Certificate of Need Peer Reviewed Studies

Relevant Literature

1. **Cantor, J. C.; DeLia, D.; Tiedemann, A.; Stanley, A.; Kronebusch, K. Reducing racial disparities in coronary angiography. Health Aff (Millwood). 2009;28:1521-31.**

ABSTRACT: Racial disparities in cardiac services are well documented; however, policies to close these gaps have not been studied. This paper evaluates a New Jersey certificate-of-need reform to reduce disparities in diagnostic coronary angiography. The number of angiography facilities in New Jersey doubled following reform, and a large black-white disparity was eliminated-a trend not observed in nearby states. Surprisingly, increases in service to African American patients following reform were concentrated in hospitals licensed before reform, while the newly licensed facilities contributed relatively little to reducing disparities. We hypothesize that added hospital competition contributed to the reduction in disparities.

2. **Conover, C. J.; Sloan, F. A. Does removing certificate-of-need regulations lead to a surge in health care spending? *J Health Polit Policy Law.* 1998;23:455-81.**

ABSTRACT: This study assesses the impact of certificate-of-need (CON) regulation for hospitals on various measures of health spending per capita, hospital supply, diffusion of technology, and hospital industry organization. Using a time series cross-sectional methodology, we estimate the net impact of CON policies on costs, supply, technology diffusion, and industry organization, controlling for area characteristics, the presence of other forms of regulation, such as hospital rate-setting, and competition. Mature CON programs are associated with a modest (5 percent) long-term reduction in acute care spending per capita, but not with a significant reduction in total per capita spending. There is no evidence of a surge in acquisition of facilities or in costs following removal of CON regulations. Mature CON programs also result in a slight (2 percent) reduction in bed supply but higher costs per day and per admission, along with higher hospital profits. CON regulations generally have no detectable effect on diffusion of various hospital-based technologies. It is doubtful that CON regulations have had much effect on quality of care, positive or negative. Such regulations may have improved access, but there is little empirical evidence to document this.

3. **Hellinger, F. J. The effect of certificate-of-need laws on hospital beds and healthcare expenditures: an empirical analysis. *Am J Manag Care.* 2009;15:737-44.**

ABSTRACT: OBJECTIVE: To estimate the effect of certificate-of-need legislation on hospital bed supply and healthcare expenditures. STUDY DESIGN: This study uses state data on several variables, including healthcare expenditures, hospital bed supply, and the existence of a certificate-of-need program, from 4 periods (1985, 1990, 1995, and 2000). METHODS: We estimate 2 multivariate regression equations. In the first equation, hospital bed supply is the dependent variable, and certificate of need is included as an independent variable. In the second equation, healthcare expenditures is the dependent variable, and hospital bed supply and certificate of need are included as independent variables. RESULTS: Certificate-of-need laws have reduced the number of hospital beds by about 10% and have reduced healthcare expenditures by almost 2%. Certificate-of-need programs did not have a direct effect on healthcare expenditures. CONCLUSION: Certificate-of-need programs have limited the growth in the supply of hospital beds, and this has led to a slight reduction in the growth of healthcare expenditures.

4. **Ho, V. Certificate of need, volume, and percutaneous transluminal coronary angioplasty outcomes. *Am Heart J.* 2004;147:442-8.**

ABSTRACT: BACKGROUND: Florida seeks high hospital volumes for percutaneous transluminal coronary angioplasty (PTCA) by enforcing certificate of need (CON) laws, whereas California has no such laws. This study compares the volume-outcome relation for PTCA in Florida and California. METHODS: The relation between the number of PTCA procedures performed at hospitals and the rate of in hospital bypass graft surgery and death for 292,457 patients in Florida and 390,880 patients in California between 1988 and 1998 was examined with descriptive statistics and logistic regressions. RESULTS: In 1988, the mean hospital PTCA volumes in Florida (237) and California (218) were not significantly different (P =.44). By 1998, Florida hospital volumes were significantly larger (724 vs 389, P <.001). Logistic regressions indicate that higher log (volume) was associated with lower mortality and urgent bypass grafting rates in both Florida and California during the sample period. Regression estimates indicate that a California hospital with the mean 1998 PTCA volume of 389 procedures had a predicted inpatient mortality rate of 1.4% and urgent bypass grafting rate of 2.2%. If the PTCA volume was raised to the 1998 Florida mean of 724 procedures, the inpatient mortality rate would not fall, although urgent bypass

