Technology Regulation Reconsidered:
The Effects of Certificate of Need on MRI Access, Quality, and Cost

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I. Introduction

Addressing the high and rising cost of medical care has been a perennial concern in the United States. Beginning early after World War II, medical costs have consistently increased more rapidly than the economy. With taxes, business revenue, and family income all growing with the economy, medical cost growth exceeding economic growth creates significant financing issues. The problem is made more acute by the fact that much of medical care spending is believed to be of low value. A range of studies suggests that between 25 and 50 percent of medical spending is not associated with improved health (Bentley et al., 2008; PricewaterhouseCoopers, 2010; Berwick and Hackbarth, 2011; NEHI, 2008; OECD, 2013; Farrell et al., 2008; Young and Olsen 2010).

Imaging is a classic example of a technology believed to be overused. Imaging has a very large range where it has low but not negative value – a type II technology in the categorization of Chandra and Skinner (2012, pg. 666), that is one for which “there are specific uses of imaging with unequivocal value, but at the margin the value approaches zero or even becomes harmful given the risk of false positives, incidental findings unrelated to the original inquiry…” Because imaging is non-invasive, it can be ordered without fear of direct, immediate harm to the patient other than time and out-of-pocket costs.\(^1\) Further, imaging is often well-reimbursed, making it profitable for the provider. Finally, physicians concerned about being sued for malpractice can often justify an image more readily than a surgical operation. Thus, it is no surprise that the high level of imaging has been subject to a good degree of skepticism. Indeed, excessive imaging is one of the most common suggestions about potentially unnecessary procedures in the Choosing Widely compendium (Morden et al., 2014).

\(^1\) Although there is research regarding the potential health harms of excess radiation, this cost would not manifest in the short term. There are other risks to MRI, however, such as potential risks related to MRI technology and contrast agents (US Food and Drug Administration 2015; Kanda et al.2013) and treatment related to false positives.
An older approach to providing appropriate access to care, controlling costs, and improving quality of care is licensing medical technology under certificate of need (CON) regulation. Although many scholars have concluded the CON was an unsuccessful policy experiment, a majority of states still require a certificate of need determination before allowing certain investments in medical technology, including creating or expanding medical care facilities. In addition, a majority of states have specific CON rules that require providers to obtain service-specific CONs to acquire or replace one or more new medical services or technologies.

Some form of CON was adopted in virtually every state, in response to capital expenditure review requirements in the Social Security Act of 1972 and the Health Planning Resources Development Act of 1974, an act meant to control total medical care costs and improve quality of care through planning the location of providers and concentrating care among high quality providers. These laws initially addressed inpatient services, but expanded to include ambulatory services such as diagnostic imaging. When the federal act was repealed in 1986, many states repealed their laws, leaving a patchwork or regulation across the country (Horwitz and Polsky, 2015). Despite this variation in regulation, there have been few studies regarding the cost or quality effects of CON.

It is difficult to identify the effects of direct state-regulation on medical technology for several reasons. A cross-sectional regression is unlikely to capture the true effects of regulation. A finding that a regulated state provides more care than an unregulated state cannot be attributed to the regulation; even a well-controlled regression cannot resolve the question of whether the regulated state would have even higher levels of provision absent the regulation. Moreover, because changes in CON occur infrequently, it is difficult to study changes in medical service provision over time or to generalize from the results. In addition, the few existing studies do not account for the likely spillover effects of regulation when regulated and unregulated states are side-by-side.

To address these identification difficulties in measuring technology use, cost, and quality, we use a regression discontinuity design, to examine the effects of CON on the provision, cost, and quality of magnetic resonance imaging (MRI). MRI, along with
other diagnostic imaging technologies, has exhibited particularly high growth in spending and has received attention for potential overuse.

First, we confirm earlier work demonstrating that CON affects the location of free-standing MRI providers, with more providers choosing to locate on the unregulated side of a state border than in a neighboring, regulated state. We also test the relationship between CON and regulation for hospital-based MRI providers. These findings, however, are limited because they left open the possibility that CON did little beyond shifting the location where patient receives their care, perhaps inconveniencing some patients by causing them to travel for treatment but not otherwise affecting the overall quantity or quality of care received (Horwitz and Polsky 2015).

Therefore, in a second set of tests using patient-level Medicare data, we study the effects of CON regulation on the quantity of MRI scans provided to individual patients and the Medicare population in total across regulated to unregulated state borders. Third, we assess the relationship between CON and quality of care. Again, we do this by analyzing whether patients on the unregulated side of a state bordering a neighboring, regulated state receive different treatment for the same diagnoses as patients across the border, alternately for clinically appropriate (trauma) and inappropriate MRIs (early imaging for lower-back pain) based on American College of Radiology and Choosing Wisely recommendations, and compare rates of MRI provision in the Medicare population living around the borders of unregulated and regulated states.

Moving from states without CON regulation to regulated states, we find an approximately six percentage point drop in the probability a Census tract has any MRI providers. A drop occurs at the border among both free-standing MRI providers and hospital-based providers, although only the drop in free-standing MRI providers is statistically significant. Second, in our analyses of the quantity of scans provided to Medicare beneficiaries, we find a very small (3 percent of the base probability of MRI) and statistically insignificant drop in whether a Medicare beneficiary receives any MRI scan in a year, and no change at the border in the probability a beneficiary receives a large number of MRIs (more than 3) in a year. However, we find that whether a Medicare beneficiary receives a scan for lower back pain is related to whether that
beneficiary lives on the regulated or unregulated side of a state border; we find about a 9 percent, statistically-significant drop on a base of just over two scans per hundred beneficiaries.

