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Variations in Cost for Magnetic Resonance Imaging Scans Based on Certificate of Need Regulations

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By

Andrew M. Hall

A doctoral project submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree Doctor of Health Administration in the College of Health Professions

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To help control rising healthcare costs, states implemented certificate of need

(CON) programs to prevent unnecessary duplication of healthcare resources. Today, 37

states and the District of Colombia have some form of CON. The scope of CON

oversight varies between states, but most states have some type of regulation for MRI

scanners, whether it be a direct requirement applicable to all MRI scanner projects or an

indirect requirement that may only impact some MRI scanner projects. The study

analyzed retrospective commercial billing data for over 275,000 encounters to quantify

differences in costs for MRI scans in each state according to the type of CON

requirements for MRI scanners. When the data were aggregated only by type of CON

requirement, directly regulated states had the lowest mean payment amounts (p-value <

0.0001) followed by indirectly regulated states (p-value < 0.0001) with unregulated states having the highest mean payment amounts. When only state mean payment amounts were considered, the variance was not significant. Based on these results, CON programs may result in lower costs on a per-unit basis.

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INTRODUCTION

Background

Healthcare costs have been growing in the United States for decades. Healthcare spending has increased from 5% of gross GDP in 1960 to almost 17% in 2012 with even more growth in spending projected from provisions related to the Affordable Care Act (ACA) (Chen, Liang, & Lin, 2016). Even though the future of the ACA is unknown due to the current political climate, healthcare costs are still a prominent issue for both federal and state governments. One method that state governments have employed to control healthcare costs are Certificate of Need (CON) laws.

CON regulations have been in existence since the 1970s. These regulations stemmed primarily from a federal law passed in 1974. The National Health Planning and Resources Development Act of 1974 (NHPRDA) provided the framework for states to establish oversight of healthcare resources and distribution. One area of oversight specified in the act was a requirement that duplicative health services be prohibited. The most common way states complied with this provision was through implementation of CON statutes. CON laws regulate the manner in which healthcare providers can offer or expand services by requiring providers to seek governmental approval prior to putting new services (as defined in statute) or pieces of equipment governed by CON regulations into use. NHPRDA was eventually repealed, but this action did not directly impact state laws. The repeal of NHPRDA allowed states to remove CON regulations, but not all did.

Currently, 37 states along with the District of Columbia, the U.S. Virgin Islands, and Puerto Rico have some form of CON or similar law (Cauchi & Noble, 2016). The scope of these statutes vary by state with some only governing hospital projects and others regulating a wide variety of medical practices and services. This wide range of legislation across the states leads to differing requirements for MRI scanners. Some states have specific language regarding MRI equipment while others have spending thresholds that may or may not apply to MRI projects depending on the capital cost. These typically encompass either major medical equipment provisions (a requirement to gain CON approval for pieces of equipment that exceed a threshold) or overall spending caps. As such, there is no consistency between states for MRI scanners and CON programs.

In some states where there are CON regulations pertaining specifically to MRI, there are additional requirements that must be met in order to apply for permission to acquire the piece of equipment. In North Carolina, for example, the North Carolina State Health Coordinating Council (SHCC), a gubernatorial advisory body, must include a need determination for an MRI scanner in the annual North Carolina State Medical Facilities Plan (SMFP) in order for there to be any CON reviews possible for MRI scanners. There is a mathematical formula in the SMFP to determine need based on historical utilization and projected population growth. Moreover, there is an additional annual comment period for potential applicants to request the inclusion or removal of a need determination if any person believes the mathematical formula did not take extenuating circumstances into account. These additional requirements exist to ensure the main purposes of CON are protected for the largest expenditures.

One main tenet of CON programs is to control healthcare costs; however, few studies examine CON's impact on cost. This study will provide information on the efficacy of CON regulations pertaining to MRI scans in controlling costs. Most studies focusing on the impact of CON relate to inpatient services or other pieces of equipment that are primarily used in the hospital setting. MRI scanners are located in both hospitals as well as freestanding imaging centers and physician offices, leading to a different setting of care than previous studies explored. Prior studies around MRI scanners and cost have shown variation in cost based on geographic location, but these studies did not take the presence of CON regulations into account (Pasalic, Lingineni, Cloft, & Kallmes, 2015).

Problem Statement

This research aims to verify whether CON regulations achieve the stated goal of containing costs. The purpose of this study is to determine whether or not CON regulations cause variation in cost for MRI scans, one of the imaging modalities that is commonly governed by CON programs. If there is a variation based on CON legislation, the study will further attempt to quantify the directionality of the difference, e.g. whether the costs are higher or lower in CON regulated states compared to those without CON regulations.

Research Questions and Research Hypotheses

The study will aim to answer two basic questions regarding the relationship between CON regulation and the costs of MRI scans. First, is there variation in cost for MRI scans in states where MRI scanners are explicitly regulated compared to CON regulated states that do not have specific MRI statutes compared to non-CON regulated

states? Second, if there is a difference, are costs higher or lower in MRI regulated CON states compared to non-CON states and non-MRI specific CON states?

The null hypothesis for both research questions is that the costs for MRI scans are the same across all three defined groups or H_0: $Cost_{Direct} = Cost_{Indirect} = Cost_{None}$ where $Cost_{Direct}$ represents cost for the states where MRI is specifically regulated by CON programs, $Cost_{Indirect}$ is the cost in states where CON regulations do not directly govern MRI projects, but rather have overarching requirements that MRI projects may fall into; and $Cost_{None}$ is the cost for states where MRI is not directly or indirectly addressed by CON programs, and states that do not have CON statutes. The alternative hypothesis is H_1: $Cost_{Direct} \neq Cost_{Indirect} \neq Cost_{None}$. The second research question can only be addressed if the null hypothesis for the first question is disproven. If there is a difference, the null hypothesis for the second question will be that costs in states with directly applicable CON requirements will be higher than those states with indirectly applicable requirements and both of those will be higher than the costs in states without any CON restrictions on MRI projects. Stated numerically, this would be H_0: $Cost_{Direct} > Cost_{Indirect} > Cost_{None}$. There are multiple alternative hypotheses to disprove the null hypothesis.

Population

The population for this study includes any adult who received an MRI scan in the United States during 2016 with some exceptions. Pediatric patients are being excluded from this study for a variety of factors, including the increased utilization of sedation during MRI procedures which is not consistent with clinical practice patterns for adults. Additionally, the claim must have a cost greater than $0.00 to rule out coding error that could be attributable to human error. The claim must also have valid entries for all the

necessary variables to properly group the claim including an MRI procedure code and state.

Assumptions

The study assumes that the administrative billing data are an accurate representation of the actual procedures performed. Billing data, or claims data, are secondary data sources. These secondary data are administrative data and are not designed for research use. Because administrative data are not collected explicitly for research purposes, there may be a lack of standardization in the application of coding procedures (Shi, 2008). For this study, we will assume that all data in the dataset are valid and coded in a standard manor. This means that we assume that all procedures performed are recorded and included in the dataset and that each coded procedure is the same as the actual procedure performed.

LITERATURE REVIEW

Methods

Peer-reviewed journal articles were sourced from Ovid/MEDLINE as accessed through the Medical University of South Carolina (MUSC) Library. In the event an article sourced through Ovid/MEDLINE was not available through the MUSC Library holdings, the Greensboro Area Health Education Center (GAHEC) Library provided a full text copy of the article of interest. Search terms in Ovid/MEDLINE included "Certificate of Need," "Cost," "Radiology and Cost," and "MRI and Cost." Results were limited to articles written in English and those pertaining to the United States. Since CON is governed by legal statutes, a search of law reviews was conducted through the American Bar Association's Legal Technical Resource Center. "Certificate of Need" was used as the search term in this query.

Certificate of Need

Development and Evolution. Once CON regulations came into effect, legal scholars began analyzing their impact. During the 1960's and 1970's, healthcare spending increased exponentially and CON was a mechanism by which states hoped to control expenditures. An early analysis of spending in states where CON existed prior to passage of NHPRDA found healthcare spending was still accelerating at a higher rate than the general inflation rate, bringing the efficacy of CON into question even before its promulgation nationally. Each state also set its own standards, leading to vast differences

in CON decisions and even the necessity to obtain a CON for a project. The makeup of the statewide body overseeing CON also varies and the involvement of multiple agencies in the review process can lead to *pro forma* approval due to the lack of clarity over ultimate authority (Schonbrun, 1979). Despite these variations, there were commonalities between most of the laws. For example, every state except Oklahoma required a CON for construction of a new hospital. States also typically require that an application for a CON be submitted on a form devised by the body by which the application will be reviewed. Most states initially allowed the review to be completed by a local planning agency, but most states have now returned control to a statewide department (Haighurst, 1973), (Cauchi & Noble, 2016). The intent for these local agencies, called Health System Agencies (HSAs) as defined in P.L. 93-641, was to allow community and local government input before granting initial approval of the application and forwarding the application to the statewide agency. These HSAs were required under NHPRDA with approval from the state's governor and could be an existing body, such as a local government agency, or a new corporation formed for the express purpose of reviewing local CON applications (Roos, 1987). Some states sought to decrease the amount of time it took to review applications and implemented policies allowing simultaneous review by both the HSA and state agency (Schonbrun, 1979).

