Expert Report of Christopher J. Conover, PhD

I am Christopher J. Conover. I hold a PhD in Policy Analysis from the Pardee RAND Graduate School, and I currently serve as a Research Scholar at the Center for Health Policy and Inequalities Research at Duke University. As illustrated by my CV, which is being produced along with this report, I have published a number of articles on health policy and health-care costs, and I have testified on these topics in front of state legislatures and the U.S. Congress, though this is my first time testifying as an expert in a court of law.

For this expert report, I have been asked to give my opinion about three questions related to Virginia's Certificate of Public Need program.[1] I have developed these opinions on the basis of my years of professional study of medical care and medical regulation in the United States, on the basis of my examination of the current state of the professional literature about medical certificate of need requirements (including literature written by me and by my co-authors), and by using statistical methods commonly used by experts in my field. A brief sketch of my opinions are as follows:

First, I was asked to examine whether there was any effect on health expenditures or on uninsured risk within a state when that state removed a CON law. This question matters because CON laws are frequently justified by the argument that they serve to reduce overall health expenditures or to improve access to those in a state's population who are uninsured. If either of these justifications were true, we would expect to see a surge in health expenditures or in the uninsured population in states that eliminated their CON restrictions. We do not see this. The data do not support this. Instead, when a state removes a CON law, it may actually result in *decreased* per capita health spending for residents of that state. In short, the data shows that removing CON laws either has *no effect* on overall health spending or may actually *reduce* overall health spending. This is the opposite of what one would expect if CON laws were serving their intended purpose.

Second, I was asked to survey the academic literature on CON requirements to estimate the overall benefits created by CON requirements. Having reviewed this literature, I find that based on the weight of a sizable body of empirical evidence regarding the effects of CON or its removal, the expected total costs associated with CON requirements are approximately $99 million annually, while the expected total benefits associated with CON requirements are approximately $0 million, annually. On balance, when you subtract benefits from cost, the net cost of the nation's CON programs is $99 million. In other words, CON laws produce little or no real benefits even as they impose cost on taxpayers and patients. In coming to this conclusion, I am agreeing with other experts in the field, including the Federal Trade Commission and U.S. Department of Justice, which (after conducting a review of the literature and hearing testimony

[1] The more common name for these programs is simply "Certificate of Need" or "CON." I use that abbreviation frequently in my professional discussions of these laws and, for simplicity's sake, I do the same here.

from expert witnesses) concluded in 2004 that CON programs are ineffective in controlling costs or enhancing health care quality or access.

While I am aware that this report is being filed in a lawsuit that has to do with burdens on interstate commerce, I should note that my conclusions about the costs and benefits of CON requirements do not take interstate commerce into account. I have not been asked to provide an opinion on exactly how much of a burden CON requirements place on interstate commerce. Instead, I have only analyzed the *local* costs and benefits generated by CON requirements in the form of the effect on healthcare expenditures and other measures. In other words, my conclusion is that (in the aggregate) CON requirements generate a net cost of $99 million nationwide. Any burdens placed on interstate commerce do not figure into that analysis.

Finally, I was asked to examine a spreadsheet of data obtained from the Defendants in this lawsuit, which provides historical information about applications for certificates of need in Virginia. The spreadsheet indicates that some applicants have been assigned "owner" numbers, while other applicants have not been assigned "owner" numbers. I have been informed by the attorneys for the plaintiffs that these "owner" numbers are assigned by the Defendants. Statistical analysis reveals that having an "owner" number is associated with having a much higher chance of having one's application approved. In general, the odds that an application from an entity with an "owner" number will be approved are 3.3 times as large as the odds that an equivalent application from an entity without an owner number would be approved. The effect is even larger when one examines only applications for diagnostic imaging equipment. For diagnostic imaging equipment, the odds that an application from an entity with an "owner" number will be approved are 5.3 times as large as the odds that an equivalent application from an entity without an owner number would be approved. While (as discussed below) I have received somewhat conflicting information about who is assigned an owner number, it is clear that owner numbers correlate strongly with successful applications.

In three parts, below, I address each of these questions at greater length.

PART ONE: ANALYSIS OF THE IMPACT OF LIFTING CON REQUIREMENTS

In order to determine what effect, if any, CON requirements have on health expenditures and uninsured risk, it is best to do a before-and-after comparison. Because most states adopted CON well before the starting period for the various dependent variables of interest, we instead focus on states that dropped CON, using a similar before and after comparison to assess whether there was a "surge" in health spending once CON restrictions were moved. If CON were effective in holding down costs, we would expect to see such a surge. On a related issue, one of the side benefits of lower health spending is a reduction in the percent of a state's population that is uninsured. Consequently, the analysis examines the effects of lifting (that is, removing) CON on several alternative measures of health spending per capita as well as uninsured risk.

What the analysis shows (as described more fully below) is that there is no "surge" in health spending when CON restrictions are removed. Instead, there may actually be a reduction in spending. This suggests that CON restrictions are an ineffective means of constraining health expenditures.

This analysis examines:

- The impact of lifting CON on total health spending per capita based on location of providers (this counts all health spending within a state's borders, i.e., including spending by non-residents, but excluding own resident spending done outside a patient's own state of residence; thus, it will overstate health spending in states that are "net exporters" i.e., whose own resident cross-border health spending exceeds the amount of spending by non-residents who cross the border to get care within that state).
- The impact of lifting CON on hospital health spending per capita based on location of providers.
- The impact of lifting CON on physician health spending per capita based on location of providers.
- The impact of lifting CON on total health spending per capita based on state of residence (this counts all health spending by a state's residents regardless of whether it is obtained in state or outside a state's borders).
- The impact of lifting CON on total health spending per Medicare enrollee (this likewise counts all health spending by a state's Medicare enrollees regardless of whether it is obtained in state or outside a state's borders).
- The impact of lifting CON on the percent of state residents who are uninsured.

Answering these questions requires data on health spending and uninsured status, all of which is generally available. For health spending by location of provider and the uninsured rate, we have 30 years (1980-2009) of data from the Centers for Medicare and Medicaid Services (CMS). We have uninsured data from the Bureau of Census for these same years. For health spending and Medicare spending by state of residence we have 19 years of data (1991-2009). For all 30 years we have companion information on a broad range of state area characteristics, health system characteristics, health insurance markets and state health regulation to account for many differences across states that might have independently affected state health spending or uninsured status regardless of CON. Thus, the analysis calculates the net effect of CON after accounting for these many differences between states. Each state constitutes an observation. Thus, we have 1,470 observations for spending by provider location analyses and 931 for spending by state of residence.

Dependent Variables

In statistical analysis, dependent variables are the variable one is trying to measure. One seeks to measure whether changes in the *independent* variable (or the covariates, discussed below) cause changes in the *dependent* variable. The following are the dependent variables in this analysis:

- Index health spending per capita, by state of provider (1=U.S. average). This expresses each state's per capita spending as a ratio of state's health spending per capita to the U.S. average (1.00=U.S. average for this index variable). We used the natural log of this variable in our regressions.

- Index hospital spending per capita, by state of provider (1=U.S. average). We used the natural log of this variable in our regressions.

- Index physician spending per capita, by state of provider (1=U.S. average). We used the natural log of this variable in our regressions.

- Index total health spending per capita, by state of residence (1=U.S. average). We used the natural log of this variable in our regressions.

- Index Medicare spending per enrollee, by state of residence (1=U.S. average). We used the natural log of this variable in our regressions.

- Uninsured index. This expresses each state's uninsured rate as a ratio of state's uninsured rate to the U.S. average (1.00=U.S. average for this index variable).

Covariates

- CON Regulation. These include indicator variables for Section 1122[2] and for various years before CON was lifted (e.g., prelift4=4 or more years prior to lifting of acute care CON): prelift1 through prelift4. There also is an indicator variable denoting the actual year CON was lifted. There are corresponding variables indicating years after CON was lifted: postlift1 through postlift4. We separately examined the impact of CON stringency on outcomes, using the American Health Planning Association definition of states having stringent CON (all other CON states were characterized as have low CON stringency).

- Area Characteristics. These include ln(population density), ln(real per capita income), and share of population age 65 and older.

- Health System Characteristics. These include ln(physicians per 100,000), general practice share of all physicians, and share of population in HMOs.

- Health Insurance Market. These include uninsured index (see above at page 4), Medicaid share of population, Medicare share of population and an indicator variable showing whether a state's Blue Cross Blue Shield plan has converted to for-profit status.

- State Health Regulation. These include variables for hospital rate-setting, health insurance mandates, other health insurance regulation, and managed care regulation.

- Year Fixed Effects. Separate indicator variables denote each year in the analysis to account for national trends affecting all states (e.g., economic swings). 1980 is the omitted reference year in analyses using 1980-2009 data; 1991 is the omitted reference year in analyses using 1991-2009 data.[3]

- State Fixed Effects. Separate indicator variables denote each state in the analysis to account for national trends affecting all states (e.g., economic swings). Alabama is the omitted reference category.

- State x Year Fixed Effects. This allows for the relationship between an independent variable (e.g., per capita income) and an outcome variable (e.g., health spending per capita) to be different across states. For example, the effects of per capita income and spending might be smaller in states with high incomes compared to low incomes.

[2] Section 1122 of the 1972 amendments to the Social Security Act required states to review all capital expenditures that exceeded $100,000, changed bed capacity or involved a "substantial change" in services; state participation in section 1122 was optional. Section 1122 did not continue past 1987.

[3] The use of reference categories is a common statistical method necessary to properly perform a regression analysis.

Analysis

- **Data Transformations**. We used the natural log of all spending variables in the analyses. We also used natural log of several independent variables as described earlier.

