

# Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON

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**Objectives.** To test whether state Certificate of Need (CON) regulations influence procedural mortality or the provision of coronary artery bypass graft surgery (CABG) and percutaneous coronary interventions (PCI).

**Data Sources.** Medicare inpatient claims obtained for 1989–2002 for patients age 65+ who received CABG or PCI.

**Study Design.** We used differences-in-differences regression analysis to compare states that dropped CON during the sample period with states that kept the regulations. We examined procedural mortality, the number of hospitals in the state performing CABG or PCI, mean hospital volume, and statewide procedure volume for CABG and PCI.

**Principal Findings.** States that dropped CON experienced lower CABG mortality rates relative to states that kept CON, although the differential is not permanent. No such mortality difference is found for PCI. Dropping CON is associated with more providers statewide and lower mean hospital volume for both CABG and PCI. However, statewide procedure counts remain the same.

**Conclusions.** We find no evidence that CON regulations are associated with higher quality CABG or PCI. Future research should examine whether the greater number of hospitals performing revascularization after CON removal raises expenditures due to the building of more facilities, or lowers expenditures due to enhanced price competition.

**Key Words.** Certificate of need, CABG, PCI, panel data methods

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Policy makers and providers seek to insure provision of high-quality health care while restraining cost growth. Many states pursue these two goals by enforcing Certificate of Need (CON) regulations, which require hospitals to obtain approval from a designated state agency before installing additional capacity or offering especially costly services. Federal law required that all states maintain CON for cardiac care in 1978. These regulations expired in 1986, leading many states to discontinue cardiac CON in the mid-1980s.

This study tests whether presence of cardiac CON regulations is associated with lower mortality or differences in the number of cardiac procedures performed in a state. Past studies reached conflicting conclusions on the effects of cardiac CON. A study by Vaughan-Sarrazin et al. (VS) found that the risk-adjusted odds of death for Medicare patients who received coronary artery bypass graft surgery (CABG) between 1994 and 1999 was 22 percent higher in states without CON for open heart surgery versus states with CON ( $p < .001$ ) (Vaughan-Sarrazin et al. 2002). The authors hypothesize that CON restricts the number of health care providers, leading to higher hospital procedure volume. Higher CABG volume has been associated with lower mortality rates in previous studies (Showstack et al. 1987; Hannan et al. 1989).

In contrast, an analysis by DiSesa et al. (DS) using cardiac registry data from 2000 to 2003 found no significant difference in risk-adjusted mortality for CABG patients in states with and without CON (DiSesa et al. 2006). Another study by Ho using hospital discharge abstracts for 1989–2000 from the Nationwide Inpatient Sample collected by AHRQ HCUP found a significant association between inpatient mortality and CON status for CABG, but the magnitude of the effect was much smaller than that identified by VS (Ho 2007).

The analyses conducted by VS and DS attribute any unexplained difference in risk-adjusted mortality between states with and without CON to the impact of the regulations. However, the differential may be due to state-level factors that influence outcomes through mechanisms unrelated to CON (DiSesa et al. 2006). DS conduct subanalyses adding state random effects to the regressions, which account for some unobserved heterogeneity, but not all types. Ho reduces concerns regarding state-level heterogeneity by estimating fixed effect regressions, which allow one to measure within-hospital changes in mortality associated with each year after which cardiac CON regulations were removed in a state. However, Ho's estimates mix mortality changes for states that dropped CON in the mid-1980s with those of states that dropped cardiac CON regulations more recently. If technology for cardiac surgery has improved over time, then the blending of mortality changes that resulted after

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CON removal, but along different points of the technology continuum, may yield misleading results.

This paper compares the experience *within* states, before and after removal of cardiac CON regulations, yielding an estimate of the effects of CON, which is less subject to between-state heterogeneity concerns. We compare changes in patient mortality and the delivery of CABG and percutaneous coronary interventions (PCI) over time for states that dropped CON with states that maintained CON throughout the sample period. In doing so, we are better able to control for changes in patient mortality, which are contemporaneous with the removal of CON but unrelated to the regulations. By limiting the analysis to states that dropped cardiac CON most recently, we avoid concerns regarding the blending of estimates of the effects of CON regulations from different time periods. The results have important implications for regulators, who are concerned about the advantages and disadvantages of CON regulation.