Proponents of CON programs point to increased planning the CON process required before initiating a project as a way to ensure hospitals and other healthcare providers completed sufficient studies and projections (Schonbrun, 1979). Proponents also point to regulations on other non-hospital industries, like utility companies, that are overseen by government bodies as examples of oversight into private business

expenditures and activities. This type of regulation already existed in the healthcare industry with health insurance companies having to submit rate increases to insurance departments (Haighurst, 1973).

Opponents of CON point to a variety of problems. First, when programs were initially developed, there was no transparency into the process. Broad statewide statutes governed the process; however, the application of statutory authority wasn't always carried out equally even within the same state by the local planning agencies (Haighurst, 1973). Second, when programs came into existence, projects in progress were exempt from applying for a CON. These limited time exemptions led some hospitals to move forward with projects ahead of schedule as to avoid the necessity of obtaining a CON (Schonbrun, 1979).

In 1986, Congress repealed the federal requirement for statewide planning and CON programs under NHPRDA. States were then able to make changes to their CON requirements or end them completely. By the time of repeal, researchers found multiple examples of healthcare providers legally circumventing the law. Roos (1987) lists various entities across the country avoiding CON review by using shell corporations to share costs, working with exempt entities (including physician groups), and splitting the project into multiple, smaller components. The denial rate for projects was also low, around ten percent, potentially confirming Schonbrun's conclusion about decision rights not being clearly assigned to one specific agency.

Even though the federal requirement for CON programs was repealed, the federal government still provides input on the need for statewide planning and healthcare regulation. In 2016, the Department of Justice (DOJ) and the Federal Trade Commission

(FTC) issued a letter to South Carolina Governor Nikki Haley regarding the South Carolina CON program. Governor Haley attempted to end South Carolina's CON program by vetoing the funding from the state budget, but the South Carolina Supreme Court ruled she did not have authority to end a program based in statute (Sausser, 2013), (Burris, 2014). Despite the ruling, Governor Haley still sought to end the program and asked for input from the federal government on a bill in the South Carolina General Assembly that would repeal the CON statutes. In the letter, the DOJ and FTC recommend that South Carolina either narrow or repeal its CON laws to enhance competition. The agencies posit CON programs restrict new entrants to the market that may offer more cost effective options or provide pressure to lower prices simply by adding another competitor (Lao & Potter, 2016).

The FTC independently issued a similar opinion to a North Carolina legislator on a bill that would have removed certain institutional health services from the purview of CON regulations in 2015. The FTC supported HB 200, a bill to exempt operating rooms, psychiatric beds, and certain radiology facilities from the CON program. In its letter, the FTC stated that its purpose in supporting the proposed legislation is to increase competition and remover barriers from access to care. The FTC also opposed CON regulations on the basis that they bolster the market share of existing facilities unfairly and protect them from competition from additional entrants in the market (Lao, Lafontaine, & Feinstein, 2015). Ultimately, as discussed later, the bill did not pass and those services remain a part of North Carolina's CON program.

More recently, the United States Secretaries of Health and Human Services, Treasury, and Labor released a report focused on competition in healthcare in response to

an Executive Order. This report built on the previously expressed views of the FTC and DOJ to reach similar conclusions, primarily around antitrust issues surrounding hospital mergers (Azar, Mnuchin, & Acosta, 2018). One of the recommendations of this report is that CON programs end the ability of opponents of a CON application to comment on pending applications. This would, in theory, aim to award more certificates by curtailing any negative discussion of the project. The Secretaries also recommend states end their CON programs, though that decision ultimately lies with the states.

Impact. Many studies assess the impact of CON regulations on a variety of different services, but most focus on those services delivered in an acute care hospital setting. In 1998, Conover and Sloan investigated whether the repeal of CON regulations led to increased spending. Their findings indicated that the presence of CON laws did limit hospital spending, but that CON programs resulted in higher costs per inpatient day. There was no impact on cost to the patient or on total healthcare spending. Their conclusion was when CON laws were repealed, some services shifted from hospital to other ambulatory settings. These shifts resulted in higher costs for hospital days as fixed costs were spread over fewer discharges, but there was no reduction in per capita cost as there was simply a shift in site of service. The authors noted that proportion of inpatient beds in the for-profit hospital sector relative to the overall supply of inpatient increased after CON laws were repealed, which may also account for the overall increase in hospital charges for acute care services.

In New York, literature shows there has been a steady outmigration of services from the hospital with the notable exception of MRI services (Berliner, 2008). Berliner attributes this shift to a variety of factors, including the advancement of medical

technology, efforts to keep patients out of the hospital, and growing employment of physicians by hospitals and health systems. Hospital employment of physicians allows physicians to access the financial resources of the hospital to equip their practices and facilities. Berliner hypothesizes the main reasons MRI services have not followed this outmigration pattern are twofold. First, New York initially limited the number of MRI scanners available across the state mainly to hospitals. Second, physicians could not bill for a facility fee – or additional reimbursement paid to hospitals to offset increased overhead – if they owned MRI scanners within their own offices. This decreased reimbursement made it much less financially viable for a private physician practice to purchase an MRI scanner.

Emergency departments are another example of a service that is regulated by CON programs in some states. Opponents of CON regulation of emergency departments argue the restriction on expansion of emergency services artificially constricts the supply of emergency department beds and can lead to longer stays as there are fewer beds to treat less acute patients while more critical patients hold for admission or surgery. Studies indicate that states with CON regulations for emergency departments have a shorter length of stay in the emergency department compared to states that do not regulate such services; however, the literature does not rule out the possibility that some other factor could be at play beyond the presence or absence of CON programs (Paul, Ni, & Bagchi, 2014).

Conclusions relative to the impact of CON on surgical services are mixed at best. Studies examine the extent to which CON laws effect surgical training programs. The authors found that states with CON regulations tend to keep more procedures at academic

medical centers, thereby improving the ability of surgical residents to learn new procedures (Fric-Shamji & Shamji, 2010). Other studies have found that CON regulations are not particularly effective at containing emerging surgical techniques. In examining linkages between CON regulations and the adoption of robotic equipment for use in urological surgery, researchers found there was not a relationship between CON regulation and purchases of robotic equipment. The researchers hypothesized various reasons why such a relationship might not exist, including the desire from the state agencies to have cutting edge equipment available to their citizens and the relatively minimal financial barrier posed by a CON application compared to the capital cost of the robotic equipment itself (Jacobs et al., 2013).

Studies also investigate the impact to a specific area within the hospital: neonatology units. While there has been research on the impact CON programs have on hospital services overall, there is not much literature pertaining to pediatric or neonatal services. In total, 30 states have CON laws regarding the provision of neonatology services. In those states, there are fewer neonatal units with the most advanced capabilities when compared to states without CON programs. This aligns with other findings of CON programs leading to fewer acute care beds; however, the supply of neonatal beds is lower on average than the number of adult beds. This leads the authors to the conclude CON programs are more restrictive on neonatal services than on general hospital services (Lorch, Maheshwari, & Even-Shoshan, 2012).

Certificate of need laws also regulate services outside of the hospital. A number of states' CON regulations apply to nursing home beds and home health agencies, two forms of post-acute care. Demand for skilled nursing care increased exponentially after

the Centers for Medicare and Medicaid Services (CMS) transitioned to a DRG based

payment system as hospitals were financially incentivized to discharge patients as soon as

medically possible. Rahman et al. (2016) found that the presence of CON laws kept

Medicare spending higher for nursing homes than home health agencies compared to

states where there were no CON regulations. In non-CON states, home health spending

grew more rapidly than nursing home spend.

CON Repeal and Reform Efforts

  Federal. To help combat the perceived weaknesses of the CON system, numerous

proposals for reform on a national scale arose. First, President Carter suggested that there

should be capital spending caps at micro and macro levels. He sought a national cap on

healthcare capital expenditures in total while also limiting individual hospitals from

increasing their costs over a benchmark amount. This would force hospitals to be

rigorous with their cost estimates and add another factor to CON agency decisions. The

agencies would have to weigh the necessity of spending money for the proposed project

in opposition to potential future projects, thereby making CON decisions more rigorous

(Schonbrun, 1979). This proposal ultimately never went into effect.

  States. There have been multiple attempts to amend and/or repeal CON laws in

multiple states in recent years. Bills have been filed for the explicit purpose of ending

CON programs, but have also been attached to other bills as amendments.

  In 2013, the North Carolina General Assembly tried to amend CON laws. House

Bill 177 aimed to remove certain categories of service from the existing CON

regulations. Specifically, House Bill 177 would exempt diagnostic centers (i.e. imaging

centers) and temporarily exempt single-specialty ambulatory surgery centers (ASCs)

from the need determination process. Any entity attempting to license an ASC would not have needed a CON as long as the license application was postmarked prior to December 31, 2013. This exemption would have allowed physicians and other parties interested in establishing ASCs an opportunity to do so without being required to wait for a need determination or compete with other applicants for a determined need. The bill was passed by the House and forwarded to the Senate where it was not considered by the Committee on Rules and Operations of the Senate prior to the end of the session.

