Three Essays on Public Economics and Economic History

by

Yiyu Xing

A dissertation submitted to the Graduate Faculty of
Auburn University
in partial fulfillment of the
requirements for the Degree of
Doctor of Philosophy

Auburn, Alabama
April 30, 2024

Keywords: Product Safety Regulation, Innovation, Administrative Practice Regulation, Labor Market Regulation

Approved by

Nicolas L. Ziebarth, Chair, Ekelund and Hebert Professor of Economics
Chris Vickers, Associate Professor of Economics
Duha T. Altindag, Associate Professor of Economics
Jong Hyun Chung, Assistant Professor of Economics
University Reader: Joel Cuffey, Assistant Professor of Agricultural Economics

Abstract

How do government regulatory policies shape economic output and consumer welfare? What are the costs and benefits of government regulations? These two fundamental inquiries are at the core of my research. In this dissertation, I assess the consequences of government regulatory policies in the healthcare sector from the following three perspectives: (1) How do product quality and safety regulations shape the development of new (medical) technologies? (2) Can regulations targeting administrative requirements influence the accessibility and provision of medical services? (3) To what extent do historical occupational licensing regulations for the healthcare workforce affect consumer welfare?

In my job market paper "*Product Safety Standards and Technological Innovation: Evidence from the 1968 Radiation Control*," I explore the effects of product safety standards on the speed and direction of medical innovation. Product safety regulation has been a widely adopted policy tool throughout history. Debates typically center around the trade-off between safeguarding consumers and stifling the development of new products. In this paper, I study how stricter safety standards influence the nature and speed of medical innovation by drawing evidence from the 1968 Radiation Control for Health and Safety Act. For the first time at the federal level, this Act mandated enforceable performance standards to control the radiation risk of electronic products. I find that in response to this act, firms developed new technologies reducing the risks of diagnostic X-ray medical equipment (an increase of 64.2% in patent count) as a key channel to lower compliance costs. I also document an increase of a similar magnitude for innovations (by 72.1%) representing new radiation-generating medical devices and show some suggestive evidence for the complementarity of risk mitigation and new technologies using radiation. I rule out a number of alternative explanations for these findings, including the introduction of the CT scan in 1972.

In the second chapter, "*Cutting Red Tape: Administrative Simplification and Treatment Capacity*," I investigate the impact of regulating prior authorization on the provision of substance abuse treatment services. Excess administrative expenses impose a strain on the U.S. healthcare system. Yet, little is known regarding how these administrative requirements affect facilities' provision of medical services. I empirically assess this question by drawing on the staggered adoption of state laws restricting prior authorization (PA) requirements for substance abuse treatments (SAT) in commercial health plans. Using multiple datasets, I find specialty care facilities are more likely to provide low-intensity (i.e., outpatient) SAT services while decreasing the provision of high-intensity ones (i.e., intensive outpatient, partial hospital, inpatient). I further corroborate supporting evidence for one plausible mechanism: lowering administrative hassles can expand both facilities' and health providers' treatment capacity. To capture welfare implications, I document the fact that imposing PA restrictions can reduce the suicide rate due to SUD issues. This paper thus highlights a novel source of costs associated with healthcare administrative processes: beyond imposing direct paperwork costs, they substantially restrain organizational treatment capacity.

In the third chapter, "*Veterinary Care Regulation and Livestock Production: Evidence from the Progressive Era*," I explore how regulating veterinary practice shaped a key dimension of agricultural development: livestock production. Exploiting the staggered adoption of state-level licensing laws for veterinary care in the late 19^{th} century and the early 20^{th} century, I document the fact that stricter licensing requirements led to a significant surge in heads of livestock (i.e., horses, mules, milch cows, and swine) per acre of farmland. I further provide some suggestive evidence for one plausible mechanism: during the Progressive Era, stricter veterinary care regulations mitigated informational asymmetries in specialized medical service, thereby altering the input choices in agricultural production. My findings thus highlight the broader effects of labor market regulation on consumer outcomes and provide important implications for ongoing debates regarding the value of occupational licensing.

This dissertation is dedicated to my family.

Acknowledgments

As "all the lines created by a tree's growth converge at the tip of its least branch," this dissertation reflects the joy, tears, and everything I have experienced throughout my Ph.D. journey.

I am deeply indebted to my advisor, Nicolas L. Zieberth, for his incredible guidance, unwavering support, and warm encouragement. Without his expertise, wisdom, and trust, I would not have been able to navigate those challenging situations and finish this dissertation. It's my fortune to meet him at the most stressful and frustrating moment in my life. His insights, passion, and dedication to economics re-inspire my pursuit of research and help expand my research agenda. Although there was a big detour in my Ph.D. training, Dr. Ziebarth helped me overcome all the sorrow. I am immensely grateful to Dr. Ziebarth for taking the time to talk, providing detailed and instructive feedback on every single draft I sent, and sharing his suggestions on my career development (e.g., developing new projects, digitizing historical datasets, presenting in seminars/conferences, searching for jobs, etc.), as well as supporting me to explore each research idea I am interested in (no matter how crazy it is at first glance). It is wonderful to have you as an advisor and mentor; I sincerely wish to keep working with and learning from you.

I also want to thank my committee members, Chris Vickers, Duha Altindag, and Jong Hyun Chung, for their thoughtful comments on my work. I appreciate all your help in writing me reference letters and guiding me in this profession. Special thanks to Ia Vardishvili, my friend and mentor, for her genuine help and support during the most challenging period of my graduate school.

Last but certainly not least, I am eternally grateful to my family, Lange Rong, Shuyu Qi, Heqing Rong, Hejian Rong, Jie Xing, and Dundun (my cat), for their unconditional

love and support for my success. Thank you for always believing in me and encouraging me to pursue my dreams along this long journey. Without your support, I cannot make it. I dedicate my dissertation to you. I also thank my friends, Sherry Ding, Mengyang Gao, Yichun Song, and Mengzhe Zhao, for their companionship and emotional support over the past decade(s). Having all of you as my best friends is my luck.

Table of Contents

List of Tables

List of Figures

Chapter 1

Product Safety Standards and Technological Innovation: Evidence from the 1968 Radiation Control

1.1 Introduction

Both historically and today, consumer product safety regulation is a ubiquitous policy tool addressing market failures due to asymmetric information. In the United States, for example, approximately 15,000 types of products are under the regulation of the Consumer Product Safety Commission (CPSC)[1], and the Food and Drug Administration (FDA) is in responsible for the oversight of more than $2.7 trillion in consumption of food, medical products, and tobacco.[2] Although aiming to safeguard consumers from potential hazards, such regulations have become a source of controversy, especially in the context of innovation (Maresova, 2023).[3] On the one hand, by scaling up compliance costs and entry costs, stricter safety standards has the potential to both impede the development of new technologies and the commercialization of new products (Peltzman, 1973). On the other hand, by reducing quality uncertainties, tighter regulatory scrutiny can increase consumers' willingness to pay for regulated products and thus spur innovation (Carpenter, Grimmer and Lomazoff, 2010). Therefore, it is crucial to understand the nexus and strike a delicate balance between timely access to new technologies and the imposition of rigorous safety standards.

To shed new light on this line of ongoing debates, I assess the causal effect of product safety standards on firms' patenting activities in the healthcare sector. Credibly capturing

[1] See https://www.cpsc.gov/Newsroom/FOIA/Guide-to-Public-Information, last accessed .

[2] https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance, last accessed .

[3] See for example, in the (de)regulation for artificial intelligence in medical technologies, https://www.nytimes.com/2023/03/03/technolog/artificial-intelligence-regulation-congress.html, and https://www.meddeviceonline.com/doc/the-fda-regulatory-landscape-for-ai-in-medical-devices-0001 last accessed .

this *full* causal effect is challenging today, especially in the healthcare sector. This is because multiple regulatory pathways are simultaneously governing the safety and effectiveness of medical products in the current regime, which would make extrapolations to zero inherently speculative. To address this issue, I drew on a large-scale consumer product safety regulation in U.S. history as an ideal natural experiment: the Radiation Control for Health and Safety Act (RCHSA) in 1968. For the first time and at the federal level, this regulation safeguarded consumers from excessive and unnecessary radiation emitted by electronic products. The RCHSA mandated minimum safety performance standards and a series of compliance and enforcement measures, conceptually increasing compliance costs and potentially influencing firms' strategic decisions to mitigate the negative effects of regulatory pressure. Focusing on diagnostic X-ray devices, I show that certain *innovations*, which reduce products' radiation risks, could be a key channel through which firms adapt to regulation. Providing empirical evidence for this channel, to my knowledge, is novel in the literature.

Economic theories suggest the effect of safety standards on innovation is ambiguous. To illustrate the key mechanisms at play, I developed a model following Viscusi and Moore (1993) who conceptualize how firms strike a balance between product safety and product novelty. In this model, the extent to which safety standards affect firms' incentives to innovate hinges on two key factors: the innovation types (i.e., demand-enhancing, product innovation vs. cost-saving, process innovation) and the nature of the regulatory costs (e.g., direct compliance costs, administrative hassles, product liability costs, etc.). Two testable predictions are generated: First, firms can develop new technologies to improve products' safety features ("*safety innovation*") in order to lower certain regulatory costs. Second, firms are also incentivized to develop new products ("*product innovation*") as long as such new products and safety innovation are complementary in production.

In the empirical section of my paper, I use a difference-in-differences (DID) framework to estimate the induced innovation effects, exploiting variation across patent subclasses over

time. To distinguish the treatment and control groups, I leverage the detailed patent classification system known as the *Cooperative Patent Classification* (CPC). The treatment group consists of all patents filed under the broad patent class `A61B6`, representing apparatus for radiation diagnosis. In my primary control group, I include all patents relating to diagnostic medical equipment based on *non-radiation* technology under the patent class `A61B`. Accounting for potential spillovers across technology types and medical products (Grennan, Gupta and Lederman, 2020), I further constructed two alternative control groups using drug patents and medical implant patents.

My analysis begins with assessing the effect of safety standards on the quantity of innovation, measured by the raw/citation-weighted patent counts under each patent subclass per year. Using the universe of granted patents applied for at the United States Patent and Trademark Office (USPTO) between 1960 and 1980, I find introducing stricter safety standards led to a significant increase in patent counts relating to diagnostic X-ray devices. Depending on the choice of control groups, this increase ranged from 52.8% to 92.6%. When comparing point estimates derived from different control groups, my findings further suggest some spillovers resulting from the RCHSA may extend to medical implant patents, which are generally unrelated to X-ray technology.

Meanwhile, I document the surge in innovation is composed of both a new wave of technologies protecting patients from unnecessary radiation exposure (*risk-mitigating technologies*) and an increase in new devices emitting radiation (*radiation generating technologies/devices*). I took two complementary approaches to identify these patents' traits: (1) relying on the detailed CPC code and selecting patent subclasses closely relevant to either radiation protection or radiation emission and (2) developing an algorithm based on text analysis to read patent files. Both methods produced similar results: Within a tightening regulatory environment, the patent count for both risk-mitigating and radiation-generating technologies significantly increased. Further, I show firms are the primary contributors to this historical spike in patenting activities, whereas independent inventors responded little

following the RCHSA. These findings are aligned with the premise of my theoretical framework: the induced innovation reflects shifts in firms' incentives to adapt to the regulation.

This paper also quantifies how stricter safety standards affected the *quality* of innovation using two metrics: the number of age-adjusted forward citations received per patent and the resultant increase in firms' market value. Across the distribution of patent quality, I find higher safety standards appear to favor high-quality patents. Patents receiving more age-adjusted forward citations experienced an increase of 102.6%, relative to their low-quality counterparts (increased by 60.5%). Regarding private market value, the RCHSA also led to a rise of 2.3% in the stock price of U.S. publicly traded firms. To sum up, my results highlight that stricter safety standards have the potential to enhance innovation quality and improve welfare.

To explore whether these findings resulted from increased compliance costs, I look to both qualitative and quantitative evidence. First, immediate enforcement and compliance actions following the passage of the RCHSA indicate an upsurge in regulatory compliance burdens. Second, institutional features suggest firms could leverage innovation and invention as a channel to combat the regulation: the RCHSA explicitly required manufacturers to "take new means" to correct existing defects and lower radiation emissions; the FDA also specified medical recommendations for "the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures" as an approach to radiation protection. Quantitatively, I focus on one specific risk-mitigating technology: apparatus or devices for preventing over-radiation errors and enhancing dosage management. This technology is commonly integrated into X-ray medical devices rather than being standalone products (e.g., protective shields), suggesting it's less likely to be categorized as product innovation. Restricting my treatment group to this technology does not substantially change my main results.

In addition to regulatory compliance costs, I conducted a variety of empirical tests to discuss alternative mechanisms at play. To begin, I argue the rise in patenting rates cannot be exclusively driven by increased product liability risks. The primary concern is twofold:

First, the RCHSA was passed in response to a large-scale voluntary product recall from General Electrics in 1967. It is thus plausible that the recall itself stimulated a contemporaneous increase in litigation risk among radiation-emitting electronic products. Second, if the RCHSA served as a public informational shock, it could have bolstered public demand for tort reforms targeting electronic products, further elevating product liability risk. Both channels could have motivated firms to innovate in response to liability risk rather than the regulation *per se*. However, by examining changes in the number of lawsuits against X-ray medical devices, I didn't document a significant, drastic increase in product liability risk. Moreover, I found limited responses in innovation from GE, who should face higher litigation risk relative to its competitors. Finally, I show foreign firms, who typically face lower product liability risk but similar regulatory compliance costs relative to the U.S. firms, also engaged in patenting X-ray medical technologies.

My paper also delves into the question of whether a demand-driven force is responsible for the increased patenting activities. On the one hand, if safety regulation effectively resolves the asymmetric information between buyers and sellers, the resultant expansion of market size could directly stimulate firms' incentives for innovation (Acemoglu and Linn, 2004). On the other hand, if the RCHSA provided informational shock and raised consumers' aversion against radiation-emitting electronic products, it might discourage firms from innovating. Using digitized data from an early version of the National Hospital Discharge Survey (1968 - 1970), I found the RCHSA did not immediately increase the utilization of radiology services, suggesting that the demand-side channel may not be the primary driver of increased patenting activities, at least in the short run. Further, I provide qualitative evidence demonstrating the RCHSA did not substantively shape the public perceptions towards medical radiation.

Along with the RCHSA, there was a notable breakthrough in radiation-based medical technologies: the clinical application of computed tomography (CT) in 1972. To rule out its confounding effects on follow-on innovation, I conducted several tests. First, I directly excluded patents within the same subclass as CT in my sample and limited the reference

period to 1960-1971. I found my primary estimates are still robust. Second, I re-estimated the innovation effects among domestic firms: Using foreign patents of each subclass as a benchmark, I controlled for common technology or demand trends taking place in the same technological areas. This additional exercise also yielded similar results, suggesting the surge in patenting could not be solely explained by the entry of CT in 1972.

Finally, I explore an indirect channel: All structural factors mentioned above (compliance costs, liability risk, shifts in demand, and technological breakthrough) have the potential to alter product market structure in the X-ray medical device industry. In turn, any resulting changes in competition pressure could distort firms' innovation incentives (Aghion et al., 2005). To test this channel, I compare the innovation effects across different types of firms. Specifically, I first found there are no significant differences in patenting rates between U.S. publicly traded firms and other domestic private firms. Further, I document little differences between firms with prior patenting history ("*prior inventors*") and their counterparts ("*new inventors*"). I view these results as suggestive evidence that potential changes in product market competition (if any) are not the primary driver of the surge in innovation. Such empirical findings are not consistent with the theoretical relationship between competition pressure and innovation: Competition encourages *neck-to-neck* firms to innovate but discourages laggard firms from innovating (Aghion et al., 2005).

In light of these findings, my paper contributes to several strands of literature. First, my work speaks to recent empirical research emphasizing the link between product quality regulation and firms' innovation activities, especially in the healthcare sector. For example, Stern (2017) found regulatory uncertainty due to prolonged approval times can bring disadvantages in the regulatory approval process for high-risk medical devices and hinder product entry. Grennan and Town (2020) analyzed the impact of regulating product entry and quality information requirements on an oligopoly equilibrium and consumer welfare.[4]

[4]Exploiting variation in pre-marketing testing requirements within EU and US medical device regulations, Grennan and Town (2020) found evidence of valuable learning from more stringent requirements and discussed the welfare implications with a structural model.

Both studies utilized cross-group variation and focused on "*mid-stage innovations*" (Grennan and Town, 2020). My paper instead exploits a quasi-experiment policy shock to shed light on how quality regulations affect research and development at even *earlier* stages.[5] In this regard, the only paper close to mine is Rogers (2023), finding that by reducing approval costs, deregulating medical devices from Class III (*high regulation*) to II (*moderate regulation*) led to an increase in both patenting rates and FDA submission rates among affected medical device types. Meanwhile, when shifting from Class II (*moderate regulation*) to Class I (*minimum regulation*), manufacturers are incentivized to emphasize safety features in both product development and patenting because of the exposure to higher-level litigation risk.

My paper is essentially distinct from Rogers (2023) in two aspects: First, in contrast to Rogers (2023) who emphasizes the role of FDA's general (de)regulation in the current context, I exploit a historical setting to assess a key channel through which product safety regulations distort firms' innovation incentives: regulatory compliance costs. Back in the 1960s and early 1970s, the historical FDA regulatory scheme did not involve a pre-marketing approval process and other administrative requirements for medical devices. This unique setting enables me to directly rule out many other confounding factors within the regulatory pathway.[6] Second, when quantifying the innovation effect of product safety regulations, my paper accounts for the interplay between different technologies. That said, I identify two key attributes of medical X-ray machine patents: risk-mitigating technologies (*cost-saving innovation*) and radiation-generating technologies (*product innovation*). Leveraging this intriguing feature, I demonstrate in a context wherein innovations are complementaries

[5]It is interesting to note that Grennan and Town (2020) mentioned "While our exercise here, estimating the welfare effects of the access/uncertainty trade-off for an exogenously given set of "mid-stage" innovations, is an important step toward better understanding this phenomenon, a more complete understanding would allow for the regulatory regime to effect research and development at even earlier stages. Analysis of this type would require a significant extension to the theory and additional data on innovative activities of the firms."

[6]Not until 1976, the FDA began to provide systematic assurance of the safety and effectiveness of general medical devices by creating a three-class, risk-based classification system and establishing both the regulatory pathways for the entry of new medical devices and the postmarket requirements. The premarket regulations include Premarket Approval (PMA) and premarket notification (501(k)). The postmarket requirements include registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices.

in production, quality regulations targeting safety performance can result in unexpected positive spillovers on the development of new products.

More broadly, this paper contributes to the extensive and still emerging studies discussing the determinants of innovation. In particular, my work adds to a line of literature exploring how changes in the regulatory environment shape innovation. Prior studies have heavily emphasized the role of labor inputs regulation (Acharya, Baghai and Subramanian, 2013; Griffith and Macartney, 2014; Bena, Ortiz-Molina and Simintzi, 2022), environment regulation, and product entry/commercializing regulation (Stern, 2017; Byrski, 2021). To my knowledge, empirical work directly addressing the interaction between product safety standards and innovation is quite limited.

Lastly, the literature studying the impact of the RCHSA *per se* is surprisingly scarce to my knowledge, given the large scale of this legislation. A notable exception is Birnbaum (1984), who argues the regulation increases consumer and competitor uncertainty, leading firms to decrease their incentives to innovate. There are several key differences between Birnbaum (1984) and mine in terms of methodology. First, the measure of innovation he took only includes patents of radiant energy, whereas my focus is medical technology relying on X-ray.[7] Second, rather than checking the correlation as Birnbaum (1984), I exploit the RCHSA as a quasi-experiment and characterize a number of control groups to capture the causal effect on innovation. Eventually, I advance my discussion on mechanisms at play by providing several empirical tests instead of purely relying on qualitative arguments.

The rest of this paper proceeds as follows: Section 1.2 provides the institutional background of the Radiation Control for Health and Safety Act of 1968. Section 1.3 sketches a conceptual framework to motivate my empirical analysis. Section 1.4 describes a number of datasets enabling me to implement the empirical analyses. Section 1.5 specified the baseline

[7]The definition of the class of interest in Birnbaum (1984) is "... *subject matter which includes sensing means responsive to electromagnetic radiation including a variable electrical member or variable radiation control member having a pointer and an associated scale calibrated in frequency or wavelength units and indicating means responsive to the sensing means to note the maximum energy detected by the sensing means whereby the scale and pointer indicate the wavelength or frequency of the radiation detected*", last accessed .

empirical strategy and some threats to identification. Section 1.6 presents the main results. Section 1.7 discusses and tests some alternative mechanisms, and Section 1.8 presents the heterogeneous effects based on firms' financing constraints. Section 1.9 finally concludes.

1.2 Historical Background

This section summarizes the institutional background of the RCHSA in 1968. Section 1.2.1 describes the legislative history of the RCHSA. Section 1.2.2 outlines the formulation of minimum safety standards. Section 1.2.3 presents the detailed features of compliance and enforcement actions within the RCHSA, and in section 1.2.4, I briefly show the efforts to educate consumers and operators of X-ray machines under the RCHSA (and why they failed to some extent). Finally, I summarize prior regulations for medical devices and radioactive materials.

1.2.1 Legislative History

In May 1967, GE initiated a large-scale, voluntary recall for approximately 90,000 color television sets due to high doses of leakage radiation.[89] A letter issued by the National Center for Radiological Health (NCRH) on May 18, 1968, commended GE's voluntary recall and stated that " *there is no evidence in the hands of NCRH to suggest that any television receivers ... have excessively exposed viewers of television sets.*" Representative Paul Rogers informed the House that he wrote to the Department of Health, Education, and Welfare regarding his concern over potential radiation emissions and was told that any radiation emission was negligible. On June 13, 1967, Rogers and John Jarmin introduced House Bill 10790, which eventually became the Radiation Control for Health and Safety Act of 1968. The hearings on House Bill 10790 initially concerned radiation emissions from television but

[8]See https://www.nytimes.com/1967/05/19/archives/general-electric-will-modify-90000-large-color-television-sets.html, last accessed April 30, 2024.

[9]There might be a concern that the documented increase in patenting was partially triggered by a surge in litigation risk due to the GE recall. To address this issue, I further searched for some qualitative descriptions of the consequences of this GE recall.

quickly expanded to include other radiation concerns, especially medical and dental x-ray use (Tran, 2006).

On October 15, 1968, the 90^{th} Congress passed this bill and enacted the RCHSA, applying to any "electronic product" defined as "any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation."[10] The primary goal of this Act is to "*establish and carry out an electronic product radiation control program designed to protect public health and safety from electronic product radiation.*" There are two main provisions under the Act: *correction of defects* and *safety performance standards*.

1.2.2 Safety Performance Standards

As the crux of the RCHSA, safety performance standards generally prescribe maximum radiation emission levels and require certification by the manufacturer that the regulated product conforms to federal standards. On August 15, 1972, the FDA issued performance regulation (*21 C.F.R. 1020.30*) targeting diagnostic X-ray products. The regulation prescribes more than 60 performance standards for X-ray systems and their components manufactured after August 1, 1974, and requires that they be certified by the manufacturer after that date as being in compliance with the standards. The FDA's program to ensure compliance with its regulations includes (1) reviewing reports that manufacturers must submit on how each type of X-ray system and major component they market will meet the standards and (2) inspecting manufacturers' records and facilities. Yet, these efforts have been limited because they lack the resources to implement these aspects of diagnostic X-ray equipment fully.

[10] Admittedly, the bill was weakened by the lobbying efforts of the Electronic Industries Association (EIA), which was designed to control the licensing of the large number of radio patents so that each member could have access to all the relevant patents necessary to build radio transmitters, antennas and receivers.

According to *21 C.F.R. 1020.30*, the following components of diagnostic X-ray systems which are manufactured after August 1, 1974 were covered: Tube housing assemblies, X-ray controls, X-ray high-voltage generators, fluoroscopic imaging assemblies, tables, cradles, file changers, cassette holders, and beam-limiting devices. The specific regulations include (1) certification by the assembler, (2) identification of X-ray components, (3) limits of responsibility, (4) warning label, (5) leakage radiation from the diagnostic source assembly, (6) radiation from components other than the diagnostic source assembly, (7) beam quality, (8) aluminum equivalent of material between patient and image receptor, and (9) battery charge indicator.

It is noteworthy that in the context of X-ray devices, there is some room for manufacturers to leverage new technologies to reduce radiation emissions. First, according to the 1972 performance standards, manufacturers shall provide "positive means" to "limit the maximum x-ray tube potential to that of the diagnostic source assembly," if "the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly. Second, based on the 1968 general provision, the FDA specified several recommendations for "the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures," as an approach to radiation protection.

1.2.3 Compliance and Enforcement Actions

Another major provision of the RCHSA is a variety of compliance and enforcement actions targeting manufacturers. FDA enforced the performance standards quite strictly and has developed a three-pronged approach: First, in factories, the FDA evaluates reports on quality control and testing programs submitted by X-ray equipment manufacturers and supplements this information with factory inspections to verify that adequate testing is being conducted. Second, the FDA inspectors, as well as inspectors from States with which FDA has contracted, survey X-ray units in hospitals, clinics, and other facilities to determine if the

systems have been assembled and are performing in accordance with the standard. Finally, the FDA tests X-ray components and some fully assembled systems in its laboratory to check for compliance (FDA, 1975).

The RCHSA also authorized the Bureau of Radiological Health to require manufacturers to repair or replace electronic products that have a defect relating to their safety use, or that fail to meet an applicable performance standard at their own expense. The corresponding manufacturers can also refund the cost of such products. Specifically, a product is considered to have a defect if it fails to conform to its design specifications regarding radiation emission or emits hazardous radiation unnecessary to accomplish its intended purpose. If a manufacturer discovers that any electronic product produced, assembled, or imported by him on or after the effective date of the Act contains a defect related to its safety of use or fails to comply with an applicable performance standard, he must immediately notify the Secretary of Health, Education, and Welfare if the product has left its place of manufacture. If a defect or failure to comply reported to or discovered by the Bureau is considered to present a potential public health hazard, the manufacturer is required to notify all dealers or distributors to which the product was delivered and all subsequent purchasers whose identity can be determined. At the same time, the manufacturer is required to submit to the Secretary of Health, Education, and Welfare a statement of the measures to be taken to repair or replace defective units of the product.

The enforcement authorities of the FDA include recalls, injunctions, seizures, civil penalties, and regulation of imports. If the manufacturer determines the radiation risk is low with the defective product, it can request an exemption from a mandatory duty to notify consumers. The FDA also can notify a manufacturer if the FDA discovers any violation of the standards. If no exemption from public notification is granted, the manufacturer must correct the defects at its own expense or refund the purchase prices. The FDA may seize non-compliance products if the manufacturer fails to institute a recall. Additionally, the FDA can impose civil penalties on manufacturers: the RCHSA authorizes a civil penalty of

not more than $\$1,000$ for each defective product, with the maximum penalty for a single party for any violations limited to $\$300,000$. Notably, the FDA can impose civil penalties on both the corporation and individuals for the same set of violations.

Under the RCHSA, the FDA also can regulate the importation of electronic products by denying the entry of products that do not comply with federal standards. If a product denied entry cannot be brought into compliance, the corresponding manufacturer must export the product at its own expense. Otherwise, the FDA may seize and destroy the non-compliant products if the product failed

1.2.4 Effort to Educate the Public

According to some descriptive evidence (e.g. Tran, 2006), while public education is not technically mandated by the RCHSA, the FDA's radiation control program has included an effort to educate consumers and healthcare providers to achieve the goals of the act. Yet, these efforts are proven to have relatively limited effects on raising public awareness of radiation protection.

Educational Tools for Medical Practitioners/Technologists: To improve physicians' radiological health practices, the FDA has also developed several educational programs. For example, *the Radiological Health Sciences Learning Laboratory* is an educational system in diagnostic radiology for medical students, radiology residents, and postgraduate physicians. However, only 30 of the nation's medical institutions have purchased the Learning Laboratory by the end of 1973. Another set of training programs on radiation protection has been developed since 1973. The series, "*Radiation Protection During Medical X-Ray Examinations*," is a self-contained training program intended to teach technologists how to protect patients and themselves from unnecessary exposure during X-ray examinations.

According to Friedell (1971), introducing the RCHSA to directly correct defects and lower radiation emissions on the manufacturers' end should not be the whole story.

> "It is the physician who must weigh benefits against hazards; to introduce some kind of regulatory mechanism into decisionmaking is dangerous. The benefits of ionizing radiation have been conservatively estimated. There should be an effort to educate, to provide more information, and to upgrade training and experience, but not to determine exactly how value judgment is to be made."

To formally address the role of medical practitioners in radiation protection, the Consumer-Patient Radiation Health and Safety Act in 1981 provides for "the establishment of minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons" and "insure that medical and dental radiologic procedures are consistent with rigorous safety precautions and standards."

Changing Consumers' Perception: Similarly, the FDA has initiated some public education programs and moved ahead to reduce unnecessary exposure to X-rays in the late 1970s. A public information program targeting pregnant women was in effect to emphasize the collective responsibilities of the referring physician, the patient, and the X-ray technologists. The program instructed physicians on the dangers of radiation to the human embryo, encouraged physicians to ask female patients routinely if they were pregnant, and encouraged patients to be proactive in protecting their fetuses from unnecessary radiation by taking such simple measures as informing their doctors of possible pregnancies.

However, as pointed out by Pelc (2014) and Galasso and Luo (2021), "historically, the main drivers for technological improvements have been the physicians' demand for improved *image quality, speed, and new clinical applications*" in radiology (especially for CT scanners) (Pelc, 2014), whereas "dose control (risk mitigation) had been a secondary consideration" (Galasso and Luo, 2021).

1.2.5 Prior Landscape of Radiation Control

Before the RCHSA of 1968 was in effect, several states had taken action to address radiation control. According to the technical reports from the Food and Drug Administration (1972),

> "Since 1951, a total of 46 States and the Commonwealth of Puerto Rico have enacted specific laws for the regulation of ionizing radiation. Some of these laws are restricted to certain occupations or are amendments to existing statutes...The technical details of regulatory control are generally not included in these enabling acts; rather this authority is delegated to State agencies."

Overall, these state-level regulations can be categorized into three groups: the management of radioactive waste and environment protection (e.g., Alabama, Alaska, Arizona, Arkansas, California, Louisiana, North Dakota, New Mexico, and Pennsylvania), credentialing operators of X-ray machines (e.g., Illinois, Kentucky, New Hampshire, New York, Texas, Wyoming), and the registration of electronic products (e.g., Indiana, Kansas).

However, such prior regulations proved both "inconsistent and ineffective" (Tran, 2006). For example, although the general radiation regulatory regime in New York City was one of the most comprehensive in the 1970s, Hanson Blatz, the director of the Office of Radiation for the NYC Department of Health, claimed that

> "While the New York City Department of Health had adopted and enforced standards to protect citizens from excessive or unnecessary radiation, citizen inquires and complaints revealed that unnecessary radiation was being emitted from various products...Shielding of X-ray equipment to protect passerby was dependent on an honor system that many operators overlooked."

At the federal level, the Atomic Energy Act of 1946 gave the Atomic Energy Commission (AEC) authority to regulate artificial radioactive materials, but its jurisdiction did not cover

consumer goods or medical devices. In sum, neither prior state-level actions nor federal-level control have effectively addressed how diagnostic X-ray medical devices should be regulated with respect to their technical performance.

1.3 Theoretical Framework

In this section, I set up a conceptual model to illustrate the theoretical effects of safety regulations on innovation. This model builds on the framework in Viscusi and Moore (1993) and conceptualizes how a regulatory regime distorts firms' investments in product safety and product novelty. The major distinction from Viscusi and Moore (1993) is that instead of centering around costs from product liability, my model extends the discussion to more general costs relating to safety and quality regulations.

Several key features are incorporated in my model: First, a typical firm faces higher costs imposed by more stringent regulations. These regulation costs include and generalize several types: (1) direct costs from compliance and enforcement actions ("*compliance costs*"), (2) administrative and financial burdens from approval delays ("*approval costs*") (Pietzsch, Zanchi and Linehan, 2013; Stern, 2017; Rogers, 2023), and (3) litigation risk because of defective products ("*liability costs*") (Viscusi and Moore, 1993; Galasso and Luo, 2022). Second, to adapt to the regulation, a firm can develop new technologies emphasizing certain product safety features, termed as "*safety innovation*" in Viscusi and Moore (1993). Third, the intensity of product safety investment (including both the regular safety investment and safety innovation) could be correlated with marginal regulation costs. For example, a higher level of *ex-ante* product safety investment can substantially reduce the probability of facing a penalty and being seized or sued because of product defects, thereby lowering the corresponding marginal cost. Finally, product innovation and safety innovation can interact within this environment. As indicated in Athey and Schmutzler (1995), cost-saving (process) innovation and demand-enhancing (product) innovation are complementary

in terms of increasing the firm's net revenue. I extend the model of Viscusi and Moore (1993) to account for this complementarity in production.

1.3.1 Set-up

In a perfectly competitive market, I construct the model in terms of the firm's unit profit function π and focus on two types of endogenous choices: safety investment (s) and product innovation (z).[11] In the context of radiation control, I consider a firm's safety investment encompassing two parts, *regular safety investment* (s_r) and *safety innovation* (s_i), which can lower the risks of radiation. The latter component, as mentioned in Galasso and Luo (2021), has the feature of *cost-saving process innovation*. For simplicity, I consider the total amount of safety investment to be the sum of *regular safety investment* and *risk-mitigating investment* (i.e., $s = s_r + s_i$, or alternatively as a linear combination of both). Following the framework proposed in Rogers (2023), I also model the regular safety investment as a mandated level of effort $\bar{s_r}$.

The unit price of the product is described by a nonlinear hedonic price function, consisting of a base product price p (for simplicity, I normalize it to zero), a premium αz for product novelty, and a damage cost function $\beta(s_r, s_i, R)$. Consumers value product novelty and thus will pay the premium (i.e., $\alpha > 0$). The unit damage cost function $\beta(s, R)$ is a decreasing function of safety investment (β_{s_r}¡0, $\beta_{s_i} < 0$), and an increasing function with the stringency of the product safety regulation ($\beta_R > 0$). Without loss of generality, the damage cost function is a nonlinear function of the level of safety under various regulatory regimes.

$c(s, z)$ captures the input to produce safety and product novelty. The input requirements increase at an increasing rate with respect to the value of each joint product (i.e., $c_{s_r} > 0$, $c_{s_i} > 0$, $c_z > 0$, $c_{s_r s_r} > 0$, $c_{s_i s_i} > 0$, and $c_{zz} > 0$). The unit cost of the input is r and can be normalized to 1.

[11] Alternatively, expanding the model to include a quantity choice would complicate the comparative statistic results by adding another equation to the system. The simplification directly follows Viscusi and Moore (1993).

1.3.2 Characterizing Firms' Decisions

A representative firm selects s_r, s_i, and z to maximize one's unit profits:

$$max_{s,z}\pi = \alpha z - \beta(s, R) - c(s, z) \tag{1.1}$$

And the first-order condition would be

$$\frac{c_s}{c_z} = -\frac{\beta_s}{\alpha} \tag{1.2}$$

Equation 1.2 here captures the optimal mix of safety investment and product innovation, which hinges on both consumers' value of novel products and the marginal damage cost of safety investment.

1.3.3 Safety Regulation and Innovation

To better understand how safety regulations affect product innovation and safety innovation, it would be helpful to think about some comparative statistics exercises. In an extremely stringent regulatory regime (i.e., a large value of R), there would be a corner solution at which the firm undertakes no product innovation and directly maximizes its safety investment by reallocating resources. For example, consider the current regulatory approval process for high-risk medical devices in the U.S., the so-called "premarket approval" (PMA). It is necessary when a medical device developer wants to market a new high-risk device. Importantly, once the first model in a product code is approved through the PMA process, all subsequent devices in that product code must all be approved through the PMA process. The PMA is thus criticized as a complex and time-consuming process for manufacturers.[12] As shown in Stern (2017), this approval process is associated with longer approval delays

[12]The average approval time for a new high-risk device is 18.1 months, although the average for a device that is first within a product code is longer, at 22.5 months (Stern, 2017).

among pioneer entrants. Small, financially constrained firms are less likely to enter new device markets.

For the general interior solutions, the effects of product safety regulations on the choice variables are characterized as:

$$\frac{ds}{dR} = \frac{c_{zz}\beta_{sR}}{D} \tag{1.3}$$

and

$$\frac{dz}{dR} = -\frac{c_{sz}\beta_{sR}}{D} \tag{1.4}$$

where $D = (c_{sz})^2 - c_{zz}(\beta_{ss} + c_{ss}) < 0$ is the determinant of the Hessian matrix at the maximum interior solution (s^*, z^*).

It is worthwhile to address some structural features of my model before deriving the theoretical predictions. From equation 1.3, it is clear whether the regulation can distort safety investment depends in part on the correlation between the intensity of safety investment and the marginal costs of regulation (β_{sR}). In essence, if investing more in product safety can efficiently decrease the marginal cost of regulation ($\beta_{sR} < 0$), firms will be more inclined to exert effort toward quality control or developing new safety technologies. By contrast, in an alternative regime where the marginal cost of regulation is merely unrelated to the *ex-ante* safety investment ($\beta_{sR} = 0$), there is a good chance firms would not comply at all. For example, if the administrative hassles associated with pre-market approvals are sufficiently large (e.g., the approval process requires an extremely long fixed period, or firms have to file complex paperwork and documents, etc.), increasing *ex-ante* safety investment is less likely to reduce the marginal cost of regulation in any case.

Hypothesis 1. *More stringent safety regulations can spur safety innovation if product safety investment directly reduces the marginal cost of regulation.*

This testable hypothesis directly follows the assumption $\beta_{sR} < 0$ and equation 1.3. Recall the institutional features of the RCHSA as described in Section 1.2: this act specified and mandated performance standards for relevant products, along with various compliance

and enforcement actions (i.e., reporting, inspections, civil penalties, recalls, and seizures). Thus, I argue this correlation β_{sR} is plausibly negative in my context. Consequently, the effect of the RCHSA on the development of risk-mitigating technologies is likely to be positive.

Hypothesis 2. *More stringent safety regulations spur product innovation if and only if product innovation and safety innovation are complementary in production.*

As mentioned above, I model the regular safety investment s_r as a mandated level of effort ($\bar{s_r}$).[13] The total safety effort is thus $s = \bar{s_r} + s_i$ and the profit-maximization in equation 1.1 can be simplified as follows:

$$max_{s_i,z}\pi = \alpha z - \beta(s_i, R) - c(s_i, z) \tag{1.5}$$

Based on equation 1.4, it is clear that whether the stricter safety regulation spurs or stifles product innovation hinges on the sign of g_{sz}, assuming $\beta_{sR} < 0$. Here g_{sz} captures the complementarity/substitutability between product innovation z and safety innovation s_i. For example, if the development of RMTs enables a firm to increase one's investment in product innovation at less cost (e.g., a reduction in the marginal expected damage cost), then $c_{s_iz} < 0$ and $\frac{dz}{dR} > 0$, indicating an increased number of patents for non-RMTs would be expected. By contrast, if the development of RMTs restrains the firm from allocating resources to other $R\&D$ projects of new products, then $c_{s_iz} > 0$ and $\frac{dz}{dR} < 0$, suggesting a decline in the number of non-RMT patents will follow the safety regulation.

My simple model thus emphasizes how product safety regulations shape innovation is eventually an empirical question. It hinges on at least two gradients: the features of a regulatory regime (β_{sR}) and the interaction between different technology types (g_{sz}). In the next section, I turn to data and empirically estimate these innovation effects.

[13]This simplification would be reasonable if more general, less-risky methods to improve products' safety profiles are preferred. In the case of X-ray medical devices, it is quite likely to hold. After all, applying new RMTs into production would require more time , relative to directly conducting pre-market quality controls.

1.4 Data

In this section, I begin by describing the various data sources I used to implement my analysis. I then discuss how to characterize key patent attributes of interest, including risk mitigation and radiation generation. Eventually, I provide some stylized facts to motivate the empirical analysis.

1.4.1 USPTO Patent Files

The first data set I used is the universe patent files from the United States Patent and Trademark Office (USPTO). These records provide the year in which the patent was applied and granted, the technology class and the corresponding subclass a patent belongs to, the detailed description of each patent, the name of the inventors and the current assignees (if any) associated with each patent, and the number of forward citations received by each patent. In Figure A7, I present an example of the `A61B6` patent file.

To identify the treatment and control groups, I exploit the classification code provided by *Cooperative Patent Classification* (CPC), a detailed and universe scheme of classes and subclasses.[14] Patent classes generally describe the broad technical field of an invention, and patent subclasses typically include more detailed technical features under a class. Throughout this paper, I define a "patent subclass" using the corresponding class-subclass pair. The treated subclasses include all patents belonging to the subclasses under `A61B6` (apparatus for radiation diagnosis, e.g., combined with radiation therapy equipment) and including the keyword "x-ray". The primary control group includes all other subclasses relating to *non-radiation* diagnostic medical devices under the broad category `A61B` (diagnosis; surgery;

[14] For detailed information about the CPC scheme, see https://www.cooperativepatentclassification.org/about, last accessed April 30, 2024.

identification).[15] I construct two alternative control groups with patent subclasses related to medical implants (A61F) and drugs (A61K), respectively.[16]

The final sample is a panel recording patent counts filed per year under each subclass spanning 1960 to 1980, and the unit of analysis is thus subclass-year. I chose the sample period to capture the symmetric window around the year 1970 (a one-year lag relative to the enactment of the RCHSA). Meanwhile, this 21-year window covers other key, relevant shocks to both my treatment and control groups: for example, the passage of the Social Security Amendments of 1965 (also known as the *Medicare and Medicaid Act*), and the Medical Device Amendments to the FD&C Act of 1976. To avoid some confounding factors introduced by the Consumer-Patient Radiation Health and Safety Act of 1981, I terminated the sample in 1980.[17]

Following extensive literature on innovation, I first use the patent count as the primary measure of innovation quantity. To account for the heterogeneity in the quality of the innovation, I also calculate the number of patents weighted by the number of their forward citations under each subclass per year. Because of the delays in granting patents, I use a patent's application year rather than their grant year.

Admittedly, there are limitations to using patent counts to measure innovation. For example, patent counts do not directly measure changes in meaningful innovation. Thus, I follow standard practice in prior literature by using the number of forward citations as

[15] To be specific, these control classes include A61B1 (instruments for performing medical examinations of the interior of cavities or tubes of the body by visual or photographical inspection, e.g. endoscopes), A61B3 (apparatus for testing the eyes; Instruments for examining the eyes), A61B5 (measuring for diagnostic purposes; identification of persons), A61B7 (Instruments for auscultation), A61B8 (diagnosis using ultrasonic, sonic or infrasonic waves), A61B9 (instruments for examination by percussion; pleximeters), A61B10 (other methods or instruments for diagnosis, e.g. instruments for taking a cell sample, for biopsy, for vaccination diagnosis; sex determination; ovulation-period determination; throat striking implements), A61B13 (instruments for depressing the tongue), and A61B16 (devices specially adapted for vivisection or autopsy).

[16] A61F includes filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g., stents; orthopedic, nursing or contraceptive devices; fomentation; treatment or protection of eyes or ears; bandages, dressing or absorbent pads; first-aid kits.

[17] The Consumer-Patient Radiation Health and Safety Act of 1981, "directs the Secretary of Health and Human Services to promulgate: (1) minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures; (2) minimum standards for the certification of persons who administer radiologic procedures; and (3) Federal radiation guidelines concerning radiologic procedures." See https://www.congress.gov/bill/97th-congress/house-bill/2457/all-info, last accessed April 30, 2024.

a proxy for patent quality. Specifically, I exploit the information regarding the number of (cumulative) forward citations received by each patent until 2020. I took several methods to adjust the fact that patents typically would receive more citations in their early lifespan. Section 1.5.3 presents details about how I construct the key outcomes.

1.4.2 Comprehensive Universe of U.S. Patents Data

The other question I aim to answer is who are the primary contributors to any innovation changes following the RCHSA. This exercise requires information on the original assignee of each patent (if any). Only recently, the available patent data sets analyzed by economists facilitated this analysis. For example, the NBER patent database (Hall, Jaffe and Trajtenberg, 2001) begins to document information of individual inventors listed on patents generally issued from January 1, 1975. In my context, this feature imposes a challenge in distinguishing between individual inventors and firms.

Economists have recently developed novel databases extending to the earliest surviving records of the U.S. Patent and Trademark Office (USPTO) and derived rich information from these patent files. The Comprehensive Universe of U.S. Patents Data (CUSP) is one such example developed by Berkes (2018).[18] From the CUSP, I collect detailed information on the type of assignee and the number of forward citations received by each patent within the technology subclasses of my primary interest.

Following Babina, Bernstein and Mezzanotti (2020), I categorize all patents into two groups: independent patents and firm patents. The former group includes either unassigned patents, patents assigned to the inventor(s), or assigned to other individuals (e.g., angel investors). The latter one, by contrast, includes patents that are assigned to firms and are produced by inventors employed by firms with in-house R&D labs who would have been contractually obliged to assign their inventions to their employers at the time of the

[18]Other historical patent datasets include Akcigit, Grigsby and Nicholas (2017), Sarada, Andrews and Ziebarth (2019), Petralia, Balland and Rigby (2016), Marco et al. (2015), etc. For an excellent review, see Andrews (2021).

patent grant date (Babina, Bernstein and Mezzanotti, 2020; Lamoreaux and Sokoloff, 2001; Lamoreaux, Sokoloff and Sutthiphisal, 2008; Nicholas, 2010).

Meanwhile, I supplement the primary USPTO data with the CUSP assignee data, merging on the unique patent number. The main goal of this analysis is to identify whether domestic or foreign firms file a patent and examine whether, compared to foreign firms, domestic ones are more/less likely to respond to the RCHSA.

There are several reasons to implement this additional analysis. For example, there might be a variety of confounding factors differentially affecting my primary treatment and control groups, such as some technological breakthroughs for diagnostic radiation technologies. Patenting by foreign firms helps control trends taking place in a given technology area that is common to the US and foreign countries. Meanwhile, it is also reasonable to argue that along with the safety standards, the product liability risk might increase, thereby driving up patenting activities. In this regard, controlling for patenting by foreign firms may alleviate the concern because the US plaintiffs typically face more complexities and additional legal costs (such as matters of personal jurisdiction, conflicts of laws, and more significant difficulties in enforcing judgment) that make foreign producers less concerned about liability risk (Klerman, 2011; Galasso and Luo, 2022).

1.4.3 Data from Kogan et al. (2017)

Another key dataset enabling me to implement some firm-level analyses is from Kogan et al. (2017), which contains U.S. patents from 1926 to 2019 linked to the Center for Research in Security Prices (CRSP)-Compustat merged data and provides estimates of each patent's private value constructed from the response of assigned firms' stock market response to news about the patent issuance.[19] I also complement this dataset with firm-level financial information from the Compustat data and the CRSP data. Figure X provides how I construct the KPSS-Compustat sample.

[19]The dataset is available here: https://github.com/KPSS2017/Technological-Innovation-Resource-Allocation-and-Growth-Extended-Data, last accessed April 30, 2024.

Besides the patent count and the number of forward citations, I leverage information from changes in stock prices for the firms in the CRSP-Compustat data following patent issuance to estimate the private value of obtaining a patent. More precisely, the private value of each patent is given by the change in the firm's stock return attributable to the value of the patent in the three days after the patent issues times the firm's market capitalization on the day before the announcement that the patent issued. To calculate how much of the firm's stock return is attributable to the value of the patent, they filter each firm's stock returns to remove movements in the stock price that are unrelated to news of patent issuance. Finally, they adjust the filtered stock returns to account for the fact that the probability that the patent will be issued is already priced into the firm's market capitalization before the patent issuance.

1.4.4 National Hospital Discharge Survey

The last dataset, the National Hospital Discharge Survey (NHDS), was a national survey "*designed to meet the need for information on characteristics of inpatients discharged from non-Federal short-stay hospitals in the United States*" and was conducted annually from 1965-2010.[20] Ideally, I expect to extract information about a variety of medical procedures from the 1968, 1969, and 1970 waves. Yet such information was not published to the public and was only available from Moien (1974). I thus turn to digitize key statistics for a collection of non-surgery medical procedures: room and care service,[21] laboratory services,[22] pharmacy services,[23] radiology,[24] operating and/or recovery room,[25] professional services,[26]

[20]This data set is available here: https://www.cdc.gov/nchs/nhds/index.htm, last accessed April 30, 2024.

[21]The room and care charge include charges for room, food, nursing service, nursery, baby formula, and intensive care.

[22]The laboratory charge includes blood counts, serology, pathology, tissue examination, basal metabolism rate, electrocardiogram, electroencephalogram, and the like.

[23]The pharmacy charge includes items charged to drugs or pharmacies.

[24]The radiology charge includes items charged to diagnostic and therapeutic radiation, e.g., X-ray, cobalt, radium, and isotopes.

[25]The use of the operating and/or recovery room is covered by this item.

[26]Professional services include charges for such items as a staff physician, anesthetist, radiologist, and pathologist.

and all other services.[27] In the case of the RCHSA, the treatment group includes all radiology services, and the control group is comprised of all other medical services except for professional services, which include services provided by radiologists. The key outcome of interest in this sample is the total number of discharges from short-stay hospitals per year by various groups (e.g., sex, age, location, and types of hospitals). In Figure A13 and Figure A14, I provide a snapshot of the publication where I obtained the NHDS data.

1.4.5 Characterizing Patent Attributes

Besides assessing the overall effect on innovation induced by the RCHSA, the second primary goal of my paper is to understand whether the heterogeneity of innovations matters. To this end, I conduct an in-depth analysis considering the interplay among various innovations. Building upon prior research which suggests a complementary relationship between product and process innovations (Athey and Schmutzler, 1995; Hullova, Trott and Simms, 2016), I carefully classify patents in the treatment group into two distinct categories: risk-mitigating patents and radiation-generating patents. Admittedly, as argued in Galasso and Luo (2021), risk-mitigating technologies can "take various forms, depending on the nature of the hazards, the magnitudes of the demand changes, and the technological possibilities" and therefore could be both process and product innovations.[28] Radiation-generating technologies, in contrast, refer to those new devices or key components of x-ray medical devices relying on radiation emission. In Figure A8 and Figure A9, two concrete examples are provided to illustrate the idea of *risk-mitigating* and *radiation-generating*, respectively.

This categorization allows for a comprehensive examination of the interactions between different types of innovation and enables me to test the theoretical predictions outlined in Section 1.3. I adopt two distinct approaches to characterizing RMT and non-RMT patents,

[27]The other services are those items that are not assigned to previous categories, such as blood, oxygen, medical and surgical supplies, physical therapy, emergency room, and personal charges.

[28]For example, an assembly-line redesign that is more effective at identifying defects or using checklists during surgeries to reduce medical errors.

including a method based on classification code and a text-analysis keyword-search algorithm. In particular, the text-analysis algorithm provides two advantages: first, it allows me to capture patents that might not be explicitly classified as risk-mitigating or radiation-generating based on patent classification codes. Some patents might not be categorized accurately in the official classification system, but their textual content can reveal their nature. Second, technologies can evolve rapidly and might not be adequately captured by existing classification codes. By reading the detailed content, text analysis helps identify emerging innovations that might not yet have specific codes assigned to them. Overall, these two complementary methods ensure the robustness and validity of my results.

Classification Code

Following Galasso and Luo (2021), I first rely on the Cooperative Patent Classification (CPC) system to classify patent subclasses related to reducing radiation risk. Based on the technical descriptions of each subclass, I identify three such RMT subclasses: `A616/10` ("application or adaptation of safety means"), `A61B6/54` ("control of apparatus or devices for radiation diagnosis"), or `A61B6/58` ("testing, adjusting or calibrating apparatus or devices for radiation diagnosis").[29] Another eight parent subclasses under `A61B6` are categorized as non-RMT patents: `A61B6/14` ("Applications or adaptations for density"), `A61B6/40` ("Applications or adaptations for density with arrangements for generating radiation specially adapted for radiation diagnosis"), `A61B6/44` ("Constructional features of apparatus for radiation diagnosis"), `A61B6/46` ("Applications or adaptations for density with special arrangements for interfacing with the operator or the patient"), `A61B6/48` ("Diagnostic techniques"), `A61B6/50` ("Clinical applications"), `A61B6/52` ("Devices using data or image processing specially adapted for radiation diagnosis"), and `A61B6/56` ("Details of data transmission or

[29]Note I coded these RMT patents at the one-dot level, parent subclasses, instead of the more specific two/three-dot level, children subclasses. As described in Galasso and Luo (2021), this aggregation is reasonable "because a parent subclass contains residual patents that cannot be easily categorized into a specific children subclass and, therefore, may include broader patents that involve features of various lower-level children subclasses."

power supply, e.g. use of slip rings"). Based on their CPC subclasses, I then assign patents to RMT vs. non-RMT groups.

One limitation of this CPC-based approach, as highlighted by Berkes (2018), is that the CPC system does not provide information on the principal technological category of a patent. In other words, there may be an overlap between RMT patents and non-RMT patents, leading to potential double-counting in analyzing the impacts on different innovation types. For example, a patent that has both RMT and non-RMT characteristics might be counted in both categories, potentially inflating the innovation effect in both areas.

One patent (`US3304423A`), for example, "pertains to an X-ray shield and film holder for use in taking dental X-rays." In this regard, its primary purpose is to protect patients and operators from radiation risk. Yet the shield itself also "facilitates the aiming of the cone of an X-ray machine" and thus could be classified as non-RMT (i.e., improves features of radiation-generating equipment). In the Appendix Table 1.21, I re-estimate my primary results using alternative samples at the class-year level and ensure my results are valid.

Text-Analysis Method

Besides the issue of *double-counting,* the CPC approach could introduce another error: There may be some patents under other patent subclasses but emphasizing *risk mitigation* or *radiation reduction*. For example, patent `US389734` depicts a high strength low attenuation couch top, providing "a relatively low cost structure having a greatly enhanced strength to weight ratio and a lower transparency to X-rays." According to the claims, this patent can result in "lower radiation dose in the patient than previously possible," consistent with the idea of *risk mitigation*. However, it is categorized under `A61B6/0442` (supports, e.g. tables or beds, for the body or parts of the body made of non-metallic materials), which is irrelevant to mitigating radiation risk according to the CPC.

To address this issue, I developed and implemented a text-analysis algorithm to distinguish risk-mitigating and radiation-generating technologies. The primary advantage of this

text-analysis approach is by digging into raw patent files and reading the claims, one can access contextual information about the technology's purpose and intended use. Analyzing this text can provide more accurate insights into the innovation type and technological category of the patent. This approach is comprised of five key steps, described as follows:

Step 1. Data Preprocessing: I employed Optical Character Recognition (OCR) software to convert all patent files under `A61B6` into readable text files. I then applied preprocessing steps to clean and normalize these text data (i.e., removing punctuations, removing stop words, lower casing, tokenization, and stemming).