## METHODS

### *Data*

We obtained data for Medicare beneficiaries ages 65 and over who received CABG surgery or PCI between 1989 and 2002. Inpatient data for 1991 through 2002 were drawn from Center for Medicare and Medicaid Services (CMS) MedPAR files, and data for 1989 and 1990 came from comparable inpatient files collected by CMS. PCI (including stents) was defined based on ICD-9-CM codes 36.0, 36.00, 36.01, 36.02, or 36.05 and CABG based on ICD-9-CM codes 36.1x in any field of the inpatient claim. Patients were counted once for both PCI and CABG if they received both during a hospital stay, but multiple occurrences of the same type of revascularization during the same hospital stay were not counted.

For patient-level analyses, the outcome variable of interest was procedural mortality for CABG or PCI (death during the same hospitalization as revascularization, or after discharge but within 30 days of surgery; Likosky et al. 2006). For state-level analyses, the outcome variables of interest were the number of facilities, the average hospital procedure volume, and the total number of CABG or PCI procedures performed on Medicare beneficiaries in a given state and year.

The explanatory variable of interest was the removal of state CON regulations for cardiac care. Information on CON status for open-heart

surgery and PCI were obtained from a survey of state health departments conducted by the American Health Planning Agency (AHPA). The details and results of the survey have been described elsewhere (Ho et al. 2007). We grouped states according to whether they maintained cardiac CON through 2002 for either PCI or open-heart surgery, versus states that dropped CON between 1989 and 2002. Seven states dropped CON for open-heart surgery during the sample period. Of these seven, six simultaneously dropped CON for cardiac catheterization. The seventh state, Delaware, did not have CON regulations for PCI during the study period. These states were compared with the 27 states that maintained CON for open-heart surgery and the 25 states that maintained CON for PCI through 2002.

We excluded data for patients treated in states that dropped cardiac CON regulations before 1989. We only have information on these states' experiences after CON regulations were dropped, not before, which is necessary for within-state comparisons. For this same reason, we excluded data from Maryland and Massachusetts in the analysis of PCI patients. These two states dropped CON for cardiac catheterization in 1990 (while maintaining CON for open heart surgery), so that there was relatively little data for the period before removal of CON.

The number of CABG or PCI procedures performed by the admitting hospital during the year the patient was treated was included as an explanatory variable in the patient-level regressions. We excluded patients treated in hospitals with < 3 procedures a year because of miscoding concerns. The studies by VS and DS excluded procedure volume, reasoning that CON influenced patient outcomes by raising average hospital volume. This analysis reports results with and without hospital volume, so that one can test whether an association exists between CON and procedural mortality even after adjusting for volume.

Several variables were included in the patient-level regressions for risk adjustment. The demographic variables included sex, age (in 5-year categories), race (black/white/other), and income. The patient's zip code of residence was used to identify the median household income as reported in the U.S. Census. Census data from 1990 and 2000 were used to extrapolate income for each year and zip code in the sample, which were then adjusted for inflation using the Bureau of Labor Statistics All Urban Consumer Price index. The secondary diagnosis codes were used to construct indicator variables for the 29 conditions comprising the Elixhauser comorbidity index (Elixhauser et al. 1998). Indicator variables were included for patients with a primary diagnosis of acute myocardial infarction (AMI) at admission, patients transferred from

another hospital, and patients whose admission status was urgent or emergent. For CABG patients, indicator variables were included for patients who received cardiac catheterization or PCI on the same day as the CABG procedure, or received an intra-aortic balloon pump before the day of the CABG procedure. For PCI patients, indicator variables were included for multivessel PCI and coronary stent insertion.

The Medicare data were merged with the American Hospital Association Annual Surveys, which contain additional hospital-level information. Hospitals affiliated with a medical school were defined as teaching hospitals. Hospitals located in a Metropolitan Statistical Area were categorized as urban (versus rural). Hospitals were classified as nonprofit, government, or for-profit facilities.

