market concentration in hospitals in certificate of need states than in states without it. However, when clustering was accounted for in the statistical model, these differences were no longer significant. State-level clustering is important to consider because hospitals and markets within states that are subject to the same state-level policies tend to deliver more uniform care within the states than between them, in addition to other factors that result in more similar care delivery patterns. Consequently, markets within states are also more similar within than across states. Previous reports of patients undergoing coronary artery by graft surgery in states without certificate of need regulation found that a larger portion of procedures evaluated for this study were performed at low-volume centers.[3,11,36] However, in the current study, evaluation of the proportion of high-risk procedures performed at low-volume hospitals yielded no significant differences across states without vs with certificate of need. The current study found that most high-risk procedures were performed in high-volume hospitals irrespective of status.

Certificate of need regulation is also thought to result in clinical benefits by reducing overuse or inappropriate care. A previous study evaluating the appropriateness of percutaneous coronary interventions in states with and without the regulation found small absolute differences between states, suggesting that certificate of need may not limit inappropriate interventions.[9] Similarly, the current study found no significant differences in procedures per 10 000 Medicare-eligible per capita within a county in states without vs with certificate of need. It could be argued that measures of market concentration and analysis of complex procedures should be performed at the level of the hospital referral regions rather than within counties as was performed in the current study. Although hospital referral regions may provide an accurate reflection of a hospital's referral base, they are not suitable for an analysis of certificate of need because hospital referral regions cross state lines resulting in facilities within a hospital referral region being subject to different certificate of need regulations. Nevertheless, an analysis by hospital referral region was performed as a sensitivity analysis and is presented in the Supplement. There was no association of certificate of need status with outcomes organized by hospital referral regions.

The findings of this study differ from 2 studies that evaluated the association between certificate of need regulation and outcomes following coronary artery bypass graft surgery. The first reported a 22% higher risk-adjusted mortality (0.8% absolute difference) in states without certificate of need regulation among Medicare patients treated between 1994 and 1999.[11] The second study evaluated Medicare patients between 1989 and 2002 and reported lower mortality in states that had repealed certificate of need regulation during the study period.[2] The contrast between these results and the findings of the current study potentially reflect the changes that have occurred across US health care during the past 2 decades. Specifically, quality improvement has received much greater emphasis, there has been a decrease in hospital length of stay, and increased efficiency, with all 3 playing an important role in reimbursement incentivizing these improvement efforts.[13] A greater societal interest in better quality of health care and linking reimbursement to the quality of care may have had an equal effect on hospitals independent of certificate of need requirements, potentially obviating the need for the certificate of need process.

Although there may no longer be a relationship between state certificate of need and clinical outcomes for the general population, it has been hypothesized that some population subgroups remain vulnerable to potential policy changes.[29-34] Where there is no certificate of need regulation, hospitals may preferentially deploy services in areas with better payer mixes. This coupled with the lack of charity care (ie, health care provided for free) provisions associated with some certificate of need regulations, could result in worsening disparities in states without the regulation. However, in the current study, evaluation of the differential association between certificate of need regulation and outcomes among racial/ethnic minorities, those older than 80 years, patients with several comorbidities, and patients with dual eligibility found no significant difference in outcomes. Although these subgroups experienced worse outcomes than non-racial/ethnic minorities, those younger than 80 years, patients with no comorbidities, and those without dual eligibility within both cohorts, there were no significant differences attributable to certificate of need regulation found in this study.

Although the regulation may no longer be associated with significant differences in markers of hospital volume or quality, improvements to the regulation, rather than repeal, may prove beneficial. There are multiple potential areas for

improvement in certificate of need laws. First, the collection of accurate regional health utilization data (eg, bed occupancy rates, use rates of medical services, and changes in local populations and demographics) must be ensured to guide appropriate health planning. Second, transparent and regularly reviewed standards for each type of medical space or service expansion should be set. Third, regulation should focus on large expansion efforts (eg, building new hospitals) rather than minor requests for increasing beds or technologies (eg, addition of <50 beds or a new computed tomographic scanner).

Limitations

This study has several limitations. First, the study design does not allow for a direct evaluation of a causal relationship between certificate of need regulation status and hospital characteristics and quality outcomes. Instead, these analyses evaluated the association of current hospital procedural volume, hospital market share, and postoperative outcomes with state status and potentially reflect prior improvements resulting from certificate of need requirements. Although a limitation, this retrospective analysis does show what the actual clinical results were under the mandate compared with states that had no such requirements. Second, other outcomes that were not studied such as financially oriented processes or access to care may be more sensitive to variation in certificate of need regulation. However, 30-day mortality, surgical site infection, and readmission are policy-relevant clinical outcomes. Third, patients younger than 65 years and those not covered by Medicare payors were excluded, potentially affecting generalizability. However, patients with Medicare, who are 65 years or older, represent a large proportion of US population undergoing the procedures included within this study (median age of patients undergoing these procedures in the US is 67 years for total hip or knee arthroplasty, 65 years for coronary artery bypass graft surgery, 63 years for colectomy, 54 years for ventral hernia repair, 67 years for lower extremity bypass, 56 years for lung resection, 62 years pancreatectomy, 69 years for cystectomy, and 64 for esophagectomy).[16,17,19] Fourth, the distinction between states without and with certificate of need regulation remains imprecise. Not only is there variation in the scope and implementation of the regulation between states, but states without it may have alternate approaches that regulate hospital and medical service expansion (eg, California's Office of Statewide Health Planning and Development). Therefore, the true effect of certificate of need regulation, or its repeal, may vary based on each states' specific politics and administration of the law. Although the current data are unable to account for these particular differences between states, the method of designating states by certificate of need status used in this work mirrors that of previous research, and the sensitivity analysis seeking to adjust for variation in state administration of certificate of need laws was unrevealing.[4,9,11,38] Fifth, certificate of need laws may regulate multiple aspects of care not limited to the 10 procedures included in this study. However, the selected procedures represent a broad range of operations that may be influenced by some of the intended objectives of certificate of need (eg, concentration of complex procedures to high-volume hospitals, limiting overuse, and preventing unnecessary expansion of facilities such as ambulatory surgery centers).

Conclusions

Among Medicare beneficiaries who underwent a range of surgical procedures from 2016 through 2018, there were no significant differences in markers of hospital volume or quality between states without vs with certificate of need laws. Policy makers should consider reevaluating whether the current approach to certificate of need regulation is achieving the intended objectives and whether those objectives should be updated.

ARTICLE INFORMATION

Accepted for Publication: October 8, 2020.

Author Contributions: Drs Bilimoria and Yuce had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Yuce, Barnard, Bilimoria.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Yuce, Barnard, Bilimoria.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Yuce, Bilimoria.
Obtained funding: Bilimoria.
Supervision: Chung, Barnard, Bilimoria.

Conflict of Interest Disclosures: None reported.

Funding/Support: Dr Yuce was supported by a postdoctoral research fellowship (AHRQ 5T32HS000078).

Disclaimer: Views expressed in this work represent those of the authors only.

Meeting Presentation: This work was presented at the Academic Surgical Congress on February 5, 2020.

Additional Contributions: We thank Bridget Orth, BS, Northwestern Memorial Health Care, for her assistance with this work, for which she was not compensated.

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