In 2015, the South Carolina General Assembly tried to repeal the state's CON program. House Bill 3250 would have, along with other changes to programs under the Department of Health and Environmental Control, repealed the CON statutes as of January 1, 2018. The House passed the bill nearly unanimously with a vote of 103-1; however, the Senate never voted on the final version of the bill that came out of the Senate's Medical Affairs committee (Worthington, 2016). As such, the bill died and was never enacted, but as discussed earlier, South Carolina continued to try different ways to end its CON program with Governor Haley's funding veto.

In 2018, the Florida Legislature attempted to remove hospitals from the purview of its CON program, but would have left other facilities, such as nursing homes, subject to CON requirements. The House Bill, HB 27, passed the House 72-36 and was referred to the Senate (Millsap, 2018). The Florida Senate never placed the identical Senate bill (SB 1492) on the calendar and it died in the Senate in March 2018. These bills passed by at least one chamber of state legislature demonstrate the interest of state governments in CON programs and their continued future in state statutes.

Repeals. While many states have made unsuccessful efforts to pass legislation to repeal CON statutes, some states have passed bills to end their CON programs. New Hampshire passed legislation in 2012 to wind down its CON program by 2016 (Sanders, 2016). Prior to New Hampshire, the last state to completely repeal its CON legislation was Indiana in 1999 (Schencker, 2016); however, in 2018 Indiana reinstituted CON for nursing home beds as a way to end a moratorium on adding incremental beds to its inventory. This plan to end the CON program was germinated by the desire to allow a for-profit cancer hospital to open a new facility in the state. This new hospital could not open under the New Hampshire CON program. New Hampshire's legislation was a model for other states' repeal efforts by including a gradual shut down of the CON program. This time allows existing and potential future providers to prepare for the end of regulation. While the CON program formally ended in 2016, there was a stopgap measure put in place to protect rural hospitals and the expansion of certain technologies (Sanders, 2016). This new requirement does not have the requirement for a CON, but rather permission from the state Department of Health and Human Services.

Cost of Healthcare

General. Healthcare in the United States has traditionally been costly. In the 1960s, consumer spending for healthcare accounted for just 5% of annual GDP in the United States. By 2012, spending increased to 16.9% of GDP due in part to changes in market forces and continued governmental spending on healthcare programs. According to the Organization for Economic Cooperation and Development, the amount of healthcare spending in the United States is nearly twice the average spend of other countries by other developed nations (Chen et al., 2016). This growth substantially

exceeds the growth of other industries in the United States as well as the inflation rate of the dollar.

Early on, CON programs were not effective in controlling the increase in healthcare inflation. After the passage of NHPRDA, healthcare inflation, and hospital expenditures, continued to outpace the general inflation rate (Schonbrun, 1979). In fact, in 1976, healthcare spending was already up to 8.7% of the United States GDP (Roos, 1987). Seemingly the only aspect that CON regulations were able to contain was hospital bed growth which did slow after the passage of NHPRDA (Schonbrun, 1979). The slowed rate of bed growth came as hospitals increased capital expenditures on technology and other facility improvements in lieu of simply adding inpatient bed capacity, so overall hospital spending was not constrained by CON regulations (Salkever & Bice, 1976).

Era of Affordable Care Act. The ACA was passed by the 111th United States Congress and signed into law by President Barack Obama on March 23, 2010. One of the main tenets of the legislation was to decrease costs for patients for both coverage and treatment. One mechanism for this cost containment was the establishment of insurance marketplaces and a mandate that all Americans have some form of insurance coverage or pay a penalty. The authors of the law intended to expand access to insurance for consumers. By doing so, patients should seek more preventative care before conditions escalate to the need for emergency care, thus removing unnecessary cost from the healthcare delivery system.

Initial studies indicate that the ACA is significantly impacting the out of pocket costs for preventive care (Bearak, Finer, Jerman, & Kavanaugh, 2016). The ACA

contains a list of covered benefits that are considered an essential part of healthcare. As

such, insurance companies must cover the cost of these services at no out of pocket cost

to the patient. Studies show access is increasing to some of these services (Bearak et al.,

2016). The use of intrauterine devices (IUD) as a form of contraception was previously a

costly method compared to other forms of birth control, particularly oral contraceptives,

as IUDs require many more visits and a minor procedure to insert and later remove the

device. Prior to the ACA, patients would have been required to share in these costs in the

form of copayments, deductibles, or co-insurance. Those costs have been eliminated

since the implementation of the ACA (Bearak et al., 2016). The study does not address

the overall cost to the system at a macro level; however, the ACA also caps the premiums

that patients must pay for coverage. As such, out of pocket costs have fallen from 11.5%

of healthcare spending in 2011 to 10.5% in 2017 (Martin, Hartman, Washington, &

Catlin, 2019).

Screening colonoscopies are another form of preventive care where ACA

provisions require insurance plans to cover the service at no cost to patients. If, however,

there are additional procedures performed during the same visit or the colonoscopy is not

a screening colonoscopy, then the normal insurance provisions apply. In an effort to

reduce the cost of both covered and non-covered costs for colonoscopies, physicians have

pursued two options: bundled payments and reference pricing.

Bundled payments exist for a variety of procedures, mostly surgical, in an effort

to better coordinate care for patients. In a bundled payment arrangement, the payor will

make one lump sum payment for all of the services associated with the procedure from

pre-procedural to post-procedural. It is, therefore, left to the individual providers

rendering services during the episode of care to ensure that their fees do not exceed what the bundled payment will cover. For colonoscopies, the biggest variability in cost was the anesthesia fee. By authorizing only one payment, the payors eliminate the variability from anesthesia fees from their area of responsibility and pass it along to the rendering physician or facility to manage.

Reference pricing is another technique that payors use to decrease the variation in pricing for procedures. Under reference pricing, the payor places an upper limit on the covered amount for a certain procedure. If the patient opts for a procedure at a higher price than the reference price, the insurance company will not provide any reimbursement for the excess cost, leaving the patient with all of the responsibility for the difference (Lieberman & Allen, 2015). While these studies explicitly referred to colonoscopies for cost control, they can be applied to a wide variety of procedures.

While the insurance exchanges were one example of how health insurance changed as a result of the ACA, employer provided health insurance also changed. Prior to the ACA, most businesses had no requirement to provide health insurance to their employees and were under no obligation to ensure the adequacy of those plans (Blavin, Shartzer, Long, & Holahan, 2015). Now, employers with more than 50 full time equivalent (FTE) employees must provide comprehensive coverage or face fines from the federal government. While most large businesses could comply with this requirement, small businesses were at a disadvantage from the high cost of providing insurance. As a response, the federal government established a small business health insurance marketplace similar to the state run exchanges for individuals. The idea behind this particular exchange was to group small businesses together to achieve better pricing from

insurers due to increased scale. All of these efforts, however, seem to have had no effect on the adoption of employer sponsored coverage (Blavin et al., 2015).

CON and Cost. Once CON programs were in place, policy makers were hesitant to end the programs for fear of unchecked spending in two fronts: initial capital investment and increased charges to generate a return on investment for those capital purchases. First, there was concern that hospitals and other providers would purchase new equipment that would have been regulated and that they would begin construction projects to house new services that they were previously prevented from offering under CON regulations. These pent-up projects would require a tremendous amount of capital that organizations would expect a substantial return on in order to fund further capital purchases. One way to ensure return would be to raise prices on those new services. This would have the effect of driving up healthcare spending as a result of the unchecked capital spending (Conover & Sloan, 1998).

Conover and Sloan examined these potential problems by looking at states that had previously repealed CON laws and compared spending and costs to those states that still had CON programs in effect. Their findings were mixed. First, they found that there was not a bolus of capital spending in states that repealed their CON programs. This could indicate that CON programs do not have any impact on capital spending. Next, they found states with mature CON programs actually did have statistically significantly lower acute care spending compared to programs without CON laws. However, overall spending was statistically equivalent when ambulatory and other non-hospital costs are added to the calculation. This result indicates that CON programs in a vacuum are not sufficient to control overall spending as there are other components to the healthcare

delivery system not in the purview of CON regulations. These programs, though, do have some impact on cost for hospital services that are regulated. Of note, though not statistically significant, the study did indicate that when states repealed their CON regulations, both hospital beds and hospital expenditures did increase. These increases simply were not sufficient to be statistically different from CON states.

Further studies have confirmed some of Conover and Sloan's conclusions. Additional work looked at acute care beds and hospital spending in CON compared to non-CON states. Researchers found that CON programs had a measureable impact on reducing the number of hospital beds, but not containing expenditures. Overall, CON states had 10% fewer beds per 100,000 residents when compared to states without CON regulations (Hellinger, 2009). While this was a statistically significant difference, the overall spending was not statistically different (though it was lower in states with CON laws). These findings validate Conover and Sloan's earlier work around CON programs constraining hospital services, but not overall costs.