Following previous research, regressions explaining average hospital volume for CABG and PCI included controls for the population age 65+ per square mile and the HMO penetration rate in the hospital's county of operation in each year, and smoking rates by state and year (Ho 2007). The state-level regressions included controls for population and market characteristics that have been associated with revascularization rates in previous studies (Ayanian and Epstein 1991; Heidenreich et al. 2002). We collected information on the percent uninsured (U.S. Census Bureau 2006), the annual share of the population enrolled in an HMO (National Center for Health Statistics 2004), and smoking rates by state and year (CDC 2006).

### *Statistical Analysis*

Mean hospital procedure volumes and procedural mortality rates for CABG and PCI by year and whether states maintained cardiac CON or dropped the regulations during the sample period are graphed to illustrate unadjusted differences in the data by CON status. Multivariable logistic regressions are used to estimate the association between CON status and procedural mortality, average procedure volume, the number of providers in the state, and the total number of procedures in the state, adjusting for covariates. Separate regressions were estimated for CABG and PCI.

Similar to VS and DS, we measured CON using a 0,1 indicator for presence or absence of CON in the year the patient was treated. But unlike these studies, we only include data from states that dropped CON during the sample period or maintained CON through the end of the sample. In doing so, we obtain a direct comparison of trends in states that dropped cardiac CON regulations versus states that maintained CON. This specification is known as

a differences-in-differences analysis in the economics literature. The first “difference” is a before-versus-after comparison of states that dropped CON during the sample period. The second “difference” is the contemporaneous experience of states that maintained CON, which serves as a control group for factors unrelated to CON that influenced outcomes in all states. Unlike VS and DS, the regressions also include state-level fixed effects. Therefore, the coefficient on the CON variable provides a *within*-state measurement of the association between dropping CON and the dependent variables of interest.

To test whether the effects of dropping CON change over time, we estimate additional regressions where we interact the CON variable with indicator variables for whether a patient was treated in a state 1 year before CON was dropped, the year CON was dropped, 1 year after, 2 years after, or 3 or more years after CON was dropped. Testing for an effect the year before CON regulations are dropped serves as a consistency check. We should find no significant association between dropping CON and outcomes the year before the regulations are dropped. If the effects of CON are still statistically significant at the 95 percent confidence level 3+ years after cardiac CON regulations were dropped, we continue to add interaction variables 1 year at a time, until we find no significant effect, or we reach the end of the sample period.

The regressions are estimated in *Stata* 10.0. The procedural mortality regressions are estimated using the *glm* command, which allows one to estimate a logistic model. The hospital and state procedure volume regressions were estimated using the *xtreg* command, which estimates linear panel data models. The regressions explaining the number of hospitals performing each procedure were estimated with the *nbreg* command, which estimates negative binomial regressions for nonnegative count data. The coefficients from the *nbreg* command are transformed so that they can be interpreted as the percentage change in the number of facilities associated with the dropping of CON. All of these regressions include state-level fixed effects and adjust the standard errors to account for the clustering of patients within hospitals for the patient-level regressions and within state for the hospital- and state-level regressions (Wooldridge 2003). Fixed effects estimates were obtained by including dummy variables for each state in the *glm* and *nbreg* regressions.

To improve the efficiency of the standard errors for our estimates, we excluded indicator variables for the components of the Elixhauser comorbidity index that had low explanatory power for procedural mortality. Comorbidities with a *p*-value > .05 in an OLS regression of procedural mortality on the full set of 29 comorbidities were excluded from the fixed effect esti-

