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TECHNOLOGY REGULATION RECONSIDERED:
THE EFFECTS OF CERTIFICATE OF NEED POLICIES ON
THE QUANTITY AND QUALITY OF DIAGNOSTIC IMAGING

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Technology Regulation Reconsidered: The Effects of Certificate of Need Policies on the Quantity and Quality of Diagnostic Imaging
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ABSTRACT

Estimates of the impact of Certificate of Need laws on medical care have been inconsistent, possibly because not all CON laws apply to all services. Using an original dataset identifying imaging-related CON laws, we estimate the effects of CON on CT and MRI, using regression discontinuities at state borders. Medicare beneficiaries in regulated states are slightly less likely to receive any image and considerably less likely to receive low-value imaging than beneficiaries in non-regulated states. High-value imaging is either unaffected or declines much less. Overall, CON reduces low value care and largely leaves high value care unaffected.

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Certificate of Need (CON) laws were designed to control medical spending and improve quality of care (Salkever, 2000). In response to two federal statutes–the Social Security Act of 1972, which conditioned Medicaid and Medicare payments on reviews of large capital expenditures, and the Health Planning Resources Development Act of 1974 (HPRDA), which offered incentives for states to review new clinical services, technology acquisition, and large capital expenditures–virtually every state implemented a CON program. In the decades that followed, however, both the 1986 repeal of the HPRDA and growing concern that laws were ineffective led many states to abolish their CON requirements (Horwitz and Polsky, 2015).

Numerous studies have examined the effects of CON regulation on medical spending and use of services. In general, the studies find mixed results (Conover and Bailey, 2020). As discussed in the next section, some find modest effects of CON on utilization of medical services, while others find none. However, there are several limitations to these studies. First, identification of CON effects is difficult. The best designed studies use difference-in-differences models, typically relating spending or service provision in a state and year to state and year fixed effects and include a variable capturing CON implementation. To the extent that the effects of CON occur over time, and there are other changes in the demographic or economic climate that will drive spending differences across states, difference-in-differences models may yield biased or imprecise answers.

Further, previous studies tend to focus on services provided in hospitals or nursing homes. The potential for regulatory capture often means that CON has less consequence for existing, relatively immobile providers than on newer entrants and relatively mobile ones, such as free-standing, limited-service providers.

In addition, few studies examine the relationship between CON laws and the quality of medical care provided, and the results of the studies that do are often inconclusive. This may be because the outcomes used–most commonly mortality and sometimes volume or appropriateness of hospital care, as noted below–are unlikely to be affected greatly by CON. Thus, it is difficult to know if cost savings result from favorable or adverse changes in medical care provided.

Finally, the legal data used in many studies are imprecise in several important respects. For example, publicly available legal data typically include only blunt measures of whether a state has any CON requirement for health services and neither whether that CON requirement applies to the particular services being studied nor whether the laws on the books are actively enforced (see Horwitz and Polsky, 2015, for a review).[1] Unlike previous studies, we determine whether a state CON's regime applies to the services we study–either explicitly for these services or via a capital expenditure requirement that would likely cover their acquisition–and we confirmed our coding with regulators in every state.

This paper examines the effects of CON on access to and use of two kinds of high-tech imaging, CT and MRI. Imaging is a particularly suitable technology with which to examine CON effects. Using categories from Chandra and Skinner (2012), imaging is the classic 'type II' technology: "there are specific uses of imaging with unequivocal value, but at the margin the value approaches zero or even becomes harmful." (p. 666). There are multiple potential harms to excess imaging, for example higher costs and increased health risks.[2] Further, inappropriate imaging can produce a "cascade" of unnecessary and potentially unsafe care (Webster et al., 2014). For these reasons, excessive imaging is one of the most-commonly cited examples of overused care in the

[1] For example, a California statute requires CON for "the initial purchase or lease by a clinic . . . of diagnostic or therapeutic equipment with a value in excess of $1,000,000 in a single fiscal year . . . ." CAL. HEALTH & SAFETY § 127170. In an email exchange with a state regulator, we were directed to a website that reports California as not having a CON program. Jason Weiss email, June 18, 2020.

[2] There is a cancer risk from CT (Armao and Smith, 2014). MRI, which does not pose a cancer risk, involves risk from contrast agents used in the procedure (US Food and Drug Administration 2015; Kanda et al., 2013).

Choosing Widely compendium (Morden et al., 2014).[3] If CON has no effect on high-tech imaging, it means that the laws had no effect on one of the most important components of medical care they were designed to address. We examine the effect of CON on the receipt of any image and also high and low value images.

Methodologically, we use an experimental approach that captures long-run differences in the effects of CON, applying a regression discontinuity design at CON–non-CON borders rather than relying on the average rate of imaging within states. In our 20% sample of Medicare beneficiaries from 2009-2014, roughly 2.4 million people are observed living within 50 miles of a CON – non-CON border (over 6 years, the sample includes 9 million person-years). Our underlying assumption is that patient demographics do not change at state borders but, as previous research demonstrates (Horwitz and Polsky, 2015), imaging availability does. We demonstrate that care receipt differs greatly from one side to the other of a CON – non-CON border, presumably driven by discontinuous changes in the type of care available at the border.

Our results show that people on the CON side of the border are slightly less likely to receive any image than on those on the non-CON side of the border, and they are considerably less likely to receive low value imaging. The probability of any MRI receipt is about 2% lower on the CON side of a border; CT receipt is unaffected. In contrast, the probability of receiving an image for a low value diagnosis on the CON side of the border is negative for all 7 of the low value services we consider, with effects sizes ranging from 20%-26% of non-CON imaging rates. The probability of a high-value MRI is unaffected at the border, and the probability of a high-value CT is lower on the CON side of the border, but by much less (6%). Our analysis thus suggests that CON implementation has a generally salutary effect on medical care provision: high value imaging is

[3] Similarly, 7 of the 31 low-value services described by Schwartz et al. (2014) concern imaging, and de Vries et al. (2016) identify imaging services as a substantial fraction of most measures of low-value care.

relatively unaffected by CON, while low value imaging is reduced appreciably.

The paper is structured as follows. Section I reviews the previous research on state certificate of need laws, the diffusion and use of MRI and CT, and the interaction between regulation and MRI/CT diffusion and use. Section II presents conceptual challenges in the evaluation impact of CON and outlines our empirical approach to estimation. Section III describes the data, including legal surveys, demographic information, and measures of patient diagnoses and reimbursements. Section IV presents empirical estimates. The last section concludes.

I. Certificate of Need Laws and MRI and CT Use

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

Numerous studies examine the relationship between CON laws and the provision of medical care and its cost (see Conover and Bailey, 2020, for a review). The results are mixed. The earliest research comparing CON-regulated states with unregulated states suggested that CON had little if any effect on supply, quality, or cost of services (Conover and Sloan, 1998). However, recent research, typically using a difference-in-differences design, produces mixed results regarding the effects of CON laws on cost, quality, and utilization.

Many studies find that CON laws do not effectively control cost growth. For example, one study concluded that the seven states eliminating CON for open-heart surgery between 1995-1998 experienced lower average Medicare reimbursement for percutaneous coronary intervention and coronary artery bypass grafting (Ho and Ku-Goto, 2013). In home healthcare markets, overall costs were higher in CON states compared to non-CON states (Ettner et al., 2020), although this effect is likely attributed to higher caseloads in CON states, as per-patient costs were lower in CON states. One study finds that CON in home health care has spillover effects, raising overall spending on nursing home care (Rahman et al., 2016). Other cross-sectional comparisons of CON-regulated states with unregulated states concluded that CON programs have no significant effect on costs related to intensity modulated radiation therapy used for prostate cancer treatment (Khanna et al., 2013) and lumbar micro-decompression reimbursement (Ziino et al., 2020).

However, other studies have demonstrated that CON regulations promote hospital efficiency by reducing the duplication of services, leading to significantly less cost-inefficiency in CON states than in non-CON states (Rosko and Mutter, 2014). 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).

In contrast to evidence that CON does not lower unit costs, several studies report significant utilization changes. Polsky et al (2014) finds that CON states are less likely to provide home health services, services that are believed to be overused, than non-CON states. Ambulatory surgery centers are also more prevalent in non-CON than CON areas. Patients living in non-CON areas were shown to be more than twice as likely than others to have cataract surgery at an ambulatory surgery center (Stagg et al., 2018). Non-CON areas also have more freestanding emergency departments per capita (Gutierrez et al., 2016) and higher length of stay in emergency departments (Paul et al., 2014).