Step 2. Keyword Identification: I extracted a list of keywords closely related to "risk-mitigating" by following Galasso and Luo (2021), reading patent files, and self-determining. The final list includes: "shielding", "shield", "mitigate", "mitigating", "safety", "safe", "reduce", "reducing", "low-dose", "protect", "protecting", "protection", "reduction", "reduce", "reducing", "overexposure", "block", "blocking", "control", "controlling", and "hazard."

Step 3. NLP Model Training: Using the preprocessed patent data under three "risk-mitigating" subclasses (`A61B6/10`, `A61B6/54`, and `A61B6/58`), I trained my `word2vec` model which captures semantic relationships between words. This `word2vec` model learned to represent words in a continuous vector space based on their distributional patterns in the patent text.

Step 4. Vectorization of Keywords and Patent Texts: The dataset used to test my model includes all patent files under other subclasses of `A61B6`. I vectorized both the keywords and each preprocessed patent document, using their word vectors from the trained `word2vec` model. These word vectors represented the semantics of the keywords, as well as my patent data.

Step 5. Relevance Scoring, Ranking, and Selection: Based on the cosine similarity between the vectorized representations of patent documents and the vectorized representations of keywords, I calculated relevance scores for each patent. These relevance scores

indicated how closely each patent document was related to the specified keywords emphasizing safety features. I next ranked the patent documents based on their relevance scores, with higher scores indicating higher relevance to the keywords. I selected the top 300 and termed them as the additional *risk-mitigating* patents.

1.4.6 Motivating Evidence

Figure 1.1 displays some motivating evidence on diagnostic x-ray device patents and other broad categories of patents during the historical episodes I study. The total number of patents are all normalized to the 0-1 scale (1960-1990).[30] The dashed vertical line encompasses the year associated with the regulatory shock in X-ray patenting. The solid line denotes the evolution of patent counts under `A61B6`. The dashed line represents the case for all non-radiation diagnostic device patents. It is clear that from 1968 to 1976/77, there were substantial increases in the rate of `A61B6` patenting, while changes in the rates of patenting in non-A61B6 diagnostic devices were not that striking.

Interestingly, we can also observe a sharp decline in the patenting rate of diagnostic X-ray medical device patents since 1976/1977. One potential explanation for this drop is the passage of the Medical Devices Amendments (MDA) of 1976, consolidating and expanding existing Federal authority over medical devices into a comprehensive system of regulating the safety and effectiveness of medical devices in proportion to the degree of risk that they pose. This classification regime based on medical devices' risks may trigger increased approval costs (or say, approval delay in commercialization), thereby deterring entry and chilling innovation. The decline in patenting rates in diagnostic X-ray devices might also be attributed to the temporary nature of this innovation wave. Firms initially responded to new safety standards, focusing their innovation efforts on compliance and prioritizing the development emphasizing safety features. However, as these standards became more established and integrated, the necessity for ongoing innovation in risk mitigation faded out over time. This observation

[30] I also normalized all values to the mean and derived similar patterns.

underscores the need to consider the dynamic and evolving nature of innovation in response to regulatory changes, somewhat consistent with prior work from Finkelstein (2004).

1.5 Empirical Strategy

This section outlines the primary empirical specifications for analyzing the effects on patent counts, attributes, and quality. I then acknowledge and address some challenges in establishing causal evidence.

1.5.1 Specification for Patent Counts

To empirically identify the causal effects of the RCHSA on patent counts, I first employ a baseline difference-in-differences (DID) specification. This identification strategy is in the same spirit as the empirical innovation literature (see, for example, Finkelstein (2004) and Galasso and Luo (2022)).

$$log(Count_{sct+1}) = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{1.6}$$

where s denotes patent subclasses, c represents aggregate patent classes, and t indexes years. $log(Count_{sct+1})$ is the key outcome of interest, the (log of) patent counts filed under each subclass-class pair sc in year $t+1$. Treat_{sc} is an indicator of whether the patent subclass-class pair is under `A61B6`, and $Post1969_t$ indicates whether the RCHSA was in effect (after 1969) in year t. ρ_{sc} and η_t are patent subclass and year fixed effects, respectively. Therefore, β would identify the impact of the RCHSA on patenting activities associated with diagnostic medical equipment based on x-rays. $\beta > 0$ implies that innovation activities increase post the RCHSA, whereas $\beta < 0$ implies that the RCHSA has a negative effect on the treated patents under `A61B6`.

Additionally, I use a Poisson regression, which is the preferred statistical model for count data, to check the robustness.[31]

[31] As mentioned in Chen and Roth (2023), log-like transformations for dependent variables including zeros might be technologically problematic. I alternatively estimate my results using raw patent counts as the

$$E[Count_{sct+1}|X_t] = exp(\alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct}) \tag{1.7}$$

Of course, how to choose the appropriate control group, which serves as the counterfactual development of patent counts for diagnostic radiation medical devices, is a critical and delicate task that significantly influences the interpretation of my estimates. In other words, the control group might be "contaminated" by the enactment of the RCHSA for several reasons.

First, medical device firms that patent both diagnostic x-ray devices and other products in the control group should be considered. Such firms may respond to the safety regulation in patenting activities for the treatment and control groups. If diagnostic x-ray devices and other medical products share technical similarities in production, a resulting surge in `A61B6` patenting can generate positive spillovers (i.e., the *complementarity* across different technologies).[32] Therefore, a positive coefficient (β) indicates a relative change in `A61B6` patenting, rather than a full increase in innovation. By contrast, if medical device firm reallocates their resources from non-radiation devices to diagnostic x-ray devices, such a *substitution* effect would generate a decline in patenting in the control group, indicating a change in the direction of innovation overall.

Second, whether treated and control patents in my setting are *complementary* or *substitute* also hinges on the demand-side environment characteristics. If this policy shock induced healthcare facilities to increase the use of radiation-based diagnostic equipment due to the quality-assurance effect, one may expect a decline in the demand for some substitutes of x-ray medical devices (e.g., other non-radiation diagnostic devices). This demand-pull spillover may incentivize manufacturers to shift resources towards radiation-based devices

dependent variable and my estimates are consistent in terms of magnitude and interpretation. Results from these robustness checks are available upon requests.

[32]For instance, if a new component of diagnostic x-ray devices can also be applied to other non-radiation devices, firms may be more incentivized to develop the technology for both types of products simultaneously. As a result, they may increase patenting activities in both `A61B6` and other technological classes in the control group.

and thereby dampen innovation in the control group. Yet, if there are certain medical products that complement the use of x-ray devices, the quality assurance effect can generate *positive* spillovers. In either case, the interpretation of my results is biased.

1.5.2 Specification for Patent Attributes

Besides the patenting rates described above, I am also interested in whether and how the RCHSA affected innovation activities associated with some key patent attributes. In particular,

To conduct this analysis, I employ the difference-in-differences method outlined in equation 1.6 and equation 1.7.

$$log(Count\ with\ an\ Attribute_{sct+1}) = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{1.8}$$

$$E[Count\ with\ an\ Attribute_{sct+1}|X_t] = exp(\alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct}) \tag{1.9}$$

The only distinction is that instead of calculating the number of all patents filed under subclass in year t, I focus on the number of patents exhibiting the attributes of interest (e.g., risk mitigation) within a specific patent subclass sc in year t within a patent subclass sc in year t.[33]

Ideally, one might expect constructing a reasonable control group to align precisely with the outcome of interest described in equation 1.8. However, this task is not quite feasible in my setting: the characteristic of risk mitigation (or non-risk mitigation) is a particularly narrow and technology-specific attribute. To underscore this point, I conducted a random selection of 25 patent filings per subclass within my primary control group (i.e., diagnostic medical devices based on non-radiation technologies) and performed the text analysis described above for these selected filings. The results indicated a notably low relevance

[33]This approach is in the similar spirit to Galasso and Luo (2021), who directly compared patent counts of RMTs with patent counts of non-RMTs in response to a set of over-radiation accidents involving CT scanners in late 2009.

score associated with "risk-mitigating" among those patents, further reinforcing the nature of RMT as a *subclass-specific* attribute.

Given this constraint, I opt to maintain patent counts as the principal metric while estimating the impact on patent attributes using the difference-in-differences (DID) specification. I would like to acknowledge that interpreting the magnitude of these DID estimates requires caution. The β coefficients in equation 1.8 and equation 1.9 encapsulate changes in the number of patents with specific attributes in response to more stringent safety standards relative to patent counts of other non-diagnostic medical devices. Given that patents within this control group lack relevance to radiation risk mitigation, any observed changes associated with β represent *absolute* increases or decreases.

1.5.3 Specification for Patent Quality

It is crucial to keep in mind that a rise or drop in patent counts does not necessarily represent changes in *meaningful* innovation. To address this concern, I begin by following the standard practice in the literature and using forward citations as a proxy for patent quality. As briefly mentioned in 1.4.1, I construct two sets of outcomes: the age-adjusted forward citations received per patent and the private market value associated with patent issuance.

When using age-adjusted forward citations as the metric of patent quality, I check the heterogeneous effects on patent counts across the *distribution* of patent quality. To do so, I first remove *application year* and *patent-class* effects and identify the (filtered) citation distribution to which each patent belongs. Concretely, I collapse all raw forward citation data to the class-year cell and then characterize the median of citation counts for each patent class in year t. In other words, I compare the number of citations each patent receives relative to its cohort (i.e., all patents applied under the same patent class and within the same calendar year). I further determine if the number of citations received by each patent is below or above this class-level median within the cohort (measured by the year of application) and separate

the below-median observations and the above-median observations for each patent subclass every year. Eventually, I re-collapse these data to the subclass-year cell. This method results in two distinct samples for each patent subclass: a "high-quality sample" and a "low-quality sample." These samples enable a detailed examination of how the RCHSA affected patent counts across different levels of patent quality. Once patents are allocated to these citation-based categories, I estimate the effect of the RCHSA on patent counts separately for the "below-median" sample and the "above-median" sample, employing the same specifications outlined in equation 1.6 and equation 1.7.

I also construct the share of high-quality patent counts for each subclass-year cell and estimate the following regression specification:

$$Share_{sct+1} = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{1.10}$$

$$\mathbf{1}_{Share_{sct+1}>0} = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{1.11}$$

where $Share_{sct+1}$ is the intensive margin — the share of high-quality patents, and $\mathbf{1}_{Share_{sct+1}>0}$ is the extensive margin, indicating whether the propensity to innovate is positive within a subclass-year cell. Using these alternative metrics ensures we capture the *relative* changes in the number of high-quality patents filed under each subclass per year evolved following the RCHSA.

When turning to the private market value as the dependent variable, I use the KPSS-Compustata sample, where the unit of observation is firm-class-year. The corresponding empirical specification is:

$$log(private\ market\ value_{isct+1}) = \alpha + \beta Treat_{sc} \times Post1969_t + \theta_i + \rho_{sc} + \eta_t + \epsilon_{isct} \tag{1.12}$$

where i denotes firm, sc represents patent subclass, and t indexes year. In addition to controlling for subclass fixed effects (ρ_{sc}) and year fixed effects (η_t), I have the flexibility to incorporate firm fixed effects (θ_i) due to the panel nature of the current sample. Consequently, the key coefficient β captures the causal effect of the RCHSA on the one-year lagged market value among publicly traded firms.

1.5.4 Threat to Identification

Admittedly, there are several concerns and limitations related to my identification strategy listed above. In this subsection, I discuss how to address some of them in turn.

Parallel Trends Assumption: The key assumption of a stylized DID framework states that in the absence of the policy shock, there should be no differences in patenting rates between the treatment and control group. To test this assumption, I employ an event study specification shown in equation 1.13:

$$log(PatentCount_{sct+1} + 1) = \alpha + \sum_{i=-8}^{11} \beta_{t+i} Treat_{sc} \times year_{t+i} + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{1.13}$$

where $year_{t+i}$ is a set of indicators denoting whether a year is the i^{th} year before or after the enactment of the RCHSA. In this specification, the baseline year is 1969 and the coefficient associated with one year prior to the treatment has been normalized to zero. This event-study approach offers several advantages over a standard difference-in-differences (DID) model. It provides a more flexible and transparent depiction of the data, ensuring that the assumption of parallel trends is satisfied in the context of this study. Additionally, it accounts for any dynamic effects that may arise due to the RCHSA.

Confounding Factors: It is possible that other concurrent shocks could affect the patenting activity of my treatment and control groups differently. If the subclass and year-fixed effects cannot fully capture such confounding factors, one would expect a correlation between $Post1969_t$ and the error term ϵ_{sct}.

For example, there might have been technological breakthroughs or other large-scale policy changes for some specific technologies that drove up the growth of patent counts in either the treatment or the control group after 1969. One such example is the introduction of computed tomography (CT) technology in the early 1970s, which revolutionized medical imaging.[34] To address this issue, I investigated the robustness of my findings by excluding the

[34]The first CT was invented in 1972 for head scanning. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8555965/, last access April 30, 2024.

subclass associated with CT, specifically `A61B6/03`, from the treatment group. Moreover, my event study analysis showed an increase in patenting activities under `A61B6` one year right after the RCHSA. The timing of these effects indicates even in the absence of CT, we could observe the positive effect on innovation. I also re-scale my analysis to the class-month-year analysis and directly restrict the sample period to 1965-1971.[35] Eventually, I used a triple difference-in-differences specification, where foreign firms serve as the additional control group, to ensure any technology breakthrough could be controlled. Taken together, all four pieces of evidence demonstrate the robustness of my results, thereby alleviating concerns due to the introduction of CT.

1.6 Results

This section first presents my main estimates for the overall effect on patent counts associated with diagnostic X-ray medical devices. In Section 1.6.2, I then discuss how two key patent attributes, the mitigation of radiation risk and the generation of radiation, are affected by more stringent safety standards. Finally, regarding patent quality, I present estimates based on the empirical specifications listed in Section 1.5.3.

1.6.1 Effects on Patent Counts

In Table 1.1, I describe my main results regarding the effects on patent counts. The estimates are derived from the specification listed in Section 1.5.1. Panel A reports the coefficient estimates based on raw patent counts, and Panel B shows all results when using the number of patents weighted by the number of their forward citations, an alternative measure of patent quantity that considers the innovation's quality.

In the first three columns, I use the baseline OLS model to quantify the effects on patent counts, measured as the natural logarithm of raw/citation-weighted patent counts. Shifting to the last three columns, a Poisson model is employed to account for the skewness

[35] I choose the starting point as 1965 to mitigate the concern that including observations prior to 1965 might introduce more confounding factors due to Medicare (in effect since 1965).

of my count data. Throughout these columns, I incorporate three distinct control groups to test the robustness of my findings: "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" refers to medical implants (under patent class `A61F`), and "Drugs" pertains to drugs (e.g., medicinal preparations containing organic active ingredients) under class `A61K`.

As illustrated by the estimates in Panel A of Table 1.1, there is a remarkable, significant upsurge in patenting rates across all specifications: the RCHSA resulted in a statistically significant increase of 79.9% (= exp(0.587)-1) in the number of patents filed relating to diagnostic x-ray medical devices, in comparison to other non-radiation diagnostic medical equipment. Equivalently, the RCHSA led to 1.33 additional patents per subclass every year (the pre-treatment average number of patents under `A61B6` is 1.66 per subclass every year). This indicates that the imposition of more stringent (enforceable) product safety standards has positively affected overall patenting activities within my particular context. Panel B of Table 1.1 provides the results for citation-weighted patent counts. The effect is slightly larger: having the RCHSA in place indicates a statistically significant increase in the quality-adjusted innovation measure by at least 123.89% (= exp(0.806)-1).

I implement two sets of exercises to address the concern of spillovers across patent classes or technology types. Firstly, throughout the main analysis, I exclude two patent classes (`A61B5` and `A61B8`) in the control group composed of non-radiation diagnostic medical device (NR-DME) patents. This is because, according to the USPTO, these two classes are most likely to share *technological similarities* with A61B6, thereby more likely to be exposed to spillovers under the RCHSA. When including them in the NR-DME control group, the magnitude of my estimates shrank substantially: the RCHSA led to an increase in the patenting rate of diagnostic medical devices by 52.81% (=exp(0.424)-1) or equivalently, 0.88 more patents per subclass every year. This change in the magnitude suggests some positive spillovers imposed by the RCHSA on `A61B5` and `A61B8`; the point estimate 0.424 reflects a *relative* increase in radiation-based medical device patents.

Further, I consider "drugs" as the least *contaminated* control group. The observed difference in magnitude may then encapsulate several spillover effects on other conceptually unaffected patents.[36] At first glance, comparing the estimates in column (3) and column (6) reveals a smaller increase in patenting rates when using non-radiation diagnostic medical equipment as the control group. This evidence suggests that the RCHSA can impose some *positive* spillovers on the conceptually "clean" group. The channels at play are at least twofold. On the supply side, firms can pool resources in innovation activities and research and development (R&D), such as labor, financial resources, equipment, technologies, etc. The innovation triggered by the RCHSA among radiation-based medical devices may further stimulate technological development for others. On the demand side, shifts in consumer risk perception following the RCHSA may lead radiologists and physicians to be more cautious about over-radiation, resulting in a greater hesitancy to prescribe relevant medical practices. Patients might also overestimate the radiation risk of such devices and opt for their substitutes (e.g., non-radiation diagnostic equipment). In either scenario, the expected expansion in market size for these non-radiation substitutes has the potential to drive an upsurge in innovation.

Meanwhile, the RCHSA appears to have a potentially negative spillover effect on innovation in medical implants. This effect can be attributed to two primary mechanisms: the substitution effect in production and the complementary effect on the demand side. The substitution effect suggests that the RCHSA might chill innovation in specific medical implants or redirect innovation efforts toward x-ray diagnostic products. This reallocation of resources could occur if a substantial portion of resources is invested into one area, consequently crowding out the resources available for developing other technologies. On the demand side, if medical implants and X-ray diagnostic devices complement each other, a decrease in demand for X-ray devices would lead to a drop in demand for medical implants.

[36]Here, regarding the least "contaminated" control group, it means drugs may share fewer technical similarities with diagnostic radiation medical devices on the supply side. On the demand side, it's also reasonable to argue that drugs are less likely to be prescribed alongside diagnostic X-ray medical practices as a substitute or complementarity.

This, in turn, could significantly reduce the market size for implants and hinder innovation activities.

Figure 1.2 plots results based on my event-study specification. Overall, the trend of these point estimates closely corresponds with the evidence presented in Figure 1.1. Prior to the passage of the RCHSA, there were no discernible differences in patenting rates between the treatment and control groups.[37] When safety standards were in effect, one can see an immediate significant rise in the patenting rate of X-ray machines. It is worth noting that in the 1960s, the average application-grant lag in patenting was approximately 2.14 years for diagnostic X-ray machines. Therefore, this jump in patent counts cannot be attributed to an anticipatory effect, whereby companies rushed to patent their existing technologies, emphasizing safety features in anticipation of the regulation.

Another noteworthy feature of these event-study estimates is that starting from 1976, the positive innovation effects began to fade out over time. As mentioned in section 1.4.6, it might be attributed to either the enactment of the 1976 Medical Device Amendments or the dynamic nature of medical innovation.

1.6.2 Effects on Patent Attributes

Apart from the direct effects on patent flows/counts, I argue earlier in Section 1.3 that the RCHSA could distinctively change the development of new technologies emphasizing different attributes. In particular, these key attributes have important implications for firms' strategies in the presence of stricter safety regulations. Empirical evidence regarding this theoretical prediction is presented in this subsection.

Risk-Mitigating Technologies

In Table 1.2, I summarize my estimates for the impact on risk-mitigating technologies following the RCHSA. Panel A and B present results based on the CPC approach and the

[37] From onwards, I define my primary control group as including all patents related to non-radiation diagnostic medical equipment.

text-analysis approach, respectively. In the first three columns, the key outcome of interest is the probability of having any patent applied under a subclass in year t; the dependent variable in the last three columns is the natural logarithm of raw patent counts. In line with the main result for the overall patenting rate in Table 1.2, I choose three control groups: non-radiation diagnostic medical devices, medical implants, and drugs.

As shown in column (1) - column (3), the number of patents with the risk-mitigating feature significantly increased, both statistically and economically. Across all specifications, this result is consistent and indicates in response to the stricter safety standards, the raw count of patents emphasizing radiation risk mitigation and consumer protection increased by 64.2% (= exp(0.496)-1) (column 1 in Panel A) relative to other non-radiation diagnostic medical equipment. Comparing results in Panel B to those derived from the CPC approach (Panel A), although the magnitude of my estimates slightly declines, both the direction and the significance remain consistent and robust. This finding is aligned with my theoretical prediction: risk-mitigating technologies serve to cope with the increased (expected) damage costs induced by the RCHSA. Later in Section 1.7, I will elaborate on this channel in greater detail and provide more supporting evidence.

When considering the interpretation of the magnitude, it's interesting to note that the magnitude of my estimates is similar when using NR-DME and drug patents as the control group. Meanwhile, the estimate is larger when using medical implant patents as the control group, again suggesting the potential negative spillovers on these medical technologies. This pattern aligns well with my results shown in Table 1.1.

Radiation-Generating Technologies

As shown in Table 1.3, the enactment of the RCHSA also induced a statistically significant increase in patent flows associated with *radiation-generating* technologies under the broad patent class `A61B6`. This increase amounted to 72.1% (= exp(0.543)-1) relative to all other non-radiation medical device patents. Once again, comparing these estimates across

different control groups suggests that the RCHSA had spillover effects on other technologies, including non-radiation diagnostic medical equipment and medical implants.

Upon examination of estimates related to radiation-generating devices and risk-mitigating technologies, it is interesting to note a similarity in magnitude (0.496 vs. 0.543 when using non-radiation diagnostic medical device patents as the primary control group). These findings appear to imply that under the RCHSA, technologies reducing radiation exposure are developed simultaneously with new X-ray devices.

Following the specification outlined in equation 1.13, again, I provide evidence against the concern that pre-existing trends drove increases in X-ray medical device patenting since the passage of the RCHSA. All the coefficient estimates associated with those pre-treatment indicators are not statistically different from zero. Meanwhile, the dynamic effects presented in Figure 1.4 also closely resemble those shown in the case of risk-mitigation technologies (Figure 1.3): the patenting rate only temporarily and slightly rose one year after the enactment of the RCHSA and then dropped (although not statistically significant). It was not until four years after the passage of the RCHSA (approximately 1973) that one could observe another wave of new technologies. Such similarities in patent flow between innovation emphasizing safety features and production innovation further indicate there's a good chance that these technologies are complementary in production.

Innovation Complementarity in Production

Why would one expect stricter safety standards can induce an increased rate of patenting among technologies emphasizing radiation-generating? As highlighted in the theoretical framework in Section 1.3, this pattern could be explained by the complementarity of innovations: When firms adopt RMT as a strategy to avoid defective products and reduce compliance costs, the marginal benefit of producing new devices relying on radiation generating also rises, thereby spurring product innovation.

To fix ideas, consider an example emphasizing both features: on December 28, 1968, General Dynamics Corporation filed a patent, namely US3567941A (the patent file is presented in the Appendix Figure 1.5).[38] According to the abstract, this is

> "A readily conveniently table nonelectrical radiographic device for exposing X-ray sensitive film by utilizing a radiation source which *emits electromagnetic radiation* at or near the X-ray region (such as pure thulium 170 as the preferred source) as a gamma ray emission source and which incorporates *multiple safety features* integrally interrelated in such a manner as to enable a relatively untrained operator to utilize the machine or exchange power sources."

The device described above apparently encompasses both the risk-mitigating feature and the radiation-generating trait, thereby being assigned under two distinct subclasses (A61B6/06 and A61B6/107). If the number of patents with both of these characteristics increases following the RCHSA, it is possible that the two features are positively correlated and complementary to each other in the production process. After examining patent files under A61B6, I have identified 86 patents that possess these particular features and have depicted their patenting trend in Figure 1.5. This suggests a strong connection between the two features.

In Table 1.4, I provide more empirical evidence supporting this channel. The outcome of interest is the number of patents filed under patent class c in year t. Instead of including all `A61B6` patents in the treatment group, I restrict my attention to this subset of patents encompassing dual features and categorize them as the treated class. In the first three columns, I report my point estimates with the OLS model and the results using a Poisson model in the last three columns. Across all columns, it is quite evident that the RCHSA indeed led to a rise in counts of patents with both risk-mitigating features and radiation-generating traits by at least 56.6%. These results show that introducing stricter product

[38]The patent file is available here: https://patentimages.storage.googleapis.com/a3/36/9a/13a0f52673f1ad/US3567941.pdf, last accessed April 30, 2024.

safety standards can simultaneously inflate the patenting rate for both RMT and product innovation, underscoring the complementary nature of these two types of innovations.

I also present some firm-level evidence to demonstrate the complementarity of risk-mitigating technologies and new radiation-based devices. In Table 1.5, I focus on a subset of publicly traded firms in the Compustat-KPSS sample, satisfying the following two conditions: (1) the firm has a prior patenting history in medical devices emitting radiation, and (2) the firm has data available throughout the sample period, 1960-1980. Overall, I find among these firms that are most likely to have "defective products," the patenting rate for risk-mitigating technologies increased significantly. At the same time, the patenting rate for radiation-generating technologies also experiences a rise with a similar magnitude. This additional evidence further demonstrates the complementarity channel at the firm level.

1.6.3 Effects on the Quality of Innovation

Beyond the quantity of innovation activities, I also follow the extensive literature on innovation and test if the safety regulation affects the quality of innovation. Essentially, the efficacy of such regulations in promoting innovation hinges on whether they foster high-quality patents that stimulate *radical innovation* or merely generate minor patents that yield limited impacts, that is, *incremental innovation*.

The Distribution of Patent Quality

A standard measure of patent quality is the number of forward citations received by each patent (Pakes and Griliches, 1980). Yet, this metric is not free of concern. One notable limitation is namely the first-mover effect: the first papers/patents in a field will receive citations at a rate enormously higher than papers/patents published later, regardless of their actual content, quality, and value (Newman, 2009, 2014). To account for this bias, I

follow the method proposed by Galasso and Luo (2022) and check the heterogeneous effects on patenting rates across the entire distribution of citations.[39]

The basic idea is straightforward: we aim to "normalize" citation counts by the average number of citations received by all patents in the focal patent's application year. To this end, I first allocate each patent to its respective citation distribution within its cohort (i.e., all patents applied under the same patent class in the same year) and classify whether it falls into the category of low quality (below the median of citations) or high quality (above the median of citations). I then aggregate all low-quality and high-quality patents at the subclass-year level, respectively. This way, I constructed two primary samples whose unit of observations is subclass-year. In the low-quality sample, each observation corresponds to the count of low-quality patents filed under subclass sc in year t. The high-quality sample, in contrast, includes the count of high-quality patents applied under a subclass per year.

Results based on this metric are shown in Table 1.6. Across all columns, the dependent variable is the natural logarithm of patent counts. A Poisson model is applied to account for the highly skewed distribution of my data. I present my estimates in the first two columns, using all `A61B6` patents within the treatment group. Interestingly, higher safety standards appear to favor innovation among high-quality patents, with an increase of 88.6% in the patenting rate. When moving to patents emphasizing the mitigation of radiation risk, the magnitude of changes in patenting rates among low-quality patents is almost identical to that of their high-quality counterparts. In the last two columns, we can again observe that the rise in patent counts among the high-quality ones is slightly more prominent. Taken together, this exercise reveals at least two patterns: First, the innovation effect is universal across the industry (i.e., all diagnostic X-ray medical devices are affected). Second, stricter safety standards favor high-quality patents, especially those emphasizing radiation generation (i.e., product innovation).

[39] Alternatively, I estimate the impacts of the RCHSA on the number of forward citations per patent and the citation-weighted patent counts (now shown in this paper): Neither of these estimates is statistically significant. These insignificant results might be partially due to the structure of my citation data and thus reinforce the necessity to consider the "*first-mover*" effect in measuring innovation quality.

Table 1.7 summarizes my results regarding the impact on the share of high-quality patents. The dependent variable is the likelihood of having at least one high-quality patent in a subclass-year cell in odd-numbered columns, while the even-numbered columns show the log of the share of high-quality patents. Overall, these point estimates imply the propensity to have high-quality patents rose significantly when the RCHSA was in effect (by 17.4 percentage points).

Private Market Values

When analyzing companies listed on American stock exchanges, I utilized the patent market value from Kogan et al. (2017) as a measure of patent quality. This metric uses the excess stock returns for patenting firms on the date of the patent's issuance date recorded in the USPTO official gazette.

In Table 1.8, I separately provide the coefficient estimate for all `A61B6` technologies, risk-mitigating technologies, and radiation-generating technologies. These results all point to the fact that in response to the RCHSA, the quality of patents filed by publicly traded firms improved. To be concrete, the market value increased by 2.3%, 1.1%, and 2.1%, respectively. Taken together, my empirical findings based on both the forward citations and private market value highlight imposing safety standards has the potential to bolster patent quality.

1.6.4 Who Invented?

Recall the premise of my theoretical framework: firms respond to regulatory pressure by innovating. In this subsection, I present supporting evidence to echo this theoretical argument.

To start, I will check directly whether the main contributors to this surge in innovation are firms or independent inventors. By reading the inventors' and assignees' names of each patent of interest, I manually separated these patents into two groups: independent and firm.

As briefly mentioned in Section 1.4.2, independent patents refer to those either without any assignee, assigned to (original) inventors, or assigned to other individuals (i.e., investors). By contrast, I define all patents initially assigned to firms as *firm* patents. This category typically includes patents from inventors employed by firms with in-house $R\&D$ labs and are obliged to assign the invention to their employers by contract.

$$Firm_{i,sc,t+1} = \alpha + \beta Treat_{sc} \times After1969_t + \theta_{sc} + \mu_t + \epsilon_{i,sc,t} \tag{1.14}$$

Equation 1.14 lists the main specification in this analysis. The dependent variable is an indicator of whether the inventor is a firm. I control for both patent subclass fixed effects and year fixed effects. Put differently, I aim to check the composition effect of the RCHSA with this specification.

The main results are presented in Table 1.9. Column (1)-(3) report the point estimates for β with the treatment group as all `A61B6` patents, `A61B6` patents emphasizing safety features, and `A61B6` patents capturing the trait of "radiation generation," respectively. Throughout all the columns, one can tell it is firms that primarily contribute to the policy-induced innovation activities. The probability of being a *firm* patent increased by 17.8 percentage points if a patent is under any subclass of `A61B6`. This pattern is consistent among `A61B6` patents emphasizing safety features and addressing radiation generation.

I also re-run the regression specified in equation (6) but focus on firm patents and individual patents separately. Table 1.10 then summarized these results. In column (1), (2), (4), and (5), the regression specification is the baseline DID model; in column (3) and column (6), a triple DID is applied:[40]

$$\begin{aligned} log(Counts_{f,sc,t+1} + 1) =& \alpha + \beta_1 Treat_{sc} \times After1969_t \times Firm_f + \beta_2 Treat_{sc} \times After1969_t + \\ & \beta_3 Treat_{sc} \times Firm_f + \beta_4 Firm_f \times After1969_t + \theta_{sc} + \mu_t + Firm_f + \epsilon_{f,sc,t} \end{aligned} \tag{1.15}$$

[40]To implement this triple DID analysis, I reconstruct my primary sample: I append the sample composed of all individual patents to the one that including all firm patents. In other words, I have another balanced panel whose unit is patent-subclass.

Results for the baseline DID model indicate that we can observe an upward surge in innovation activities among firms along both the extensive and intensive margins (column 1 and 4). Conversely, a decline in the outcome of interest is consistently observed (column 2 and 5) among individual patents. The point estimates from column 3 and column 6 reinforce these patterns: Compared to individual patents, the increase in patenting rate is more evident among firm patents.

In summary, the distinction between the responses of firms and individual inventors in innovation underscores two key points: First, firms are indeed actively involved in developing and patenting more relevant technologies following the RCHSA, which is in line with the theoretical argument I presented. Second, individual inventors' lack of response or even negative response suggests that the RCHSA might impose some adverse effects on (local) angel investors. For example, a more stringent and rigid regulatory environment can reshape local investors' risk perception toward new projects for radiation-related products. If such investors exhibit more concerns about radiation risk in general, a decline in the supply of external funding might hinder innovation from independent inventors. This argument is consistent with a prior agenda claiming that (local) angel investors are the key source of financing/marketing for independent inventors (Babina, Bernstein and Mezzanotti, 2020; Nicholas, 2010).

1.7 Mechanisms

1.7.1 Regulatory Compliance Costs

To start, I provide some qualitative evidence about the increasing compliance costs imposed by the RCHSA. According to United States. Department of Health and Welfare (1973), enforcement and compliance actions were taken right after the passage of the RCHSA.

> " ... Fifty-eight manufacturing plant inspections were made during 1972 involving 45 microwave oven manufacturers, 12 television receiver manufacturers, and one cold-cathode demonstration tube manufacturer ... At the end of 1972, there were 28 active compliance investigations involving defects, noncompliance with

a performance standard, or test program disapproval ... 7 cases involve dental X-ray equipment, 4 involve medical X-ray equipment investigation ..."

" During the past year (1972), eight compliance actions were initiated involving medical and dental X-ray equipment. In one compliance case, a pinhole radiation leak was discovered in the tube housing of a diagnostic X-ray machine, creating the possibility of unnecessary exposure to patient or operator. Six compliance cases were initiated against the importers and distributors of a dental X-ray machine. In another compliance case, a fluoroscopy table was found to have an unacceptable failure rate, which could expose a patient to up to 2-1/2 times the required radiation. The manufacturer is replacing the defective diode in all machines in order to correct the problem."

In light of these descriptions, the FDA acted to go against the radiation risk associated with defective devices and components. To provide more quantitative evidence, I revisited my primary results in Table 1.2: In the treatment group, I only include patents under two subclasses `A61B6/54` ("control of apparatus or devices for radiation diagnosis") and `A61B6/58` ("testing, adjusting or calibrating apparatus or devices for radiation diagnosis"), which both directly emphasize *controlling and lowering radiation emissions*, instead of protecting patients with *external safety apparatus* (e.g., shield under `A61B6/10`). In Figure A11 and Figure A12, two examples of the `A61B6/54` patent and the `A61B6/58` patent are presented.

As shown in Table 1.11, the patenting rate increased by 65.9% (= exp(50.8)-1) among subclass `A61B6/54` and `A61B6/58` (column (3)), relative to that of other diagnostic medical device patents. The magnitude of these estimates is quite similar to that of my main results (shown in column (1)). This additional evidence demonstrates manufacturers are incorporating "new means", which can directly reduce radiation emissions, to lower compliance costs in response to the regulation.

1.7.2 Litigation Risk of Defective Products

The first alternative channel through which the RCHSA increased firms' innovation incentives is by amplifying litigation risk associated with defective products. It is noteworthy that when referring to litigation risk, I refer to cases arising from *private litigation* due to product liability (Viscusi and Moore, 1993). The concern here is two-fold: first of all, the initial GE recall in 1967 not only triggered the enactment of the RCHSA, but also scaled up litigation risk associated with all electronic products emitting radiation. Second, the RHSA *per se* can substantially change the legal environment, thereby inducing a spike in liability risk.[41]

In terms of the relationship between litigation risk and innovation, several prior studies provide some insights. For example, Viscusi and Moore (1993) argue that when the litigation risk is sufficiently low, the correlation between innovation intensity and litigation risk is positive. Galasso and Luo (2022) found that in the context of medical implants, liability risk can percolate throughout a vertical chain and impose a significant chilling effect on downstream innovation. Rogers (2023) documented the fact that when being exempted from litigation risk, firms would respond positively in innovation.

Private Litigation Targeting X-ray Medical Devices

To empirically explore this mechanism, I collect information from Westlaw on the number of federal/state cases involving GE as one of the defendants and general X-ray medical devices.[42]. In particular, I searched the database using two keywords in the full text: General Electric (and other variations of the company's name) and X-ray medical device(s). I primarily focus on lawsuits in the following categories: personal injury/health care/pharmaceutical personal injury/product liability; personal injury/product liability, personal property/product liability, and contract/product liability.

[41]For example, the 1960s and 1970s were decades of "tumult in products liability law." Courts were transforming a negligence regime into a strict liability regime based on product "defect" rather than manufacturers' or retailers' "fault." State jurists sought to extirpate from strict product liability several concepts grounded in negligence or fault-based liability" (Bell, 2019).

[42]See https://legal.thomsonreuters.com/en/westlaw, last accessed April 30, 2024

Figure 1.6 plots the number of litigations involving X-ray medical devices due to product defects. There was no discernible change in case counts around the focal point of 1967, suggesting that the surge in patenting activity observed in Section 6 may not be tremendously driven by an increase in product liability litigation.[43]

Patenting Activities between Domestic and Foreign Firms

To demonstrate litigation risk (if any) did not have a tremendous impact on innovation, I also compare changes in patenting activities between domestic and foreign firms. Conceptually, one might expect that if liability risk were the sole driving factor, the RCHSA would impose little effect on innovation efforts that address safety enhancements among foreign firms. This argument is built on some narrative evidence drawn from prior legal studies. For example, Klerman (2011) argues that

> "Product liability law in many foreign jurisdictions is less consumer-friendly than in the United States, and contingent fees are seldom allowed. As a result, the costs of suing abroad and the low probability of fully compensatory damages mean that injured consumers are likely not to sue at all if the only available forum is outside the United States. This, of course, reduces the incentive of foreign manufacturers to design and produce safe products. In addition, it gives foreign companies a competitive advantage over American firms and encourages U.S. firms to relocate abroad."

Overall, it suggests that "even though foreign producers selling products in the US generally face the same product liability rules as domestic producers, US plaintiffs face complexities and additional legal costs (e.g., matters of personal jurisdiction, conflicts of laws, and greater difficulties in enforcing judgment) that make foreign producers less concerned about liability risk (Galasso and Luo, 2022)."

In the meantime, recall in Section 1.2, I briefly described that "any relevant electronic product offered for importation into the United States which fails to comply with applicable performance standards or to which is not affixed a certification in the form of a label or tag

[43]Using the timing and number of lawsuits as a proxy for litigation risks is in the similar spirit of Galasso and Luo (2022), who plot the evolution of lawsuits against DuPont in Appendix Figure A1.

in conformity with section 358(h) shall be refused admission into the United States." In this regard, it suggests the innovation incentives for some foreign manufacturers may also get inflated following the RCHSA.

Table 1.12 reports my primary empirical evidence. In Panel A and B, I summarize the estimates for U.S. and foreign firms separately. The dependent variable is the number of patents filed by U.S./foreign firms in a subclass-year cell. In column (1) and column (3), the results are based on the baseline DID specification. Consistent with the above theoretical argument, domestic firms are more inclined to patent both risk-mitigating and radiation-generating technologies following the RCHSA. Examining the magnitudes associated with the estimates (0.551 vs. 0.557), we can re-assure that risk-mitigating and radiation-generation technologies are likely complementary in production. Meanwhile, it is interesting that even accounting for uncertainties in the domestic legal environment, the innovation effect on foreign firms is statistically significant and positive. It thus suggests a large part of the rise in innovation activities could be attributed to the regulation *per se*.

Another advantage of comparing patenting activities between domestic and foreign firms is that it enables me to better control for potential confounding factors affecting my treatment and control groups differentially. For example, if there were technological progress for radiation-based diagnostic medical devices during the reference period, one may raise concerns about the validity of my identification strategy. To address this issue, I incorporate the country of patent assignees as the additional variation in a triple DID model. Put differently, foreign firms serve as the control group and account for some common trends in patenting X-ray diagnostic medical technologies. The results in Table 1.13 indicate that relative to foreign firms, US firms are more likely to respond to the RCHSA in patenting both risk-mitigating and radiation-generating technologies (by 57.3% and 34.3%).

Patenting Activities between GE and Non-GE Firms

Last but not least, I directly assess whether the patenting activities of GE significantly differ from those of other firms. The basic assumption is that the initial GE recall in 1967 might have imposed more litigation risk on GE *per se* relative to its competitors in the market.

Table 1.14 presents the estimated effects on patent counts by technology for GE and non-GE domestic firms. The treatment group in the first two columns includes all patents under class `A61B6`. In column (3) and column (4), the treatment group is defined as a subsample of `A61B6` patents emphasizing safety features. The last two columns in Table 1.14 represent the case where the treatment group comprises all `A61B6` patents addressing radiation-generating technologies. Point estimates in the odd-numbered columns are based on a sample consisting of patents filed by GE. Results from the even-numbered columns represented the case for all non-GE firms.

Based on what we can observe in all odd-numbered columns in Table 1.15, little evidence shows that GE responded positively in innovation following the RCHSA. By contrast, patent counts increased significantly (by 65.9% for risk-mitigating technologies and by 57.1% for radiation-generating technologies) within non-GE domestic firms. In an event study specification similar to equation (13), I separately estimate the dynamic effects of the RCHSA on patent flows for GE and non-GE firms. As shown in Figure 1.3 - Figure 1.4, the upward surge in patenting (for both risk-mitigating technologies and radiation-generating technologies) is exclusively contributed by non-GE firms. The point estimates from Figure A17 and Figure A18 implies that first of all, there is no significant and sizable rise in patent counts around the incidence of GE recall; second, higher performance standards did not induce GE to develop either risk-mitigating technologies or new products.

The above empirical findings are clearly not aligned with the hypothesis that increased litigation risk encouraged GE *per se* to prioritize investing in innovation. More interestingly, one possible channel to rationalize the decline in GE's patenting rate is that if most of GE's products have met the minimum performance standards under the RCHSA, GE could stand to benefit from these standards and reduce investments in innovation. This is because higher safety standards protected GE from competing or at least helped GE avoid higher compliance costs.

1.7.3 (Expected) Market Size Expansion

According to Leland (1979), imposing minimum quality standards would mitigate asymmetric information between buyers and suppliers. This *quality assurance effect* improves the

average quality available to consumers *ceteris paribus*, thereby increasing their willingness to pay for these regulated goods and services. In the presence of this positive demand shock for medical procedures involving equipment based on X-rays, firms' incentives to innovate will increase in response to this (expected) expansion in market size (Schmookler, 1966).

To investigate whether changes in consumer demand may have contributed to the increased patenting activity, I construct a novel data set by digitizing information from the National Hospital Discharge Survey (NHDS), as described in Section 1.4. Specifically, I use the number of short-term hospital discharges per year as a proxy for demand and define the treatment group as the radiology service. To estimate the effect of changes in demand on patenting activities, I employ the following regression model:

$$y_{imt} = \alpha + \beta Treat_m \times Post1969_t + \psi_i + \theta_m + \mu_t + \epsilon_{imt} \tag{1.16}$$

where y_{imt} is the natural logarithm of the total number of discharges related to service type m under the demographic/hospital/regional group i in year t. $Treat_m$ is an indicator equaling to one if the medical procedure is the radiology service, and $After1969_t$ denotes whether the year includes and after 1969. ψ_i is a set of group-specific fixed effects (i.e., age group, gender, region, or hospital size). θ_m and μ_t are the medical procedure fixed and year fixed effects, respectively.

Table 1.15 delivers some tentative evidence. The dependent variable is the natural logarithm of the number of discharges, and through column (1) to column (3), I separately estimate equation 1.11 with three samples based on patients' age and sex, the size of hospitals, and the region where a hospital is located. Point estimates from Table 1.3 all indicate that when imposing the RCHSA of 1968, the number of short-stay hospital discharges involving radiology services did not change significantly, suggesting that relative to other types of medical procedures, stricter safety regulations targeting diagnostic x-ray medical devices imposed little effects on the utilization of radiation-based medical devices.

1.7.4 Approval Uncertainties

Besides regulatory compliance costs, the passage of the RCHSA may also introduce another type of fixed cost on firms' end: approval costs, or, say, costs stemming from approval uncertainties Stern (2017). For example, the presence of more stringent safety performance standards can mechanically result in longer periods for the FDA to review and approve products. Faced with a process for any new device with higher approval costs, firms may strategically shift their innovation efforts and prioritize the development of technologies and features that directly address safety features outlined in these standards. By doing so, firms can streamline the approval process, minimize delays, and reduce fixed costs.

However, this theoretical hypothesis does not align with the historical institution during the 1960s and 1970s. As highlighted in Section A.2. in the Appendix, the FDA had little power of pre-marketing approval or subsequent disapproval in the case of medical devices before 1976 Finck (1974). In particular, general medical device manufacturers did not go through the pre-marketing approval process for any new device that was produced. The manufacturer is not mandated to show that a new device is effective, safe, and reliable for its purported use. Instead, the historical regime centers on *ex-post* regulations: the FDA relied on complaints or its own discoveries before the regulatory authority could be invoked.

1.7.5 Changes in Product Market Competition

The last plausible explanation for the observed increase in patenting activities is associated with changes in market structure following the RCHSA. In essence, stricter product safety regulations can substantially change product market competition in equilibrium (Atal, Cuesta and Sæthre, 2022), thereby distorting firms' incentives to innovate.

As the first-order effect, setting higher (minimum) safety performance standards can directly influence product market competition (PMC) through at least two key channels, among many others: increasing fixed costs and driving up market size.[44] Following the

[44]Admittedly, another complexity regarding product market structure is that manufacturers may collude and endogenously set the minimum performance standards by forming trade organizations and lobbying the government. For example, if a trade organization successfully lowers the stringency of safety standards (i.e., reducing the extent to which the minimum quality standard dampens the quality competition), it then leaves room for firms to collude further and reduce competition.

theoretical models outlined in Budish, Roin and Williams (2015) and Atal, Cuesta and Sæthre (2022), I briefly summarize these two forces in turn.[45]

[45]From the theoretical perspective, Marette (2007) argues under perfect information about safety for consumers, the standard is always compatible with competition: The absence of standard due to safety overinvestment by firms only emerges under competition in quantities and a relatively low cost of safety improvement. However, under imperfect information about safety among consumers, the standard often leads to a monopoly situation, essentially covering the cost of safety improvement. However, for relatively high values of this cost, a standard cannot impede the market failure arising from the lack of information.

Increased Fixed Costs: On the supply side, one can conceptualize that a typical firm would face a two-stage decision when innovating: *invention* and *commercialization* (Budish, Roin and Williams, 2015; Rogers, 2023). In the first stage, firms develop ideas and invest in $R\&D$ till the new technology is patentable. In the second stage, firms decide whether the newly invented technology/product could enter the market. Higher safety performance standards can inflate fixed costs in both phases. To be concrete, during the invention phase, these standards may drive up regulatory pressure and mandate firms to comply with ("*regulatory compliance costs*").[46] At the point of entry or say, commercialization, higher performance standards would potentially result in approval delays, thereby triggering approval costs.[47] [48] Together, if these two types of fixed costs are too high, safety performance standards can lead to exit, deter entry, and stifle product market competition Atal, Cuesta and Sæthre (2022).

Expanded Market Size: Consumers also demand new medical devices subject to friction due to asymmetric information. Without the intervention of any product safety regulation, consumers cannot distinguish between high- and low-quality products. As a result, safety performance standards serve to resolve market failure, thus increasing consumers' willingness to pay for products under regulation.

In sum, the equilibrium effect of safety regulations on market structure hinges on several factors. A thorough analysis of this *first-order* effect is beyond the scope of my paper and essentially requires a structural model ((see for example, Atal, Cuesta and Sæthre, 2022)). Building on these theories and taking into account changes in product market structure (if any), I now turn to discuss the indirect impact of safety regulations on innovation activities via competition.

[46]The theoretical framework outlined in Section 1.3 builds on this line of argument.

[47]For example, firms may face financing costs if approval costs exceed their assets Buera and Shin (2013).

[48]Of course, in the current regulatory regime, the approval requirement of the FDA plays a key role in delaying product commercialization (Pietzsch, Zanchi and Linehan, 2012). However, it is noteworthy that these approval costs might be negligible in my context, wherein the current risk-based regulatory regime has not been introduced. This is because the FDA's historical regulation for medical devices did not require manufacturers to register with the Secretary of the Department of Health, Education, and Welfare. Put differently, the Secretary had no power of approval and subsequent disapproval before a medical device was marketed. The Appendix discussed detailed institutional features in Section A.2.

Prior seminal work has emphasized an inverted-U relationship between competition and innovation (see, for example, Aghion et al., 2005): product market competition discourages *laggard* firms from innovating but encourages *neck-and-neck* firms to innovate.[49] Drawing on this line of theoretical predictions, if higher safety standards reduced product market competition, one may expect the documented rise in patent counts to reflect a surge in innovation incentives of non-incumbent firms exclusively. In contrast, if the increase in market size is sufficiently large and intensifies competition pressure, incumbent firms could primarily contribute to the induced innovation. That said, in either case, there should be a significant difference in innovation activities between incumbents and new entrants with stricter safety standards in place.

From the empirical perspective, it's challenging to test this channel when product-firm-level data are unavailable directly. As a result, I implement three complementary exercises to provide suggestive evidence: drawing on the description from Birnbaum (1984), taking publicly traded firms as a proxy for incumbents, and using a firm's prior patenting history to infer whether it's incumbents.

Narrative Evidence from Birnbaum (1984)

As mentioned in Birnbaum (1984), in March 1980, eleven semistructured interviews of up to two hours were conducted among congressional representatives and administrators from the Bureau of Radiological Health, the Bureau of Medical Devices, the National Electrical Manufacturers Association, the Health Industries Manufacturing Association, and the American Association for Medical Instrumentation. In the meantime, complementary questionnaire responses were collected from firms representing 62 percent of the medical diagnosis and medical therapy market segments. Based on such qualitative data, seven firms were identified that accounted for 78% of the medical diagnostic market and 90% of the medical therapy market in 1980.

[49] As Aghion et al. (2005) argued, firms' innovation incentives hinge heavily on the difference between post-innovation and pre-innovation rents of firms. As a result, more competition can facilitate innovation when it reduces a firm's pre-innovation rents by more than it reduces its post-innovation rents, thereby enabling such firms to escape from competition. This *escaping competition* effect is more prominent in sectors where incumbent (or, say, *neck-to-neck*) firms are operating at similar technological levels. In contrast, when innovations are made by laggard firms with low initial profits in the first place, increased competition pressure would primarily affect post-innovation rents and thus hinder innovation.

Combined data on market share in 1974 (drawn from Hale and Hale (1978)), Birnbaum (1984) argued "*major changes in market leadership were identified.*" In addition, based on the average growth rate of 23.3% over the 16 years, the medical X-ray market grew in excess of the U.S. economy, and one would "*expect greater competition and volatility over market share earlier in the growth phase before 1974.*" Overall, this description suggests that throughout the 1960s and 1970s, the medical X-ray industry did not experience a substantial reduction in product market competition.

Innovation Activities from Publicly Traded Firms vs. Other Private Firms

To supplement the above qualitative evidence, I next use U.S. publicly traded firms identified in the KPSS-Compustat sample as a proxy for *incumbents*. Table 1.16 reports my estimated effects on patent counts filed by publicly traded firms (column (1) and column (4)) and other private firms (column (2) and column (5)), respectively.

My first set of regressions is the baseline difference-in-differences analysis with patents filed by US publicly traded firms in a class-year cell as the dependent variable.[50] Results are reported in the first and the fourth columns of Table 1.16: relative to non-radiation diagnostic medical device technologies, both risk-mitigating and radiation-generating technologies experienced a significant and sizable increase after 1969. I repeat this exercise and focus on patents filed by other private firms in column (2) and column (5). Similarly, I documented a significant rise in patenting rate within these non-publicly traded firms. I also report the main results in the third and last column using a triple difference-in-differences specification. That said, for each class-year cell, I crate two observations, one for patent counts for publicly traded firms and the other for other private firms as the assignee. The total number of observations is thus twice as many as that in column (1) (2) (4) and (5). The key coefficient associated with the triple interaction term ($Treat_c \times Post1969_t \times KPSS$) captures the differential effect of the RCHSA on innovation between incumbents and entrants.

[50] When aggregating patent counts at the subclass-year level, data distribution for publicly traded firms is highly skewed. Therefore, I choose to aggregate data at the class-year level.

Innovation Activities from Firms with Prior Patenting History

In addition, I follow Gross (2023) and use a firm's patenting history to infer if it's an incumbent. Concretely, a firm will be defined as an "incumbent" if it has filed at least one patent application between 1950 and 1967. Of course, this approach is not free of concerns. For example, since there is no way to track the history of a firm's entry, exit, and mergers/acquisitions, it is indeed quite hard to tease out potential selection bias.

Table 1.17 summarizes these results by technology types: in column (1) and column (3), the point estimates represent the impact on innovation among all incumbent firms; coefficient estimates for entrants are listed in the even-numbered columns. In sum, we can observe both incumbents and entrants are more engaged in innovation following the RCHSA. Together with results from Table 1.16, it implies that the RCHSA did not shape technology progress for incumbent firms and new entrants in a substantially different way. These findings contrast with the hypothesis that changes in competition are a primary driver of innovation in my context.

1.7.6 Technological Breakthrough

In a 1963 article published in the *Journal of Applied Physics*, Allan Cormack proposed a method to improve tomographic imaging: computed tomography (CT) technology. Rather than use X-rays to make photographs, Cormack suggested that physicians measure X-rays after they passed through a body to see how much radiation had been absorbed. In 1972, EMI developed and started selling its first generation of head scanners using CT techniques, targeting the U.S. market. EMI was also able to secure reimbursement for CT procedures from Medicare after demonstrating the effectiveness of its head scanner.

It is reasonable to argue that the entry of CT head scanners shocked manufacturers, leading to a wave of follow-on innovations in X-ray medical devices. As a result, the upward surge in `A61B6` patent counts could be partially attributed to this technology-specific breakthrough. However, note that my event-study results in Figure 1.3 and Figure 1.4 show that there was a significant rise in patenting rates for both the risk-mitigating technology and radiation-generating technology in one year right after the RCHSA. In other words,

the timing of effects helps alleviate concerns that the invention and entry of CT technology primarily drives my results.

Furthermore, I implemented another exercise to prove the robustness of my results besides drawing evidence from event-study results. Instead of using a subclass-year panel, I reconstructed my sample, and the unit of observations is now at the class-month-year level. Put differently, this new sample tracks information for the number of patents filed under each broad patent class within each month of the year. I then estimate the following regression model:

$$y_{cmy} = \alpha + \beta Treat_c \times Post1968_{my} + \theta_c + \mu_m \times \psi_y + \epsilon_{cmy} \tag{1.17}$$

where c denotes patent classes, m indexes months, and y indexes years. $Treat_c$ is an indicator for whether a patent belongs to `A61B6` and $Post_{my}$ means whether a month-year pair is after 11/1968. I include a set of "month-year" fixed effects and patent class fixed effects in this specification.