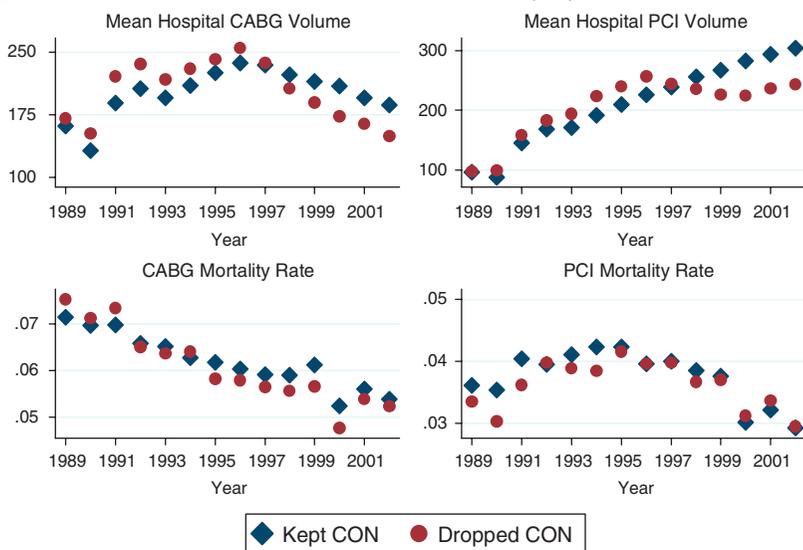
mates. For both CABG and PCI, the indicators for HIV and AIDS, alcohol abuse, drug abuse, and chronic peptic ulcer disease were excluded. The indicators for blood loss anemia, complicated hypertension, hypothyroidism, lymphoma, and solid tumor without metastasis were dropped for CABG as well. The indicator for depression was dropped for PCI.

## RESULTS

The sample contained data on 1,580,186 CABG and 1,730,733 PCI procedures from 1989 to 2002. Figure 1 graphs the mean procedure volume and mean procedural mortality rates for CABG and PCI for states that maintained cardiac CON regulations through 2002, and for those states that dropped the regulations during the study period. The seven states that dropped CON (DE, ND, NE, NV, OH, OR, and PA) did so within a narrow time frame, between 1995 and 1998.

For both CABG and PCI, mean hospital volume peaks in 1996 for states that dropped cardiac CON regulations between 1995 and 1998. For both procedures, mean hospital volume in 1998 for these states falls below that for states that maintained CON; and remains lower through 2002. Previous

Figure 1: Mean Procedure Volume and Mortality by CON Status



literature on the volume–outcome relationship for cardiac procedures would suggest that these declines in mean procedure volume would be associated with increases in patient mortality. However, states that dropped cardiac CON between 1995 and 1998 appear to have higher or equal unadjusted CABG mortality relative to states that maintained CON through 1994; but lower unadjusted CABG mortality relative to CON states in 1995 through 2002. For the most part, there appears to be no such systematic difference in mortality rates by CON status for PCI. These unadjusted data require more detailed examination in the context of regression analyses.

Table 1 presents estimates of the association between CON status and procedural mortality for CABG and PCI. Column 1 indicates that removal of CON is associated with significantly lower mortality for CABG (OR = 0.898,  $p < .001$ ). When we examine the effects of dropping CON by year in Column 2, we find no tangible association with procedural mortality in the year before dropping CON, or the year when CON was dropped. The significant association between dropping CON and mortality is in the years 1 (OR = 0.928,  $p = .03$ ), 2 (OR = 0.855,  $p = .003$ ), and 3 or more years (OR = 0.887,  $p = .003$ ) after removal of the regulations. When we add additional 1-year interaction terms, we find in Column 3 that the association between CON removal and procedural mortality for CABG patients becomes insignificant 5 or more years out (OR = 0.918,  $p = .08$ ). Although we do not report the results here, adding an additional interaction term 6 or more years beyond CON removal yields an even less precise association between dropping CON and mortality (OR = 0.915,  $p = .22$ ).

Columns 4 and 5 of Table 1 suggest no association between removal of cardiac CON regulations and procedural mortality for PCI. All of the specifications in Table 1 suggest a significant association between hospital procedure volume and procedural mortality. In each case the odds ratio lies between 0.999 and 1.0, and the  $p$ -values are well under 0.05. We re-estimated all of the regressions in Table 1 excluding hospital procedure volume, to test whether the beneficial volume effect would lead to a positive association between CON removal and procedural mortality. In each case, the coefficient estimates and  $p$ -values changed only slightly, and the conclusions regarding the effects of dropping CON remained the same.