- **Regression Analysis**. We performed a series of linear longitudinal regression analyses using a difference-in-difference model. For each dependent variable listed above, we ran the identical model using all covariates with 2 exceptions. The first exception is that in the model using uninsuredindex as a dependent variable, uninsureindex was excluded as an explanatory variable; the model for this dependent variable also excludes two other health insurance characteristics variables: daily Medicare share of population and daily Medicaid share of population since these might affect the uninsured measure and contaminate estimates of the impact of CON removal. The second exception is that for the 2 set of regressions using health spending measured by place of residence as outcomes. Three variables related to outdated regulations not in operation in the 1991-2009 time period were not included in these models.

Major Findings

We essentially are estimating the "net" impact of a state's lifting CON over time, where the "net" effect means the difference in the outcome from a "statistical twin" state that retained CON to the state that lifted its CON.

- **States that lifted CON did not experience an "explosion" in health spending: These states were found to have lower health spending per capita measured using location of provider around and after the time of CON lifting than states that did not lift CON.**

    - States that lifted CON already had had statistically significant lower health spending per capita a few years before CON was lifted relative to what would have happened had they retained CON. That is, compared to the period four or more years prior to lifting CON, health spending in the year before lifting already was 1.9% lower than it would have been in an equivalent state that did not lift CON—a statistically significant reduction.

    - More importantly, states that lifted CON continued to report lower relative spending through the post-lift period. Four or more years after a state lifted its CON program, average per capita health spending was still 3.2% lower (with statistical significance) than it would have been in an equivalent state that did not lift CON.

- In short, lifting CON did not trigger a "surge" in health spending that continuation of CON might have averted. On the contrary, states that lifted CON reported 0.6% lower (with a trend towards statistical significance) average annual health spending in their whole post-lift period compared to equivalent states that didn't lift their CON.

- **Lifting CON does not result in an "explosion" in hospital spending per capita measured using location of provider.**

  - Similar results were found for hospital spending per capita. Hospital spending per capita in the year before lifting was 2.4% lower (with statistical significance) than it would have been in equivalent states that did not lift CON; four or more years after CON was lifted, this spending was on average 3.5% lower (with statistical significance).

  - In states that lifted CON, we didn't find significant difference in average annual hospital spending through the entire whole post-lift period from that of states that didn't lift their CON. So lifting CON may not reduce hospital spending, but neither is our result consistent with a picture of hospital spending "exploding" once CON restrictions are removed.

- **Lifting CON appears to reduce physician spending measured using location of provider.**

  - Physician spending per capita was 4.2% lower (with statistical significance) in the year before CON was lifted and in the four or more years after lifting was on average 8.3% lower (with statistical significance) compared to a "statistical twin" state that didn't lift its CON.

  - States that lifted CON reported 2.8% lower (with statistical significance) average annual physician spending in their whole post-lift period than states that didn't lift their CON.

- **States that lifted CON have lower health spending per capita measured using state of residence and also show no evidence of an "explosion" in health spending.**

  - Our results using the residence-based measure of health spending show a similar pattern compared to results based on location of providers. In the year prior to CON removal, health spending per capita was 1.3% lower (with statistical significance) than that of a statistical twin state which didn't lift CON.

- Four or more years following CON removal, health spending was 1.2% lower (with a trend towards statistical significance) than it would have been in an equivalent state that did not lift CON.

- **Lifting CON appears to lower Medicare spending per enrollee measured using state of residence only temporarily**.
    - The Medicare results do not exactly mirror results for the general population. One year prior to CON removal, Medicare spending per enrollee was 1.6% lower (with statistical significance) than that of a statistical twin state which didn't lift CON.
    - One year following CON removal, Medicare spending was 1.7% below that of a statistical twin state which didn't lift CON (with statistical significance). However, the difference (and statistical significance) gradually disappeared during the post-lift years, suggesting that any Medicare cost reductions were temporary.
- **CON lifting has no net impact over time on state's uninsured rate as a ratio to US average.**
    - We didn't find statistically significant change in the uninsured ratio in the years around and following CON lifting compared to four or more years before CON lifting above and beyond change over time among states where there was no CON lifting.
- **Stringent CON does not appear to be associated with a provider-based measure of health spending**.
    - States with low CON stringency show 0.5% higher (with a trend towards statistical significance) "net" health spending per capita measured by state of provider.
    - No similar statistical significance, or trend, was found in association of high stringency to health spending per capita.
- **Stringent CON is not associated with a provider-based measure of hospital spending**.
    - Low stringency CON states have 0.9% higher (with statistical significance) net hospital spending per capita measured by state of provider.
    - No statistical significance, or trend, was found in association of high stringency CON to hospital spending per capita.
- **Stringent CON is not associated with a provider-based measure of physician spending**.

- States with low stringency CON have 2.3% higher (with statistical significance) net physician spending per capita measured by state of provider.
- No statistical significance, or trend, was found in association of high stringency CON to this outcome.

- **Stringent CON is not associated with Medicare spending per enrollee**.
  - States with low stringency CON have 0.9% lower (with statistical significance) net Medicare spending per enrollee measured by state of residence.
  - No statistical significance, or trend, was found in association of high stringency to this outcome.
- **Stringent CON is not associated with a state's uninsured rate**.
  - No statistical significance, or trend, was found in association of high or low CON stringency to the uninsured index.

PART TWO: A SURVEY OF THE LITERATURE INDICATES SMALL OR ZERO BENEFITS FROM CON REQUIREMENTS

Section I. Research Questions

This Part of my expert report is adapted from a working paper that performs an in-depth literature review of the medical and scientific literature on certain questions related to the impact of certificate of need regulation in the U.S. Our primary goal was to identify, review, and evaluate the published literature to develop an interim estimate of the costs and benefits of certificate of need regulation for the year 2008; our secondary goal was to identify areas where no evidence exists or where the evidence has important limitations and then describe the type of data that would be needed to more fully address the question. The inclusion criteria only include literature from 1975-2010. Thus, the results reported here do not include the empirical results described in Parts One or Three.

The questions we addressed in our literature review are listed below by topic area, along with a brief description of our analytical approach, including outcomes of interest.

Costs of Certificate of Need Regulation

Question 1a. *What is the amount of government regulatory costs related to certificate of need regulation?* This includes state costs to monitor and enforce rules related to certificate of need for hospitals, nursing homes, or other facilities to which CON is applicable.

Question 1b. *What is the amount of industry compliance costs related to certificate of need regulation?* This includes all administrative costs and enforcement penalties borne by private, state or locally owned health facilities subject to state CON regulations. Monetary penalties may be viewed as a transfer, but the remaining costs represent real resource losses to society.

Benefits of Certificate of Need Regulation

Question 2a. *What is the net impact of CON on health expenditures?* Historically, CON policy was justified on market-perfecting grounds to overcome the weak incentives for economic discipline resulting from a combination of cost-based reimbursement and pervasive third-party payment for health care. According to this theory, CON could enhance efficiency by regionalizing expensive tertiary facilities and preventing the costly duplication of technology or facilities. But skeptics argue that CON is a form of industry protection from competition, pointing out that states that first adopted CON were more likely to have more hospital beds and lower occupancy rates. Reduced competition could have adverse effects on health expenditures (by allowing facilities to charge higher prices). Therefore, our search allowed for the possibility that CON could decrease, increase, or have no impact on health expenditures.

Question 2b. *What is the impact of CON on health outcomes?* To the extent that facilities with higher volumes of selected procedures have better outcomes, regionalization resulting from CON could have a corollary benefit in the form of improved patient outcomes. Likewise, to the extent that CON efforts to prevent "cream-skimming" were successful, this might allow the survival of certain facilities such as large urban public hospitals that might otherwise be forced to

shut down for lack of sufficient paying patients. In theory, this too could result in health benefits and/or reductions in avoidable hospitalizations if indigent patients were able to receive essential care on a timely basis. But limitations on competition also have the potential to result in lower quality care, so we sought literature that related CON to outcomes in either direction. Changes in either morbidity or mortality could be monetized using conventional methods.

Question 2c. *What is the impact of CON on access to care?* Another rationale for CON is to ensure access to disadvantaged populations or provide cross-subsidies to help offset uncompensated care costs. Whether informally or formally through explicit commitments required for approval, CON regulators have the power to restrict approval to facilities willing to supply services perceived to be in the public interest, such as charity care or care in medically underserved areas (Pacella 2005). Even if they had no measureable impact on health outcomes, such improvements in access to care would be of value, so we sought to ensure to include literature focused on this dimension of CON performance. However, some have raised concerns that CON may restrict access to care through output restriction and market division. That is the CON process may allow regulated hospitals or facilities to "carve out" the distribution of patients, beds or suites (both geographically or by specialty niche). "Output restriction and market division are two classical tactics that are used by economic oligopolies to manage supply and create market power" (Pacella 2005:1105). Such practices may be tacitly encouraged through CON programs. Therefore, our search allowed for the possibility that CON could decrease, increase or have no impact on access to health services.

Limitations of Review

The purpose of this literature review is to seek evidence from the medical and scientific literature to determine the magnitude of costs and benefits of CON regulation. The information gathered may be useful in determining the magnitude of regulatory costs and benefits, but it does not provide specific guidance on ways in which the objectives of certificate of need regulation might be pursued more cost-effectively.

Section II. Methods

Literature Search and Review

Sources

Peer-Reviewed Literature

We performed electronic subject-based searches of the literature using the following databases:

- MEDLINE® (1975-2010) and CINAHL® (1975-2010) which together cover all the relevant clinical literature and leading health policy journals.

- *Health Affairs*, the leading health policy journal, whose site permits full text searching of all issues from 1981-2010.

- ISI Web of Knowledge (1978-2010) which includes the *Science Citation Expanded*®, *Social Sciences Citation Index*®, and *Arts & Humanities Citation Index*™ covering all major social sciences journals.

