Certificate of Need Regulations and Use of Coronary Revascularization After Acute Myocardial Infarction

Ioana Popescu, MD
Mary S. Vaughan-Sarrazin, PhD
Gary E. Rosenthal, MD

Context Certificate of need regulations were enacted to control health care costs by limiting unnecessary expansion of services. While many states have repealed certificate of need regulations in recent years, few analyses have examined relationships between certificate of need regulations and outcomes of care.

Objective To compare rates of coronary revascularization and mortality after acute myocardial infarction in states with and without certificate of need regulations.

Design, Setting, and Participants Retrospective cohort study of 1 139 792 Medicare beneficiaries aged 68 years or older with AMI who were admitted to 4587 US hospitals during 2000-2003.

Main Outcome Measures Thirty-day risk-adjusted rates of coronary revascularization with either coronary artery bypass graft surgery or percutaneous coronary intervention and 30-day all-cause mortality.

Results The 624 421 patients in states with certificate of need regulations were less likely to be admitted to hospitals with coronary revascularization services (321 573 [51.5%] vs 323 695 [62.8%]; $P<.001$) or to undergo revascularization at the admitting hospital (163 120 [26.1%] vs 163 877 [31.8%]; $P<.001$) than patients in states without certificates of need but were more likely to undergo revascularization at a transfer hospital (73 379 [11.7%] vs 45 907 [8.9%]; $P<.001$). Adjusting for demographic and clinical risk factors, patients in states with highly and moderately stringent certificate of need regulations, respectively, were less likely to undergo revascularization within the first 2 days (adjusted hazard ratios, 0.68; 95% confidence interval [CI], 0.54-0.87; $P=.002$ and 0.80; 95% CI, 0.71-0.90; $P<.001$) relative to patients in states without certificates of need, although no differences in the likelihood of revascularization were observed during days 3 through 30. Unadjusted 30-day mortality was similar in states with and without certificates of need (109 304 [17.5%] vs 90 104 [17.5%]; $P=.76$), as was adjusted mortality (odds ratio, 1.00; 95% CI, 0.97-1.03; $P=.90$).

Conclusions Patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with certificate of need regulations. However, differences in the availability and use of revascularization therapies were not associated with mortality.

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CERTIFICATE OF NEED REGULATIONS emerged in the 1970s as a mechanism to control health care expenditures and the diffusion of costly technologies. Certificate of need programs are administered by states and require hospitals to obtain approval prior to establishing certain clinical services, such as coronary revascularization.

In 1984, federal legislation mandating states to maintain certificate of need programs was revoked. Since then, 25 states have repealed certificate of need programs for open-heart surgery, including 19 states that repealed certificate of need regulations altogether. Within individual states, there is active debate about whether certificates of need should be maintained, rescinded, or, in the case of states that have eliminated certificates of need, reimplemented. During 2002, state legislatures discussed more than 30 proposals related to certificates of need.[1]

Opponents argue that certificates of need limit competition and protect low-quality providers from competition.[2,3] Conversely, proponents believe that certificates of need prevent overuse of services, maintain higher-volume clinical programs, and promote higher quality of care.[4]

However, few empirical evaluations of the impact of certificate of need programs on quality of care and patient outcomes have been conducted, with mixed results. An earlier study found

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Author Affiliations: Center for Research in the Implementation of Innovative Strategies in Practice (CRIISP), Iowa City VA Medical Center, and Division of General Internal Medicine, Department of Internal Medicine, University of Iowa Carver College of Medicine, Iowa City.
Corresponding Author: Ioana Popescu, MD, Department of Internal Medicine, University of Iowa Hospitals and Clinics, 200 Hawkins Dr, SE615-GH, Iowa City, IA 52240 (ioana-popescu@uiowa.edu).

that certificates of need were associated with increased mortality for several medical and surgical conditions.[5] More recent research reported significantly lower risk-adjusted mortality in states with certificates of need for percutaneous coronary interventions (PCIs) or coronary artery bypass graft (CABG) surgery.[6,7]

Because of the limited prior literature, we conducted the current study to evaluate the relationship between certificates of need and outcomes of acute myocardial infarction (AMI). Specifically, we sought to compare differences in the use of coronary revascularization with either PCI or CABG surgery and risk-adjusted mortality in states with and without certificates of need. We also sought to examine relationships between the stringency of certificate of need regulations in individual states and these end points.