Column 1 of Table 2 indicates the removal of CON is associated with 31 percent lower mean hospital volume for CABG ( $p = .009$ ). Column 2 suggests that the drop in procedure volume begins the year that CON is removed (– 13 percent,  $p = .03$ ). The magnitude of the drop increases in each subsequent year, reaching 37 percent ( $p = .008$ ) for 3 years or more beyond the removal of

Table 1: Logistic Estimates of the Association between CON and Procedural Mortality for CABG and PCI

	CABG		PCI		
	(1)	(2)	(3)	(4)	(5)
After CON dropped	0.898** (0.848, 0.950)			1.019 (0.963, 1.079)	
1 year before CON dropped		0.964 (0.881, 1.054)	0.964 (0.881, 1.055)		1.028 (0.944, 1.120)
Year CON dropped		0.980 (0.902, 1.064)	0.980 (0.903, 1.064)		1.032 (0.934, 1.139)
1 year after CON dropped		0.928* (0.869, 0.990)	0.928* (0.869, 0.990)		1.040 (0.961, 1.125)
2 years after CON dropped		0.855** (0.771, 0.949)	0.855** (0.770, 0.950)		1.030 (0.946, 1.111)
3+ years after CON dropped		0.887** (0.820, 0.960)			1.03 (0.962, 1.102)
3 years after CON dropped			0.864** (0.810, 0.921)		
4 years after CON dropped			0.877* (0.782, 0.983)		
5+ years after CON dropped			0.918 (0.836, 1.009)		
Hospital volume	0.9996** (0.9995, 0.9997)	0.9996** (0.9995, 0.9997)	0.9996** (0.9995, 0.9997)	0.9999* (0.9999, 0.9999)	0.9999* (0.9998, 0.9999)
Sample size		1,580,186			1,730,733

Regressions include indicator variables for each sample year, sex, age, race, transfer patient, urgent and emergent admissions, principal diagnosis of AMI, Elixhauser comorbidities, teaching hospital, urban hospital, and nonprofit or government-owned hospital, as well as income, a constant, and state-level fixed effects. CABG regressions also include indicators for same-day PCI, same-day cardiac catheterization, and use of an intra-aortic balloon pump on the day prior to CABG. PCI regressions also include indicators for multivessel PCI and coronary stent placement.

\* $p$ -value  $\leq .05$ .

\*\* $p$ -value  $\leq .01$ .

AMI, acute myocardial infarction; CABG, coronary artery bypass graft surgery; CON, certificate of need; PCI, percutaneous coronary interventions.

Table 2: Estimates of the Association between CON and Hospital Volume for CABG and PCI

	CABG			PCI		
	(1)	(2)	(3)	(4)	(5)	(6)
After CON dropped	- 0.311** (- 0.537, - 0.085)					
1 year before CON dropped		- 0.041 (- 0.108, 0.026)	- 0.042 (- 0.109, 0.024)	- 0.293** (- 0.486, - 0.099)	0.036 (- 0.087, 0.159)	0.035 (- 0.089, 0.160)
Year CON dropped		- 0.132* (- 0.250, - 0.013)	- 0.131* (- 0.249, - 0.014)		- 0.047 (- 0.228, 0.134)	- 0.046 (- 0.227, 0.134)
1 year after CON dropped		- 0.232** (- 0.384, - 0.079)	- 0.229** (- 0.379, - 0.079)		- 0.171** (- 0.275, - 0.067)	- 0.170** (- 0.274, - 0.065)
2 years after CON dropped		- 0.339** (- 0.550, - 0.129)	- 0.339** (- 0.548, - 0.129)		- 0.313** (- 0.453, - 0.173)	- 0.313** (- 0.451, - 0.176)
3+ years after CON dropped		- 0.369** (- 0.635, - 0.104)			- 0.327** (- 0.537, - 0.117)	
3 years after CON dropped			- 0.267* (- 0.475, - 0.059)			- 0.257* (- 0.460, - 0.055)
4 years after CON dropped			- 0.362 (- 0.616, - 0.108)			- 0.354* (- 0.629, - 0.080)
5 years after CON dropped			- 0.442* (- 0.779, - 0.105)			- 0.364** (- 0.520, - 0.209)
6 years after CON dropped			- 0.525** (- 0.773, - 0.278)			- 0.379** (- 0.566, - 0.193)
7 years after CON dropped			- 0.259 (- 0.598, 0.081)			- 0.286 (- 0.721, 0.149)
Sample size		7,857			8,233	

Regressions include indicator variables for each sample year, the log of population per square mile in the hospital's county, the county's HMO penetration rate, and the state smoking rate by year, as well as a constant, and state-level fixed effects.

