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DOI: 10.1111/1475-6773.12619
RESEARCH ARTICLE

The Effect of Certificate of Need Laws on All-Cause Mortality

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Objective. To test how Certificate of Need laws affect all-cause mortality in the United States.

Data Sources. The data of 1992–2011 all-cause mortality are from the Center for Disease Control’s Compressed Mortality File; control variables are from the Current Population Survey, Behavioral Risk Factor Surveillance System, and Area Health Resources File; and data on Certificate of Need laws are from Stratmann and Russ (2014).

Study design. Using fixed- and random-effects regressions, I test how the scope of state Certificate of Need laws affects all-cause mortality within US counties.

Principal Findings. Certificate of Need laws have no statistically significant effect on all-cause mortality. Point estimates indicate that if they have any effect, they are more likely to increase mortality than decrease it.

Conclusions. Proponents of Certificate of Need laws have claimed that they reduce mortality by concentrating more care into fewer, larger facilities that engage in learning-by-doing. However, I find no evidence that these laws reduce all-cause mortality.

Key Words. Certificate of Need, all-cause mortality, health planning, health quality

Currently, 35 states have Certificate of Need (CON) laws on the books. These laws require health care providers to get the permission of a state board before opening a new facility or substantially expanding an existing facility. As states have debated whether to repeal or reintroduce their CON laws, proponents of these laws claim they will reduce mortality by concentrating more care into fewer, larger facilities that engage in learning-by-doing. Opponents of the laws claim they will increase mortality by reducing competition between hospitals.

Many researchers have examined the effect of CON laws on the mortality rate of specific surgical procedures, especially heart surgery procedures. This literature has found mixed results, with some finding that CON laws increase mortality (Ho, Ku-Goto, and Jollis 2009; Cutler et al. 2010), some finding they reduce mortality (Vaughan-Sarrazin et al. 2002; Popescu,

Sarrazin, and Rosenthal 2005; Ho 2006), and others finding that they have no significant effect (Robinson et al. 2001; DiSesa et al. 2006; Popescu, Vaughan-Sarrazin, and Rosenthal 2006).

Using data from the Center for Disease Control's Compressed Mortality File, which records all deaths in the United States, I find that CON laws do not decrease mortality.

BACKGROUND: CERTIFICATE OF NEED LAWS

CON laws require health care providers to win the approval of a state board before opening a new facility or before doing a large expansion to an existing facility. While hospitals are the largest targets of CON laws, some states also require nursing homes, home health providers, intermediate care facilities, medical offices, and dialysis centers to obtain a CON before opening. The CON process is separate from regulations meant to ensure that a new facility meets safety and quality standards; instead, CON programs evaluate the economic necessity of the new facility and how it will impact existing providers. To make an air travel analogy, CON boards are more like the Civil Aeronautics Board (which managed competition and determined the need for new routes) than the Federal Aviation Administration (which regulates to ensure flight safety).

By 1980, every state except Louisiana had enacted a CON program. The federal government repealed its mandate for state CON programs in 1986. Since then, 15 states have ended their CON programs, leaving CON in place in 35 states and the District of Columbia.

The original justification for CON as laid out in the *National Health Planning and Resource Development Act of 1974* was to restrain health care costs and to promote equal access to care. Later, proponents also claimed that CON laws could reduce mortality: "repeal of certificate of need regulations may have adverse effects on patient outcomes and may promote the development of low-volume surgical programs. . . . surgical volume has become an important proxy for quality in recent initiatives to measure quality and reward high quality clinicians" (Vaughan-Sarrazin et al. 2002).

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EFFECT OF CERTIFICATE OF NEED LAWS ON MORTALITY IN THEORY

CON laws are restrictions on entry into a market. Such entry barriers lead to reduced levels of competition (FTC 2004; Cutler, Huckman, and Kolstad 2010). The effect of reduced competition on the quality of care provided is unclear in theory. In standard economic models, the effect depends on whether consumers care more about prices or quality—competition increases quality if consumers care about it more than price (Gaynor, Kate, and Robert 2014). If consumers (patients or insurers) care mostly about lower prices, firms will compete to deliver them by lowering costs, which may mean lowering quality.