We chose to study AMI and coronary revascularization because much of the debate surrounding certificates of need in individual states has focused on the development of new programs in cardiovascular medicine.

METHODS

Data Sources

Patients were identified using Medicare Provider Analysis and Review (MedPAR) data files obtained from the Center for Medicare & Medicaid Services. The MedPAR files contain data on all Medicare fee-for-service hospitalizations, including patient and hospital unique identifiers, demographics, dates of admission and discharge, admission acuity, codes for diagnoses and procedures as classified by the *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*), and discharge disposition. MedPAR files are also matched quarterly to the Medicare enrollment database to incorporate dates of death after hospital discharge. Additional information regarding patient economic status was measured using ZIP code–level median household income data from the US 2000 Census Summary File (publicly available at http://factfinder.census.gov). Prior to conducting this study, approval with a waiver of consent was obtained from the University of Iowa institutional review board.

Information on certificate of need regulation for individual states was obtained from the National Directory of Health Planning, Policy, and Regulatory Agencies for 2000-2003.[8] During 2000-2002, 27 states (including the District of Columbia) had continuous certificate of need regulations for open-heart surgery. Missouri dropped certificate of need regulations for open-heart surgery in 2003. The remaining states had no certificates of need for open-heart surgery during the entire period. States with certificates of need were further categorized according to the stringency of the certificate of need regulations into 3 groups—high, moderate, and low stringency—as previously defined by Conover and Sloan.[9] Stringency assessment considered general capital and equipment expenditure thresholds, level-of-review thresholds, other supporting legislation, the scope of service covered, and expert opinion to assign weights to each of the factors.[10] Stringency categories by state were available for the years 2000 and 2001, during which 3 states had high, 8 states had moderate, and 16 states had low certificate of need stringency. Because these categories were stable within individual states in 2000 and 2001 and because review thresholds and scope of regulations for acute care did not change in 2002 and 2003 from 2001,[8] categories from 2001 were applied to 2002 and 2003.

Patient Population

The study cohort included 1 139 792 Medicare beneficiaries aged 68 years or older who were hospitalized for AMI (identified by a primary *ICD-9-CM* code 410) between January 1, 2000, and September 30, 2003. Patients admitted for AMI, PCI, or CABG surgery within the previous 3 years were excluded to limit the cohort to patients with initial episodes of MI. The cohort was further limited to patients aged 68 years or older at the time of admission to ensure at least 3 years of prior Medicare data. For each admission, we identified deaths occurring within 30 days of admission and the date of the first revascularization procedure by CABG surgery or PCI performed within 30 days of admission. Revascularizations were further categorized according to whether the procedure occurred 1 to 2 days or 3 to 30 days after admission and whether the procedure occurred at the admitting hospital, at a transfer hospital, or during readmission within 30 days. Transfers were defined as admission to a second acute care facility within 1 day of discharge from the admitting hospital. Admissions to acute care facilities occurring 2 or more days after discharge from the admitting hospital were considered readmissions. Transfers and readmissions were determined by linking hospitalizations based on the unique patient identifiers in the MedPAR data.

Data Analysis

Demographic and clinical characteristics, rates of revascularization, and mortality rates of patients in states with and without certificates of need were compared using the *t* test and the χ^2 test. The Cochran-Armitage test for trend was used for comparison of proportions across certificate of need stringency categories. Median annual Medicare AMI and revascularization (CABG surgery or PCI) volumes of hospitals in states with and without certificates of need were compared using the Wilcoxon rank sum test. Analysis of variance with Bonferroni adjustment was used to compare hospital volumes across certificate of need stringency categories.