While not directly related to cost, studies have also evaluated the impact of CON on hospital efficiencies (Ferrier, Leleu, & Valdmanis, 2009), (Rosko & Mutter, 2014). Efficiency was calculated on a state-by-state basis to eliminate any differences that could arise from other state regulations. The research shows that states with CON programs have more efficiency due to more concentrated levels of knowledge in hospitals (Ferrier et al., 2009). The research also shows that states without CON programs have more efficiency due to size of hospitals. Both of these findings corroborate previous findings around CON regulations constraining hospital bed growth. In CON states with fewer beds, there are fewer opportunities for physicians, nurses, and other workers to seek

employment and use their skills. As such, they are more highly concentrated. On the other hand, hospitals with fewer beds have less negotiating power with suppliers and payors, leading to less efficient operations due to scale (Ferrier et al., 2009). The efficiencies experienced by hospitals in CON states outweighed the efficiencies in those states without CON programs, leading to the conclusion that some form of regulation on hospitals and healthcare systems does have a positive impact on efficiency, and as a proxy, costs (Ferrier et al., 2009). Further research into this topic using more recent data yielded similar results (Rosko & Mutter, 2014). This additional study demonstrates a positive correlation between CON programs and cost efficiency. Beyond the overall efficiency, hospitals in CON states had higher occupancy rates and a lower cost when adjusted for acuity. This did, however, result in smaller operating margins for hospitals in states with CON programs (Rosko & Mutter, 2014). This latest study provides key insights into the impact of CON regulations on hospital costs.

Radiology Costs. Hospitals and other providers in the United States first purchased MRI scanners in the 1980s. The initial adaptation of MRI technology in hospitals was slower when compared to CT scanners due to the high capital cost of the technology and the lack of clear diagnostic advantage of an MRI when compared to CT. As such, the majority of early MRI scanners were either mobile units serving multiple locations or fixed units located in freestanding, for-profit imaging centers (Bell, 1996). The proliferation and adaptation of MRI technology continued with more advanced technology now available. Today, hospitals use MRI scans at a higher rate than in the past with MRI volumes growing almost 20% over a five year period (Agarwal et al.,

2010). This growth demonstrates a substantial increase in utilization of MRI scanners and the need to better understand the costs associated with the technology.

The cost for radiology procedures varies across the setting for care. Inpatient imaging studies are typically not separately reimbursed as most payors provide a bundled payment to the hospital for all services during an inpatient stay based on the patient's diagnosis related group (DRG) at discharge. Outpatient imaging procedures, however, are paid on a fee-for-service basis and imaging centers and other radiology providers are free to determine their own charges. Due to this freedom in price setting, there is wide variation in charges and payments for the same service across the country. Studies have shown that not only to prices for knee MRIs differ in various regions across the country, but there are also some areas with wide differentials in price within localities (Pasalic et al., 2015). Pasalic and his colleagues found that quoted prices for a knee MRI ranged from $250 to $2,042 and that within localities there were variations in price from $0 (one area had no variation between all sites) and $1,592 for the exact same procedure. However, there was no variation in average price based on the region of the country in which the imaging center was located. These results indicate that there is no control on cost for radiological procedures and providers set their prices at whatever level they determine to be fair, but that there is some consistency for pricing across the country (Pasalic et al., 2015).

Non-academic publications also anecdotally support the conclusion of wide ranging costs for MRI scans. Articles published in *Forbes*, *Money*, *USA Today*, and *The Washington Post* all back the conclusions of Pasalic anecdotally. Price ranges quoted in these articles were as high as $13,000 (Glover, 2014) and commonly indicate that

hospitals have higher prices (O'Donnell & Rudavsky, 2017), (Ashford, 2014). These articles rely on a modicum of research, but are much more readily accessible to consumers looking to reduce their health care spending than peer reviewed research. Some articles indicate patients may save money simply by forgoing their insurance completely (O'Donnell & Rudavsky, 2017); however, in certain circumstances, that could lead to charges of fraud. CMS's Office of the Inspector General (OIG) issued guidance indicating that failure to collect required copayments or bill CMS for services rendered to Medicare beneficiaries constitutes fraud under the anti-kickback statute or the false claims act, or both (Brown, 1994). Patients and providers need to exercise caution when following the advice given by these news articles as to avoid violations in the pursuit of economic benefit.

The literature suggests mixed results when determining the relative cost of an MRI scan relative to the overall cost of care for the episode of care (Beinfeld & Gazelle, 2005), (Parker et al., 2008), (Kan et al., 2009), (DellaBadia, Bell, Keyes, Mathews, & Glazier, 2002), (Baker, 2010). Evidence suggests that increased usage of imaging can reduce overall cost by reducing length of stay (Beinfeld & Gazelle, 2005). In looking at a variety of relationships via a multivariate regression for inpatients, researchers found the largest driver of increased hospital cost was additional time spent in intensive care units. Each day in an intensive care unit averaged a cost of over $4000. By spending less than 10% of that cost on additional imaging, the model indicated the ability to reduce length of stay by one day (Beinfeld & Gazelle, 2005). In this instance, MRI scans can be used to avoid more costly inpatient stays.

Some studies predict MRI utilization may be reduced as a diagnostic tool in favor of other, less costly modalities (Parker et al., 2008). Ultrasound is one possible alternative to MRI scans. A panel of three radiologists retrospectively analyzed de-identified patient records to determine whether the patient could have been diagnosed more accurately with MRI, more accurately diagnosed with ultrasound, or diagnosed equally as well with either modality. The findings demonstrate a substantial cost-saving potential to CMS with just under one-half of all cases examined having ultrasound deemed as accurate or more accurate than MRI in diagnosing the injury. Over a fourteen-year period, these savings could amount to nearly $7 billion in cost avoidance. However, in injuries occurring most frequently in the data set (meniscus disorder [n=592], rotator cuff disorder [n=551], arthritis [n=291], and fracture [n=233]), there is a limited or no ability to substitute MRI for ultrasound (Parker et al., 2008). As such, the savings may be limited to less common injuries and not represent an overall opportunity to reduce cost.

A study in pediatric patients also found opportunities to lower the overall cost of care by increasing utilization of MRI scans (Kan et al., 2009). Pediatric patients presenting to the emergency department with signs and symptoms of a broken bone typically receive a diagnostic x-ray to determine if the bone is actually broken. In some cases, the x-ray is not sensitive enough to detect the fracture. In these cases, the patient would need to return and have additional testing and treatment at an increased cost. Researches devised a clinical pathway to incorporate MRI scans into the treatment of these patients. The results of the increased use of MRI for these patients allowed patients to receive more appropriate treatment initially and did not increase overall costs because of the reduction of costs for follow-up care (Kan et al., 2009).

MRI may also be used in lieu of even more expensive imaging modalities or other diagnostic modalities (DellaBadia et al., 2002). For patients with diagnosed epilepsy that may benefit from surgery, neurologists use a variety of diagnostic tests available to determine how well patients could benefit from surgery. Patients may undergo continuous EEG monitoring, WADA tests (a form of EEG where a hemisphere of the brain is chemically blocked to determine which hemisphere of the brain controls vital functions), MRI scans, PET scans, or a combination of any or all of the aforementioned exams. The combination of these tests is expensive for the patient, so researchers examined if a simpler battery of tests could provide the same accuracy at a reduced cost to the patient and the healthcare system. The study examined EEG, MRI, and PET scans as the options for determining surgical viability and found that EEG and MRI combined provided the best value for accuracy in predicting surgical viability (DellaBadia et al., 2002). In this instance, although MRI is a more expensive study than an EEG, it was used as a cost deterrent compared to other, more expensive tests, such as PET scans.

In contrast, other research draws opposing conclusions by demonstrating an increase in overall cost of care for MRI utilization. The study focuses on MRI scans performed on machines owned by orthopedic surgeons. In a time-based study, Baker found that physicians who owned MRI machines ordered scans at a rate 38% higher than those who did not. The increased scan rate led to higher spending over the entire episode of care (Baker, 2010). The data indicate that the increase in spending is not attributable to any changes in the demographics of orthopedic surgery patients or factors that orthopedic surgeons face by owning MRI scanners as opposed to any other physician or facility. Moreover, the clinical findings for physician-owned MRI scanners are more negative

when compared to scans performed on other machines (Amrhein et al., 2013). The authors speculate that physicians may have less stringent criteria for ordering MRI scans when the scan would take place on their owned MRI scanner.

Use of Claims Data in Research

Large data sources from public and private sources is crucial for health services research. The MarketScan database has been previously used by researchers for radiology research due to the comprehensive nature of the data (Nazarian et al., 2016). The dataset contains de-identified data at the individual claim level with information including the patient demographics, diagnosis and procedure codes, costs and payments made by the payors and patients, and dates of service. The commercial MarketScan database contains data from third-party payors that are both provided by employers and those plans purchased privately by beneficiaries (Breslin, Banerjee, Gust, & Birkmeyer, 2013). These claims cover both hospital and non-hospital encounters that cover any imaging location and the professional fee from a radiologist or other physician that performs the interpretation of the MRI if it was charged separately from a technical fee.