With respect to utilization, multiple studies on various treatments show that although CON laws may decrease levels of inappropriate service provision they do not significantly reduce growth rates of utilization. For example, CON does not limit the use of intensity modulated radiation therapy among patients with low-risk prostate cancer (Jacobs et al., 2012; Kim et al., 2016), or anterior cervical discectomy and fusion (ACDF) utilization (Ziino et al., 2020). Although regulated states have lower per capita utilization of total knee arthroplasty, utilization growth rates are not significantly different from those in unregulated states. (Browne et al., 2018). In addition, rarely indicated cardiac treatments are slightly less common in regulated states than in those without CON (Chui et al., 2019). On the other hand, lumbar decompression surgery, a service believed to be overused, is more common in CON states than in non-CON states (Ziino et al., 2020).

The few studies that examine the association between CON and quality of care have produced mixed findings. A recent body of research examining the effects of CON on quality with respect to specific procedures--including total hip, knee, and shoulder arthroplasty, percutaneous coronary intervention, and prostate cancer treatment patterns--demonstrates that CON has uncertain, no, or even negative effects on quality (Schultz, 2021; Chiu et al., 2019; Casp et al., 2019, Browne et al., 2018, Camarata et al., 2015). Some studies have found significant effects of CON on the provision of services in high-volume centers (often associated with higher quality), such as in the concentration of neonatal intensive care into high volume units (Lorch et al., 2012) and an increase in the percentage of total shoulder arthroplasty performed at high-volume facilities (Degen et al., 2019).

Some studies have found that unregulated states may have higher quality care than CON states, as is the case for home health agencies (Wu et al., 2019). Moreover, a study examining the effects of the expiration of Pennsylvania's CON program in 1996 on hip and knee replacement concluded that after the CON program expired, Pennsylvania observed reductions in the probability of dying from the procedures and increased length of stay (Averett et al., 2019). Similarly, papers by Stratmann and Wille (2016) and Stratmann (2022) found that mortality and readmission rates were higher in regulated states, concluding that CON led to lower quality care for some measures of quality. CON may also be associated with lower quality care in the nursing home industry (Fayissa et al., 2020).

B. Overuse of Diagnostic Imaging

Although high-tech diagnostic imaging has improved medical practice, it is often also overused (Rao et al. 2012; Iglehart 2009; America's Health Ins. Plans 2008; Levin et al. 2011; Levin et al. 2010; Medpac, 2014; Mitchell 2008; Levin 2004; Hillman et al., 1990). One indication of overuse is that there are more MRI units in the US per capita than any other OECD country, and patients in the U.S. receive far more MRI images (except for Germany and Japan) and CT scans (OECD, 2023). Imaging use has also grown rapidly over time, with total machines doubling between 2000 and 2011.

Attempting to improve patient health through better treatment choices, reducing risk, and managing costs, physician groups have developed objective measures of appropriate care. For example, the *Choosing Wisely* campaign of the ABIM Foundation has compiled lists of medical practices that "physicians and patients should question" (Morden et al., 2014). Diagnostic imaging appears prominently on the lists, comprising 24 of the initial 45 recommendations (Morden et al. 2014; Rao and Levin 2012).[4]

C. How CON Addresses CT and MRI

CTs and MRIs are both advanced imaging technologies which can be situated in a hospital or a freestanding facility. Both are common.

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[4] 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).

The total price of acquiring CT or an MRI machine varies considerably based on the type of machine, such as whether it is mobile or fixed, and whether a provider needs to renovate associated space to house the unit. For an MRI purchase, we found estimates to convert a mobile to a fixed machine from the past twenty years as low as $252,000 (New York State Hospital Rev. & Plan, February 2010, pg. 209). For purchases of new MRIs, depending on the sophistication and strength of a system, estimates ranged from $1-2 million (Cosmus and Parizh, 2011), $2 million (PA Health Care Cost Containment Council, 2004), and up to $3 million for a state-of-the-art machine (Glover, 2014). Nonetheless we found state regulatory documents listing considerably higher prices (see, e.g., New York State Hospital Rev. & Plan, August 2010, pgs. 216-7; June 2010, pg. 382-3; NC Department of HHS 2022; Vermont Green Mountain Care Board, 2021; Tennessee Health Facilities Commission). In our main analyses, we coded 20 states as requiring CON either directly for MRI acquisition or for spending $1.5-1.6 million or more on a capital investment (see Appendix Table 1).

Although the average cost of a CT is lower than that of an MRI, to be consistent we use the same $1.5-1.6 million expenditure amount as in the MRI analyses, and, therefore, we consider 19 states as effectively regulating CT because they either explicitly require CON for CT acquisition or for capital expenditures of $1.5-1.6 million or higher. Because more CT scans are likely to fall below this threshold, and CT technology has been around longer, we expect a less robust estimate of the impact of CON regulation on CT scanners.

II. Examining the Effects of CON

CON laws are designed to reduce excessive use of medical care in a state. If two states differed only by CON status, one would expect the availability of technology and medical spending in the regulated state to fall over time relative to similar outcomes in the unregulated state. Because CON regulations apply to new expenditures and not existing technology, any regulatory effects are likely to be small initially and grow as new applications are filed, making it imperative to examine any effects over time.

Consider the example of imaging. The imaging rate in area i (e.g., a Census tract or zip code) that is part of state s at time t is given by m_{ist}. The imaging rate depends on two sets of factors: patient characteristics, denoted x_{ist}, including behavioral risk factors such as smoking and obesity, insurance coverage, and income; and physician practice patterns, p_{st}. Practice patterns are shown as state, but not area, dependent, and reflect physician beliefs about appropriate care patterns (b_{st}, possibly driven by what technology is available) and regulations such as CON (C_{st}): $m_{ist} = f(x_{ist}, p_{st}(b_{st}, C_{st}))$.

Researchers typically examine the effects of CON on imaging either by 1) estimating differential levels of imaging in states that adopt CON relative to states that did not, or 2) comparing the growth rate of imaging during time periods subject to CON regulation compared to a pre-CON period in states implementing CON relative to those not implementing CON. (See, for example, Conover and Sloan 2003; Conover and Sloan 1998, Antel et al. 1995). In our notation, denote t=0 for the pre-CON time period and t=1 for the CON time period. The difference-in-difference estimate of the level of imaging is given by:

$$DID_C = (m_{Ct=1} - m_{Ct=0}) - (m_{NCt=1} - m_{NCt=0}), \qquad (1)$$

where C and NC denote CON and non-CON states respectively. We do not indicate the *a* subscript as such analysis is typically done at the state level.

Estimating such models is complicated by both conceptual and statistical issues. One conceptual concern is that CON implementation may be endogenous to state spending. If states with higher levels (or more rapid growth) of medical spending are more likely to adopt CON laws, as seems likely, there may well be more imaging facilities in regulated states than unregulated states. It is theoretically possible to identify this pattern by examining changes in the growth rate of utilization from the pre-CON to the CON era rather than examining levels of utilization, but reliably estimating differential trends pre and post-CON implementation is difficult in short panels (Bilinski and Hatfield, 2018; Roth, 2022). Moreover, such analyses are particularly challenging to implement when the data exhibit high variation in underlying growth rates across areas.[5]

A second concern is the inability to perfectly control for other factors that can influence imaging trends, the x_{ist} variables noted above. Differences in trends of behavioral risk factors, insurance coverage, and income would all be expected to lead to differential trends in imaging over time. Regressions can control for some x's, but the controls may be insufficient to account for all these factors, especially in models that examine spending differences over long periods of time. Since CON effects might not manifest for some time, the possibility of omitted variables is particularly problematic.

Consequently, we pursue an alternative approach to estimating the effects of CON, employing a regression discontinuity design (RD) at state borders that examines differences in imaging at the border of regulated and unregulated states.[6] This model assumes that demographic and economic characteristics do not change discontinuously at state borders. Thus, any change in imaging associated with being on the CON side of the border relative to the non-CON side can be attributed to the impact of CON. The RD estimator of the impact of CON implementation is given by:

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[5] Using data over the 30 year period from 1991 through 2020, the standard deviation of per capita medical spending growth rates across states is 0.4 percent. The cross-state variability is even greater over smaller intervals. Statistics based on authors' calculations from the National Health Expenditure Accounts.

[6] Chiu (2021) uses a similar design, looking at changes in heart attack mortality at state borders.

$$RD = \lim_{\varepsilon \downarrow 0} E[m_{ist} | d_i = \underline{d} + \varepsilon] - \lim_{\varepsilon \uparrow 0} E[m_{ist} | d_i = \underline{d} + \varepsilon]. \quad (2)$$

In equation (2), $\underline{d}$ is the distance marker associated with the CON–Non-CON border, so the difference is between imaging rates as the distance to the border on either side is reduced. We explain the empirical implementation of equation (2) below.

Regression discontinuity estimation raises several concerns, only some of which we can address. The first issue is the same endogeneity concern discussed above: the CON side of the border may have the same or higher rates of imaging than the unregulated side if CON offsets what would have been an even higher rate of imaging absent regulation. More formally, the RD design is predicated on the idea that the x_{ist} variables do not vary at the state border. If the physicians on either side of the border have different beliefs or practice under other constraints, however, the rate of imaging may change at the border for reasons other than CON regulation. In the view that CON is endogenous, we expect that the physicians on the CON side of the border would practice in a more intensive way without CON. If true, the effects of CON estimated from equation (2) will understate the true effects.