The relationship between certificate of need and revascularization or death was then evaluated using multivariable models to adjust for differences in sociodemographic characteristics, comorbidity, and AMI severity. Models for mortality were estimated using generalized estimating equations, while models for revascularization used Cox proportional hazards models to account for censoring prior to revascularization due to death. Nonproportionality was accounted for by including an interaction term between certifi-

cate of need and follow-up time. Both sets of models were calibrated using a robust sandwich covariance matrix estimate to account for clustering of patients within hospitals.[11-13]

Individual patient risk factors associated with revascularization or mortality in bivariate analyses ($P<.10$) or found to be predictors in previous studies[14-16] were included in the multivariable models. Sociodemographic factors included sex, race, median household income (based on residential ZIP code–level data), and age. Age was included in models alternately as a continuous variable and using indicator variables for specific ranges (ages ≤69, 70-74, 75-79, 80-84, and ≥85 years); both approaches yielded similar results. Race was based on MedPAR data and was categorized as white, black, or other. Other predictors included comorbid conditions (as defined by *ICD-9-CM* secondary diagnosis codes using previously defined algorithms[17,18]), year of discharge, and location of MI (categorized into 4 groups defined by *ICD-9-CM* codes, indicating anterior or lateral, inferior or posterior, subendocardial, or other unspecified locations). Models for mortality were also generated with and without variables indicating the use of an intra-aortic balloon pump or nonoperative mechanical ventilation on the day of admission. Because these variables might represent practice variation, rather than patient severity, models were estimated with and without these variables; both sets of analyses yielded similar results.

Since indications for revascularization vary in time (ie, procedures during the first 2 days are more likely to be considered emergent), the hazard of revascularization in states with certificates of need relative to states without certificates of need was estimated separately for revascularizations occurring on days 1 and 2 and days 3 through 30 after admission, using separate indicator variables for revascularization occurring on days 1 and 2 and days 3 through 30 and interactions between these variables and certificate of need status.

For analyses of both mortality and revascularization, the effect of certificates of need was estimated using 2 approaches—first, by including an indicator variable for the presence or absence of a certificate of need regulation in the state and year the patient was admitted, and second, by including separate indicator variables for states with high, moderate, and low stringency of certificate of need regulations. The referent category for both sets of analyses included patients admitted to hospitals in states without certificates of need.

Finally, models for revascularization and mortality were generated for all patients and separately for subgroups defined by location of MI. *P* values were 2-sided. Statistical significance was defined using a conservative criterion of $P<.01$ to account for the multiple comparisons of high-, moderate-, and low-stringency states vs states without certificates of need. All analyses were performed using SAS statistical software, version 9.1 (SAS Institute Inc, Cary, NC).

RESULTS

During the study period, 515 371 patients (45%) were hospitalized for AMI in states without certificate of need regulations and 624 421 (55%) in states with certificate of need, including 369 222 (32%) in low-stringency, 185 159 (16%) in moderate-stringency, and 70 040 (6%) in high-stringency certificate of need states.

Patients in states with certificates of need were more likely to be female, to be black, and to have a number of comorbid conditions (TABLE 1). How-

Table 1. Characteristics of Patients Admitted to Hospitals in States With and Without Certificate of Need Regulations During 2000-2003