In the meantime, I also complement the above analysis with a two-part spline specification with knots in June 1969 and January 1973, which summarizes the event-study estimates and improves the precision of estimation relative to the event-study specification.

$$y_{cmy} = \alpha + \beta_1 Treat_c \times Post1968_{my} + \beta_2 Treat_c \times Post1973_{my} + \theta_c + \mu_m \times \psi_y + \epsilon_{cmy} \tag{1.18}$$

where β_1 and β_2 capture the impacts on innovation, following the RCHSA and the entry of CT, respectively.

Finally, I directly drop all patents under subclass `A61B6/03` to check the robustness of my main results. I also exclude patents under the parent subclass `A61B6/02` in this round of robustness checks to account for the fact that a parent subclass may contain residual patents that cannot be easily categorized into a specific children subclass.

Table 1.18 presents these results. Across columns, coefficient estimates in Panel A suggest that, on average, the RCHSA was associated with an increase in patent counts of `A61B6` (excluding CT patents) by 25.5%, or 0.366 per month. Rescaling this number to the annual level, it indicates having the RCHSA in place, there was an increase of 4.392 in patent counts under `A61B6` per year, similar to our main results (an increase of 4.184 per year at

the patent class level). In Panel B, I repeat the exercise but extend the reference period to 1975: Again, I find the positive effect associated with the passage of the RCHSA is not absorbed by an indicator for the entry of CT technology, thereby ruling out the possibility that my treatment group was substantially contaminated by this additional shock. In Panel C, all the magnitude, direction, and significance of my estimates are quite similar to those shown in Table 1.1.

1.7.7 The Medical Device Amendments of 1976

It is worth noting that the Medical Device Amendments to the FD&C Act in 1976 is another important policy shock that may affect the causal interpretation of the estimates.[51] The 1976 Act was enacted to ensure the safety and effectiveness of medical devices and introduced a risk-based classification system for all medical devices. The Act also established regulatory pathways for new medical devices prior to their marketing and introduced several key post-market requirements. There is a potential concern that including the post-MDA period may lead to differential effects on innovation incentives for treated and control subclasses due to institutional changes. To address this concern, I changed the reference period and restricted my sample to 1960-1975, one year prior to the 1976 Amendments. At the same time, I drop all patents under `A61B6/03`.

Based on the coefficient estimates presented in Table 1.19, it appears that, on average, the RCHSA resulted in a 44.9% increase in patenting (or an increase of 0.64 patents per year) in the `A61B6` subclass. This represents a slight decrease in the estimated effect size relative to the results in Table 1.1, which suggested an increase of 58.7% (or say, 0.85 more patents per year). Thus, this exercise reassures me that the potential confounding effect of the MDA is not a serious concern in my setting.

[51] See https://www.govinfo.gov/content/pkg/STATUTE-90/pdf/STATUTE−90−Pg539.pdf, last accessed April 30, 2024.

1.8 Heterogeneous Effects: Financing Constraint

So far, I have demonstrated that the safety regulation increased both the quantity and quality of innovation related to diagnostic X-ray medical devices. In this section, I turn to explore whether and how these effects depend on firms' financing constraints.

A voluminous literature emphasized the relationship between financial frictions and innovation (see, for example, Caggese, 2019). In a context like mine, financial frictions may arise in the product development phase. For example, in the presence of stricter product safety standards, firms with better access to financial resources have more flexibility in choosing cost-saving innovation as an option to combat higher compliance costs. As noted in Miravete and Permoas (2006), whether product innovation and process innovation are complements or substitutes in production is determined by the supply-side environment. One such driver could be the availability of accessible resources: If a company has limited resources, it may have to trade off its investment in new products against improvements in process innovation. By contrast, if a large company has sufficiently relaxed resource constraints, it could pursue both types of innovation simultaneously, leading to a complementary relationship between product innovation and RMTs. Drawing on firm-level data from Kogan et al. (2017), I examine the sensitivity of firms' patenting rates to firms' financing constraints as follows.

To start with, I first assess if the RCHSA *per se* directly distorted firms' financing performance, including capital intensity (*capital-labor ratio*), financial leverage (*debt/assets*), cash balances (*cash/assets*), cash flow (*cash flow/assets*), dividend payout (*current dividends/assets*), and sales. Along all the above dimensions, there is little evidence that the imposition of safety regulations significantly altered relevant outcomes. It thus suggests that the regulation did not significantly affect firms' financial performance, as well as their input mix.

In Table 1.20, I estimate a firm-level regression as follows to capture the heterogeneous effects:

$$y_{ict+1} = \alpha + \beta Treat_c \times Post1969_t + log(\#\text{of employees}) + \theta_i + \psi_c + \phi_t + \epsilon_{ict} \qquad (1.19)$$

where y_{ict+1} denotes the number of patents filed by firm i under class c in year $t+1$. The annual number of employees within a firm here is a proxy for firm size and has been included as a control. $Treat_c$ indicates whether a patent belongs to diagnostic x-ray medical equipment. $Post1969_t$ denotes whether the RCHSA is in place in year t. A number of fixed effects are also included: firm fixed effects (θ_i), class fixed effects (ψ_c), and year fixed effects (ϕ_t).

Table 1.20 presents how the RCHSA affected the patenting rate across the distribution of firms' dividend payout, which is often seen as an inverse proxy for the severity of financing constraints. In particular, I allocate assignees (firms) into four categories: whether the dividend payout of a firm is below the 25^{th} percentile, between the 25^{th} percentile and the 50^{th} percentile, between the 50^{th} percentile and the 75^{th} percentile, or above the 75^{th} percentile. Overall, I find the increase in patent counts is significant among firms with higher levels of dividend payouts.

1.9 Conclusion

Striking a balance between safeguarding consumers and advancing medical technology poses a multifaceted challenge, especially within the medical device industry. In this paper, I empirically assess how imposing stricter safety performance standards affected new technologies' development through a historical lens. Exploiting the passage of the Radiation Control for Health and Safety Act (RCHSA) in 1968 as a quasi-experiment, I find patents related to diagnostic X-ray medical devices experienced a drastic increase in quantity (by at least 42.4%), as well as quality. These positive effects hold for both technologies emphasizing radiation protection and new devices relying on radiation, which are likely to be complementarities in production.

To disentangle the mechanisms at play, I conducted various empirical tests. My findings, together with narrative evidence, suggest that regulatory compliance costs drive up firms' innovation incentives rather than increased liability risk, higher approval uncertainties, expanded market size, or substantial changes in product market competition. To elaborate, a rise in compliance costs under stricter safety standards induced firms to prioritize cost-saving innovation, thereby resulting in a surge in new technologies mitigating radiating risk. This

influx of risk-mitigating technologies, in turn, intensifies the marginal benefits of developing new X-ray-based medical devices and further fosters product innovation.

My paper provides novel evidence to the sparse empirical work investigating the interplay between product quality regulation and innovation. In particular, it emphasizes that, facing a highly stringent regulatory regime, firms can take innovation as a strategy to combat increased costs and mitigate risk. It also highlights the delicate nature of designing policy instruments to address product safety and quality: in a context wherein technologies themselves can interact, even regulations targeting a single dimension can create unexpected spillovers to other technology classes.

This paper emphasizes at least two priorities for future research. Beyond quantifying firms' innovation strategies and activities, assessing how such safety regulations affect the diffusion and adoption of relevant technologies is crucial. For example, besides altering consumers' perceived quality, stringent safety regulations could bolster healthcare facilities' incentives to adopt X-ray medical machines if the profitability of adopting *safer* devices outweighs its costs. Measuring effects along this margin is important because the overall welfare effects of product quality regulation hinge on whether consumers can directly access these induced new technologies. Further, reconciling various channels, which are outlined in both prior work (Viscusi and Moore, 1993; Galasso and Luo, 2022; Rogers, 2023) and mine, within a structural model offers another promising and challenging avenue for future research.

Table 1.1: Effects of the RCHSA on Patent Counts (1960-1980)

	OLS			Poisson		
	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
Panel A. raw counts						
$Treat_c \times Post1969_t$	0.587***	0.674***	0.557***	0.607**	0.805***	0.728***
	(0.122)	(0.120)	(0.119)	(0.200)	(0.236)	(0.203)
Panel B. citation-weighted						
$Treat_c \times Post1969_t$	0.806***	0.998***	0.845***	0.501**	0.471**	0.298*
	(0.221)	(0.203)	(0.185)	(0.199)	(0.238)	(0.178)
# of obs.	1,407	1,974	2,667	1,407	1,974	2,667
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period (1960-1980). The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the outcome of interest is constructed based on the raw patent counts and in Panel B, the outcome is constructed using the citation-weighted patent counts. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.2: Effects of the RCHSA on Patent Attributes (Risk-Mitigating)

	OLS			Poisson		
	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
Panel A. CPC approach						
$Treat_c \times After1969_t$	0.496***	0.583***	0.466***	0.602***	0.799***	0.722***
	(0.108)	(0.105)	(0.104)	(0.221)	(0.254)	(0.223)
# of clusters	54	81	114	54	81	114
# of obs.	1,134	1,701	2,394	1,134	1,701	2,394
Panel B. text-analysis						
$Treat_c \times After1969_t$	0.425**	0.513***	0.395***	0.809***	1.006***	0.930***
	(0.114)	(0.112)	(0.111)	(0.169)	(0.211)	(0.173)
# of clusters	67	94	127	67	94	127
# of obs.	1,407	1,974	2,667	1,407	1,974	2,667
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The treatment group in this set of regressions includes all `A61B6` patents emphasizing risk-mitigating. The dependent variable of all regressions in columns (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the treatment group is constructed based on the CPC code; in Panel B, the treatment group is constructed using the text analysis algorithm. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.3: Effects of Radiation Control on Patent Attributes (Radiation Generating)

	OLS			Poisson		
	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
Panel A. CPC approach						
$Treat_c \times After1969_t$	0.543***	0.630***	0.513***	0.754**	0.951***	0.874***
	(0.170)	(0.168)	(0.167)	(0.295)	(0.320)	(0.296)
# of clusters	59	86	119	59	86	119
# of obs.	1,239	1,806	2,499	1,239	1,806	2,499
Panel B. text-analysis						
$Treat_c \times After1969_t$	0.492***	0.579***	0.462***	0.934***	1.132***	1.055***
	(0.136)	(0.134)	(0.133)	(0.246)	(0.276)	(0.248)
# of clusters	67	94	127	67	94	127
# of obs.	1,407	1,974	2,667	1,407	1,974	2,667
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period (1960-1980). The treatment group includes all `A61B6` patents. The dependent variable of all regressions in column (1) - column (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - column (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`,)and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the treatment group is constructed using the CPC-code approach; in Panel B, the treatment group is constructed using the text-analysis algorithm (i.e., I choose `A61B6` patents with low relevance score). All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.4: Effects of Radiation Control on Patent Attributes (Dual Features)

	OLS			**Poisson**		
$Treat_c \times Post1969_t$	0.730**	0.752***	0.566**	1.259***	1.433***	1.403***
	(0.288)	(0.266)	(0.267)	(0.404)	(0.389)	(0.391)
# of obs.	126	147	273	126	147	273
control group	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is class-year. The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. Standard errors are in parenthesis.

Table 1.5: Evidence of Innovation Complementarity

	Dependent Variable: log(patent counts+1)	
	Risk-Mitigating	Radiation-Generating
$Treat_c \times Post1969_t$	0.134***	0.102*
	(0.048)	(0.058)
firm FE	Yes	Yes
class FE	Yes	Yes
year FE	Yes	Yes
# of obs.	1,134	1,134

Note: Data are drawn from the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is at the firm-class-year level. The dependent variable of both regressions is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. Standard errors are in parenthesis.

Table 1.6: Effects on Patent Counts across Patent Quality Distribution

	Dependent Variable: log(patent counts+1)					
	All		Risk Mitigating		Radiation Generating	
$Treat_{sc} \times Post1969_t$	0.706***	0.473***	0.533***	0.334***	0.664***	0.346**
	(0.123)	(0.134)	(0.052)	(0.087)	(0.155)	(0.170)
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
sample	high-quality	low-quality	high-quality	low-quality	high-quality	low-quality
# of clusters	68	68	54	54	59	59
# of obs.	1,428	1,134	1,134	1,239	1,239	1,239

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO and CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is patent subclass-year. The dependent variable of all regressions is the annual patent counts filed under a patent (sub)class in year t. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.7: Effects of the RCHSA on Share of High-Quality Patents

	All		**Risk Mitigating**		**Radiation Generating**	
	$\mathbf{1}_{\text{share}>0}$	log(share+1)	$\mathbf{1}_{\text{share}>0}$	log(share+1)	$\mathbf{1}_{\text{share¿0}}$	log(share+1)
$Treat_{sc} \times Post1969_t$	0.174***	0.047*	0.114***	-0.016	0.174***	0.058
	(0.049)	(0.028)	(0.038)	(0.018)	(0.062)	(0.040)
# of clusters	68	68	54	54	59	59
# of obs.	1,428	1,428	1,134	1,134	1,239	1,239
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO and CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The dependent variable of all regressions is the share of high-quality patents filed under a patent subclass in year t. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.8: Effects on Innovation Quality among Publicly Traded Firms

	Dependent Variable: log(average market value)		
	All `A61B6` Tech	Risk-Mitigating	Radiation Generating
$Treat_c \times Post1969_t$	0.023^{***}	0.011^{***}	0.021^{***}
	(0.006)	(0.004)	(0.006)
class FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
firm FE	Yes	Yes	Yes
# of obs.	22,965	22,965	22,965

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO and CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is firm-subclass-year. The dependent variable of all regressions is the annual patent counts filed by firm i under a patent (sub)class in year t. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.9: Effects on the Composition of Inventors (Firms vs. Independent Inventors)

	Dependent Variable: $\mathbf{1}_{\text{Firm Patent}}$		
	All A61B6 Patents	Risk-Mitigating	Radiation Generating
$Treat_{sc} \times After1969_t$	0.178***	0.278***	0.185***
	(0.028)	(0.081)	(0.032)
subclass fixed effects	Yes	Yes	Yes
year fixed effects	Yes	Yes	Yes
Observations	10,641	9,148	9,786

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is individual patents. The dependent variable of all regressions indicates whether the patent was assigned to firms. All standard errors are clustered by patent subclass.

Table 1.10: Effects on Patent Counts (Firms vs. Individual Inventors)

	Dependent Variable: log(patent counts+1)					
	Risk-Mitigating			Radiation Generating		
$Treat_{sc} \times Post1969_t$	0.778***	-0.165***	-0.165***	0.709***	-0.032	-0.032
	(0.142)	(0.056)	(0.055)	(0.190)	(0.053)	(0.052)
$Treat_{sc} \times Post1969_t \times Firm_f$	-	-	0.942***	-	-	0.740***
	-	-	(0.160)	-	-	(0.168)
$Firm_f$	-	-	0.255***	-	-	0.255***
	-	-	(0.057)	-	-	(0.057)
# of clusters	52	52	52	59	59	59
# of obs.	1,092	1,092	2,184	1,239	1,239	2,478
sample	firm	individual	full	firm	individual	full
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the log of patent counts filed under a patent class in year t. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.11: Effects of RCHSA on Patent Counts (Risk-Mitigating)

	Including A61B6/10		**Excluding A61B6/10**	
	OLS	Poisson	OLS	Poisson
$Treat_{sc} \times Post1969_t$	0.479***	0.596***	0.508***	0.874***
	(0.108)	(0.221)	(0.146)	(0.254)
# of clusters	52	52	51	51
# of obs.	1,092	1,092	1,071	1,071
subclass FE	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the log of patent counts filed under a patent class in year t. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.12: Effects on the Composition of Inventors (Domestic vs. Foreign Firms)

	Dependent Variable: log(Patent Counts+1)			
	Risk-Mitigating		Radiation Generating	
Panel A. domestic firms				
$Treat_{sc} \times After1969_t$	0.609***	0.551***	0.611***	0.557***
	(0.143)	(0.139)	(0.196)	(0.197)
# of private litigation	-	0.022**	-	0.020***
	-	(0.010)	-	(0.007)
Panel B. foreign firms				
$Treat_{sc} \times After1969_t$	0.155**	0.138*	0.316**	0.280**
	(0.067)	(0.073)	(0.136)	(0.120)
# of private litigation	-	0.007	-	0.013
	-	(0.007)	-	(0.008)
# of clusters	52	52	59	59
# of obs.	1,092	1,092	1,239	1,239
subclass fixed effects	Yes	Yes	Yes	Yes
year fixed effects	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the USPTO in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the log of the annual patent counts filed under a patent class in year t. The sample in Panel A includes all patents filed by domestic firms; Panel B includes all patents filed by foreign firms. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.13: Effects of the Radiation Control on Domestic vs. Foreign Firms

	Dependent Variable: log(Patent Counts+1)					
	Risk Mitigating			Radiation Generating		
$Treat_{sc} \times Post1969_t$	0.609***	0.155**	0.155**	0.611***	0.316**	0.316**
	(0.143)	(0.067)	(0.066)	(0.196)	(0.136)	(0.134)
$Treat_{sc} \times Post1969_t \times Domestic$	-	-	0.453**	-	-	0.295**
	-	-	(0.182)	-	-	(0.126)
sample	domestic	foreign	full	domestic	foreign	full
# of clusters	52	52	52	59	59	59
# of obs.	1,092	1,092	2,184	1,239	1,239	2,478
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the USPTO in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed under a patent subclass in year *t*. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.14: Effects of the RCHSA on Patent Counts (GE vs. Non-GE Firms)

	Dependent Variable: log(patent counts+1)					
	All Tech		Risk-Mitigating		Radiation-Generating	
$Treat_{sc} \times Post1969_t$	-0.021	0.410***	0.019	0.506***	-0.024	0.452**
	(0.073)	(0.124)	(0.167)	(0.117)	(0.090)	(0.183)
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
sample	GE	non-GE	GE	non-GE	GE	non-GE
# of clusters	66	66	52	52	59	59
# of obs.	1,386	1,386	1,092	1,092	1,239	1,239

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed under a patent subclass in year t. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.15: Effects of RC on the Utilization of Medical Services (1968-1970)

	(1) Demographic Groups	**(2)** Hospital Sizes	**(3)** Regional Groups
$Treat_c \times Post1969_t$	0.098	0.089	0.077*
	(0.077)	(0.088)	(0.044)
service type FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
age × gender FE	Yes	No	No
hospital size FE	No	Yes	No
region FE	No	No	Yes
# of obs.	120	108	72

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from NHDS sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. I digitized key statistics for a variety of medical procedures. The unit of analysis is group-type (of medical procedures)-year. The dependent variable of all regressions is the natural logarithm of the annual number of discharges within a group (age, gender, region, or type of hospital). "Demographic Groups" denotes that the data are collected based on patients' age and gender, "Hospital Sizes" represents the sample is grouped by the size of hospitals, and "Regional Groups" means the data are assembled based on where a hospital is located. Standard errors are in parenthesis.

Table 1.16: Effects on Patent Counts (Publicly Traded vs. Other Private Firms)

	OLS			Poisson		
$Treat_c \times Post1969_t$	1.351***	0.818**	0.818***	1.476***	0.903***	0.903***
	(0.303)	(0.314)	(0.287)	(0.210)	(0.256)	(0.270)
$Treat_{sc} \times Post1969_t \times KPSS$	-	-	0.533	-	-	0.573
	-	-	(0.410)	-	-	(0.361)
# of obs.	126	126	252	126	126	252
sample	incumbent	entrants	full	incumbent	entrants	full
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Note: Data are drawn from the USPTO sample and the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is class-year. The dependent variable of all regressions in column (1)-(3) is the natural logarithm of the annual patent counts filed under a patent class in year t. The dependent variable in column (4)-(6) is the patent count filed under each patent class in year t. Standard errors are in parenthesis.

Table 1.17: Effects of the RCHSA on Patent Counts (by Prior Patenting History)

	propensity to patent			log(patent counts+1)		
$Treat_c \times Post1969_t$	0.017**	0.018***	0.018***	0.023**	0.017***	0.017***
	(0.008)	(0.004)	(0.004)	(0.010)	(0.003)	(0.003)
$Treat_{sc} \times Post1969_t \times$ *Incumbent*	-	-	-0.001	-	-	0.006
	-	-	(0.009)	-	-	(0.010)
mean of DV (1960-1967)						
# of obs.	7,550	15,415	22,965	7,550	15,415	22,965
sample	incumbent	entrants	full	incumbent	entrants	full
firm FE	Yes	Yes	Yes	Yes	Yes	Yes
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Note: Data are drawn from the KPSS-Compustat sample. The unit of analysis is firm-class-year. The dependent variable of all regressions in column (1)-(3) is an indicator for whether a patent has been filed by firm i under a patent class c in year t. The dependent variable in column (4)-(6) is the natural log of patent count filed by firm i under each patent class c in year t. Standard errors are in parenthesis.

Table 1.18: Did the Entry of CT Matter?

	NR-DME	**Medical Implants**	**Drugs**
Panel A: 1/1965-12/1971			
$Treat_c \times Post1969_{my}$	0.227^{**}	0.290^{**}	0.252^{**}
	(0.113)	(0.118)	(0.107)
class FE	Yes	Yes	Yes
month×year FE	Yes	Yes	Yes
# of obs.	504	756	1,092
Panel B: dropping `A61B6/03`			
$Treat_c \times Post1969_{my}$	0.561^{***}	0.674^{***}	0.557^{***}
	(0.122)	(0.120)	(0.119)
subclass FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
Observations	1,344	1,974	2,667

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. All standard errors are clustered by patent subclass in Panel C. Standard errors are in parenthesis.

Table 1.19: Did the Medical Device Amendments to the FD&C Act in 1976 Matter?

	OLS			**Poisson**		
	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
$Treat_c \times Post1969_{my}$	0.371***	0.462***	0.386***	0.447***	0.612***	0.533***
	(0.116)	(0.116)	(0.112)	(0.164)	(0.187)	(0.170)
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	1,056	1,504	2,032	1,056	1,504	2,032

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample. The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. All standard errors are clustered by patent subclass. Standard errors are in parenthesis.

Table 1.20: Effects of the RCHSA on Innovation (by Dividend Payout)

	Dependent Variable: log(patent counts+1)			
	below 25th	25th-50th	50th-75th	above 75th
$Treat_c \times Post1969_t$	0.005	0.023***	0.030***	0.020*
	(0.007)	(0.008)	(0.009)	(0.011)
# of obs.	4,945	5,300	5,400	5,510
class FE	Yes	Yes	Yes	Yes
firm FE	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is firm-class-year. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed by a firm under a patent class in year t. Standard errors are in parenthesis.

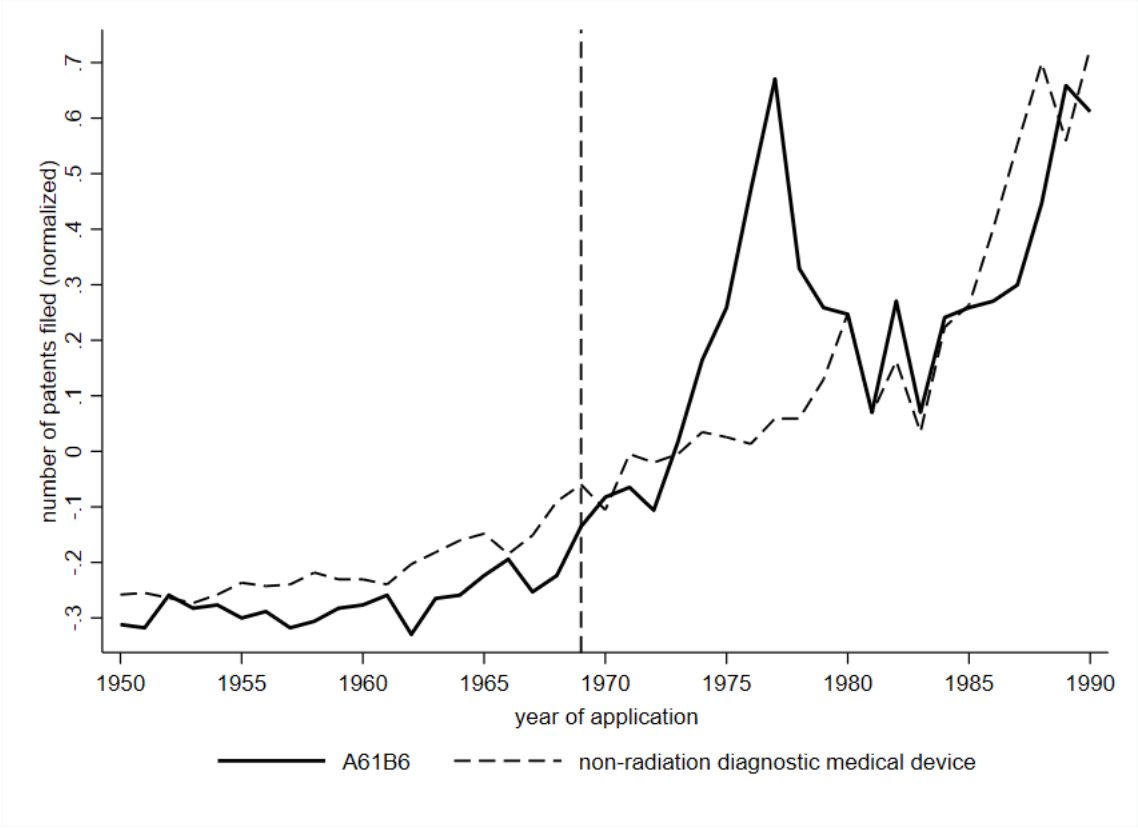


Figure 1.1: Patenting Patterns for A61B6 vs. Non-Radiation Diagnostic Medical Devices

Note: Data are drawn from the USPTO data (1950-1990). The variable of interest is patent count in each class-year cell.

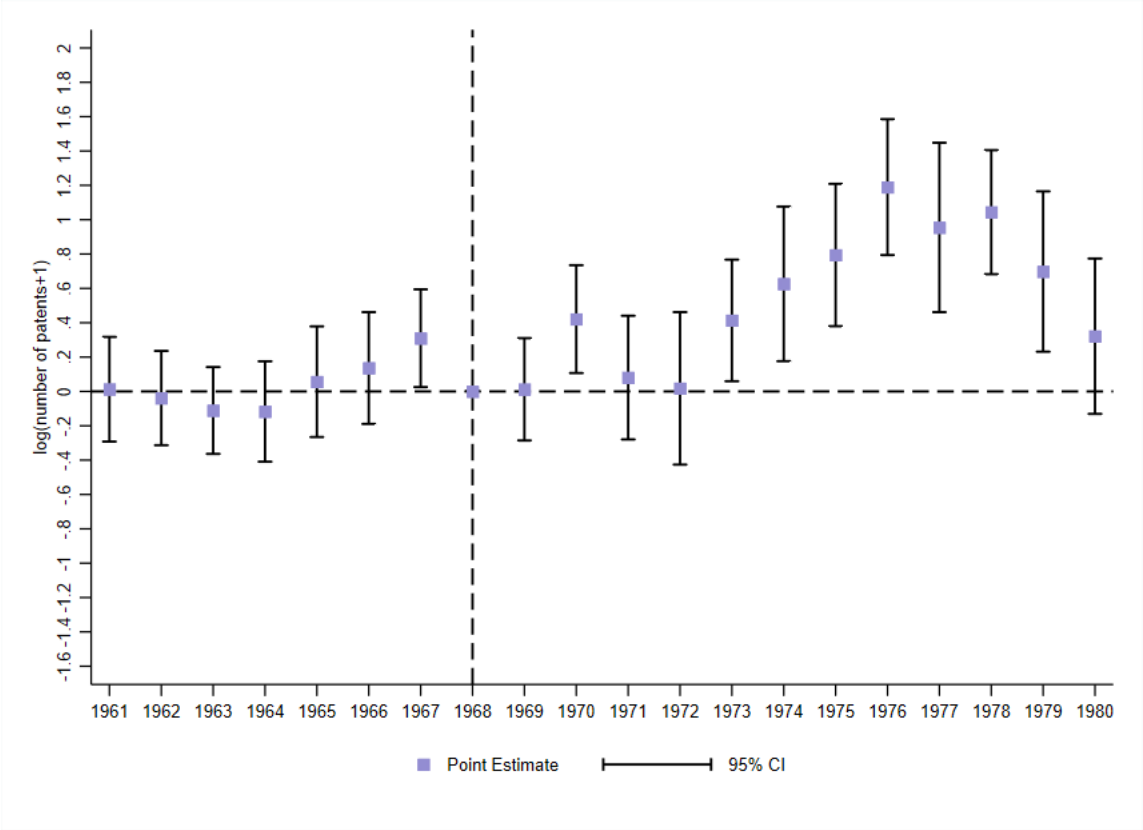


Figure 1.2: Event-Study Estimates for All A61B6 Patents

Note: Data are drawn from the USPTO sample Results are derived from the event-study specification in equation 13. The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

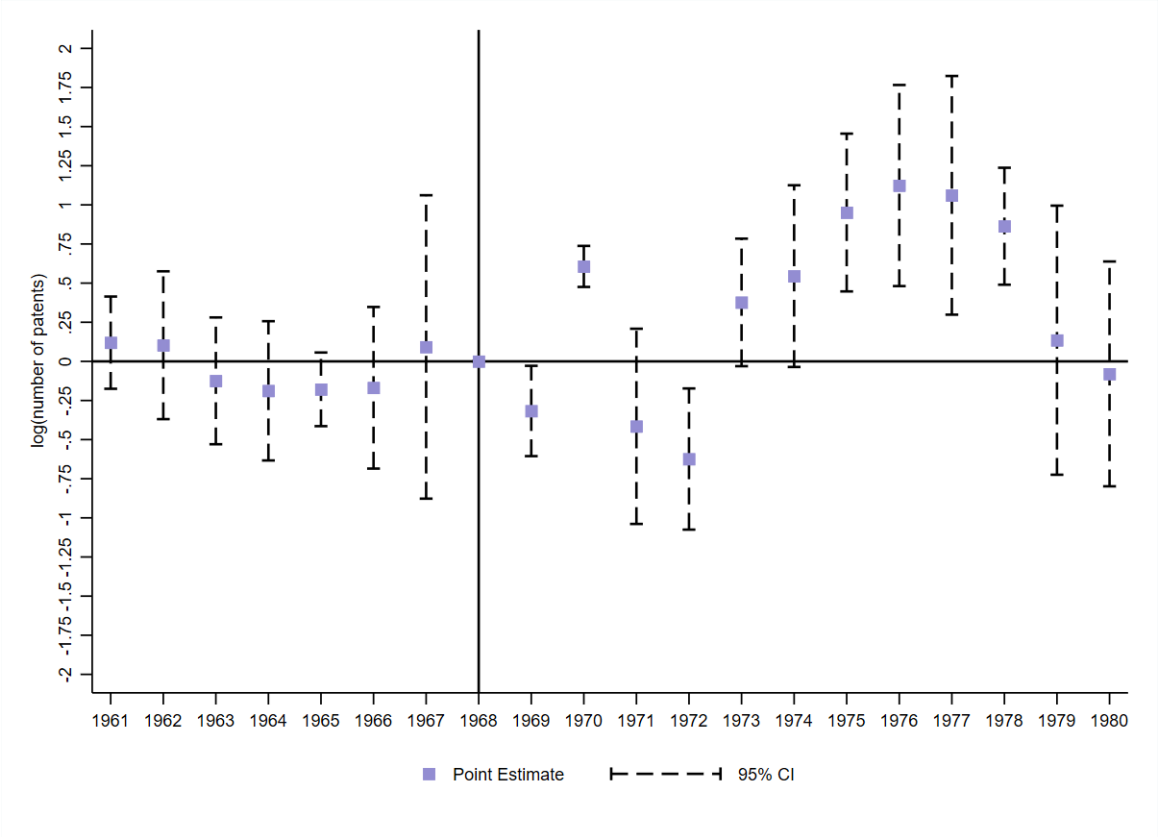


Figure 1.3: Event Study Estimates for A61B6 Patents Emphasizing Risk-Mitigating

Note: Data are drawn from the USPTO sample. Results are derived from the event-study specification in equation 13. The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

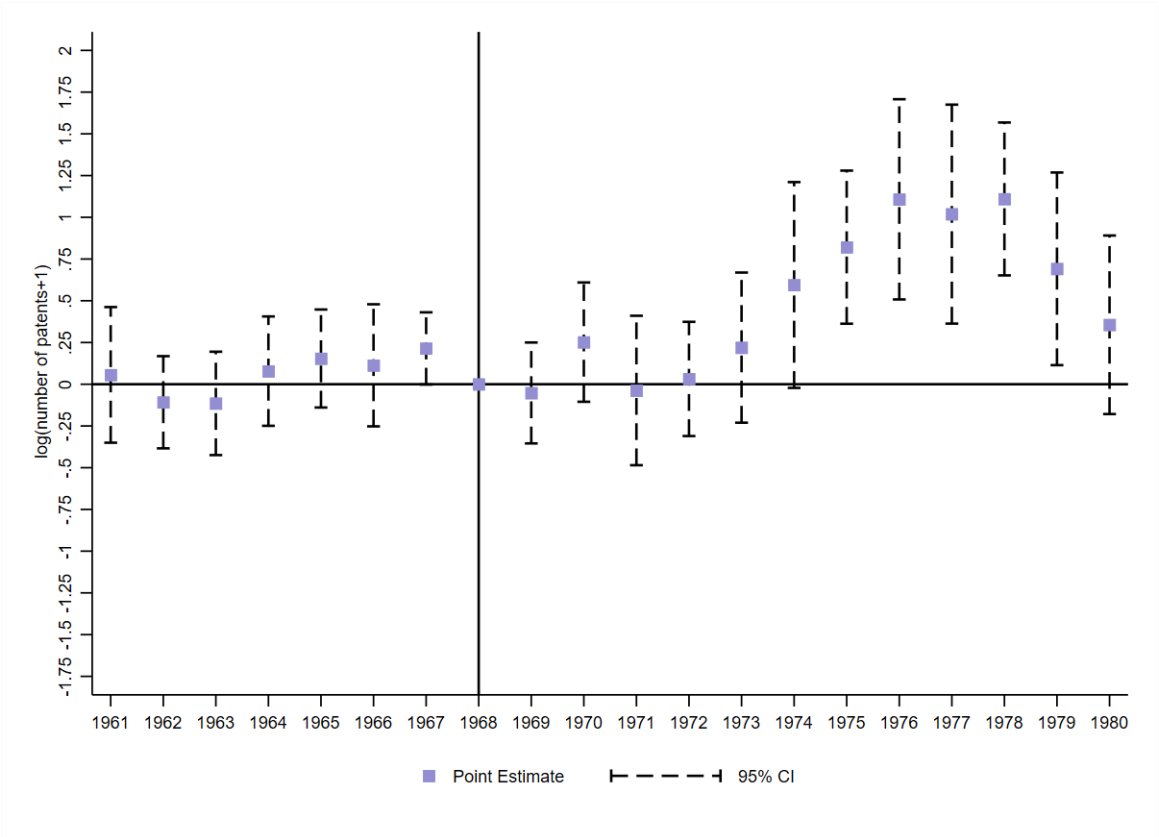


Figure 1.4: Event Study Estimates for A61B6 Patents Emphasizing Radiation Generating

Note: Data are drawn from the USPTO sample. Results are derived from the event-study specification in equation 13. The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

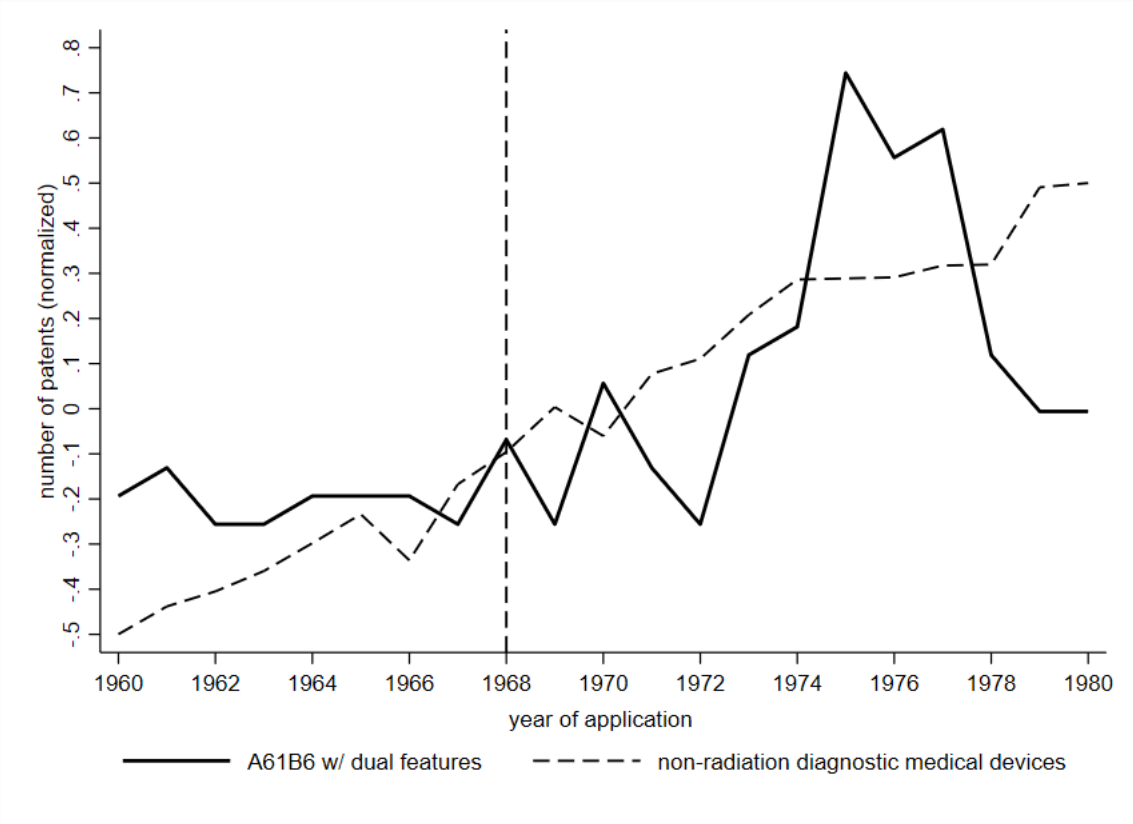


Figure 1.5: Patenting Trend of A61B6 with Dual Features

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. Results are derived from the event-study specification in equation 13. The control group includes all non-radiation diagnostic medical device patents.

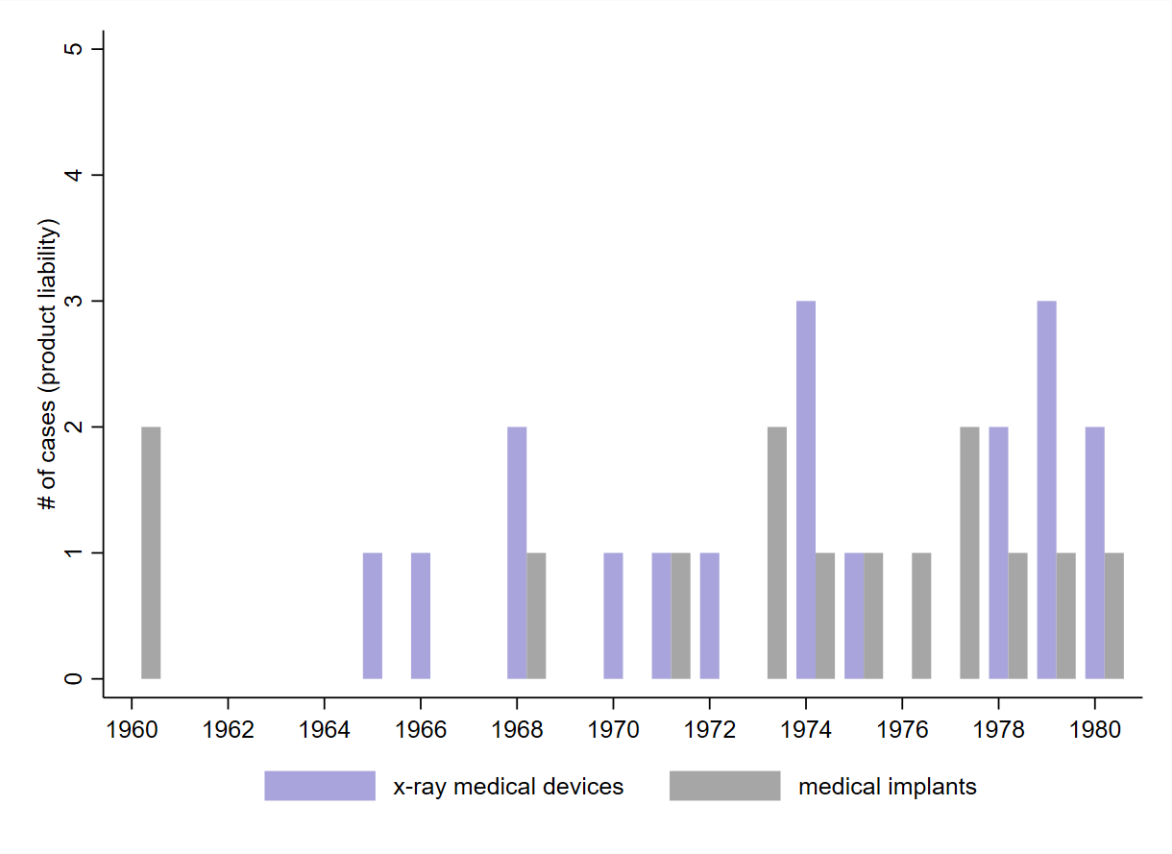


Figure 1.6: Trends in the Number of Lawsuits towards X-ray Medical Devices

Note: Data are drawn from Westlaw. This figure plots the number of lawsuits involving X-ray medical devices from 1960 to 1980.

Appendices

A.1. Historical Legislation and Regulation for Medical Devices

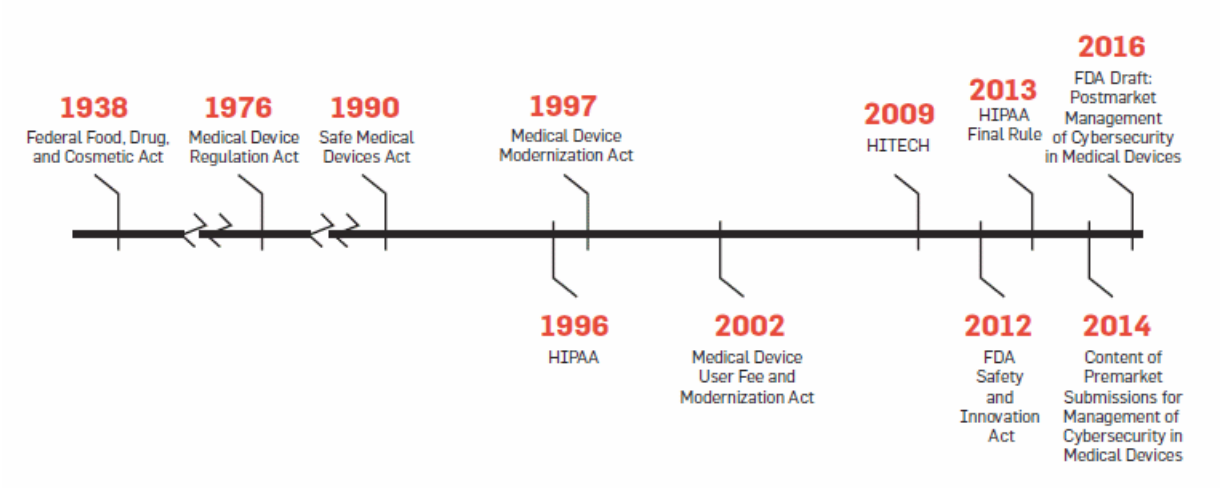


Figure A1: Timeline of Key Legislation and Regulation for Medical Devices

Note: This figure is from Burns, Johnson and Honeyman (2016), summarizing a collation of key legislation and regulatory actions governing medical devices in the U.S.

A.1.1. Legislative History of Device Regulation Prior to 1976

This section briefly summarized the regulatory regime of medical devices in the U.S. prior to the Medical Device Amendments in 1976. Most institutional information is directly drawn from Finck (1974) and Udall (1984).

Medical device regulation was first established under two milestone legislative actions, the *Pure Food and Drug Act of 1906* and the *Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938*.[52] In the 1906 Act, the FDA was granted the power to regulate "*all medicines and preparations ... for internal or external use ... intended for cure, mitigation or prevention of diseases ...*" Yet, it was not until the 1938 Amendments that the word "device" appeared

[52]This Act is widely known for requiring pre-market notification for the safety of new *drugs*. The pre-market approval of the efficacy was included in the Drug Amendments of 1962.

in the statutes and the FDA "*embarked upon the prosecution of defective medical devices moving in interstate commerce.*" Medical devices were defined as (*21 U.S.C. § 321 (h)*):

> ... instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, care, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

There are some similarities between the statutory sanctions governing drugs and those governing medical devices. For example, both drugs and devices are subject to prohibitions against adulteration and misbranding. Once the case of adulteration and/or misbranding is confirmed, the FDA can proceed and seize the item. Drugs and devices are subject to identical court proceedings with an injunction following the seizure.

However, the FDA does not have the same authority over device manufacturers as it does over drug manufacturers. For instance, device manufacturers are not required to register with the Secretary of the Department of Health, Education and Welfare. They are free to produce and market new devices without maintaining records or proving that the new device is either safe, reliable, or effective. In other words, the Secretary has no power of approval or subsequent disapproval. Moreover, the device manufacturer can even refuse the Secretary to inspect records, files, papers, processes, production control procedures, and facilities in case of suspected adulteration or misbranding. In particular, as noted in Finck (1974), the FDA typically has to rely on complaints to its own discoveries before regulatory authority can be revoked. Therefore, the regulatory scheme did not ensure the discovery of deficient medical devices at all.

In terms of *ex-post* regulation, the FDA can act against a medical device in various ways. First, it can seize one single device. The single seizure is followed by an *in rem* proceeding during which the FDA seeks to have the device declared adulterated or misbranded. However, the FDA is prohibited by statute from seizing others until an injunction is obtained. Second, the FDA can secure an injunction against shipments of the defective device in interstate commerce if the device has been declared adulterated or misbranded and experienced a

further hearing. Third, if the device is believed to create imminent danger to health, the FDA is empowered to make unlimited seizures.

From the early 1960s to 1975, six Presidential messages were given and 28 bills were introduced to address medical device legislation. In congressional hearings in 1973, more examples of hazards associated with medical devices were provided: prosthetic and orthopedic implants of improper materials, cardiac defibrillators with faulty electrical circuitry, incubators in which temperatures tubes with obstructions, and faulty valves on emergency oxygen respirators (Udall, 1984). Eventually, such advancements culminated in the passage of the Medical Device Amendments of 1976.

A.1.2. The Medical Device Amendments of 1976

The Medical Device Amendments of 1976 established an elaborate and detailed scheme, more than doubling the length of the FFDCA (1938). The primary goal of this 1976 Amendment is to "provide reasonable assurance of the safety and effectiveness of medical devices" (FDA).[53]

The FDA was granted the authority to (1) create a three-class, risk-based classification system for all medical devices, (2) establish the regulatory pathways for new medical devices (devices that were not on the market prior to May 28, 1976, or had been significantly modified) to get to market, (3) create the regulatory pathway for new investigational medical devices to be studied in patients, (4) establish several key postmarket requirements: registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices, and (5) ban devices. Most importantly, the 1976 Amendments provided regulation based on the degree of potential risk posed by a device.

A.2. Details on State Radiation Control

As of March 1, 1969, although 47 of 53 "states" (including Puerto Rico, the Virgin Islands, and the District of Columbia) have passed legislation to authorize the control of

[53]See https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states, last accessed April 30, 2024.

ionizing radiation (Udall, 1984). Only 50% of these have adopted most of the provisions of the Council of State Governments' model regulations. As mentioned in Udall (1984),

> "Major inadequacies in a number of State programs include (1) lack of regulations or failure to update regulations to implement radiation control authority, (2) insufficient funds and personnel to conduct comprehensive control programs in the areas of ionizing and non-ionizing radiation, (3) no provision to license, certify, or set qualifications for operators of X-ray machines used in the healing arts, and (4) lack of uniformity in the control of health hazards from the use of radium and accelerator-produced radionuclides including **safety standards**, inspection-requirements, regulations, and enforcement."

A.3. Sample Selection and Construction

In the primary analysis, I used several historical patent datasets to construct my samples of interest. I first collected patent data from *Google Patents*, which directly records information on successful applications for patents granted by the USPTO between 1960-1980. These data include the full text of the patent (title, abstract, claims, and description) as well as patent identification numbers, names of inventors/assignees (if any), CPC classification, and application and publication (issue) years. One example of these patent files is provided in Figure A7.

There are two primary limitations of this original USPTO sample. First, the information on patent assignee only reflects the *current* assignees of a patent. Second, data on patent citations are missing. To fix these issues, I turn to the supplementary dataset, *the Comprehensive Universe of U.S. Patents* Berkes (2018), draw information on each patent's original assignee and the cumulative citations counts, and merge patent identification number to the USPTO data.

A.3.1 Other Historical Patent Data

Besides the CUSP (Berkes, 2018), there are several other historical patent datasets available. For example, HistPat (Petralia, Balland and Rigby, 2016) contains issued U.S.

Table 1. - Enabling Acts for Radiation Protection Regulations by State, as of June 30, 1972

State	Act/Year	Effective Date of Act	Responsible Agency or Remarks[a]
Alabama	Act 582/63	9/16/63	
Alaska	Chapter 66/57	3/18/57	Dept. of Environmental Conservation
Arizona	Chapter 30/64	7/15/64	Arizona Atomic Energy Commission
Arkansas	Act 8/61; as amended by H.B. 441/71	12/20/61; 4/28/71	Bureau of Environmental Health Services NOTE: To exclude any therapeutic instrument approved or licensed by the Federal Communications Commission from the definition of electronic products.
California	Chapter 1711/61; as amended by A.B. 2491/71	7/1/62; 11/8/71	NOTE: Radioactive Waste
Colorado	Chapter 156/57; S.B. 231/65; as amended by S.B. 108; as amended by S.B. 1	3/13/57; 4/23/65 6/1/67; 7/1/68	
Connecticut	Public Act 550/67	6/20/67	
Delaware	Chapter 74	4/26/68	
Florida	Chapter 290/61; S.B. 670/71	2/21/62; 6/18/71	NOTE: Nonionizing
Georgia	Act 936/64; as amended by H.B. 864; as amended by H.B. 1586	7/1/64; 4/3/68 4/8/68	Department of Human Resources
Hawaii	Chapter 18/51	5/2/51	
Idaho	Chapter 243/61; H.B. 519/72	5/2/61; 3/27/72	
Illinois	S.B. 515/59; as amended by S.B. 756/63; as amended by H.B. 1041/71	8/16/63; 7/10/71 7/10/71	NOTE: Extend license to users of radium and radioactive materials artifically-produced
Indiana	Chapter 77/59; as amended by Chapter 116/61 as amended by S.B. 601/71	3/4/61; 4/14/71	NOTE: Electronic Products
Kansas	Chapter 290/63; as amended by S.B. 236/72	7/1/63; 2/18/72	NOTE: Electronic Products
Kentucky	Section 152.120 (1A), 152.125, & 152.190, Ky. Rev. Stat.; as amended by S.B. 284/60; H.B. 404/72; as amended by H.B. 362/72	3/25/60 3/29/72; 3/30/72	NOTE: User Control X-ray and Electronic Products
Louisiana	Act 84/62; as amended by H.B. 1165	8/1/62; 7/31/68	Louisiana Board of Nuclear Energy
Maine	Chapter 403/61	3/2/62	
Maryland	Article 43; as amended by Chapter 88/60 as amended by S.B. 93	6/1/60 6/1/68	
Massachusetts	Chapter 633/60, Chapter 224/61; S.B. 1148	11/28/60; 612/61 10/9/68	Massachusetts Department of Labor and Industries
Minnesota	Chapter 361/57	4/11/57	
Mississippi	H.B. 499/64	4/24/64	
Missouri	S.B. 322/63	10/13/63	
Montana	H.B. 245/67	7/1/67	
Nebraska	L.B. 19/63; L.B. 1405/72	10/19/63; 4/8/72	NOTE: Create Regional Radiation Health Center to provide care and treatment of radiation casualties
Nevada	A.B. 495/63	7/1/63	
New Hampshire	H.B. 597/63; as amended by A.B. 207/71	7/2/63; 6/8/71	NOTE: Nonionizing and license fees for ionizing x rays
New Jersey	Chapter 116/58; as amended by S.B. 2901/71	7/8/58; 12/30/71	Dept. of Environmental Protection Agency NOTE: Nonionizing radiation
New Mexico	Chapter 185/59; as amended by H.B. 426/71	6/12/59; 4/8/71	Environmental Improvement Agency NOTE: Radioactive materials
New York	Section 201 & 255, P.H. Law, as amended by Chapter 628/60, and S.B. 4570/66 S.B. 6480.71; S.B. 4888/71 as amended by S.B. 7278/72; A.B. 8041/71; S.B. 8118/72 & A.B. 8381/72	4/18/60; 5/23/66 7/2/71; 6/17/71 4/5/72; 4/25/72 6/2/72; 6/2/72	NOTE: 1 chiropractor and x-ray technologist
North Carolina	Chapter 104-C, General Statute, as amended by H.B. 34/63	6/26/63	
North Dakota	S.B. 202/65; Chapter 446/65	7/1/65; 7/1/65	N. Dak. Water Conservation Commission
Ohio	H.B. 410/59	11/4/59	
Oklahoma	S.B. 26/63; as amended by H.B. 678/63 H.B. 1020	7/1/63; 6/18/63; 4/22/68	
Oregon	Chapter 664/61	8/9/61	
Pennsylvania	Act 578/65; as amended by S.B. 320	1/28/66; 9/30/68	Dept. of Environmental Resources
Puerto Rico	Act 79/65; as amended by H.B. 462	7/1/65; 3/26/67	
South Carolina	Act 302/67	5/1/67	
South Dakota	S.B. 162/67	7/1/67	
Tennessee	Chapter 66/59; as amended by S.B. 167/71	7/1/59; 4/16/71	
Texas	Chapter 72/61; as amended by S.B. 3271/71 and H.B. 733/71	4/17/61; 5/25/71 and 6/9/71	NOTE: User, chiropractic, and nonionizing legislation
Utah	H.B. 137/67	5/9/67	
Vermont	H.B. 59/67	7/1/67	
Virginia	Chapter 158/64; Chapter 314/68	3/3/67; 6/28/68	
Washington	Chapter 207/61; as amended by S.B. 15/65	6/30/61; 8/6/65	
Wisconsin	Chapter 325/63; as amended by Chapter 459/63	9/25/63; 1/4/84	
Wyoming	Chapter 153/55	2/19/55	Registration Statute

[a]Unless otherwise specified, statutes designate the State health department as the agency responsible for radiation protection with the authority to adopt regulations.