In addition to reducing competition, CON laws may also have the more direct effect of reducing the supply of health facilities, straightforwardly reducing the amount of health care available. As long as the demand for medical care is downward sloping, this reduction in supply will reduce the total amount of care used—in fact, reducing the use of care is one of the goals many CON proponents have for the programs (Hellinger 2009). But this reduction in health care use could increase mortality. In particular, the reduction in the number of hospitals and health facilities caused by CON may make it less likely for individuals to enter the medical system in the first place and more likely to die at home.

EFFECT OF CERTIFICATE OF NEED LAWS ON MORTALITY IN PRACTICE

A large body of literature in economics, medicine, and health services research, summarized in Table 1, has attempted to determine the effect of CON laws on mortality. This literature has fallen into surprisingly narrow tracks, examining mortality only among small subsets of the population. Most papers only consider mortality among Medicare enrollees older than 65 years. The literature is somewhat dated, with no paper using data more recent than 2003. Finally, the entire literature examines mortality only among patients who have recently been hospitalized, using data only from hospital discharge records or claims. Only Shortell and Hughes (1988) consider the effect of CON on the mortality of patients other than those hospitalized because of a heart condition.

Table 1: Literature on CON and Mortality

<i>Paper</i>	<i>Effect of CON of Mortality</i>	<i>Years Studied</i>	<i>States Studied</i>	<i>Dataset</i>	<i>Mortality Measured among</i>
Vaughan-Sarrazin et al. (2002)	-22%	94-99	50	Medpar	CABG patients
Popescu, Sarrazin, and Rosenthal (2005)	-6%	98-00	50	Medpar	AMI patients
Ho (2006)	-2.50%	88-00	49	HCUP	CABG patients
Robinson et al. (2001)	0	94-99	PA	PHC4	CABG patients
DiSesa et al. (2006)	0	00-03	50	STS	CABG patients
Popescu, Vaughan-Sarrazin, and Rosenthal (2006)	0	00-03	50	Medpar	AMI patients
Cutler, Huckman, and Kolstad (2010)	3.50%	94-03	PA	PHC4	CABG and PTCA patients
Shortell and Hughes (1988)	5%	83-84	45	Medpar	Patients w/1 of 16 conditions
Ho, Ku-Goto, and Jollis (2009)	10%	89-02	50	Medpar	CABG and PCI patients

Notes: PHC4 data are from the Pennsylvania Health Care Cost Containment Council. STS data are from the Society of Thoracic Surgeons' National Cardiac Surgery Database. HCUP is the Healthcare Cost and Utilization Project. Medpar is Medicare claims data.

Because CON laws restrict the number of hospitals, hospital beds, and the number of hospitals offering a given service like cardiac surgery, people may be less willing or able to seek medical care in hospitals in the first place. The existing literature, which relies solely on inpatient data, would not observe someone who died at home or en route because CON (or the lack of CON) kept the person from going to or getting to a hospital. CON also applies to many health care providers other than hospitals, including dialysis facilities, nursing homes, and medical office buildings. CON could affect mortality by affecting the use of these facilities, independent of its effect on hospitals. Existing approaches using only inpatient data cannot detect someone who dies because CON (or the lack of CON) made the person's dialysis facility lower quality or harder to access.

Therefore, a full evaluation of the effect of CON on mortality should use comprehensive, all-cause mortality data. The Center for Disease Control provides such data, and I use it in this analysis. I aim to answer, for the first time, the question of how CON laws affect all-cause mortality in the general population.

DATA AND METHODS

The key regression equation of my paper is as follows:

$$\text{Mortality}_{\text{ct}} = \beta_0 + \beta_1 * \text{CON}_{\text{st}} + \beta_2 * \text{X}_{\text{st}} + \text{State}_{\text{s}} + \text{Year}_{\text{t}} + \varepsilon_{\text{ct}},$$

where $\text{Mortality}_{\text{ct}}$ gives annual county-level age-adjusted mortality, CON_{st} indicates the scope of the CON laws in effect in a given state and year, X_{st} is a vector of state-level controls, and State_{s} and Year_{t} give state and year fixed effects. The baseline regression is estimated using ordinary least squares; fixed-effects and random-effects estimators are also considered. The main regressions use 1992–2011 data.