Characteristics	States With Certificates of Need (n = 624 421)	States Without Certificates of Need (n = 515 371)
Age, mean (SD), y	78.3 (8.1)	78.2 (8.0)
Race, No. (%)		
White	555 786 (89.0)	463 250 (89.9)
Black	51 389 (8.2)	27 056 (5.3)
Other	17 246 (2.8)	25 065 (4.8)
Female, No. (%)	316 913 (50.8)	251 692 (48.8)
Mean (SD) income, ZIP code level, $	43 547 (17 519)	41 381 (15 130)
Location of myocardial infarction, No. (%)		
Anterior/lateral	99 908 (16.0)	87 444 (17.0)
Inferior/posterior	107 629 (17.2)	95 787 (18.6)
Subendocardial	344 131 (55.1)	266 548 (51.7)
Other location	72 753 (11.7)	65 292 (12.7)
Comorbidities, No. (%)		
Congestive heart failure	253 374 (40.9)	200 838 (39.0)
Arrhythmia	191 121 (30.6)	152 256 (29.6)
Valve disorder	100 508 (16.1)	77 441 (15.0)
Chronic obstructive pulmonary disease	138 947 (22.3)	109 666 (21.3)
Diabetes mellitus	166 427 (26.7)	132 776 (25.8)
Peripheral vascular disease	49 905 (8.0)	40 009 (7.8)
Fluid electrolyte imbalance	104 780 (16.8)	82 033 (15.9)
Renal failure	43 488 (7.0)	34 033 (6.6)
Metastatic cancer	6406 (1.0)	5106 (1.0)
Weight loss	6431 (1.3)	8081 (1.3)
Dementia	24 535 (3.9)	17 645 (3.4)
Neurological disease	32 523 (5.2)	26 967 (5.2)
Liver disease	2807 (0.5)	2319 (0.5)
Lymphoma	3601 (0.6)	2948 (0.6)
Intra-aortic balloon pump on day of admission, No. (%)	15 836 (2.5)	16 285 (3.2)
Mechanical ventilation on day of admission, No. (%)	33 237 (5.3)	24 755 (4.8)

ever, the magnitude of the differences was small for most characteristics.

Median annual hospital volumes for AMI and revascularization procedures were higher in states with certificates of need compared with states without certificates of need (TABLE 2). Among states with certificates of need, both AMI and revascularization volumes were directly related to certificate of need stringency.

Overall 30-day coronary revascularization rates were lower in states with certificates of need than without certificates of need (246 862 [39.5%] vs 219 392 [42.5%]; $P<.001$) and were inversely related to certificate of need stringency (TABLE 3). Among patients undergoing revascularization within 30 days of admission, a higher proportion of patients underwent CABG as a first procedure in states with certificates of need compared with states without certificates of need (79 601 [32.2%] vs 65 369 [29.8%]; $P<.001$). Further analyses found that patients in states with certificates of need were less likely to be admitted initially to hospitals with revascularization (321 573 [51.5%] vs 323 695 [62.8%]; $P<.001$); the likelihood of admission to a hospital with revascularization was also inversely related to certificate of need stringency (205 852 [55.8%], 92 038 [49.7%], and 23 683 [33.8%], respectively, in states with low, moderate, and high stringency). Thirty-day revascularization rates were relatively similar for patients in states with and without certificates of need for subgroups admitted to hospitals with revascularization and to hospitals without revascularization (Table 3). Moreover, revascularization rates actually were highest in states with high certificate of need stringency in analyses stratified by whether patients were admitted to hospitals with or without revascularization.

Notable differences were observed in the timing of revascularization. Patients in states with certificates of need were less likely to undergo revascularization during the first 2 days after admission compared with patients in states without certificates of need but were slightly more likely to undergo revascularization on days 3 through 30 (TABLE 4). Similarly, patients in states with certificates of need were less likely to undergo revascularization at the admitting hospital but were more likely to undergo revascularization at a transfer hospital. The likelihood of revascularization at the admitting hospital decreased as certificate of need stringency increased, while the likelihood of revascularization at a transfer facility increased as certificate of need stringency increased.