Finally, we examine a narrow measure of quality of MRI provision. We analyze the effect of CON on the receipt of a medically appropriate scan (MRI for trauma) and a medically inappropriate scan (MRI within the first six weeks of a report of lower back pain absent other diagnoses indicating the need for a scan). We find no effect on the probability of the provision of medically indicated MRIs. However, we find a drop in the probability of a Medicare beneficiary receiving a contraindicated MRI associated with CON regulation, a scan during the first six weeks of a diagnosis of lower back pain absent other diagnoses indicating the need for a scan. The drop is 0.002 (two tenths of one percent) in the probability of receiving an MRI scan, representing an approximately 14 percent drop in the probability of a patient in our sample receiving, although the results do not statistically differ from no change at the border. *(NB: we believe that the reason the results in this test are not significant is because of the small percentage of people receiving this kind of scan in a 20% Medicare sample size. We will rerun our study on a sample including 100 percent of Medicare beneficiaries, a five-fold increase in sample size).*

These results suggest that the effects of regulation are not limited only to the geographic location where patients receive their MRI care, but also may affect the quantity, quality, and cost of care patients receive. Because our patient-level data are a randomly sampled twenty percent of fee-for-service Medicare patients, we cannot know the effects of CON on overall MRI use. However, our results suggest that CON regulation is associated with less questionable care and no less clearly valuable care.

Section 2 of the paper reviews the previous research on state certificate of need laws and related regulations, the diffusion and use of MRI, and the interaction between regulation and MRI diffusion and use. Section 3 describes the empirical approach to estimating the effects of technology regulation on the provision of MRI services. Section 4 describes the data including legal surveys, demographic information, and measures of
patient diagnoses and reimbursements. Section 5 presents empirical estimates, and Section 6 concludes.

II. Certificate of Need Laws and MRI Use

A. Previous Research on the Effects of Certificate of Need Regulation and Medical Care

Previous studies provide extensive overviews of research on certificate of need laws, including the limited research on its relationship with the provision of diagnostic imaging services (See, e.g., Horwitz and Polsky 2015, Salkever 2000). In sum, the results of research on CON are mixed. The earliest research, largely based on cross-sectional comparisons of CON-regulated states with unregulated states, frequently demonstrated that CON had little if any effect on supply, quality, or cost of services (Connover and Sloan 1998).

A more recent body of research has concentrated on the relationship between CON and invasive, hospital-based services, and has also generated mixed results regarding its effects. Some of this research is based on changes in regulation over time and, therefore, avoids some of the problems associated with earlier cross-sectional studies such as an inability to control for unobservable state-level factors such as whether those retaining CON had comparatively high rates of service consumption at baseline. Ho (2009) reviewed the mixed findings of studies on CON and cardiac treatments in a study that itself finds no evidence that CON is associated with utilization rates or quality of care.

In sum, the most recent studies continue to be limited by their methodological approach and generate mixed results. Some have demonstrated significant effects of CON. For example, CON has been shown to promote hospital efficiency by reducing the duplication of services (Rosko and Mutter, 2014), such as concentrating neonatal intensive care into high volume units (Lorch et al., 2012). These efficiency gains may come with higher costs per unit, at least in the case of the most stringent versions of the laws (Rivers et al., 2010). Still, others continue to find no effect on quantity, as in the case of intensity-modulated radiotherapy dissemination (Jacobs 2012).
There is very little research on the relationship between CON and diagnostic imaging. In a study focusing on the cross-border effects of regulation on MRIs, Horwitz and Polsky (2015) find fewer MRIs in regulated counties that border unregulated states than in counties on other borders. They note, however, that identifying the effects of CON on provider location does not identify the welfare effects of CON, “an evaluation of which would need to address the effects of barriers to entry on price, volume, and quantity.” (Id., pg. 21). This study addresses this gap in the research.

B. MRI and Overuse of Diagnostic Imaging

Although diagnostic imaging has contributed to improving medical practice, such as by making diagnoses more precise and by replacing invasive procedures with less expensive and risky scans, diagnostic imaging, including MRI, is often identified as a medical service that is overused (Rao et al. 2012; Iglehart 2009; America’s Health Ins. Plans 2008; Levin et al. 2011; Levin et al. 2010). At the broadest level, comparisons to use in other countries suggest that higher domestic use may be, in part, attributed to inappropriate use. Using data from the Organization for Economic Cooperation and Development on spending and technology use in thirteen industrialized countries, Squires (2012) finds that the United States is an outlier; relative to the other countries, in 2009 the U.S. was far above average in terms of the number of MRI machines (25.9 per million population v. a median of 8.9 machines per million population), with only Japan higher at 43.1 devices per million population. The U.S. also exhibits the highest use of MRIs with a median of almost one in ten Americans receiving an MRI scan every year, more than double the median number of scans performed in other OECD countries (median 91.2 per 1,000 population v. median of 43 per 1,000 population) (Squires, 2012).