One of the largest drawbacks of a third-party database is the potential for error to enter into the data. Since there are multiple data sources flowing into MarketScan and different plans require different information for payment processing, the data may not be standardized. Given the lack of an alternative and the previously demonstrated reliability of the dataset in research at large and specifically for MRI, the benefits of using MarketScan data outweigh any potential downside.

METHODS

This study aims to determine if there is a linkage between CON regulations on MRI scanners and cost healthcare at both a micro and macro level, by examining the cost per MRI scan and the overall cost for MRI services.

Study Design

The study used a retrospective archival data analysis based on outpatient claims data from the United States. The data for this study are from Truven Health Analytics' MarketScan commercial research database. Truven Health Analytics, now under the umbrella of IBM's Watson division, provides de-identified patient level detailed records for commercial payors, Medicare Advantage, and Medicaid patients that include all administrative detail including payments made. The commercial dataset was chosen over other publically available data, such as Medicare or Medicaid data from CMS, due to the nature of healthcare reimbursement. Since CMS reimburses providers on a fee schedule, there is no significant variation in reimbursement amounts to providers for the same procedure. For commercial payors, providers have the ability to negotiate rates and set chargemaster prices to influence the amount of reimbursement received. The use of the commercial dataset will ensure that this variation is accounted for in the analysis.

The hypotheses derived from the research questions will be evaluated by looking at the descriptive statistics through a means analysis and then performing a multivariate analysis. This method will remove the variation for variables that do not impact the

dependent variable (cost) while allowing the study to directly control for two variables that do impact cost: procedure type and state. Due to the unequal distribution of the populations, the data will necessarily be transformed as part of the regression calculations. These procedures will be run twice: first by aggregating the data only by type of CON requirement for MRI scanners and then by grouping the data by state first and treating each state with equal weight.

The analyses will be performed by using SAS and tables and graphs will be compiled in Microsoft Excel. A p-value of <0.05 will demonstrate statistical significance for this study.

Hypotheses

There are two research questions from one hypothesis for this study: one question focusing on micro costs and one focusing on macro costs. The first research question aims to analyze micro-level costs for MRI scans. This null hypothesis is that there is not a difference in per scan cost for MRI scans in states with CON regulations dealing directly with MRI scanners, in states with CON regulations that do not directly address MRI scanners, and states without CON regulations for MRI scanners and those states without CON statutes. The second research question looks at the macro level costs for MRI and can only be answered if the null hypothesis is disproven. The second hypothesis is that if the null hypothesis is disproven and there is a difference in cost between the three groups, overall spending will be higher in states without CON restrictions on MRI scanners. This hypothesis would support previous studies that found higher spending for patients seeing providers who owned MRI scanners (Baker, 2010).

Population and Sample

The population for this study includes all patients contained within the Truven

Health Analytics' MarketScan database who had an MRI scan in 2016. The population

will then be narrowed down to those patients who receive an MRI for an upper extremity

joint, either a shoulder, elbow, or a wrist based on the CPT procedure codes as shown in

Table 1. These scans were chosen for two main reasons. First, these are scans that are

commonly performed on a routine basis and should have sufficient volume from which to

draw conclusions. Second, these scans are performed in all care settings, thereby

eliminating variation in cost due to site of care. This second reason also ruled out the use

of lower joint scans as injuries to lower limbs have a higher rate of visits to higher acuity

of settings due to these injuries impacting the ability to bear weight.

Table 1. List of CPT Codes Used to Identify Upper Extremity Joint MRI Scans

CPT Code	CPT Description
73221	Magnetic resonance imaging, upper extremity joint without contrast material
73222	Magnetic resonance imaging, upper extremity joint with contrast material
73223	Magnetic resonance imaging, upper extremity joint without and with contrast material

The remaining claims will then be separated into three categories based on the

state in which the scan was performed to evaluate the impact of any CON regulations on

the cost of the scan. A list of states and the categories is shown in Table 2 and the

applicable statutes and regulations used to classify the states are listed in the appendix.

Table 2. States by Type of CON Program

Category 1: States with directly applicable MRI CON Statutes	Category 2: States with indirectly applicable CON statutes to MRI projects	Category 3: States without CON programs and states without CON requirements for MRI projects
Connecticut, Hawai'i, Kentucky, Massachusetts, Michigan, Missouri, North Carolina, Rhode Island, Tennessee, Vermont, Virginia, West Virginia	Alabama, Alaska, Delaware, District of Columbia, Georgia, Illinois, Iowa, Maine, Maryland, Mississippi, Montana, New York, South Carolina	Arizona, Arkansas, California, Colorado, Florida, Idaho, Indiana, Kansas, Louisiana, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Utah, Washington, Wisconsin, Wyoming

Variables

The variables described below allow for variations due to patient characteristics to be controlled. The independent variable will be state as a proxy for presence of CON regulations for MRI services with 0 representing states that explicitly address MRI scanners in the CON statutes, 1 representing states that have CON programs that could potentially impact MRI projects, and 2 for states where the CON program does not govern MRI at all and those states without CON programs. The categorization of states into these three groups is contained in Table 2. The control variables will be use of contrast dye, bill type, provider network status, insurance plan type, urban or rural location, and facility type. By controlling for these variables in the methodology, any variation should be due to differences in CON regulations and not due to any other external factor. Additionally, the cost of the scan as reported in the MarketScan database will be adjusted according to the Bureau of Economic Analysis Regional Price Parities (2016) by state to eliminate any differences due to cost of living or cost of labor in different areas of the country (Sen & Scavette, 2017). These data are limited to non-rent

services to eliminate any variation in pricing due to housing costs or the cost of goods. These data will be merged into the patient level record based on the state of residence.

Exclusion Criteria

Records where the net payment for the MRI is less than $0.01 will be excluded to eliminate any claims where cost data are not available or not valid or where the patient was eligible for charity care. Additionally, any patients under age 18 will be excluded due to the increased use of sedation during pediatric imaging procedures (Mason et al., 2008). This additional cost for pediatric patients could bias the data in whichever state has more pediatric scans.

Limitations

The largest limitation in the study is the use of administrative data. The Truven Health Analytics' MarketScan database relies on secondary administrative data, which have been coded based on the primary information. The nature of the data introduce chances for error based on coding at either the site where the study was ordered, the site where the study was performed, or the site where the payment was made. Additionally, the main purpose of the codes analyzed in this study is billing. Since these codes are not primarily designed for research purposes, they may not have the accuracy necessary for researchers. By limiting the codeset to the specific CPT codes for certain MRI scans, there is a chance that scans that imaged a larger portion of the body, including the shoulder, may be excluded even if those scans were used to diagnose a musculoskeletal injury. However, those scans most likely were ordered for injuries beyond a shoulder injury and wouldn't be comparable to the scans analyzed in this study.

RESULTS

Overview

The MarketScan dataset contained a total of 275,023 records that met the criteria described in Chapter 3 to be included in the analysis. Data use agreements prohibit the disclosure of data identified by state; however, Figure 1 displays the mean payment value between states with the states being deidentified, Table 3 contains the number of records by state while Figure 2 shows the mean payment amounts for each state according to the CON category. The number of records in the dataset ranges from a minimum of 28 in Hawai'i to a maximum of 22,428 in Texas. The mean payment values by state range from a minimum of $323 in the state with the lowest mean payment to $1,636 in the state with the highest mean payment value.
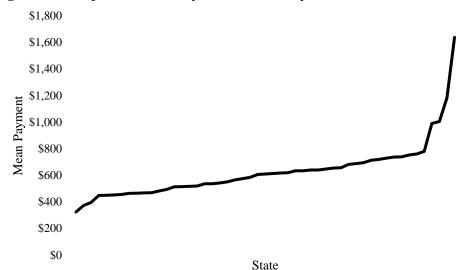
Figure 1. Unadjusted Mean Payment Amount by State

Table 3. Number of Records by State

State Name	Number of Records	State Name	Number of Records
Alabama	4,996	Montana	318
Alaska	293	Nebraska	888
Arizona	3,983	Nevada	1,700
Arkansas	1,896	New Hampshire	882
California	15,108	New Jersey	6,366
Colorado	4,089	New Mexico	616
Connecticut	2,309	New York	21,497
Delaware	1,478	North Carolina	7,437
District of Columbia	142	North Dakota	148
Florida	16,206	Ohio	14,041
Georgia	11,123	Oklahoma	4,763
Hawaii	28	Oregon	2,607
Idaho	4,753	Pennsylvania	8,328
Illinois	8,244	Rhode Island	523
Indiana	6,287	South Carolina	14,836
Iowa	1,640	South Dakota	325
Kansas	2,308	Tennessee	7,687
Kentucky	7,041	Texas	22,428
Louisiana	14,761	Utah	2,310
Maine	504	Vermont	167
Maryland	2,851	Virginia	5,158
Massachusetts	5,561	Washington	5,375
Michigan	12,343	West Virginia	745
Minnesota	2,315	Wisconsin	4,598
Mississippi	3,293	Wyoming	382
Missouri	7,346		

Figure 2. Unadjusted Mean Payment Amount by State by CON Category

● Direct ■ Indirect ▲ None

Research Question 1

The null hypothesis for the first research question, that there is no variation in cost between directly regulated CON states, indirectly regulated CON states, and unregulated CON states, is potentially disproven by the results.