Figure A2: Enabling Acts for Radiation Protection Regulations by State

patents filed from 1790 to 1978, collected from USPTO-digitized patent images. I prefer to use the raw USPTO data, supplemented with the CUSP as the baseline patent data in this analysis, instead of the HistPat, for several reasons.

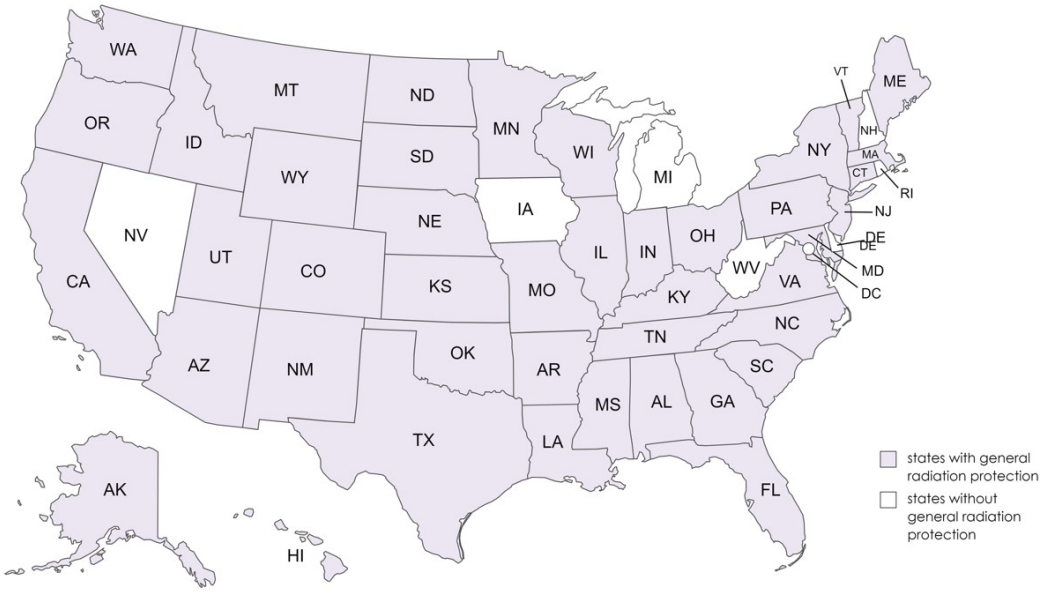


Figure A3: State Actions for General Radiation Protection

First, the fact that the HistPat only contains the data on patent issue dates rather than patent filing dates is a central limitation. Because what I am interested in is exploring how firms' patenting activities responded to the RCHSA, long lags between patent applications and patent grants can make my results more difficult to interpret. I thus extract information from the CUSP data, which includes both filing and issue dates for each patent.

Second, the HistPat data only covers patents filed by U.S. firms and independent inventors. However, as mentioned in Section 7.1.2, I am interested in investigating responses from both domestic and foreign firms following the RCHSA to control for unobserved technological breakthroughs uniformly affecting all entities. Note, as pointed out in , Andrews (2021), while both the CUSP and HistPat datasets are very accurate, the CUSP has a slightly higher error rate for the sample patents for patents according to the spot-checking. For this reason, I first merge the CUSP data to the primary USPTO sample on patent identification numbers, and then carefully and manually identify whether a patent was filed by foreign entities based on the nationality of its assignees.

Third, another limitation of the HistPat data is its relatively short time span (being terminated in 1978). Recall in Figure 1.1, I emphasized the innovation effect induced by the

RCHSA appears to fade out over time. To directly and transparently examine this pattern, an event-study specification with detailed data on patenting in the subsequent period is necessary. To do so, I rely on the USPTO-CUSP sample to implement such exercises.

A.3.2 Constructing KPSS-Compustat Sample

The primary firm-level sample of interest is constructed in the following three steps. First, I merge all patent data under the broad category `A61B` from the KPSS data to the CRSP data using the unique stock ID (`permno`). This way, I identify 443 unique firms in total. Put differently, all firms have filed at least one `A61B` patent application from 1950 to 1990. Second, I manually merge the CRSP data of these 443 firms to the Compustat data using the 9-digit firm identifier (`CUSIP`) and construct the CRSP-Compustat sample, which includes 365 unique firms and 13,009 firm-year observations. Specifically, for each firm with a history of `A61B` patenting, I include its relevant data from the Compustat at the annual frequency. Finally, I collapse all patent data under `A61B` in the KPSS sample at the firm-class-year level and merge these collapsed data back to the CRSP-Compustat sample. The value zero is assigned to observation ($patent_{ict} = 0$) if the given firm i did not apply for any patent under the class c in year t.

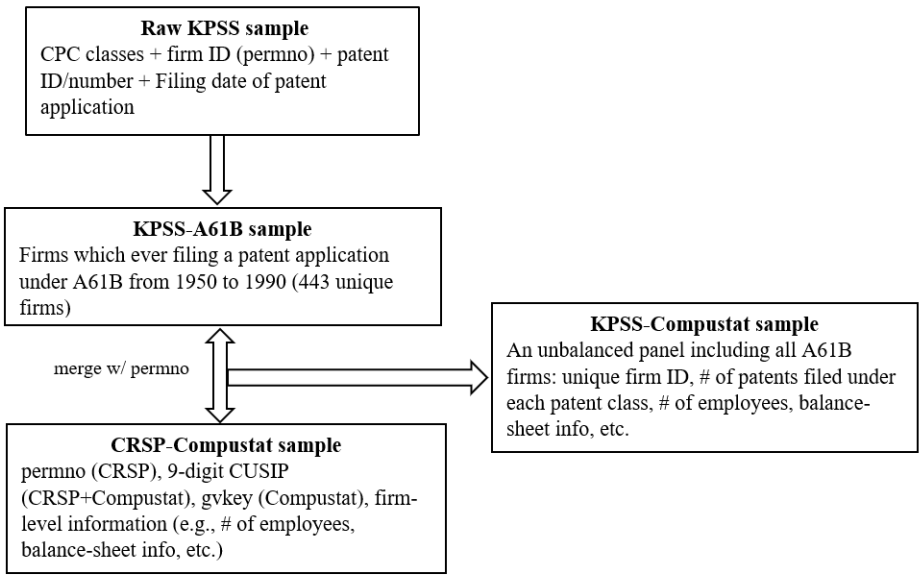


Figure A4: Construction of the KPSS-Compustat Sample

A.4 Robustness of the CPC Approach

In the primary analysis, I relied on the detailed CPC code to distinguish the treatment and control groups and identify key patent attributes. Here, I discuss some limitations of this approach and how I address some of them in robustness checks.

Recall the information on the *principal* technological category of a patent is unavailable in the CPC system. Thus, when using the patent subclass as the basic unit of analysis, it is possible we may double-count a patent. To mitigate the concern, I re-collapsed all patents to the *class-year* level and re-estimated the innovation effects. Table A1 presents the results of this robustness check: relative to other non-radiation diagnostic medical equipment patents, patent count relating to diagnostic X-ray medical devices increased by 61.8%, or say 13.65 patents per year under the class `A61B6`. These estimates are consistent with the results in Section 1.6: there is a 42.4% increase (or equivalently 0.83 patents per subclass-year) among diagnostic X-ray medical device patents.[54]

[54]Under the patent class `A61B6`, there are 16 two-dot subclasses. Thus, the class-level increase is equivalent to 13.28 patents per class-year.

Table 1.21: Effects of Radiation Control on Patent Counts (Class-Level Analysis)

	OLS			Poisson		
	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
$Treat_c \times Post1969_t$	0.618***	0.788***	0.654***	0.569***	0.814***	0.801***
	(0.159)	(0.157)	(0.141)	(0.116)	(0.117)	(0.118)
mean of DV (1960-1967)	22.09	25.33	39.52	22.09	25.33	39.52
# of obs.	168	189	273	168	189	273
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`.

A.5. Details on Text Analysis

In this section, I discuss my text-analysis approach in detail. I begin by describing the primary objective of my text-analysis algorithm and then provide an illustrative example. I also address a few threats to my current algorithm and propose some future directions to improve the performance.

A.5.1. Reading Data from Patent Files

The primary goal of employing text analysis, as mentioned in Section 4.5.2, is to more precisely describe and identify the patent attribute. To do so, I analyze the texts of diagnostic X-ray medical device patents and determine if a patent emphasizes risk mitigation. I finally categorize patents in my treatment group (`A61B6`) into two subsets: risk-mitigating patents and radiation-generating patents.

The approach applied in my paper is somewhat similar to the sentiment analysis in prior literature (Shapiro and Wilson, 2019; Shapiro, Sudhof and Wilson, 2022), which ranks and rates the sentiment of a publication, writer, or speaker. Recent papers in innovation also employed similar methods to describe and identify patent attributes (Dechezleprêtre et al.,

2019; Clemens and Rogers, 2022). In particular, my approach is in the same spirit as the simple *Lexical Methodology*, which "assigns a document a sentiment score based on the sum or mean of the values assigned to the words in its text by the lexion" (Clemens and Rogers, 2022). Similar to the algorithm that makes use of lexicons that assign positive and negative values to the sentiment associated with extensive lists of words, my text analysis vectorizes both the keyword list and the patent data and assigns a relevance score to each patent by using word embeddings.

A.5.2. Examples of Patent Texts

As mentioned in Clemens and Rogers (2022), when using algorithms to "extract economic information from (patent) text, researchers must overcome errors driven by the complexity of language." In other words, there could be errors stemming from variations in a word's meaning across contexts. In particular, two terminologies capture these issues: polysemy and synonymy (Magerman et al., 2011). The former refers to the case wherein words may have multiple, context-specific meanings, while the latter arises when multiple words have the same meaning. Both may generate errors in my context.

For example, one of these keywords, "*protection*," is tricky to work with since it has multiple meanings under different scenarios. In one patent `US4289142A`, the word "protection" has been captured multiple times, but in most cases, it does not indicate consumer protection. Instead, it emphasizes protecting the X-ray system against damage in the subject while respiration is being monitored.

> "Electrodes E1, E2 and EC are all coupled to suitable over-voltage protection circuitry 210. Over-voltage protection circuitry 210 is primarily to protect against damage to the monitor in the event of defibrillation procedures on the subject. The over-protection circuitry, in effect, couples electrodes E1 and E2 and the common reference electrode EC to the respective input terminals of a high input impedance differential amplifier 212. Suitable over-protection circuitry 210 and high input impedance amplifier 212 are shown in schematic form in FIG. 2b."

Meanwhile, when describing the trait "*risk-mitigation*," inventors might use a variety of terms. For example, in patent US4062518, three keywords are employed to emphasize the feature of risk mitigation: shield/shielding, minimize, and protect/protecting/protection. In this case, the issue of false negatives may arise when a relevant term relating to risk-mitigating is not detected.

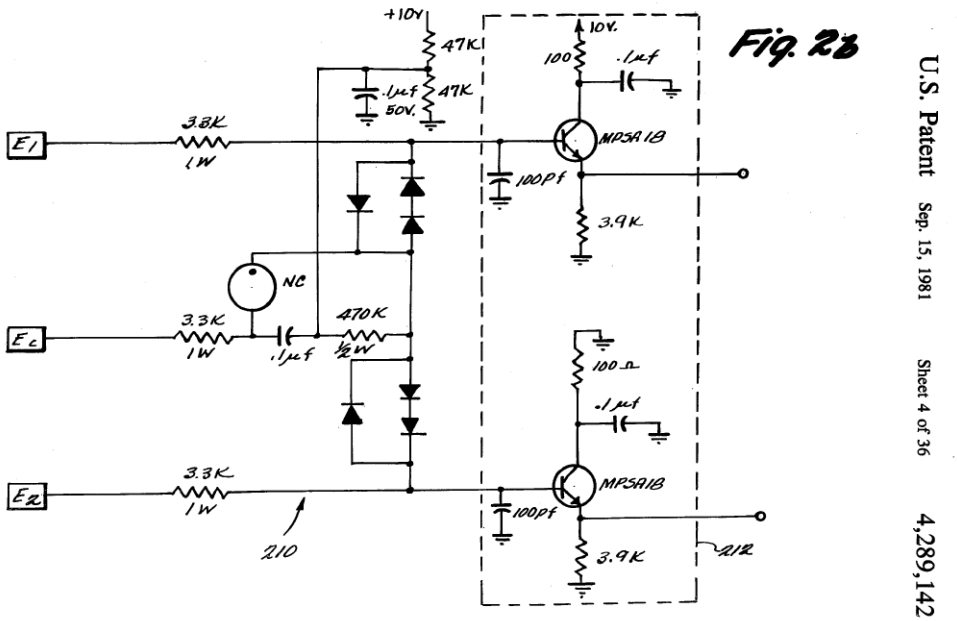


Figure A5: Example of Polysemy

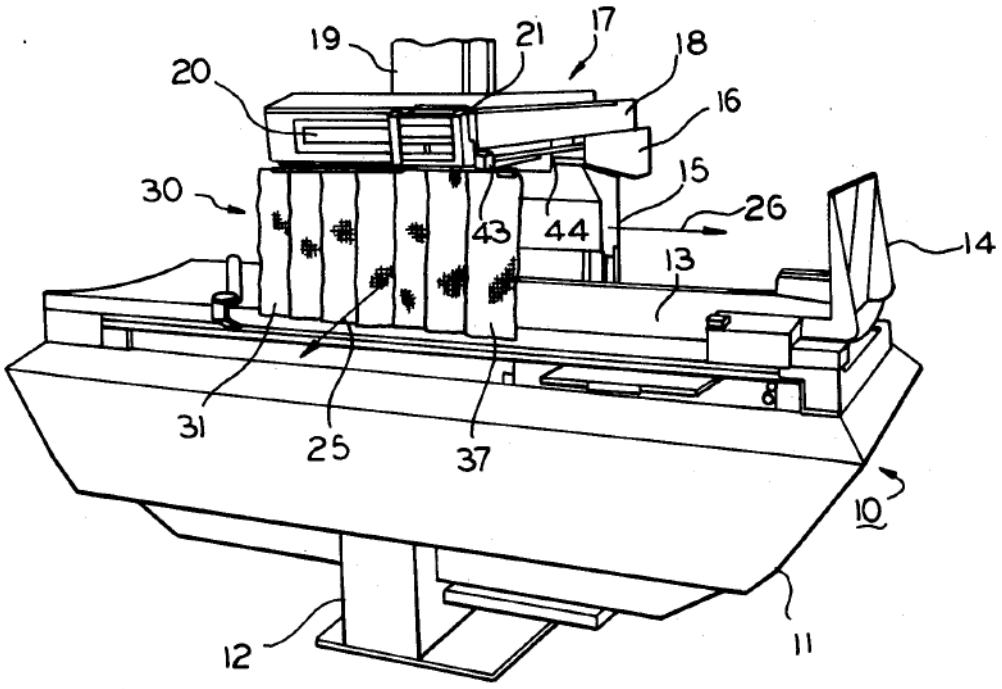


Figure A6: Example of Synonymy

A.5.3. Future Work to Improve Accuracy

Going forward, I will focus on improving the accuracy of my algorithm. Most importantly, I am following Clemens and Rogers (2022) to construct a model "directly targeting the issues of synonymy and polysemy." In particular, instead of creating a relatively arbitrary list of keywords like Galasso and Luo (2021), I will first identify each keyword's synonyms. The basic idea is to map all the patent text corpora to a vector space and use Word2Vec to calculate the cosine similarity between each keyword and relevant synonyms within these patent data. This modified model can generate a more comprehensive and less arbitrary list of keywords to capture key traits, including risk-mitigating and radiation-generating.

A.6. Patent Classification

Table 1.22: Description of Subclasses under A61B (Diagnosis)

A61B1	Instruments for performing medical examinations of the interior of cavities or tubes of the body by visual or photographical inspection, e.g. endoscopes; Illuminating arrangements therefor
A61B3	Apparatus for testing the eyes; Instruments for examining the eyes
A61B5	Measuring for diagnostic purposes; Identification of persons
A61B6	Apparatus for radiation diagnosis, e.g. combined with radiation therapy equipment
A61B7	Instruments for auscultation
A61B8	Diagnosis using ultrasonic, sonic or infrasonic waves (imaging of objects using sonar G01S 15/00)
A61B9	Instruments for examination by percussion; Pleximeters
A61B10	Instruments for examination by percussion; Pleximeters
A61B13	Instruments for depressing the tongue
A61B16	Devices specially adapted for vivisection or autopsy (similar devices for medical purposes, see the relevant groups for such devices ; autopsy tables A61G 13/0027)

Table 1.23: Description of Subclasses under A61F

A61F2	Filters implantable into blood vessels; Prostheses, i.e. artificial substitutes or replacements for parts of the body; Appliances for connecting them with the body; Devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g. stents
A61F3	Lengthening pieces for natural legs
A61F4	Methods or devices enabling patients or disabled persons to operate an apparatus or a device not forming part of the body
A61F5	Orthopaedic methods or devices for non-surgical treatment of bones or joints
A61F6	Contraceptive devices; Pessaries; Applicators therefor
A61F7	Heating or cooling appliances for medical or therapeutic treatment of the human body
A61F9	Methods or devices for treatment of the eyes; Devices for putting-in contact lenses; Devices to correct squinting; Apparatus to guide the blind; Protective devices for the eyes, carried on the body or in the hand
A61F11	Methods or devices for treatment of the ears or hearing sense; Non-electric hearing aids; Methods or devices for enabling ear patients to achieve auditory perception through physiological senses other than hearing sense; Protective devices for the ears, carried on the body or in the hand
A61F13	Bandages or dressings; Absorbent pads
A61F15	Auxiliary appliances for wound dressings; Dispensing containers for dressings or bandages
A61F17	First-aid kits

Table 1.24: Description of Subclasses under A61K

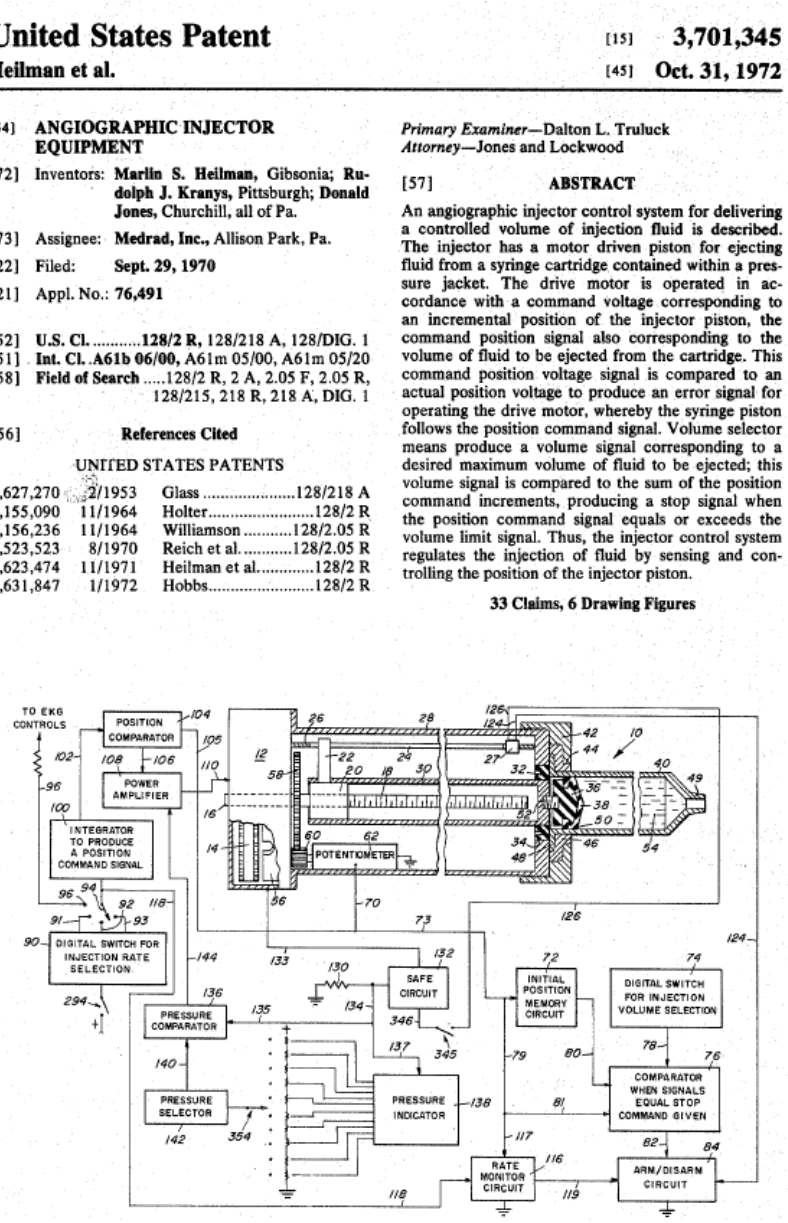
A61K6	Preparations for dentistry
A61K8	Cosmetics or similar toiletry preparations
A61K9	Medicinal preparations characterised by special physical form
A61K31	Medicinal preparations containing organic active ingredients
A61K33	Medicinal preparations containing inorganic active ingredients
A61K35	Medicinal preparations containing materials or reaction products thereof with undetermined constitution
A61K36	Medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicines
A61K38	Medicinal preparations containing peptides
A61K39	Medicinal preparations containing antigens or antibodies
A61K41	Medicinal preparations obtained by treating materials with wave energy or particle radiation
A61K45	Medicinal preparations containing active ingredients not provided for in groups A61K 31/00 - A61K 41/00
A61K47	Medicinal preparations characterised by the non-active ingredients used, e.g. carriers or inert additives; Targeting or modifying agents chemically bound to the active ingredient
A61K48	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
A61K49	Preparations for testing in vivo
A61K51	Preparations containing radioactive substances for use in therapy or testing in vivo
A61K2121	Preparations for use in therapy
A61K2123	Preparations for testing in vivo
A61K2236	Isolation or extraction methods of medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicine
A61K2300	Medicinal preparations characterized by the non-active ingredients used, e.g. carriers or inert additives; Targeting or modifying agents chemically bound to the active ingredient
A61K2300	Mixtures or combinations of active ingredients, wherein at least one active ingredient is fully defined in groups A61K 31/00 - A61K 41/00
A61K2800	Properties of cosmetic compositions or active ingredients thereof or formulation aids used therein and process related aspects

Table 1.25: Patent Attributes under A61B6

Attributes	**CPC subclass**	**Description**
radiation risk mitigating	A61B6/10	Application or adaptation of safety means
	A61B6/54	Aspects of radiation diagnostic devices concerning control of the device or parts of the device.
	A61B6/58	Means for assessing and adjusting the parameters of the device as a function of the system geometry.
(relying on) the generation of radiation	A61B6/14	Radiation diagnosis devices specially adapted for a dental examination, e.g. devices for panoramic imaging of the teeth.
	A61B6/40	Radiation diagnostic devices comprising a radiation source for generating radiation and arrangements for manipulating said radiation by shaping the radiation beam, displacing it or modifying its characteristics.
	A61B6/44	Diagnostic devices comprising structural or mechanical arrangements allowing a specific usage or property, e.g. movement, modularity.
	A61B6/46	Radiation diagnosis devices comprising input and/or output means structurally or functionally designed for allowing a specific interaction with the device user or the patient.
	A61B6/48	Diagnostic devices involving a specific use of ionising radiation to perform a particular type of diagnosis. Imaging techniques are independent of the device used for implementing them.
	A61B6/50	Clinical applications: Classification in this group depends on the body part or organ which is to be diagnosed.
	A61B6/52	Radiation diagnosis devices involving any kind of processing of data (raw data or diagnostic data) or image processing for enhancement purposes, e.g. artefacts reduction or resolution improvement.
	A61B6/56	Radiation diagnosis devices comprising: means for transmitting/receiving data to/from an external device or between components of the device, e.g. image transmission to a remote physician workstation for diagnosis; or means for supplying power to any component of the device, e.g. between stationary and moving parts.

Attributes	CPC subclass	Description
the detection of radiation	A61B6/06	Diaphragms specially adapted for particular diagnostic applications, e.g. tomography. Devices adapted to modify the spatial confinement of the cross-section of the radiation beam, e.g. collimators, situated between the source unit and the patient.
	A61B6/08	Radiation diagnosis devices comprising means for assessing direction and/or extent of the radiation beam before acquisition.
	A61B6/10	This class covers the use of radiation diagnostic devices to determine the position of a surgical instrument during an operation.
the patient support	A61B6/04	Any means, e.g. tables, beds, chairs, suitable for positioning the patient in the diagnostic device.

A.7. Additional Figures



United States Patent

Heilman et al.

[15] **3,701,345**

[45] **Oct. 31, 1972**

[54] **ANGIOGRAPHIC INJECTOR EQUIPMENT**

[72] Inventors: **Marlin S. Heilman,** Gibsonia; **Rudolph J. Kranys,** Pittsburgh; **Donald Jones,** Churchill, all of Pa.

[73] Assignee: **Medrad, Inc.,** Allison Park, Pa.

[22] Filed: **Sept. 29, 1970**

[21] Appl. No.: **76,491**

[52] **U.S. Cl.** .....**128/2 R,** 128/218 A, 128/DIG. 1

[51] **Int. Cl. A61b 06/00,** A61m 05/00, A61m 05/20

[58] **Field of Search** .....128/2 R, 2 A, 2.05 F, 2.05 R, 128/215, 218 R, 218 A, DIG. 1

[56] **References Cited**

UNITED STATES PATENTS

2,627,270	2/1953	Glass	128/218 A
3,155,090	11/1964	Holter	128/2 R
3,156,236	11/1964	Williamson	128/2.05 R
3,523,523	8/1970	Reich et al.	128/2.05 R
3,623,474	11/1971	Heilman et al.	128/2 R
3,631,847	1/1972	Hobbs	128/2 R

Primary Examiner—Dalton L. Truluck
Attorney—Jones and Lockwood

[57] **ABSTRACT**

An angiographic injector control system for delivering a controlled volume of injection fluid is described. The injector has a motor driven piston for ejecting fluid from a syringe cartridge contained within a pressure jacket. The drive motor is operated in accordance with a command voltage corresponding to an incremental position of the injector piston, the command position signal also corresponding to the volume of fluid to be ejected from the cartridge. This command position voltage signal is compared to an actual position voltage to produce an error signal for operating the drive motor, whereby the syringe piston follows the position command signal. Volume selector means produce a volume signal corresponding to a desired maximum volume of fluid to be ejected; this volume signal is compared to the sum of the position command increments, producing a stop signal when the position command signal equals or exceeds the volume limit signal. Thus, the injector control system regulates the injection of fluid by sensing and controlling the position of the injector piston.

33 Claims, 6 Drawing Figures

Figure A7: Example of A61B6 Patent Files

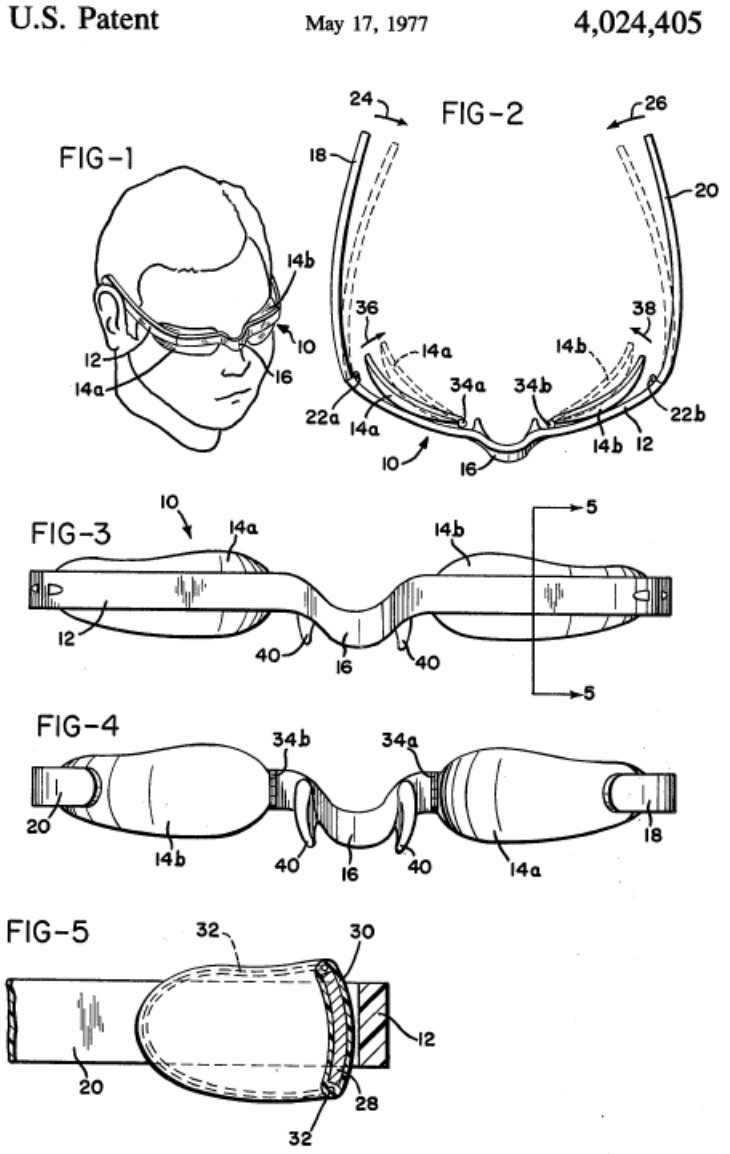


Figure A8: An Example of Risk-Mitigating Technology

Note: This is an example of technology reducing radiation exposure ("risk-mitigating technology"), which is an X-ray eye shield useful in protecting eye tissue from radiation during dental radiography.

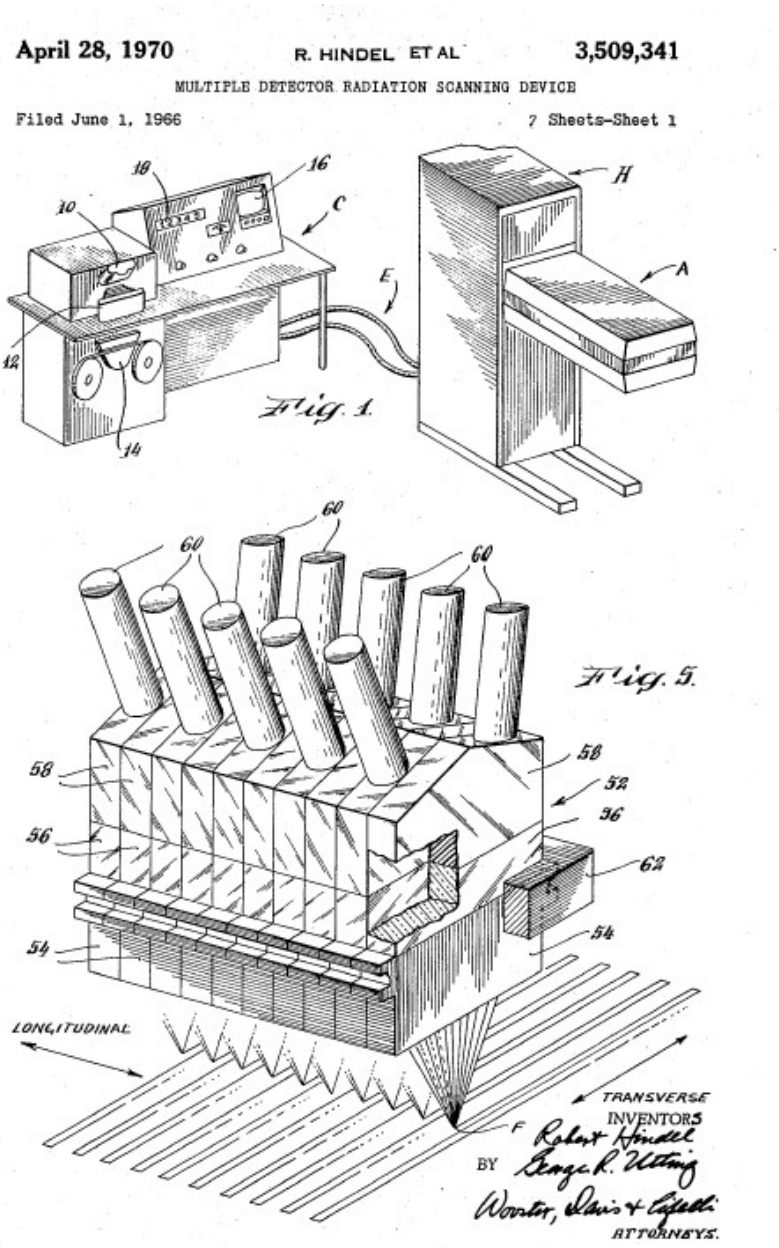


Figure A9: An Example of Radiation-Generating Technologies

Note: This is an example of technology representing new devices functioning based on radiation ("radiation-generating technology"), which is a multiple detector radiation scanning device.

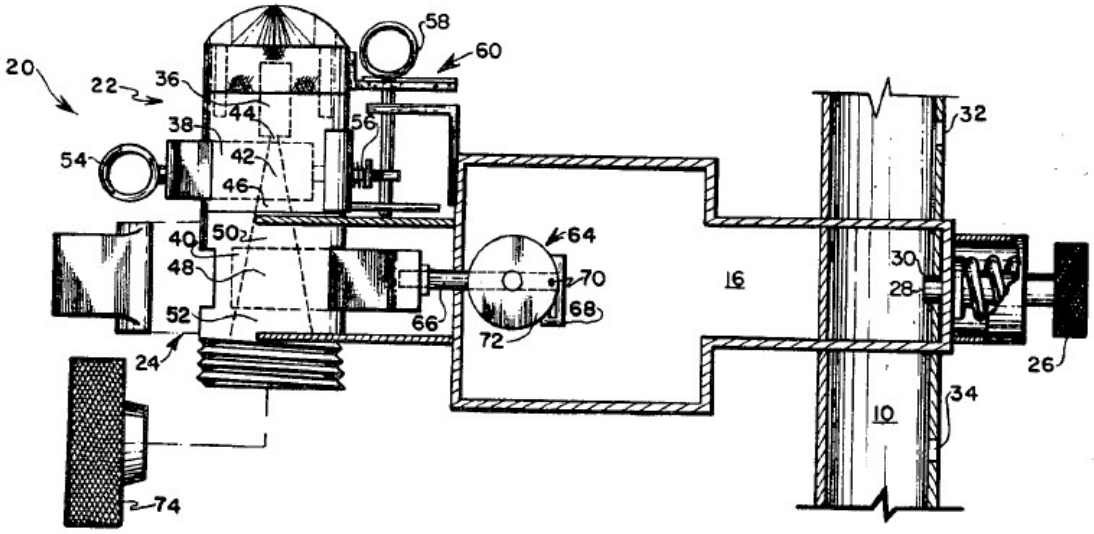


Figure A10: Example of Patents with Dual Features

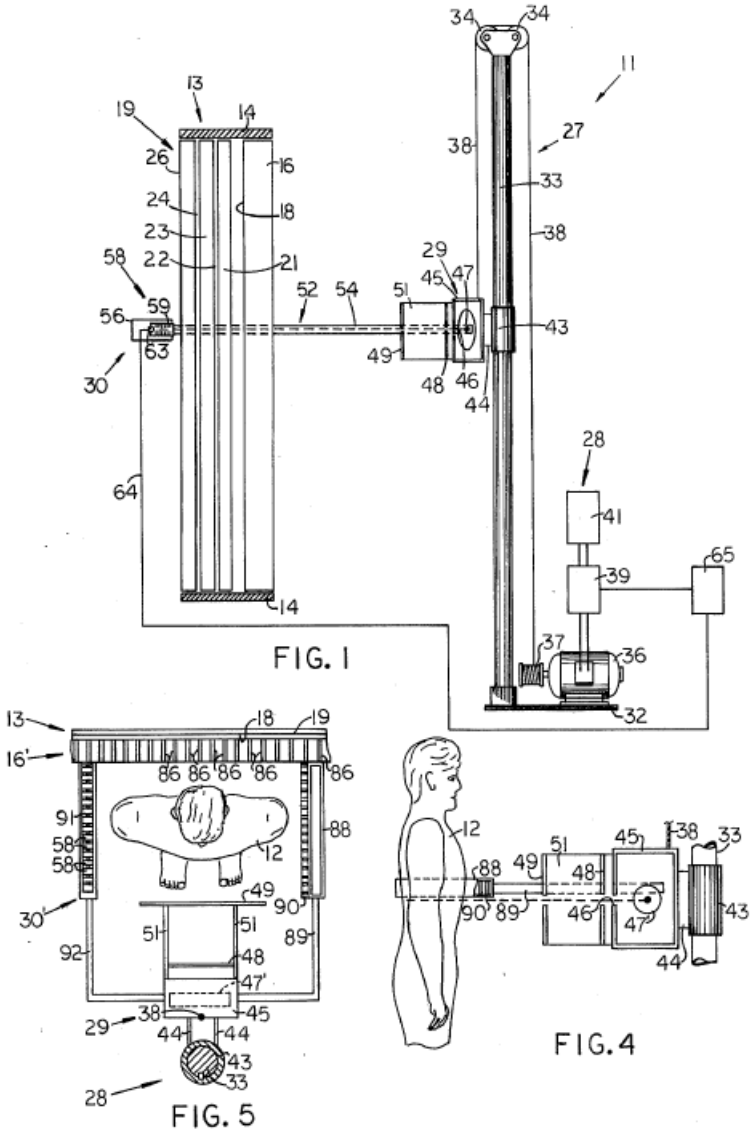


Figure A11: Example of Patents under Subclass A61B6/54

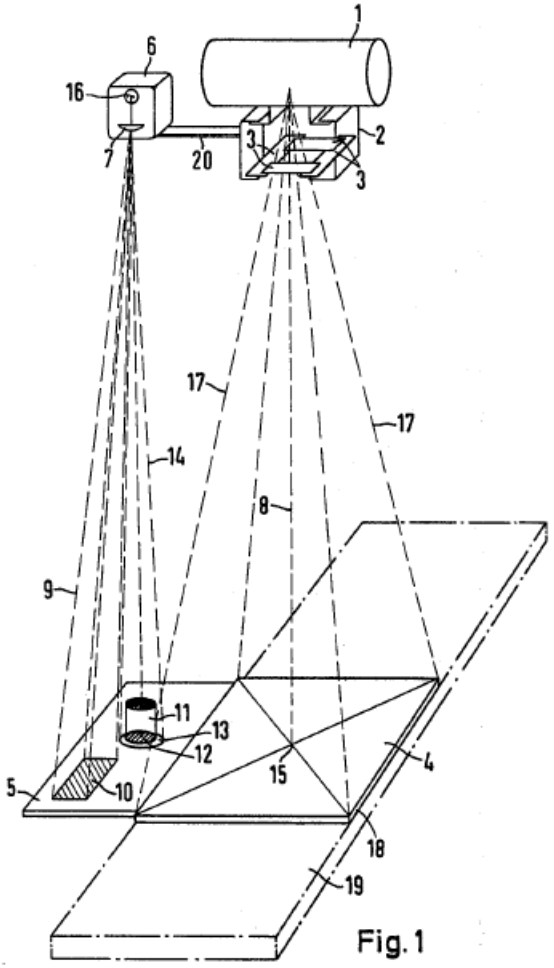


Fig. 1

Figure A12: Example of Patents under Subclass A61B6/58

Table 4. Total charges and percent distribution for discharges from short-stay hospitals by type of hospital service, according to geographic region and bed size of hospital: United States, 1968-70—Con.

[Excludes Federal hospitals, deliveries, and newborn infants]

Geographic region and bed size	All discharges	Room and care	Laboratory	Pharmacy	Radiology	Operating and/or recovery room	Professional services	Other services
1968	Charge in millions of dollars							
All hospitals	13,154	7,732	1,500	966	693	795	146	1,322
Region								
Northeast	3,798	2,351	459	193	211	219	60	305
North Central	4,113	2,377	469	322	214	247	16	468
South	3,307	1,850	367	314	177	192	38	369
West	1,937	1,154	205	136	90	138	32	182
Bed size								
6-99 beds	1,973	1,082	220	227	117	103	13	214
100-199 beds	2,453	1,387	295	206	144	139	26	256
200-299 beds	2,491	1,536	252	141	122	164	26	250
300-499 beds	3,977	2,361	457	267	200	260	58	374
500-999 beds	1,822	1,030	244	116	100	120	17	195
1,000 beds or more	438	336	32	9	11	10	6	34

Figure A13: A Snapshot of the NHDS

Table 1. Number and percent of discharges form short-stay hospitals, by sex and age of patient and type of hospital service: United States, 1968-70—Con.

[Excludes Federal hospitals, deliveries, and newborn infants]

Sex and age	All discharges	Room and care	Laboratory	Pharmacy	Radiology	Operating and/or recovery room	Professional services	Other services
1968								
Both sexes[1]	Number in thousands							
All ages[3]	24,531	24,471	23,100	22,049	15,164	10,458	2,756	21,479
Under 15 years	4,112	4,102	3,881	3,485	2,090	2,012	396	3,346
15-44 years	8,326	8,301	7,660	7,302	4,549	4,021	811	7,213
45-64 years	6,410	6,386	6,076	5,870	4,398	2,682	685	5,732
65 years and over	5,678	5,676	5,478	5,387	4,123	1,740	864	5,181
Male								
All ages[3]	11,370	11,351	10,603	10,071	7,280	4,513	1,310	9,826
Under 15 years	2,291	2,284	2,164	1,929	1,173	1,115	216	1,866
15-44 years	3,313	3,308	3,008	2,855	2,042	1,403	362	2,817
45-64 years	3,138	3,133	2,924	2,824	2,180	1,166	332	2,769
65 years and over	2,623	2,623	2,503	2,459	1,883	828	400	2,370
Female								
All ages[3]	13,102	13,061	12,441	11,925	7,848	5,922	1,437	11,601
Under 15 years	1,809	1,806	1,706	1,545	913	891	178	1,470
15-44 years	4,998	4,979	4,639	4,433	2,498	2,613	450	4,383
45-64 years	3,257	3,239	3,138	3,033	2,209	1,512	348	2,951
65 years and over	3,037	3,035	2,957	2,913	2,226	906	462	2,795

Figure A14: A Snapshot of the NHDS

A.8. Additional Event-Study Estimates

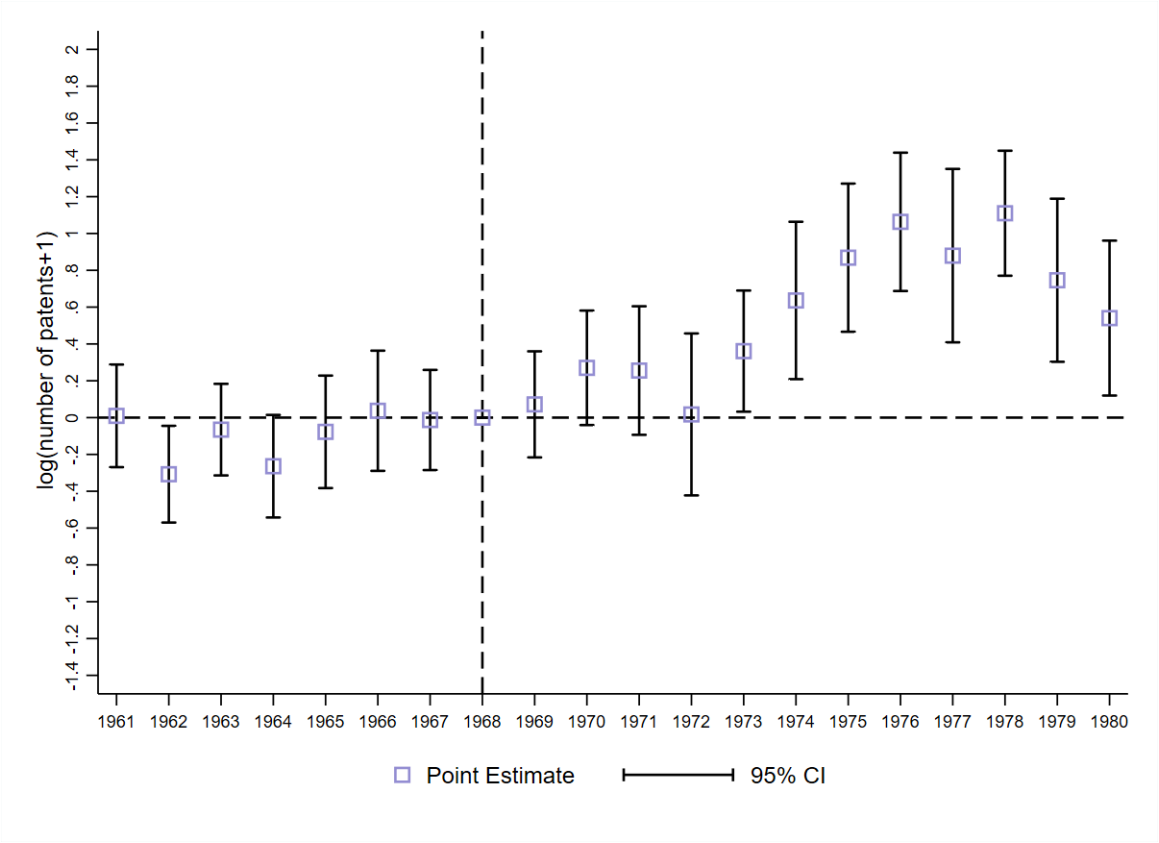


Figure A15: Event Study Estimates (with Medical Implants as the Control Group)

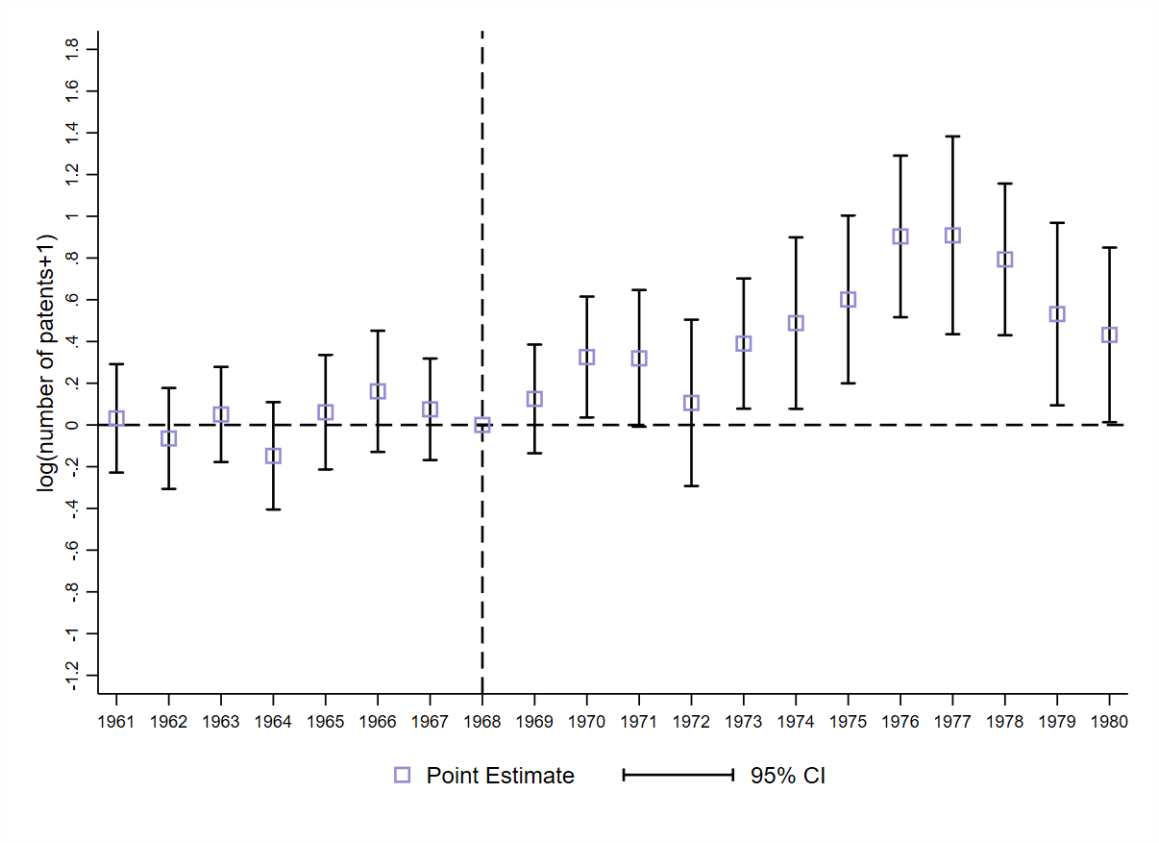


Figure A16: Event Study Estimates (with Drugs as the Control Group)

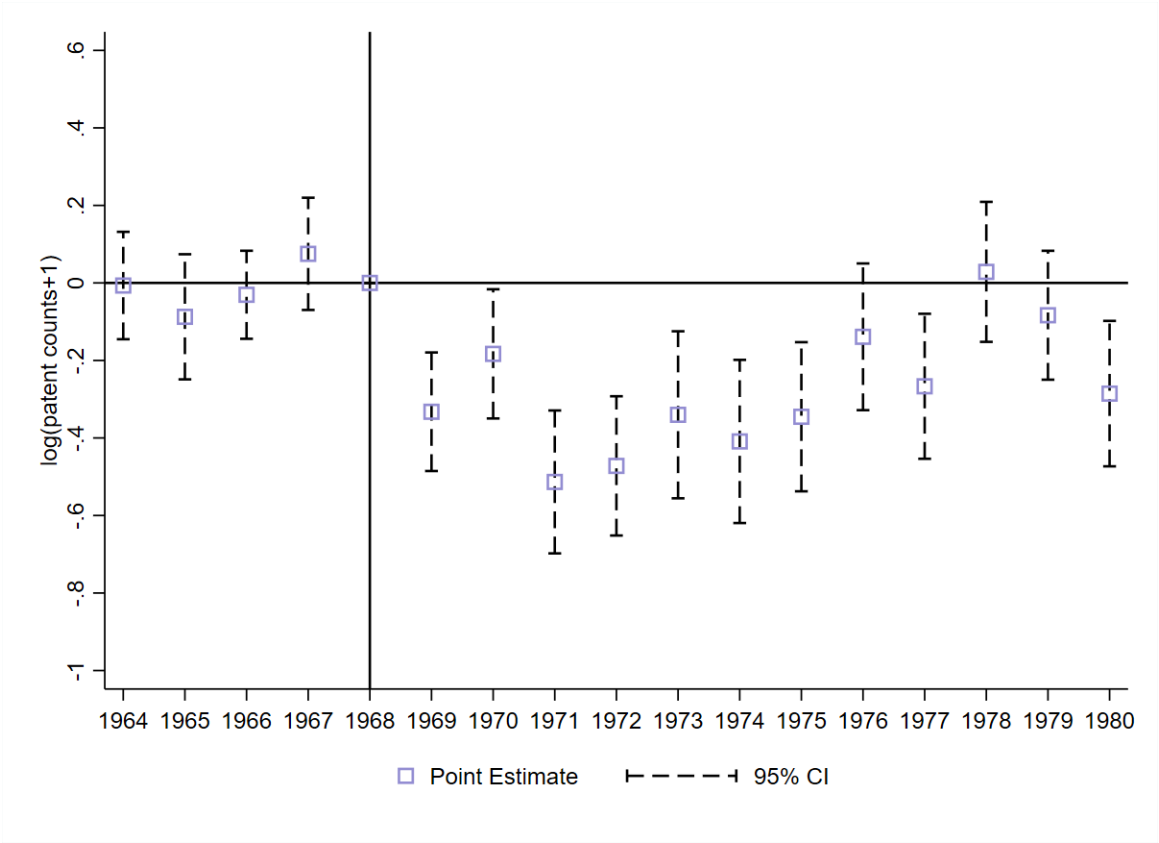


Figure A17: Event-Study Estimates (GE, Risk-Mitigating Technologies)

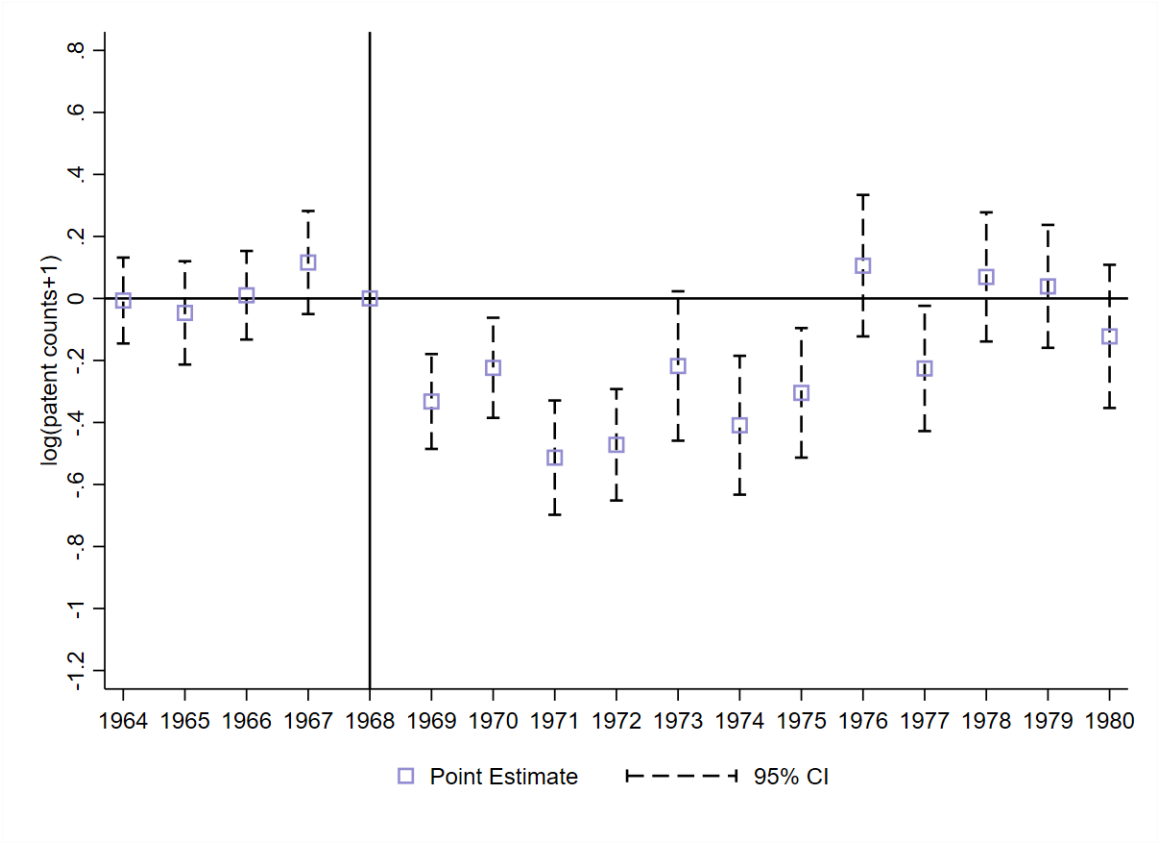


Figure A18: Event-Study Estimates (GE, Radiation-Generating Technologies)