From 2000-2011 the number of MRI scans among Medicare beneficiaries grew rapidly. For example, MRI scans of the brain increased from 44 to 76 per 1,000 beneficiaries and other types of MRI scans increased from 58 to 129 per 1000 beneficiaries; from 2011 to 2012, the rates remained flat (Medpac, 2014, pg. 107 chart 7-19). A US Government Accountability Office (GAO) estimate showed that “in 2010, providers who self-referred made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring. These additional referrals cost CMS
more than $100 million in 2010 alone. To the extent that these additional referrals are unnecessary, they pose unacceptable risk for beneficiaries…” (GAO, 2015, pg. 24).

MRI and pharmaceutical use related to MRI has raised spending concerns as well. For example, in a 2015 report addressing concerns on spending by the Medicare Part B program and its patients, the GAO listed Lexiscan, a drug used for pharmalogical cardiac stress testing, often in the MRI setting, as the fifth highest expenditure drug among the Medicare population in 2013; total expenditures on Lexican in 2013 $257 million, or $215 per Medicare Part B beneficiary (GAO, 2015).

In addition to the government, researchers have shown concern that the massive increases in diagnostic imaging in the early 2000s (see, e.g., Mitchell 2008) can be accounted for not only because of improvements in the effectiveness of scanning but also because of long-standing inappropriate use, including some self-referrals (see, e.g., Levin 2004; Hillman et al., 1990)). Although some studies do not find evidence of self-referrals in their study samples (Mitchell 2007). Nonetheless, as Ho (2008) explains, despite its benefits, a great deal of diagnostic imaging is unnecessary; she describes in detail how contractual arrangements between physicians and facilities can be designed to skirt anti-referral rules.

Physician groups have recently begun to provide objective measures of appropriate care in an effort to improve patient health through better treatment choices, a reduction in risks, and management of costs. For example, the Choosing Wisely campaign, an initiative of the ABIM Foundation that promotes patient-physician conversations about unnecessary medical tests and procedures, has provided lists of medical practices that “physicians and patients should question” (Morden et al., 2014). Diagnostic imaging appears prominently on the Choosing Wisely lists, comprising 24 of the initial 45 recommendations (Morden et al. 2014; Vijay and Rao 2012). For example, number two on the list by The American College of Physicians is “Don’t obtain imaging studies in patients with non-specific low back pain. In patients with back pain that cannot be attributed to a specific disease or spinal abnormality following a history and physical examination (e.g., non-specific low back pain), imaging with plain radiography,
computed tomography (CT) scan, or magnetic resonance imaging (MRI) does not improve patient outcomes.” (Choosing Wisely, 2012).

III. **Empirical Approach**

   **A. MRI location, Freestanding v. Hospital Based MRI**

   Because obtaining a determination of need under a CON regulation adds an additional layer of bureaucracy and cost to expanding medical services, facilities located in similar locations – but just inside or just outside states with effective CON regulation – might be expected to prefer the location just outside. This regulatory difference will create a discontinuity in the density of distance to the border among MRI facilities, with a higher density just below zero (distance in non-CON states expressed as a negative distance to the border) than just above zero (distance in CON states expressed as a positive distance to the border). The statistical significance of the discontinuous change in density can be tested using the semiparametric procedure described by McCrary (2008).

   Like free-standing providers, hospitals located just inside (or just outside) of a regulated state will have a relatively harder (or easier) path to adding MRI service. Therefore, we expect hospitals with distance just below zero (in a non-CON state, but close to a CON state) to have discontinuously higher probabilities of offering MRI, compared to hospitals with distance just above zero (in a CON state, but close to a non-CON state). However, because a single or limited-service provider, such as medical imaging provider, entering the diagnostic imaging business will have greater choice of where to locate than a hospital, which already exists in a fixed location, the effects CON on free-standing MRI providers in terms of location will likely be greater than those on hospital based MRI services. Therefore, in addition to testing the effects of CON regulation on the location of free-standing facilities and hospital-based services together, we test the effects separately.

   Preliminary evidence on the role of CON status in influencing MRI availability can be seen in Figures 1 & 2. Figure 1 shows the national relationship of CON status and MRI availability. CON is largely a phenomenon of the east and Midwest.
To explore this further, we assign each MRI provider to their Census tract, and compare the probability of each Census tract of having one or more MRI facilities. We expect census tracts in CON states close to non-CON states to have lower probabilities of MRI presence, compared to Census tracts in non-CON states but close to CON states. We do not expect these Census tracts to be substantially different in other respects.

The local regression gives maximal weight to tracts closest to the boundary; weights decay using a triangle kernel that places weight zero on tracts \( h \) miles away. Using a triangle kernel of width \( h \), weights decline linearly in distance, where \( h \) is the bandwidth of the kernel chosen to minimize mean squared error (a smaller \( h \) results in lower squared bias but higher variance while a larger \( h \) results in larger squared bias and lower variance, so the “optimal” mean-squared-error minimizing choice balances these undesirable features, as described in Imbens and Kalyanaraman (2009). We use twenty miles as the baseline bandwidth, balancing the competing objectives across multiple regressions, but report results for many alternative bandwidths in Table 2 and in the appendix.