Means. The initial analysis of taking the mean of payment for the three categories is shown in Table 4.

Table 4. Unadjusted Mean Payment Amount by CON Group

CON Group	N	Mean Payment Amount
Direct	56,345	$529
Indirect	71,215	$542
None	147,463	$635

The mean payment amount for states with directly applicable statutes for MRI scanners is $529, while the mean payment amount for states with indirectly applicable CON statutes for MRI scanners is $567 and the mean payment amount for states without any applicable CON regulations is $605. This initial analysis demonstrates that the means for payments between the three groups are different, but does not provide any

measurement as to the magnitude of the difference and whether or not the difference is significant.

The second means test groups the records by state and then took the mean of the mean payment amount for each state. This aimed to eliminate any variation in the data caused by the varying magnitude in the number of records for each state. As such, there are only 51 records in this analysis, one each for each state and the District of Colombia. The results are summarized in Table 5.

Table 5. Unadjusted Mean Payment Amount by State and CON Group

CON Group	N	Mean Payment Amount
Direct	12	$618
Indirect	13	$646
None	26	$624

The mean payment amount when treating each state equally irrespective of the number of records yields different results than analyzing the records in totality. Directly regulated states now have a mean payment amount of $618 while indirectly regulated states have a mean of $646 and states with no CON regulations for MRI scanners have a mean payment of $624. As with the previous means analysis, no statistical tests were performed to determine whether the differences were significant.

Controlling for Procedure. The first regression analysis controls for the type of procedure, specifically whether the MRI scan was with contrast, without contrast, or was both with and without contrast. The model is not biased based on the distribution of the data (scaled deviance/degree of freedom = 1.12). Using the least squares means test to adjust for the specific procedure, the mean changes compared to the simple means test. The regression provides means of $634 ($p<0.0001$) for directly regulated states, $681 ($p<0.0001$) for indirectly regulated states, and $726 ($p<0.0001$) for unregulated states.

To ensure the values are significantly different, the analysis also uses the 95% confidence intervals for the calculated mean payment amounts. These ranges are shown in Figure 3.
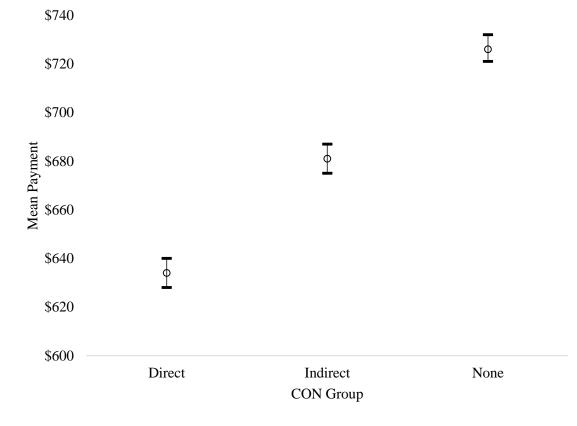
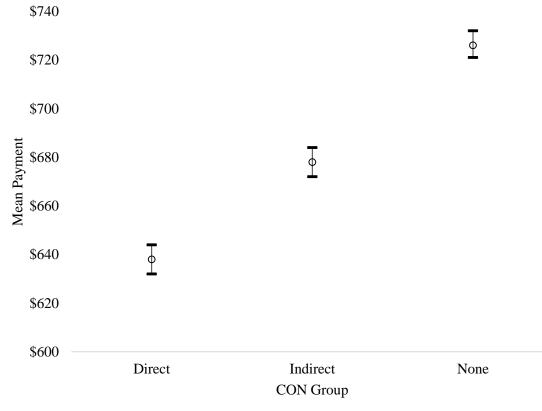**Figure 3.** Mean Payment when Controlling for Procedure (95% CI)

The analysis was run again by using the mean payment amount for each state in lieu of the payment for each individual records. Unlike the first analysis, there was no statistical difference between the three groups with the directly regulated states and unregulated states having p-values of 0.78 and 0.66 when compared to the indirectly regulated states respectively.

Controlling for Procedure and State. The second regression analysis controls for both procedure type and state. This will remove any variation due to the resources needed to perform the particular type of scan as well as the different purchasing power of

each state. As with the previous model, the regression isn't biased due to the gamma distribution (scaled deviance/degree of freedom = 1.12). This model also produces means that are different from the simple means analysis. The mean payment for directly regulated states is $638 (p<0.0001), while the mean payment for indirectly regulated states is $678 (p<0.0001), and the mean payment for unregulated states is $726 (p<0.0001).

Figure 4 contains these calculated mean values with the 95% confidence intervals for each group of states.

Figure 4. Mean Payment when Controlling for Procedure and State Purchasing Power (95% CI)

With the confidence intervals not overlapping for any values in either analysis, the study concludes that the costs for MRI scans in each of the different groups is different with at least 95% confidence.

As shown in Figure 5, there is substantial variation within the three groups. Directly regulated CON states range from the second lowest to the second highest mean payment amount while indirectly regulated states have the highest mean payment amount. Due to this variation, some of the conclusions drawn at the aggregate level may be due to variations within the CON group rather than the effect of CON regulations. A map showing states by quartile is included in the appendix and the variation in payment are shown in Figures 6 through 8 below.

Figure 5. Mean Payment by State Controlling for Procedure and State Purchasing Power
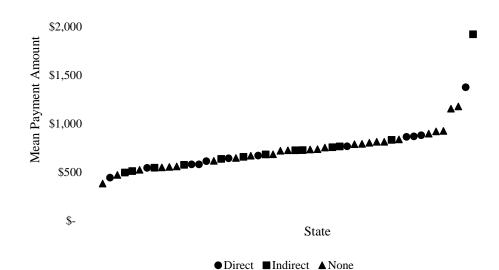
Figure 6. Mean Payment by State for Directly Regulated States Controlling for Procedure and State Purchasing Power
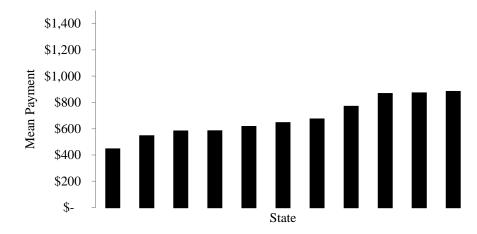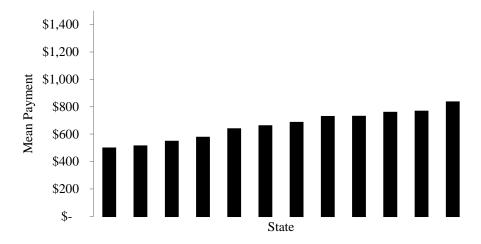

Figure 7. Mean Payment for Indirectly Regulated States Controlling for Procedure and State Purchasing Power (Outlier State Removed)
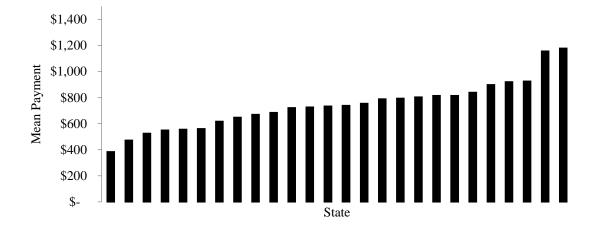
Figure 8. Mean Payment for Unregulated States Controlling for Procedure and State Purchasing Power

Research Question 2

The second research question could only be answered if the null hypothesis was disproven. Since there are differences between the three groups, the second research question can be addressed. The null hypothesis for the second research question, that costs for states with direct CON regulations for MRI scanners will be higher than costs for states with indirect CON regulations for MRI scanners, which in turn will both be higher than states without CON programs or with CON programs which do not impact MRI scanner projects, is potentially disproven.

Table 6 summarizes the findings from the analyses performed to answer the first research question.

Table 6. Summary of Analysis Results

Statistical Test	Direct	Indirect	None
Means in Aggregate	$529	$542	$605
Means by State	$618	$646	$624
Control for Procedure	$634	$681	$726
Control for Procedure by State*	$606	$626	$599
Control for Procedure and State Purchasing Power	$638	$678	$726

*No significant differences

In all of the analyses performed by aggregating all the data, the group of states with explicit requirements to obtain a certificate of need for MRI scanner projects had the lowest cost per procedure. Moreover, those states with indirect requirements also had lower costs than unregulated states, though the costs were higher compared to states with directly applicable requirements. However, when each state is weighted equally, the difference between the three groups is eliminated. As such, the study concludes that there may be variation in cost for an MRI scan based on certificate of need requirements and that those requirements might result in lower costs.

DISCUSSION

Discussion of the Results

Certificate of need programs purport to contain cost for medical services by not allowing unnecessary duplication (Parento, 2017). This study estimated the mean payment amount as a proxy for cost for MRI scans of an upper extremity joints by state. The states were then grouped by their CON requirements surrounding MRI scanner projects: those with directly applicable to MRI scanners, those with indirectly applicable requirements for MRI projects, and those states with CON programs that do not impact MRI scanners and those states without CON statutes.