In principle, embedding a difference-in-differences design into the regression discontinuity framework–estimating border discontinuities before and after CON implementation—addresses this problem. In practice, our time series of data is relatively short (5 years), and our variable of interest, CON status, did not change over this time period. Thus, we treat the data as a single cross section even though our estimate may represent a lower bound on the effect of CON on imaging.

A second concern about the regression discontinuity design is the potential impact of strategic placement of imaging facilities on the results. Having detected unmet demand for imaging in regulated states, imaging owners in unregulated states may strategically locate near the border. Such strategic placement is consistent with previous research finding fewer MRIs in regulated counties that border unregulated states than in counties on other borders (Horwitz and Polsky, 2015). If some people cross state borders to receive medical care, we would find a smaller effect of CON on imaging utilization at the border than would be true if CON were implemented nationally.

We can test for the effect of strategic facility location by examining how imaging use varies by distance from the border. If strategic placement is important for utilization, imaging utilization in regulated states should be higher near the border and decline as one moves away from the border. The same would be true in unregulated states, as the higher density of imaging facilities near the border should make it easier for people living near the border to obtain images. If strategic location is not important for the imaging rates, we would not see such an effect.

A. Empirical Implementation

Our empirical implementation of the RD estimation is as follows. Let i denote geographic location (either Census tracts or zip codes, as noted below) and d the distance from the center of the tract to a boundary between a CON and a non-CON state. $d>0$ indicates distance into a CON state and $d<0$ indicates distance into a non-CON state. CON_i is a dummy variable for the state having a CON law (i.e., $CON_i=1$ if $d_i>0$). The equation that we estimate is a local linear regression model of the form:

$$y_i = \beta_1 * I(CON_i=1) + \beta_2 * d_i + \beta_3 * I(CON_i=1) * d_i + \varepsilon_i \quad (1)$$

In our first models, y is a dichotomous variable measuring whether a census tract has any MRI or CT providers (hospital or freestanding facility). β_1 measures the jump in the probability of an imaging facility at the boundary. β_2 shows how distance from the border is related to imaging facility location in non-CON states, and β_3 captures how availability of a unit changes with distance in CON states relative to non-CON states. As in all regression discontinuity designs, the identification is clearest for the jump at the discontinuity, though some theories predict β_2 and β_3 as well. If there is strategic location of imaging facilities on the non-CON side of a border and people are willing and able to cross the border for care, there would also imply a jump at the border ($\beta_1<0$), which then dissipates farther into the interior of both states ($\beta_2>0$ and $\beta_3>0$).

Our primary specification involves a triangular kernel, where weight falls linearly away from the boundary to a weight of zero at the distance given by the bandwidth.[7] We estimate facility placement with a 100-mile bandwidth and imaging receipt using 20 miles as the baseline bandwidth. The large distance for facility placement is because there are relatively few facilities, and so we need to have sufficient observations to estimate an effect. Conventional estimates of optimal bandwidth suggest such a distance is optimal. With respect to imaging receipt, few people travel more than 20 miles to receive an image. The appendix reports results for alternative bandwidths as well as models with a rectangular kernel (for all bandwidths), and results using a logit functional form.

The models for location of an imaging facility are at the Census tract level. Census tracts are the smallest unit for which we have population data to use in denominators (approximately 4,000 people live in each Census tract). We do not expect these Census tracts to be substantially different in other respects, and we confirm that attributes of tract populations do not change across the boundary on average, nor does the inclusion of such attributes affect our point estimates on average. We differentiate between hospital-based imaging facilities and freestanding imaging facilities. Because a single or limited-service provider, such as medical imaging provider, entering

[7] Using a smaller window in terms of distance from the border results in lower squared bias but higher variance, whereas a larger window results in larger squared bias and lower variance. The "optimal" mean-squared-error minimizing choice balances these undesirable features, as described in Imbens and Kalyanaraman (2009) and Calonico, Cattaneo, Farrell, and Titiunik (2017).

the diagnostic imaging business will have greater choice of where to locate than a hospital, which already exists in a fixed location, the effects of CON on freestanding MRI and CT providers may be greater than those on hospital-based MRI and CT services.

In measuring the quantity and quality of care provided, we use as dependent variables whether a patient received any MRI scan or a CT scan in a year. Because we do not observe the Census tract in which a Medicare beneficiary lived, we use zip codes for this analysis. We do the same with measures of appropriate and inappropriate MRI or CT, as defined below.

III. Data

Data on state certificate of need laws significantly improves on prior, publicly available data. Both the MRI and CT datasets cover all states in the continental United States and the District of Columbia. They were constructed by law-student research assistants supervised by Horwitz and JD-Law Librarians. For each state, the researchers analyzed state statutes, related regulations, and secondary sources, and conducted interviews with state regulators in every state to determine whether laws on the books accurately reflected the regulatory environment. The MRI dataset was first developed for and described in detail in Horwitz and Polsky (2015). To determine whether a state regulated MRI in 2016-17, we updated the results in 2020 and 2023. The CT dataset was newly built for this project with research conducted in 2012, 2016-17, 2020, and 2023. Where rules differed for freestanding and hospital-based acquisitions or according to the type of entity acquiring the technology, we coded a state program according to its most extensive set of rules, because the rules typically applied to the entities and owners best able to respond to the regulations in entering a market or choosing a location.

Figure 1 shows the coding of CON laws and regulations that apply to CT or MRI. In 2016-

2017, there were 29 states with no CON regulation, 19 states where CON applied to both CT and MRI, and 1 state where CON applied to MRI but not CT (Kentucky). CON is largely a phenomenon of the East and Midwest. Only two of the regulated states are west of the Mississippi, with almost all in the northeast and Midwest. See Appendix, Table 1 for list of states.

Data on MRI and CT provider location and number and type of scans come from several sources. The location of hospital-based MRI and CT providers comes from the American Hospital Association's Annual Survey of Hospitals in 2018. We assembled the locations of free-standing CT and MRI providers from 2020 data provided by three accreditation bodies: the American College of Radiology, the Intersocietal Accreditation Commission, and RadSite. Data to construct demographic control variables are from the 2010 Census, based on aggregates at the tract and zip code tabulation area.

To measure MRI and CT use, we create a database of billing data for Medicare inpatients and outpatients at the beneficiary level, from 2008 to 2014; because we use a one-year lookback for medical records to define risk pools, our analysis sample includes records from 2009 to 2014.[8] We use 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 Medicare Provider Analysis and Review (MEDPAR) file, merged to 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 or CT scan depends on the data source. In some sources it is a scan per patient stay (we define the stay using the last date of service) 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. We construct outcomes for each patient by flagging

[8] The switch to ICD-10 in 2015 make it difficult to compare imaging for specific diagnosis before and after that date.

whether they had at least one of the named scans during a year.

Our measure of appropriate imaging is MRI or CT imaging with a diagnosis of trauma in the coincident set of billings (defined as a "stay") (Hussain et al., 2021). Inappropriate imaging comes from the work of Schwartz et al. (2014), which draws on the Choosing Wisely (Colla et al. 2014) recommendations. There are seven imaging measures in their coding of low value care: MRI imaging for patients with non-specific low back pain; CT of the sinuses for uncomplicated acute rhinosinusitis; CT head imaging in the evaluation of syncope; CT head imaging in the evaluation of headache; CT carotid imaging with syncope diagnosis; CT screening for carotid artery disease in asymptomatic adults; and CT imaging for diagnosis of plantar fasciitis. Appendix Table 2 shows the prevalence of the seven conditions. The most prevalent of the seven low value care measures are CT screening for carotid artery disease in asymptomatic adults (2.5% annual prevalence) and MRI imaging for patients with non-specific low back pain (2.2% annual prevalence).

IV. Results

The regression discontinuity design we use rests on the 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, there are few differences in the population at the zip code level (comparisons of Census tracts or counties show similar balance). Indeed, the differences shown in Table 1 do not represent statistically significant changes at the border when we conduct regression discontinuity tests where a zip-code-level population characteristic is the outcome measure.

A. Location of MRI and CT providers

Figure 2 shows the location of MRI and CT providers in CON and non-CON states. In each case, we differentiate hospital-based from freestanding facilities. As can be seen in the maps, hospital-based providers are more evenly distributed across the US than are freestanding providers; these different location choices may be because there are government-owned hospitals in relatively unpopulated areas and because freestanding 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.

Figure 3 shows an example of providers choosing to locate in non-CON states (Indiana and Ohio) just across the border with a regulated state (Michigan). The rectangle inset, which covers an area of about 20 miles north of the Michigan border to 20 miles south of the border, shows many more providers in the unregulated states, just South of 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.