<sup>†</sup>Dependent variable = Natural log of hospital volume.

\*  $p$ -value  $\leq .05$ .

\*\*  $p$ -value  $\leq .01$ .

CABG, coronary artery bypass graft surgery; CON, certificate of need; PCI, percutaneous coronary interventions.

CON for open heart surgery. The relative decrease in volume continues out to 6 years beyond CON removal in Column 3 (– 53 percent,  $p = .012$ ), although the differential becomes insignificant 7 years after CON removal, at the end of the sample period (– 26 percent,  $p = .13$ ).

Columns 4 through 6 of Table 2 suggest similar findings for PCI. On average, removal of cardiac CON is associated with a 29 percent drop in mean hospital volume ( $p = .004$ ). Column 6 indicates that the effect is tangible 1 year after CON is removed (– 17 percent,  $p = .002$ ), and increases in magnitude up to 6 years after removal of CON (– 38 percent,  $p < .001$ ).

We find in Column 1 of Table 3 that dropping CON is associated with 15.2 percent increase in the number of hospitals performing CABG ( $p = .001$ ). More detailed analysis in Column 2 indicates that 4.7 percent ( $p = .049$ ) additional facilities are present the year that cardiac CON is dropped, and 17.3 percent ( $p = .003$ ) more hospitals are performing CABG 3 or more years out. In Column 3, we find that dropping CON is associated with 24.6 percent ( $p = .001$ ) more hospitals performing CABG up to 6 years after CON is dropped.

Columns 4 through 6 suggest similar findings for PCI. On average, removal of CON is associated with a 12.1 percent ( $p < .001$ ) increase in the number of hospitals performing PCI. Column 6 indicates that the effect is tangible 1 year after CON removal (7.7 percent,  $p = .004$ ) and increases in magnitude to 13.7 percent ( $p < .001$ ) up to 5 years after CON removal.

To conserve space, we do not report the coefficient estimates relating CON removal to the statewide number of procedures performed. However, for both CABG and PCI, we find no significant association between removal of CON and the total number of procedures performed. For example, the estimated association between CON removal and the percentage change in statewide procedures is – 5.9 percent ( $p = .44$ ) for CABG and – 13.8 percent ( $p = .22$ ) for PCI.

## DISCUSSION

We find that removal of state cardiac CON regulations is associated with an increase in the number of hospitals performing CABG and PCI. The statewide number of procedures is unaffected by CON removal, so that average procedure volume per hospital for both CABG and PCI declines relative to states that maintained these regulations. These differentials between states that dropped cardiac CON regulations in the 1990s versus states that maintained

Table 3: Negative Binomial Regression Estimates<sup>†</sup> of the Association between CON and the Number of Hospitals Performing CABG and PCI

	CABG			PCI		
	(1)	(2)	(3)	(4)	(5)	(6)
After CON dropped	15.2** (11.1, 19.3)			12.1** (8.9, 15.3)		
1 year before CON dropped		0.3 (0.3, 0.3)	0.2 (0.2, 0.2)	-3.6 (-4.0, -3.2)	-3.6 (-4.0, -3.2)	
Year CON dropped		4.7* (4.1, 5.3)	4.7* (4.1, 5.3)	-0.3 (-0.3, -0.3)	-0.3 (-0.3, -0.3)	
1 year after CON dropped		11.8** (10.4, 13.2)	11.8** (10.4, 13.2)	7.7** (6.8, 8.6)	7.7** (6.8, 8.6)	
2 years after CON dropped		16.3** (14.5, 18.1)	16.3** (14.5, 18.1)	13.4** (11.9, 14.9)	13.4** (11.9, 14.9)	
3+ years after CON dropped		17.3** (13.5, 21.1)		12.2** (9.6, 14.8)		
3 years after CON dropped			14.7** (13.0, 16.4)		10.3** (9.2, 11.4)	
4 years after CON dropped			17.8** (15.8, 19.8)		14.1** (12.6, 15.6)	
5 years after CON dropped			18.1** (16.2, 20.0)		13.7** (12.3, 15.1)	
6+ years after CON dropped					11.0 (9.7, 12.3)	
6 years after CON dropped			24.6** (22.3, 26.9)			
7 years after CON dropped			4.0 (3.7, 4.3)			
Sample size		476			448	

Regressions include indicator variables for each sample year, the log of population per square mile in the hospital’s county, the county’s HMO penetration rate, and the state smoking rate by year, as well as a constant, and state-level fixed effects.