- Lexis-Nexis (1975-2010), which covers all major law publications.

- Public Affairs Information Service (PAIS), including PAIS International and PAIS Periodicals/Publishers (1975-2010) which together index information on politics, public policy, social policy, and the social sciences in general. Covers journals, books, government publications, and directories.

- Dissertation Abstracts (1975-2010).

- Books in Print (1975-2010).

As is customary in my field, a professional librarian was used to conduct each search, customizing the searches for each research question. In cases where we already had identified a previous literature synthesis that included items known to be of relevance, we developed a list of search terms based on the subject headings from these articles and from the official indexing terms of MEDLINE and other databases being used. We performed multiple searches with combinations of these terms and evaluated the results of those searches for sensitivity and specificity with respect to each topic. We also performed searches on authors known or found to have published widely on a study topic. In addition to performing electronic database searches, we consulted experts in the field for further references. Finally, we reviewed the references cited by each article that was ultimately included in the synthesis. We did not hand search any journals. This review was limited to the English-language research literature. A complete listing of search terms and results is being produced along with this report.

"Fugitive" Literature

In some cases, relevant "fugitive" literature was cited—that is, we discovered citations to works that had not been turned up by our initial searches—in which case we made every effort to track it down. We also performed systematic Web searches at the following sites:

- Health law/regulation Web sites.

- Health industry trade organizations.

- State agency trade organizations and research centers.

- Major health care/health policy consulting firms.

- Health policy research organizations.

- Academic health policy centers.

- Major health policy foundations.

These searches varied by site. In cases where a complete publications listing was readily available, it was hand-searched. In other cases, we relied on the search function within the site itself to identify documents of potential relevance. Because of the volume of literature obtained through the peer-reviewed literature, including literature syntheses, we avoided material that simply summarized existing studies. Instead, we focused on retrieval of documents in which a new cost estimate was developed based on collection of primary data (e.g., surveys of state agencies) or secondary analysis of existing data (e.g., compilation of agency enforcement costs available from some other source). We excluded studies that did not report sufficient methodological detail to permit replication of their approach to cost estimation.

Inclusion Criteria

We developed the following inclusion criteria:

- Sample: wherever results from nationally representative samples were available, these were used in favor of case studies or more limited samples.

- Multiple Publications: whenever multiple results were reported from the same database or study, we selected those that were most recent and/or most methodologically sound.

- Outcomes: we selected only studies in which a measurable impact on costs or benefits was either directly reported or could be estimated from the reported outcomes in a reasonably straightforward fashion.

- Methods: we only selected studies in which sufficient methodological detail was reported to assess the quality of the estimate provided.

Where possible, we limited the review to studies from 1975 through December 31, 2010, reasoning that any earlier estimates could not be credibly extrapolated to the present given the sizable changes in the health care industry during the past two decades. Other exclusions were as follows:

- Unless we had no other information for a particular category of costs or benefits, we excluded qualitative estimates of impact.

- Estimates of impacts derived from unadjusted comparisons were discarded whenever high quality multivariate results were available to control for differences between states or across time.

- Estimates that focused on measuring system-wide impact generally were selected over narrower estimates (e.g., per capita health spending vs. cost per inpatient day) on

grounds that savings achieved in one sector may have induced higher spending elsewhere in the system; hence narrower comparisons might inadvertently lead to an inappropriate conclusion.

Section III. Results[4]

Empirical Evidence

In contrast to the dearth of studies available on other aspects of health regulation, there is a comparative embarrassment of riches in the area of CON, as it was the first major state-level initiative to curtail health spending. Kessler & McClellan (2000) show that in the 1980s, the welfare effects of hospital competition were ambiguous; but in the 1990s hospital competition unambiguously improves social welfare, i.e., lowering average expenditures per patient and mortality among Medicare patients being treated for heart attacks in the 1990s. Thus, in cases where evidence is conflicting, more recent evidence about CON's effects has been given greater weight than earlier studies.

An important consideration in evaluating the quality of a study's results is whether it addresses the issue of endogeneity or omitted variables bias. Endogeneity arises, for example, if states with lower-than-average health spending tended to drop CON, they might experience higher-than-average growth in health spending as spending in these states converges on the national average. Such convergence has been observed over decades both for per capita income and per capita health spending as differences between the highest and lowest states tended to narrow (Conover 2012). But a comparison that failed to take this into account would inappropriately attribute higher spending growth to removal of CON even though it might have happened even if every state had retained CON regulation.

But even if CON were randomly implemented across states, there is a great deal of heterogeneity across states that might produce statistically significant differences across states in various outcomes even if those states maintained identical CON regimes. For example, if states with CON tended to be those where hospitals typically use shorter anesthesia times, faster adoption of digital imaging, or greater use of anticoagulants, then cross-sectional comparisons may incorrectly attribute mortality differences to CON, even if these differences actually are related to differences in hospital practices.

Researchers generally try to control for known differences between the states that might have an influence on an outcome variable of interest. But they can never be certain they have

[4] The following acronyms are commonly used in the literature and are therefore used in summarizing the literature:

CABG	Coronary Artery Bypass Grafting
CON	Certificate of Need
CMS	Centers for Medicare and Medicaid Services
HCFA	Health Care Financing Administration is the former name for CMS
OHS	Open heart surgery
OHU	Open heart unit
PTCA	Percutaneous Transluminal Coronary Angioplasty
PCI	Percutaneous Coronary Intervention

taken into account every unobserved difference that might matter. Consequently, studies that rely on adjusted cross-section variation in the experience of states with and without CON regulations to measure the impact of CON, are therefore more subject to this sort of potential confounding from unobserved heterogeneity across states.

There are several different methods to address these problems, the most common being to use before and after comparisons, along with state fixed effects. State fixed effects are separate indicator variables for each state that essentially pick up the joint effect of any unmeasured variables. This allows the analysis to focus on changes within each state, so that the results are not confounded by systematic differences in unobserved characteristics. An alternative, less common approach is to use two-stage least squares to explicitly account for the factors that may have led some states to retain CON while other states dropped it. Or one can use the first-difference of potentially endogenous variables to break the link between that variable's absolute values and CON regulation. Another strong research design (especially in combination with using state fixed effects) is the differences-in-differences approach: this type of analysis 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.

Question 1a: Government Regulatory Costs

The closest approximation of government regulatory costs is the total staffing for state CON agencies, which are reported in DHHS (1986).

Question 1b: Industry Compliance Costs

While we found sporadic allusions to costs incurred by CON applicants and/or delays imposed by the CON process, we found no systematic literature summarizing such costs or providing reliable parameters from which to construct a national estimate.

Question 2a: Impact on Health Expenditures

Hospital CON

The evidence regarding CON's effect on costs is generally mixed, although in my expert opinion, the weight of this evidence is that CON has no impact on health costs overall. At most, there is some evidence that might suggest that imposing CON requirements on hospitals affects hospital expenditures per capita without affecting overall spending per capita. Even taking this evidence for all its worth, though, it does not demonstrate any overall reduction in spending per capita in the medical sector (as opposed to just the hospital sector).

Because of the sheer number of studies available, including several of high quality that examine CON's impact on overall health expenditures, we have excluded many other narrowly focused studies that examined CON's effects on cost per day or cost per stay since one cannot reliably extrapolate from these results to a global cost effect.[5] Some more recent studies have

[5] Conover and Sloan (2003) provide a thorough review of this large body of literature.

found that CON produces a savings in the hospital sector while having no detectable impact on health expenditures overall (Conover and Sloan 1998; Sloan and Conover 2003). In addition, most early studies did not correct for the endogeneity of CON regulation. More recent studies have corrected this oversight by using either two-stage models to estimate demand for regulation (Lanning, Morrisey and Ohsfeldt 1991) or using state-level fixed effects estimators (Antel, Ohsfeldt and Becker 1995; Conover and Sloan 1998; Sloan and Conover unpublished).

- Using HCFA time series cross section state level per capita spending data for 1969, 1972 and 1976-1982, Lanning, Morrisey and Ohsfeldt found that CON was associated both with an increase in per capita hospital spending (20.6 %) and per capita spending on other health services (9.0 %), for a net increase of 13.6 % in health spending overall.

- Using the same HCFA data from 1980-1993, Conover and Sloan (1998) found that CON had a long run effect of reducing hospital spending per capita by 5 %, but there was no significant impact on overall health spending per capita.

- In an update that makes use of these data for the 1980-1998 model, Sloan and Conover (2003) find that dropping CON for acute care services had no significant effect on total per capita health spending, its components (hospital and physician spending) or Medicare spending per eligible. Stringent CON was associated with a statistically significant reduction in hospital spending, but not in overall per capita expenditures, along with a 1.8 % decline in Medicare spending per eligible.

- The Federal Trade Commission and U.S. Department of Justice (2004), after extensively reviewing the available literature and hearing from expert witnesses, concluded the following: “The Agencies believe that CON programs are generally not successful in containing health care costs and that they can pose anticompetitive risks. As noted above, CON programs risk entrenching oligopolists and eroding consumer welfare. The aim of controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anticompetitive risks” (Chapter 8, p. 5).

- Hellinger (2009) used general estimating equations to examine the impact of CON in four years: 1985, 1990, 1995, and 2000. He found that states with certificate-of-need programs that cover short-term hospitals experience healthcare expenditures per capita that are 1.8% (41 × 0.045%) lower than those in states without such a CON program. Similarly, this implies that states with stringent certificate-of-need programs experience healthcare expenditures per capita that are 3.4% (76 × 0.045%) lower than those in states without stringent CON programs. While the analysis controls for many state characteristics, it does not use state fixed effects. Moreover, this core finding is undercut to some extent insofar as when CON is included as a covariate to explain health spending, it is not significant. In other words, there is no statistically significant relationship between CON and health spending using this study’s data. The study’s premise is that CON first reduces beds and this reduction in beds ultimately produces a later reduction in health spending. But it is puzzling that such a reduction in spending is not observed in the very same year that there are fewer beds, etc.