Table 2 shows regression analysis for the location of MRI and CT facilities. As shown in the first two columns, there is a reduction in the probability of an MRI facility at a CON – non-CON border, but no reduction in the probability of a CT scanner locating there. As the remaining columns show, the decline in MRI scanners locating just on the CON side of the border represents both hospital and freestanding facilities.

To examine the sensitivity of this finding, Figure 4 shows regression discontinuity estimates in the probability that there is an MRI provider (figure a) or CT provider (figure b) in a Census tract for different bandwidths. MRI effects are roughly similar at any distance from 30 miles on. The CT estimates are positive but not statistically significant at low bandwidths before becoming essentially 0. The regression discontinuity estimates for the 100 mile bandwidths are shown in figures c and d. The discontinuity at the border is clear for MRI imaging availability but not CT availability.

B. Quantity and Quality of MRI and CT Use

Tables 3 and 4 show the effects of CON on the receipt of CT and MRI images. Columns 1 and 2 in Table 3 show results for any receipt of MRI and any receipt of CT. There is a reduction in probability of a patient receiving any MRI scan at the border. The decline is 0.3 percentage points, or roughly 2% of the mean on the non-CON side of the border (rows 4 and 5). There is no change in any receipt of a CT image.

Moving away from the border, receipt of a CT or MRI image declines in a non-CON state (recall that d<0 in a non-CON state, reflecting distance from the border), consistent with the idea of strategic location of new facilities near the border with a CON-regulated state affecting utilization near the border. There is no statistically significant change in the probability of receiving an image in the CON-regulated side of the border, however. People may be somewhat hesitant to cross the border for care, or physicians may not refer them to another state.

Columns (3) and (4) report the effect on receiving an appropriate MRI or CT image – with a trauma diagnosis. MRI images for trauma do not change at or near the border. CT images fall 6% at the border but do not change on either side moving away from the border. These effects are much smaller than for low value imaging, as discussed next.

Table 4 shows the effect of CON on low-value imaging. The first column is for lower back MRI; the remaining columns are for CT images. In all seven cases, there is a reduction in the probability of receiving a scan on the CON side of the border; in six of the cases, the effect is statistically significant. The reductions are large. Compared to the rate of imaging receipt on the unregulated side of the border, receipt on the CON side of the border is 20-26 percent lower.

We find little tendency for overall utilization of imaging to change as one moves into the interior of a non-CON state. Most of the estimates suggest that utilization is a bit higher at the border than in the interior of an unregulated state, but the estimates are generally not statistically significant. In contrast, all of the estimates indicate that use of low value imaging rises as one moves into the interior of a regulated state, and six of the seven estimates are statistically significant. Because facilities choose to locate on the non-CON side of the CON – non-CON border, one might have expected imaging rates to be higher for people just on the CON side of the border than as one moves towards the interior of the CON state. However, we do not see this. By 20 miles in from the border, the rate of use is higher in CON states than at the border in non-CON states.

To understand the magnitude of our findings about lower rates of imaging on the CON side of a CON – non-CON border, we consider the implications if they applied to the entire Medicare population of approximately fifty million beneficiaries. Under this scenario, there would be approximately 100,000 fewer scans for lower back pain in a year. In 2014, the price of an MRI scan ranged from $300 to $3,000 (Wu et al, 2014), suggesting potential savings of thirty to three-hundred million dollars per year for this one type of scan.

C. Sensitivity Results

In addition to showing the triangle kernel results using a local linear model, in the appendix we also show alternative bandwidths, an alternative (rectangular kernel) and local logit regression results (for all bandwidths and both kernels) in figures showing point estimates and confidence intervals. In other work not reported here, we also controlled for the percentage of the population in different age groups, and fractions of the population by income or race/ethnic category. Adding these controls does not qualitatively affect the results (indicating any jumps in zip-code-level characteristics at the border were orthogonal to discontinuous changes in individual patient experiences at the border).

Moreover, although we discuss only the results for the twenty-mile bandwidths using a triangle kernel in the text, we tested several bandwidths (reporting for 10, 20, 30, 40, and 50 miles) and kernels. The larger bandwidths include more people and therefore have smaller confidence intervals. However, the bandwidth for a triangle kernel refers to the width the entire kernel (where weight is nonzero), so with a 20-mile bandwidth, for example, half of the people included in the estimate live within 5.86 miles. Most of the information, therefore, is drawn from within a fairly narrow area around the relevant state border using a triangle kernel. We report results from the same bandwidths using a rectangular kernel, meaning all zip codes within the given distance are assigned equal weight. In addition, we report results from the regression discontinuity tests using both local linear regression and logit regressions (using both a triangular kernel and a rectangular kernel at each bandwidth), which yield similar results. The estimates are reasonably stable at bandwidths greater than 10 miles, and confidence intervals become larger at bandwidths below 20 miles, illustrating the variance tradeoff described above.

V. Conclusion

Our findings suggest that Certificate of Need regulation affects the location of MRI and CT providers and the care that patients receive. Moving across a state border from a state that does not regulate MRI to one that does results in a roughly 14 percent reduction in the probability that a census tract has an MRI provider, though no impact on having a CT provider. Part of the change appears to be due to strategic location of imaging facilities just on the non-CON side of a CON – non-CON border.

Although patients in CON-regulated states could move across states to receive images, they do not fully do so. Imaging use is lower on the CON side of the border than the non-CON side. This reduction in utilization is especially true for low value imaging. At the border, there is a 20-26 percent reduction in seven measures of low value imaging. Imaging rates rise as one moves away from the border on the CON side, consistent with CON states generally having greater rates of medical care utilization. In contrast, high value images are generally invariant across state borders – changing not at all for MRI and a smaller amount (6%) for CT. The mix of diagnoses where a scan is indicated and where it is contraindicated leaves the overall probability not much different on each side of the CON – non-CON border. This may be good news: appropriate scans are equally likely to be done in CON and non-CON states, while potentially inappropriate scans are less likely in CON states.

Spending on MRI and CT scans is high in the U.S. 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 (Schwartz et al. 2014; Webster et al. 2014), and some evidence that the probability of a patient receiving a scan is related to physician ownership of MRI equipment (Baker, 2010). If, as this analysis suggests, certificate of need regulation is associated with a reduction in utilization of low value or contraindicated treatments, such regulation may not only constrain provision of those treatments, it may also contribute to cost control. The avoided excess costs associated with CON regulations are potentially much larger than the costs of scans themselves, because of the potential of a “cascade” of unnecessary treatment (Ganguli et al., 2019; Webster et al. 2014).

There are a few limitations to our study. First, because of data limitations, our study design is using only six years of scans (2009-2014), and the panel of patient records is essentially used as a cross section (except insofar as lookbacks to prior year medical records are required to rule out prior diagnoses and procedures), i.e. we do not use patient fixed effects to eliminate sources of individual heterogeneity as would be the case with a “mover” design. Second, the states that enforced CON for MRI and CT are geographically clustered in the Midwest and Northeast. It is possible that the results do not generalize over time or to different regions of the country. Third, we consider only two types of imaging technology, MRI and CT, although they represent particularly overused technologies. Fourth, we limited our analysis to using Medicare data from the elderly, fee-for-service population to measure the quantity of scans and the quality of medical treatment.

Even with these caveats, however, having CON in place leads to lower use of low value care and little to no impact on use of high value care, suggesting that CON could be a part of a government’s cost containment arsenal.

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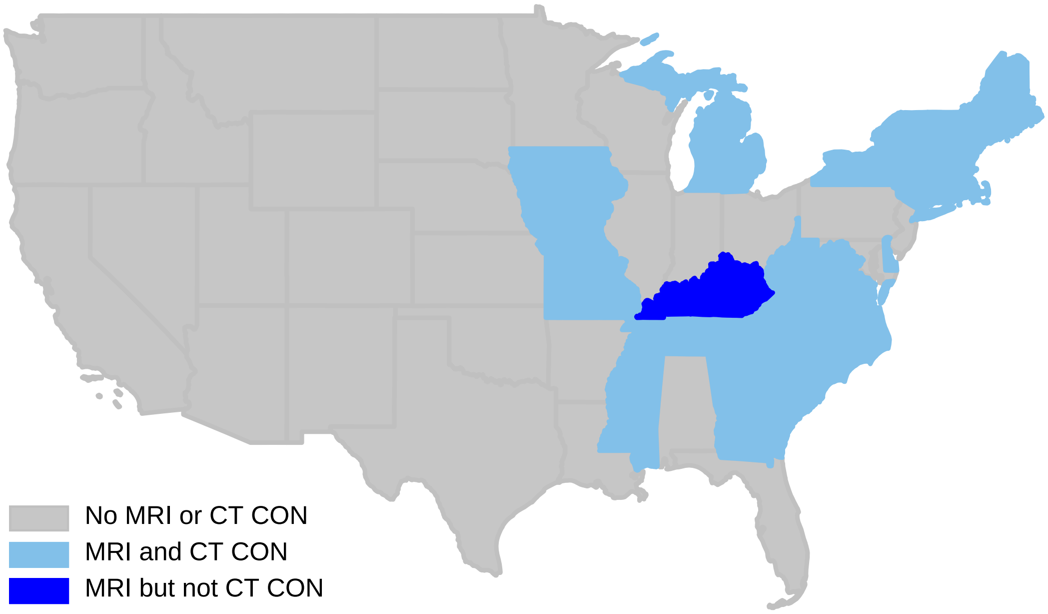
Figure 1: CON for CT and MRI, 2017