Three analyses were performed. First, a comparison of the unadjusted means were calculated. The analysis was performed twice: first by analyzing all records in each CON category and then by grouping the data first by state and only analyzing state results. This showed that the costs among all groups were different, but did not include any information about the magnitude or significance of those differences. Next, a multivariate analysis of the data to control for the different procedures was performed. Again, it was performed twice – once based on all data and once based on state level results. Finally, another multivariate was performed to control for both the different procedures and the state in which the patient lived. In all analyses performed on the unaggregated data, the cost for MRI scans in those states with directly applicable statutes for MRI projects was lower than those states with indirectly applicable statutes. Both of the aforementioned

groups were lower than the combined group of states without CON programs and those states with CON programs that do not relate to MRI projects. However, when the data were grouped by state and each state was given equal weight irrespective of the number of records included in the dataset, there was no difference between any of the CON groups.

There are multiple reasons to use this type of analysis in order to determine comparative costs. First, the analysis allows the study to control for variables that may impact cost. The three different procedure types for MRI scans of an upper extremity joint (without contrast, with contrast, and both with and without contrast) require different resources to complete and the combined scan requires two different images. The state in which the scan was performed may also impact the cost of the scan. By controlling for state purchasing power, any differences due to cost of living differences and other economic factors based on state are accurately accounted for.

Second, by grouping states with similar CON requirements together, it eliminates any potential bias based on differences in one individual state that may not otherwise be accounted for in the statistical model. If a given state has other requirements around MRI scanners, such as a licensure moratorium on new MRI scanners that is separate and distinct from certificate of need, that variance would be balanced out by the other states in the grouping. This may also explain why the results are different when states are weighted equally. Variances would be amplified by not allowing the magnitude of the records to factor into the calculations.

Contrary to the findings of the FTC and DOJ (Lao et al., 2015) and others who oppose certificate of need programs, this study has found that costs are lower on a per-

unit basis for MRI scans of upper extremity joints in states with directly applicable CON requirements. There are a multitude of reasons this may be true. First, fixed costs per scan increase when there are more MRI scanners in service (Lexa, Mehta, & Seidmann, 2005). Assuming that the market for MRI scans is not dependent on the number of MRI scanners, each scanner would perform fewer scans per scanner. Due to the decreased volumes, the cost per scan would necessarily increase in order to recoup the necessary fixed costs of owning and maintaining an MRI scanner.

Beyond fixed costs, labor costs also factor into the overall cost for MRI services. If the supply of MRI scanners is not restricted and open to the free market, there would be additional demand for labor to operate the incremental number of scanners. Increased demand for labor can lead to increased staffing costs as MRI technicians can demand higher salaries (Leibenhaut, 2005).

The study also found that even CON programs with indirectly applicable requirements for MRI programs resulted in lower costs on a per-unit basis than states without CON programs and those states with CON requirements that do not apply to MRI scanner projects. Some of the same conclusions that apply to directly regulated states can also apply to these states as unnecessary duplication may be limited. The higher costs when compared to states with directly applicable requirements to obtain a CON for an MRI scanner could be due to the ability to acquire MRI scanners without a CON. By not strictly regulating the supply of MRI scanners, these states may not gain all of the efficiencies of scale when compared to those states which do have explicit CON requirements for MRI scanners.

Limitations

The largest limitation in the study is the varying number of records in each state. When the analyses were run giving equal weight to each state regardless of the number of records, the results were different compared to the analyses run on the dataset as a whole. There could be irregularities in the data in those states with fewer records that are not offset by other records in the state. This could lead to skewed results in the state level analyses.

This study takes advantage of Truven Health Analytics' MarketScan commercial payor database. As this dataset does not contain records for Medicare or Medicaid patients, the conclusions reached in this study may not be applicable to those patient populations. Furthermore, because the dataset does not represent the overall market for MRI scans, no conclusions can be drawn around utilization of MRI scanners in each state nor the overall cost of MRI services based on utilization at a macro level.

As stated previously, these administrative data are used primarily for billing purposes. This leads to potential sources of error if providers do not file claims in a timely manner, do not record the revenue received to the correct account, or do not record the revenue to the correct procedure. The data also do not contain any information regarding potentially applicable charity care policies that may have reduced the payment amount.

Future Research

Future research into this topic could continue on a variety of paths. Studies could continue to evaluate other health care services that are commonly regulated by certificate of need programs, such as hospital inpatient beds, operating rooms, or nursing home

beds. Research could also continue into MRI costs to determine if the conclusions reached by this study hold true for other populations, such as the Medicare enrollees, or if the lower per-unit cost for MRI scans is offset by higher utilization, which may ultimately lead to higher overall costs for care.

Conclusions and Implications

The findings of the study of both direct and indirect CON regulations for MRI scanners present opportunities for legislators to reevaluate the efficacy of certificate of need programs as part of efforts to reform the health care system. As legislators at both a state and federal level attempt to control the continuing rise of health care costs and spending, CON programs may indeed offer some of the benefits initially hoped for when NHPRDA was first passed.

Summary

Health care costs have risen exponentially and now represent nearly 18% of the United States gross domestic product (Martin et al., 2019). Certificate of need programs were initially designed to help contain costs. This study finds that CON regulations result in lower costs per scan even if the requirements are not specific to MRI projects. Policy makers should evaluate the potential cost savings of these programs against the barriers to entry as they weigh the future of these programs.

APPENDIX

Table A1. CON Statutes and Regulations by State Relating to MRI Projects

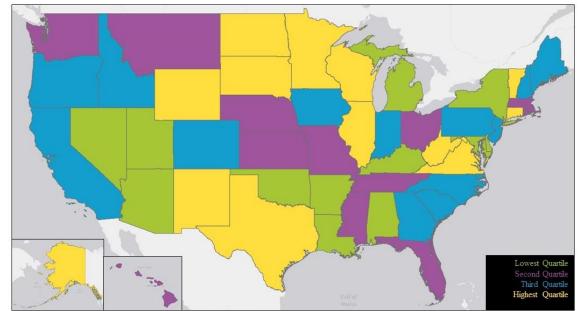| State	Statute/Regulation
Alabama	Code of Alabama 22-21-263(a)(2)
Alaska	7 AAC 01.0001
Connecticut	C.G.S. Sec. 19a-638(10)
Delaware	16 Del C. §9305
District of Columbia	D.C. Code § 44-401(6B)(A)
Georgia	O.C.G.A. § 31-6-40(a)(3)
Hawai'i	HRS § 323D-12
Illinois	20 ILCS 3960
Iowa	Code of Iowa Chapter 135.61
Kentucky	KRS 216B.061(f)
Maine	22 M.R.S.A. §328(16)
Maryland	COMAR 10.24.01.02.A.5
Massachusetts	M.G.L. c. 111, §§ 25C
Michigan	Mich. Comp. Laws § 333.22209(1)(c)
Mississippi	MS Code § 41-7-191(1)(d)(xii)
Missouri	19 CSR 60-50.300 (11)(E)
Montana	Mont. Code Ann. § 50-5-301(a)
New York	10 NYCRR Section 710.1(c)(3)
North Carolina	N.C.G.S. § 131E-176(16)(f1)(7)
Rhode Island	216-RICR-40-10-22.2(A)(20)(i)
South Carolina	S.C. Code An. Regs. 61-15.102(1)(f)
Tennessee	TN Code § 68-11-1607(a)(4)
Vermont	18 V.S.A. § 9405 (CON Standard 3.5)
Virginia	Va. Code § 32.1-102.1
West Virginia	W.Va. Code § 16-2D-8(b)(6)

Figure A1. Map of Mean Payment Amount by State Controlling for Procedure and State Purchasing Power

REFERENCES

Agarwal, R., Bergey, M., Sonnad, S., Butowsky, H., Bhargavan, M., & Bleshman, M. H. (2010). Inpatient CT and MRI utilization: trends in the academic hospital setting. *J Am Coll Radiol, 7*(12), 949-955. doi:10.1016/j.jacr.2010.08.015

Amrhein, T. J., Lungren, M. P., Paxton, B. E., Srinivasan, R., Jung, S. H., Yu, M., . . . Kilani, R. K. (2013). Journal Club: Shoulder MRI utilization: relationship of physician MRI equipment ownership to negative study frequency. *AJR Am J Roentgenol, 201*(3), 605-610. doi:10.2214/AJR.12.9977

Ashford, K. (2014, October 31, 2014). What I Learned When I Asked How Much My MRI Would Cost.   Retrieved from www.forbes.com

Azar, A. M., Mnuchin, S. T., & Acosta, A. (2018). *Reforming America's Healthcare System Through Choice and Competition*. Washington, D.C. Retrieved from https://www.hhs.gov/.