We estimate the following local linear regression equation:

\[
y = a*d + b*I(d>0) + c*I(d>0)*d + e
\]

where \( y \) is a dichotomous variable measuring whether a census tract has any MRI provider, \( b \) measures the jump in expected \( y \) at the boundary (\( d=0 \)), \( d \) measures distance to a CON regulated state (this value is negative for non-CON state), and \( a \) and \( c \) capture the dependence of mean outcomes on distance away from the boundary. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary where \( d=0 \) to a weight of zero at the distance given by the bandwidth.

**B. Quantity Effects of CON**

Having identified the location effects of CON on presence of MRI providers, we consider whether CON affects the quantity of care provided. Even if CON affects the location of providers, CON may not affect the quantity of care provided, either measured as scans per patient or scans per capita provided in a geographic area. For example, all
patients – those in unregulated or regulated states -- may receive the same quantity of care they otherwise would have received, but patients in regulated states may have to travel farther for their care than other patients. Because we cannot know the true rate of care that would be provided if all states were regulated or if none were, we cannot measure these effects directly. We can, however, measure whether patients who live in regulated states on the border of unregulated states, and thus live near fewer MRI providers, receive different levels of care than corresponding patients who live just across the border in unregulated states and, therefore live near more MRI providers.

To estimate the effect of CON on quantity of MRIs, we use the same equation (1) above, substituting \( y \) to measure, alternately, in 2011: 1) whether a patient in a census tract received any MRI scan in a year, 2) three or more scans, and 3) whether a patient received any scan for a particular diagnosis, lower back pain.

C. Appropriate and inappropriate technology use

Having identified the location and quantity effects of CON on MRI, we then consider the quality effects. We do this by alternately comparing the likelihood that Medicare patients in our sample receive appropriate and inappropriate MRI scans. We rely on American College of Radiology Appropriateness Criteria to create new measures of appropriate use of MRI (American College of Radiology), and we rely on previously created measures related to Choosing Wisely to measure inappropriate scans (Colla et al 2014). The Choosing Wisely program relies on independent determinations of appropriateness or value as determined by clinician specialty societies. For example, we test the probability of a beneficiary who has a lower-back pain diagnosis receiving a scan within six weeks of the initial diagnosis (Choosing Wisely, Colla et al. 2014). Importantly, we identify a patient as having received a contra-indicated scan only if that patient does not have any additional diagnoses indicating that a scan is warranted (e.g. trauma).

Using the same equation (1) from above, we substitute \( y \) to measures, alternately, 1) whether a patient in a census tract received a scan that is medically recommended, a scan for treatment of trauma, and 2) whether a patient in a census tract received a scan
that is not medically recommended, a scan within the first six weeks of reported lower back pain and absent evidence of other diagnoses for which scanning is appropriate.

IV. Data

Data on state certificate of need laws as applied to MRI are from an original dataset developed for and described in detail in Horwitz and Polsky (2015). That dataset, covering all states in the continental United States and the District of Columbia in 2012, was constructed from an analysis of state statutes, related regulations, secondary sources, and interviews with state regulators to determine whether laws on the books were actively enforced. In that dataset, there were 14 states with no CON regulation, 13 states with CON regulation but not for MRI, and 21 states and the District of Columbia with CON regulation covering MRI. Only two of the regulated states are west of the Mississippi, with almost all in the northeast and Midwest (Figure 1).

Data on MRI provider location, number of scans, and cost come from several sources. For the location of MRI providers, we rely on two sources. First, the location of hospital-based MRI providers comes from the American Hospital Association’s Annual Survey of Hospitals 2010. Second, for the location of free-standing MRI providers, we use data from Horwitz and Polsky (2015), assembled from lists MRI facilities accredited by the American College of Radiology and the Intersocietal Accreditation Commission. Both of these sources of data indicate the existence of an MRI provider and its location, but do not identify the number of machines or scans. Data to construct demographic control variables are from the United States Census 2010.

To measure MRI use, we create a single database of 2011 billing data for both inpatient and outpatients at the beneficiary level. We used Parts A (hospital) and B (physician services) Medicare fee-for-service administrative claims data for a 20% representative sample of the Medicare population. More specifically, data are from the the Medicare Provider Analysis and Review (MEDPAR) File, merged on the inpatient, outpatient, and skilled nursing facility standard analytic files and the Carrier file (physician/ supplier part b claims file). Our measure of an MRI scan depends on the data source. In some sources it is a scan per patient stay (we define the stay as the last date of
service, and we allow only one scan if the patient had any scans during the stay) or in other sources we construct a comparable variable, which is usually the date of service and for which there is generally only one scan.

To measure appropriate use and overuse of MRI, we rely on designations of high- and low-value diagnostic services based on American College of Radiology Appropriateness Criteria and research related to the Choosing Wisely initiative of the American Board of Internal Medicine Foundation. More specifically, we rely on Colla et al. (2014, appendix) to identify specific diagnoses for which imaging is not recommended; although this source appeared after our study period, it was based on evidence that was widely available before Choosing Wisely appeared. We use measures of 1) inappropriate imaging – imaging within the first six weeks of a complaint -- for low back pain when no red flags are present and 2) appropriate imaging defined as an MRI scan provided when there is a diagnosis that indicates trauma in the coincident set of billings (defined as a “stay”) in the data.

To calculate a rough estimate of the potential cost of MRIs for lower back pain related to absence of certificate of need regulation we use the Medicare National Physician Fee Schedule 2013.