My source of mortality data is the Center for Disease Control’s Compressed Mortality File (CMF), which is available for the years 1968–2013. The CMF gives annual county-level data on deaths, the death rate, and the age-adjusted death rate, based on the universe of mortality data. The CDC computes age-adjusted mortality by observing the mortality rate of each age group (0–4, 5–9. . . . 81–84, 85+) in a county, and calculating what the overall mortality rate of the county would be if the age distribution of the county was the same as the age distribution of the United States as a whole was in the year 2000. Using age-adjusted mortality means that counties with higher mortality are not simply counties with older populations, but counties where people of a given age die more often. The CMF aggregates restricted individual-level data on all US death certificates, drawn from the National Center for Health Statistics’ Vital Statistics System. Figure A1 shows that mortality is normally distributed across counties, and Figure A2 shows a general downward trend in age-adjusted mortality rates over time.

All-cause mortality is a very broad measure, likely to be affected by many things besides CON laws, or even the medical system in general. Because of this, I use control variables for other factors that may influence mortality from the Integrated Public Use Microdata Series (IPUMS) compilation of the March Current Population Survey. Control variables used are state-level measures of age, gender, race, ethnicity, education, poverty, and health insurance status (private insurance, Medicare, Medicaid). In some regressions, I also include state-level measures of Medicare Advantage enrollment from the Area Health Resources file and measures of obesity, tobacco use, and alcohol use from the Behavioral Risk Factor Surveillance System’s Prevalence data. Obesity is defined by the proportion of individuals with a body mass index over 30; tobacco use by the proportion of smokers; and alcohol by the proportion who engaged in binge drinking (five drinks/occasion for men, four for women) within the past 30 days.

Data on whether states have hospital CON laws or not are readily available; most papers on the subject list when each state has a hospital CON

program in place (see, e.g., Hellinger 2009), and these assessments have been quite consistent. Most of the previous literature has used such a binary measure of CON—is there any program in place or not? In some regressions, I use such data on the presence of CON from the National Conference of State Legislatures (NCSL 2016).

However, there is a problem with this common strategy of considering CON laws as a binary variable. States with CON programs vary widely in the scope and intensity of their laws. Some states require CON boards to approve only a single type of health provider expansion, such as acute care hospital beds, while leaving most large expansions and capital expenditures up to hospital discretion. Other states, such as Vermont, require CON board approval for as many as 28 separate types of expansion—from equipment purchases like MRI and PET scanners, to operating new services like obstetrics, cardiac care, or psychiatrics. It is reasonable to expect that broader CON laws should have stronger effects, so treating all CON regimes as identical could lead to misleading estimates.

Therefore, my main regressions use data on the scope of CON laws in the years 1992–2011 from Stratmann and Russ (2014). Their data are derived from reports of the American Health Planning Association, who have monitored state CON laws and tracked whether states have each of 28 types of CON law. Table A1 gives each of these 28 categories. Using these data, I sum up the number of separate CON restrictions in place in each state to create a measure of CON intensity. Table 2 gives the number of CON restrictions each had in place as of 2011. This counting approach, used by Stratmann and Russ to study how CON affects access to indigent care, is novel to the literature on CON and mortality (the closest precedent is Shortell and Hughes’s division of CON programs into strict and not strict).

Considering the differences in the scope of CON laws is also crucial because states have changed the scope of CON laws much more often than they have started a totally new CON regime or ended an existing one—especially since the rapid wave of CON repeals in the mid-1980s. No state has started an entirely new CON regime since Wisconsin in 1993, and only three states (Indiana, North Dakota, and Pennsylvania) dropped CON entirely during the 1992–2011 period. But states are continuously adding or subtracting restrictions from their existing CON programs; a state might be requiring CON for cardiac care but drop it for MRI machines. Figure 1 shows how the scope of CON programs has changed over time.