- Ho et al. (2009) using Medicare inpatient claims data for 1989-2002 found that 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. Thus, it is possible this results in higher spending in states that dropped CON even though this was not measured directly. This study relied on a differences-in-differences model with state fixed effects to address endogeneity concerns.

- Rivers et al. (2010), using a panel representing 2,168 short-term general, nonfederal US hospitals operating during the period 1999–2003, show that CON has no statistically significant impact on cost per adjusted admissions for all hospitals. However, states with stringent CON regulations had higher costs per adjusted admissions for all hospitals. This replicates findings from numerous studies in the 1970s and 1980s but is noted here because the analysis used superior methods and examined a period after the introduction of the Medicare PPS for hospitals (1983) and widespread emergence of managed care in the 1990's. Researchers used a fixed-effect model relying on first-differences to overcome the limitations of prior studies.

CON and Hospital Efficiency. Several studies have examined CON's impact on the measured efficiency of the hospital industry.

- In one of the earliest such studies, Eakin (1991) estimated minimum costs based on a cross-section of data of 331 U.S. short-term hospitals. To identify major contributors to inefficiency, hospital-specific estimates of allocative inefficiency were regressed against hospital attributes and regulation variables. Estimated coefficients on the binary variable of CON were positive and significant, showing that hospitals subject to CON regulations have a greater level of inefficiency by .88 to 1.03 %.

- Bates et al. (2006) measured technical efficiency using a technique known as data envelopment analysis (DEA). They then regressed the efficiency scores on a dummy variable for CON regulation and other elements of market structure (e.g., HMO activity). Based on their regression results, the authors concluded that, on average, CON laws did not reduce efficiency.

- Using data from 1994-2002, Ferrier et al. (2010) found that in general, the hospital sector in states with active CON regulations had 2.1% lower aggregate technical inefficiency, 0.8% lower structural inefficiency and 2.0% lower mix inefficiency, irrespective of the stringency or laxness of this oversight. "Hence, the presence of any CON has a positive impact measured by improved resource allocation and by definition, lower social costs." However, these efficiency gains were counterbalanced by 1.3% higher scale inefficiency, implying that hospitals in CON states tended to have more excess capacity even though CON in principle was designed to curtail this. It is worth noting that this model contained time fixed effects, but not state level fixed effects, controlling only for the percent of population living in rural areas and the share of hospital beds in private, public and

federal hospitals. Without controlling for endogeneity of CON adoption, it is conceivable that other unmeasured differences between the states are driving this result.

Nursing Home CON

We found at least a half dozen studies that examined the effects of nursing home CON on bed capacity, but most of these are at least two decades old and not directly informative of the net effect on health spending (since even demonstrated reductions in nursing home bed supply may simply spill over into expenditures on home and community-based substitutes). However, two more recent studies explicitly examined the impact of nursing home CON on health expenditures.

- Using a random effects model on data for 1991 through 1997 with states as the unit of analysis, Miller, et al. (2002) found that the presence of either a nursing home CON, a nursing home moratorium or both a CON and moratorium had a (positive) statistically insignificant effect on nursing home care per capita expenditures. The same study did find that the presence of a nursing home CON, a nursing home moratorium and both a CON and moratorium had a positive and significant effect on Medicaid long-term per capita expenditures. However, we did not include that result in this analysis on grounds that the first result suggests that any Medicaid savings may have been offset by increased nursing home spending by other payers. As well, this study did not control for state or year fixed effects.

- In contrast, Grabowski et al. (2003) used a fixed effects model on data for 1981 through 1998, to account for unobserved state-specific and time-specific factors that could have influenced either the elimination of nursing home CON or moratoria or the level of nursing home and long-term care expenditures. His study showed that states without CON or moratorium policies have a (very small positive) statistically insignificant effect on both Medicaid nursing home spending as well as Medicaid long-term care outlays.

- Chen (2005:101) shows that nursing home CON or moratoria are associated with a 1-3 percentage point decrease in cost inefficiency (p. 101) but a 1.4 percentage point reduction in technical efficiency (p. 102).

Other Types of CON

Hospice CON. Carlson (2005) used data from 1992-2000 to show that states that did not have certificate of need regulation of hospices experienced a statistically significant increase in the number of hospice entrants during this time period; market areas (defined as MSAs or counties in areas not part of MSAs) without CON experienced .72 more hospice entrants over the nine year period. Since hospices are associated with savings of $2,309 per user (Taylor et al. 2007) and two-thirds of hospices serve under 100 users annually (Carlson 2005:34), each hospice foregone in a market area represents $230,000 in potential annual savings lost. A typical state

with hospice CON regulation would have 46 market areas[6] and potential annual savings foregone of $850,000.

Kidney Dialysis. Ford and Kaserman (1993) analyzed impacts of CON regulations on entry into the dialysis industry from 1980 to 1989 showing that these regulations have constrained the entry and expansion in this industry, which led to higher costs for dialysis.

Question 2b: Impact on Health Outcomes

The Federal Trade Commission and U.S. Department of Justice (2004), after extensively reviewing the available literature and hearing from expert witnesses, concluded the following: "The Agencies believe that CON programs are generally not successful in containing health care costs and that they can pose anticompetitive risks. As noted above, CON programs risk entrenching oligopolists and eroding consumer welfare. The aim of controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anticompetitive risks. *A similar analysis applies to the use of CON programs to enhance health care quality and access*" (emphasis added, Chapter 8, p. 5).

Mortality Losses

There is debate in the literature about whether imposing CON requirements is associated with a reduction in mortality. Three studies (each of which has flaws) have found that CON requirements for hospitals reduce mortality risk; four studies have found that these CON requirements for hospitals have no effect on mortality risk; and one study finds that these CON requirements *increase* mortality risk.

Beneficial Effects of CON on Mortality. Three studies have found that CON is associated with a reduction in mortality.

- **Coronary Artery Bypass Surgery (CABG)**.
    - Vaughan-Sarrazin et al. (2002) conducted a national retrospective cohort study using Medicare Provider and Analysis Review (MedPAR) Part A data for over 900,000 patients admitted to over 1,000 hospitals across all 50 states from 1994 through 1999. Risk-adjusted mortality was 22% higher in 18 states that had no CON regulation of open heart units during this period compared to 26 states that maintained such regulation during the entire period. Mean patient volume per center in the 26 states with continuous CON was 84% higher than in the 18 states with no CON (191 annual cases vs. 104). Thus, a significantly higher percentage

[6] According to OMB: Of 3,143 counties in the United States, 1,167 will be in the 381 metropolitan statistical areas in the United States, and 641 counties will be in the 536 micropolitan statistical areas (1,335 counties are outside the classification). This implies there are 2,357 market areas as defined in the hospice study, or 46 per state.

of cases were performed in low-volume hospitals, consistent with the hypothesis that CON led to improvements in outcomes by regionalizing facilities. While this study controlled extensively for various patient characteristics, it did not control for other factors such as Medicare managed care penetration, physician-to-population density, or physician specialty mix, regional differences in the use of PTCA or various efforts by states to report CABG outcomes to consumers. The exclusion of patients in Medicare managed care plans may be particularly important: "therefore, the differences in hospital volume and mortality identified in this study may be upward biased due the higher rate of managed care penetration in states without CON regulation in their sample." (Ho, 2006:304). Moreover, its cross-sectional nature limits the ability of the authors to draw cause-and-effect conclusions, as it is conceivable that states without CON regulation of open heart surgery had worse surgical outcomes anyway for reasons unrelated to CON. More concretely, it does not include state fixed effects or other methods to address endogeneity. Consequently, much (or all) of the large mortality differential reported may be due to factors which are related to the presence or stringency of CON regulation in a state.

  - Ho (2006), using AHRQ HCUP National Inpatient Sample data from 1988-2000, found that CON regulations increase patient volume (14 years after dropping CON, the average number of CABG procedures per hospital declined by 27%). Using the measured relationship between procedure volume and risk-adjusted inpatient mortality, the author calculated that "for an average hospital in a state 14 years beyond repeal of CON rules, inpatient mortality rates for CABG are .1 percentage points higher than they otherwise would have been" (p. 315). This compares to an average risk-adjusted mortality rate in states that dropped CON of 3.9% in 2000. Further calculations by Ho showed that the average state dropping CON would experience roughly 4 additional CABG deaths a year due to this decline in patient volume. A limitation of this study is that all of the states in the HCUP sample except one discontinued their cardiac CON program prior to 1988. Therefore, the analysis focused on examining differences in hospital procedure volume as a function of the number of years since CON legislation was repealed in a given state.

- **Coronary Revascularization (CABG or PTCA).** In a retrospective cohort study of nearly 800,000 Medicare beneficiaries aged 68 years or older with AMI who were admitted to 4,587 US hospitals during 1998-2000, Popescu et al. (2005) found that compared to patients in states without CON, patients in states with CON regulations had slightly lower mortality risk. It is worth noting that a follow-up study using the same methods but more recent data from 2000-2003 found no mortality differences in CON versus non CON states (Popescu et al., 2006). As well, this study design has important weaknesses detailed in the discussion of the latter study results.

No Effects of CON on Mortality. By contrast, four studies have found no statistically significant impact of CON on mortality risk.