V. Results

The regression discontinuity design we use rests on the reasonable assumption that there are few differences in the demographic characteristics of populations living just on one side of a state boundary compared to the other. As can be seen in Table 1 reporting descriptive statistics, there are few differences in the population at the county level. In unreported tests, we find that even the small differences shown in Table 1 –

2 Roughly speaking, red flags include previous low back pain diagnoses, cancer diagnoses (excluding melanoma skin cancer), IV drug use, HIV, unspecified immune deficiencies, or intra-spinal abscess within 12 months before an imaging event, or imaging claims for trauma diagnoses in the first four fields on a claim. See Colla et al. 2014 for more information.
differences in the mean values of demographic measures at the county level – do not appear at the border where we conduct our regression discontinuity tests.

A. Location of MRI providers

First, hospital-based MRI providers are more evenly distributed across the US than are free-standing MRI providers; these different locations are likely because free-standing providers have more flexibility to locate in areas with lower costs and barriers to entry than do hospital-based providers which are tied to existing hospital locations. These differences can be seen in Figure 1, in which the hospital-based MRI providers (represented by squares) are more evenly distributed throughout the country than are the free-standing MRI providers (represented by circles). Second, in addition providers are more likely to locate just across the unregulated side than on the regulated side of state borders dividing regulated and unregulated states. For example, Figures 2a and b show the border of a regulated state, Michigan, and two unregulated states, Indiana and Ohio. The rectangle in 2b, which covers an area of about 20 miles north of the Michigan border to 20 miles south of the Michigan border, shows many more providers in the unregulated state, just below the border. Moreover, although there are two small cities south of the Michigan border, South Bend, Indiana to the west and Toledo, Ohio to the east, the suburban population of those cities extends into Michigan. And there are no obvious population centers in the approximately 170 miles in the middle three-quarters of the rectangle. Because so much of this area has low population density, we suspect that the regulation is leading to the change in MRI location.

Using the same data as in Figure 1, Figure 3 shows the probability that there is an MRI provider in a census tract. As can be seen in the figure, there is a 6.3 percentage point jump (p<0.001) in the probability of a census tract having an MRI provider, free-standing or hospital based, just on the unregulated side of a state bordering a regulated state. As can be seen in Figures 4 and 5, the higher probability of a MRI provider in a tract on the unregulated side of a state border exists for both free-standing and hospital-based providers, but in separate tests of the two types of providers the difference at the border is only statistically significant among the free-standing providers. The effects are similar using local linear regression or local logistic regression, and if we use count of
MRIs instead of a binary outcome, either in a linear regression or a generalized linear model.

B. Quantity of MRI Use

As discussed above, results showing that technology regulation affects a provider’s choice of where to locate, the geographic effects do not address the quantity of care received by patients. The number of scans per person in our sample is similar to other reported measures. For example, the base rate of MRI’s per Medicare beneficiary just on the side of a regulated state bordering an unregulated state is a mean of 0.107, more than one scan for every patient annually; the median for the entire U.S. population is slightly lower, 9.12 scans for every person annually (Squires, 2012).

We find no significant effects of a Medicare patient’s location, as measured by location relative to the border by the zip code of a beneficiary’s residence, on the probability of a beneficiary receiving an MRI scan in a year. On the unregulated side of a state bordering a regulated state, an average of 10.7 percent of the sample population receive a scan each year, and 10.4 percent receive one on the regulated side, and these differences are not statistically significant (p=0.346). This can be seen most easily in Figure 6. Moving from a regulated to an unregulated state, the line is relatively flat and the gap is small at the state border. These results can also be found in Table 2, Column 1, which shows no statistically significant change in the probability of a beneficiary in the sample receiving an MRI, moving from a non-CON to CON state, i.e. going from negative distance to positive distance, and the results show a small and statistically insignificant difference in probabilities of getting an MRI at the border. We find essentially no gap at the border, in the probability a beneficiary receives three or more MRIs in a year (results not reported).

However, examining one diagnosis (lower back pain) we find large differences in the probability of receiving an MRI scan at the border. As can be seen in Table 2 (column 3, 20-mile estimate), at the border moving to a regulated state patients on the regulated side there is a 0.002 drop in the probability of receiving a scan, representing about a 9 percent drop on a base of just over two scans per hundred beneficiaries.
Our analyses are based on a localized comparison of the effect of regulation, making it difficult to generalize the effects of regulation to large geographic areas or those far from a border. Nonetheless, one can calculate a range of measures to conceptualize the effects of CON such as in the case of scans for lower back pain. A conservative analysis, generalizing the results to counties that are regulated by CON that border unregulated counties, produces 6,125 fewer scans per year for lower back pain in our 20 percent Medicare sample alone. Generalizing to the entire Medicare population of approximately fifty million beneficiaries yields approximately 100,000 fewer scans for lower back pain in a year. We do not know whether these scans are valuable, however we now that they represent scans currently being provided to only some patients depending on the zip code where they live.

C. Quality

To determine whether certificate of need regulation affects the quality of care provided to patients in our sample, we test the probability of whether patients receive treatment for particular diagnoses. First, we find no statistically significant differences in the probability of receiving an MRI with a trauma diagnosis, a recommended treatment (Table 2, Column 5).