The associations between certificates of need and the timing of revascularization persisted after adjusting for demographics, comorbidity, and AMI location using Cox proportional hazards regression. The likelihood of revascularization was 15% lower in states with certificates of need relative to states without certificates of need during the first 2 days after admission (hazard ratio [HR], 0.85; 95% confidence interval [CI], 0.79-0.91; $P<.001$). The likelihood of revascularization during the first 2 days decreased as certificate of need stringency increased; in states with low, medium, and high certificate of need stringency, HRs were 0.90 (95% CI, 0.84-0.97; $P=.009$), 0.80 (95% CI, 0.71-0.90; $P<.001$), and 0.68 (95% CI, 0.54-0.87; $P=.002$), respectively. These relationships were generally similar in analyses stratified by AMI location (TABLE 5), although the likelihood of revascularization during days 1 and 2

Table 2. Median Annual Hospital Volumes in Medicare Beneficiaries for AMI and Coronary Revascularization With Either Coronary Artery Bypass Graft Surgery or Percutaneous Coronary Intervention According to Certificate of Need Status*

Certificate of Need Status	Annual AMI Hospital Volume, Median (IQR)	Annual Revascularization Hospital Volume, Median (IQR)
No certificate of need regulations	29 (12-71)	236 (127-385)
Overall with certificate of need regulations	49 (19-108)	409 (214-702)
By stringency		
High	101 (59-107)	820 (354-107)
Moderate	55 (22-109)	467 (310-893)
Low	41 (16-100)	339 (189-599)

Abbreviations: AMI, acute myocardial infarction; IQR, interquartile range.
*$P<.001$ for the comparison of median annual hospital volumes in states with and without certificate of need regulations and $P<.001$ for the comparison of volumes between states with high-, moderate-, and low-stringency certificates of need and states without certificates of need.

Table 3. Revascularization Rates in States With and Without Certificate of Need Regulations According to Initial Admission to Hospitals With and Without Revascularization Services

	30-Day Revascularization Rates, No./Total (%)					*P* Value (Overall With vs Without Certificates of Need)	*P* Value for Trend*
	States With Certificates of Need, by Stringency				States Without Certificates of Need		
	High	Moderate	Low	Overall			
Hospitals without revascularization	13 231/ 46 357 (28.5)	24 348/ 92 038 (26.2)	44 572/ 163 370 (27.3)	82 151/ 302 848 (27.1)	51 882/ 191 676 (27.1)	.65	.09
Hospitals with revascularization	12 836/ 23 683 (54.2)	47 502/ 93 121 (51.6)	104 373/ 205 852 (50.7)	164 711/ 321 573 (51.2)	167 510/ 323 695 (51.8)	<.001	.10
All hospitals	26 067/ 70 040 (37.2)	71 850/ 185 159 (38.8)	369 222/ 369 222 (40.4)	246 862/ 624 421 (39.5)	219 392/ 515 371 (42.5)	<.001	<.001

*The *P* value for trend represents the comparison of revascularization rates across states with high-, moderate-, and low-stringency certificate of need regulations and states without certificate of need regulations.

in states with certificates of need was somewhat lower for subendocardial AMI than for other AMI locations. This was also consistent across certificate of need stringency categories.

In contrast, the likelihood of revascularization during days 3 through 30 was identical in states with and without certificates of need (HR, 1.00; 95% CI, 0.97-1.02; *P*=.80) and did not vary in states with high, medium, and low certificate of need stringency.

Unadjusted mortality rates were similar at 30 days in states with and without certificates of need (109 304 [17.5%] vs 90 104 [17.5%]; *P*=.76) and did not vary by certificate of need stringency (12 169 [17.4%], 31 833 [17.2%], and 65 302 [17.7%], respectively, in states with high, moderate, and low certificate of need stringency; *P*=.07). After adjusting for demographics, comorbidity, and AMI location, the odds of 30-day mortality were similar in states with certificates of need relative to states without certificates of need (odds ratio [OR], 1.00; 95% CI, 0.97-1.03; *P*=.90). Adjusted odds of death within certificate of need stringency groups were of borderline significance for high-stringency certificate of need states (OR, 0.95; 95% CI, 0.90-1.00; *P*=.07) but were similar for moderate- and low-stringency certificate of need states. These results were similar in analyses stratified by AMI location.