- **Coronary Artery Bypass Surgery (CABG)**.
    - Robinson et al. (2001) used inpatient data on all CABG surgeries performed in Pennsylvania hospitals between 1994-1999 to compare CABG outcomes 3 years prior to Pennsylvania's elimination of CON to 3 years afterwards. Despite a 25 percent increase in the number of open heart surgery programs once CON was lifted, the authors found no significant difference in the mortality experience of hospitals that were approved under CON to perform CABG compared to those that developed open-heart programs following CON's removal. Thus, the advantage of this study is that it is a longitudinal comparison that focuses on the impact of lifting CON. The disadvantage is that it is a case study of a single state, and one that happened to also have a statewide public performance monitoring system that included hospital reporting of CABG outcomes. Absent this reporting system, it is conceivable that very different results might have been found.

    - Using cardiac registry data from 2000-2003, DiSesa et al. (2006) show that CON states have significantly higher hospital average CABG surgery volumes but similar mortality compared with non-CON states. Thus, even though CON evidently succeeded to some extent in regionalizing CABG surgeries, this did not have the intended effect of reducing mortality. This study used more detailed clinical data and controls for regional confounding than Vaughan-Sarrazin et al. (2002), although it too does not include state fixed effects. The study also included subanalyses using state random effects: these account for some unobserved heterogeneity, but not all types.

- **Coronary Angioplasty (PTCA: Percutaneous Transluminal Coronary Angioplasty)**.

    - Ho (2004), using hospital discharge data for 1988-1998, found that Florida CON laws were associated with higher average PTCA volumes per hospital relative to California hospitals, where no such laws exist. Simulations showed that increasing the mean PTCA volume in California from its 1998 level of 389 procedures to the Florida mean of 724 would not change inpatient mortality rates, although the probability of urgent bypass grafting surgery would decline from 2.2% to 2.0% for a representative patient. The author concluded that "because a higher PTCA volume was associated with moderately better outcomes, CON may be marginally effective in improving outcomes for PTCA."

    - Ho (2006), using AHRQ National Inpatient Sample data from 1988-2000, found that although CON appears to lead to a sizeable increase in average hospital PTCA volume, there is no evidence that beneficial reduction in inpatient mortality accompanies this volume change.

- **Coronary Revascularization (CABG or PTCA).** In a retrospective cohort study of 1.1 million Medicare beneficiaries aged 68 years or older with AMI who were admitted to 4,587 US hospitals during 2000-2003, Popescu et al. (2006) found that the odds of 30-day mortality were similar in states with CON relative to states without CON. Adjusted

odds of death within CON 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 CON states. The authors speculate that "higher hospital volumes in states with certificates of need may counteract any adverse effects of limiting access to revascularization services" (p. 2146). The authors concede "the study design cannot discern a cause-and-effect relationship between certificates of need and use of revascularization or mortality" (p. 2146). The analysis did not control for a variety of factors that might have contributed to observed mortality differences including managed care penetration, regional physician practice variation, concurrent efforts to improve quality, or differences in other diagnostic and therapeutic choices (e.g, use of thrombolytics, aspirin, Beta-blockers), as these were not captured by administrative data.

Adverse Effects of CON on Mortality. There is only one study that has shown adverse effects of CON on mortality in general. All of the remaining studies have focused on CON's adverse impact on CABG outcomes.

- **General Mortality**. Using Medicare inpatient claims data from 1983-1984 for 981 hospitals, Shortell and Hughes (1988) examined mortality rates among hospital inpatients for 16 selected diagnoses, showing that the ratio of actual to expected deaths was 5-6% higher in states with stringent CON regulation compared to states with less stringent CON. This study was done before any states had dropped CON, so the only available comparison was between more restrictive and less restrictive CON programs. The ratio of actual to expected deaths was 1.06 in stringent CON states, .966 in states with medium stringency and .999 in states with the least stringent CON regulations. The authors conduct a statistical test showing the association of CON stringency with mortality is statistically significant, but do not provide pairwise comparisons of medium stringency vs. low CON states, so there is no way of knowing whether this difference is statistically significant.

- **National CABG Studies**. As noted above, the remaining studies all relate to CABG outcomes.

    - Ho, Ross et al. (2007) using data for 1989–2002 found a significant association between inpatient mortality and CON status for CABG. Ho accounted for state-level heterogeneity, which is taken into account by using fixed effect regressions (this allows for the measurement of within-hospital changes in mortality associated with each year after which cardiac CON regulations were eliminated). However, a shortcoming is that the study mixes mortality changes for states that dropped CON in the mid-1980s with those of states that dropped cardiac CON regulations more recently. This may yield misleading results if technology for cardiac surgery has improved over time, since combining the mortality changes following CON removal from two distinct periods along a technology continuum could mask the magnitude of potential mortality changes currently available to states dropping CON.

- Ho et al. (2009) using Medicare inpatient claims data for 1989-2002 found that states that dropped CON experienced lower CABG mortality rates relative to states that kept CON, although the differential is not permanent. This analysis examined procedural mortality for CABG or PCI (death during the same hospitalization as revascularization, or after discharge but within 30 days of surgery) and relied on a differences-in-differences model with state fixed effects to address endogeneity and unmeasured variable concerns.

- **CABG Case Studies**. Because of the intrinsic uncertainty about how accurately their findings can be generalized to other states, case study evidence generally is weaker than studies examining many or all states.

  - Cutler et al. (2009) also examined how the 1996 repeal of CON legislation in Pennsylvania affected the market for cardiac surgery in the state. They found that entry led to a redistribution of surgeries to higher-quality surgeons and that this entry was approximately welfare neutral. This is the only CON study to explicitly assign an economic value to mortality gains resulting from CON removal.

  - Kolstad (2009) found that repeal of CON in Pennsylvania led to a redistribution of CABG surgeries from lower- to higher-quality surgeons. Specifically, as new programs entered the market, volume shifted from incumbents to new entrants and from lower- to higher-quality surgeons. He estimates that the value of the improved outcomes resulting from this shift—11 deaths averted annually, or 88 life years--was roughly equal to the additional fixed costs incurred by new entrants ($13 million per program). Thus, overall social welfare neither increased nor decreased from removal of CON as it relates to CABG surgery.

Other Health Outcomes

A handful of studies have examined health outcomes unrelated to mortality risk.

- **Kidney Dialysis**. Ford and Kaserman (1993) analyzed impacts of CON regulations on entry into the dialysis industry from 1980 to 1989 showing that these regulations have constrained the entry and expansion in this industry; which led to a decrease in the quality of care for dialysis.

- **Coronary Angioplasty (PTCA: Percutaneous Transluminal Coronary Angioplasty)**. Ho (2004) using hospital discharge data for 1988-1998, found that Florida CON laws were associated with higher average PTCA volumes per hospital relative to California hospitals, where no such laws exist. Simulations showed that increasing the mean PTCA volume in California from its 1998 level of 389 procedures to the Florida mean of 724 would reduce the probability of urgent bypass grafting surgery from 2.2% to 2.0% for a representative patient. The author concluded that “because a higher PTCA volume was associated with moderately better outcomes, CON may be marginally effective in improving outcomes for PTCA” (p. 442). But the author also cautions: “lack of access to

angioplasty as a result of regionalization may have negative health consequences for patients in less populated areas who require emergency angioplasty" (p. 447).

- **Cardiac Catheterization**. Ross et al. (2007) examined chart-abstracted data for more than 137,000 Medicare patients admitted for acute myocardial infarction between 1994 and 1996 at 4,179 US acute-care hospitals. Patients were categorized into three groups: a) whether they had characteristics suggesting catheterization was generally recognized as "beneficial, useful, and effective" (strong indication); b) were patients for whom data on the effectiveness of the procedure were unclear (equivocal indication); or c) were patients who had conditions for which cardiac catheterization was considered unlikely to be effective (weak indication), Using multi-level modeling to account for a variety of patient, hospital and state characteristics, the authors found that CON regulation was associated with 12% lower rates of catheterization among patients with equivocal indications and a 16% lower rate of catheterization among patients with weak indications. There were no significant differences in catheterization rates among patients with strong indications. The authors conclude that this "suggests either that physicians do discriminate on the basis of procedure appropriateness when faced with reduced capacity to provide care or that facilities refer fewer less appropriate patients for catheterization when greater facility volume is ensured" (p. 1016). The authors also caution: "we found substantial underuse of appropriate care, because only 50% of patients with strong indications in states with and without CON regulation received cardiac catheterization after admission for AMI." Thus CON may improve quality by reducing use of catheterization when not medically appropriate, but it does not appear to increase the use of catheterization when it is appropriate either. The authors further note that the observational, cross-sectional design can only suggest but not prove a cause-and-effect relationship between CON regulation and use of cardiac catheterization.

Nursing Home Quality

There is a companion literature on the impact of nursing home CON on quality measured in terms of structure, process and outcome indicators.

- Using a two-stage least squares model to analyze 1987 data, Zinn (1994) showed that the presence of a statewide nursing home construction moratorium is associated with a lower level of quality of care, measured in terms of both lower RN staffing and a higher percentage of residents who are physically restrained.

- In theory, a binding CON policy provides no incentive to nursing homes to compete for Medicaid residents on the basis of quality; the theory argues that under such a binding constraint, a higher payment level actually leads to lower quality. It also can lead to access problems for Medicaid patients such as "cream-skimming" patients likely to require less intensive nursing home services. A large body of literature (excellently reviewed in Caldwell (2006)) examines evidence related to this theory (and to "cream-skimming" and other access barriers faced by prospective nursing home patients on Medicaid), but recent evidence in a series of studies by David Grabowski suggests higher Medicaid payments do result in higher nursing home quality, contradicting a raft of

earlier results by Gertler and Nyman. Nursing home occupancy rates have declined over time, suggesting less "excess demand" (which in turn suggests that either nursing home CON may impose less of a binding constraint or that substitutes for nursing home have arisen that dissipate some of the adverse consequences that nursing home CON might historically have imposed.