Second, we test one particular form of inappropriate scan. We find an approximately 14 percent effect of regulation on the probability of beneficiaries receiving an MRI within six weeks of receiving a diagnosis code of lower back pain and no other diagnoses indicating a medical need for an MRI, although these results are not statistically significant. This can be seen in Table 2 (column 4, 20-mile band width) where there is approximately a -0.0002 reduction on base rate of approximately 1265 patients per million (0.001 or 0.1 percent of the Medicare population in the sample) receiving this inappropriate treatment on the regulated side. As this diagnosis is only one of many that constitute total scans for lower back pain, we do not know whether the

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3 There are 209 counties regulated by CON for MRI that border unregulated states. These counties have an average 14,653 Medicare beneficiaries in the 20 percent sample. We multiplied these numbers by the -0.002 coefficient found in table 2, column 3, at the 20-mile band width.
reduction in overall scans for lower back pain associated with CON represents appropriate or inappropriate care.

\[ D. \text{ Cost} \]

Although it is difficult to determine the relationship between regulation and spending on health care, we can make a back-of-the-envelope calculation from our results based on listed Medicare prices. Including Medicare reimbursement for the average baseline MRI fee (the global component) for various types of MRIs and adding the technical component and the professional component for MRIs the Medicare price of an MRI is roughly $470 per scan in a hospital. Using the estimates of scans for lower back pain related to certificate of need regulation on above, annual spending in unregulated counties near regulated counties on MRI scans for lower back pain is $2.9 million higher than in regulated counties near unregulated counties. Generalizing to the entire Medicare population, Medicare spends roughly $47 million on these scans alone.

VI. \textbf{Sensitivity Testing and Limitations}

\[ A. \text{ Sensitivity Testing} \]

First, a virtue of the model is that providers (and, alternately, patients) are compared only with providers (and, alternately, patients) within a few miles of each other, thus incorporating the local nature of medical care provision. Indeed, the regression discontinuity approach we use rests on the assumption that there are few relevant differences in populations who live just across the state borders. However, in the event that there are some differences in population, we also test the relationship between CON and provider location accounting for other characteristics in the census tract (or zipcode) by adding covariates to the local linear regression, still putting most weight on tracts close to state boundaries. Specifically, we control for the percentages of the population based on different age groups. Reassuringly, adding these controls does not qualitatively effect the results.

Second, although we report only the results for the twenty mile bandwidths in the text, we tested several band widths. The larger bandwidths include more people and
therefore have smaller confidence intervals. However, the bandwidth refers to the width of a triangle kernel, so with a 20-mile bandwidth, for example, half of the people included in the estimate live within 5.86 miles. All of the zip codes, therefore, are within a fairly narrow area around the relevant state border. In addition, we report results from the regression discontinuity tests using local linear regression based on a triangular kernel. Similar tests using a rectangular kernel yield similar results. Figures illustrating the relationship between the bandwidths and the results are in the appendices. The estimates are remarkably stable at bandwidths greater than 10 miles, and confidence intervals become very large at bandwidth below 20 miles, illustrating the variance tradeoff described above.

Finally, the results for MRI coincident with lower back pain diagnoses are very robust. If we alter the cutoff, pretending the cutoff is consistently z (say, 20 or 50) miles away from the border, we can get a placebo test which is a good indication of true power, similar to a permutation test. For MRI coincident with lower back pain diagnoses, 5 percent of all estimates away from the true cutoff are rejected at the 95 percent level, and half are positive estimates. This result indicates that the negative and significant estimate at the true cutoff is plausibly measuring a real drop in MRI probability as one moves from a non-CON to CON state. However not every type of estimate yields these results in tests of robustness: far less than 5 percent of the "any MRI" estimates differ significantly from zero, indicating that standard errors may tend to be overestimated for these models and there may well be an effect that we have not been able to specify.

B. Limitations

There are several limitations to our study. First, because of data limitations, our study design is using only one year of scans, and the panel of patient records is essentially used as a cross section. Moreover, the states that retained and enforced CON for MRI are in the Midwest and Northeast. It is possible that the results do not generalize over time or to different regions of the country. Second, we consider only one type of technology, MRI, and we do not know which specific type of machine was used for a scan. Third, we were limited to using Medicare data from the elderly, fee-for-service population to measure the quantity of scans, total costs, and the quality of medical
treatment. The results may not generalize to the non-elderly population or beneficiaries who are enrolled in a managed care plan.

Finally, while the measure of inappropriate use of MRI has been broadly used, this is the first measurement of appropriate MRIs. Clinical decisions hinge on information that may not be available in an administrative claims record. However, it is unlikely that bias in observation of conditions that would shift a MRI from appropriate to inappropriate or vice versa are correlated with CON regulation.

VII. Conclusion

Our findings suggest that Certificate of Need regulation affects the location of MRI providers. Moving across a state border from a state that does not regulate MRI to one that does results in a 6.3 percentage point reduction in the probability that a census tract has an MRI provider. This estimate is a conservative measure of the break at the border, as smaller bandwidths produce estimates larger in absolute magnitude. Other estimates using a different model show 6.9 fewer providers per million people on base of an average of 11.6 providers per million people (Horwitz and Polsky 2015), using county-level estimates representing a smaller bandwidth. These results not only demonstrate the effect of regulation within a regulated state, but also the effects of state regulation on neighboring populations in other states and the importance of considering spill-over effects when studying state-based regulation.