Table 2: Number of Certificate of Need Restrictions in Each State, 1992 and 2011

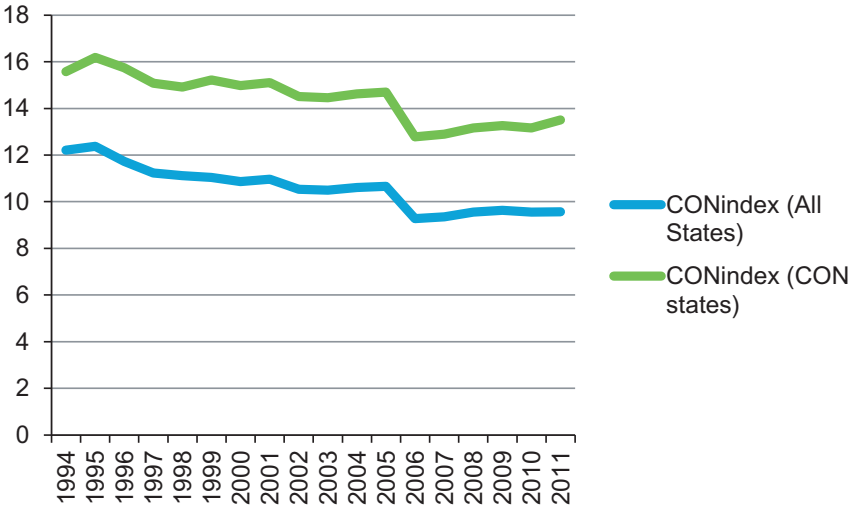
<i>State</i>	<i>Mean(CONindex)</i>		<i>State</i>	<i>Mean(CONindex)</i>	
	1992	2011		1992	2011
Alabama	13	18	Missouri	14	13
Alaska	0	18	Montana	8	6
Arizona	0	0	Nebraska	7	1
Arkansas	2	4	Nevada	0	3
California	0	0	New Hampshire	0	12
Colorado	0	0	New Jersey	20	11
Connecticut	1	15	New Mexico	0	0
Delaware	6	7	New York	19	17
District of Columbia	19	26	North Carolina	15	22
Florida	13	9	North Dakota	0	0
Georgia	15	16	Ohio	10	0
Hawaii	8	25	Oklahoma	4	3
Idaho	0	0	Oregon	0	2
Illinois	19	14	Pennsylvania	6	0
Indiana	2	0	Rhode Island	10	19
Iowa	7	8	South Carolina	14	18
Kansas	0	0	South Dakota	0	0
Kentucky	18	16	Tennessee	17	18
Louisiana	2	2	Texas	0	0
Maine	0	23	Utah	0	0
Maryland	11	14	Vermont	15	28
Massachusetts	11	13	Virginia	18	18
Michigan	16	17	Washington	5	15
Minnesota	0	0	West Virginia	20	19
Mississippi	15	16	Wisconsin	0	2
			Wyoming	0	0

Source: Stratmann and Russ (2014).

RESULTS

Table 3 shows the result of the basic regression of CON stringency on all-cause mortality. Stronger CON laws are estimated to have a positive, but not statistically significant effect on mortality. The results are sensitive to the choice of estimator, becoming closest to significance when random effects are used. Fixed-effects estimators only use variation within states or counties over time, while the random-effects estimator also takes variation between different states and counties into account. In general, fixed-effects estimators are considered the more trustworthy by economists when they show different coefficients from random effects (which a Hausman test confirms they do in

Figure 1: Number of CON Restrictions in the Average State over Time



Note: The blue line shows the average number of separate CON restrictions over all states; the green line shows the average number of separate CON restriction over states that have any CON program [Color figure can be viewed at wileyonlinelibrary.com].

this case). Only random effects is comparing the extent to which persistently high-CON states have different mortality from persistently low-CON states; this is both its advantage (to the extent we can learn from cross-state variation) and its disadvantage (to the extent states are simply different from each other, and some of this difference is falsely attributed to CON).

Omitted regressions show that the results are also highly sensitive to choice of time control and clustering level; using a linear time trend or clustering at the county level pushes the results over into significance at the 5 percent level. However, it seems most appropriate to cluster standard errors at the level that CON policies are determined (the state level) and to use year fixed effects rather than a linear time trend (given that the linear time trend is more restrictive, and there is no shortage of degrees of freedom).

The magnitudes of the results are substantial. In the case of the county fixed-effects estimator shown in column (2), they imply that one additional CON law is associated with an increase in the mortality rate of just over 0.34 deaths per 100,000 people per year. The mean annual county death rate over the 1992–2011 period is 891, so 0.34 deaths represent a 0.038 percent increase

Table 3: Association of Certificate of Need Laws and Age-Adjusted All-Cause Mortality