grafting rates were predicted to fall to 2.0%. CONCLUSIONS: Florida CON laws were associated with higher average PTCA volumes relative to California hospitals, where no such laws exist. Because a higher PTCA volume was associated with moderately better outcomes, CON may be marginally effective in improving outcomes for PTCA. Future studies should revisit this hypothesis with data from several states.

5. **Ho, V.; Ku-Goto, M. H.; Jollis, J. G. Certificate of Need (CON) for cardiac care: controversy over the contributions of CON. *Health Serv Res.* 2009;44:483-500.**

ABSTRACT: 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.

6. **Ho, V.; Ku-Goto, M. H. State deregulation and Medicare costs for acute cardiac care. *Med Care Res Rev.* 2013;70:185-205.**

ABSTRACT: Past literature suggests that Certificate of Need (CON) regulations for cardiac care were ineffective in improving quality, but less is known about the effect of CON on patient costs. We analyzed Medicare data for 1991-2002 to test whether states that dropped CON experienced changes in costs or reimbursements for coronary artery bypass graft (CABG) surgery or percutaneous coronary interventions. We found that states that dropped CON experienced lower costs per patient for CABG but not for percutaneous coronary intervention. Average Medicare reimbursement was lower for both procedures in states that dropped CON. The cost savings from removing CON regulations slightly exceed the total fixed costs of new CABG facilities that entered after deregulation. Assuming continued cost savings past 2002, the savings from deregulating CABG surgery outweigh the fixed costs of new entry. Thus, CON regulations for CABG may not be justified in terms of either improving quality or controlling cost growth.

7. **Lorch, S. A.; Maheshwari, P.; Even-Shoshan, O. The impact of certificate of need programs on neonatal intensive care units. *J Perinatol.* 2012;32:39-44.**

ABSTRACT: OBJECTIVE: To determine the impact of state certificate of need programs (CON) on the number of hospitals with neonatal intensive care units (NICU) and the number of NICU beds. STUDY DESIGN: The presence of a CON program was verified from each state's department of health. Multivariable regression models determined the association between the absence of a CON program and each outcome after controlling for socioeconomic and demographic differences between states. RESULT: A total of 30 states had CON programs that oversaw NICUs in 2008. Absence of such programs was associated with more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and NICU beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation, and increased all-infant mortality rates in states with a large metropolitan area. CONCLUSION: There has been an erosion of CON programs that oversee NICUs. CON programs are associated with more efficient delivery of neonatal care.

8. **Popescu, I.; Vaughan-Sarrazin, M. S.; Rosenthal, G. E. Certificate of need regulations and use of coronary revascularization after acute myocardial infarction. *JAMA.* 2006;295:2141-7.**

ABSTRACT: 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.

9. **Rosko, M. D.; Mutter, R. L. The association of hospital cost-inefficiency with certificate-of-need regulation. *Med Care Res Rev.* 2014;71:280-98.**

ABSTRACT: Certificate-of-need (CON) regulations can promote hospital efficiency by reducing duplication of services; however, there are practical and theoretical reasons why they might be ineffective, and the empirical evidence generated has been mixed. This study compares the cost-inefficiency of urban, acute care hospitals in states with CON regulations against those in states without CON requirements. Stochastic frontier analysis was performed on pooled time-series, cross-sectional data from 1,552 hospitals in 37 states for the period 2005 to 2009 with controls for variations in hospital product mix, quality, and patient burden of illness. Average estimated cost-inefficiency was less in CON states (8.10%) than in non-CON states (12.46%). Results suggest that CON regulation may be an effective policy instrument in an era of a new medical arms race. However, broader analysis of the effects of CON regulation on efficiency, quality, access, prices, and innovation is needed before a policy recommendation can be made.