COMMENT

Using Medicare claims data for patients hospitalized for AMI during January 2000 through September 2003, the current study found that rates of coronary revascularization were lower in states with certificate of need regulations compared with states without certificates of need. Differences in rates were greatest in states with more stringent certificate of need programs. In addition, we found notable differences in the timing of revascularization, with patients in states with certificates of need less likely to undergo revascularization during the first 2 days after admission and more likely to be transferred to another acute care facility for revascularization. Differences in the timing of revascularization were also greater in states with more stringent certificates of need. Moreover, the impact of certificates of need on the use of early revascularization tended to be greater for patients with a principal diagnosis of subendocardial AMI, a group of patients for whom the clinical benefits of revascularization following AMI are less clear.

Additional analyses found that a higher proportion of patients with AMI in states with certificates of need are admitted to hospitals that do not provide coronary revascularization procedures and that the proportions of patients admitted to hospitals without revascularization were directly related to certificate of need stringency. Interestingly, in separate analyses of patients admitted to hospitals with and without revascularization services, rates of revascularization were actually higher in states with high-stringency certificate of need. In aggregate, these findings indicate that the lower overall use of revascularization in states with certificates of need is primarily driven by the fewer number of hospitals that offer such services.

Despite the lower use of early revascularization in states with certificates of

Table 4. Revascularization Rates Within 30 Days in States With and Without Certificate of Need Regulations, by Days Since Admission and by Hospital Admission

	Revascularization, No. (%)						
	States With Certificates of Need, by Stringency						
	High	Moderate	Low	Overall	States Without Certificates of Need	*P* Value (Overall With vs Without Certificates of Need)	*P* Value for Trend*
By days since admission							
1-2	9363 (13.4)	29 997 (16.2)	66 997 (18.2)	106 357 (17.0)	106 386 (20.6)	<.001	<.001
3-30	16 704 (23.8)	41 853 (22.6)	81 948 (22.2)	140 505 (22.5)	113 006 (21.9)	<.001	<.001
By hospital							
Admitting hospital	12 921 (18.5)	46 444 (25.1)	103 755 (28.1)	163 120 (26.1)	163 877 (31.8)	<.001	<.001
Transfer hospital	11 902 (16.9)	22 490 (12.1)	38 987 (10.6)	73 379 (11.7)	45 907 (8.9)	<.001	<.001
Readmission	1244 (1.8)	2906 (1.6)	6203 (1.7)	10 353 (1.7)	9608 (1.9)	<.001	<.001

*The *P* value for trend represents the comparison of revascularization rates across states with high-, moderate-, and low-stringency certificate of need regulations and states without certificate of need regulations.

Table 5. Hazard of Revascularization 1 to 2 Days After Admission Among Patients in States With Certificate of Need Regulations Relative to Patients in States With No Certificate of Need Regulations, Stratified by Location of AMI

	HR (95% CI) [*P* Value] of Revascularization on Days 1-2, by AMI Location			
	Subendocardial	Anterior or Lateral	Inferior or Posterior	Other Location
Overall with certificates of need	0.83 (0.76-0.89) [*P*<.001]	0.87 (0.82-0.93) [*P*<.001]	0.87 (0.81-0.93) [*P*<.001]	0.91 (0.81-1.01) [*P* = .09]
By stringency				
High	0.63 (0.48-0.82) [*P*<.001]	0.78 (0.62-0.96) [*P* = .02]	0.72 (0.57-0.91) [*P* = .006]	0.78 (0.58-1.03) [*P* = .09]
Moderate	0.77 (0.68-0.87) [*P*<.001]	0.83 (0.73-0.93) [*P* = .001]	0.83 (0.74-0.92) [*P*<.001]	0.87 (0.73-1.04) [*P* = .11]
Low	0.90 (0.82-0.98) [*P*<.001]	0.91 (0.85-0.98) [*P* = .01]	0.92 (0.86-0.99) [*P* = .02]	0.94 (0.83-1.07) [*P* = .37]

Abbreviations: AMI, acute myocardial infarction; CI, confidence interval; HR, hazard ratio.