<i>Variables</i>	(1)	(2)	(3)
CON	0.266 (0.351)	0.343 (0.347)	0.803 (0.432)
Population	-3.22e-05*** (1.08e-05)	-0.000198*** (3.89e-05)	-6.01e-05*** (1.70e-05)
Male	25.36 (99.05)	43.47 (97.32)	-51.43 (101.8)
Black	77.82 (70.37)	71.42 (69.33)	329.1*** (65.99)
Asian	154.8 (117.8)	135.0 (105.7)	64.49 (83.34)
Hispanic	83.47 (87.28)	102.7 (87.18)	-56.99 (48.88)
College	-273.5** (115.6)	-254.7** (114.1)	-449.1*** (125.9)
Income	-0.00280** (0.00136)	-0.00294** (0.00135)	-0.00245 (0.00129)
Poor	-131.9 (87.97)	-134.2 (86.41)	-158.8 (104.8)
PrivateIns	40.04 (65.81)	47.58 (64.28)	-180.5** (71.42)
Medicaid	71.27 (81.08)	72.48 (79.55)	-41.98 (78.21)
Medicare	170.2** (77.28)	177.4** (75.85)	136.5 (84.66)
Time control	Year FE	Year FE	Year FE
Geographic control	State FE	County FE	County RE
Observations	55,052	55,052	55,052
R-squared	0.359	0.191	0.186

**Indicates p -value < .05.

***Indicates p -value < .01.

Robust standard errors clustered by state are shown in parentheses. The mortality rate is measured as annual age-adjusted deaths per 100,000 residents.

FE, fixed effects; RE, random effects.

in mortality. The average state with a CON program has 14 separate CON restrictions, implying that the average CON program is associated with a mortality increase of 14×0.038 percent = 0.534 percent.

Table 4 shows the results when additional controls from the 1995–2010 Behavioral Risk Factor Surveillance System are added. Obesity and tobacco smoking are seen to increase mortality rates, while binge drinking is not. Table A6 maintains these controls and adds a proxy for managed care penetration (percent of Medicare recipients with Medicare Advantage) from the Area Health

Table 4: Association of Certificate of Need Laws and Age-Adjusted All-Cause Mortality (with Additional Controls)

<i>Variables</i>	(1)	(2)	(3)
CON	0.0144 (0.475)	0.0755 (0.469)	0.558 (0.470)
Population	-0.00003*** (0.00001)	-0.0002*** (0.00004)	-0.00005*** (0.00002)
Male	-115.1 (100.3)	-105.5 (100.2)	-174.8 (96.16)
Black	74.73 (55.66)	72.62 (55.48)	278.8*** (54.40)
Asian	56.02 (65.40)	41.93 (57.81)	-38.80 (36.91)
Hispanic	24.24 (76.11)	32.08 (76.70)	-50.34 (36.94)
College	-279.0** (107.7)	-248.9** (105.5)	-324.5*** (106.3)
Income	-0.00139 (0.00117)	-0.00157 (0.00113)	-0.00120 (0.00116)
Poor	-20.71 (99.83)	-31.16 (97.56)	-44.67 (113.3)
PrivateIns	9.384 (64.44)	13.64 (64.64)	-230.2*** (67.91)
Medicaid	6.155 (82.27)	8.437 (82.64)	-143.7 (77.25)
Medicare	181.7 (92.92)	171.3 (90.07)	78.46 (103.5)
Obesity	3.626*** (0.947)	3.582*** (0.938)	4.070*** (1.106)
Tobacco	2.123** (0.879)	2.133** (0.865)	4.210*** (0.981)
Alcohol	-0.329 (0.693)	-0.425 (0.696)	-2.613*** (0.499)
Time control	Year FE	Year FE	Year FE
Geographic control	State FE	County FE	County RE
Observations	39,744	39,744	39,744
R-squared	0.367	0.182	0.325

**Indicates p -value < .05.

***Indicates p -value < .01.

Robust standard errors clustered by state are shown in parentheses. The mortality rate is measured as annual age-adjusted deaths per 100,000 residents.

FE, fixed effects; RE, random effects.

Resources File (1997–2010, missing 2001,6,7). The estimated effect of CON laws remains positive but statistically insignificant when these controls are added.

The effect of CON laws may not be felt immediately. When CON restrictions are repealed, hospitals are able to expand more easily, but it may

still take years for their new services or investments to actually open and begin affecting outcomes. Table A2 looks for delayed effects of CON laws—how the scope of CON laws this year affects mortality up to 3 years later. The magnitudes found imply that the average CON restriction is associated with an increase in mortality of at most 0.055 percent after 3 years, so the average state’s CON program (which includes 14 separate restrictions) is associated with an increase in mortality of at most 0.770 percent after 3 years. However, none of these estimates is statistically significant at conventional levels.