Question 2c: Impact on Access

One justification for CON entry restrictions is the need to maintain provider financial margins so they may cross-subsidize indigent care (Madden 1999). Indeed, as of 1994, most CON programs required facilities to provide a "reasonable amount" of care to the poor (Greene 1994).

Positive Effects of CON on Access

Some research has shown that some states explicitly use their CON authority to protect existing providers that serve underserved populations (Campbell and Ahern 1993; Campbell and Fournier 1993).

- **Access to Disadvantaged Populations**.

    - Miller and Hutton (2000) show that state health agencies gave favorable treatment in the CON review process to hospitals with a high volume of Medicaid and indigent patients (cited in Gau 2007:56).

    - Using 2002 – 2004 State Inpatient Data HCUP data on hospitals in 12 states with CON and 5 states without CON, Zhang (2008) assessed the impact of CON on the number of uninsured hospital admissions and percentage of hospital admissions due to uninsured patients. He controlled for a variety of market and hospital characteristics, and used both a generalized least squares (GLS) model as well as an instrumental variable model designed to account for endogeneity. He found that CON laws increased both the number of nonprofit hospital admissions for the uninsured (11 per year per hospital) and uninsured percent admissions (by 0.07%.). These small effects were significant in the GLS model (which did not account for endogeneity); somewhat larger effects were found using the IV model, but were not statistically significant. GLS results did not show that CON laws have any effect on for-profit hospital's number of uncompensated care admissions; however, CON laws are significantly positively related to the percent of admissions for the uninsured by for-profit hospitals, again by a small amount (0.25%). The IV model produces much larger effects (6.9% increase) but these are not significant. Zhang concedes weaknesses in both models but emphasized the consistency in general direction of results from both as an indication that what was being measured was a genuine phenomenon.

- **California Case Study**. Campbell and Ahern (1993) used two-period California data to explore the effect of CON on uncompensated care provision. Specifically, they ran separate multivariate regressions for California hospitals in 1963 and 1987 to examine the determinants of hospital provision of uncompensated care. They found a positive relationship between net profitability of private nonprofit hospitals and the amount of uncompensated care they provide. They argue that this finding suggests government regulators reward heavily burdened uncompensated care providers with profitable CON licenses. Since no CON variables are actually used in estimating the amount of uncompensated care given by providers, this study fails to demonstrate a direct connection between CON activities and actual provision of indigent care.

- **Florida Case Study**. Both Campbell and Fournier (1993) in a descriptive study and Fournier and Campbell (1997) using an empirical model, have shown how Florida CON regulators used the licensing power to create entry barriers forcing existing providers to subsidize indigent care with higher than normal profit from other services. They found that, controlling for the endogeneity of indigent care, regulators in Florida systematically awarded CON licenses to hospitals providing greater amount of care to the poor. The authors noted that while this method of financing the indigent care may be preferred by legislators who do not want to face the political consequences of increasing taxes to pay for the service, the undesirable effects of restraining the provision of hospital services must be taken into account.

- **Pennsylvania Case Study**. In Pennsylvania, the CON program also tended to reward providers who agreed to supply more uncompensated care. (Alpha-Center 1999).

- **Safety Net Hospitals**. Mendelson and Arnold (1993) found that regulators in Ohio used CON to protect access to care for the disadvantaged by denying applications that could have adverse effects on the financial viability of safety net hospitals in inner cities. Lewin and Alpha Center's report (1991) to the Ohio Department of Health provided similar evidence (cited in Zhang 2008:17).

- **Access for General Population**

  - **Selected Surgical Procedures**. In a retrospective study that used HCUP State Inpatient data compiled by the Health Care Utilization Project, Fric-Shamji and Shamji (2008) examined mean per capita rates of 6 surgical procedures in 21 states with CON laws and 5 states without between 2004 and 2005. While CON laws did not affect procedure rates, various procedures exhibited a shift from for-profit to nonprofit facilities including lumbar disectomy (20% versus 9%), acoustic neuroma resection (5.5% versus. 0.2%), MVD (20% versus 3%), and rotator cuff repair (23% versus 10%). CON status had no effect on the proportion of cases occurring at teaching facilities. Thus, CON regulation does not negatively

affect resident access to sufficient caseload for surgical training. This study has a very weak design as it does not control in any way for differences between states that might have accounted for observed differences in surgery rates.

- **Selected Surgical Procedures**. In a retrospective study that used HCUP State Inpatient data compiled by the Health Care Utilization Project, Fric-Shamji and Shamji (2010) examined mean per capita rates of 26 diverse surgical procedures were evaluated in 21 states with CON laws and 5 states without between 2004 and 2006. Rates were higher in CON states for some procedures and lower for roughly the same number. However, when the comparison was limited to procedures performed in teaching hospitals, there were 12 procedures for which this rate was higher by a statistically significant amount in CON states and only 1 (cardiac transplant) in which CON states had a lower rate than states without CON. The authors conclude: "Increased procedural rates were seen in more profitable surgeries, such as cardiac and orthopedic, whose surpluses may then be used to fund medical care to the poor and uninsured. These results suggest that health care planning agencies may be strategically granting certificates to teaching facilities as a means of preserving uncompensated health care" (p. E83). This study has a very weak design as it does not control in any way for differences between states that might have accounted for observed differences in surgery rates.

No Effects of CON on Access

Only one study has found evidence that CON has no impact on access.

- **Selected Surgical Procedures**. In a retrospective study that used HCUP State Inpatient data compiled by the Health Care Utilization Project, Fric-Shamji and Shamji (2008) examined mean per capita rates of 6 surgical procedures were evaluated in 21 states with CON laws and 5 states without between 2004 and 2005. CON laws did not affect procedure rates for any of the surgeries examined. This study has a very weak design as it does not control in any way for differences between states that might have accounted for observed differences in surgery rates.

Negative Effects of CON on Access

The Federal Trade Commission and U.S. Department of Justice (2004), after extensively reviewing the available literature and hearing from expert witnesses, concluded the following: "The Agencies believe that CON programs are generally not successful in containing health care costs and that they can pose anticompetitive risks. As noted above, CON programs risk entrenching oligopolists and eroding consumer welfare. The aim of controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anticompetitive risks. *A similar analysis applies to the use of CON programs to enhance health care quality and access*" (emphasis added, Chapter 8, p. 5).

There are a number of studies showing that CON reduces the number of facilities offering a given regulated service yet no statistically significant change in the number of procedures. We

have treated these as adversely affecting access since fewer available facilities implies greater patient travel times for care.

- **Coronary Revascularization (CABG or PTCA).** In a retrospective cohort study of 1.1 million Medicare beneficiaries aged 68 years or older with AMI who were admitted to 4,587 US hospitals during 2000-2003, Popescu et al. (2006) found that compared to patients in states without CON, patients in states with CON regulations were a) less likely to be admitted to hospitals with coronary revascularization services (51.5% vs 62.8%) b) less likely to undergo revascularization at the admitting hospital (26.1% vs 31.8%); and c) more likely to undergo revascularization at a transfer hospital (11.7% vs. 8.9%), all statistically significant results. But it is important to note these differences did not result in measured mortality differences in CON versus no CON states. As well, the authors concede "the study design cannot discern a cause-and-effect relationship between certificates of need and use of revascularization or mortality" (p. 2146). The analysis did not control for a variety of factors that might have contributed to observed mortality differences including managed care penetration, regional physician practice variation, concurrent efforts to improve quality, or differences in other diagnostic and therapeutic choices (e.g, use of thrombolytics, aspirin, Beta-blockers), as these were not captured by administrative data.

- **Percutaneous Coronary Intervention (PCI)**.
    - Using national data for 1989 and 2002, Ho (2007) found that the presence of continuous CON regulations was associated with fewer hospitals per capita performing PCI. Multivariate regressions indicated that the presence of CON regulations was associated with 19.2% fewer PCIs per 1000 elderly in the population.

    - Ho et al. (2009) used the same 1989-2002 data but this time used a difference-in-difference-in-difference analysis with state fixed effects showing that removal of state cardiac CON regulations is associated with a 12.1% increase in the number of hospitals performing PCI. But there was no significant association between removal of CON and the total number of procedures performed.

- **Coronary Artery Bypass Grafts (CABG)**. Three studies have produced mixed results.

    - Robinson et al. (2001) compared CABG outcomes 3 years prior to Pennsylvania's elimination of CON to 3 years afterwards, showing a 25 percent increase in the number of open heart surgery programs once CON was lifted, but no significant increase in the number of CABG surgeries performed.

    - Using cardiac registry data from 2000 to 2003, DiSesa et al. show that CON states have significantly higher hospital average CABG surgery volumes.

    - Ho (2006), using AHRQ HCUP National Inpatient Sample data from 1988-2000, found that CON regulations increase the mean number of CABG procedures per

hospital. The author concludes: “These data are consistent with the hypothesis that CON restricts entry, allowing CON hospitals to grow larger on average.”

- Popescu (2006) found greater revascularization rates for patients with acute myocardial infarction (AMI) in non-CON versus CON states and indirect evidence of fewer facilities performing revascularization in CON states.

- Using national data for 1989 and 2002, Ho, Ross et al. (2007) found that each year, the per capita number of hospitals performing CABG was higher in states without CON (3.7 per 100,000 elderly for CABG in 2002), compared with CON states (2.5 for CABG in 2002). However, multivariate regressions found no difference in CABG utilization rates between states with and without CON.

- Ho et al. (2009) used Medicare inpatient claims data for 1989-2002 in a difference-in-difference-in-difference analysis with state fixed effects, showing that removal of state cardiac CON regulations is associated with a 15.2% increase in the number of hospitals performing CABG. But there was no significant association between removal of CON and the total number of procedures performed.