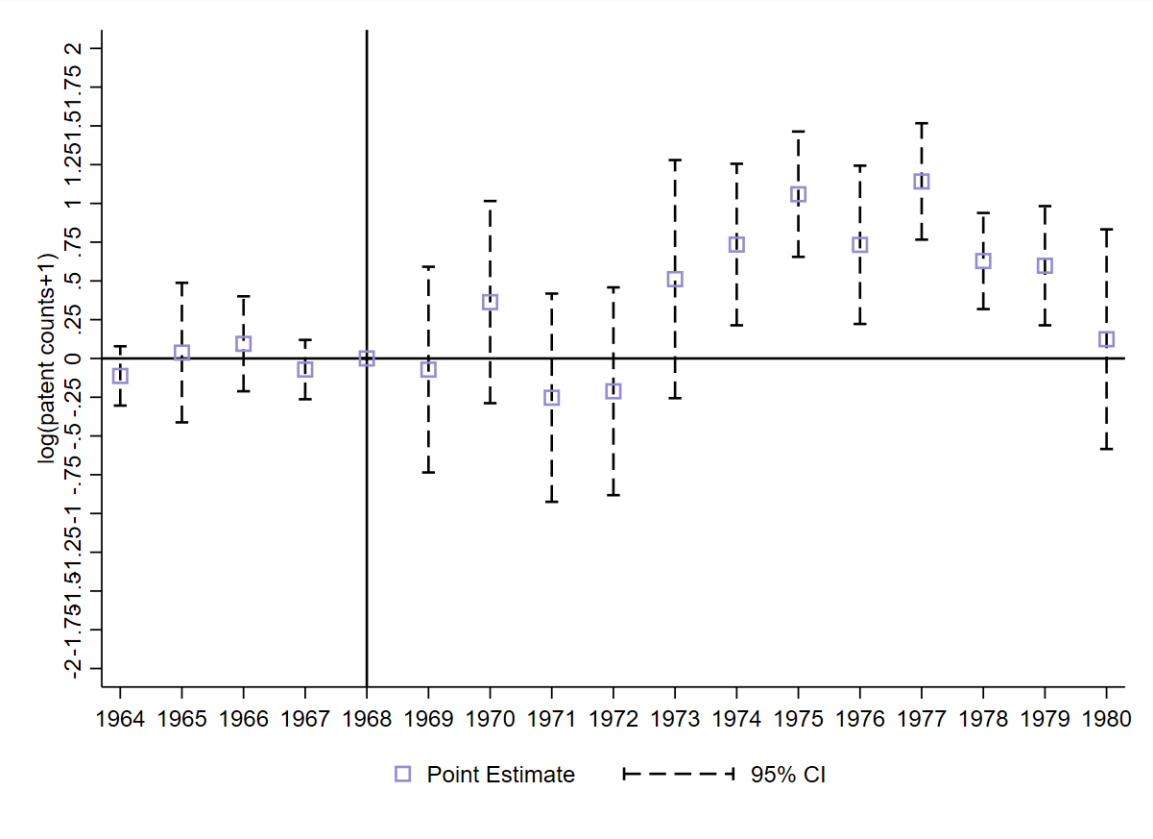


Figure A19: Event-Study Estimates (Non-GE Firms, Risk-Mitigating Technologies)

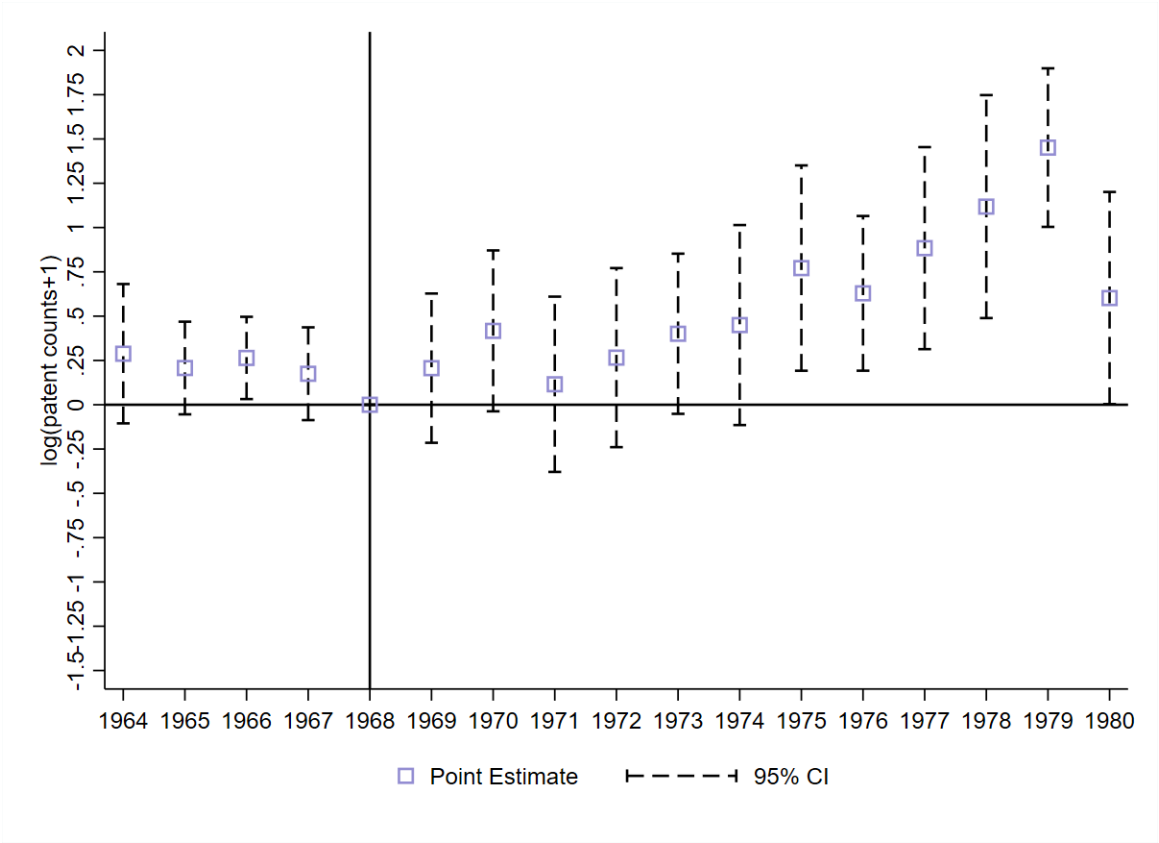


Figure A20: Event-Study Estimates (Non-GE Firms, Radiation-Generating Technologies)

Chapter 2

Cutting Red Tape: Administrative Simplification and Treatment Capacity

2.1 Introduction

Central to the ongoing debates in the U.S. healthcare system is balancing cost containment with providing high-quality services. Among many other issues, excess administrative spending is a critical concern, with prior estimates indicating that it accounts for approximately 20%to 34% of healthcare expenditures (Dunn et al., forthcoming).[1] A noteworthy feature of some administrative processes (e.g., cost control process) is that they present a delicate trade-off between mitigating consumer moral hazard in service utilization (Brot-Goldberg et al., 2023) and restraining facilities' treatment capacity. On the one hand, demonstrating and verifying medical necessity is essential to preventing over-utilization of healthcare services (Cutler, 2020), reducing unnecessary medical spending, and enhancing quality (GAO, 2018).[2] On the other hand, the imposition of these administrative processes can create sizable burdens on providers, hindering them from allocating resources efficiently. For example, prior authorization, quality limits, and step therapy are common cost control processes that can create barriers and lead to negative health outcomes among patients by delaying or denying access to treatments and increasing administrative costs for providers, who must navigate complex and often inconsistent rules and regulations across different plans.[3]

In this paper, I aim to add some empirical evidence along this line of discussion and investigate whether simplifying medical administrative requirements would affect the provision of behavioral healthcare services. To this end, I exploit the staggered roll-out of state

[1] Billing and coding costs, physician administrative activities, and insurance administrative costs are all primary drivers of these expenses (Chernew and Mintz, 2021).

[2] See https://www.gao.gov/assets/gao-18-341.pdf, last accessed April 30, 2024.

[3] For a detailed discussion regarding how prior authorization restrains providers' capacity of treatment, see https://www.ama-assn.org/practice-management/prior-authorization, last accessed April 30, 2024.

laws restricting the use of prior authorization in private health plans for substance abuse treatment (SAT) and explore if the provision of various SAT services is affected. Health plans routinely require physicians to obtain approval for a prescribed health service or medication in order to control costs and oversee coverage decisions. This process, named "*prior authorization requirement*," can impose a unique barrier for individuals seeking substance use disorder (SUD) treatment by delaying the initiation of care when an individual needs treatment, which places the patient at risk of continued substance use, medical complications, overdose, and death.(Weber, 2020). Starting in 2016, 18 states enacted laws to limit private insurers from imposing prior authorization requirements on an SUD service or medication.

Because the provision of SAT services hinges on The extent to which restricting PA affects the supply of SAT is theoretically ambiguous in the pairwise interactions between patients, private insurance companies, healthcare providers, and facilities. For example, among many other competing channels, removing PA requirements can trigger adverse selection and moral hazard in commercial insurance markets, thereby creating plausibly exogenous demand shocks to healthcare facilities. In the meantime, as shown in Dunn et al. (forthcoming), adding administrative ordeals in health plans may induce selective contracting between providers and insurers: Administrative burdens created by prior authorization can increase the marginal cost per treatment episode and deter providers. Further, prior authorization could add more general administrative burdens to facilities by tightening the capacity constraint regarding providing treatment and allocating medical resources. Last but not least, restricting the use of PA might also substantially influence individual providers' financial incentives if removing administrative costs can alter the medical price per treatment. Taken together, it is essential to rely on data to investigate the consequences of restricting PA on providers' decisions and responses.

In the empirical portion of this paper, I employ a stylized staggered difference-in-differences framework and assemble a variety of data sources to test relevant hypotheses. I start by checking PA restrictions' direct effects on the supply of SAT services of different intensities. Using detailed facility-level data from the National Survey of Substance Abuse Treatment Services (N-SSATS), I document two pieces of evidence: First, when restricting the use of prior authorization in private plans, the likelihood of solely providing

low-intensity services (i.e., regular outpatient service) significantly increases by 13.79%, relative to the probability of solely providing high-intensity services (i.e., intensive outpatient service, partial hospital service, residential inpatient service, and hospital-based inpatient service). Second, the likelihood of offering both types of service increased significantly by 5.95% relative to the likelihood of only offering high-intensity services. I further find that given the aggregate number of these specialty care facilities does not change, these results indicate a redirection in providing high-intensity care to low-intensity care.

I then turn to empirically test several potential channels to rationalize the shift from high-intensity to low-intensity care. First, I argue simplifying the administrative process can substantially expand facilities' treatment capacity (i.e., time and labor available to patients). I compile client-level data from the Treatment Episode Data Set (TEDS) and construct a key proxy for facilities' treatment capacity: the likelihood of experiencing any involuntary medical delay among newly admitted patients. By construction, this involuntary medical delay primarily reflects the issue of a facility's treatment capacity.

Consistent with the conceptual premise, I find that among patients within a regular outpatient setting, there is a significant decline in the likelihood of experiencing any normal and severe facility-induced medical delay by 10 percentage points, 4.4 percentage points, and 1.8 percentage points, respectively, following the law change. This evidence, along with my main results, thus emphasizes that when simplifying the administrative process, the treatment capacity of healthcare facilities has indeed been expanded. I further argue that the decline in high-intensity care provision can be partially explained by a mechanical shift in the demand for SAT (from high to low), the reallocation of medical resources, and facilities' dynamics (entry and exit). I am still in the middle of compiling more administrative data to probe the validity of these stories.

I also check an alternative mechanism if the shift of SAT services can be explained by patient quantity and composition changes. In other words, I test whether simplifying the administrative process can substantially change the composition of patients receiving this behavioral healthcare service. To do so, I first collapse both the admission data and the discharge data to the state-year cells and find there are no changes along these two margins, indicating PA restrictions do not affect the aggregate number of patients within all SAT

facilities. I then analyze if introducing PA restrictions induces any changes associated with key characteristics of both the newly admitted and newly discharged. Again, no statistically significant results are documented in this exercise. Overall, these two pieces of evidence rule out the possibility that PA restrictions significantly change the composition of within-facility patients and further suggest the observed shift in providing SAT services is not primarily driven by either adverse selection or moral hazard in the private insurance market (i.e., patients w/ higher risks of developing SUDs are more likely to get covered by private plans), or the moral hazard at the admission margin (i.e., conditional on being covered, marginal patients are incentivized to utilize more low-cost SUD services).

As for the second alternative explanation, I ask if the observed shift in provision towards low-intensity care is a result of *ex-post* moral hazard along the margin of treatment (i.e., conditionally on getting admitted, patients with higher background risk are more likely to continue the treatment or say, less likely to drop out of the program voluntarily). Extracting information for the TEDS (TEDS-D) discharge set, I construct a coarse measure of *ex-post* moral hazard — whether the discharge is because of voluntary decisions/intentions. My preliminary results show this proxy is not significantly affected by PA laws, thereby ruling out the channel of demand shocks due to moral hazard along the treatment margin.

Moving on to explore some alternative supply-side driving forces, I begin by examining whether changes in providers' prescribing and diagnosing behaviors can partially explain the redirection from high-intensity to low-intensity care. In these exercises, I restrict my attention to medication-assisted treatment (MAT) because it largely reflects individual providers' decisions (instead of decisions from an entire team) and is also more vulnerable to the use of PA. I first check the heterogeneous effects of PA by the type of outpatient services: whether it is the regular service (i.e., counseling and behavioral therapy) or medication-assisted service. My main results hold for both types, indicating the increased provision of outpatient care indeed reflects a mix of channels. Secondly, I also showed that in response to the law change, there is a decline in the equilibrium number of patients receiving outpatient MAT (as a proxy for the equilibrium utilization) and an increase in the likelihood of dropping out of an outpatient MAT program (as a measure of consumers' demand). Both findings are (again) in contrast to the conclusion that demand-pull forces drive up the provision of

low-intensity care; meanwhile, the evidence here also highlights that changes in the provision of MAT indeed stem from providers' prescribing behaviors following the removal of PA.

I then searched for any evidence of selective contracting between facilities and private insurers.[4] I use information from the N-SSATS to create an indicator for whether the facility accepts private/public plans/patients with no insurance respectively.[5] Results indicate that although simplifying PA processes does not affect the propensity to accept a private plan, the law creates some positive spillovers to the public insurance market.

Eventually, I highlight that there is little evidence showing changes in the local market structure can primarily explain the patterns in my data. In particular, I find the aggregate numbers of SAT facilities providing any SAT services are insignificantly influenced by the passage of PA laws. Interestingly, this aggregate-level analysis confirms the *redirection* story holds: the number of specialty care facilities only offering low-intensity SAT services increased, while the number of specialty care facilities solely offering high-intensity ones decreased.

I examine the impacts on health outcomes to shed light on the welfare implications of PA restrictions. I draw data from the state-level Vital Statistics and calculate each state's annual mortality rates due to SUDs. My empirical findings suggest imposing PA restrictions can significantly reduce suicide rates related to SUDs and mortality rates related to alcohol abuse.

This paper can contribute to a small yet growing strand of literature that emphasizes the consequences of administrative processes in the healthcare sector. Two recent papers address both the benefits and costs: Brot-Goldberg et al. (2023) study the key trade-off (moral hazard vs. administrative burden) for prior authorization restriction policies in Medicare Part D, and find the cost savings resulting from PA likely exceed beneficiaries' willingness to pay for foregone drugs. Dunn et al. (forthcoming) quantify one of many potential costs

[4]Following Dunn et al. (forthcoming) argue the medical administrative cost is an implicit tax. Therefore, removing such administrative requirements will incentivize physicians to take more patients covered by health plans.

[5]Admittedly, one caveat here is that I cannot explicitly examine whether other critical dimensions of a private plan have changed due to the PA restriction, given the limited scope of my data. For example, the reimbursement rate associated with a private plan can increase/decrease, or the patient has shifted from one private plan to another within the same treatment episode in response to these PA restrictions.

associated with healthcare billings: More aggressive use of claim denials reduces the willingness of providers to contract with insurers. My work contributes by quantifying a novel dimension of the costs induced by administrative processes: The (over)use of prior authorization requirements may largely limit healthcare facilities' treatment capacity and trigger medical delays.

Broadly speaking, my paper can add value to another strand of literature in public finance, addressing the role of administrative ordeals facing potential program beneficiaries. These ordeals may improve program targeting (see e.g., Finkelstein and Notowidigdo, 2019; Deshpande and Li, 2019). In other contexts, program complexity deters beneficiaries' participation (e.g., Currie et al., 2001). My paper contributes to this line of literature by showing beyond the context of safety net programs, administrative processes, and costs can harm consumers' welfare by limiting access to healthcare services.

The rest of this paper proceeds as follows: section 2.2 provides the institutional background. Section 2.3 sketches a simple conceptual framework to illustrate why an exogenous increase in facilities' treatment capacity can influence the provision of medical services. Section 2.4 sketches some alternative mechanisms that might rationalize why the provision of medical services responds to PA restrictions. Section 2.5 specified the primary empirical strategies. Section 2.6 describes a number of datasets enabling me to implement the empirical analyses; section 2.7 presents the main results. Section 2.8 discusses how I test and rule out some mechanisms. Section 2.9 investigates the welfare implications of this policy intervention and section 2.10 concludes by proposing some future work.

2.2 Instituaionl Background

In this section, I briefly discuss the institutional details regarding prior authorization *per se* and how recent state legislation aims to restrict the use of such administrative requirements.

2.2.1 Prior Authorization for Substance Use Disorder Services

Prior authorization (PA) is a process requiring health care providers to obtain pretreatment approval from health plans before a prescription medication or medical service is delivered to the patient (American Medical Association).[6] Health insurance companies typically require PA for certain medical procedures, treatments, and drugs that are likely to trigger high costs or high abuse potentials.[7] Insurers claim that prior authorization requirements are necessary to protect patients from unsafe prescribing decisions and limit rapidly increasing prescription drug expenditures.[8].

Originating from the 1960s and getting widely adopted since the 1990s, prior authorization requirements have been utilized in both private and public health plans.[9] [10] Common types of care requiring PA include prescription drugs, durable medical equipment, diagnostic radiology, surgical procedures, inpatient stays, and behavioral health treatments. In the context of substance use disorder services and medications, the presence of prior authorization requirements is more frequent than many other medical procedures (Weber, 2020). According to Nguyen et al. (2022), commercial insurers impose PA requirements on buprenorphine: with 23% of formularies having at least one buprenorphine product with prior authorization requirements in 2017. In 2008, the Mental Health Parity and Addiction Equity Act barred the discriminatory use of prior and continuing authorizations.

[6]See https://www.ama-assn.org/practice-management/sustainability/prior-authorization, last access April 30, 2024.

[7]See https://fixpriorauth.org/resources, last accessed April 30, 2024.

[8]See https://www.statnews.com/2021/01/01/prior-authorization-whos-choosing-americans-medications-doctors-or-insurers/, last accessed on April 30, 2024

[9]In the appendix, I describe how a PA request works in detail.

[10]https://www.priorauthtraining.org/the-evolution-of-prior-authorizations/, last accessed on April 30, 2024.

Conceptually, the presence of *prior authorization* is akin to an administrative hassle (Brot-Goldberg et al., 2023). Indeed, according to a national survey conducted by the American Medical Association (AMA):

> Among all patients with PA in one's treatment, 94% experience delayed access to necessary care due to PA, and 80% report that PA can at least sometimes lead to treatment abandonment ... Physicians and their staff spend an average of almost two business days each week completing PAs, nearly 35% of physicians have staff who work exclusively on PA, and 88% of physicians describe the burden associated with PA as high or extremely high ... 64% of physicians report that PA has led to ineffective initial treatments, 62% of physicians report that PA has led to additional office visits, and 46% of physicians report that PA led to immediate care and/or ER visits (i.e., highly intensive treatment).

The adverse events due to PA might not be too surprising in the context of substance use disorder (SUD): Addiction typically affects the parts of the brain responsible for motivation and decision-making, creating narrow and shifting windows in which a patient is motivated to engage in treatment. Consequentially, requesting and obtaining prior authorization can impose delays in the initiation of care, which can lead to serious consequences for the patient, including failing to return for subsequent appointments, resuming substance use, medical complications, overdose, and even death (Weber, 2020).

2.2.2 State-Level Restrictions on Prior Authorization

In response to the opioid epidemic, several states have removed some prior authorization requirements and aim to improve the efficacy of accessing and delivering substance abuse treatment (SAT) (Weber, 2020). As of April 20, 2020, 18 states have enacted laws restricting the use of prior authorization for SUD treatment in private health plans. Of course, the legal languages vary substantially across different states: Some states have adopted a range of standards in limiting prior authorization for at least one type of SUD medications, some require any FDA-approved SUD medication on the plan's formulary or preferred drug list to be covered without prior authorization, and others limit prior authorization for specific

time periods within a treatment episode, or limit prior authorization requests to one per year (Weber, 2020). In terms of the general SUD services, a number of states restrict the use of prior authorization for inpatient and/or outpatient services delivered by state-licensed/certified providers/facilities, while others limit prior authorization only for services involving medication-assisted treatment (MAT), such as behavioral therapy and counseling (Weber, 2020).

2.3 Theoretical Framework

In this section, I provide a conceptual framework, which closely follows Harris, Liu and McCarthy (2020) to illustrate how an exogenous shock on facilities' capacity, which is induced by the prior authorization (PA) restriction, can influence the provision of medical treatment.

2.3.1 Set-up

Throughout the analysis, I assume a typical *behavioral healthcare facility* is the key decision maker instead of the individual physician as Harris, Liu and McCarthy (2020). The primary reason to do so is two-fold: First, in the setting of substance abuse treatment (SAT) services, various types of healthcare professionals can jointly deliver such services, including psychiatrists, psychologists, social workers, advanced practice psychiatric nurses, certified prevention specialists, addiction counselors, etc.[11] Second, the primary data source I relied on in the empirical portion reflects facilities' decisions instead of individual providers' responses. When discussing the alternative channels, I also show there is little evidence that imposing PA restrictions can influence individual providers' prescribing behavior.

In the context of SAT service, I define "*treatment capacity*" as the aggregate, facility-level time available to meet with patients, which is the product of time available per provider to meet a patient's needs of care and the number of providers available within a facility.[12] Essentially, I assume imposing a restriction on the use of PA for SAT services is equivalent

[11] See here, for example, https://www.samhsa.gov/workforce, last accessed April 30, 2024.

[12] For simplicity, I ignore the teamwork of the medical workforce, the substitution/complementarity between different healthcare professionals, etc.

to an exogenous expansion of facilities' treatment capacity. It's reasonable to conceptualize PA as a treatment capacity constraint because, on the supply side, capacity and financial constraints within the specialty SUD treatment delivery system limit the ability of providers to increase access to newly insured individuals (Andrews et al., 2015). For instance, many specialty SUD treatment facilities fail to provide open slots and allocate time to admit new patients (Carr et al., 2008; Jones et al., 2015). Meanwhile, this assumption is also consistent with my empirical findings: state-level PA restrictions reduce the likelihood of experiencing involuntary medical delay among patients in an outpatient setting; such involuntary medical delay is primarily driven by "programs' capacity issue."

As suggested in prior research (Harris, Liu and McCarthy, 2020), this conceptual framework also accommodates a key stylized fact of medical services where labor is the primary input and the quality of the service provided is a function of time with the customer: a reduction in the treatment capacity is equivalent to a proportional increase in the arrival rate of patients to a typical facility. I also assume the likelihood of providing a specific type of service is the *extensive* margin of healthcare provision. Put differently, if the optimal amount of time a facility provides to meet patients' demands is positive, facilities will provide the service.[13]

2.3.2 Facilities' Problem

As shown in Harris, Liu and McCarthy (2020), individuals are assumed to arrive following a Poisson process, with the mean arrival rate denoted as λ over a unit of time normalized to one. Service time per facility is assumed to be distributed exponentially, with a mean service time μ. The primary goal in this setting for facilities is to ensure that a patient's needs for care are met by choosing both the intensive (i.e., the amount of time) and extensive (i.e., whether to provide or not) margins of SAT service.[14]

Mathematically, a typical facility minimizes the loss function in each period with respect to the average time spent with each patient. The function can be decomposed into two parts:

[13]Due to the data limitation, it's not feasible to check the intensive margin (i.e., the number of hours spent on service) empirically.

[14]For simplicity, I do not assume behavioral healthcare facilities can choose the price endogenously.

the disutility of spending less time on average with existing patients, and the disutility of leaving new patients unseen.

$$U(\mu|\gamma,\lambda) = \underbrace{f(\gamma-\mu)}_{\text{loss from spending less time with admitted patients}} + \underbrace{g(\lambda-\frac{1}{\mu})}_{\text{loss from not admitting new patients}} \tag{2.1}$$

where γ is the fixed amount of time one facility can spend, and the number of new, unseen patients is $(\lambda - \frac{1}{\mu})$. $f(\cdot)$ and $g(\cdot)$ are both decreasing and convex.

For simplicity, we can assume $f(\cdot)$ and $g(\cdot)$ are exponential functions, and the loss function would be expressed as

$$U(\mu|\gamma,\lambda) = -exp(\alpha(\gamma-\mu)) - exp(\beta(\lambda-\frac{1}{\mu})) \tag{2.2}$$

where α captures the disutility from spending less time than ideal with existing patients; β captures the disutility from leaving new patients unseen. As mentioned above, the facility's decision is to choose the optimal amount of time μ to minimize the loss. As a result, if we take the derivative with respect to μ, the first-order condition would be:

$$\alpha \times exp(\alpha(\gamma-\mu^*)) - \frac{\beta}{\mu^{*2}} \times exp(\beta(\lambda-\frac{1}{\mu^*})) = 0 \tag{2.3}$$

Based on equation (3), when $\lambda \leq \frac{1}{\gamma}$, the optimal amount of time allocated to medical treatment would be $\mu^* = \gamma$. This is simply because the provider's time constraint is not binding. Intuitively, when the arrival rate of patients is sufficiently low (or, say, the treatment capacity is sufficiently high), facilities can freely allocate time to each patient without incurring any disutility from turning new patients away. When $\lambda > \frac{1}{\gamma}$, the facility would choose the optimal μ^* as shown above.

2.3.3 Comparative Statics

In this framework, I conceptualize a prior authorization restriction as an exogenous, positive shock on facilities' treatment capacity (or, equivalently, a negative shock on the arrival

rate of patients, λ). Put differently, imposing PA restrictions will increase the (aggregate) time available at the facility level.

Based on the implicit function theorem, the comparative statistic is captured by the following equation:

$$\frac{d\mu^*}{d\lambda} = \frac{\frac{\beta^2}{\mu^2} \times exp(\beta\lambda - \beta/\mu)}{\frac{\beta(2\mu-\beta)}{\mu^4} \times exp(\beta\lambda - \beta/\mu) - \alpha^2 \times exp(\alpha\gamma - \alpha\mu)} \tag{2.4}$$

Overall, the direction and the magnitude of adjusting μ^* with respect to λ hinge on several gradients: the preference parameters α (which captures how facilities value the treatment of existing patients) and β (which captures how facilities value the treatment of unseen, new patients), the current capacity to start with $(\gamma - \mu)$, and the value of the arrival rate of patients λ. As shown in Harris, Liu and McCarthy (2020), there are several key takeaways from this equation:

Initial treatment capacity $(\gamma - \mu)$: the change in μ^* with respect to the shock in treatment capacity (i.e., changes in λ) hinges on the initial level of time available within a facility $(\gamma - \mu)$. In particular, Harris, Liu and McCarthy (2020) found the numerical solution: an increase in λ is associated with a decline in μ^*. The negative relationship suggests the increasing marginal disutility of $(\gamma - \mu)$ dominates.[15] This is a reasonable prediction: If the facility is crowded in the first place, it's more challenging to reallocate time and labor to accommodate new patients and offer new medical services.

Preference parameters (α and β): when a facility values seeing new patients (β) more than spending the ideal level of time with each patient (α), $\frac{\mu^*}{\lambda} < 0$. Intuitively, this indicates if a facility cares about ensuring more patients can get proper medical services on time, an expansion in treatment capacity would lead to an increase in the time allocated to providing new SAT services. Mathematically, this means β and α satisfy the following condition:

$$(\beta\lambda - \beta/\mu)^{\frac{\beta(2\mu-\beta)}{\mu^4}} < (\alpha\gamma - \alpha\mu)^{\alpha^2} \tag{2.5}$$

[15] Recall g() is a convex function.

In Figure 2 of Harris, Liu and McCarthy (2020), they show that numerically, the magnitude of the decline in μ^* is larger when α is a smaller portion of β.

Initial arrival rate of patients (λ): according to Figure 2 shown in Harris, Liu and McCarthy (2020), as the initial value of λ keeps increasing, $\frac{d\mu^*}{d\lambda}$ approaches to zero. The numerical solution should not be surprising: if the number of patients is extremely high and the facility is overcrowded in the first place, the facility has neither incentives nor capacity to reallocate time and labor to deal with new patients.

Taking together, the effects of an exogenous increase in treatment capacity (or, say, an exogenous decline in the arrival rate of patients) on the time and effort allocated to the provision of medical treatment is theoretically ambiguous:

First, when the arrival rate is sufficiently low (i.e., $\lambda \leq \frac{1}{\gamma}$), the facility does not need to adjust one's allocation of time they spend with each patient because the time constraint is not binding at all.

Second, when the initial λ is close to its capacity (i.e., $\lambda > \frac{1}{\gamma}$), a decreased arrival rate would result in a surge in μ^*, representing the increased provision of healthcare services.

Third, if a facility has an extremely large amount of patients to begin with, changes in the arrival rate barely have any effects on the optimal time μ^* because providers are not willing to spend extra time with any patient.

Note that there are two broad categories of settings, which provide high-intensity services and low-intensity services, respectively. The exogenous shock induced by the PA removal does not necessarily affect a facility's decision along this margin similarly.

2.4 Alternative Mechanisms

This section briefly discusses several alternative channels through which a PA restriction can affect the provision of healthcare services. The provision of SAT services hinges on pairwise interactions among patients/consumers, private insurance companies, healthcare professionals, and facilities.

Besides the treatment capacity story mentioned above (section 2.3), removing PA requirements from commercial plans can (1) trigger substantial changes in the commercial health insurance market *per se* with adverse selection and moral hazard, (2) *ex-post* moral

hazard in utilizing healthcare services among existing, admitted patients, (3) strategic contracting between healthcare facilities and commercial plans through network formation, (4) changes in prescribing behaviors of healthcare professionals (i.e., physicians and other providers) due to financial incentives, and (5) changes in local market structure. I briefly discuss each in turn as follows.

2.4.1 Adverse Selection and Moral Hazard in Insurance Market

As a first-order effect, restricting the use of prior authorization in private health plans would plausibly increase the intensity of asymmetric information regarding one's health conditions between consumers and insurers, thereby triggering both adverse selection (i.e., when individuals who have a choice among insurance plans select their plan, those who are more likely to require SUD care tend to choose more generous plans) and moral hazard (i.e., when insured individuals bear a smaller share of their medical care costs, they are likely to consume more care). Specifically, an insurance company is now strictly restrained from requesting detailed information about the patient's medical history and treatment progress.

In a new equilibrium (of the insurance market), removing PA requirements can thus change one's coverage status of SAT services in a health plan and the utilization of SUD treatment services. This is because the plan covers more and/or such a plan attracts individuals with greater underlying health needs. In either case, we would expect these first-important effects in the commercial insurance market will result in an increased demand for SUD treatment along the admission margin,[16] mechanically driving up the provision of such services.

2.4.2 Ex-post Moral Hazard of Existing Patients

The second alternative explanation for changes in the provision of SAT services concerns ex-post moral hazard among existing patients. Similar to the argument in section 2.4.1, patients who are admitted by a facility are less likely to terminate their treatment voluntarily because of a more generous plan without checking medical necessity. Again,

[16]For example, being covered by more generous plans will induce patients to use more unnecessary SAT services.

this induced increase in medical demand can lead to a mechanical surge in providing SAT services. Treatment facilities eventually provide care to patients who may not benefit significantly from continued treatment but remain enrolled due to improved insurance coverage and reduced administrative barriers.

2.4.3 Facilities' Selective Contracting with Insurers

PA restrictions can also change providers' decisions through selective contracting with private insurers: the more burdensome and restrictive the PA process, the more likely providers are to limit their contracting with insurers that require PA for certain treatments or services. The underlying mechanism is akin to the argument from Dunn et al. (2021) that more aggressive use of claim denials reduces the willingness of providers to contract with insurers. Theoretically, as an administrative ordeal, prior authorization would increase the marginal cost per treatment. This increasing marginal cost may encompass providers' efforts in reviewing paperwork, back-and-forth confirmations with insurers, resubmitting, etc. In turn, the selection in contracting with insurers can substantially alter the scope of services provided on-site.

In this regard, with *less-stringent* PA requirements in place, one may expect that providers are more inclined to accept private plans. One noteworthy caveat, however, is that due to the limitations of my data and methodology, other margins related to the network formation and bargaining over reimbursement rates between providers and insurers (see, for example, Ho and Lee (2017)) are beyond the scope of this paper. Taking these margins into account could largely complicate the analysis: For example, if the restriction of PA substantially changes the reimbursement rates of private plans, then providers may strategically admit and/or discharge consumers due to financial incentives. Future research should address such issues with detailed claim/client-level data and/or structural models to shed light on some welfare effects.

2.4.4 Physicians' Diagnostic and Prescribing Behaviors

Another noteworthy channel through which PA restrictions influence the provision of such behavioral healthcare services is relevant to physicians' financial incentives. A large

line of literature investigates how changes in reimbursement rates or other general changes in medical prices influence providers' diagnostic, prescribing, and treatment choices (see, e.g., Gruber and Owings, 1996; Dafny, 2005; Clemens and Gottlieb, 2014; Alexander, 2020). Prior work found that physicians/providers tend to prescribe more services in response to either an increase or a decrease in the related reimbursement rates. The typical explanation is that when the price of a service is lowered, physicians will prescribe more of the service in order to make up for the lower unit price to maintain an income target; when the price of a service is raised, physicians will have an incentive to prescribe more of that service to increase his/her income.

In the context of prior authorization, this provider-induced demand theory can rationalize changes following the restriction: For example, if administrative hassle is valued as an implicit tax per treatment, the removal of such a tax would largely increase the price of medical services, thereby driving up/down physicians' diagnostic incentives.[17] Particularly, one may expect more profound changes in SUD treatment based on medication, *medication-assisted treatment* (MAT). This is simply because MAT requires doctors, nurse practitioners, or physician's assistants who meet certain qualifications to treat opioid patients with drugs approved by the FDA for the treatment of opioid dependence: buprenorphine, methadone, and naltrexone.

2.4.5 Changing Local Market Structure

The last but not the least influential factor is related to the local market structure of behavioral healthcare facilities. All structural factors mentioned above (i.e., facilities' treatment capacity constraint, the interplay between consumers and insurers, the increased demand due to ex-post moral hazard among existing patients, facilities' strategic contracting with insurers, and physicians' diagnostic/prescribing behaviors) can induce the aggregate-level provision of SAT services, which in turn would alter the incentive of individual facilities to offer relevant SAT services. From the empirical perspective, prior research found the impact of competition (market structure) on the provision, quality, and cost of medical

[17] Of course, it is empirically challenging to clearly tell apart changes in providers' incentives and changes in demand for relevant services. I will elaborate on how I separate these two channels in data in section 8.

services is quite mixed (see, for example, Kessler and Geppert, 2005; Karlsson, 2007; Gaynor, Moreno-Serra and Propper, 2013).

2.5 Empirical Strategy

The main objective of this paper is to examine whether restricting the use of prior authorization requirements affects the provision of substance abuse treatment. Throughout the analysis, I focus on measuring the probability of providing different types of healthcare services. I leverage the phase-in of state laws restricting the use of PA as a quasi-experiment and employ the following staggered difference-in-difference (DID) model to identify the causal effect:

$$y_{ist} = \alpha + \beta PALimit_{st} + X_{ist}^{'}\gamma + \rho_{st} + \eta_t + \psi_s + \epsilon_{ist} \tag{2.6}$$

where i denotes facilities, s represents states, and t indexes years. y_{ist} is the key outcome of interest, the likelihood of offering various SUD services in facility i located in state s in year t. $PALimit_s$ is an indicator of whether there is a state law restricting the use of PA for SAT services in state s in year t. X_{ist} is a set of facility-specific controls, and ρ_{sc} represents a collection of state-specific controls. I also include state fixed effects (ψ_s), and η_t are patent subclass and year fixed effects, respectively. Therefore, β would identify the impact of PA restrictions on providing services.

Of course, the key assumption of this difference-in-differences model is that controlling for state and year-fixed effects, changes in key outcomes would have been comparable among different states without prior authorization laws. To directly test this assumption, I estimate a stylized event study model as follows in equation 2.7:

$$y_{ist} = \alpha + \sum_{i=-5}^{4} \beta_{t+i} Treat_{st} \times year_{t+i} + \rho_{st} + \eta_t + \epsilon_{ist} \tag{2.7}$$

where $year_{t+i}$ is a set of indicators denoting whether a year is the i^{th} year before or after the enactment of the PA law. In this specification, the estimate associated with one year prior

to the treatment is normalized to zero. This way, β_{t+i} also captures the dynamic effects of restricting PA.

Another threat to identification is the reverse causality issue. For example, one might imagine that states enacting restricting laws are also those with a higher level of demand for SUD treatment and/or a smaller amount of specialty facilities providing behavioral health services in the first place. If changes in PA restrictions are correlated with underlying legal, economic, political, or social trends, it would be challenging to use such variation to isolate the effects of restrictions on healthcare provision. In subsequent analysis, I corroborate the evidence that the provision of SAT services does not differentially change in years prior to changes in PA restrictions. Meanwhile, I also provide supplementary analyses by testing whether other changes in political, social, and economic features predict PA restriction changes.

Eventually, a growing strand of work emphasizes the sensitivity of a staggered difference-in-differences specification: the traditional staggered difference-in-differences estimation cannot fully capture the dynamic treatment effects with staggered adoption and heterogeneous treatment effects (Goodman-Bacon, 2021; Sun and Abraham, 2021). I am still in the middle of checking the robustness of my results using such alternative specifications (e.g., Callaway and Sant'Anna, 2021; Wooldridge, 2023).

2.6 Data

This section summarizes the data assembled from multiple resources and provides motivational evidence. To implement the empirical analysis, I collect data on (1) the timing of adopting the state-level limits on substance abuse treatment (SAT) in private health insurance and (2) measures of the facilities' capacity to provide various types of treatments and the probability of participating the private health insurance market. I then describe how to construct each measure, enabling me to conduct the empirical analysis in turn.

2.6.1 Adoption of PA Limits on Substance Abuse Treatment

To obtain information on the state laws restricting the use of prior authorization in substance abuse treatment (SAT), I mainly rely on the report from the Legal Action Center (LAC) and collect policy data on the Westlaw legal library.[18] In particular, the LAC report provides a helpful starting point but lacks the detailed information needed for the empirical analysis. As a supplement, I investigated changes in PA limits for each state over time via text mining to construct a panel policy database including the timing of change, the type of service/medication covered, and the During the sample period (2012-2020), there are 18 states enacting laws to restrict private insurers from imposing prior authorization requirements on a SUD service of medication. Of course, there is substantial variation in the state legal language regarding the content of PA limits. At a higher level of generalization, I exploit the variation in timing for the baseline estimation. Table A1 in the appendix lists the corresponding states, the effective dates of PA limits, and a summary of these laws.

2.6.2 National Survey of Substance Abuse Treatment Services

The primary data source enabling me to implement the empirical analysis is the National Survey of Substance Abuse Treatment Services (N-SSATS), a national annual survey of specialty SAT facilities.[19] The N-SSATS is widely used to study SUD treatment outcomes by economists (see for example, Carpenter, 2007; Popovici, Maclean and French, 2017; Hamersma and Maclean, 2021, etc.). The sampling frame for the N-SSATS is the Inventory of Behavioral Health Services (I-BHS), including a registry of the universe of SAT facilities known to the Substance Abuse and Mental Health Services Administration (SAMHSA). Data collection for the N-SSATS occurs between late March and early December each year when surveys are sent to all facilities on the I-BHS. New facilities that are discovered by SAMHSA during this period and also included in the N-SSATS and subsequently placed on the I-BHS for the following year. Facilities fill out questionnaires about the services they

[18] See https://www.lac.org/assets/files/Prior-Authorization-Spotlight-FINAL-use-this-one.pdf and https://legal.thomsonreuters.com/en/westlaw for the LAC report and Westlaw legal library, last accessed on April 30, 2024.

[19] The dataset is available here https://www.datafiles.samhsa.gov/dataset/national-survey-substance-abuse-treatment-services-2020-n-ssats-2020-ds0001, last accessed April 30, 2024.

provide, the counts of clients currently receiving treatment, and the counts of beds dedicated to SAT clients (if applicable).[20]

To measure the treatment capacity of an SAT facility, this paper exploits two categories of outcomes in the N-SSATS: *the probability of providing inpatient/outpatient services*, and *the propensity to participate in the private health insurance market*. Specifically, a specialty SAT facility included in N-SSATS can be a hospital or other facility with an SAT program offering any of the following services: outpatient, inpatient, and residential/rehabilitation treatment; detoxification; opioid treatment; and halfway-house services. N-SSATS does not include SUD treatment providers that exclusively treat incarcerated patients. Providers included in N-SSATS often provide other services (e.g., mental healthcare); a requirement for inclusion is that the provider offers specialty SUD treatment, not that this treatment is the provider's primary focus (Hamersma and Maclean, 2021).

2.6.3 Annual Reports for N-SSATS

Besides the detailed, facility-level data derived from the N-SSATS, I also complement my analysis by digitizing the annual reports of the N-SSATS and collecting state-level information. The primary reason for conducting this exercise is to measure the likelihood of providing early-stage interventions for SUD among these specialty facilities. Due to confidential concerns, such information is not publicly available in the annual N-SSATS.

Specifically, I construct the annual number of facilities offering a variety of assessment and pre-treatment services as a proxy for the propensity to provide early interventions. These services include brief intervention, screening for SUD, comprehensive assessment and diagnosis, and outreach services for each state; thus, the unit of this analysis is state-year. Figure A1 presents a snapshot of the annual survey for the N-SSATS.

2.6.4 Treatment Episode Data Set

Another primary data source I relied on in this paper is the Treatment Episode Data Set (TEDS), which compiles client-level data for substance abuse treatment admissions from

[20]The reference date for residential and hospital inpatient beds and client counts was March 30/31.

state agency data systems. State data systems collect data from facilities about their admissions to treatment and discharges from treatment.[21]

The TEDS is one component of a broader data inventory maintained by SAMHSA to track both the quantity and quality of specialty SUD treatment within the U.S. The TEDS includes information on approximately two million admissions to specialty SUD treatment each year and contains nearly the universe of specialty SUD treatment facilities that receive financing from the state or federal government, are certified by the state to provide specialty SUD treatment, or are tracked for some other reason. Thus, TEDS reflects admissions financed by multiple payers (e.g., self-payment, private insurance, Medicaid, Medicare). TEDS is commonly employed within the policy literature to study SUD treatment (Anderson, 2010; Dave and Mukerjee, 2011; Pacula et al., 2015; Powell, Pacula and Jacobson, 2018) and is used by the Federal government to estimate the costs of SUD treatment to the U.S. economy (Office of National Drug Control Policy 2012).

The TEDS comprises two parts: the Admission set (TEDS-A) and the Discharges set (TEDS-D). The former one contains records on admissions of people aged 12 and older and includes information on admission demographics (for example, age, sex, race/ethnicity, employment status) and substance use characteristics (for example, substances used, age at first use, route of use, frequency of use, number of prior admissions). Another noteworthy feature is that TEDS-A records represent admissions rather than individuals, as a person may be admitted to treatment more than once. By contrast, the TEDS-D contains records on discharges of people aged 12 and older and includes information on admission demographics (for example, age, sex, race/ethnicity, employment status) and substance use characteristics (for example, substances used, age at first use, route of use, frequency of use, number of prior admissions).

[21]This data set is available here https://www.datafiles.samhsa.gov/dataset/teds-d-2020-ds0001-teds-d-2020-ds0001 and https://www.datafiles.samhsa.gov/dataset/treatment-episode-data-set-admissions-2020-teds-2020-ds0001, last accessed April 30, 2024.

2.7 Main Results

In this section, I present my main results relating to various measures of the provision of healthcare services based on equation 2.6 and discuss how to interpret the magnitude, as well as the implications.

2.7.1 Effects of Any Restriction

In Table 2.2, I report the coefficient estimates for β, which captures the impacts on SAT provision. The key outcome of interest in the first two columns is the probability of solely providing low-intensity SAT services relative to only offering high-intensity SAT services. In column (3) and column (4), I focus on the probability of offering both low-intensity and high-intensity services, compared to only providing low-intensity ones. Eventually, in the last two columns, the dependent variable is the likelihood of providing both, relative to only offering services in a high-intensity setting. In all odd-numbered columns, the sample includes all specialty care facilities, while in the even-numbered, the sample is composed of facilities accepting commercial plans.[22]

Based on results from Table 2.2, we can see that following the PA restriction, the probability of only offering low-intensity service significantly increases by 8.8 percentage points (relative to only providing high-intensity ones). This is equivalent to an increase of 13.79% (=8.8/63.8). The point estimates in column (3) and column (4) indicate that the imposition of PA restrictions leads to a decline in the probability of offering both low- and high-intensity SAT services (relative to offering only low-intensity ones). However, these negative effects are sensitive to the specification: Among facilities accepting private plans, the negative effect is statistically insignificant. Finally, I focus on the likelihood of providing both types of SAT services (relative to solely providing high-intensity SAT services) in the last two columns: it increases significantly by at least 4.3 percentage points (or 5.95%).

Overall, the coefficient estimates in this round of regressions suggest restricting the use of PA in commercial plans would incentivize more specialty care facilities to offer low-intensity

[22]I also found the probability of accepting commercial plans does not change among these specialty care facilities.

SAT services. This surge reflects two patterns: First, facilities shift from only providing high-intensity SAT services to low-intensity ones (or, say, the number of facilities only offering low-intensity SAT increases compared to that of those only offering high-intensity ones). Second, facilities also shift from only offering high-intensity services to providing both types. Put differently, the number of facilities with both SAT services increases compared to that of those only offering high-intensity ones.

2.7.2 Heterogeneous Effects by the Type of Restrictions

As shown in Table 2.1, there are two primary types of restrictions: PA restriction on general SAT services and PA restriction on SAT medication. Meanwhile, there are various PA restrictions on SAT services in Medicaid. In Table 2.3, I examine the heterogeneous effects by the type of these restrictions. The specification is quite similar to equation (6):

$$y_{ist} = \alpha + \beta_1 ServiceRestriction_{st} + \beta_2 MedRestriction_{st} + \beta_3 MedicaidRestriction_{st} + X'_{ist}\gamma + \rho_{st} + \eta_t + \psi_s + \epsilon_{ist} \tag{2.8}$$

where $ServiceRestriction_{st}$ refers to the PA restriction on general SAT services in commercial plans in state s and year t, $MedRestriction_{st}$ represents the PA restriction on SAT medication in commercial plans within state s and year t, and $MedicaidRestriction_{st}$ denotes an indicator for a PA restriction in Medicaid for SAT services.

My results are shown in Table 2.3. Based on estimates from the first and second rows, the significant effects of PA restriction primarily come from the restriction on general SAT services. For example, imposing general PA service restrictions is associated with a significant increase in the probability of solely offering low-intensity services by 8.4 percentage points (13.17%) and another increase by 3.5 percentage points (4.84%) in the probability of offering both types (compared to only offering high-intensity SAT services). Interestingly, I also find that PA restrictions within Medicaid for SAT services would increase the provision of low-intensity services (by 14.8 percentage points, or 23.2%, related to solely providing high-intensity SAT services).

2.7.3 Threats to Identification

As I mentioned in Section 2.5, my identification strategy could raise various concerns. This section addresses some of them.

Event-study specification: I first estimate the event-study specification shown in equation 2.7 and plot the coefficient estimates in Figure A6 to Figure A8. Overall, there is no obvious reason to believe that the assumption of parallel trends is violated. At the same time, among all three exercises, I find the PA restriction is associated with positive effects on providing low-intensity services for at least four years. The likelihood of offering both types (compared to offering low-intensity) significantly declined, while the probability of providing both types would increase relative to the probability of offering only high-intensity ones for at least four years.

Alternative DID Specifications: one critic for the staggered difference-in-differences model is that Goodman-Bacon (2021). To take care of this issue, I use Callaway and Sant'Anna (2021) to demonstrate the robustness of my main estimates. In Table 2.4, we can see the increased provision of low-intensity SAT services is still statistically significant (as shown in column (1) and column (2)) by 6.9% (=4.4/63.8*100%).

Policy Endogeneity: Another concern relevant to my identification strategy is policy endogeneity. For example, one may argue the high mortality rate due to SUDs and/or the lack of SAT services provision partially contribute to the enactment of these PA restrictions. To alleviate the concern, I took two exercises: First, I follow Johnson, Lavetti and Lipsitz (2023) and test whether states' social and economic characteristics predict PA law changes. In particular, I collect information from the University of Kentucky Center for Poverty Research's National Welfare Data (University of Kentucky Center for Poverty Research, 2018) on state population, unemployment rates, state GDP, minimum wage, the number of Medicaid beneficiaries, the level of SNAP benefits, and the level of TANF benefits.[23] I also collect data on mortality rate due to "mental and behavioral disorders due to psychoactive substance use" from the CDC WONDER online databases .[24][25]

[23]See https://cpr.uky.edu/resources/national-welfare-data, last accessed April 30, 2024.

[24]According to UCD-ICD-10 Codes, the causes of mortality due to SUDs are captured by F10-F19 (mental and behavioral disorders due to psychoactive substance use) .

[25]See https://wonder.cdc.gov/, last accessed April 30, 2024.

In Table 2.5, I present my point estimates regarding the enactment of any PA restriction on SAT, PA restrictions on general services of SAT, and PA restrictions on medication of SAT, respectively. The results suggest that the only two factors contributing to enacting PA laws are state-level minimum wages and the level of state population (though sensitive to the specification). Higher minimum wages lead to an increase in the probability of enacting such PA restrictions, while states with more residents are less likely to impose these restrictions. Intuitively, these findings are reasonable: higher minimum wage levels can potentially prevent individuals from SUDs. Meanwhile, the correlation between the state-level death count due to SUDs and the enactment of PA restrictions is not statistically significant, indicating the reverse causality concern should be minimal. In the main analysis, I include both the level of state population and the state minimum wage to attenuate this endogeneity issue.

As for the second exercise, recall in Figure A6, Figure A7, and Figure A8, I showed that there is little evidence suggesting that the provision of SAT services does not differentially change in years prior to a PA law change.

2.7.4 Suggestive Evidence on the Provision of Early Interventions

Of course, besides offering traditional SAT services, facilities also have the option to provide some early interventions, including assessment and pre-treatment services, education and counseling services, etc. Such services are crucial to prevent the development of SUDs. For example, according to the SAMHSA, screening can quickly "assess the severity of substance use and identify the appropriate treatment level" and brief intervention "focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change." By providing these early interventions, facilities can help individuals at risk for developing SUDs avoid the need for more intensive and costly treatments in the future.

Turning to this margin, I rely on information hand-collected from the 2012/5-2020 annual reports for N-SSATS and construct four relevant measures: the provision of brief intervention, the provision of screening services for SUDs, the provision of comprehensive assessments, and the provision of outreach services.[26] Results in Table 2.4 then display some

[26]For a detailed description of these early-stage interventions, see https://www.ncbi.nlm.nih.gov/books/NBK571017/, last accessed April 30, 2024.

suggestive evidence: From column (1), one can directly tell that with a PA restriction in place, the propensity to offer brief intervention services increases by 63.3 percentage points at the state level. Similarly, the propensity to provide other early-stage interventions increases, although these estimates are relatively imprecise based on the coarse data.

2.8 Discussing Mechanisms

In this section, I empirically unravel several potential mechanisms at play (mentioned in section 3 and section 4) to explain why there are changes in the provision of SAT services. To be concrete, I test whether the observed shift in providing SAT services is a result of (1) an expansion in treatment capacity at the facility level, (2) changes in the quantity and composition of patients receiving SAT services, (3) increased demand for SAT services due to moral hazard among on-site patients, (4) changes in providers' prescribing behaviors, (5) facilities' willingness to accept private plans, and (6) changes in the local market structure of behavioral healthcare facilities.

2.8.1 Facility-Level Treatment Capacity

As shown in section 2.3, I argue that the primary channel associated with the *increased* provision of low-intensity SAT services stems from an expansion in treatment capacity (i.e., time and labor available within a facility).

To test this hypothesis, I extract client-level information from the TEDS-A and construct three measures of facility-induced medical delays: an indicator for *any delay* ("whether there are any days waiting before receiving treatments"), an indicator for *normal delay* ("whether there is at least one week waiting before receiving treatments"), and another indicator for *severe delay* ("whether there are at more than two weeks waiting before receiving treatments") among the newly admitted.[27] Particularly, such information regarding the

[27]Of course, there could be selection along the margin of admission — for example, some patients may be directly deterred by the long waiting time and thus seek other outside options. With this selection bias, my analysis would *underestimate* the true effect. For example, deterred patients may have more severe substance use disorders subject to more stringent PA requirements or face greater barriers to treatment access, making them more vulnerable to delays in care. If this is the case, then the effect of PA restrictions on waiting times for treatment may be larger for patients who are not deterred by long waiting times than for those who are. Failing to account for this selection bias could lead to underestimating the true effect.

waiting time is designed to indicate the number of days from the first contact or request for a substance use treatment service until the client was admitted and the first clinical substance use treatment service was provided. This measure is intended to capture the number of days the client must wait to begin treatment because of program capacity, treatment availability, admissions requirements, or other program requirements and should not include time delays caused by client unavailability or client failure to meet any requirement or obligation.