In addition to considering the relationship between state regulation and provider location, this article examines some of the effects of regulation on utilization among the local population. These results are consistent with findings that the residence of a Medicare beneficiary seems to influence the care that beneficiary receives (Gottlieb, 2010, Song, 2010). The mix of diagnoses where an MRI is indicated and where it is contraindicated leaves the overall probability apparently no different on each side of a border separating a regulated and an unregulated state, even while the prevalence of providers changes abruptly. However, this result may mask treatment differences because it is driven by cases in which an MRI is indicated (or in a grey area). The results demonstrate different treatment based on CON regulation, where a beneficiary is much
more likely to receive an MRI for lower back pain if that beneficiary lives just over the border on the unregulated side of a state bordering a regulated state. We cannot know whether these scans are medically warranted, but MRI is a service for which a great deal of the use is of low value.

Investigating the quality of care received in more detail shows that regulation does not seem to affect the probability of receiving an MRI scan when the scan is medically indicated, as is the case for a scan for a trauma diagnosis. However, although the results are not statistically significant in this small sample, there is a difference in the probability of treatment when a scan is contraindicated, a scan within six weeks of a lower back pain diagnosis and absent other indications for treatment.

Spending on MRI is high compared to other countries, and there are concerns that both insurers and beneficiaries bear these costs. Moreover, there is evidence of questionable medical utility of many scans, and some evidence that the probability of a patient receiving a scan is related to physician ownership of MRI equipment (Baker, 2010). There is anecdotal evidence that the price of an MRI scan is higher in regulated states than in other states. However, the unit price is only one important factor in health care spending. Total spending, and the benefits that accrue from that spending, must be considered in any analysis of the welfare effects of regulation. If, as this analysis suggests, certificate of need regulation is associated with a modest reduction in utilization of low value or contraindicated treatments, such regulation may not only constrain provision of those treatments, it may contribute to cost control.
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Figure 1. Free-standing and Hospital-based MRI Facilities (2012)

Notes: This map represents 6,757 facilities in 6,540 distinct locations in the 48 contiguous states and the District of Columbia.

Sources: Coordinates for each of the hospital-based MRI locations are from the American Hospital Association Annual Survey of Hospitals 2009. Coordinates for the free-standing MRI providers are from addresses found in the membership lists of the two agencies that accredit free-standing MRI facilities—the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC), both accessed in December 2012.
Figure 2: Location of MRI Providers in CON Regulated (Michigan) v. Unregulated (Ohio and Indiana) States

Notes: The rectangle captures the southern border of Michigan, the lower edge is given by 41.5 N latitude, upper 42 N latitude, left edge longitude -83.2 and right longitude -86.2, running about 20 miles north and south along the MI border.

Sources: Coordinates for each of the hospital-based MRI locations are from the American Hospital Association Annual Survey of Hospitals 2009. Coordinates for the free-standing MRI providers are from addresses found in the membership lists of the two agencies that accredit free-standing MRI facilities—the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC), both accessed in December 2012.
Figure 3. Probability of an MRI Facility in a Census Tract, hospital-based (2009) or free-standing (2012)

Notes: This figure illustrates the results from a test of discontinuity in density following McCrary (2008) of whether a census tract has any MRI facility, free-standing or hospital-based. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at a 20-mile bandwidth.

Sources: Locations of hospital-based MRI facilities are from the American Hospital Association Annual Survey of Hospitals 2009. Locations for the free-standing MRI providers are from addresses found in the membership lists of the two agencies that accredit free-standing MRI facilities—the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC), both accessed in December 2012.
Notes: This figure illustrates the results from a test of discontinuity in density following McCrory (2008) of whether a census tract has any free-standing MRI facility. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at a 20-mile bandwidth.

Sources: Locations of hospital-based MRI facilities are from the American Hospital Association Annual Survey of Hospitals 2009. Locations for the free-standing MRI providers are from addresses found in the membership lists of the two agencies that accredit free-standing MRI facilities—the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC), both accessed in December 2012.
Figure 5. Probability of an MRI Facility in a Census Tract, Hospital-Based (2012)

Notes: This figure illustrates the results from a test of discontinuity in density following McCrary (2008) of whether a census tract has any hospital-based MRI facility. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at a 20-mile bandwidth.

Sources: Locations of hospital-based MRI facilities are from the American Hospital Association Annual Survey of Hospitals 2009. Locations for the free-standing MRI providers are from addresses found in the membership lists of the two agencies that accredit free-standing MRI facilities—the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC), both accessed in December 2012.
FIGURE 6. MRI per Beneficiary (2011) at State Borders, Certificate of Need v. Non-Certificate of Need State

Notes: This figure illustrates the results from a test of discontinuity in density following McCrary (2008) of whether a Medicare beneficiary received an MRI scan during 2011, based on twenty-percent sample of fee-for-service Medicare beneficiaries. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at a 20-mile bandwidth. Beneficiary location determined by zip code of home address.

Sources: State regulatory status from Horwitz and Polsky (2015). Data are from 2011 billing data for both inpatient and outpatients at the beneficiary level. We used Parts A (hospital) and B (physician services) Medicare fee-for-service administrative claims data for a 20% representative sample of the Medicare population including data from the Medicare Provider Analysis and Review (MEDPAR) File, merged on the inpatient, outpatient, and skilled nursing facility standard analytic files and the Carrier file (physician/supplier part b claims file).