- Kolstad (2009) shows that in the 7 years following repeal of CON in Pennsylvania, the number of CABG programs grew by 49%. By comparing trends in New Jersey and New York during the same period, the author concludes that between 10 and 16 of the 24 new programs added could be attributed to CON repeal. The average CABG recipient traveled 2.3 fewer miles (a 9% reduction in travel distance); this amount was valued at $7.50 patient inclusive of family visits. As well, 15% of incumbent facilities accepted Medicaid patients compared to 10% of new entrants (although it also should be noted that most new entrants were located in suburbs).

- **Cardiac Angiography**. Using N.J. data from 1995 to 2004, Delia et al. (2009) found that a CON reform designed to expand cardiac angiography (CA) capacity increased CA utilization overall and did so more rapidly for blacks, leading to a large reduction in the disparity. However, this reduction was *not* attributable to services provided by new entrants to the CA market, since they were located in mostly white suburban areas. Instead, the new entrants cut into the incumbents’ share of white CA patients who had previously traveled from the suburbs to receive the procedure at inner-city incumbent hospitals. As a result, it appears that incumbents were forced to serve more black patients in their local area to maintain their CA volume. These findings suggest that prior restrictions on CA capacity contributed to the historical disparity in access to the procedure.

- **Carpal Tunnel Release**. Fric-Shamji and Shamji (2008) compared rates of CTR and lumbar discectomy in states with and without CON, finding CTR rates per 100,000 population 22% lower in states with CON (in contrast, the difference in rates for lumbar discectomy was not statistically significant).

- **Cancer Procedures**. Short et al. (2008) examined Medicare data for beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002. The study found that hospital availability was higher in non-CON than CON states, yet procedure use was similar across all states. Correspondingly, hospital procedure volume tended to be higher in CON states than in non-CON states. The number of hospitals per cancer incident was lower in CON states versus non-CON states for colectomy, rectal resection, and pulmonary lobectomy. Hospital volume was significantly higher in CON states versus non-CON states for colectomy and pulmonary lobectomy. There were no differences between states with and without CON in the number of procedures per cancer incident. This was a cross-sectional design that controlled for a number of state characteristics but not state fixed effects, so causal inferences are limited.

Feldstein (2002) cites many cases in which the courts found that the CON process was used in an arbitrary and capricious manner against new hospitals attempting to enter the market of an existing provider (cited in Gai 2007).

Net Assessment

As previously discussed, there is a wide range of evidence contained in the research regarding the possible benefits of CON policies. There are certainly some studies that indicate that CON requirements (at least CON requirements on large-scale providers like hospitals) may result in some improved health results or even cost savings. But there is more evidence showing that CON requirements are at best neutral and at worst affirmatively counterproductive—that is, that they result in *higher* spending, *worse* health outcomes, and *more* deaths without even taking into account the programs' regulatory and other costs. On balance, I join in the opinion of other experts (and the Federal Trade Commission and U.S. Department of Justice) in concluding that CON requirements fail to achieve any benefits that would justify their large direct costs.

Below, I describe more firmly our estimate of exactly what the costs and benefits of CON requirements are:

- *Government Regulatory Costs*. We multiply average CON staffing per state in 1986 times the number of states with CON in 2008 and multiply this times the average total compensation of state employees in 2008. Since we do not know whether CON employees have total compensation that is lower or higher than the average for all state employees, we use +/- 25% for upper and lower bounds.

- *Industry Compliance Costs: Administrative Costs*. Lacking a firm estimate, we assume the ratio of industry compliance costs to government regulatory costs is 3:1 (1, 5) and estimate compliance costs accordingly. These identical ratios were used for number of health services regulations examined where empirical evidence was lacking.

- *Indirect Costs: Impact on Health Expenditures.* In light of all the mixed findings regarding CON on total expenditures, we use no reduction in spending as our expected value. We use the 1.8 percent reduction in Medicare expenditures in stringent CON states

as our lower bound. i.e., making it a benefit. We apply this percentage to Medicare expenditures in states with stringent CON, using CMS estimates of state health expenditures in 2008 to determine the latter. Because the Lanning, Morrisey and Ohsfeldt study is so dated, we use half their estimate as an upper bound. We estimated the fraction of personal health spending in 2008 occurring in the states with CON in 2008 and applied half the 13.6 percent increase to determine the total increase in expenditures attributable to CON.

- *Indirect Costs: Health Losses*. In light of the mixed results regarding CON's effect on mortality risk, we use zero impact on mortality as our most likely case. The Vaughn-Sarrazin finding that CON reduces mortality is suspect especially in light of subsequent (often methodologically superior) studies showing either no effect of CON on CABG outcomes (2 studies) or an adverse effect on CABG mortality (4 studies). Because of its methodological limitations, we use the Vaughan-Sarrazin results as a lower bound (applied only to CABG mortality rates for the elderly). We monetize this estimated mortality reduction using the estimated life expectancy and quality of life of a typical CABG survivor and multiplying the net increase in quality-adjusted life years (QALYs) times a willingness-to-pay estimate of the value of a QALY. Similarly, because it measured effects using data now nearly 2 decades old and also has its own methodological limitations, we use the Shortell and Hughes result as an upper bound (applied to all elderly hospitalization mortality for the elderly in states with stringent CON). We monetize this estimated mortality increase using an adjusted value of statistical life for the elderly that takes into account their lower life expectancy relative to the general population (i.e., this calculation assumes the elderly place the same value on an added year of life as the general population, but this means the aggregate value they place on mortality risk reductions is lower since they have fewer years of life remaining).

- *Social Welfare Losses: Efficiency Losses from Tax Collection*. To account for the efficiency losses associated with raising taxes to pay for government regulatory costs, we multiply the latter times the marginal cost of income tax collections.

- *Social Welfare Losses: Efficiency Losses from Regulatory Costs.* All industry compliance costs are presumed to be roughly equivalent to an excise tax, i.e., raising prices and reducing demand/output correspondingly. We therefore multiply these costs times the marginal excess burden associated with output taxes, using 21% (15%, 28%) as the expected value of MEB.

In total the expected annual cost of CON is $99 million (17, 92,523) while the expected benefits are $0 million (0, 3,562).

It is worth noting that there is some uncertainty in the literature about CON, which is to be expected in the social sciences. It is impossible for me to categorically say that it is impossible for CON to have net benefits; I can only say that I think it is highly improbable. That said, one must consider the weight of the evidence. As noted above, there are empirical studies that purport to show benefits to CON—and, as explained above, I think these studies have serious flaws. But even if one sets aside these flaws and assumes these studies are perfectly

correct, they at most show a (very small) chance that CON has benefits as large as $3.5 billion a year. But if one viewed the studies showing *costs* to CON with similar credulity, they would show a (very small) chance that CON has costs as high as $92.5 billion a year. In both cases, there is considerable doubt about whether the empirical results that represent the upper and lower bounds are genuine or simply anomalous results.[7] The weight of the evidence matters, as does the magnitude of the possible effects, and both of those cut strongly against any possibility of CON having net local benefits. Put differently, in order to believe CON is even a 50/50 bet for achieving any net local benefits, I would not only have to be wrong about my estimates of the costs of the policy; I would have to be wrong by a factor of 26.

Given the many years that I have studied this issue, I have a very high degree of confidence that I have not overstated the worst-case costs of CON by a factor of 26, nor do I

[7] Let me explain what I mean by "doubt": All empirical studies of CON represent efforts to determine the true state of the world by examining a microcosm (a sample of patients, hospitals, states etc.). We can then try to confirm or disconfirm those results by seeing if we get the same result with a different microcosm (or different sample). I can have confidence in many of the results above because they match up with results found using different samples, but I cannot have this confidence in the studies showing benefits to CON. Instead, those studies (because of flaws in study design) seem likely to be statistical anomalies. For example, the Vaughan-Sarrazin study, using 1994-99 data, showed a 22% increase in risk-adjusted mortality rates for CABG patients in states without CON. I believe this is very unlikely to characterize the true state of the world for the following reason: If the V-S result were true, it would be very difficult to explain why six different follow-on studies found very different and sometimes opposite results. Admittedly, three of these are case studies of one state: Pennsylvania (1 finding no impact on CABG mortality and 2 finding that CABG mortality went down following the removal of CON as CABG patients shifted from lower-quality to higher-quality surgeons). It's certainly possible that Pennsylvania is a unique situation whose improvement in CABG outcomes may instead have been related to the introduction of a statewide public performance system that included hospital reporting of CABG outcomes shortly before CON was lifted. And even if the improvements were due to CON removal, it is certainly possible that Pennsylvania is an outlier unrepresentative of what was going on in states that removed CON more generally.

But even if we set aside the Pennsylvania results, we are left with a national study using 2000-03 data showing no effect of CON on CABG mortality. This study used more detailed clinical data and controls for regional confounding than did V-S, which may explain why it got a different result. If that is the explanation, it means the V-S result was a statistical artifact arising from the failure to account for unmeasured variables. Alternatively, it may be that CON was beneficial in 1994-99 but no longer beneficial in the 2000-03. If so, it would seem that the more recent results are most pertinent to a decision about CON's potential harms or benefits in 2014.

And this conclusion is strengthened even further when we consider two more studies using 1989-2002 data and methodologically superior models that do a much better job of accounting for unmeasured variables: both found that inpatient mortality for CABG patients is lower in states that removed CON. Thus, we have 3 different national studies and 3 case studies (admittedly, all of the same state) providing zero empirical support for a hypothesis that removing CON will increase CABG mortality rates by 22%. Using the principle of Occam's razor, it is much more straightforward to conclude that the V-S finding is an anomalous result arising from methodological limitations rather than concluding that the V-S finding is correct, while the consistent results of other (methodologically superior studies) are all anomalous. If V-S were more methodologically rigorous than the studies that came after it, there would be a reason to consider this possibility. But since it is not, there is no good scientific reason to accord V-S greater weight than these other studies. Indeed, the opposite is true: The V-S study is entitled to less weight than are the six studies that condradict it. So I cannot categorically rule out the possibility that V-S accurately depicts the true state of the world, just as one cannot categorically rule out the possibility that a boxer who is disfavored at 100:1 odds will actually win the fight. But like the underdog boxer, the possibility that the V-S study is actually correct is very slight given the wealth of other evidence we have available.

believe the chances of the $3.5 billion potential benefit of CON being an accurate depiction of reality are 26 times greater than the chances that CON actually is imposing costs to the tune of $92.5 billion. What is known for certain are the actual costs of the CON process, borne by Virginia taxpayers, patients and providers. In light of the evidence I have presented, it is difficult to argue that is a worthwhile expenditure.