Table 2.6 presents the corresponding results. In columns (1) and (2), I focus on all admissions to an inpatient setting (i.e., residential care, hospitalization, and intensive outpatient care), while turning to new admissions to an outpatient setting in columns (3) and column (4). In all odd-numbered columns, the outcome of interest is the indicator for *normal delay*, and the dependent variable is an indicator for *severe delay* in the even-numbered columns. Across all specifications, one can see that when enacting a PA law, there is a significant drop in the propensity to experiencing both *normal delay* (by 4.2 percentage points or 25.6%) and *severe delay* (by 1.8 percentage points. Mapping these results to the documented changes in the provision of SAT services (section 2.7) implies that relaxed capacity constraints mainly drive the shift from high-intensity care to low-intensity care: Without the administrative burden associated with PA, facilities can better reallocate medical resources from high-intensity to low-intensity services. Relaxed capacity constraints mainly drive the shift from high-intensity care to low-intensity care: Without the administrative burden associated with PA, facilities can better reallocate medical resources from high-intensity to low-intensity services.

Turning to the *decreased* provision of high-intensity treatment, I further argue there are three channels: (1) mechanical shift of patients, (2) reallocation of medical resources (within facilities), and (3) facilities' dynamics (i.e., entry and exit).

Mechanical shift of patients: I should first highlight the observed decline in high-intensity SAT provision could reflect a mechanical change in patients. Patients who experienced delays in the outpatient setting were initially placed in an inpatient setting (due to worsening health outcomes); when the removal of PA can expand facilities' treatment capacity and admit patients on time, those who were "mistakenly" placed in an inpatient setting

got the chance to receive less intensive one. In other words, this mechanical reduction in demand for high-intensity services thus explains the pattern in my data.[28]

Ideally, one can implement empirical exercises to test this channel using individual-level data in TEDS-A. If the mechanical shift story holds (or at least dominates), one would expect (1) the aggregate number of patients getting admitted to high-intensity settings would decline and/or (2) the likelihood of being transferred from low-intensity to high-intensity would decrease among existing patients.[29] Admittedly, I don't have some administrative patient-facility matching data, so it's extremely hard to examine medical transfers across facilities at this point. I thus run the following regression to investigate the admission margin:

$$\frac{\#\text{newly admitted patients}_{st}}{100,000\text{pop}_{st}} = \alpha + \beta PARestriction_{st} + X_{st}^{'}\gamma + \psi_s + \eta_t + \epsilon_{st} \tag{2.9}$$

The outcome of interest is the number of newly admitted patients to (high-intensity or low-intensity or all) facilities per 100,000 state residents. X_{st} includes various state-level controls. Others are identical to those in equation (6). Therefore, β captures the causal effects of imposing PA restrictions. Regressions are all weighed by the state population per year.

In Table 2.7, I present my main results regarding how the aggregate number of admissions responds to the PA law change, by the type of policies and by the setting of SAT services. In odd-numbered columns, the coefficient estimates capture the impact of imposing any PA restriction; in even-numbered columns, I separately examine the effects of PA services restrictions and PA medication restrictions. In the first two columns, I focus on all types of admissions, and in the rest of the columns, I check admissions to the low-intensity setting (column 3-column 4) and admissions to the high-intensity setting (column 5-column 5), respectively. Although the estimates here are less precise, the takeaway is that there is little evidence suggesting the presence of a PA restriction will substantially reduce the size

[28]Of course, to provide more rigorous evidence for this argument, I will keep assembling more administrative data, especially regarding individual-level information about medical transfers.

[29]Of course, it would be empirically challenging to disentangle the demand-side and supply-side factors. However, as I argue and show in the subsequent analysis, the aggregate number of facilities providing high-intensity services does not change following a PA restriction, suggesting patients' access to such services is unchanged. As a result, if there is any change along the admission margin, there's a good chance that it reflects a mechanical shift story.

of new patients receiving such services, especially the high-intensity ones. The findings here thus indicate the observed reduction in high-intensity SAT provision is probably not driven by an immediate, mechanical surge in the corresponding demand.

Reallocation of medical resources: The second channel I argue is regarding reallocating available medical resources within a facility. With the amount of demand for SAT services fixed, removing PA relaxes facilities' treatment capacity constraints, thereby enabling facilities to reallocate limited hours per provider and/or the number of healthcare workers across departments and settings (i.e., from high-intensity ones to low-intensity ones). Put differently, the presence of administrative hassles (e.g., prior authorization) distorts the efficient allocation of medical resources in the first place.

Facilities' dynamics: Besides any changes within facilities, it's also possible to argue that the increased provision of low-intensity SAT service and the declined provision of high-intensity services represent changes along the extensive margin: firms' dynamics. This alternative story is plausible due to several reasons. For example, if the removal of PA leads to a significant expansion (reduction) in the network between insurers and facilities, new specialty care facilities might be incentivized to enter. Meanwhile, if removing these administrative costs can largely decrease the general entry barrier, a surge in new entrants would also be expected.

At this stage, I clearly don't have precise measures of providers' time allocation, the number of healthcare providers, and detailed facility identifiers over time in the current datasets. To tackle this issue, I am talking to staff from the Substance Abuse and Mental Health Services Administration (SAMHSA) and plan to submit a FOIA request to access facility identifiers if it's feasible. This way, it would enable me to directly distinguish any within-facility shift (from high- to low-intensity services) and changes in firms' dynamics. In the meantime, I am looking into a dataset, the National Sample Survey of Registered Nurses (NSSRN, 2008, 2018, and 2022), which provides rich information regarding registered nurses' location, industry, occupation, work time, earnings, and demographic characteristics.

2.8.2 Quantity and Composition of Patients

To empirically and explicitly identify a variety of alternative demand/supply-side factors mentioned in section 2.4 is an extremely challenging task: both the coverage status of SAT services in a health plan and the admission/discharge decisions are equilibrium outcomes, hinging on the interplay among consumers, healthcare facilities, and private insurers. Due to the lack of detailed claim-level data and/or a structural model, I turn to conduct a two-stage test and directly check if removing such administrative hassles induces any changes in the composition of patients on site. This exercise enables me to identify/rule out some channels beyond the margin of treatment within facilities. For example, if there is little evidence showing that both the aggregate number and the key characteristics of on-site patients are affected by a PA restriction, one can somewhat be assured that neither changes in insurance coverage status nor *ex-post* moral hazard at the admission margin should be primary drivers of results documented in section 2.7.[30]

I first explore whether the aggregate number of admissions and discharges among these SAT facilities changes significantly following a prior authorization restriction. In the second stage, I examine whether there are any changes in a number of key characteristics (demographic information, pre-existing health conditions, and the coverage status of various plans) associated with the newly admitted and discharged. Drawing on evidence from these two exercises allows me to infer whether restricting PA substantially alters the composition of current patients getting treated within SAT facilities.

Changes in the aggregate number of admissions and discharges: To implement the first-stage analysis, I rely on the TEDS-A/D and collapse these data to the state-year cells. In other words, I construct a panel documenting the aggregate number of new admissions/discharges of SAT facilities for each state per year. To avoid some institutional complications related to the criminal justice system, I drop all observations referred by any police official, judge, prosecutor, probation officer, or other person affiliated with a federal,

[30]Again, due to the lack of information regarding the reimbursement rates and/or premiums, my results in this subsection cannot directly rule out the following possibility: the content of a private plan may change among these on-site patients (i.e., a higher level of premiums, a decline in the reimbursement rate, etc.), thereby affecting providers' financial incentives to treat.

state, or county judicial system.[31] I then estimate a regression specification similar to equation 2.9. The outcomes of interest include both the aggregate numbers of new admissions and discharges.

In Table 2.8, I repeat the exercise shown in section 2.8.1 and again find little evidence that the enactment of PA laws could significantly affect the aggregate number of discharges from SAT facilities. Taken together, I argue there is little strong evidence that the introduction of PA restrictions in the private insurance market influences the aggregate number of patients in these behavioral healthcare facilities.

Changes in key characteristics of the newly admitted and discharged: In the second stage, I turn to assess if introducing PA restrictions would alter a number of key characteristics associated with newly admitted and discharged patients. Table 2.9 shows relevant point estimates: None of these key features are affected significantly by the law, indicating that there are little changes among the stock of patients within facilities regarding one's demographic characteristics, pre-existing conditions, and insurance coverage status. These estimates further mitigate the concern that the redirection in providing SAT services is partially a result of changes in the private insurance market. Instead, this shift towards low-intensity care is likely to be driven by the interaction between providers and patients who are already within one's treatment program.

2.8.3 Ex-post Moral Hazard Among Existing Patients

Recall that in section 2.4, I mention that besides the margin of admission, moral hazards can also occur among some marginal patients who are already being treated. To be concrete, the PA law may increase information asymmetry about a patient's condition because the insurance company is now restrained from requesting detailed information about the patient's medical history and treatment progress. It can thus trigger another type of *ex-post* moral hazard, resulting the increased incentives to keep utilizing available resources, although they may not be medically necessary.

[31] Including this set of admissions in the primary sample may reflect not only patients' willingness to get treated but also responses from the criminal justice system. See, for example, https://nida.nih.gov/sites/default/files/podat_1.pdf for a detailed description of how the criminal justice system plays a role in SUD, last accessed April 30, 2024.

A central question relevant to this channel is to what extent we should be concerned about *ex-post* moral hazard in behavioral healthcare services in the first place. *A prior,* I would argue medical services targeting SUDs are less likely to suffer from *ex-post* moral hazard issues.

First, both policymakers and researchers worry about the *underutilization* of SAT services rather than the *overutilization*.[32] This unique pattern could be attributed mainly to demand-side psychological factors, including public stigma, self-stigma, and structural stigma (Allen, Nolan and Paone, 2019).

Second, based on some descriptive evidence, the concern about overutilizing SAT services is also minimal. I collect data from the National Survey on Drug Use and Health (NHDUH): According to the 2021 data, 94% of people aged 12 or older with a substance use disorder did not receive any treatment. Among this population, nearly did not think they needed treatment. In this regard, it reinforces the idea that instead of having incentives to use unnecessary treatment, other factors (e.g., social, cultural, psychological, etc.) may hinder people from taking up treatment targeting SUDs.

Using data from the TEDS-D, I construct a relatively "coarse" measure to capture the existence of moral hazard along the treatment margin: whether one has been discharged due to a voluntary dropout. Specifically, this type of dropout includes clients choosing not to complete one's treatment program, with or without specific advice to continue treatment. In Table 2.11, I find that the propensity to drop out of a treatment program voluntarily has slightly declined in the presence of PA restrictions among all patients discharged from these facilities by 2.2 percentage points (column (1)). However, when turning to those actually covered and discharged with commercial plans (as shown in the even-numbered columns), the effects are positive and statistically insignificant. Therefore, it is less likely that my results shown in section 2.7 are primarily attributed to a sizable change in moral hazard at the treatment margin.

[32]For example, recent research has identified that less than half (41%) of all people treated for OUD in the United States receive methadone or buprenorphine through substance use disorder (SUD) treatment programs. When the referral source to a treatment program is the criminal justice system (i.e., coercive), the proportion of people receiving MAT drops to just under 5% (Krawczyk et al., 2017).

2.8.4 Providers' Prescribing and Diagnostic Behaviors

According to the provider-induced demand theory (Arrow, 1978), any changes in the medical price would alter providers' financial incentives, thereby influencing one's prescribing and diagnostic behaviors. If removing PA requirements can largely change the price of each SAT treatment, one would expect my main results to reflect a redirection in providers' treatment decisions. To empirically test this hypothesis, I restrict my attention to medication-assisted treatment (MAT) for two primary reasons:

First, insurer requirements for prior authorization of MAT are historically widespread, with prior authorization requirements being one of the most frequently cited buprenorphine prescribing barriers in studies of clinicians (Barbara Andraka-Christou and Stein, 2023). For SAT services, the presence of prior authorization requirements is more frequent than many other medical procedures (Weber, 2020). [33]

Second, prescribing MAT solely relies on licensed healthcare providers (i.e., physicians, physician assistants (PAs), or nurse practitioners who have completed mandatory training and obtained specific authorization from SAMHSA). In contrast, other SUD counseling and individual/group therapy are jointly provided by various professionals.[34] In this vein, focusing on MAT enables me to better capture individual providers' decisions instead of opinions from a joint team.

Prior work typically argues empirical tests for models of physician-induced demand are remarkably challenging because it is difficult to separate the demand and the supply sides — overuse of medical procedures or drugs could also reflect consumer demand and/or physicians' belief about consumer demand (Currie, Lin and Meng, 2014). To tackle this issue, I use information from the 2012-2020 TEDS-D to examine whether imposing a PA restriction affects (1) the likelihood of providing low-intensity MAT services (as a proxy for firms' decisions), (2) the actual utilization of low-intensity MAT services (as a proxy for the

[33] According to Nguyen et al. (2022), commercial insurers impose PA requirements on buprenorphine, with 23% of formularies having at least one buprenorphine product with prior authorization requirements in 2017.

[34] To name a few, such professionals include clinical social workers, professional counselors, mental health counselors, marriage and family therapists, clinical alcohol and drug counselors, peer specialists, and many others.

equilibrium outcome), and (3) the probability of voluntarily drop out from outpatient MAT services as a proxy for consumers' demand.

The corresponding results are presented in Table 2.11 and Table 2.12. Starting with Table 2.11, I show the heterogeneous effects of PA restrictions by the type of low-intensity services. The outcome of interest in the first two columns is the probability of offering low-intensity regular SAT services (i.e., counseling and behavioral therapy); the dependent variable is the likelihood of providing low-intensity medication-assisted treatment. In column (1) and column (3), I include all discharges from the specialty care facilities regardless of whether and how one is insured. In column (2) and column (4), I restrict my attention to those discharges paid by private plans. The point estimates in Table 11 suggest that imposing PA restrictions on commercial plans would significantly increase the provision of low-intensity regular SAT services and the provision of low-intensity medication-based SAT. Given MAT services are more likely to reflect individual providers' incentives, I argue the exercise demonstrates the surge in low-intensity service provision (shown in section 7) might result from both an expansion in treatment capacity and a significant change in providers' financial incentives.

To further corroborate some evidence, I continue with another exercise in Table 2.12. The dependent variable in the first two columns is a dummy variable for being admitted to an outpatient MAT program. The dependent variable in the last two columns is the likelihood of dropping out of an outpatient MAT program. In column (1) and column (3), I include all discharges from the specialty care facilities regardless of whether and how one is insured. In column (2) and column (4), I restrict my attention to those discharges paid by private plans. Interestingly, the coefficient in column (2) indicates having a PA restriction leads to a decline in the admission margin, conditional on having private plans. This finding suggests in equilibrium, the utilization of MAT services decreases. The coefficient estimate in column (4) means having PA restrictions incentivizes consumers to drop out and reduce the demand for such services. Taken together, I would argue these two patterns highlight the increased provision of MAT services in an outpatient setting cannot be fully attributed to substantial increases on the demand side.

Putting these results together (Table 2.12 and Table 2.13), I provide suggestive evidence that both an increase in the facility's treatment capacity and a surge in individual providers' financial incentives can explain the patterns we document in section 2.7. Due to the limitation of my current data, I cannot clearly disentangle these two mechanisms and thus encourage future work to keep pursuing this interesting topic using much more detailed claim data.

2.8.5 Facilities' Contracting with Private Plans

To test if the willingness to accept private insurance is a key margin where providers adjust decisions, I present the regression results in Table 2.14 regarding the propensity to accept various types of payments among SAT facilities. This exercise sheds some light on whether changes in the provision of SAT services are driven by firms' selective contracting (mentioned in section 2.4).

In column (1) and column (2), I start with a baseline OLS regression where the key outcome of interest is the propensity to accept private health plans as the primary method of payment. In columns (3) and (4), I turn to a specification with the dependent variable as an indicator equaling to one if an SAT facility is inclined to accept any public insurance plans (i.e., Medicare, Medicaid, and other state-funded plans). In the last two columns, I focus on the case where the dependent variable is the likelihood of accepting cash or other self-payment. Another noteworthy feature is that in all even-numbered columns, I check the robustness of my results by directly excluding states with a Medicaid prior authorization law in place.

Based on the estimated coefficients in column (1) and column (2), one can tell that the enactment of prior authorization restrictions has imposed insignificant effects on the propensity to accept private plans for a SAT facility. In contrast, when moving to the results in columns (3) and (4), it suggests that restricting the use of PA in private plans has created some positive spillovers on the participation in the public insurance market: the presence of PA laws is associated with a significant increase in the propensity to participate in the public insurance market by 2.6 - 4.6 percentage points. Conceptually, this spillover across different insurance markets may result from changes in firms' financial incentives following

the PA restriction. For example, if PA requirements impose substantial administrative costs on healthcare facilities, removing these administrative costs may relax firms' capacity constraints and incentivize firms to accept low-margin consumers. This channel is quite relevant in the context of SAT services, given that public insurance reimbursement rates are generally lower than private plans.

2.8.6 Local Market Structure of Specialty Healthcare Facilities

Last but not least, I compile some aggregate-level data to test if changes in the local market structure (i.e., competition) can partially explain specialty facilities' decisions.[35] A long literature in healthcare has demonstrated that increased competition pressure can alter the provision, quality, and costs of medical services (see, for example, Kessler and Geppert, 2005; Karlsson, 2007; Gaynor, Moreno-Serra and Propper, 2013). The key concern here is that structural factors mentioned above in this section can all contribute to substantial changes in the market structure of specialty behavioral health facilities, further altering individual facility's provision decisions.

The empirical exercise I took here tests if the number of facilities offering any SAT per 100,000 population within a state change following the PA restriction.[36] To do so, I aggregate all facilities reporting to the N-SSATS per year to the state-year level and re-scale it by the state population. All regressions are weighted by state population. I present my results in Table 2.15. The dependent variable of interest is the number of facilities offering relevant SAT services per 100,000 state population per year across all columns. Column (1) focuses on all such specialty care facilities offering any SAT service. In column (2), the variable of interest is the number of facilities solely offering low-intensity ones; the estimates in column (3) capture the impacts on the number of facilities providing only high-intensity service. Eventually, in the last column, I restrict my attention to the number of facilities offering both high- and low-intensity SAT services. Panel A presents my estimates for imposing any PA restrictions, and Panel B shows the estimates for both the PA restriction on general SAT services and the PA restriction on medication-assisted treatment.

[35] Admittedly, without a structural model to explicitly disentangle various mechanisms, I cannot rule out this competition story for sure.

[36] This idea is consistent with Knowles (2022).

Overall, I observe some interesting patterns from the data. First, there is no significant effect on the aggregate number of facilities available within a state (column (1)), suggesting the null impact on the local market structure of such specialty care associated with a PA restriction. Second, consistent with the facility-level analysis shown in section 7, the number of facilities offering only low-intensity SAT services significantly went up in response to the PA law change by 0.277 units per 100,000 population (column (2)), while the number of facilities offering high-intensity SAT services dropped by 0.159 units per 100,000 population (column (3)). These two findings thus reinforce that removing PA can induce a shift in the provision of facilities (from high-intensity to low-intensity).

From Figure (17) to Figure (20), I plot my estimates from an event-study specification for four types of facilities respectively: facilities offering any SAT service (Figure (17)), facilities offering only low-intensity SAT service (Figure (18)), facilities offering only high-intensity SAT service (Figure (19)), and facilities offering both low- and high-intensity services (Figure (20)). Among these estimates, I only find some significant results in Figure (18) and Figure (19): removing PA requirements largely scaled up the provision of share of facilities solely providing low-intensity SAT, and the impact here is persistent.

2.9 Welfare Implications

To close the discussion, I finally investigate some welfare implications related to the PA law change. Motivated by the descriptive evidence from the American Medical Association (AMA),[37] I compile state-level mortality rates due to SUDs to estimate the impacts of restricting PA requirements on health outcomes.

To identify deaths related to substance use disorders, I check the CDC Wide-ranging ONline Data for Epidemiologic Research (WONDER) system and exploit the ICD-10 code. In particular, I first define suicides due to all substance use disorders as follows: deaths caused by mental and behavioral disorders due to psychoactive substance use (ICD-10 F10-F19) and suicide (U03, terrorism intentional suicide; X60-X84, intentional self-harm; Y87, sequelae of

[37] See https://www.ama-assn.org/practice-management/prior-authorization/1-3-doctors-has-seen-prior-auth-lead-serious-adverse-event, last accessed April 30, 2024.

intentional self-harm, assault, and events of undetermined intent).[38] I also construct the state-level mortality rate caused by drug and alcohol reasons.[39]

The estimates are presented in Table 2.16. In the first two columns, the dependent variable is the suicide rate due to SUDs per state year. In the last four columns, I focus on alcohol-induced deaths. The outcome of interest is the number of all deaths linked to alcohol-related issues per 100,000 population in column (3) and column (4); the dependent variable of interest is the number of deaths due to alcohol issues within medical facilities per 100,000 population in column (5) and column (6). Based on the results shown in Table 2.16, we can see that restricting the use of PA in commercial plans on the general SAT service leads to a significant decline in suicides due to SUDs (by 0.122 cases per 100,000 population), all alcohol-induced deaths (by 0.911 cases per 100,000 population), and alcohol-induced deaths within medical facilities (by 0.437 cases per 100,000 population).

An event-study specification as follows is estimated:

$$y_{st} = \alpha + \sum_{i=-5}^{4} \beta_{t+i} ServiceRestriction_s \times year_{t+i} + X_{st}^{'}\gamma + \rho_s + \eta_t + \epsilon_{ist} \tag{2.10}$$

where $ServiceRestriction_{st}$ indicates whether a state has ever had a PA restriction on general SAT services. The corresponding point estimates from the event-study specification are plotted in Figure A21, Figure A22, and Figure A23. Interestingly, the post-treatment estimates are statistically significant three years after the law change, suggesting the health improvement might take a while to be in effect.

2.10 Concluding Remarks and Future Work

This paper finds that restricting the use of prior authorization (PA), a widely used administrative practice in health plans, can significantly influence the provision of behavioral healthcare services. In response to a restriction on PA in commercial plans targeting substance abuse treatment (SAT) can increase the provision of low-intensity services (i.e.,

[38]Due to privacy protection, statistics from some states are suppressed. I show the availability of the suicide data in Figure 4.

[39]See for example, https://wonder.cdc.gov/mcd.html, last accessed April 30, 2024.

regular outpatient services) while decreasing the provision of high-intensity services (i.e., intensive outpatient service, partial hospital service, hospital inpatient service, and residential inpatient service).

I further corroborate evidence for two potential channels: First, the removal of PA largely expanded facilities' treatment capacity (i.e., time and labor available to patients), thereby increasing the provision of low-intensity medical services on time. Second, restricting the use of this administrative hassle also alters providers' (financial) incentives in prescribing, diagnosis, and treatment. In the meantime, my empirical results suggest the shift from high-intensity service to low-intensity one cannot be primarily attributed to noticeable changes in the private insurance market *per se*, *ex-post* moral hazard problems among existing patients, facilities' contracting with private insurers, and the changing market structure.

Going forward, I aim to compile more restricted data and empirically test other potential channels. Among many others, I am investigating potential explanations for the decline in providing high-intensity SAT service.

Mechanical Shift of Patients: Besides the tentative evidence shown above, I also expect to assemble individual-level medical transfer records from SAMHSA (i.e., whether a patient is transferred from low-intensity (high-intensity) settings to high-intensity (low-intensity) settings). To my knowledge, the restricted N-SSATS includes such information, and I plan to submit a FOIA request to obtain the data.

Medical Resource Reallocation within Facilities: There are two potential ways to test this channel. First, I will look into the NSSRN data (2008, 2018, and 2022) to examine whether PA restrictions influence the work hours of registered nurses within behavioral healthcare facilities. Second, I will check with the SAMHSA for any information on the behavioral healthcare workforce within such facilities.

Facilities' Dynamics: As mentioned in section 8.1, I am discussing with staff from the SAMHSA regarding the availability of facility identifiers from 2015 and onwards. With the additional ID, I can construct a facility-level panel and track a facility's history in providing medical service over time. This way, I can tell apart the *medical resource realocation* channel and the *facilities' dynamics* channel.

Table 2.1: Limits on Prior Authorization in SAT

State	Effective Date	SUD Services	SUD Medication
Arizona	4/26/2018	A health care services plan must allow at least one modality of medication-assisted treatment to be available without prior authorization.*(ARIZ. REV. STAT. §20-3402(B))*	A health care services plan must allow at least one modality of medication-assisted treatment to be available without prior authorization. *(ARIZ. REV. STAT. §20-3402(B))*
Arkansas	4/12/2019		Except in the case of injectables, a healthcare insurer, including Medicaid, shall not require prior authorization in order for a patient to obtain coverage of buprenorphine, naloxone, naltrexone, methadone, and their various formulations and combinations approved by the United States Food and Drug Administration for the treatment of opioid addiction. *(ARK. CODE ANN. §23-99-1119)*
Colorado	5/16/2019		A health benefit plan subject to this subsection must provide coverage without prior authorization for a five-day supply of at least one of the FDA-approved drugs for the treatment of opioid dependence
Delaware	5/29/2017	Carriers may not impose prior authorization for the diagnosis and treatment of drug and alcohol dependencies, including inpatient treatment. (*DEL. CODE ANN. tit. 18, §§3343*)	
Illinois	1/1/2019	Prior authorization shall not be utilized for the benefits under this subsection. The substance use disorder treatment provider or facility shall notify the insurer of the initiation of treatment. *(IL ST CH 215 § 5/370c)*	
Maine	6/13/2019	A carrier may not require prior authorization for medication-assisted treatment for opioid use disorder for the prescription of at least one drug for each therapeutic class of medication used in medication-assisted treatment, except that a carrier may not impose any prior authorization requirements on a pregnant woman for medication-assisted treatment for opioid use disorder. *(PL 2019, c. 273, §2)*	A carrier may not require prior authorization for medication-assisted treatment for opioid use disorder for the prescription of at least one drug for each therapeutic class of medication used in medication-assisted treatment, except that a carrier may not impose any prior authorization requirements on a pregnant woman for medication-assisted treatment for opioid use disorder. *(PL 2019, c. 273, §2)*
Maryland	5/25/2017		An entity subject to this section may not apply a prior authorization requirement for a prescription drug: (1) when used for treatment of an opioid use disorder; and (2) that contains methadone, buprenorphine, or naltrexone.

State	Effective Date	SUD Services	SUD Medication
Massachusetts	7/1/2016	Insurers (including state employee health plans) may not impose prior authorization or utilization review for up to 7 days on acute treatment services and clinical stabilization services. *(MASS. GEN. LAWS ch. 32A § 17N)*	
Missouri	8/28/2019		Health plans must cover buprenorphine tablets, methadone, naloxone, extended-release injectable naltrexone and buprenorphine/naloxone combination (and these dispensed when through an opioid treatment program), without prior authorization.
Montana	1/1/2020		A health insurance issuer may not impose prior authorization or step therapy requirements for an oral therapy prescription used to treat opioid use disorder. *(MONT. CODE ANN. § 33-32-215)*
New Hampshire	1/1/2017	When SUD services are covered, managed care plans may not require prior authorization for the first two outpatient visits in an episode of care for SUD. Prior authorization cannot be required for the first 24 hours of inpatient withdrawal management and clinical stabilization services.	
New Jersey	5/16/2017	Insurers may not require prior authorization for inpatient and outpatient SUD services for the first 180 days or visits of treatment during a year. Carriers are required to provide 28 days of inpatient treatment without retrospective or concurrent review and 28 days of intensive outpatient and partial hospitalization without any retrospective review.	Insurers may not require prior authorization for outpatient medications used to treat SUD.
New York*	6/22/2016 and 4/12/4018	authorization for inpatient treatment in in-network state-certified facilities and may not conduct concurrent review for the first 28 days of treatment. Insurers may not impose prior authorization on outpatient, intensive outpatient, outpatient rehabilitation, and opioid treatment in in-network state-certified facilities and may not conduct concurrent review for the first four weeks/28 visits.	

State	Effective Date	SUD Services	SUD Medication
Oregon	10/6/2017		In reimbursing the cost of medication prescribed for the purpose of treating opioid or opiate withdrawal, an insurer offering a health benefit plan as defined in ORS 743B.005 may not require prior authorization of payment during the first 30 days of treatment. *(OR. REV. STAT. § 743B.425)*
Vermont	1/1/2020	A health insurance plan shall not require prior authorization for all counseling and behavioral therapies associated with medication-assisted treatment for a patient who is receiving medication-assisted treatment. *(VT. STAT. ANN. tit. 18, § 4754)*	A health insurance plan shall not require prior authorization for prescription drugs for a patient who is receiving medication-assisted treatment if the dosage prescribed is within the U.S. Food and Drug Administration's dosing recommendations. *(VT. STAT. ANN. tit. 18, § 4754)*
Virginia	3/21/2019		Require that no prior authorization be required for at least one drug prescribed for substance abuse medication-assisted treatment, provided that (i) the drug is a covered benefit, (ii) the prescription does not exceed the FDA-labeled dosages, and (iii) the drug is prescribed consistent with the regulations of the Board of Medicine
Washington	7/28/2019		For health plans issued or renewed on or after January 1, 2020, a health carrier shall provide coverage without prior authorization of at least one federal food and drug administration approved product for the treatment of opioid use disorder in the drug classes opioid agonists, opioid antagonists, and opioid partial agonists. *(WASH. REV. CODE ANN. § 48.43.760)*
West Virginia*	3/27/2018		The benefits for outpatient prescription drugs to treat substance use disorder shall be provided when determined medically necessary by the covered person's physician or psychiatrist without the imposition of any prior authorization or other prospective utilization management requirements. *(W. Va. Code, § 33-16-3cc)*

Note: Data are collected from Westlaw and the Legal Action Center (accessible at https://www.lac.org/resource/spotlight-on-legislation-limiting-the-use-of-prior-authorization-for-substance-use-disorder-services-and-medications). Particularly, New York and West Virginia enacted separated laws regarding outpatient and inpatient treatments.

Table 2.2: Effects of PA Limits on the Provision of SAT Services

	low vs. high		**both vs. low**		**both vs. high**	
PA restriction$_{st}$	0.088***	0.079***	-0.042***	-0.023	0.043**	0.054**
	(0.029)	(0.024)	(0.015)	(0.014)	(0.019)	(0.023)
state FE	✓	✓	✓	✓	✓	✓
other state SUD policies		✓		✓		✓
accepting private plans		✓		✓		✓
mean (pre-treatment)	0.638	0.670	0.597	0.650	0.723	0.790
# of obs.	59,720	37,508	107,070	77,156	86,070	62,345

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of only offering any low-intensity (i.e., outpatient) services relative to only offering any high-intensity (i.e., intensive outpatient, partial hospital, residential inpatient, and hospital-based inpatient) in columns (1) and (2), and the probability of offering both low- and high-intensity services relative to only providing low-intensity ones in column (3) and column (4). In column (5) and column (6), the dependent variable is the probability of offering both types of services relative to offering only high-intensity ones. Data are obtained from the 2012-2020 N-SSATS. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.3: Effects of PA Limits on the Provision of Inpatient Service

	low vs. high		**both vs. low**		**both vs. high**	
PA service restriction$_{st}$	0.084***	0.067***	-0.040**	-0.022	0.035**	0.045**
	(0.028)	(0.024)	(0.019)	(0.018)	(0.017)	(0.020)
PA medication restriction$_{st}$	0.029	0.044*	-0.007	0.003	0.025	0.038**
	(0.030)	(0.024)	(0.022)	(0.019)	(0.017)	(0.019)
Medicaid PA restriction$_{st}$	0.148***	0.249***	-0.050	-0.234***	0.066*	0.035
	(0.054)	(0.054)	(0.053)	(0.071)	(0.038)	(0.054)
state FE	✓	✓	✓	✓	✓	✓
year FE	✓	✓	✓	✓	✓	✓
other state SUD policies		✓		✓		✓
accepting private plans		✓		✓		✓
mean (pre-treatment)	0.638	0.670	0.597	0.650	0.723	0.790
# of obs.	59,720	37,508	107,070	77,156	86,070	62,345

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of only offering any low-intensity (i.e., outpatient) services relative to only offering any high-intensity (i.e., intensive outpatient, partial hospital, residential inpatient, and hospital-based inpatient) in columns (1) and (2), and the probability of offering both low- and high-intensity services relative to only providing low-intensity ones in column (3) and column (4). In column (5) and column (6), the dependent variable is the probability of offering both types of services relative to offering only high-intensity ones. Data are obtained from the 2012-2020 N-SSATS. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.4: Effects of PA Limits on SAT Provision (Callaway and Sant'Anna (2021))

	low vs. high		**both vs. low**		**both vs. high**	
PA restriction$_{st}$	0.044***	0.043***	-0.023**	-0.012	0.015	0.021*
	(0.012)	(0.015)	(0.010)	(0.011)	(0.010)	(0.011)
state FE	✓	✓	✓	✓	✓	✓
accepting private plans		✓		✓		✓
mean (pre-treatment)	0.638	0.670	0.597	0.650	0.723	0.790
# of obs.	59,720	37,508	107,070	77,156	86,070	62,345

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of only offering any low-intensity (i.e., outpatient) services relative to only offering any high-intensity (i.e., intensive outpatient, partial hospital, residential inpatient, and hospital-based inpatient) in columns (1) and (2), and the probability of offering both low- and high-intensity services relative to only providing low-intensity ones in column (3) and column (4). In column (5) and column (6), the dependent variable is the probability of offering both types of services relative to offering only high-intensity ones. Data are obtained from the 2012-2020 N-SSATS. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, the natural log of the population, the natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.5: Effects of PA Limits on the Provision of Early Interventions

	Brief Intervention	**Screening**	**Comp Assessment**	**Outreach**
PA limit$_{st}$	0.633**	0.653*	0.698*	0.528*
	(0.274)	(0.370)	(0.351)	(0.291)
state FE	✓	✓	✓	✓
year×division FE	✓	✓	✓	✓
state controls	✓	✓	✓	✓
Mean (pre-treatment)	4.871	5.718	5.598	3.644
N	441	294	294	294

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the number of facilities offering brief intervention, screening for SUD, comprehensive assessment and diagnosis, and outreach services through column (1) to column (4). Data are obtained from the 2012-2020 Annual Reports for N-SSATS in column (1) and assembled from the 2015-2020 Annual Reports for N-SSATS in column (2)-column (4). State controls include ACA Medicaid Expansion, SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.6: Do Social and Economic Factors Predict the Enactment of PA Restrictions?

	Any PA Restriction	**Service Restriction**	**Medication Restriction**
log(population)	-2.993*	-2.914*	-0.168
	(1.730)	(1.627)	(1.644)
parity laws	-0.011	-0.017	-0.000
	(0.010)	(0.010)	(0.009)
log(# of SNAP recipients)	-0.060	-0.088	-0.215
	(0.275)	(0.245)	(0.202)
log(# of TANF recipients)	0.095	0.063	0.001
	(0.082)	(0.079)	(0.075)
log(state GDP)	0.921	0.458	0.162
	(0.667)	(0.537)	(0.583)
state unemployment rate	0.013	0.002	0.001
	(0.031)	(0.023)	(0.025)
state minimum wage	0.129***	0.073*	0.118***
	(0.039)	(0.037)	(0.039)
annual SUD deaths	0.000	0.000	-0.000
	(0.000)	(0.000)	(0.000)
Observations	459	459	459

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variable is the probability of enacting any PA restriction in state s and year t in column (1), the probability of enacting PA restrictions on general SAT services in column (2), and the probability of enacting PA restrictions on medication-assisted treatment (MAT) in column (3). State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, the natural log of the population, the natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Regressions are weighted by state population. Standard errors are in parenthesis.

Table 2.7: Effects of PA Limits on Medical Delay (Due to Facilities' Capacity Issues)

	low-intensity			**high-intensity**		
	any delay	*normal delay*	*severe delay*	*any delay*	*normal delay*	*severe delay*
PA restriction$_{st}$	-0.100**	-0.044***	-0.018*	-0.021	-0.000	0.004
	(0.044)	(0.014)	(0.009)	(0.039)	(0.013)	(0.009)
state FE	✓	✓	✓	✓	✓	✓
year FE	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓
# of observations	2,487,244	2,487,244	2,487,244	3,227,149	3,227,149	3,227,149

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: In column (1), column (2), and column (3), the sample includes all patients admitted to a low-intensity (i.e., regular outpatient) setting. In column (4), column (5), and column (6), the sample includes all patients admitted to a high-intensity (i.e., intensive outpatient, partial hospital, residential inpatient, and hospital-based inpatient) setting. The dependent variables are the probability of experiencing any medical delay (any days prior to the treatment), normal medical delay (at least seven days prior to the treatment), and severe medical delay (at least two weeks prior to the treatment). Data are obtained from the 2012-2020 TEDS-A. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.8: Effects of PA Limits on the Number of Admissions to SAT Facilities

	any SAT services		**low-intensity SAT**		**high-intensity SAT**	
PA restriction$_{st}$	140.00	-	139.11	-	0.89	-
	(149.08)	-	(130.85)	-	(33.14)	-
PA service restriction$_{st}$	-	171.47	-	131.97	-	39.51
	-	(164.97)	-	(147.92)	-	(35.03)
PA medication restriction$_{st}$	-	244.24	-	251.41	-	-7.17
	-	(213.21)	-	(182.76)		(55.41)
state FE	✓	✓	✓	✓	✓	✓
year	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓
# of observations	459	459	459	459	459	459

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the number of initial admissions to any SAT setting per 100,000 population in columns (1) and (2) and the number of initial admissions to a low-intensity setting per 100,000 population in column (3) and column (4). In column (5) and column (6), the dependent variable is the number of new admissions to a high-intensity setting. Data are obtained from the 2012-2020 TEDS-A. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Regressions are weighted by the state population. Standard errors are in parenthesis.

Table 2.9: Effects of PA Limits on the Number of Discharges to SAT Facilities

	any SAT services		**low-intensity SAT**		**high-intensity SAT**	
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
PA restriction$_{st}$	79.12	-	82.03	-	-2.86	-
	(129.26)	-	(121.55)	-	(21.13)	-
PA service restriction$_{st}$	-	199.78	-	143.18	-	56.71**
	-	(173.03)	-	(157.03)	-	(25.71)
PA medication restriction$_{st}$	-	140.06	-	171.32	-	-31.38
	-	(187.03)	-	(173.74)		(29.57)
state FE	✓	✓	✓	✓	✓	✓
year	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓
# of observations	459	459	459	459	459	459

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the number of initial discharges to any SAT setting per 100,000 population in columns (1) and (2) and the number of discharges to a low-intensity setting per 100,000 population in column (3) and column (4). In column (5) and column (6), the dependent variable is the number of discharges a high-intensity setting. Data are obtained from the 2012-2020 TEDS-A. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Regressions are weighted by the state population. Standard errors are in parenthesis.

Table 2.10: Effects of PA Limits on the Composition of Patients

	male	**black**	**high school**	**drug and alch**	**prior arrests**	**private ins**	**public ins**	**self-paid**
Panel A. Admissions								
PA limit$_{st}$	0.001	-0.081	-0.005	-0.005	-0.004	-0.009	0.043	-0.035
	(0.006)	(0.004)	(0.009)	(0.016)	(0.006)	(0.011)	(0.031)	(0.029)
state FE	✓	✓	✓	✓	✓	✓	✓	✓
year FE	✓	✓	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓	✓	✓
N	10,432,043	10,432,043	10,581,019	11,558,253	10,090,998	5,166,925	5,166,925	5,166,925
Panel B. Discharges								
PA limit$_{st}$	0.005	-0.002	-0.000	-0.006	-0.005	0.006	-0.010	-0.007
	(0.007)	(0.007)	(0.009)	(0.013)	(0.005)	(0.010)	(0.020)	(0.012)
state FE	✓	✓	✓	✓	✓	✓	✓	✓
year FE	✓	✓	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓	✓	✓
N	10,015,460	9,782,326	9,315,549	10,018,717	8,461,177	3,397,226	3,397,226	3,397,226

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the indicator for being male, black, with at least a high-school diploma, with issues in both alchol and drugs, with a history of prior arrests within 30 days, with coverage from a private plan/public plan/no plan through column (1) to column (8), respectively. Data are obtained from the 2012-2020 TEDS-A/D. State controls include ACA Medicaid Expansion, SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural population log, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.11: Effects of PA Limits on Voluntary Dropout

	dependent variable: prob(voluntarily dropout)					
	All Discharges		*Low-Intensity*		*High-Intensity*	
Panel A. Any Restriction						
PA restriction$_{st}$	-0.022**	0.012	-0.014	0.031	-0.024**	0.014
	(0.010)	(0.016)	(0.016)	(0.024)	(0.011)	(0.012)
Panel B. Policy Heterogeneity						
PA service restriction$_{st}$	-0.035*	0.012	-0.031	0.017	-0.028	0.017
	(0.020)	(0.025)	(0.025)	(0.028)	(0.021)	(0.020)
PA medication restriction$_{st}$	0.006	-0.015	0.014	-0.003	-0.003	-0.009
	(0.023)	(0.023)	(0.029)	(0.022)	(0.024)	(0.017)
state FE	✓	✓	✓	✓	✓	✓
year	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓
sample	all	private	all	private	all	private
# of observations	8,088,908	364,827	3,156,893	117,905	4,931,275	246,889

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of voluntarily dropping out of a program (vs. completing a program). In column (1) and column (2), the sample includes all discharges of a specialty care facility. In column (3) and column (4), the sample includes all patients who initially receive low-intensity SAT services. In column (5) and column (6), the sample includes all patients who initially receive high-intensity SAT services. In odd-numbered columns, the sample includes all patients regardless of their method of payment. In even-numbered columns, the sample includes patients with private plans as the primary method of payment. Data are obtained from the 2012-2020 TEDS-D. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.12: Effects of PA Restrictions on Low-Intensity Regular SAT vs. MAT

	Regular SAT		**Medication SAT**	
PA restriction$_{st}$	0.035***	0.036***	0.056*	0.070**
	(0.012)	(0.012)	(0.032)	(0.035)
state FE	✓	✓	✓	✓
year FE	✓	✓	✓	✓
state controls	✓	✓	✓	✓
facilities accepting commercial plans		✓		✓
# of observations	106,513	73,825	53,930	39,121

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of offering regular low-intensity SAT service in column (1) and column (2) and are the probability of offering medication-assisted, low-intensity SAT services in column (3) and column (4). In odd-numbered columns, the sample includes all specialty care facilities. In even-numbered columns, the sample includes specialty care facilities accepting private plans. Data are obtained from the 2012-2020 N-SSATS. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.13: Effects of PA Limits on Outpatient Medication-Assisted Treatment (MAT)

	initial admission		**voluntary dropout**	
	(1)	**(2)**	**(3)**	**(4)**
PA restriction$_{st}$	0.005	-0.025**	0.005	0.088***
	(0.013)	(0.011)	(0.017)	(0.032)
state FE	✓	✓	✓	✓
year FE	✓	✓	✓	✓
state controls	✓	✓	✓	✓
paid by commercial plans		✓		✓
# of observations	7,839,817	323,450	630,002	12,629

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of getting admitted to an outpatient MAT program instead of other settings in column (1) and column (2) and the probability of voluntarily dropping out of a MAT program (vs. completing a MAT program) in column (3) and column (4). In odd-numbered columns, the sample includes all discharges regardless of the method of payment. In even-numbered columns, the sample includes discharges paid by commercial plans. Data are obtained from the 2012-2020 TEDS-D. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.14: Effects of PA Restrictions on the Participation in Insurance Market

	private plans	**Medicaid**	**Medicare**	**self-payment**
PA restrictions$_{st}$	-0.010	0.004	0.021*	0.003
	(0.014)	(0.014)	(0.011)	(0.006)
state FE	✓	✓	✓	✓
year FE	✓	✓	✓	✓
state controls	✓	✓	✓	✓
# of observations	114,382	114,212	113,561	115,029

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variables are the probability of accepting commercial plans, Medicaid payments, Medicare payments, and any cash or self-payments. Data are obtained from the 2012-2020 N-SSATS. State controls include SAT parity laws, pain clinic regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and the effective state-level minimum wage. All standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 2.15: Effects of PA Restrictions on Local Market Structure

	DP: # of facilities per 100,000 pop			
	all facilities	*only low*	*only high*	*both types*
Panel A. any restrictions				
PA restrictions$_{st}$	0.184	0.277***	-0.159*	0.066
	(0.166)	(0.095)	(0.087)	(0.107)
Panel B. policy heterogeneity				
PA service restrictions$_{st}$	0.193	0.281**	-0.140*	0.052
	(0.211)	(0.130)	(0.078)	(0.111)
PA medication restrictions$_{st}$	-0.010	0.069	-0.096	0.016
	(0.259)	(0.154)	(0.098)	(0.179)
state FE	✓	✓	✓	✓
year FE	✓	✓	✓	✓
state controls	✓	✓	✓	✓
# of observations	459	459	459	459

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variable is the number of all specialty care facilities per 100,000 population in column (1), the number of specialty care facilities only offering low-intensity SAT services per 100,000 population in column (2), the number of specialty care facilities only offering high-intensity SAT services per 100,000 population in column (3), and the number of specialty care facilities offering both high- and low-intensity SAT services per 100,000 population in column (4). In column (3) to column (6), all dependent variables are conditional on accepting private health insurance. In Panel A, the key independent variable is a dummy variable for whether there is a PA restriction in state s and year t. In Panel B, I take into account the policy heterogeneity. Data are obtained from the 2012-2020 N-SSATS. State controls include SAT Parity, Pain Clinic Regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and effective state minimum wage. All standard errors are clustered at the state level. Regressions are weighted by the state population. Standard errors are in parenthesis.

Table 2.16: Effects of PA Restrictions on Mortality Rate Related to SUDs

	SUD suicide		*all alcohol-induced*		*alcohol-induced (medical facilities)*	
PA Restriction$_{st}$	0.019	-	-0.112	-	-0.098	-
	(0.069)	-	(0.407)	-	(0.167)	-
Service Restriction$_{st}$	-	-0.122*	-	-0.911**	-	-0.437**
	-	(0.061)	-	(0.422)	-	(0.181)
Medication Restriction$_{st}$	-	0.144	-	0.641	-	0.218
	-	(0.095)	-	(0.549)	-	(0.237)
state FE	✓	✓	✓	✓	✓	✓
year FE	✓	✓	✓	✓	✓	✓
state controls	✓	✓	✓	✓	✓	✓
# of observations	459	459	459	459	459	459

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Notes: The dependent variable is the number of deaths due to SUD-induced suicide per 100,000 population in column (1) and column (2), the number of deaths induced by alcohol use issues per 100,000 population in column (3) and column (4), and the number of deaths induced by alcohol use issues within medical facilities per 100,000 population in column (5) and column (6). In odd-numbered columns, the key independent variable is a dummy variable for whether there is a PA restriction in state s and year t. In even-numbered columns, I take into account the policy heterogeneity. Data are obtained from the 2012-2020 CDC WONDER system. State controls include SAT Parity, Pain Clinic Regulation, PDMP mandates, state unemployment rates, natural log of the population, natural log of the state GDP, and effective state minimum wage. All standard errors are clustered at the state level. Regressions are weighted by the state population. Standard errors are in parenthesis.