10. **Salkever, D. S.; Bice, T. W. The impact of certificate-of need controls on hospital investment. *Milbank Mem Fund Q Health Soc.* 1976;54:185-214.**

ABSTRACT: Certificate-of-Need (CON) controls over hospital investment have been enacted by a number of states in recent years and the National Health Planning and Resources Development Act of 1974 provides strong incentives for adoption of CON in additional states. In this study, we review the questions that have been raised about the effectiveness of CON controls and then we develop quantitative estimates of the impact of CON on investment. These estimates show that CON did not reduce the total dollar volume of investment but altered its composition, retarding expansion in bed supplies but increasing investment in new services and equipment. We suggest that this finding may be due to (1) the emphasis in CON laws and programs on controlling bed supplies and (2) a substitution of new services and equipment for additional beds in response to financial factors and organizational pressures for expansion. Finally, we caution against the conclusion that CON controls should be broadened and tightened, though our results might be so interpreted, because of the practical difficulties involved in reviewing and certifying large numbers of small investment projects.

11. **Short, M. N.; Aloia, T. A.; Ho, V. Certificate of need regulations and the availability and use of cancer resections. *Ann Surg Oncol.* 2008;1837-45.**

ABSTRACT: BACKGROUND: Several states use certificate of need regulations (CON) to control the growth of acute-care services, but the possible association between these restrictions and the provision of cancer surgery has not been assessed. This study examines the association between acute-care CON, the availability of cancer surgery hospitals, and provision of six cancer operations. METHODS: Medicare data were collected for beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002. Hospital, procedure, and incidence rates for each cancer diagnosis were stratified by state and year. The number of hospitals performing each operation per cancer incident, the number of procedures performed per cancer incident, and hospital volume were compared between states with and without CON, and those that discontinued CON during the sample period were noted. RESULTS: The number of hospitals per cancer incident was lower in CON states versus non-CON states

for colectomy (P = .022), rectal resection (P = .026), and pulmonary lobectomy (P = .032). Hospital volume was significantly higher in CON states versus non-CON states for colectomy (P = .006) and pulmonary lobectomy (P = .043). There were no differences between states with and without CON in the number of procedures per cancer incident. CONCLUSION: Although use of cancer procedures was similar in CON and non-CON states, those with acute-care CON had fewer facilities performing oncologic resections per cancer patient. Correspondingly, average hospital procedure volume tended to be higher in CON states. These differences may have important implications for patient outcomes and costs.

12. Shortell, S. M.; Hughes, E. F. The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. *N Engl J Med.* 1988;318:1100-7.

ABSTRACT: We examined the influence of the regulation of hospital rates, state certificate-of-need programs, competition, and hospital ownership on mortality rates among inpatients receiving care under Medicare for 16 selected clinical conditions that were studied as a group. Data were obtained from the records of 214,839 patients who received care in 981 hospitals in 45 states from July 1, 1983, through June 30, 1984. We found significant associations between higher mortality rates among inpatients and the stringency of state programs to review hospital rates (P less than or equal to 0.05), the stringency of certificate-of-need legislation (P less than or equal to 0.01), and the intensity of competition in the marketplace, as measured by enrollment in health maintenance organizations (P less than or equal to 0.05). Hospitals in the states with the most stringent review procedures for hospital rates had ratios of actual to predicted death rates that were 6 to 10 percent higher than those of hospitals in states with less stringent rate-review programs (P less than or equal to 0.001). Hospitals in the states with the most stringent procedures for reviewing applications for certificates of need had ratios of actual to predicted death rates that were 5 to 6 percent higher than those of hospitals in states with less stringent certificate-of-need procedures (P less than or equal to 0.05). There was no statistically significant association between mortality rates among inpatients and either the type of hospital ownership or the number of hospitals competing in the market area. Additional analyses, which examined alternative explanations for these findings, failed to change the results. These findings raise serious concerns about the welfare of patients who are admitted to hospitals in highly regulated areas and those admitted to hospitals in relatively competitive markets. They suggest that it is important to incorporate quality-assurance procedures and systems to monitor patients' outcomes into public and private programs designed to contain costs or promote competition, or both.