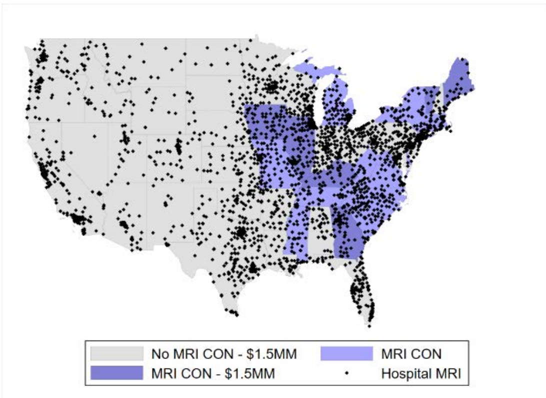


Notes: States are coded as regulating MRI or CT if the CON laws requiring review for adoption of MRI or CT or for expenditures ≥ \$1.5-1.6 million.
Sources: Data on state certificate of need laws were constructed by law-student research assistants supervised by Horwitz and JD-Law Librarians researching statutes, regulations, various secondary sources, and interviews with state regulators. The MRI dataset was first developed for and described in Horwitz and Polsky (2015) and was updated to reflect regulation in 2016-17 with 2020 and 2023 research. The CT dataset was created with legal research conducted in 2012, 2016-17, 2020, and 2023. Where rules differed for freestanding and hospital-based acquisitions or according to the type of entity acquiring the technology, we coded a state program according to its most extensive set of rules.

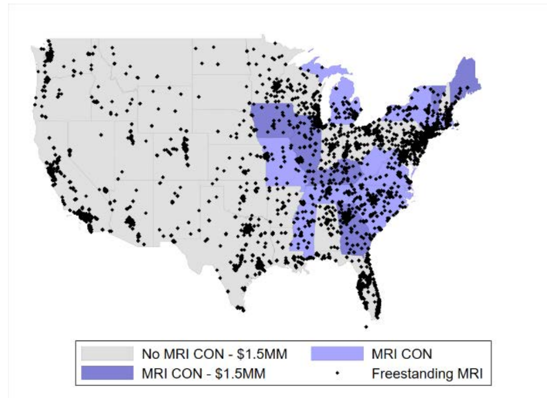
Figure 2. Freestanding and Hospital-based MRI and CT Facilities

MRI availability

(a) Hospital-based MRI

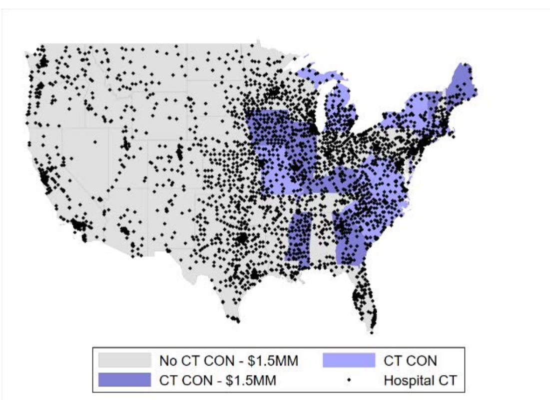


(b) Freestanding MRI

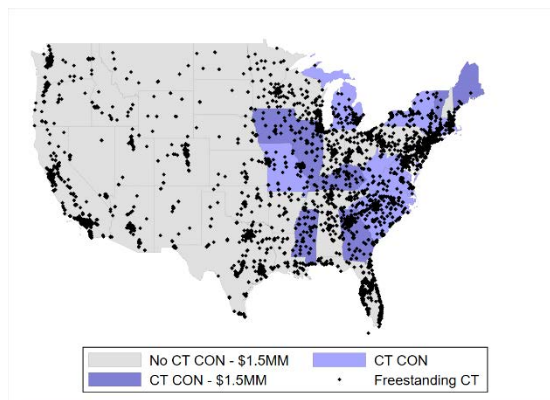


CT availability

(c) Hospital-based CT

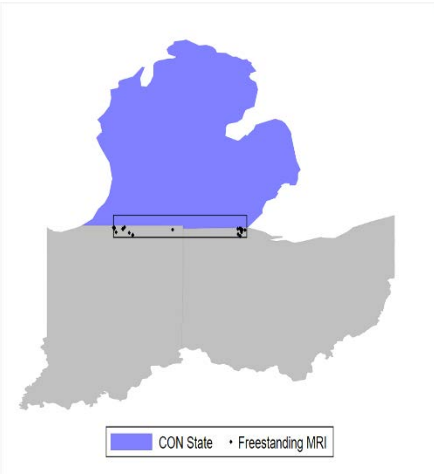


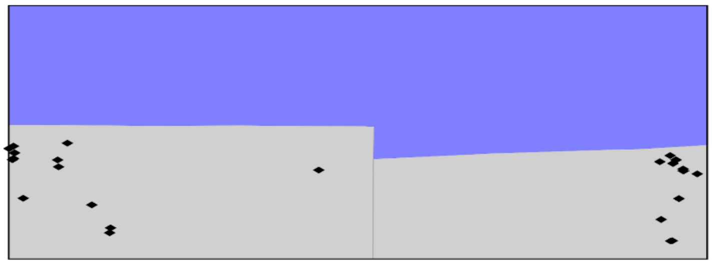
(d) Freestanding CT



Sources: Coordinates for each of the hospital-based locations are from the American Hospital Association Annual Survey of Hospitals 2018. Coordinates for the free-standing providers are from addresses found in the membership lists of the three independent agencies that accredit freestanding facilities—the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and RadSite, all acquired in 2020.

Figure 3: Location of MRI Providers in CON Regulated (Michigan) v. Unregulated (Ohio and Indiana) States