One concern with the results given thus far is that the data are not all at the same geographic level—mortality data are given at the county level, while controls are only at the state level. The controls are from the Current Population Survey, which is too small a survey to produce reliable estimates for small counties, and so only provides county identifiers for the largest counties. In Table A3, I provide results when county-level controls are used (though this means dropping most counties for lack of data). The estimates are similar to the main results—CON has a positive but statistically insignificant effect on mortality. In the same table, I use state-level mortality data to match the state-level controls and CON laws. Here, the estimated effect of CON turns negative but remains statistically insignificant.

In a robustness check, I consider the effect of entire CON programs rather than using a measure of the scope of CON laws. Using data from the National Council of State Legislatures, I assign a value of 1 to states that have any CON program in place in a given year and a value of 0 to states that do not. The results using this definition of CON are shown in Table A4. The results using fixed effects are negative and statistically insignificant, while the results using random effects are positive and statistically insignificant at the 5 percent level; the difference between fixed and random effects is especially strong here because there is very little variation within states in the presence of overall CON programs in his period.

My main approach of counting separate CON restrictions does not fully account for the differences in the strengths of CON programs across states. For instance, some CON restrictions cover common procedures like MRI, while others cover relatively rare procedures like organ transplantation. Some cover treatments such as heart surgery that very clearly affect mortality, while others cover treatments like lithotripsy where a connection to mortality is less obvious. In an alternative approach, I create an index of the strength of CON laws that attempts to account for these differences, putting greater weight on CON restrictions that apply to more common procedures and to procedures more likely to affect mortality. Table A5 gives greater detail on the creation of

the index, as well as the results of using it. Compared to the baseline results, the point estimates are somewhat smaller but remain positive and statistically insignificant.

CONCLUSION

State CON laws were meant to be a way to restrain spending while improving quality of care and outcomes—moving more procedures into high-volume hospitals that experience “learning-by-doing.” The idea that CON laws can improve the quality of medical care and reduce mortality is one reason why most U.S. states have retained their CON programs even after the federal push for CON subsided. However, I find no evidence that CON laws reduce mortality. States with a CON program do not see a statistically significant reduction in mortality, nor do states with broad programs see a reduction in mortality compared to states with narrower programs. In fact, most point estimates of the effect of CON are positive, implying that states with broader CON laws experience higher all-cause mortality, although these estimates are not statistically significant.

Previous research on CON and mortality focused almost entirely on the effect of CON restrictions on mortality for heart surgery. The one previous paper to examine a broader range of mortality outcomes, Shortell and Hughes (1988), found that strict CON programs led to higher mortality among Medicare patients. In this paper, I have examined CON at the highest level of generality, asking how CON affects all-cause mortality, and I found no effect. However, this should not be the final word on CON and mortality; the null effect in general may conceal substantial increases or decreases in mortality for certain types of CON or certain types of people. While this possibility has been widely investigated in the case of heart surgery, the field remains wide open for future research on how CON affects the quality of other procedures.

ACKNOWLEDGMENTS

Joint Acknowledgment/Disclosure Statement: Thanks to the Mercatus Center for financial support and helpful comments, and to Thomas Stratmann and Jacob Russ for sharing their data. The author has no other conflicts of interest to report. Thanks to Chris Conover, Nathan Blascak, Eleanor Lewin, Thomas

Stratmann, Jacob Russ, Lyden Marcellot, Leah Kitashima, and audience members at the Eastern Economic Association and Southern Economic Association 2015 meetings for helpful comments.

Disclosure: None.

Disclaimer: None.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Figure A1: Kernel Density Estimate of Age-Adjusted Death Rate of U.S. Counties, 1992–2012.

Figure A2: Trend of Age-Adjusted Mortality over Time.

Table A1: Components of Certificate of Need Measure.

Table A2: Lagged Association of Certificate of Need Laws and Age-Adjusted All-Cause Mortality.

Table A3: Effect of Certificate of Need Laws on Age-Adjusted All-Cause Mortality at Various Geographic Levels of Observation.

Table A4: Effect of Overall Certificate of Need Program (Rather Than a Measure of Its Scope) on Age-Adjusted All-Cause Mortality.

Table A5: Weighted Certificate of Need Law Measure and Age-Adjusted All-Cause Mortality.

Table A6: Association of Certificate of Need Laws and Age-Adjusted All-Cause Mortality (with Additional Controls).