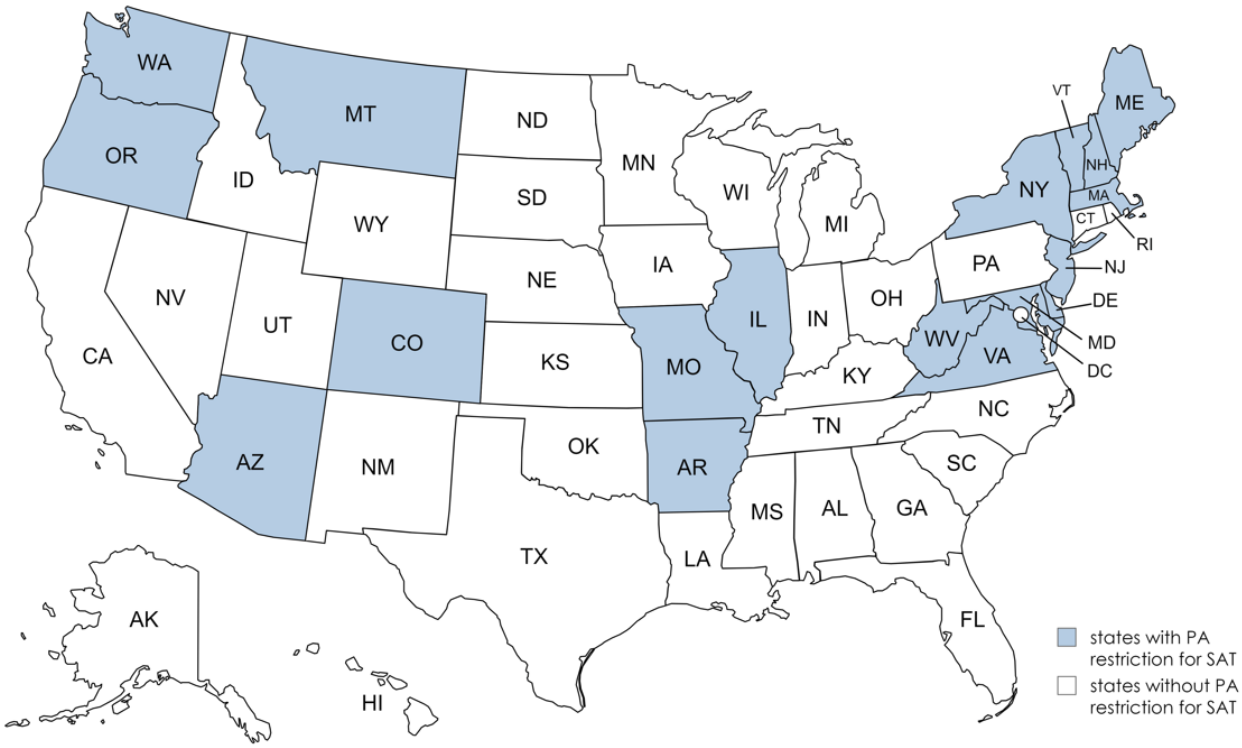


Figure A1: Distribution of State PA Restrictions on SAT in Commercial Plans

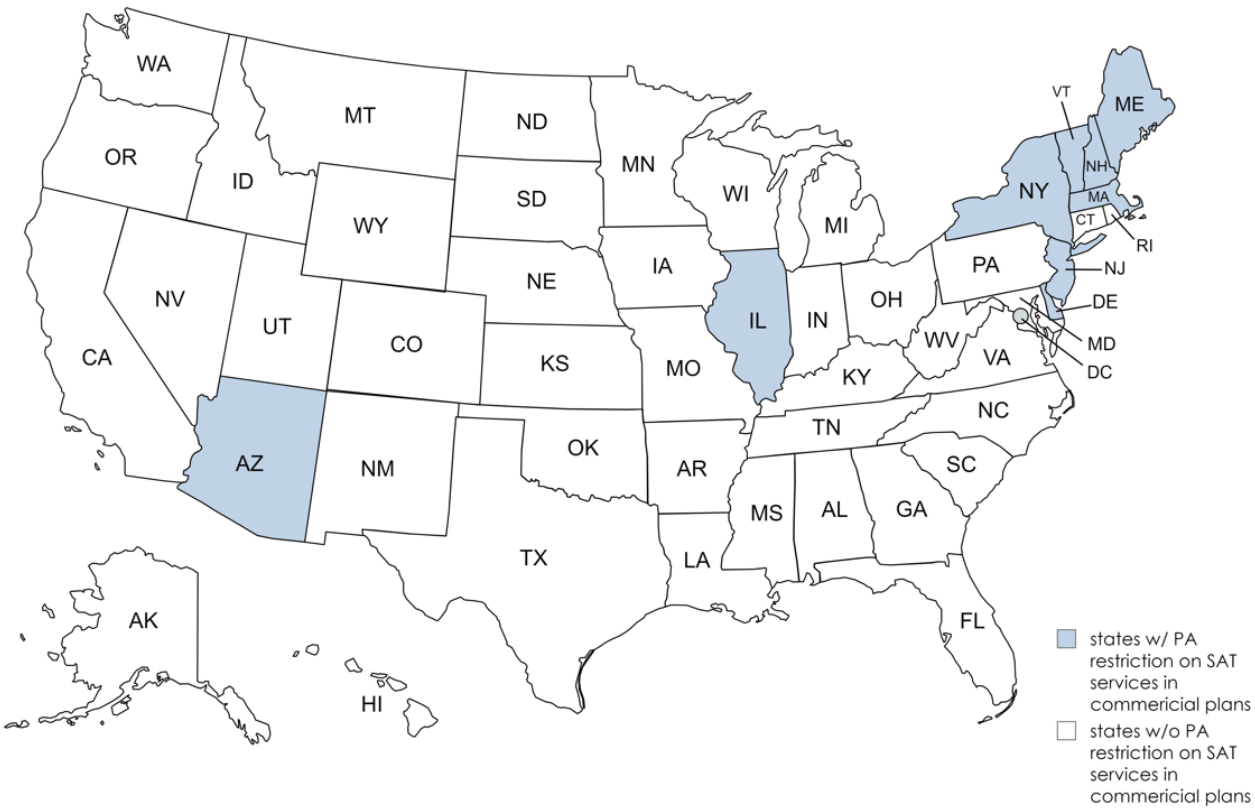


Figure A2: Distribution of State PA Restrictions on General SAT Service in Commercial Plans

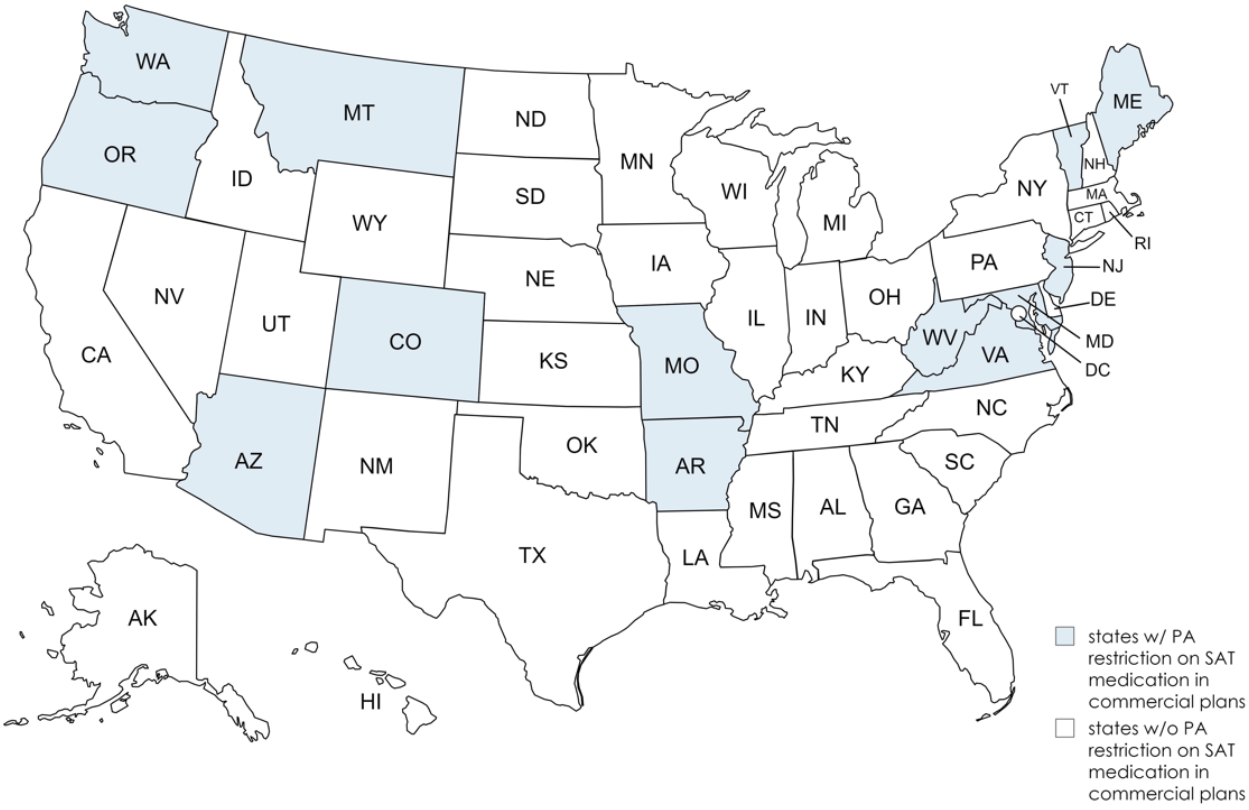


Figure A3: Distribution of State PA Restrictions on SAT Medication in Commercial Plans

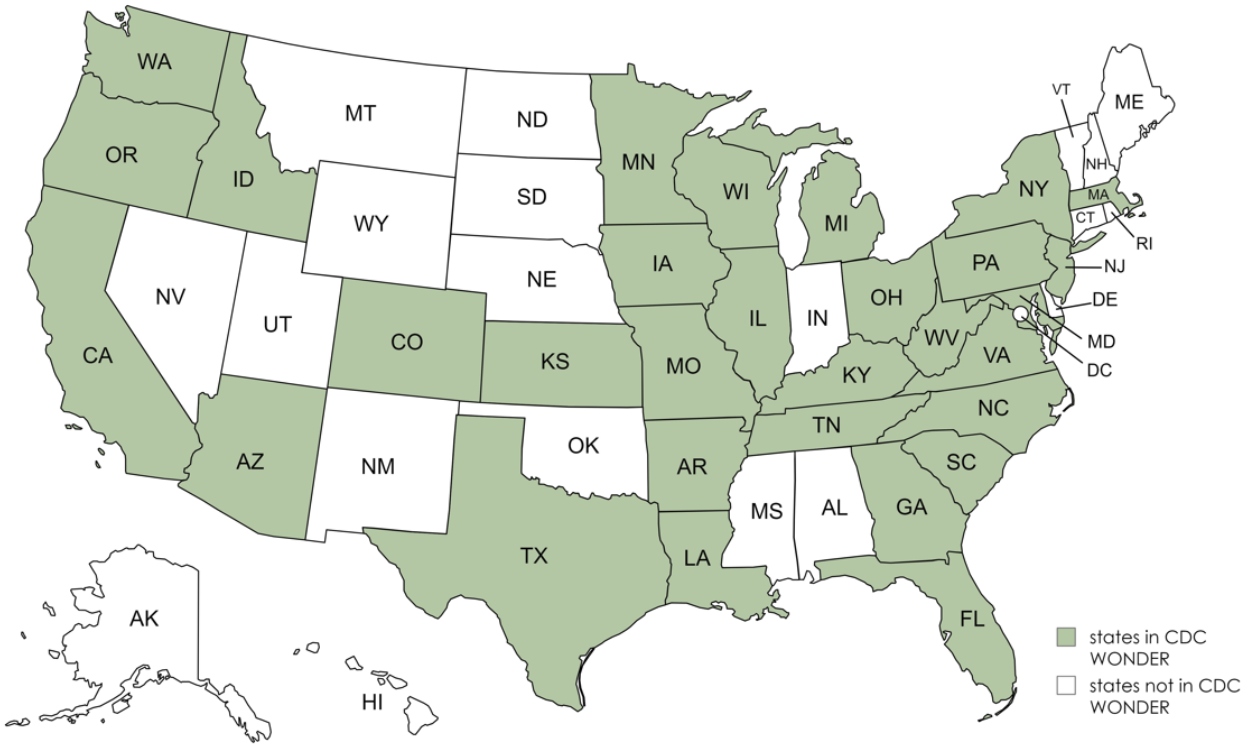


Figure A4: Availability of CDC WONDER States (SUD Suicide)

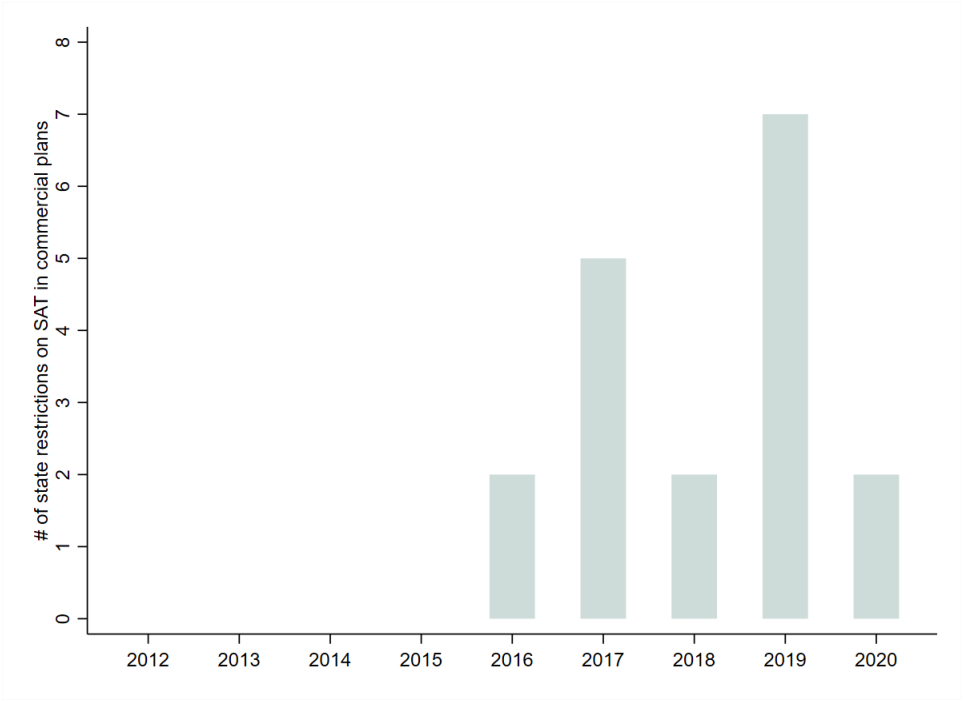


Figure A5: Evolution of State Laws Restricting PA on SAT in Commercial Plans

Table 6.6a. Type of assessment and pre-treatment services offered by facilities, by state or jurisdiction: Number, 2020

State or jurisdiction[1]	Total[2]	Assessment and pre-treatment services: Screening for substance abuse	Screening for mental health disorders	Comprehensive substance abuse assessment or diagnosis	Comprehensive mental health assessment or diagnosis	Screening for tobacco use	Outreach to persons in the community who may need treatment	Interim services for clients when immediate admission is not possible	Professional interventionist/ educational consultant	None of these assessment and pre-treatment services offered
Total	16,066	15,594	12,787	15,167	9,344	12,187	10,653	8,043	3,446	121
Alabama	155	153	95	141	55	104	129	101	28	2
Alaska	105	102	94	100	77	91	83	80	21	--
Arizona	447	434	373	422	303	311	296	227	95	6
Arkansas	171	165	150	158	117	128	145	99	34	1
California	1,734	1,689	1,305	1,600	829	1,178	1,199	788	409	29
Colorado	393	387	312	375	231	273	251	207	80	2
Connecticut	210	204	196	197	167	184	125	83	33	4
Delaware	49	45	46	48	41	34	35	28	10	--
District of Columbia	28	27	22	26	17	21	21	10	11	--
Florida	712	695	604	678	476	506	446	346	189	4
Georgia	348	341	261	321	193	197	234	141	65	2
Hawaii	161	156	85	154	45	138	92	94	34	1
Idaho	110	109	100	108	91	69	80	61	22	--
Illinois	713	699	545	675	387	482	452	374	173	5
Indiana	416	402	336	388	244	329	256	174	67	5
Iowa	185	180	152	181	87	162	129	134	34	1
Kansas	170	170	99	165	73	90	111	119	34	--
Kentucky	477	473	376	458	305	314	330	218	129	1
Louisiana	155	154	111	149	81	115	119	88	44	--
Maine	196	193	167	193	115	178	90	66	43	--
Maryland	432	413	316	406	249	350	302	184	103	10
Massachusetts	440	425	321	409	235	411	253	139	73	8
Michigan	455	443	392	436	270	310	281	213	87	1
Minnesota	401	369	299	385	221	286	237	141	70	4
Mississippi	105	104	89	96	74	64	78	57	23	--
Missouri	278	272	222	256	163	219	164	166	50	4
Montana	129	126	122	122	87	105	105	92	34	--
Nebraska	123	122	112	115	80	98	75	87	26	1

Continued. See notes at end of table.

Figure A6: Screenshot of the Annual Report of the N-SSATS

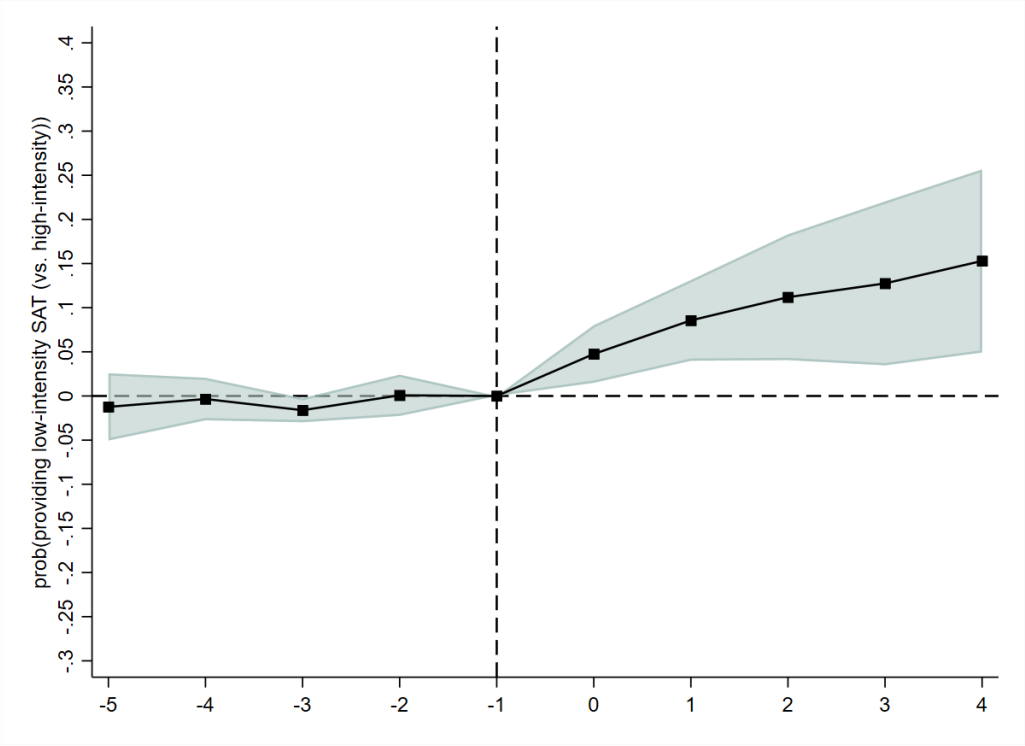


Figure A7: event-study estimates for providing only low-intensity (vs. only high-intensity) SAT

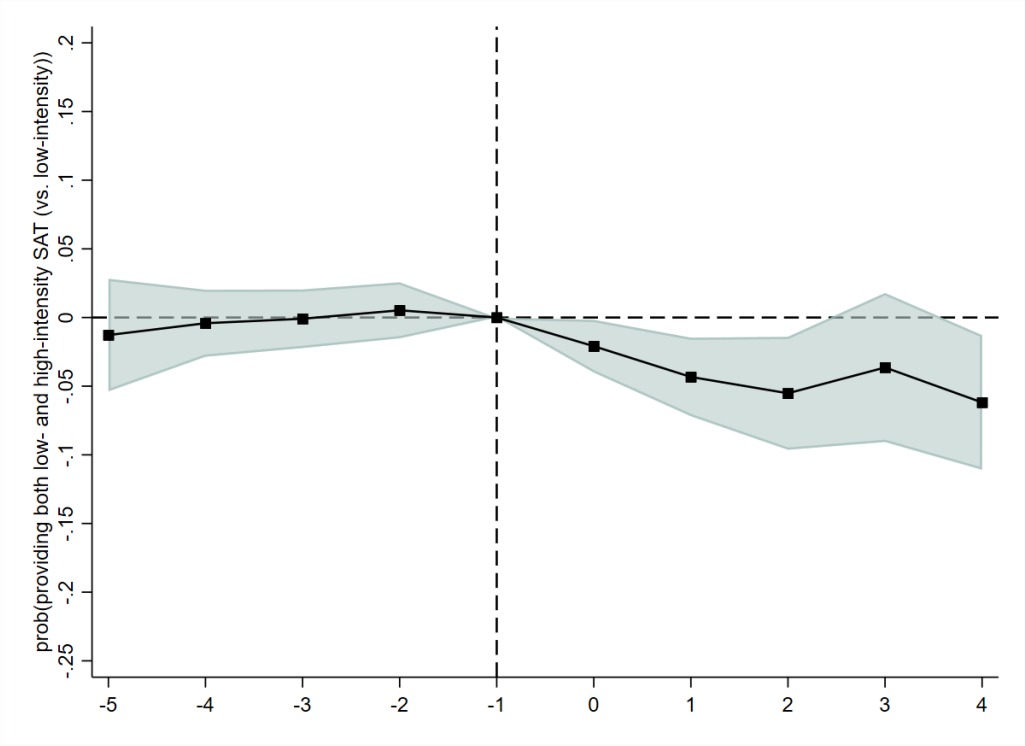


Figure A8: event-study estimates for providing both (vs. only low-intensity) SAT

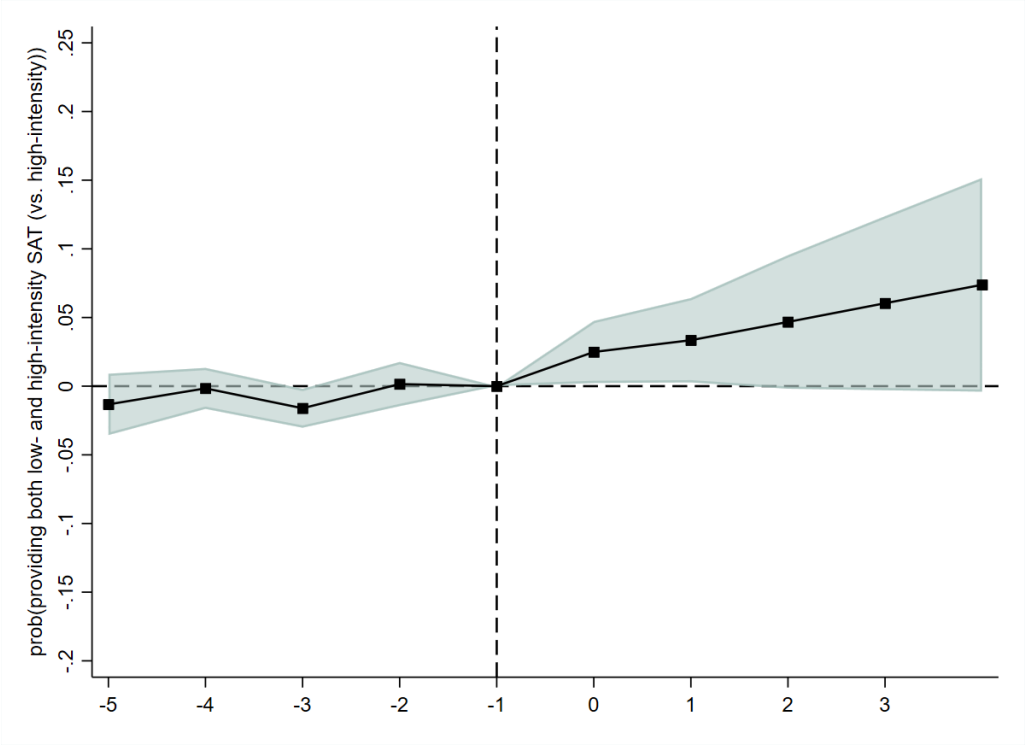


Figure A9: event-study estimates for providing both (vs. only high-intensity) SAT

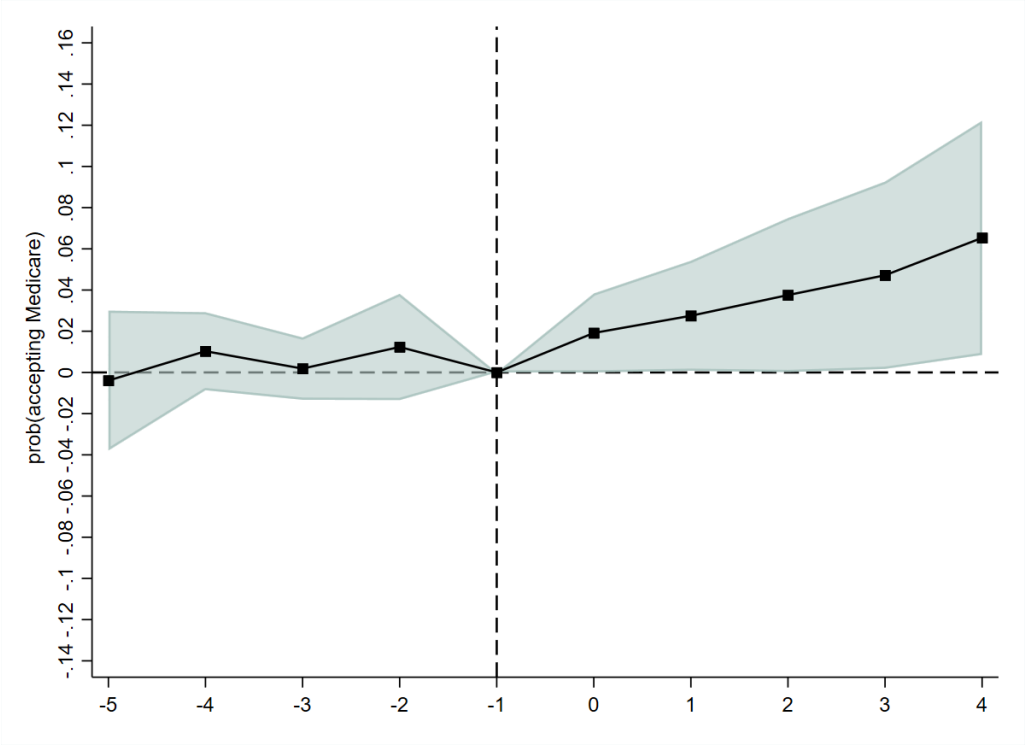


Figure A10: event-study estimates for accepting Medicare

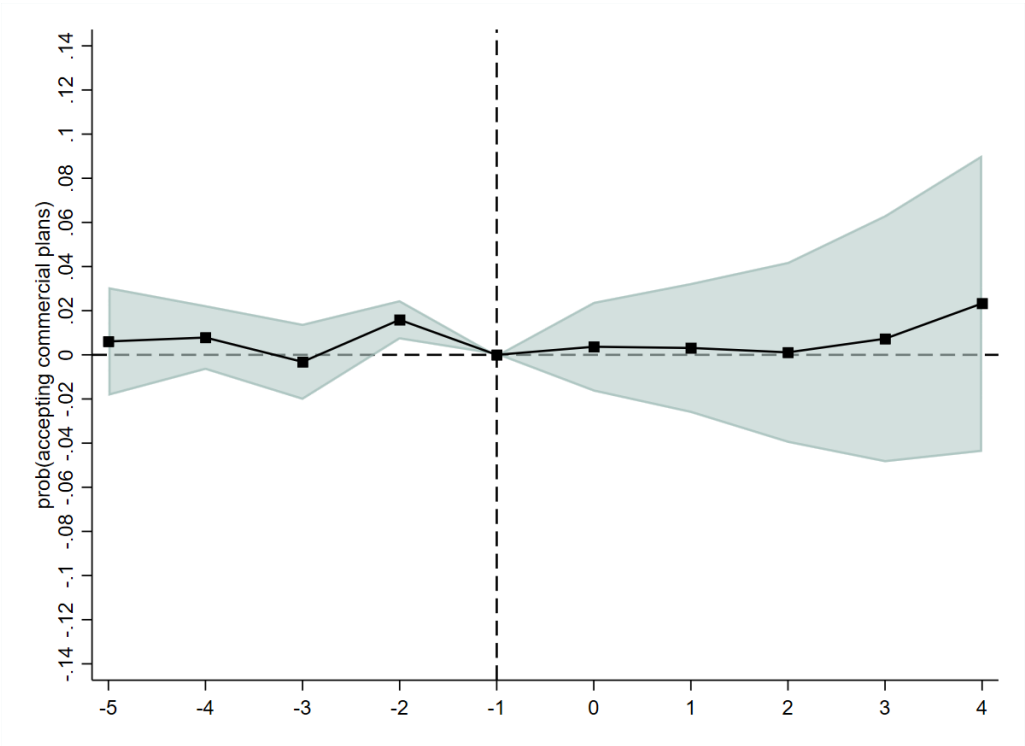


Figure A11: event-study estimates for accepting commercial plans

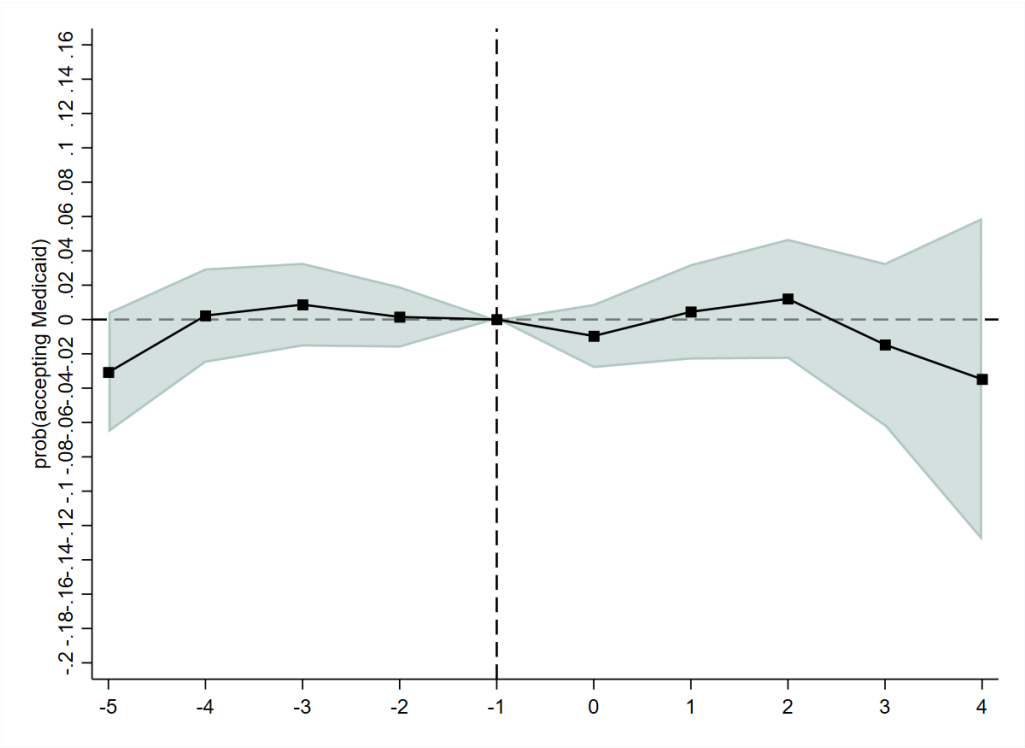


Figure A12: event-study estimates for accepting Medicaid

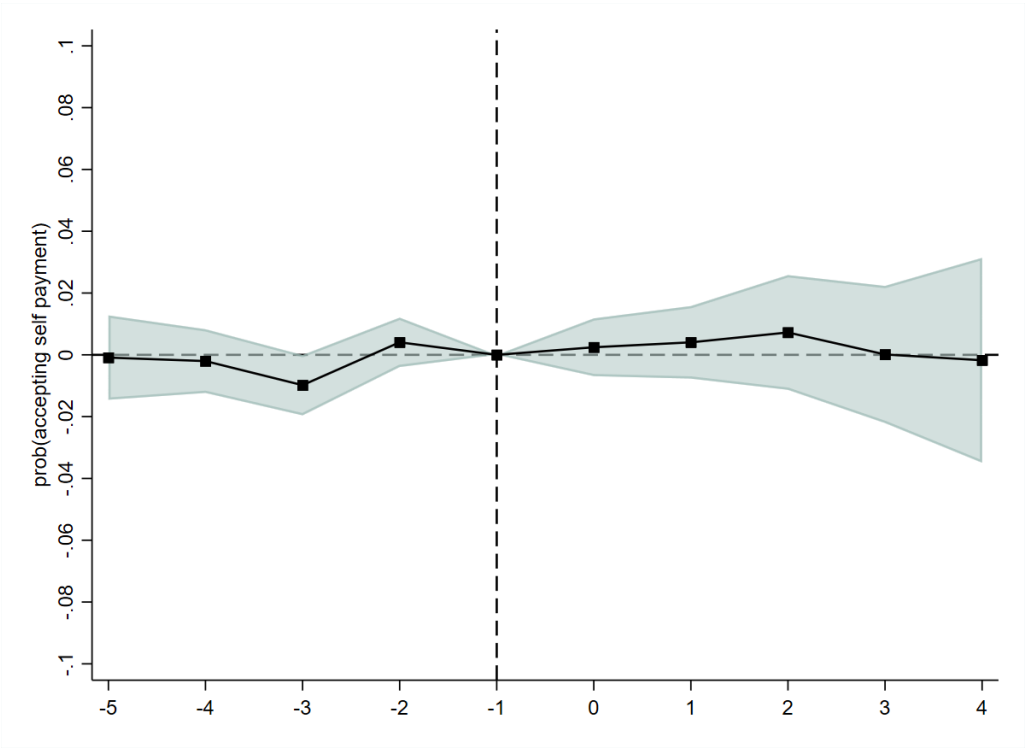


Figure A13: event-study estimates for accepting uninsured

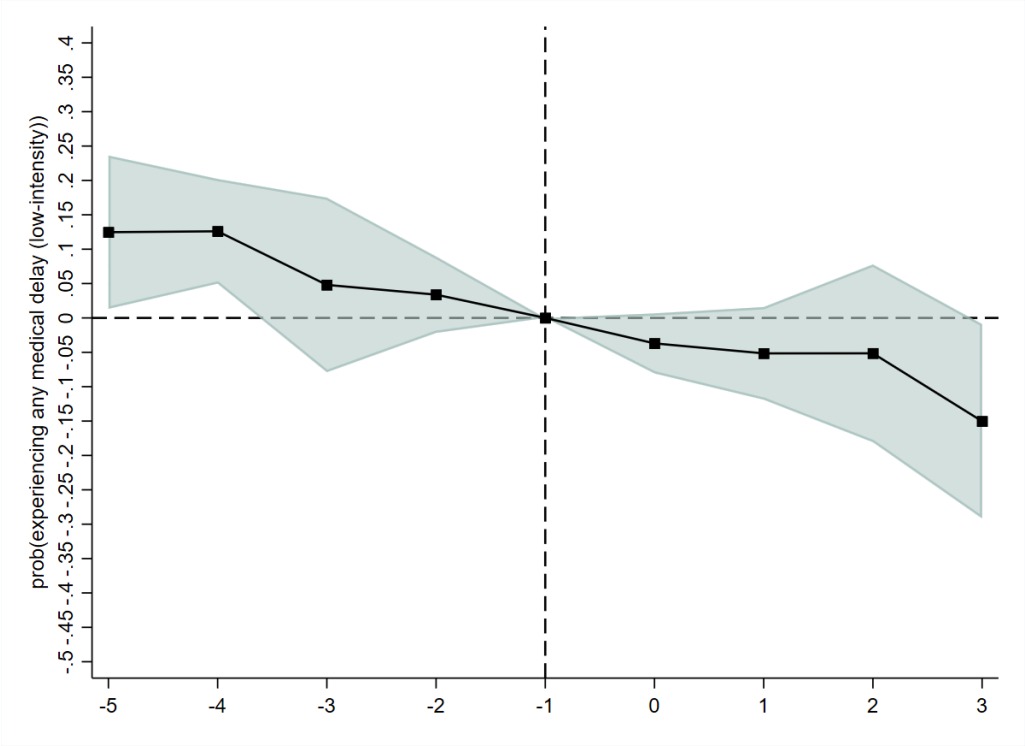


Figure A14: event-study estimates for experiencing any medical delay

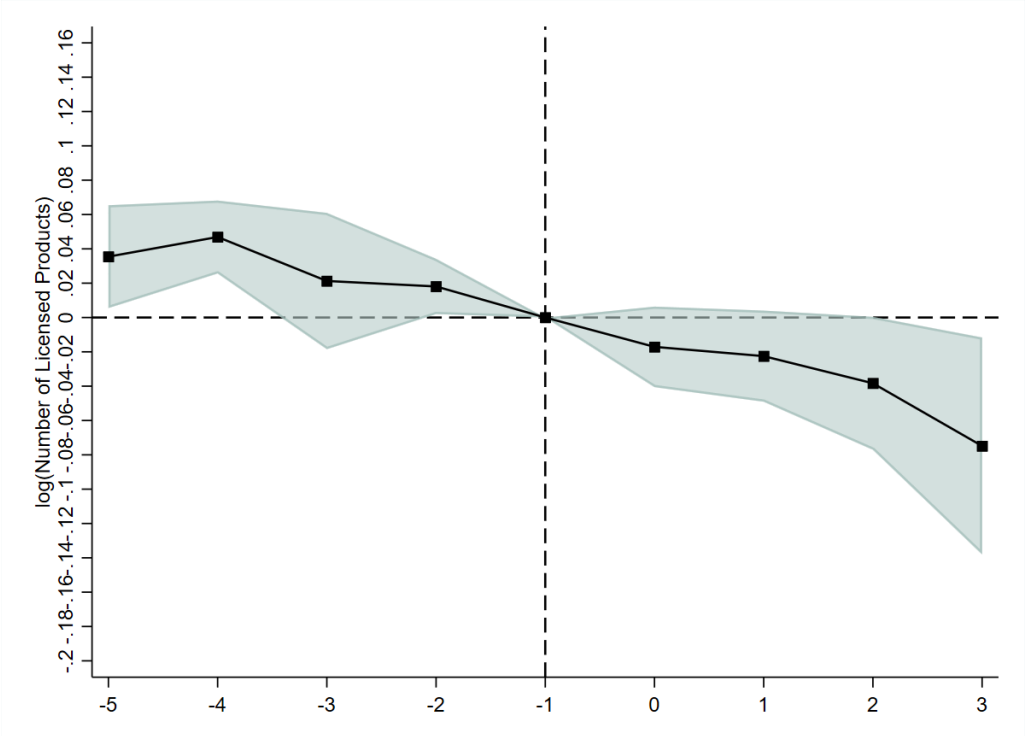


Figure A15: event-study estimates for experiencing normal medical delay

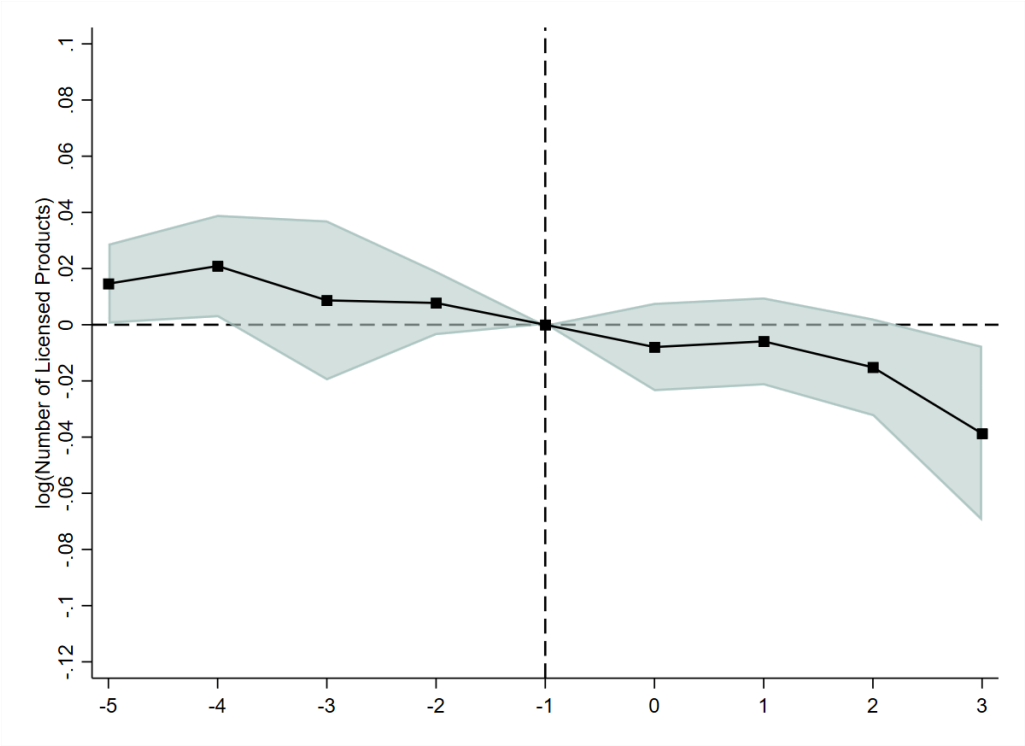


Figure A16: event-study estimates for experiencing severe medical delay

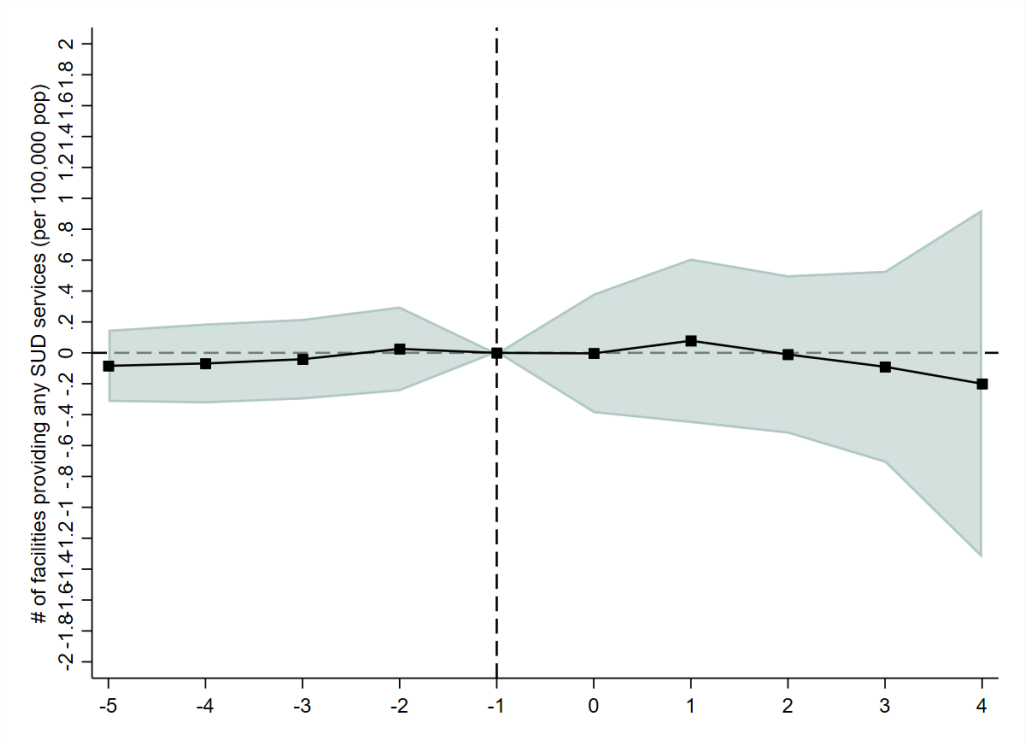


Figure A17: event-study estimates for # of facilities providing any SAT services (per 100,000 pop)

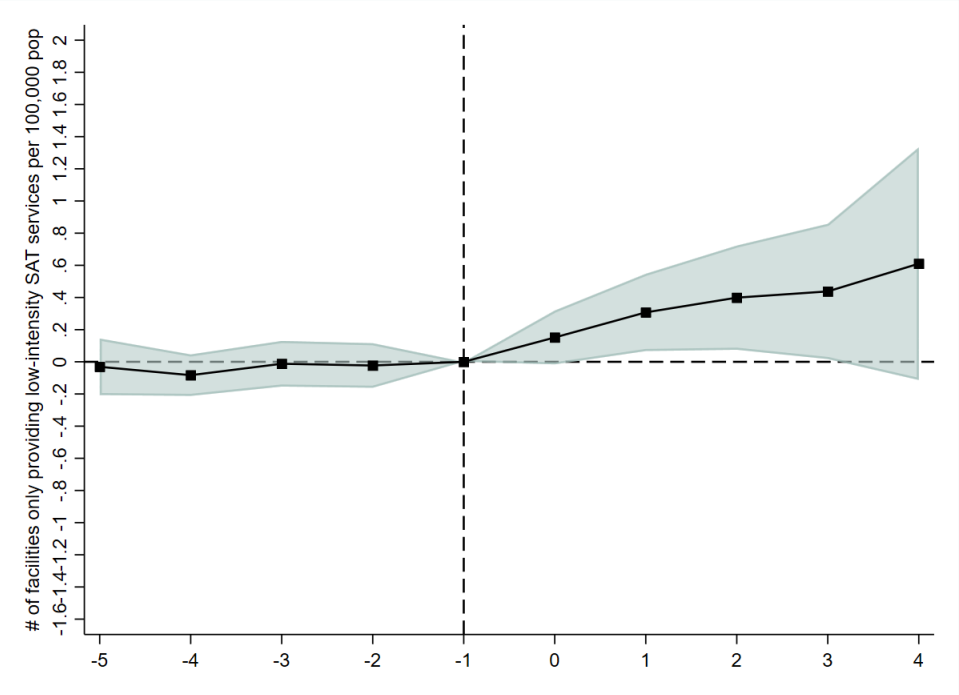


Figure A18: event-study estimates for # of facilities only providing low-intensity SAT services (per 100,000 pop)

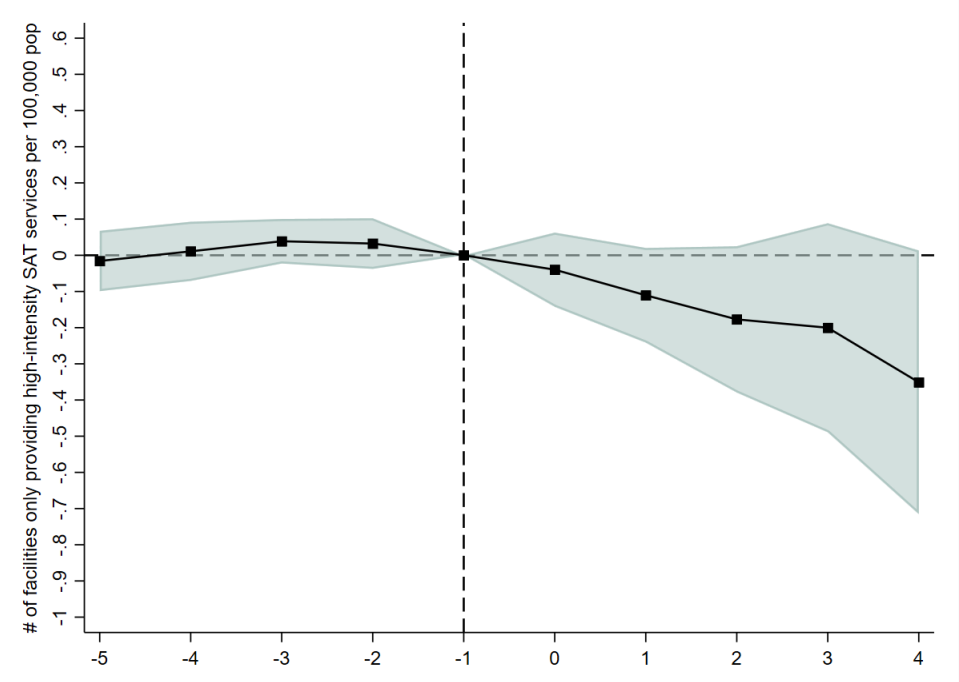


Figure A19: event-study estimates for # of facilities only providing high-intensity SAT services (per 100,000 pop)

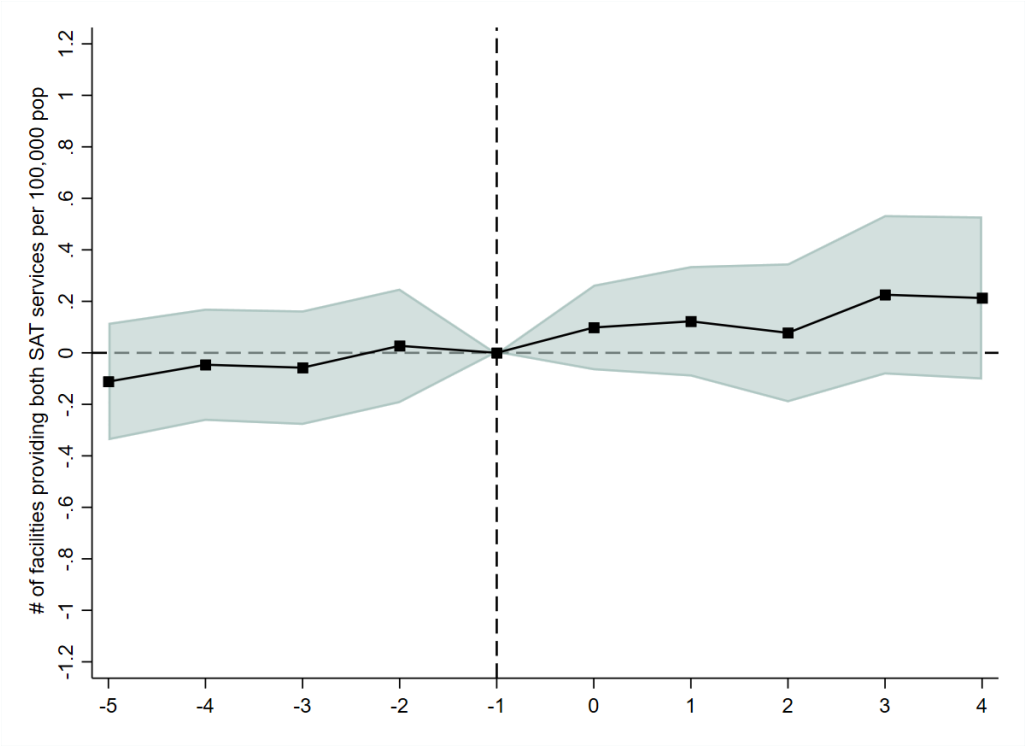


Figure A20: event-study estimates for # of facilities providing both low- and high-intensity SAT services (per 100,000 pop)

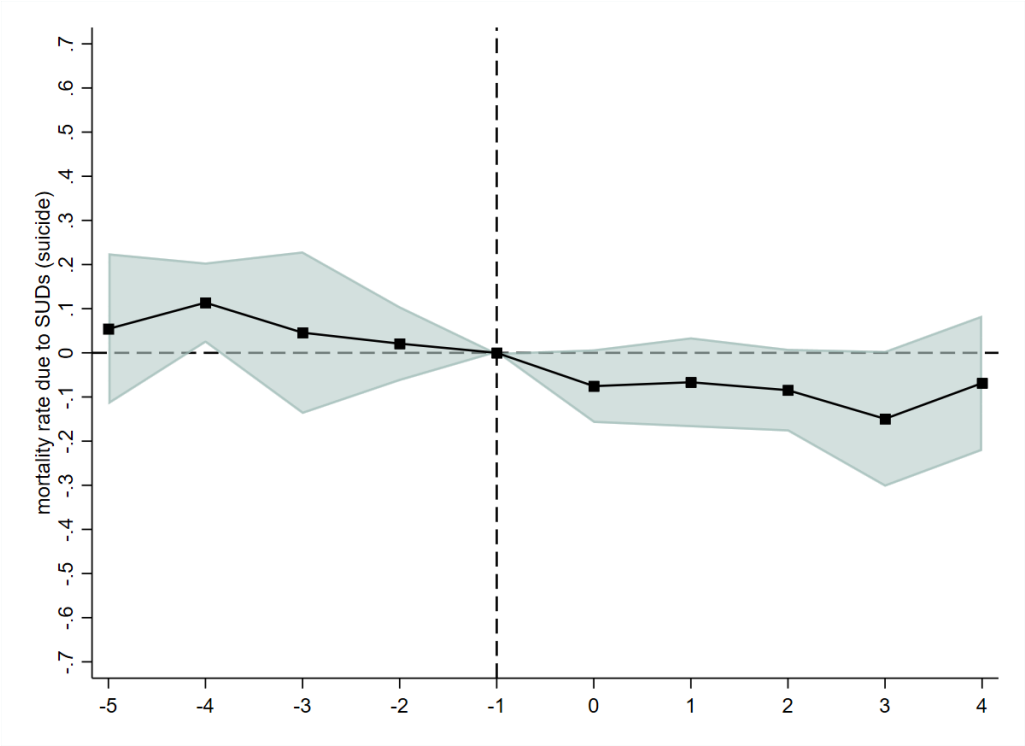


Figure A21: event-study estimates for # of death due to SUD suicide per 100,000 pop

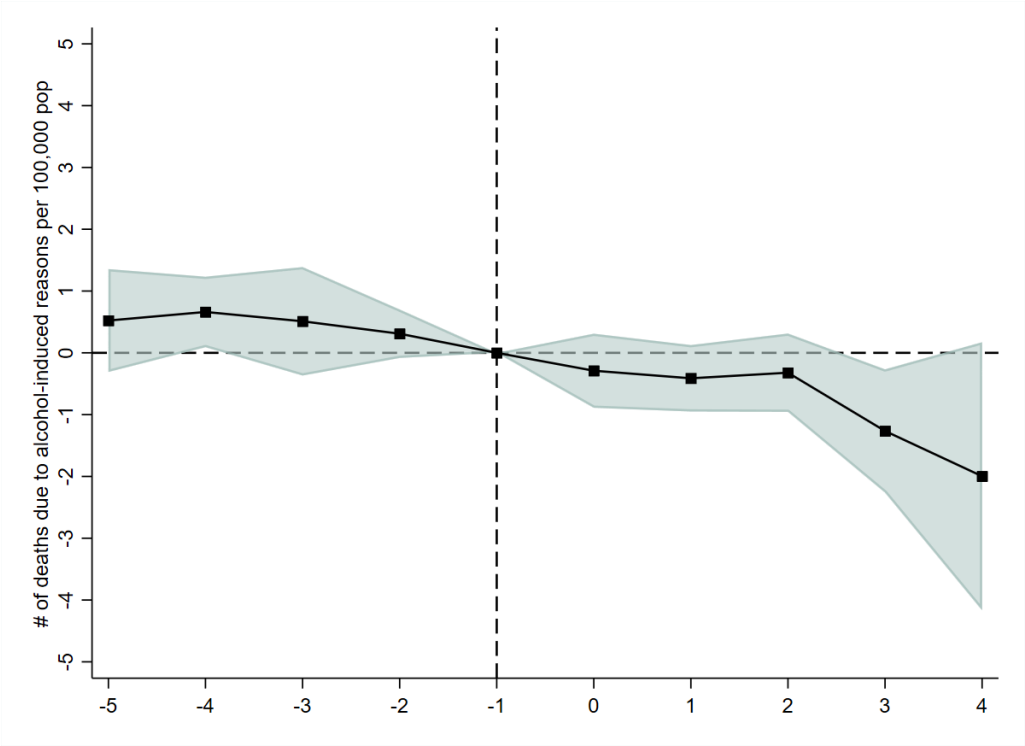


Figure A22: event-study estimates for # of death due to alcohol use reasons per 100,000 pop

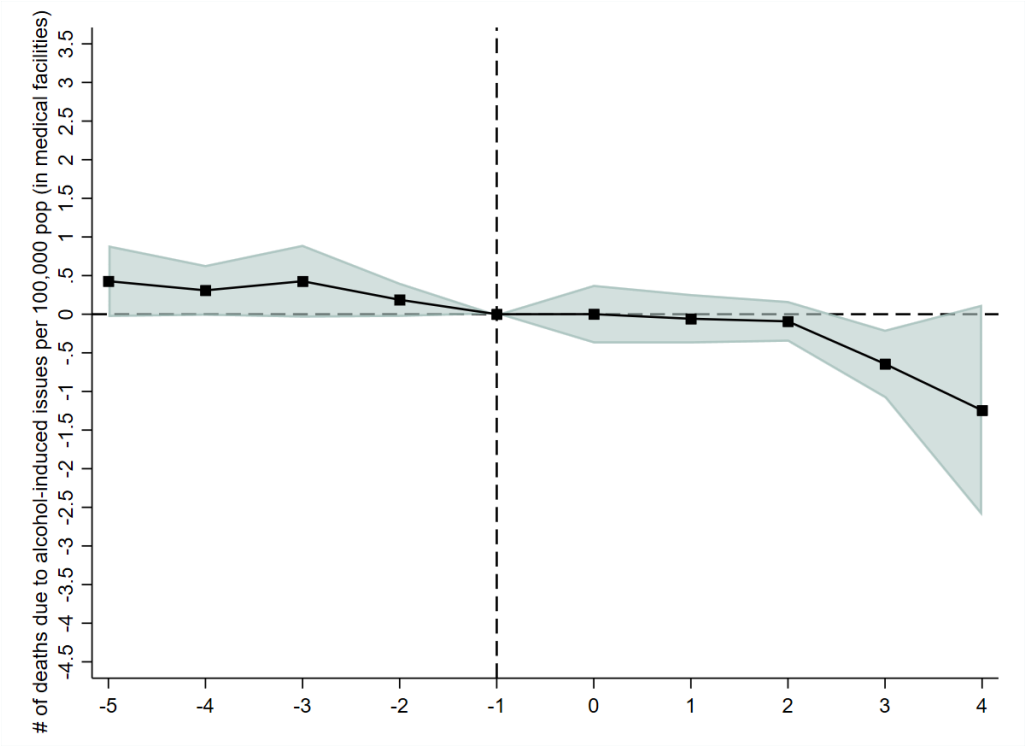


Figure A23: event-study estimates for # of death due to alcohol use reasons per 100,000 pop (within medical facilities)

Appendices

A.1. Prior Authorization

Prior authorization refers to a requirement by health plans for patients to obtain approval of a healthcare service or medication before the care is provided (KFF).[40] Typically, PA aims to help plans evaluate whether care or treatment is medically necessary and otherwise covered. Such standards (usually called *medical necessity criteria*) for this pre-treatment review are often developed by the plans themselves, based on medical guidelines, costs, utilization, and other information (KFF).

A standard process to obtain prior authorization can vary across insurers but typically involves the following steps: containing the payer's PA form, completing all required clinical and administrative information, submitting the form to the health plan, and, if necessary, contacting service representatives or other personnel at the plan for follow up (Turner, Miller and Clark, 2019). Common methods for submitting PA requests include electronic medical records (EMR), fax, secure email, phone, and the payer's digital portal. The submitted PA request, along with any supporting materials, will be reviewed by the clinical staff (e.g., pharmacists, registered nurses, etc.). The length of time before requests are processed varies by type of care, payer type, use of automation, and many other factors, ranging from the same day to several days.

In terms of the results of a PA request, it can be approved or denied. In the case that a PA request is denied, providers and patients have the option to appeal. Physicians have reported that, overall, 72% of PA requests are approved on initial request and an additional 7% are approved on appeal. In addition, PAs are typically only valid for a specified length of time, after which additional requests must be submitted for continued prescription refills or therapies (Turner, Miller and Clark, 2019).

[40] See for example, https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/, last accessed April 30, 2024.

A.2. Substance Abuse Treatment Services

In terms of substance abuse treatment (SAT) services, according to the American Society of Addition Medicine (ASAM), there are 5 levels of treatment:[41]

Level 0.5 treatment is usually called *Early Intervention*. Early intervention can consist of assessment and education for people at risk of developing a substance use disorder or programs like DUI classes for people arrested for driving under the influence. The primary goal here is to intervene before a person develops a substance use disorder.

Level 1 treatment includes outpatient treatment consisting of treatment for substance use that is less than 9 hours a week. Level 1 is appropriate for people with less severe disorders as a starting point or as a step-down from more intensive services.

Level 2 treatment includes *intensive outpatient services* and *partial hospitalization*. The former consists of at least 9 and no more than 20 hours per week of treatment. These programs typically offer medical care 24 hours a day by phone or within 72 hours in person. Partial hospitalization is at least 20 hours a week but is less than 24-hour care. This level of care provides structural and daily oversight for people who need daily monitoring but not 24/7 care.