Baker, L. C. (2010). Acquisition of MRI equipment by doctors drives up imaging use and spending. *Health Aff (Millwood), 29*(12), 2252-2259. doi:10.1377/hlthaff.2009.1099

Bearak, J. M., Finer, L. B., Jerman, J., & Kavanaugh, M. L. (2016). Changes in out-of-pocket costs for hormonal IUDs after implementation of the Affordable Care Act: an analysis of insurance benefit inquiries. *Contraception, 93*(2), 139-144. doi:10.1016/j.contraception.2015.08.018

Beinfeld, M. T., & Gazelle, G. S. (2005). Diagnostic imaging costs: are they driving up the costs of hospital care? *Radiology, 235*(3), 934-939. doi:10.1148/radiol.2353040473

Bell, R. A. (1996). Economics of MRI technology. *J Magn Reson Imaging, 6*(1), 10-25. doi:10.1002/jmri.1880060105

Berliner, H. S. (2008). The Movement of Services Out of the Hospital. *International Journal of Health Services, 38*(4), 625-639. doi:10.2190/HS.38.4.c

Blavin, F., Shartzer, A., Long, S. K., & Holahan, J. (2015). An early look at changes in employer-sponsored insurance under the Affordable Care Act. *Health Aff (Millwood), 34*(1), 170-177. doi:10.1377/hlthaff.2014.1298

Breslin, T. M., Banerjee, M., Gust, C., & Birkmeyer, N. J. (2013). Trends in advanced imaging use for women undergoing breast cancer surgery. *Cancer, 119*(6), 1251-1256. doi:10.1002/cncr.27838

Brown, J. G. (1994). *Publication of OIG Special Fraud Alerts*. Washington, D.C.

Bureau of Economic Affairs. (2016). Regional Price Parities by State.

Burris, R. (2014, April 14). SC Supreme Court upholds state regulation of hospitals. *The State*. Retrieved from http://www.thestate.com

Cauchi, R., & Noble, A. (2016). CON-Certificate of Need State Laws.   Retrieved from http://www.ncsl.org/

Chen, W. Y., Liang, Y. W., & Lin, Y. H. (2016). Is the United States in the middle of a healthcare bubble? *Eur J Health Econ, 17*(1), 99-111. doi:10.1007/s10198-015-0668-y

Conover, C. J., & Sloan, F. A. (1998). Does removing certificate-of-need regulations lead to a surge in health care spending? *Journal of Health Politics, Policy and Law, 23*(3), 455-481.

DellaBadia, J., Jr., Bell, W. L., Keyes, J. W., Jr., Mathews, V. P., & Glazier, S. S. (2002). Assessment and cost comparison of sleep-deprived EEG, MRI and PET in the prediction of surgical treatment for epilepsy. *Seizure, 11*(5), 303-309. doi:10.1053/seiz.2001.0648

Ferrier, G. D., Leleu, H., & Valdmanis, V. G. (2009). The impact of CON regulation on hospital efficiency. *Health Care Management Science, 13*(1), 84-100. doi:10.1007/s10729-009-9113-z

Fric-Shamji, E. C., & Shamji, M. F. (2010). Effect of US State Certificate of Need regulation of operating rooms on surgical resident training. *Clinical Investigative Medicine, 33*(2).

Glover, L. (2014, July 16). Why Does an MRI Cost So Darn Much?   Retrieved from www.time.com

Haighurst, C. C. (1973). Regulation of Health Facilities and Services by "Certificate of Need". *Virginia Law Review, 59*(7), 1143-1232.

Hellinger, F. J. (2009). The effect of certificate-of-need laws on hospital beds and healthcare expenditures: an empirical analysis. *American Journal of Managed Care, 15*(10), 737-744.

Jacobs, B. L., Zhang, Y., Skolarus, T. A., Wei, J. T., Montie, J. E., Schroeck, F. R., & Hollenbeck, B. K. (2013). Certificate of need legislation and the dissemination of

robotic surgery for prostate cancer. *J Urol, 189*(1), 80-85. doi:10.1016/j.juro.2012.08.185

Kan, J. H., Estrada, C., Hasan, U., Bracikowski, A., Shyr, Y., Shakhtour, B., & Hernanz-Schulman, M. (2009). Management of occult fractures in the skeletally immature patient: cost analysis of implementing a limited trauma magnetic resonance imaging protocol. *Pediatr Emerg Care, 25*(4), 226-230.

Lao, M., Lafontaine, F., & Feinstein, D. L. (2015). *FTC Staff Comment Regarding North Carolina House Bill 200*. Washington, D.C.

Lao, M., & Potter, R. (2016). *Joint Statement of the Federal Trade Commission and Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250*. Washington, D.C.

Leibenhaut, M. H. (2005). Radiology applications of financial accounting. *J Am Coll Radiol, 2*(3), 241-253. doi:10.1016/j.jacr.2004.08.030

Lexa, F. J., Mehta, T., & Seidmann, A. (2005). Managerial accounting applications in radiology. *J Am Coll Radiol, 2*(3), 262-270. doi:10.1016/j.jacr.2004.08.020

Lieberman, D., & Allen, J. (2015). New Approaches to Controlling Health Care Costs: Bending the Cost Curve for Colonoscopy. *JAMA Intern Med, 175*(11), 1789-1791. doi:10.1001/jamainternmed.2015.4594

Lorch, S. A., Maheshwari, P., & Even-Shoshan, O. (2012). The impact of certificate of need programs on neonatal intensive care units. *J Perinatol, 32*(1), 39-44. doi:10.1038/jp.2011.47

Martin, A. B., Hartman, M., Washington, B., & Catlin, A. (2019). National Health Care Spending In 2017: Growth Slows To Post-Great Recession Rates; Share Of GDP Stabilizes. *Health Aff (Millwood), 38*(1). doi:10.1377/hlthaff.2018.05085

Mason, K. P., Zurakowski, D., Zgleszewski, S. E., Robson, C. D., Carrier, M., Hickey, P. R., & Dinardo, J. A. (2008). High dose dexmedetomidine as the sole sedative for pediatric MRI. *Paediatr Anaesth, 18*(5), 403-411. doi:10.1111/j.1460-9592.2008.02468.x

Millsap, A. (2018, February 13). Florida's Certificate-Of-Need Laws Should Go. *Forbes*.

Nazarian, S., Reynolds, M. R., Ryan, M. P., Wolff, S. D., Mollenkopf, S. A., & Turakhia, M. P. (2016). Utilization and likelihood of radiologic diagnostic imaging in patients with implantable cardiac defibrillators. *J Magn Reson Imaging, 43*(1), 115-127. doi:10.1002/jmri.24971

O'Donnell, J., & Rudavsky, S. (2017, August 23). Need an MRI? It pays to shop around. Big time. *USA Today*. Retrieved from www.usatoday.com

Parento, E. W. (2017). Certificate of Need in the Post-Affordable Care Act Era. *Kentucky Law Journal, 105*(2), 201-259.

Parker, L., Nazarian, L. N., Carrino, J. A., Morrison, W. B., Grimaldi, G., Frangos, A. J., . . . Rao, V. M. (2008). Musculoskeletal imaging: medicare use, costs, and potential for cost substitution. *J Am Coll Radiol, 5*(3), 182-188. doi:10.1016/j.jacr.2007.07.016

Pasalic, D., Lingineni, R. K., Cloft, H. J., & Kallmes, D. F. (2015). Nationwide price variability for an elective, outpatient imaging procedure. *J Am Coll Radiol, 12*(5), 444-452. doi:10.1016/j.jacr.2014.11.024

Paul, J. A., Ni, H., & Bagchi, A. (2014). Effect of certificate of need law on emergency department length of stay. *J Emerg Med, 47*(4), 453-461 e452. doi:10.1016/j.jemermed.2014.04.027

Rahman, M., Galarraga, O., Zinn, J. S., Grabowski, D. C., & Mor, V. (2016). The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures. *Med Care Res Rev, 73*(1), 85-105. doi:10.1177/1077558715597161

Roos, R. M. (1987). Certificate of Need for Health Care Facilities: A Time for Re-examination. *Pace Law Review, 7*(2), 491-530.

Rosko, M. D., & Mutter, R. L. (2014). The association of hospital cost-inefficiency with certificate-of-need regulation. *Med Care Res Rev, 71*(3), 280-298. doi:10.1177/1077558713519167

Salkever, D. S., & Bice, T. W. (1976). The impact of certificate-of need controls on hospital investment. *Milbank Mem Fund Q Health Soc, 54*(2), 185-214.

Sanders, B. (2016, June 24). State pulls plug on NH Certificate of Need board. *New Hampshire Business Review*. Retrieved from https://www.nhbr.com/

Sausser, L. (2013). Health care industry scrambles to interpret S.C. Certificate of Need suspension. *The Post and Courier*. Retrieved from http://www.postandcourier.com

Schencker, L. (2016). State certificate-of-need laws weather persistent attacks. *Mod Healthc, 46*(4), 12-13.

Schonbrun, M. K. (1979). Making Certificate of Need Work. *North Carolina Law Review, 57*(6), 1259-1315.

Sen, E., & Scavette, A. (2017). Regional Spotlight: Purchasing Power across the U.S.
Economic Insights, 2(4).

Shi, L. (2008). *Health Services Reseach Methods* (2 ed.). Clifton Park, NY: Delmar
Cengage Learning.

Worthington, D. (2016, January 13). S.C. certificate of need program could face
legislative battle. *The Herald*. Retrieved from https://www.heraldonline.com/