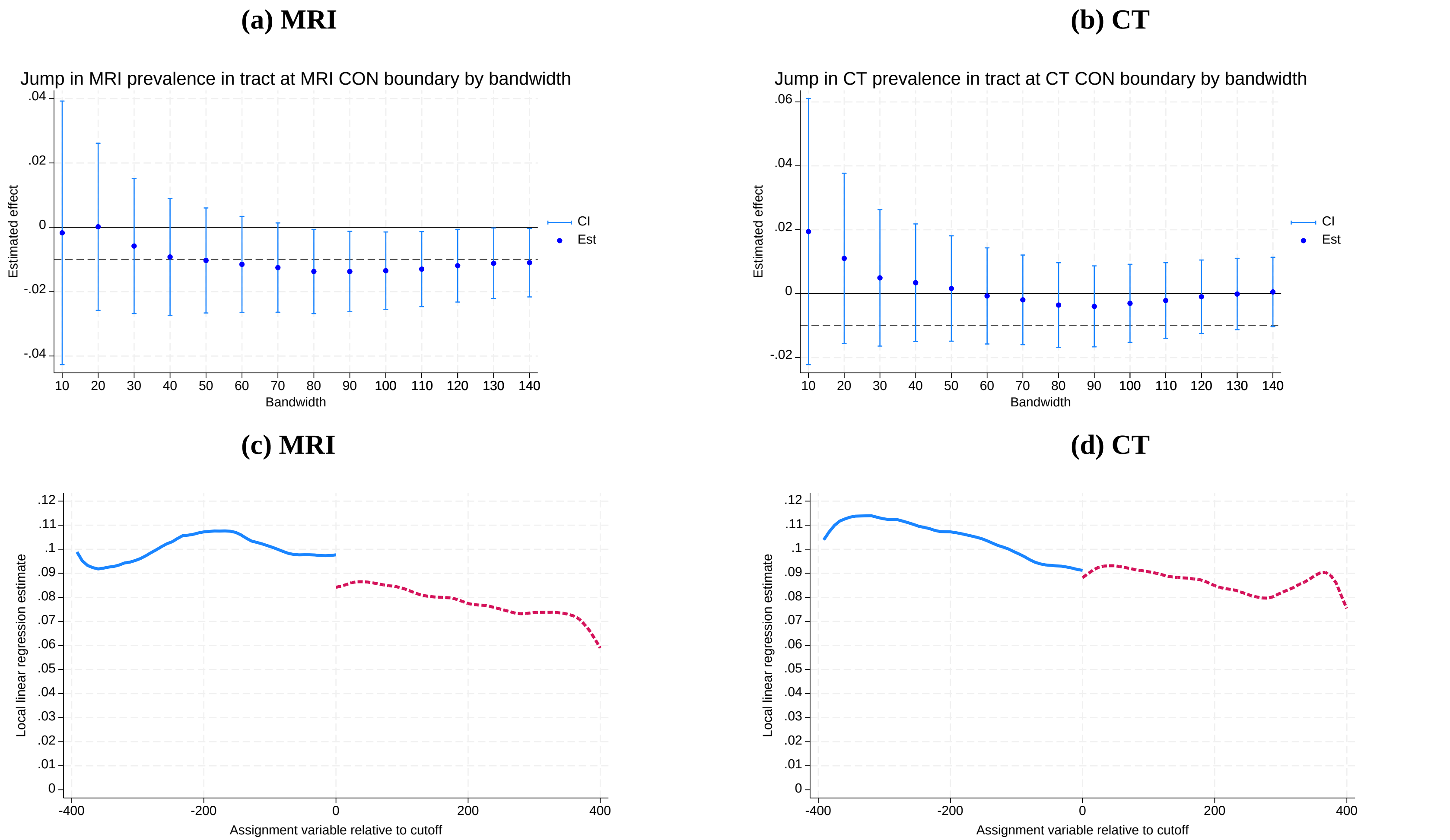




Notes: The rectangle captures the southern border of Michigan, the lower edge is given by 41.5 N latitude, upper 42 N latitude, left edge longitude -83.2 and right longitude -86.2, running about 20 miles north and south along the MI border.

Sources: Coordinates for each of the hospital-based locations from the American Hospital Association Annual Survey of Hospitals 2018. Coordinates for the free-standing MRI providers are from addresses found in the membership lists of the two agencies that accredit freestanding facilities—the American College of Radiology (ACR), Intersocietal Accreditation Commission (IAC), and RadSite, all acquired in 2020.

Figure 4. Change in Probability Census Tract has an Imaging Facility at the CON v. non-CON Border



Notes: Each data point in (a) and (b) shows the estimate and the confidence interval for the specified bandwidth; each data point in (c) and (d) shows a local kernel-weighted mean for a bandwidth of 100 miles. All regressions weighted using a triangle kernel, where weight falls linearly away from the boundary to a weight of zero at the indicated bandwidth. Sources: Locations of hospital-based facilities are from the American Hospital Association Annual Survey of Hospitals 2018. Locations for the free-standing providers are from addresses found in the membership lists of the two agencies that accredit free-standing facilities—the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and RadSite, all acquired in 2020.

Table 1: Descriptive Statistics

	Within 20 miles of MRI Border		Within 20 miles of CT Border	
Variable (percent)	**Non-CON Zips**	**CON Zips**	**Non-CON Zips**	**CON Zips**
In nursing homes	0.5%	0.5%	0.5%	0.5%
Families by annual income				
<$25,000	15.4%	17.5%	16.2%	17.9%
$25,000-$50,000	22.5%	23.2%	23.1%	23.7%
$50,000-$75,000	20.0%	19.5%	20.2%	19.6%
≥$75,000	42.1%	39.8%	40.5%	38.8%

Source: United States Census 2010, ACS 5-year file for tract-level totals, aggregated to zip codes.

Table 2: Effect of CON on Facility Location

Variable	Any Facility MRI	Any Facility CT	Hospital-based Facility MRI	Hospital-based Facility CT	Freestanding Facility MRI	Freestanding Facility CT
Jump at border	-.0135**	-.0031	-.0054	-.0047	-.0068	.0016
	(-2.20)	(-0.49)	(-1.32)	(-1.07)	(-1.26)	(0.30)
Distance from border	.000023	-.000023	-.000115	-.000122	.000124	.000055
	(0.23)	(-0.24)	(-1.69)	(-1.69)	(1.44)	(0.67)
Distance from border * CON side	.000050	.000183	.000294**	.000406**	-.000275**	-.000141
	(0.36)	(1.34)	(3.13)	(4.08)	(-2.35)	(-1.24)
Non-CON prevalence at border	9.8%	9.1%	4.0%	4.4%	7.3%	6.1%
N - tracts	29,953	29,490	29,953	29,490	29,953	29,490

Note: Observations are Census tracts. Observations are in a 100 mile window from the border. t-statistics are in parentheses.

Table 3: Effect of CON on Receipt of Any and High Value Imaging

Variable	Any Image MRI	Any Image CT	High value Imaging: Trauma DX MRI	High value Imaging: Trauma DX CT
Jump at border	-.00312**	-.00121	.00006	-.00030**
	(.00087)	(.00110)	(.00004)	(.00014)
Distance from border	.00029**	.00030**	-.0000041	.000014
	(.00007)	(.00008)	(.0000032)	(.000011)
Distance from border * CON side	-.00013	-.00002	.0000040	-.000022
	(.00009)	(.00012)	(.0000047)	(.000014)
Non-CON prevalence at border	13.0%	24.6%	0.04%	0.46%
Change relative to non-CON border				
- At border	-2%	-0.5%	15%	-6%
- 20 miles from border, non-CON state	-5%	-2%	-6%	0%
- 20 miles from border, CON state	0%	2%	15%	-10%
N – Observations	4,776,017	5,104,676	4,776,017	5,104,676
People	1,274,129	1,362,360	1,274,129	1,362,360
Clusters	878,305	944,845	878,305	944,845

Note: Data are from Medicare analysis sample, 2009-2014. Observations are people in a 20 mile window of a CON – non-CON border. High value imaging is defined in Appendix Table 2. Standard errors are in parentheses.

Table 4: Effect of CON on Low Value Imaging

Variable	MRI: Back imaging	CT Scan: Sinus	Head imaging – syncope	Head imaging – headache	Carotid imaging – syncope	Carotid screening	Plantar fasciitis
Jump at border	-0.01252**	-0.00077**	-.00224**	-0.00570**	-0.00143**	-0.00723**	-0.00062**
	(0.00182)	(0.00020)	(0.00037)	(0.00092)	(0.00040)	(0.00181)	(0.00019)
Distance from border	0.00010	0.00000	0.00000	0.00019**	0.00000	0.00010	0.00002
	(0.00010)	(0.00001)	(0.00002)	(0.00005)	(0.00003)	(0.00010)	(0.00001)
Distance from border* CON	0.00049**	0.00008**	0.00014**	0.00010	0.00009*	0.00043**	0.00000
	(0.00116)	(0.00002)	(0.00003)	(0.00008)	(0.00004)	(0.00018)	(0.00002)
Non-CON prevalence at border	5.7%	0.3%	0.8%	2.3%	0.7%	3.6%	0.3%
Change relative to non-CON border - At border	-22.15%	-23.46%	-26.42%	-24.65%	-21.60%	-19.90%	-19.92%
- 20 miles from border, non-CON state	-3.69%	2.08%	-0.67%	-16.52%	-0.57%	-5.65%	-12.20%
- 20 miles from border, CON state	16.85%	39.97%	30.39%	7.32%	22.17%	22.93%	-6.33%
N – Observations	6,875,597	6,415,393	6,415,393	6,415,393	6,415,393	6,415,393	6,415,393
People	1,571,888	1,467,536	1,467,536	1,467,536	1,467,536	1,467,536	1,467,536
Clusters	3,238	3,171	3,171	3,171	3,171	3,171	3,171

Note: Data are from MedPAR, 2009-2014. Observations are people in a 20 mile window of a CON – non-CON border. Low value imaging is as defined in Appendix Table 2. Standard errors are in parentheses.

Appendix

Specification Tests are shown below as point estimates and confidence intervals for a variety of low-value scan outcome measures on each graph, each shown for each bandwidth of 10, 20, 30, 40, and 50 miles (in each graph, the top confidence interval is for a 10-mile bandwidth and the bottom one is for a 50-mile bandwidth, with 20-, 30-, and 40-mile bandwidths in between). Each outcome is shown for either MRI or CT CON, in figures 1-4 or figures 5-8, respectively.