<sup>†</sup>Coefficient estimates have been converted to represent percentage changes.

<sup>‡</sup>Dependent variable = Natural log of hospital volume.

\*p-value ≤ .05.

\*\*p-value ≤ .01.

CABG, coronary artery bypass graft surgery; CON, certificate of need; PCI, percutaneous coronary interventions.

them are statistically significant as many as 5 years after removal of the regulations. Adjusting for differences in hospital volume, we find a within-state reduction in procedural mortality for CABG up to 4 years after CON regulations have been dropped.

The increase in providers after CON removal is consistent with a previous study documenting Pennsylvania’s experience with removal of CON

regulations (Robinson et al. 2001), and prior studies have associated CON with higher hospital volume for CABG and/or PCI (Vaughan-Sarrazin et al. 2002; DiSesa et al. 2006; Ho 2007). We differ from previous studies in finding that removal of CON is associated with lower CABG mortality. Previous studies relied on adjusted cross-section variation in the experience of states with and without CON regulations to measure the impact of the regulations, and are therefore more subject to confounding from unobservable heterogeneity across states. For example, if states that maintained CON tended to be those where hospitals generally had shorter anesthesia times, faster adoption of digital imaging, or greater use of anticoagulants, then cross-section analysis may attribute any mortality effects to CON, even if it is unrelated to the regulations.

In contrast, the differences-in-differences approach we utilize attributes a change in outcomes to CON only if the change is concurrent with the removal of CON regulations, *and* if the change in outcomes differs from that observed in states that maintained CON over the same time period. In addition, state fixed effects allow one to focus on changes within each state, so that the results are not confounded by systematic differences in unobservables, such as anesthesia times or anticoagulant use across states.

Why might the removal of cardiac CON be associated with lower mortality? Perhaps the elimination of CON oversight led hospitals to alter their casemix for CABG, avoiding surgery for lower income, high-risk patients that many CON regulators would expect to be treated; and treating additional lower risk patients instead. To test this hypothesis, we calculated the expected mortality for each CABG patient by estimating logistic regressions of mortality as a function of patient characteristics by year. We regressed predicted mortality rates derived from these regressions on the CON indicator variable, and the hospital characteristics, year indicators, and state dummy variables used in our previous regressions. We find that removal of state CON regulations is associated with a 0.1 percent ( $p < .001$ ) increase in expected mortality rates. Given that observable patient characteristics suggest that CON removal is associated with treatment of a higher risk patient population, we conclude that it is unlikely that deregulated hospitals shifted their casemix toward unobservably lower risk patients.

It may be that removal of CON led state regulators to consider other options for oversight that improved the quality of care for CABG patients. We contacted the state health departments in all seven states that dropped CON in the 1990s to inquire about their experience with cardiac CON removal. Both Ohio and Pennsylvania introduced requirements around the time that CON regulations were dropped, that hospitals report CABG

outcome data to the state health department. Hospitals were notified that poor outcomes could trigger a detailed licensing review by the state (Maryland Health Care Commission 2000). The CON regulations in these two states contained minimal oversight of facilities once they received initial approval to open. Therefore, the new oversight measures may have led to reductions in procedural mortality. None of the five remaining states introduced new oversight regulations for CABG. Moreover, none of the seven states received additional funds to support oversight of CABG programs after CON was dropped. The lack of funding may explain why the decrease in procedural mortality for CABG patients after CON was dropped lasted for 4 years, and not longer.

The temporary drop in CABG mortality after CON removal may also represent a Hawthorne effect. Short-term improvements in productivity associated merely with observing worker performance were first identified in a series of experiments at the Hawthorne Works company from 1924 to 1932 (Landsberger 1958). It may be that hospitals temporarily devoted more attention to outcomes improvement for CABG, because they were concerned that removal of CON would lead to additional scrutiny of their performance, and perhaps new regulatory measures. This effect would be more plausible for CABG versus PCI, because mean CABG mortality rates are higher, and therefore greater cause for concern by both hospitals and regulators.