Notes: This figure illustrates the results from a test of discontinuity in density following McCrary (2008) of whether a Medicare beneficiary received an MRI for lower back pain during 2011, based on twenty-percent sample of fee-for-service Medicare beneficiaries. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at a 20-mile bandwidth. Beneficiary location determined by zip code of home address.

Sources: State regulatory status from Horwitz and Polsky (2015). Data are from 2011 billing data for both inpatient and outpatients at the beneficiary level. We used Parts A (hospital) and B (physician services) Medicare fee-for-service administrative claims data for a 20% representative sample of the Medicare population including data from the Medicare Provider Analysis and Review (MEDPAR) File, merged on the inpatient, outpatient, and skilled nursing facility standard analytic files and the Carrier file (physician/ supplier part b claims file).
FIGURE 8. MRI within Six Weeks of Lower Back Pain Diagnosis, per Beneficiary (2011) at State Borders, Certificate of Need v. Non-Certificate of Need State

Notes: This figure illustrates the results from a test of discontinuity in density following McCrary (2008) of whether a Medicare beneficiary, in 2011, received an MRI for lower back pain within the first six weeks of a report and absent other diagnoses indicating the need for a scan based on twenty-percent sample of fee-for-service Medicare beneficiaries. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at a 20-mile bandwidth. Beneficiary location determined by zip code of home address.

Sources: State regulatory status from Horwitz and Polsky (2015). Data are from 2011 billing data for both inpatient and outpatients at the beneficiary level. We used Parts A (hospital) and B (physician services) Medicare fee-for-service administrative claims data for a 20% representative sample of the Medicare population including data from the Medicare Provider Analysis and Review (MEDPAR) File, merged on the inpatient, outpatient, and skilled nursing facility standard analytic files and the Carrier file (physician/ supplier part b claims file).
Table 1. Descriptive Statistics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non-CON Counties, Near CON</th>
<th>CON Counties, Near CON</th>
<th>Non-CON State, near CON</th>
<th>CON State, near non-CON</th>
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<tr>
<td>Population, mean(^a)</td>
<td>99,471</td>
<td>86,102</td>
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<td>Log population density</td>
<td>4.38</td>
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<td>% Medicare beneficiaries, MRI 2011(^b)</td>
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<tr>
<td># Medicare beneficiaries</td>
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<td>% Medicare beneficiaries male, &lt;65</td>
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<td>0.107</td>
<td>0.089</td>
<td>0.097</td>
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<td>105 or more</td>
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<td>0.001</td>
<td>0.001</td>
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<tr>
<td>% Medicare beneficiaries female, &lt;65</td>
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<td>0.092</td>
<td>0.084</td>
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<td>105 or more</td>
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<td>0.50</td>
<td>0.94</td>
<td>0.91</td>
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</table>

Sources: \(^a\)=United States Census 2010, \(^b\)=Centers for Medicare and Medicaid from analysis files 20 percent sample. Percentage of beneficiaries by age group are based on analysis file.
Table 2. Jump in the probability of receiving an MRI in 2011, Non-CON to CON State across boundary

|                  | Any MRI (P>|z|) | >=3 MRIs (P>|z|) | MRI, lower back pain (P>|z|) | MRI, 6 weeks, lower back pain diagnosis (P>|z|) | MRI for trauma (P>|z|) |
|------------------|----------------|----------------|-----------------------------|----------------------------------|-------------------|
| 10-mile bandwidth| -.005 (0.381)  | -2.3e-05 (0.963)| -.003 (0.071)*               | -.0002 (0.310)                  | 4.83e-05 (0.541)  |
| 20-mile bandwidth| -0.003 (0.346) | -3.73e-06 (0.990)| -.002 (0.044)**              | -0.0002 (0.274)                 | -3.06e-05 (0.583) |
| 30-mile bandwidth| -.001 (0.639)  | 3.86e-05 (0.868) | -0.002 (0.052)**             | -0.0001 (0.320)                 | -4.92e-05 (0.284) |
| 40-mile bandwidth| -0.001 (0.727) | 1.08e-04 (0.586) | -0.002 (0.008)**             | -0.0001 (0.364)                 | -2.49e-05 (0.540) |
| Base rate, MRI/Pop (Non-CON) | 0.107          | .0024          | 0.023                       | 0.001                           | 1.755e-06         |
| Base rate, MRI/Pop (CON)     | 0.104          | .0022          | 0.021                       | 0.001                           | 1.686e-05         |

Notes: This table presents the coefficients from regression discontinuity estimates of the discontinuous change in the probability of a patient in the sample receiving an MRI scan at the border, comparing a county in a state that is not regulated by certificate of need for MRI to a county in a state that is regulated by certificate of need for MRI. The regression is weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at the distance given by the bandwidth in the first column of each row. Standard errors are robust to heteroscedasticity and are clustered at the zip code level. The Base Rate of MRIs represents the rate at which Medicare beneficiaries who live just on the unregulated side of a state bordering a regulated state, or vice versa, receive an MRI for a given diagnosis in the study year.
Jump in Pr(any MRI in 2011 | 6 weeks after LBP dx) at CON border