Figure 1. Rectangular kernel, local linear regression for impacts at MRI CON border

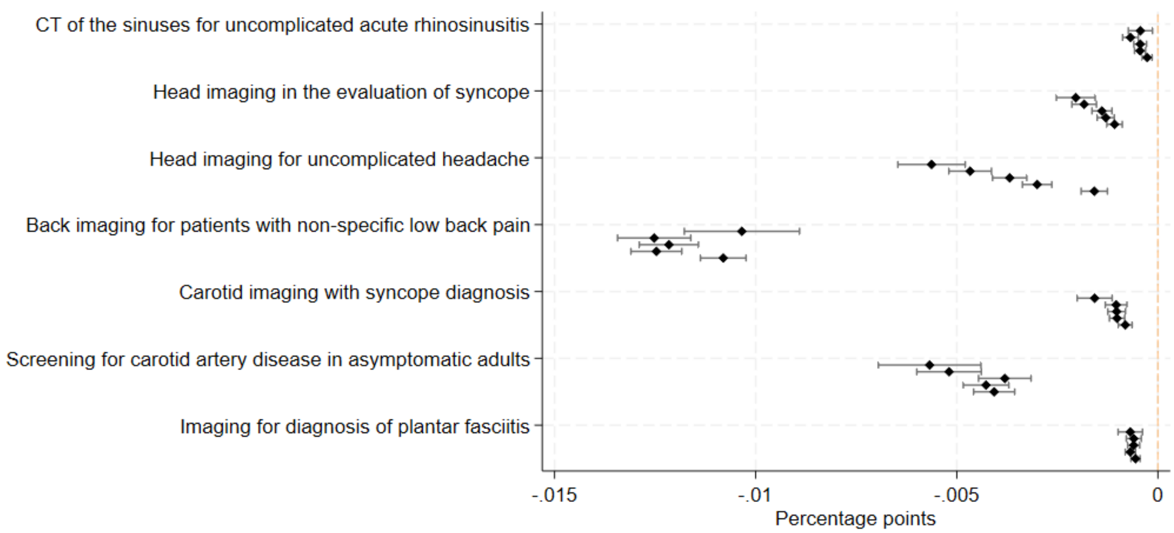


Figure 2. Triangular kernel, local linear regression for impacts at MRI CON border

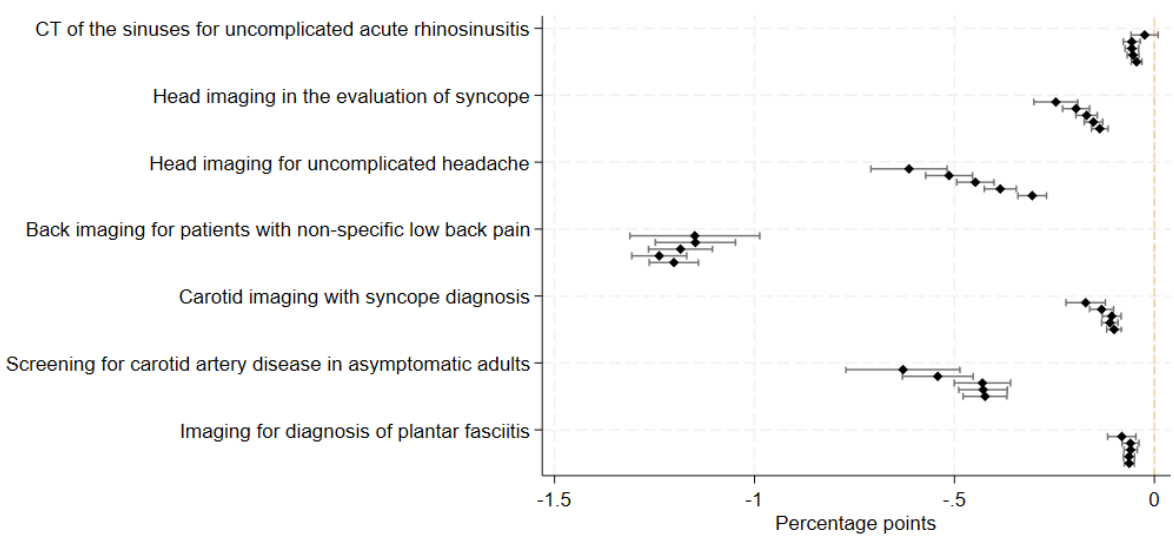


Figure 3. Rectangular kernel, local logit regression for impacts at MRI CON border

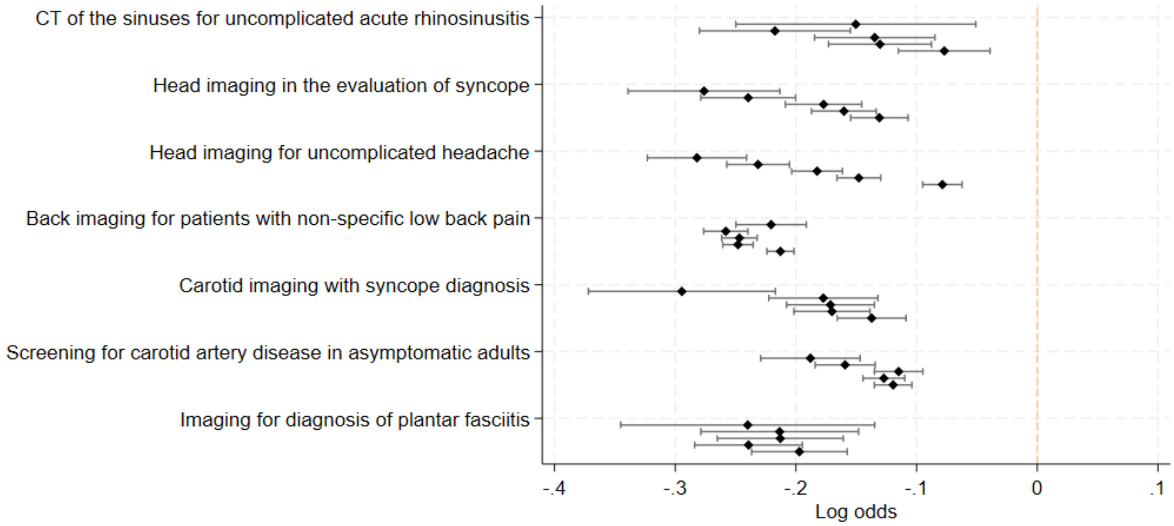


Figure 4. Triangular kernel, local logit regression for impacts at MRI CON border

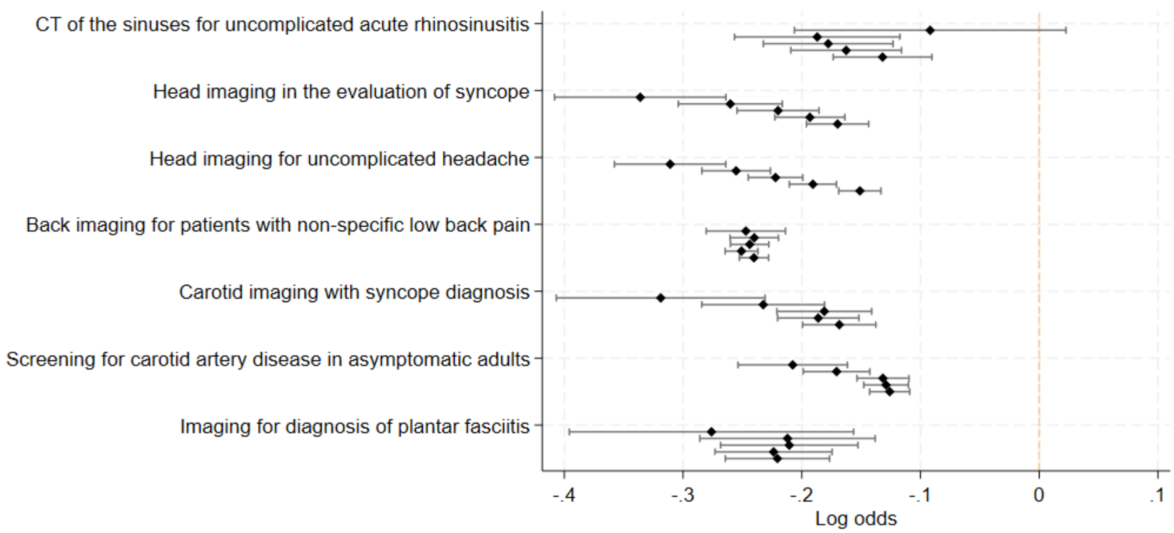


Figure 5. Rectangular kernel, local linear regression for impacts at CT CON border

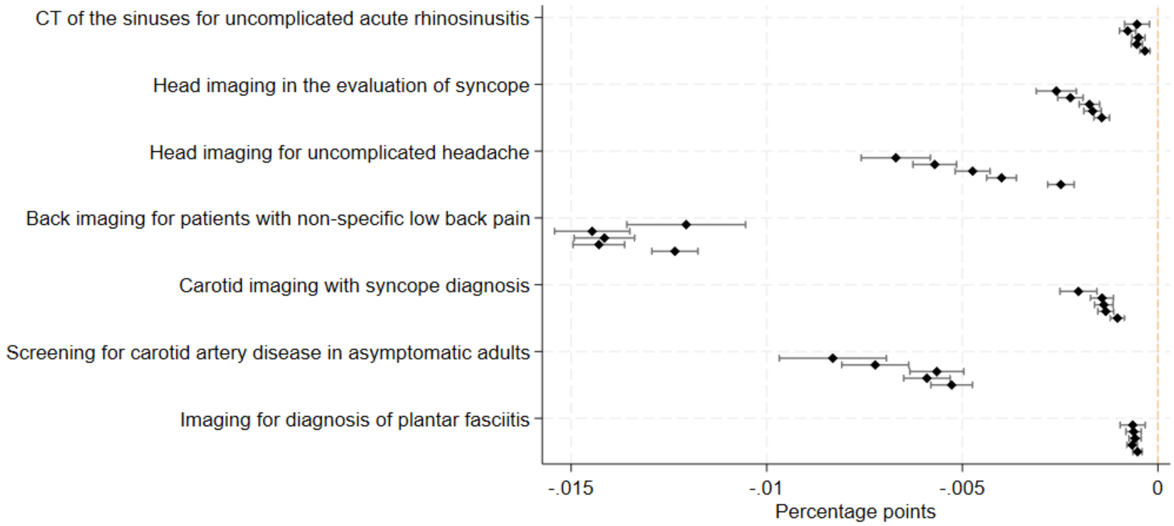


Figure 6. Triangular kernel, local linear regression for impacts at CT CON border