13. Sloan, F. A.; Steinwald, B. 1980. Effects of regulation on hospital costs and input use. (no abstract)

No impacts on costs. The results are consistent with three alternative views: (a) the regulations examined in this study do not have the capability of controlling hospital costs; (b) the regulations are effective, but our empirical approach was inappropriate to capture these effects; or (c) the regulations are potentially effective, but the time period studied was not long enough or was too soon after implementation in most cases for these effects to have become measurable.

14. Vaughan-Sarrazin, M. S.; Hannan, E. L.; Gormley, C. J.; Rosenthal, G. E. Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulation. *JAMA.* 2002;288:1859-66.

ABSTRACT: CONTEXT: Certificate of need regulation was designed to control health care costs by preventing health care facilities from expanding unnecessarily. While there have been several studies investigating whether these regulations have affected health care investment, few have evaluated the relationship between certificate of need regulation and quality of care. OBJECTIVE: To compare risk-adjusted mortality and hospital volumes for coronary artery bypass graft (CABG) surgery in states with and without certificate of need regulation. DESIGN, SETTING, AND PARTICIPANTS: Retrospective cohort study of 911 407 Medicare beneficiaries aged 65 years or older, who underwent CABG surgery between 1994 and 1999 in 1063 US hospitals. MAIN OUTCOME MEASURES: States (and the District of Columbia) with continuous (n = 27), none (n = 18), or intermittent (n = 6) certificate of need regulation; mortality (in-hospital or within 30 days of CABG surgery) rates; and mean annual hospital volumes for CABG surgery. RESULTS: Unadjusted mortality was 5.1% in states without certificate of need regulation compared with 4.4% in states with continuous regulation, and 4.3% in states with intermittent certificate of need regulation (P<.001 for each comparison). Adjusting for demographic and clinical factors, mortality remained higher in states without certificate of need regulation compared with states with continuous certificate of need regulation (odds ratio [OR], 1.22; 95% confidence interval [CI], 1.15-1.28; P<.001). Using the same groups for comparison, the mean annual hospital volume for CABG surgery was 84% lower in states without certificate of need regulation (104 vs 191; P<.001) and more patients underwent

CABG surgery in low-volume hospitals (<100 procedures annually) (30% vs 10% for states with continuous certificate of need programs; P<.001). Following the repeal of certificate of need regulation in states categorized as intermittent, the percentage of patients undergoing CABG surgery in low-volume hospitals tripled. CONCLUSIONS: Mortality rates for Medicare patients undergoing CABG surgery were higher in states without certificate of need regulation. Repeal of certificate of need regulations during the study period was associated with declines in hospital volume for CABG surgery.

15. **Vaughan Sarrazin, M. S.; Bayman, L.; Cram, P. Trends during 1993-2004 in the availability and use of revascularization after acute myocardial infarction in markets affected by certificate of need regulations. *Med Care Res Rev.* 2010;67:213-31.**

ABSTRACT: This study examines trends in the diffusion of coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI) during 1993-2004 for patients with acute myocardial infarction in markets with and without Certificate of Need (CON) regulations for open-heart surgery or cardiac catheterization and in markets that repealed CON for either of these procedures. In contrast to prior studies, this study accounts for regional hospital markets that cross state boundaries-often with different CON activities in each state. The overall use of CABG increased modestly throughout the 1990s and subsequently decreased, corresponding to a dramatic increase in PCI. There was a greater rise in the number of CABG programs in markets with significant reduction in CON regulations during 1993-2004 compared with other markets, but CON reduction was not related to growth of PCI programs. Reimbursement, ease of use, clinician endorsement, and technological advances in PCI may outweigh effects of CON.