Our results differ from those reported by Ho et al. (2007), which used the same dataset we analyzed, but found that CON was successful in restraining the number of PCI procedures performed relative to non-CON states. However, the prior study did not include either state-level random or fixed effects to control for unobserved differences in the propensity to perform PCI across states. For example, if states with CON tended to have physicians who were more likely to recommend medical management of angina rather than interventional therapy, failure to include either state random or fixed effects may cause this correlation to be reflected in the coefficient on the CON indicator variable.

There are several caveats to our analysis. The MedPAR data only contains information for the Medicare population, not the population under age 65. We examined data for all hospitals with CABG and PCI patients in the AHRQ HCUP dataset from 1988 to 1999. For the 2,034 hospital/years in this dataset, the correlation between the procedure volumes for the 65+ population and the total population is 0.98. Therefore, differences across hospitals in the number of patients aged 65+ receiving either CABG or PCI are an

excellent proxy for differences in the total number of patients receiving these procedures at a given hospital.

The MedPAR database lacks information on Medicare HMO patients, who are younger, have less disability, and lower mortality rates than fee-for-service patients (Maciejewski et al. 2001). In the mortality regressions, year dummies and fixed effects were included in the regressions to account for differences in managed care penetration across states. In addition, the state regressions included managed care penetration as a control variable.

We lack information on ejection fraction, rates of left main disease, smoking, and hypercholesterolemia, which may influence the need for revascularization. No database contains information on these variables by state for our study period. Thus, we are limited in our ability to compare procedure appropriateness in CON and non-CON states. However, past research finds no association between cardiac revascularization and admission rates for AMI for Medicare patients across different parts of the United States (The Center for the Clinical Evaluative Sciences and The Center for Outcomes Research and Evaluation 1999). These findings suggest that heart disease risk factors are not the principal cause of variability in revascularization rates between CON and non-CON states.

Despite these caveats, the results have important implications for the debate regarding the benefits of regulation for cost control. Dropping CON does not appear to influence the statewide number of CABG or PCI procedures, but spreads these revascularizations over a larger number of facilities. Both CABG and PCI have significant fixed costs, and lower hospital volume has been associated with higher costs per patient for both of these procedures (Ho 2002; Ho and Petersen 2007). Therefore, cardiac CON regulations may be successful in restraining cost growth, by limiting fixed cost investments in cardiac surgery to fewer facilities. This hypothesis requires careful future study, because a previous comprehensive analysis based on both primary data collection and review of the previous literature found no evidence that CON succeeded in hospital cost containment or reducing total expenditures per capita (Conover and Sloan 1998). However, this past study found no evidence of a surge in expenditures or bed supply after CON laws were lifted, whereas we found a significant association between lifting CON and the number of hospitals offering CABG and PCI. In addition, the prior study by Conover and Sloan was based on data from 1980 to 1993, before the series of CON changes that we examined. Future research should also test whether removal of CON for CABG and PCI is associated with enhanced price competition. More providers in the market may lead hospitals to lower the price of cardiac services for private-pay patients.

Cardiac CON regulations often require that facilities providing open-heart surgery provide hematology, nephrology, radiology, and neurology services, intensive care, and 24-hour emergency care for cardiac emergencies. Even though these requirements should improve quality, we find no evidence that cardiac CON regulations lower procedural mortality rates for CABG or PCI. Nevertheless, the additional oversight introduced by Ohio and Pennsylvania after the removal of cardiac CON leaves open the possibility that some form of regulatory intervention may be beneficial for patient outcomes. As states seek to restrain cost growth while encouraging the provision of high-quality care, the benefits and costs of alternative regulatory interventions should be carefully weighed for each medical treatment.

## ACKNOWLEDGMENTS

*Joint Acknowledgment/Disclosure Statement:* Support was given from a grant awarded to Dr. Ho by the National Heart, Lung, and Blood Institute (R01 HL073825-01A1).

*Disclosures:* None.

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## SUPPORTING INFORMATION

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Appendix SA1: Author Matrix.

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