need, no adverse associations with 30-day mortality were observed. While the beneficial effects of emergent revascularization on short-term mortality in patients with ST-elevation AMI are well known,[19] the lack of difference in AMI mortality in the current study may reflect a number of other factors. First, we also found that hospitals in states with certificates of need had higher volumes for both AMI and revascularization. The relationship between hospital volumes and outcomes of CABG and PCI is well documented.[20-22] Moreover, 2 prior studies of certificates of need found lower risk-adjusted mortality after CABG surgery[6] and PCI[7] in states with certificate of need regulations and associated these mortality advantages with higher revascularization volumes in states with certificates of need. Thus, the higher hospital volumes in states with certificates of need may counteract any adverse effects of limiting access to revascularization services.

Second, it is possible that certificates of need may decrease the use of revascularization in patients who are likely to derive marginal benefits from the procedures. Indeed, some ambiguity remains regarding appropriate indications for revascularization among patients who do not have ST-elevation AMI.[23-25] This possibility is also supported by results of studies that failed to discern better survival or lower rates of recurrent disease in association with higher use of coronary revascularization.[26-33] Finally, it is possible that the results of randomized trials on the beneficial effects of revascularization, which are likely conducted in higher-volume specialized medical centers, may not be generalizable to clinical practice.

This study has several limitations. First, the study design cannot discern a cause-and-effect relationship between certificates of need and use of revascularization or mortality. It is possible that relationships observed in the study reflect other aspects of care that are independent of certificates of need. These factors may include managed care penetration, regional physician practice variation, concurrent efforts to improve quality, or differences in other diagnostic and therapeutic choices (eg, use of thrombolytics, aspirin, β-blockers), which are not captured by administrative data. Second, the analysis was limited to Medicare beneficiaries and, thus, only includes older patients. However, it is likely that if patterns of care were different for Medicare patients relative to other patients, these differences would be similar across states and would not necessarily bias study findings. Third, our analysis of certificate of need stringency may not have accounted for all of the heterogeneity in certificates of need across states in terms of coverage limits, administrative review processes, and the intensity of enforcement. Furthermore, states without certificate of need regulations often have other regulatory restrictions, such as licensure or limits on capital diffusion. Finally, the development of risk-adjustment models based on administrative data is itself subject to limitations. The reliability of individual diagnoses codes may vary across hospitals, and important prognostic variables cannot be ascertained from administrative data.

Despite its limitations, the current study has several implications for health care policy. Existing perceptions of the general lack of effectiveness of certificate of need regulations are based on evidence showing its inability to control health care costs.[34] On the other hand, certificates of need may be effective in controlling the diffusion of costly medical technologies and services, such as open-heart surgery.[35,36] This potential effect of certificates of need is illustrated by the ongoing controversy over the emergence of specialty hospitals focusing on lucrative aspects of medical practice, such as orthopedic and cardiac procedures.[37] Most of these hospitals have appeared in states without certificates of need,[38] presumably because of reduced barriers to entry. While the temporary moratorium placed by the federal government on further specialty hospital development has expired,[39] the market factors that have encouraged their emergence remain.

Although certificates of need may be effective in limiting the expansion of some services and may promote the development of clinical centers of excellence, the role of certificates of need on a national level would be best debated in the context of empirical evidence of the impact of certificates of need on the quality and effectiveness of health care delivery. Thus, the current findings are important because they add to a relatively sparse knowledge base about the effects of certificates of need on patient outcomes. In this study, while the presence of certificate of need regulations and the stringency of these regulations were associated with lower use of revascularization after AMI, no adverse effects on mortality could be demonstrated.

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Study concept and design: Popescu, Vaughan-Sarrazin, Rosenthal.
Acquisition of data: Vaughan-Sarrazin, Rosenthal.
Analysis and interpretation of data: Popescu, Vaughan-Sarrazin, Rosenthal.
Drafting of the manuscript: Popescu, Rosenthal.
Critical revision of the manuscript for important intellectual content: Popescu, Vaughan-Sarrazin, Rosenthal.
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