PART III: INCUMBENCY (AS MEASURED BY THE PRESENCE OF AN "OWNER" NUMBER) IS CORRELATED WITH A LARGE ADVANTAGE IN CERTIFICATE-OF-PUBLIC-NEED APPLICATIONS

Finally, I was asked to determine whether there was any relationship between whether an applicant had been assigned an "owner" number by the Defendants in this lawsuit and the outcomes of that applicant's applications for a Certificate of Public Need in Virginia. My understanding is that Defendants assign "owner" numbers to certain entities in their discretion; there are no objective criteria guaranteeing the issuance of an "owner" number, and there is no mechanism to apply for an "owner" number. It is simply used by Defendants for internal tracking purposes.

Counsel for the plaintiffs in this action informed me that they had been told by counsel for Defendants that "owner" numbers were assigned to entities that had applied for multiple certificates of need. I am informed that, later in discovery, this assertion was amended to state that the entities that had "owner" numbers were almost entirely entities that had applied for multiple certificates of need, but that some small number of "owner" numbers had been assigned to entities that had only applied once. Regardless, an "owner" number signifies at least some degree of repeat-player status (that is, incumbency).

To determine whether possessing an "owner" number signifies any kind of advantage in the CON application process, my team and I examined three questions:

- Whether non-incumbent applications are more likely than incumbent applications to be denied.
- Among those applications granted with a CON, whether non-incumbent applications are more likely than incumbent applications to have conditions attached.
- Whether the length of time to make a decision about non-incumbent applications is greater than for incumbent applications.

Data

Counsel for Plaintiffs have provided 13 years (2000-2012) of data from the Virginia Division of Certificate of Public Need (DCOPN) involving 1,565 CON decisions. Each observation = an application on initiating a project at a medical care facility, with a decision made by the DCOPN.

Dependent Variables

- Granted. 1=application was approved; 0=application was denied. Three observations with value “No review required” or “no COPN needed (separate license)” were excluded from the regression analysis.

- Conditions. 1=application approved with conditions; 0=application approved without conditions. Values of 7 observations were missing and multiply imputed.

- Duration = number of days between date application was received and a decision was made (range=0-1,639). For the purpose of regression analysis, this variable was natural log-transformed to better fit the normal distribution. Values of 6% (87) observations were missing and multiply imputed.

Covariates

- Incumbent. 1=yes; 0=no. This variable simply indicates whether an applicant had an owner number (or did not).

- Experience=number of applications to CON agency since the inception of a medical care facility (range=0-166). This was recoded into five experience categories: exp1=none (1), exp2=limited (2), exp3=modest (3-4), exp4=solid (5-7) and exp5=extensive (8 or more). The omitted reference category in all analyses was exp5. There were no missing observations for this variable. In sensitive analyses, log-transformed experience score was used in place of experience category dummies.

- Requested capital cost=dollar value of project being approved (range=0-1.004 billion). This variable was natural log-transformed to better approximate a normal distribution. Values of one third of observations were missing and multiply imputed.

- Imaging. Indicates whether request was for diagnostic imaging equipment. 1=yes; 0=no. Values of 7 observations were missing and multiply imputed.

- Batch. Indicates what type of project is under consideration (including diagnostic imaging). Coded as A-G in the raw data received; this was recoded into 5 dummy variables: if Batch=A then Batch1=1 …; if Batch=B then Batch2=1 …; etc. Only 2 observations reported 2 codes and were treated as if they reported a single code, which is the code with a lower prevalence in the whole sample. Batch4 is equivalent to Imaging. The omitted reference category in all analyses was Batch2. Values of 7 observations were missing and multiply imputed.

- Competing. Indicates whether there was a competing application being considered. 1=yes; 0=no. Missing values were replaced by zero.

- IFFC Scheduled. Indicates whether there was an internal fact-finding hearing scheduled. 1=yes; 0=no. There were no missing observations for this variable.
- IFFC HELD. Indicates whether an internal fact-finding hearing was actually held. 1=yes; 0=no. Values of 42% observations were missing and multiply imputed.

- RHPA. Indicates the region of the state where the applicant facility would be located (range=0-5). Separate dummy variables have been created: All=1 when RHPA=0; HPR1=1 when RHPA=1, HPR2=1 when RPHA=2, etc. Values of 10 observations were missing and multiply imputed.

- Year. Indicates the year that a letter of intent was received. Values of 2% (28) observations were missing and multiply imputed.

Analysis

Multiple Imputation. The data set provided is missing some data for both dependent variables and covariates. We used multiple imputation to create 20 multiply-imputed datasets for analysis. Specifically, missing values were predicted 20 times based on all the available information of variables without missing values in the dataset using multivariate normal model, logistic model, and multivariate logistic model to predict missing values, whichever model was applicable in light of the type of variable having missing values. IFFC held (42% values were missing), Requested capital cost (a third values were missing), Duration (6% values were missing), Year (2% values were missing), RHPA (10 values were missing), Batch/Imaging (7 values were missing) and Conditions (7 values were missing) were imputed.

Data Transformations. We used the natural log of both duration (plus 1) and requested capital cost (plus 1) in all analyses. We also used natural log of the experience score in sensitivity analyses.

Regression Analysis. We performed a series of regression analyses. For each dependent variable listed below, we ran three models: the first using only applications for diagnostic imaging equipment, the second using all observations and the third using all observations with an interaction term to isolate the effects of incumbency on diagnostic imaging equipment applications.

- Granted. We used a logistic regression to assess the impact of incumbency on whether a project is approved using all covariates listed (n=1,541-1,544 for full sample; n=584-585 for diagnostic imaging sub-sample).

- Conditions. We used a logistic regression to assess the impact of incumbency on whether an approved project has conditions attached to its approval using all covariates listed. This analysis was restricted to applications which were granted (n=866 for full sample; n=329-330 for diagnostic imaging sub-sample).

- Duration. We used a standard linear regression model to assess the impact of incumbency on time to approval using all covariates listed (n=1,551 for full sample; n=588-589 for diagnostic imaging sub-sample).

Statistical Consult. We obtained a statistical consult with ISDS http://stat.duke.edu/statistical-consulting-center. We made several changes to the model in light of our various discussions with them and their written report to us. In particular, the year fixed effects variables (which allow the model to take into account any unmeasured changes in state health policy or the medical market that might have caused a change in the likelihood of project approval relative to other periods examined in the 13 years examined) were statistically significant for a number of years included: their inclusion reduced the estimated magnitude of the association between incumbency status and project approval. This gives us more confidence that we have accounted for a variety of potential unmeasured effects and are accurately measuring the net effects of incumbency on the COPN approval process. Also, we ran an additional model to explore potential relationship of Granted and Conditions to Duration, but didn't find any statistically significant association.

Major Findings

All effects described below are taken into account: a) a project's capital costs; b) an applicant's experience; c) whether the applicant faced a competing applicant for a similar project; d) whether an internal fact-finding hearing was scheduled; e) whether such hearing was held; f) the region of the state for which the applicant applied; g) type of the application (including diagnostic imaging equipment) was considered and h) year fixed effects.

- **Incumbency is associated with a much higher probability of project approval**.
    - For applications involving diagnostic imaging equipment applications, the odds of approval for incumbent applicants were 5.3 times as large as the odds for statistically equivalent applicants who were non-incumbents.
    - A similar pattern was observed for all applications (inclusive of those for diagnostic imaging equipment) where the odds of success for incumbent applications were 3.3 times as large.

- In a model that divided all diagnostic imaging equipment applications according to whether competing applications were present, the odds that an incumbent applicant received approval were 4.8 times the odds that a non-incumbent applicant received approval in the subgroup of diagnostic imaging applications.

- **Incumbency does not appear to be associated with lower odds that an equipment project will be approved with conditions attached.**

  - For both diagnostic imaging and all approved applications, there was no statistically significant difference in the odds that conditions were attached to approval for incumbent applicants compared to non-incumbents (p=.285 for imaging applications, p=.407 for all applications).

  - Similarly, in a model that divides all approved diagnostic imaging equipment applications according to whether competing applications were present, we still didn't find a statistically significant association of incumbency on whether conditions were attached to approval (p=.163).

- **Incumbency may be associated with a shorter duration of the review process for diagnostic imaging applications**.

  - In the analysis of diagnostic imaging applications, incumbency is associated with a shorter review process, but the result is not statistically significant (p=.181). However, an alternative model using all applications and an alternative way of isolating the effects of incumbency on diagnostic imaging applications found that incumbent applications related to diagnostic imaging were associated with a shorter review process, with result approaching statistical significance (p=.062); this might have reached significance with a larger sample.

  - In contrast, incumbency has no statistically significant effect on duration of the review process (p=.911) for all applications.

In short, incumbency (that is, the presence or absence of an owner number) is very strongly related to stronger odds of a successful application, and this effect is even larger for imaging equipment. It does not appear to have a significant relationship to whether an application is approved with or without conditions.

I certify that the foregoing is an accurate reflection of my opinions in this matter.

April 30, 2014

Dr. Christopher J. Conover, Ph.D.