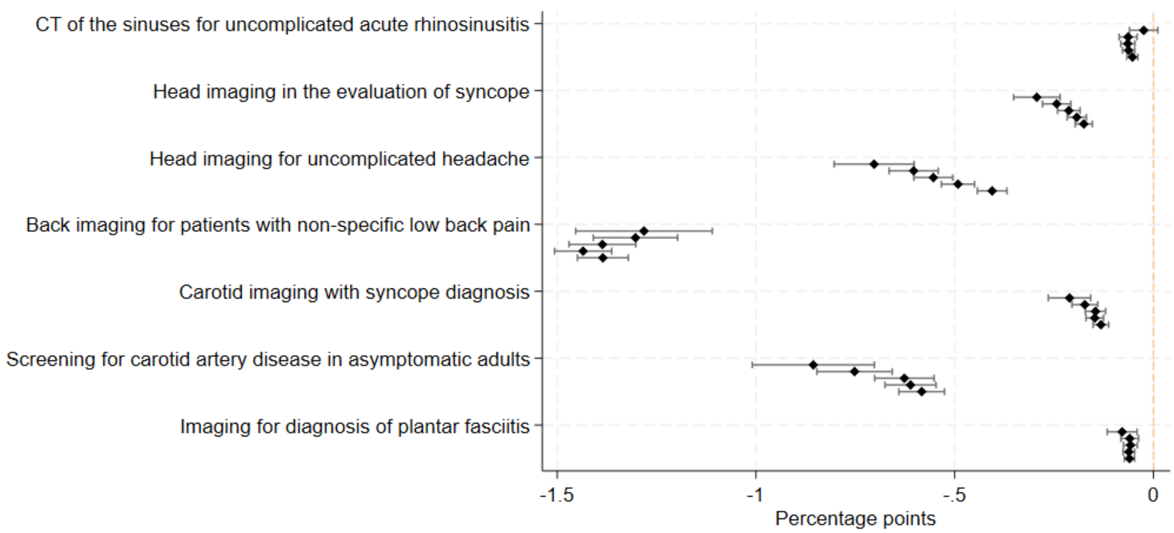


Figure 7. Rectangular kernel, local logit regression for impacts at CT CON border

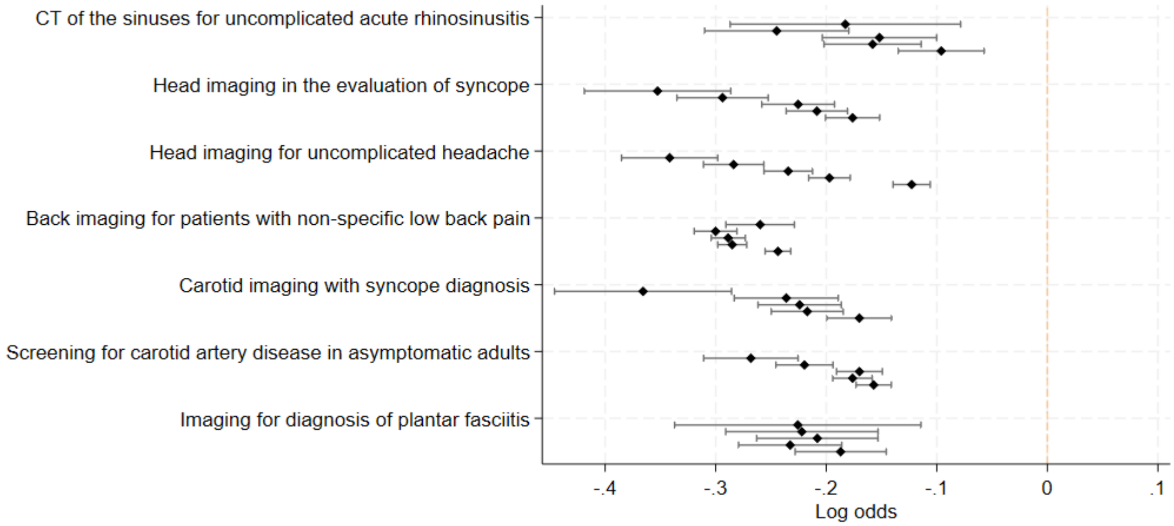
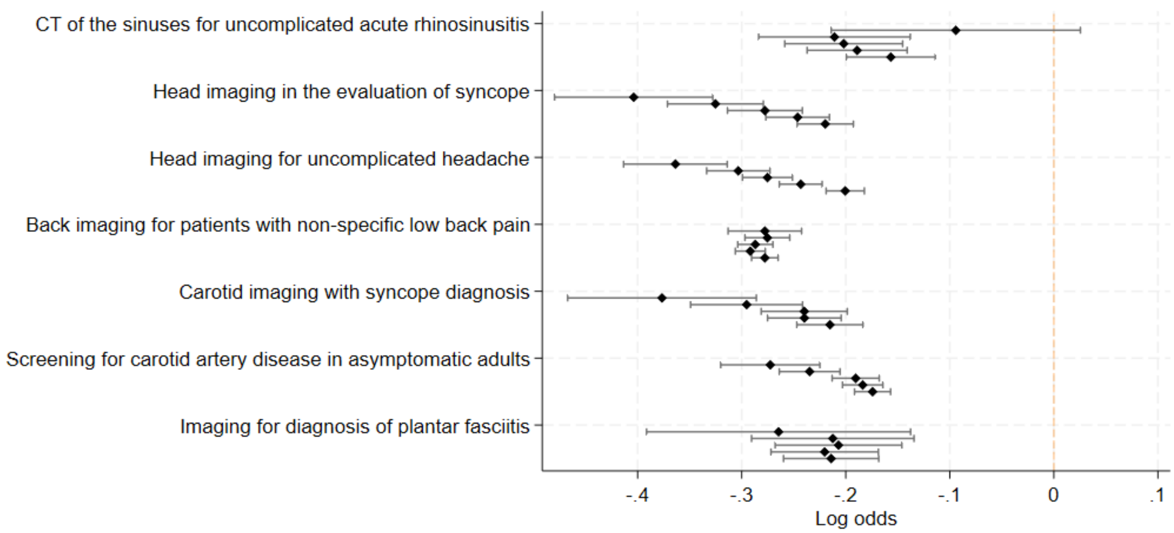


Figure 8. Triangular kernel, local logit regression for impacts at CT CON border



Appendix Table 1: List of States by CON Status for MRI or CT, Primary Analyses

	No CON	MRI CON Only	Both MRI and CT CON
Alabama	X		
Arizona	X		
Arkansas	X		
California	X		
Colorado	X		
Connecticut			X
Delaware			X
D.C.			X
Florida	X		
Georgia			X
Idaho	X		
Illinois	X		
Indiana	X		
Iowa			X
Kansas	X		
Kentucky		X	
Louisiana	X		
Maine			X
Maryland	X		
Massachusetts			X
Michigan			X
Minnesota	X		
Mississippi			X
Missouri			X
Montana	X		
Nebraska	X		
Nevada	X		
New Hampshire			X
New Jersey	X		
New Mexico	X		
New York			X
North Carolina			X
North Dakota	X		
Ohio	X		
Oklahoma	X		
Oregon	X		
Pennsylvania	X		
Rhode Island			X
South Carolina			X
South Dakota	X		
Tennessee			X
Texas	X		
Utah	X		
Vermont			X
Virginia			X
Washington	X		
West Virginia			X
Wisconsin	X		
Wyoming	X		

Appendix Table 2: List of High and Low Value Imaging

Example	**Prevalence**
High value imaging	
MRI with trauma diagnosis	0.04%
CT with trauma diagnosis	0.46%
Low value imaging	
Back imaging for patients with non-specific low back pain	2.2%
CT of the sinuses for uncomplicated acute rhinosinusitis	0.2%
Head imaging in the evaluation of syncope	0.5%
Head imaging in the evaluation of headache	1.5%
Carotid imaging with syncope diagnosis	0.4%
Screening for carotid artery disease in asymptomatic adults	2.5%
Imaging for diagnosis of plantar fasciitis	0.2%

Source: Colla et al. (2014); Schwartz et al. (2014)