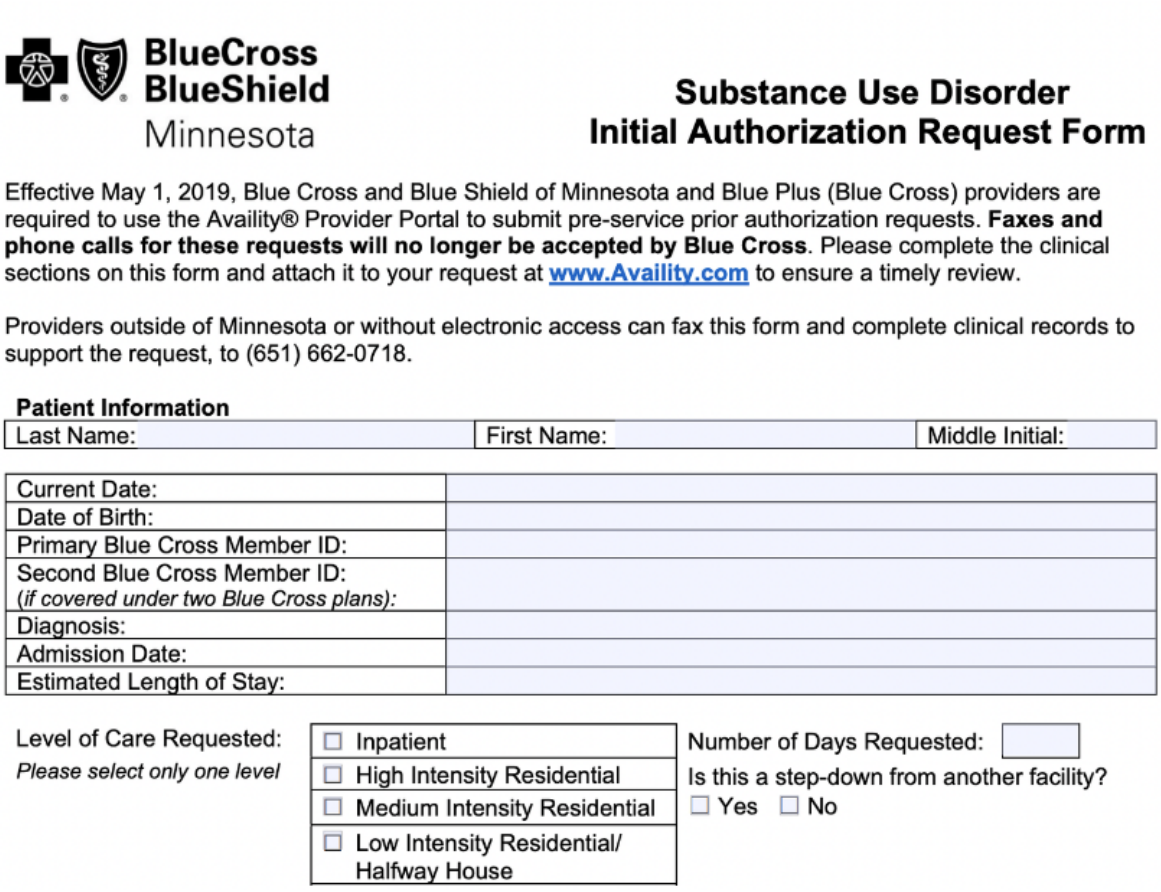
Level 3 treatment is the *inpatient services*, which can include clinically managed low-intensity residential treatment, managed high-intensity and population-specific services, clinically managed residential services, and hospital-based high-intensity inpatient treatment services. Clinically managed low-intensity residential treatment provides a group home and only requires 5 hours per week, which helps people with such topics as relapse management. Clinically managed high-intensity and population-specific services provide treatment designed to move at a slower pace, for people with cognitive functioning issues, including people with traumatic brain injuries, the elderly, or people with developmental disabilities. Clinically managed residential services are designed for people with serious psychological or social issues who need 24-hour oversight and are at risk of imminent harm. Eventually, medically managed high-intensity inpatient treatment is for people who need intensive medical or psychological monitoring in a 24-hour setting but do not need daily physician interaction.

[41] See https://americanaddictioncenters.org/rehab-guide/asam-criteria-levels-of-care, last accessed April 30, 2024.

Level 4 treatment provides 24-hour nursing care and daily physician visits. People in this level of care need daily physician monitoring, along with 24-hour oversight. It is designed for people with severe biomedical, emotional, behavioral and/or cognitive conditions that require primary medical and 24-hour nursing care. Services are provided in hospital settings, such as acute care units, and involve medically directed evaluation and treatment. Primarily designed to provide stabilization, this level then helps people transition to another level of care.[42]

[42]See for example, https://americanaddictioncenters.org/rehab-guide/levels-of-care, last accessed April 30, 2024.

A.3. Tables and Figures



BlueCross BlueShield Minnesota

Substance Use Disorder Initial Authorization Request Form

Effective May 1, 2019, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) providers are required to use the Availity® Provider Portal to submit pre-service prior authorization requests. **Faxes and phone calls for these requests will no longer be accepted by Blue Cross**. Please complete the clinical sections on this form and attach it to your request at www.Availity.com to ensure a timely review.

Providers outside of Minnesota or without electronic access can fax this form and complete clinical records to support the request, to (651) 662-0718.

Patient Information

Last Name:	First Name:	Middle Initial:

Current Date:	
Date of Birth:	
Primary Blue Cross Member ID:	
Second Blue Cross Member ID: *(if covered under two Blue Cross plans):*	
Diagnosis:	
Admission Date:	
Estimated Length of Stay:	

Level of Care Requested:
Please select only one level

- ☐ Inpatient
- ☐ High Intensity Residential
- ☐ Medium Intensity Residential
- ☐ Low Intensity Residential/ Halfway House

Number of Days Requested:

Is this a step-down from another facility?
☐ Yes ☐ No

Figure A24: snapshot of prior authorization requests

Chapter 3

Veterinary Care Regulation and Livestock Production: Evidence from the Progressive Era

3.1 Introduction

Over the last 60 years, the number of jobs requiring an occupational license or government approval to practice a profession has grown from approximately 5% to 25% (National Center for Interstate Compacts).[1] Occupational licensing laws typically require professional workers to submit verification of training, testing, and education before legally entering a chosen field and practicing. When appropriately implemented, occupational licensing requirement aims to help protect the health and safety of consumers. However, relatively little empirical work has been done regarding whether occupational licensing requirements influence consumers' outcomes (i.e., choices, health outcomes, etc.). Instead, most studies emphasized its labor market effects (see for example, Kleiner and Kudrle, 2000; Kleiner et al., 2016).

Economic theory provides relatively limited guidance about how stricter occupational licensing requirements would influence consumer outcomes *a priori*: On one hand, increasing the regulatory stringency can raise the average quality of those who actually practice and provide service and simultaneously deter unqualified providers (Shapiro, 1986; Kleiner, 2000; Goldin and Katz, 2016; Anderson et al., 2020). On the other hand, such occupational licensure may also adversely impact the quality of service and other consumer outcomes if stricter licensure could lead to higher prices and reduced consumers' access to the service, resulting in an increase in demand for other low-quality, inferior substitutes (Shepard, 1978; Adams, Ekelund and Jackson, 2003; Kleiner and Kudrle, 2000; Anderson et al., 2020).

[1] See https://compacts.csg.org/our-work/licensing/, last accessed April 30, 2024.

Empirical work centering on this question is also sparse, partly due to the enormous complexity of contemporary regulations safeguarding consumers' safety and health. To provide some of the first evidence, I assess how the occupational licensure targeting veterinary care shaped one dimension of agricultural development: *livestock production*, measured by the head of draft animals per acre (Koch et al., 2019) and the amount of agricultural products. To do so, I draw historical evidence from the initial adoption of state-level licensing laws for veterinarians in the US during the late nineteenth century and the early twentieth century. There are two primary advantages of focusing on this historical episode: First of all, during the sample period, there was little prior regulation for veterinary practice and livestock welfare in the U.S.[2] Most importantly, in the modern agricultural sector, where many veterinarians are already licensed, tightening licensing requirements represents only an incremental change in the overall licensing regime. Thus, there is a higher chance that my research can capture an immediate and profound effect associated with the initial adoption of occupational licensing laws.

Another advantage of leveraging this unique historical episode to document causal effects is that before the late 1910s, U.S. agricultural production completely relied on animal power (Dimitri, Effland and Conklin, 2005): early 20th-century agriculture was labor intensive, and it took place on a large number of small, diversified farms in rural areas where more than half of the U.S. population lived. These farms employed close to half of the U.S. workforce, along with 22 million work animals. Within this context, my analysis centers on a crucial aspect of agricultural production and development, thereby shedding new light on the incidence of occupational licensing regulations.

My empirical analysis uses data from 1870-1930, during which 47 states adopted the licensing requirements for veterinarians. Exploiting geographical and temporal variation in adopting such requirements, I explore their effects on livestock production, proxied by the heads of horses/mules/swine/dairy cows per acre of farmland. To do so, I assemble data from the Census of Agriculture (Haines and Rhode, 2018) and construct a balanced panel

[2]By contrast, the contemporary regulatory regime for both veterinarians and livestock is far more complicates. For example, see https://libguides.libraries.wsu.edu/veterinarymedicine/vetlaws, last accessed April 30, 2024.

including 2,332 counties in total throughout the sample period. Using a staggered difference-in-differences specification, I document the adoption of licensing requirements is associated with a statistically significant increase in the head of livestock per acre of farmland. These results are robust to alternative specifications that better control for state-specific time trends. My results from the event-study specification also highlight some of these effects are persistent. I eventually implemented various robustness checks to address the issue of policy endogeneity (or, say, reverse causality).

I also examine the heterogeneous effects of these licensing requirements for veterinary care along three dimensions: (1) whether the county is rural or urban, (2) whether the licensing agency is independent (versus being governed by the state's Department of Agriculture), and (3) whether the licensing board is solely selected by the state government (versus being selected by both the state government and the local occupational association). These results suggest the positive effects are more prominent among states with independent licensing agencies and licensing boards with professionals involved. The positive effects here indicate requiring professional veterinarians to get occupational license can improve the direct outcomes associated with consumers. Meanwhile, I extend my baseline analyses to the heterogeneous effects based on regions. My results suggest that the positive effects associated with state occupational licensing laws for veterinarians are more prominent in the Great Plains, which has historically been an agricultural factory of immense proportions.

In terms of the mechanisms at play, there are two theoretical arguments that can rationalize my findings. First, the increased stringency of occupational licensing regulations can substantially improve service quality available in the market by deterring the entry of (low-quality, unqualified) workers (Kleiner, 2000). As a result, the number of veterinarians declined, and the average quality of service went up. Second, the increased stringency

Another plausible mechanism is adopting licensing requirements can largely resolve the issue of asymmetric information in specialized medical services. Either the regulation *per se* or the observable labor market dynamics of veterinarians might be valued as a signal of service quality (i.e., livestock productivity), thereby encouraging consumers to change the input choice of agricultural production. In this regard, I found even controlling for consumers' access to veterinarian services (i.e., # of veterinarians per county year), we can

still observe a significant increase in the density of livestock, especially draft animals that are more likely to be an input in agriculture production.

This paper can contribute to several strands of literature. First, it directly relates to a large and still emerging line of work emphasizing the consequences of imposing occupational licensure. Instead of focusing on the first important labor market effects, my paper provides novel evidence regarding the incidence of such labor market regulations on consumer outcomes. Previous studies in this line have found that the incremental tightening of licensing requirements has little effect on the health outcomes among consumers (Carroll and Gaston, 1981; Kleiner and Kudrle, 2000; Kleiner et al., 2016; Markowitz et al., 2017).

In this vein, the closest work to mine is from Anderson et al. (2020), finding that requiring midwives to be licensed reduced maternal mortality and led to modest reductions in infant mortality. Their results demonstrate that licensing restrictions can improve the *health* of consumers. There are two key distinctions between my work and Anderson et al. (2020). First, my paper captures the positive effects on consumer outcomes in a different setting, agricultural production, and development, thereby suggesting broader impacts associated with such labor market regulations. Second, my work highlights a novel margin of consumer outcomes, consumers' choices *per se*. Results along this dimension can be quite informative: after all, the health outcome is determined in equilibrium by both the provision of professional service and the choices/decisions of consumers.

My work also speaks to another large literature in economic history, discussing the determinants of agricultural development in the US. Prior work has highlighted the role of technological diffusion (Olmstead and Rhode, 2004), environmental catastrophe (Lange, Olmstead and Rhode, 2009; Hornbeck, 2012; Hornbeck and Keskin, 2014), property rights (Hornbeck, 2010), rural electrification (Kitchens and Fishback, 2015), immigration restrictions (Clemens, Lewis and Postel, 2018), and many others. To my knowledge, little work has been done to investigate the interplay between labor market regulations, especially occupational licensing regulations, and agricultural development. In this vein, my work provides a fresh perspective on this topic and demonstrates the plausible improvement in agricultural productivity linked to the increased stringency of occupational licensure.

The rest of this paper proceeds as follows: section 3.2 provides the institutional background. Section 3.3 specified the baseline empirical strategy and some threats to identification. Section 3.4 describes the datasets enabling me to implement the empirical analyses; section 3.5 presents the main results. Section 3.6 discusses the mechanisms, and eventually, section 3.7 concludes.

3.2 Historical Background

In this section, I first briefly summarized the evolution of veterinary medicine in the US and then described the education for veterinarians in the early nineteenth century and the late twentieth century.

3.2.1 Veterinary Workforce

The veterinary medical profession in the US has a long history of ensuring that "*the needs of a society could be met by the sufficient numbers of veterinarians with sufficient amounts of training* (Dicks, 2013)." As mentioned in a 1964 statement from the Joint Committee on Veterinary Education of the AVMA, the Association of American Veterinary Medical Colleges, and the Association of the State Universities and Land-Grant Colleges,

> Livestock losses in the developing United States caused President Abraham Lincoln in 1862 to sign a bill establishing the U.S. Department of Agriculture. The accumulated data on the death of animals from disease clearly indicated the need for well-trained veterinarians to cope with this problem. The Morrill Act signed by President Lincoln in 1862 enabled each state and territory to support the instruction of veterinary medicine.

By 1900, there were an estimated 9,000 veterinarians in the U.S., most of whom were involved in "*the control, prevention, and eradication of livestock and poultry diseases to ensure [sic] the milk, eggs, meat and their products are disease-free* (Dicks, 2013)." Throughout history, the veterinary profession has faced both dramatic increases in the demand for its general services and changes in the types of specific tasks needed, given the interaction between humans and animals has changed. As a result, the total number of veterinarians

has increased to approximately 90,705 today. Meanwhile, the number of veterinarians per 100,000 people also increased from 11.6 in 1962 to 28.1.

Throughout the nineteenth century, most individuals who doctored animals professionally obtained their training through *experience or apprenticeship*, as did physicians and lawyers. Defining oneself as a "veterinarian" thus required no legal sanction, "merely an ability to persuade potential consumers that one's service was worth the price Jones (2003)." Only some veterinarians were trained in formal schools or programs, and the quality of such education often varied greatly. Most of those doctoring animals came to their vocation through experience in relevant occupations like driving, farriery, animal breeding, or assisting a practicing veterinarian.

Before the 1890s, the culture of doctoring animals primarily borrowed from that of the "stable and barnyard," and the usual denizens of both occupied lowly positions on the social ladder. For example, R.J. Dinsmore, who worked in his father's livery stable as a boy and later graduated from Harvard Veterinary School, described the early 1890s' image of the horse doctor as (Jones, 2003):

> Nobody was laughed at more than the horse doctor. Horse doctors were supposed to be a coarse, ignorant group who had made a failure of blacksmithing or farming and had turned to doctoring. That they actually knew anything about medicine was an absurd notion ... Most were not real veterinarians, but farriers."

Another statement of the situation in 1870 came from D.E. Salmon, the first Chief of the Bureau of Animal Industry:

> The opinions of veterinarians have not only been treated as valueless but, in many cases, have been ridiculed. There seems to be no limit to the numbers who, with the assurance that ignorance and self-conceit all the observations of the veterinary profession on this point, as well as against the established facts of anatomy, physiology and pathology. I admit the profession has so far established few claims to recognition in this country, but our stock owners can thank themselves for it, for it has been their indifference and want of sympathy that has kept it in an undeveloped state. As a member of that profession, however, I wish to record

> my objections to this 'relic of barbarism' — this tradition from the superstitious quacks and horse-jockeys of the past.

Traditionally, most early-stage veterinarian patients were animals being valued for their productive abilities as workers or food. Veterinarians could "easily make an uncomplicated economic argument for the worth of their services to individual owners or the livestock industry (Jones, 2003)." The entire profession supported the "unfettered use" of horses as workers in agricultural production and cattle, hogs, sheep, and poultry as food producers. Consequently, the procedures of veterinarians in the nineteenth century are somewhat similar to the "heroic treatments" of physicians and surgeons (Jones, 2003): burning, firing, blistering, surgery without anesthesia, bleeding, and strong purgatives. These treatments are argued as "serving tradition, clients' expectations, and self-image (Jones, 2003)."

In the meantime, there is a consensus that Americans' interdependence with burgeoning populations of domestic animals ensured an increasing demand for veterinarians' professional services (Jones, 2003). For example, 25.6 people occupied every square mile by 1900, and so did 72.8 large domestic animals (excluding cats, dogs, and poultry).

3.2.2 Veterinary Education

The transformation of doctoring animals with heroic treatments to more professional care proceeded at the turn of the twentieth century. The loss of many valuable horses during the Civil War and the outbreaks of epizootics among cattle dramatically contributed to the arguments that "aspiring veterinary educators used to justify the establishment of veterinary schools (Jones, 2003)," as well as the professional development of veterinarians. Overall, the perception is that veterinary education should better serve the profession's interest in taking care of the most economically valuable animals. For example, as emphasized by veterinarian A. S. Copeman in a lecture at the opening ceremony for the New York College of Veterinary Surgeons,

> ... the great problem of veterinary medicine is how to preserve the health of domestic animals and thereby increase the wealth of the nation.

Historically, those who officially made their living as animal doctors represented only a fraction of animals' medical caretakers (Jones, 1997). Animal health care was provided by both graduate and non-graduate veterinarians, a few physicians, stable owners, grooms, animal owners and their family members, well-meaning relatives and friends, and community members. Until the 1880s, very few Americans could claim college training in veterinary medicine simply because few veterinary courses existed (Jones, 1997). By the end of the 1890s, Americans can attend veterinary schools in Toronto, Montreal, New York City, Chicago, Detroit, Kansas City, Indianapolis, and Grand Rapids. Such veterinarians received training in these formal programs but the quality of education varied.

I present the geographic distribution of such veterinary schools in Figure A2 and Figure A3. Both figures are derived from Smith (2013): In the late half of the nineteenth century, veterinary practices emerged in American cities surrounded by people, horses, physicians, and medical schools. The development of these veterinary schools and colleges can be described in three clusters.

The first group includes proprietary schools, which offered practical instruction and short programs of study targeting young men who would serve the health needs of horses in urban areas Smith (2013). By the end of 1913, 30 such colleges had emerged in cities in the East, Midwest, and West, including the Chicago Veterinary College (1883-1920), Kansas City Veterinary College (1891-1918), and the McKillip Veterinary College (1894-1920). The second group was typically associated with medical schools: Harvard University (1882-1901), New York University (1913-1922), George Washington University (1908-1918), and the University of Pennsylvania. The third group of veterinary schools and colleges was established under the *Land Grant Act* and most were established in rural areas: Pullman (Washington), Fort Collins (Colorado), Manhattan (Kansas), Ames (Iowa), College Station (Texas), Auburn (Alabama), East Lansing (Michigan), Columbus (Ohio), and Ithaca (New York). The primary focus of these veterinary colleges was related to the health of livestock and horses Smith (2013).

3.2.3 State Licensing Regulation for Veterinary Practice

Meanwhile, educational distinctions became more important to the marketability of a practitioner in the 1890s: state veterinary practice acts mandated registration of those making their living as "animal doctors." As pointed out by Jones (1997), "veterinary practice acts sought to raise the standard of veterinary practice, but such regulation also benefited graduate veterinarians, who worked tirelessly to reserve membership in the fledgling profession for themselves."

In particular, states with veterinary schools or large populations of graduates led the way in securing professional regulation (Jones, 1997). For example, 83% of the states that passed veterinary practice regulations before 1900 had an active veterinary school at the time. By 1916, 44 states had enacted such occupational licensing regulations. Taking Pennsylvania as an example, W. Horace Hoskins, head of the legislative committee of the Pennsylvania Veterinary Medical Association, lobbied state legislators to get the first Pennsylvania Practice Act passed in 1895. As a result, the examination requirements within the regulation have reduced the number of registered Pennsylvania veterinarians from approximately 2,000 in 1891 to 825 in 1906. With the imposition of these practice acts, Jones (1997) mentioned, "graduate veterinarians expected not only the level of marketplace competition to fall but also the level of practitioner expertise to rise."

By the end of 1952, 48 states licensed veterinarians, and many states exempted emergency treatment and some minor treatments. Applicants are often required to meet qualifications of a minimum age of 21 and good moral character. There are few general educational requirements. Two years of pre-veterinary work are required for admission to approved veterinary schools, and most states require applicants to graduate from these schools.

The primary goal of these laws regulating the practice of veterinary medicine is to "ensure the reasonable competence of those attempting to practice (Hemenway, 1916)." Anyone who had refused to register when a state adopted such an act could no longer legally practice what was now called "veterinary medicine." States containing veterinary schools or large numbers of graduate veterinarians passed the first restrictive legislation. By the beginning of the twentieth century, these legal restrictions ensured that most licensed

veterinary practitioners would be graduates of one of the several veterinary schools. Once protected by state practice acts, veterinarians felt that they could make a legitimate claim to proprietary knowledge and competence that justified their role as guardians of the health of animals.

As a consequence, registered practitioners of veterinary medicine began to debate and revisit the ideological goals of their professional role at the end of the nineteenth century: most of the rank and file focused on treating the medical problems of horses and the daily grind of attracting and retaining clients remained paramount (Jones, 2003). By the end of the 1890s, veterinary school leaders characterized the profession as providing "economic stability for practitioners and improve American society at large (Jones, 2003)."

To collect relevant policy data, I looked into of State Governments (1952*a*), which documents the detailed information of such state laws regulating veterinarians. I summarized the timing and features of these state laws in Table 3.1. Figure A4 presents the evolution of such requirements; Figure A6 - Figure A9 then map the geographic distribution of state licensing laws by 1900, 1910, 1920, and 1930.

Regarding the specific legal languages, the first requirement typically has been "the possession of a diploma from a legally incorporated medical college, or an examination before a board of examiners composed of experts (Hemenway, 1916)." The second requirement was to "specify certain standards for the school whose diplomas will be accepted, and then to require both diploma and examination (Hemenway, 1916)."

Veterinary licensing boards regulate this occupation, and in some cases, they are attached to departments of agriculture. The boards have three to seven members. All members are veterinarians except for ex-officio members in Arkansas, Indiana, Kentucky, Ohio, and Pennsylvania. Terms vary from two to six years.

For example, the 1893 law for California states that

> Section 1. An act entitled "An act to ensure the better education of practitioners of veterinary medicine, and to regulate the practice of veterinary medicine in the State of California" to provide for the creation of a board of five members who shall act under and in accordance with the provisions of this act; to provide for their appointment, and define their powers, duties, and compensation; to

define offenses committed by acts done contrary to the provisions of this act, and providing penalties for the violation thereof; providing for the revocation or suspension, in certain cases, of licenses issued hereunder...

Under Pub. Acts 1907. p. 315. No. 244 of Michigan, it states that

... The State Veterinary Board shall register no person as a veterinarian or veterinary surgeon without satisfactory proof that he is the lawful possessor of a diploma from a regular veterinary college or veterinary department of a state institution of learning or college of medicine having a curriculum of at least three sessions of six months each, etc. An applicant must have personally attended such an institution and completed a course of three sessions of six months each and the mere fact that at the time he received his diploma from a veterinary college it had adopted a course of three sessions of six months each would not quality him, where he had taken only the former two years' course...

3.3 Theoretical Arguments

In this section, I briefly discuss two strands of literature regarding the effects of service quality regulation on firms' and consumers' behaviors.

On the one hand, the regulation of occupational entry is primarily motivated by a profession's self-interest in "creating a monopoly situation to limit competition and raise prices (Law and Kim, 2005)." Starting with Friedman and Kuznets (1945), economists have long argued that the regulatory regime has been captured by industry to erect entry restrictions for its own benefits (Stigler, 1971). If licensing regulation results from *industry capture*, then the quantity of professional workers would decline, but the quality of professional services would not change at all.

On the other hand, Leland (1979), Shapiro (1986), and Klein and Leffler (1981) argue that assuming a competitive environment, the imposition of a binding occupational licensing regulation (or say, a binding minimum quality standard) can mitigate the informational asymmetries between sellers and buyers, thereby increasing the average service quality and consumers' willingness to pay for relevant goods and services. In other words, an occupational license *per se* can be valued as a signal in the product market, altering consumers' choices (Farronato et al., 2020).[3]

Of course, we should also note that market structure can affect the distribution of service quality in a market, the provision of services, and consumers' choices. For example, Ronnen (1991) and Crampes and Hollander (1995) found that more stringent minimum quality standards can induce quality and price competition among sellers in less perfectly competitive markets. Garella and Petrakis (2008) also found such strategic (quality-increasing) responses to minimum quality standards are quite sensitive to the degree of substitutability of products, the share of consumers with limited information, and the presence of variable costs of producing high-quality goods and services.

[3]Farronato et al. (2020) found in the contemporary context, platform-verified licensing status of a professional is unimportant for consumer decisions relative to review ratings and price. This might not be the case in the early 20th century because there were fewer market-level signals for a professional's service quality.

Taken together, whether and how occupational licensing requirements influence consumers' behaviors and the quality of service is an empirical question. In the following section, I analyzed the impacts of occupational licensing requirements on consumers' choices and the quality of service in agriculture production.

3.4 Empirical Strategy

In this section, I discuss the primary empirical strategy of identification and address some threats when estimating the effects on livestock production.

3.4.1 Baseline Specification

To empirically identify the effects of occupational licensing laws on the key outcomes of interest, I employ a baseline difference-in-differences (DID) model specified as follows:

$$y_{cst} = \alpha + \beta Licensing_s \times Post_t + X'_{cst}\gamma + \rho_c + \eta_t + \epsilon_{cst} \tag{3.1}$$

where c denotes county, state s refers to state, and t indexes years. y_{cst} is the key outcome of interest, the density of draft animals in county c, state s, and year t. $Licensing_s$ is an indicator of whether a state s has an occupational licensing law for veterinaries, and $Post_t$ indicates whether there was a licensing law in year t. X_{cst} includes the county-level urbanization rate and the county-level population. Urbanization rate is defined as the share of the population within cities having more than 2,500 people. ρ_c and η_t are county and year fixed effects, respectively. The county-fixed effects control for county-level determinants of livestock productivity that are constant over time; the year-fixed effects control for nationwide shocks to livestock productivity due to, for example, innovations in veterinary medical technologies. In some specifications, I also add the state-specific linear time trends to control for time trends within a state. Therefore, β would capture the causal effects of adopting occupational licensing laws.

3.4.2 Threats to Identification

Admittedly, there are various concerns related to my identification strategy listed above. I characterize and discuss some of them in this subsection.

Parallel Trends Assumption: The assumption of a stylized DID framework states that in the absence of the policy shock, there is no difference in patenting between the treatment class and the control. To test this assumption, I employ an event study specification shown in equation 3.2:

$$y_{cst} = \alpha + \sum_{i=-25}^{35} \beta_{t+i} Licensing_s \times year_{t+i} + \rho_c + \eta_t + \epsilon_{cst} \tag{3.2}$$

where $year_{t+i}$ is a set of indicators denoting whether a year is the i^{th} year (the tenth, twentieth, thirtieth, or fortieth year) before or after the adoption of licensing requirements. In this specification, the baseline year is when the law has been adopted, and its coefficient has been normalized to zero.

Confounding Factors: There could be other concurrent confounding factors that affect the density of livestock within a county. To name a few, the boll weevil (Lange, Olmstead and Rhode, 2009), the adoption of tractors (Olmstead and Rhode, 2001), and the USDA's effort in eradicating bovine tuberculosis (Olmstead and Rhode, 2004) may all substantively affected livestock production. More robustness checks are left for some future work.

Endogeneity of Policy Change: A key concern related to the causal interpretation of my results is the *reverse causality* issue. One might imagine that states enacting licensing laws for veterinarians were also those with a higher level of demand for veterinary care and/or more veterinary graduates before the policy change. Indeed, there are good reasons to believe this concern is valid. According to Jones (1997), states with veterinary schools or large populations of graduate veterinarians led the way in imposing such professional regulations.

I took three approaches to address this endogeneity issue in the empirical analysis. I first restrict my attention to the region without concentrated veterinarian schools and colleges.

The basic idea is even if one believes the story of lobbying (i.e., graduate veterinarians lobbied state governments to pass the law), this concern should be minimized in areas with few graduate veterinarians and veterinary schools to begin with. Based on Figure A2 and Figure A3, there were relatively few veterinary colleges available in the western states. By checking the heterogeneous effects across regions, I could sweep out the concern that graduates from such colleges lobbied state governments to pass the law.

The second approach is to examine the heterogeneous effects by livestock species separately. This exercise builds on the fact that high-quality veterinarians were dramatically demanded in the Progressive Era due to the shortage of horses post-Civil War. This could be a valid concern and source of endogeneity: areas with a larger number of horses (or say, higher demand for veterinary care) are more likely to come up with the licensing requirement. In other words, the density of other species (e.g., milch cows and swine) might be unrelated primarily to enacting such laws, especially in urban areas.

Eventually, Law and Kim (2005) found for the Progressive Era, both the initial size of the occupational group and urbanization were key determinants positively influencing the adoption of regulation for veterinarians. In a set of regressions, I explicitly controlled for such factors and found little differences between my baseline and robustness estimates.

Staggered Difference-in-Differences Design: A growing strand of work emphasizes the sensitivity of a staggered difference-in-differences specification: the traditional staggered difference-in-differences estimation cannot fully capture the dynamic treatment effects with staggered adoption and heterogeneous treatment effects (Goodman-Bacon, 2021; Sun and Abraham, 2021). To check the robustness of my results, I exploit the alternative DID specification proposed by Callaway and Sant'Anna (2021) and present these results in the appendix.

3.5 Data

In this section, I describe the datasets I used to implement my empirical analyses: the Census of Agriculture (1870-1930) and the full-count Census of Population (1870-1930). I also describe how relevant outcomes of interest are constructed.

3.5.1 Census of Agriculture

The key outcome variables in my sample are the density of livestock used in production (as a proxy for consumers' choices) and the actual productivity per dairy cow (as a measure of livestock productivity). Both are constructed using the Census of Agriculture from 1870 to 1930 (Haines and Rhode, 2018).

These data first provide a relatively consistent measure of livestock counts at the county level over time: the *density* of draft various livestock, including mules, horses, cattle, milch cows, swine, and sheep. I slightly prefer to focus on the density of *draft* animals because such species are more likely to be the input of agricultural production in farming instead of the final products. The density is defined as

$$\text{density} = \frac{\text{\# of draft animals}}{\text{\# of acres of land}}$$

Here *# of draft animals* refers to the head counts of mules/horses/cattle/milch cows/sheep/swine within a county, and *# of acres of land* means the number of acres of all lands in the farm within the county. This specific measure of animal power in production is consistent with prior paper (Koch et al., 2019).

3.5.2 Census of Population

To explore the mechanism(s) at play, I also collect data from the full-count U.S. Decennial Census data from 1870 to 1930. In this dataset, I can observe the number of people who worked within the agriculture sector and reported veterinarian as their occupation. I aggregate the individual self-reports to the county-year level. I then create a variable, *Veterinaries*, which measures the number of people in county c and year t whose occupation

was reported as "veterinaries" per 100,000 people. This variable can be valued as a proxy for the supply of *trained, professional* veterinaries in the agricultural sector. Of course, due to data limitations, this way, I cannot capture those who were not trained professionals but described themselves as "veterinarians."

By 1900, an estimated 9,000 veterinarians in the United States were involved in "the control, prevention, and eradication of livestock and poultry diseases to ensure [sic] the milk, eggs, meat and their products are disease free." By 1962, there were 21,565 veterinarians in the United States, with less than half involved in food animal health and approximately 21% involved in the small animal practice, 12% involved in government service, 14% involved in teaching, and 4% involved in other areas.

3.5.3 Summary Statistics

In Table 3.2, I summarize some key statistics for the outcomes of interest. On average, the heads of mules, horses, and cattle per acre of farmland are 0.006, 0.022, and 0.104, respectively; the number of agricultural veterinarians with full literacy is 48.434. Interestingly, within the Great Plains, the densities of cattle and horses are both a bit higher (0.198 per acre and 0.027 per acre), suggesting these areas relied more on animal power in agricultural production.[4] Meanwhile, the number of educated agricultural veterinarians per 100,000 people is also higher in the Great Plains. These patterns motivate me to check the heterogeneous effects by region further in the following analyses.

[4]The "Great Plains" refers to the areas located west of the Mississippi River and east of the Rocky Mountains. In this paper, the Plain states include CO, IA, KS, MN, MO, MT, ND, NE, NM, OK, SD, TX, and WY.

3.6 Main Results

In this section, I present my main estimates of the effect on livestock productivity based on equation (1). Additionally, I check the heterogeneous effects by rural status, the type of licensing agencies, the composition of board members, and location. I eventually discuss several identification concerns and how I address them in turn.

3.6.1 Effects on Livestock Production

Table 3.3 first reports my results. The outcome of interest is the density of mules, horses, cattle, milch cows, swine, and sheep, defined as the head of animals per acre. In Panel A, I present my estimates from the baseline specification, including county fixed effects and year fixed effects. In Panel B, I also include the state-specific linear time trends to account for the fact that the density trends might vary across states.

Based on the point estimates from Table 3.3, one can tell that the imposition of stricter occupational licensing laws for veterinarians can significantly increase the head of mules per acre by 0.001 heads, the head of horses per acre by 0.006, the heads of milch cows per acre by 0.011, and the heads of swine per acre by 0.038. These results are robust to the alternative specification including state-specific linear time trends.

It's worthwhile to interpret the implications of these estimates carefully. Particularly, among all species of livestock mentioned here, the density of draft animals (i.e., mules and horses) is more likely to represent owners' input choices of livestock production. This is simply because other species like swine, cattle, dairy cows, and sheep can be valued as both inputs and final outputs of agricultural production. Put differently, an increased density of draft animals can better capture owners' (e.g., farmers') decisions instead of a mixture of production strategies and market demand for relevant animal products (e.g., beef, dairy, eggs, etc.). The estimated increases in the density of draft animals imply two potential interpretations: (1) higher-quality veterinary care, resulting from stricter licensing laws, may contribute to improved health and productivity among draft animals, and (2) stricter licensing laws *per se* might enhance consumers' perceptions of the quality of veterinary care available, thereby scaling up the demand for draft animals.

To further supplement the analysis for livestock productivity, I am assembling some other historical data. For example, historical annual reports of the state veterinarian are available for various states in the early 20^{th} century. I plan to digitize relevant information within such documents and construct other measures of livestock productivity. In Figure 10, I present such an example page from the 1918 annual report of the state veterinarian in Alabama.

3.6.2 Heterogeneous Effects

Heterogeneity by Rural Status: I start by investigating the heterogeneous effects of stricter occupational licensing requirements by the rural status of a county. The main results are presented in Table 3.4. To determine whether a county is rural or urban, I merge Haines and Rhode (2005) to Haines and Rhode (2018). I categorize a county as an urban one if the share of the urban population within this county is above 90% in 1880.[5]

In Table 3.4, I present the estimates for rural counties and urban counties in Panel A and Panel B, respectively. Comparing these estimates, we can see that there is little difference between rural and urban counties for draft animals (0.001 for mules and 0.006 for horses). Among other livestock (milch cows and swine), the significant effects associated with stricter licensing are primarily driven by rural counties (i.e., 0.009 more milch cows and 0.032 more swine per acre of farmland within a rural county).

Heterogeneity by Types of Laws: There are some heterogeneities in the state laws requiring licensing for veterinarians. As shown in Table 3.1, 21 states had independent licensing agencies, while in 18, they are attached to departments of agriculture under state governments. Regarding the method of selecting board members, state governors usually appoint board members, but at least six state appointments must be from lists submitted by state veterinary associations (of State Governments, 1952*b*). The boards have from three to seven members. All members are veterinarians except for ex-officio members in Arkansas, Indiana, Kentucky, Ohio, and Pennsylvania. Terms typically vary from two to six years.

In Table 3.5 and Table 3.6, I explore whether these types of laws affected livestock productivity differentially. Starting with Table 3.5, I check the heterogeneous effects by the

[5]My estimates are robust when I use other reference years (e.g., 1870 or 1890).

type of licensing agencies. In Panel A, all the data comes from 21 states with independent licensing boards; in Panel B, all the observations are drawn from states whose licensing agencies were attached to state governments. Based on these estimated results, we can tell for mules, the positive effect is more prominent among states with affiliated licensing agencies. For cattle, it's more pronounced among states with independent licensing agencies.

In Table 3.6, I distinguish my estimates by the method of selecting board members. In Panel A, the outcome of interest is the density of livestock within states having governors to appoint board members. In the second panel, the outcome is the density of livestock among states, with both governors and occupational associations assigned board members. Requiring occupational licensure is associated with a significant increase in both the density of mules and the density of horses, but it is only prominent among states whose licensing boards have professionals involved. Such evidence might suggest when taking into account professional opinions and expertise, there's a higher chance stricter licensing regulations can yield improvements in consumer outcomes.

Heterogeneous Effects by Region: I also check the effects of regulating occupation licensure by region. In Table 3.7, I investigate the heterogeneity along this margin. In the first three columns, the sample is restricted to counties within the Great Plains states (Colorado, Iowa, Kansas, Minnesota, Missouri, Montana, North Dakota, Nevada, New Mexico, Oklahoma, Texas, and Wyoming). I focus on all other states out of this score in the last three columns. Based on the estimates shown in Table 3.7, we can see the positive effects associated with state licensing laws are more profound in the Great Plains relative to other states. Such results should not be so surprising given the Plains states were known for historically high agricultural production levels.

3.6.3 Discussing Threats to Identification

As mentioned in section 3.2, several concerns related to my identification strategy threaten the causal interpretation of the results. In this subsection, I addressed each concern in turn and presented these robustness checks.

To start, I implemented the event-study specification in equation 3.2. My main results are shown in Figure A9 - Figure A20 by species and rural status. Overall, except for swine, the event-study estimates coincide with my baseline DID results: the impact of stricter licensing regulations stems from changes in rural counties for non-draft livestock; the patterns look almost identical between rural and urban counties among horses and mules. Meanwhile, my point estimates before the treatment suggest there is no violation of the assumption of parallel trends. Interestingly, compared to dairy cows and horses, the surge in the density is temporary among mules.

I further took several empirical exercises to address the concern of policy endogeneity as follows:

First, *a priori*, the concern of policy endogeneity should be minimal. According to the qualitative evidence, states with concentrated veterinary schools and large populations of veterinarian graduates were more likely to adopt such regulations, reflecting their perceptions that "*the level of marketplace competition would fall and the level of practitioner expertise can rise* (Jones, 1997)" as a result of such regulations. Graduate students and faculty members also lobbied the state government's legislation agency. Both suggest the adoption of such regulations was less likely to link to demand-side factors that directly determine livestock production.

In the meantime, prior work in economic history (Law and Kim, 2005) documented supporting evidence that among many other factors, *urbanization* and *the size of the current profession* are key drivers of adopting state-level licensing requirements for veterinarians.[6] Conceptually, they argue that at least for veterinarians in the Progressive Era, stricter licensing regulation is partially a result of *industry capture theory.*

[6]According to Law and Kim (2005), the increased size of veterinarians and a higher rate of urbanization are associated with a higher likelihood of adopting occupational licensing laws at the state level.

Second, because the shortage of horses due to the civil war was linked to a dramatically increasing demand for professional veterinarians, I argue if there's any endogeneity concern, it should be more prominent among horses. In other words, concerns regarding policy endogeneity could be mitigated if one documented an increased density of other livestock following the regulation. Recall my main results shown in Table 3.3: the positive, statistically significant point estimates for mules, milch cows, and swine are consistent with the argument.

Third, since a concentration in graduate veterinarians and veterinary schools led the way for stricter licensing regulation, policy endogeneity is less concerned in areas with fewer graduates and schools. I thus checked the heterogeneous effects of these occupational licensing laws by region. In particular, the western states did not have too many veterinary schools concentrated by the end of 1900. In Table 3.9, I present the estimates for 11 western states (Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming): among all livestock, the density of mules, cattle, and sheep all increased significantly while the density of swine declines by 0.01 heads per acre of farmland.

Eventually, I present results using alternative staggered DID specifications from Callaway and Sant'Anna (2021) by the type of law and region (whether a county is within the Great Plains). Overall, I found at least within the Great Plains states, we can observe the positive effects on livestock production are robust. In future work, I will keep addressing this issue and applying other DID specifications to show the robustness of my results.

3.7 Mechanisms

In this section, I briefly discussed two primary mechanisms that can rationalize the findings above and presented some suggestive evidence.

3.7.1 Provision of High-Quality Veterinary Medicine

The first mechanism is that stricter licensing requirements can mechanically improve the provision of *high-quality, professional* veterinary care and deter the low-quality counterparts. From the empirical perspective, one would expect (1) a decline in the aggregate *number* of veterinarians available in the market and (2) an improvement in the *quality* of veterinarian practice (i.e., the health outcomes of livestock, or the productivity of livestock).

To test this hypothesis, I first borrow some empirical evidence from prior work (Law and Kim, 2005). In their paper, Law and Kim (2005) found the initial licensing regulation is associated with a decline in the number of veterinarians per 1,000 population within a state per year using both an OLS analysis and an IV regression model.

In Table 4 of Law and Kim (2005), the key coefficient associated with occupation licensing regulations is 0.02 (statistically significant at the 5% level) with the OLS model and 0.06 (statistically insignificant) with the IV model (i.e., using an index variable that equals the number of other occupations licensed by a given state in a given year as the instrument). Such results suggest that imposing licensing regulations led to a modest significant effect or no effects on the entry of new veterinarians. In Table 5 of Law and Kim (2005), they also found the imposition of stricter regulations is associated with a decline in the growth rate of veterinarians by 0.16 (OLS estimate) and 0.68 (IV estimate). Overall, these results suggest that strict occupational licensing regulations can deter the entry of new veterinarians as a mechanical effect.

To capture the effects on the quality of medical services, I constructed a measure of milch cows' productivity, *the amount of butter produced per cow*, as follows:

$$\#\text{ of butter per cow}_{ct} = \frac{\#\text{ of butter produced}_{ct}}{\#\text{ of milch cows}_{ct}} \tag{3.3}$$

where c refers to county and t represents year. This is a reasonable measure of service quality, as veterinary service has played a key role in controlling the quality of milk and dairy products.[7] For example, Hardenbergh (1936) found veterinarians applied to control and eradication measures of bovine plagues, implemented administrative and inspectional duties, conducted product quality control, and perhaps most importantly, helped herd owners maintain herds on a healthy and economic basis.

Table 3.11 shows the corresponding results. Across all columns, we did not observe any statistically significant effects following the occupational licensing laws, suggesting the quality of veterinarian practice was not essentially improved. In the meantime, I also hand-collected historical statistics on the number of cattle slaughtered due to Tuberculosis from Arizona, Florida, Idaho, Nevada, New Mexico, and South Carolina from 1918 to 1931. Overall, I did not document any significant impacts of licensing laws on this mortality rate. Both empirical findings suggest that the quality of medical service is not directly influenced by the law *per se*.

I also provided a snapshot of the historical records for licensed veterinarians in New York in 1909 in Figure A31. "*Diploma*" indicates the registered veterinarian holds a license, and "*Affidavit*" can include people who passed the oral exams but did not hold a diploma from veterinary schools and colleges.

3.7.2 Consumers' Perceptions for Veterinary Practice

The other plausible channel is relevant to the demand side: stricter occupational licensing requirements can largely mitigate the issue of asymmetric information in this specialized medical profession. As a result, such laws positively influence consumers' perceptions of service quality (for example, the expected productivity of livestock), thereby altering one's input choices for agricultural production (e.g., increasing the usage of more (expected) productive livestock). Put differently, the regulation *per se* or/and the observed decline in entry can serve as a signal to farmers and owners of livestock.

[7]Of course, there is a slight difference between the health outcomes of animals and the productivity of animals. Yet, in the Progressive Era I focus on, most veterinarians (as well as the livestock owners) still support the unfettered use of livestock, instead of caring about the welfare of such animals. In this vein, I would argue that compared to the direct health outcomes of dairy cows, real productivity is a better measure of service quality that veterinarians contribute.

This argument is consistent with Law and Kim (2005): occupational licensing during the Progressive Era substantially improved the quality of services that consumers *expect* to receive. In particular, veterinary care services tended to be purchased directly by consumers, for which the costs associated with low-quality service were potentially greatest. At the same time, dramatic technological advances gave rise to greater heterogeneity in professional quality, making it increasingly challenging for consumers to judge the quality of professional services (Law and Kim, 2005).

To provide supporting evidence, I implemented one additional exercise. In this alternative specification, I control the number of veterinarians per 100,000 population within the county per year, which is a proxy for local access to professional veterinary care. By controlling for veterinarian access, I argue the key coefficient β captures the impact of occupational licensing regulations on livestock density through channels other than physical access to medical services.[8] In Table 3.10, I compare the magnitude of my estimates from the baseline analysis to those from the specification with the number of veterinarians on the right-hand side. In Figures A24 - A29, I also plot and compare the estimates from these two specification groups.

Interestingly, for draft animals (horses and mules), the direction, significance, and magnitude all look identical. The finding here thus suggests beyond the provisioning channel, there should be other primary driving forces of the increased density. Given my prior claim that draft animals are a better proxy for the input of agricultural production (see section 5.1), I further argue one plausible channel is the improved consumers' perception: livestock owners expected an increase in livestock productivity due to the law, thereby altering the production decision.

In terms of the impact on other livestock (dairy cows and swine), we also observe a quite similar estimate: requiring occupational licensing would increase dairy cows' density by 0.016 units, as well as a surge in the density of swine by 0.052 units. Combining the results from section 6.1 (licensing laws did not necessarily improve the productivity of dairy cows,

[8] Admittedly, I am only controlling for the *quantity* of veterinary care provision. It is still reasonable to argue with me that the *quality* can be improved even if the *quantity* does not necessarily change.

measured as the amount of butter per head), it reinforces the idea that stricter licensing laws indeed reshaped farmers' choice of production inputs.

3.8 Concluding Remarks

In this paper, I use the spatial and inter-temporal variation in state occupational licensing laws for veterinarians to explore their effects on livestock production. Exploiting a staggered difference-in-differences regression model, I show that increasing the stringency of entry regulation for veterinarians improved livestock density, including mules, horses, dairy cows, and swine. In the meantime, the effect was not symmetric: I found such positive significant effects are more profound among states with independent licensing agencies, licensing boards with professional guidance, and agriculture-intensive regions (the Great Plains). To disentangle the mechanisms at play, I provide suggestive evidence for one plausible channel: during the Progressive Era, the initial adoption of stricter occupational licensing requirements largely mitigated the issue of asymmetric information regarding the service quality of veterinarians. It reshaped consumers' (e.g., herd owners, farmers, etc.) perceptions of the productivity of livestock, thereby altering consumers' input choices in agricultural production.

Quantifying the effect of professional licensing regulations can provide critical, novel insights for ongoing policy debates. A wave of legislation has been spreading nationwide, relaxing state occupational licensing rules. Policymakers contend that there is a trade-off between safeguarding consumers and imposing barriers in the labor markets.[9] but the evidence in support of this contention is largely absent. Results in this chapter highlight the potential economic benefits of occupational licensure in shaping the development of agriculture.

My top priority in future work is to continue disentangling the provision channel and the demand channel discussed above. To do so, I will compile new data to test relevant hypotheses.

[9]For example, see https://wisconsinexaminer.com/2020/01/09/occupational-licenses-consumer-safeguard-or-job-barrier/, last accessed April 30, 2024.

Linked Veterinarian Sample: For example, I aim to construct a panel tracking veterinarians over time, using the linked full-count Census data (1870, 1880, 1900, 1910, 1920, and 1930). So far, I have documented 6,252 *linkable* agricultural veterinarians throughout this sample period. Specifically, being "linkable" means an individual who claimed oneself as an agricultural veterinarian before 1920 presents at least twice in the 1870-1930 Census sample. Looking forward, I will use these linkable observations to check if professional licensing requirements influenced their location decisions, as well as their earnings which could be a coarse measure of veterinarian quality.

Livestock Productivity and Health: Another relevant task is to construct more measures of livestock productivity and wellbeing. I plan to look into historical reports from the Bureau of Animal Industry (BAI) and state-level agencies/institutions (e.g., state Department of Agriculture, various agricultural experiment stations, etc.) and check information on contagious diseases among livestock.

Table 3.1: State Occupational Licensing Laws for Veterinarians

State	Year	Licensing Agency	Method of Selecting Board Members
Alabama	1915	Independent	governor + occupational association
Arizona	1923	Independent	governor
Arkansas	1915	Independent	governor
California	1892	state government	governor
Colorado	1909	independent	governor
Connecticut	1905	independent	governor
Delaware	1915	independent	governor
Florida	1925	independent	governor
Georgia	1908	state government	governor
Idaho	1921	state government	governor
Illinois	1899	state government	governor
Indiana	1905	state government	governor
Iowa	1900	state government	governor
Kansas	1907	independent	governor
Kentucky	1916	state government	governor
Louisiana	1908	independent	governor + occupational association
Maine	1905	unknown	unknown
Maryland	1895	independent	unknown
Massachusetts	1904	state government	unknown
Michigan	1907	state government	unknown
Minnesota	1896	state government	governor
Mississippi	1914	unknown	unknown
Missouri	1905	state government	governor
Montana	1913	independent	governor + occupational association
Nebraska	1905	state government	governor + occupational association
Nevada	1919	independent	governor
New Hampshire	1901	unknown	unknown
New Jersey	1902	unknown	unknown
New Mexico	1931	independent	governor
New York	1893	state government	governor + occupational association
North Carolina	1903	independent	governor
North Dakota	1895	independent	governor
Ohio	1894	state government	governor
Oklahoma	1913	independent	governor
Oregon	1903	independent	governor
Pennsylvania	1889	state government	governor
Rhode Island	1909	unknown	unknown
South Carolina	1923	independent	governor + occupational association
South Dakota	1904	unknown	unknown
Tennessee	1905	unknown	governor
Texas	1911	independent	governor + occupational association
Utah	1907	state government	governor + occupational association
Vermont	1912	independent	governor
Virginia	1896	state government	governor
Washington	1907	state government	governor
Wisconsin	1907	department	no board
Wyoming	1915	independent	governor

Table 3.2: Summary Statistics (1870-1930)

	mean	std	minimum	maximum
Panel A. Full Sample				
density of mules	0.006	0.013	0	0.371
density of cattle	0.743	19.110	0	875
density of horses	0.036	0.087	0	2.500
density of milch cows	0.054	0.169	0	4.575
density of swine	0.153	0.391	0	15.938
density of sheep	0.136	0.381	0	8.705
# of educated agricultural veterinarian	48.434	73.997	0	423
# of state residents	3,621,705	7,304,535	0	9.26e+07
Panel B. Rural Counties				
density of mules	0.007	0.013	0	0.371
density of cattle	0.745	19.827	0	875
density of horses	0.036	0.092	0	2.500
density of milch cows	0.054	0.169	0	4.575
density of swine	0.159	0.408	0	15.938
density of sheep	0.134	0.353	0	8.705
# of educated agricultural veterinarian	54.117	65.824	0	266
# of state residents	2,395,983	2,448,794	9,118	1.16e+07
Panel C. Urban Counties				
density of mules	0.004	0.006	0	0.032
density of cattle	0.827	11.562	0	180.272
density of horses	0.036	0.029	0	0.321
density of milch cows	0.152	0.565	0	7.852
density of swine	0.098	0.179	0	2.520
density of sheep	0.152	0.565	0	7.852
# of educated agricultural veterinarian	46.732	76.31	0	423
# of state residents	3,988,944	8,187,629	0	9.26e+07

Note: Data are drawn from the Census of Agriculture and the Census of Population (1870-1930).

Table 3.3: Effects of Licensing on Livestock Density (1870-1930)

	dependent variable: density					
	mules	*horses*	*cattle*	*milch cows*	*swine*	*sheep*
Panel A: baseline analysis						
$Licensing_s \times Post_t$	0.001***	0.006***	0.149	0.011***	0.038***	0.086
	(0.001)	(0.002)	(0.108)	(0.004)	(0.011)	(0.080)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
Panel B: time trends						
$Licensing_s \times Post_t$	0.001***	0.007***	0.099	0.010***	0.039***	0.011
	(0.000)	(0.002)	(0.088)	(0.003)	(0.010)	(0.017)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
state-specific time trends	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.033	0.191	0.049	0.130	0.142
# of observations	18,104	18,104	18,104	18,104	18,104	18,104

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the number of each species, mule, cattle, and horse, per acre of farmland. All standard errors are clustered by state. Standard errors are in parenthesis.

Table 3.4: Effects of Licensing on Livestock Density (1870-1930, by Rural Status)

	dependent variable: density					
	mules	*horses*	*cattle*	*milch cows*	*swine*	*sheep*
Panel A: Rural Counties						
$Licensing_s \times Post_t$	0.001***	0.006**	0.101	0.009***	0.032***	0.089
	(0.001)	(0.002)	(0.113)	(0.003)	(0.010)	(0.087)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.007	0.032	0.240	0.051	0.158	0.126
# of observations	16,160	16,160	16,160	16,160	16,160	16,160
Panel B: Urban Counties						
$Licensing_s \times Post_t$	0.001**	0.006**	0.635	0.018*	0.062	0.062*
	(0.001)	(0.003)	(0.591)	(0.009)	(0.037)	(0.034)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
state-specific time trends	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.004	0.034	0.064	0.046	0.101	0.141
# of observations	1,944	1,944	1,944	1,944	1,944	1,944

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the density of each species, mule, horse, cattle, milch cows, swine, and sheep. All standard errors are clustered by state. I define a county as "rural" if it has a share of the rural population above 90% in 1880. Meanwhile, the rural status of a county does not change following the imposition of veterinary regulation. Standard errors are in parenthesis.

Table 3.5: Effects of Licensing on Livestock Density (by Licensing Agency, 1870-1930)

	dependent variable: density					
	mules	horses	cattle	cows	swine	sheep
Panel A: independent agencies						
$Licensing_s \times Post_t$	0.002***	0.007***	0.239	0.019***	0.019***	0.268**
	(0.000)	(0.001)	(0.276)	(0.004)	(0.006)	(0.113)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.009	0.035	0.500	0.069	0.175	0.146
# of observations	5,392	5,392	5,392	5,392	5,392	5,392
Panel B: government agencies						
$Licensing_s \times Post_t$	0.001***	0.003***	0.004	0.006***	0.027***	0.005
	(0.000)	(0.000)	(0.003)	(0.001)	(0.002)	(0.006)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.004	0.032	0.056	0.040	0.118	0.126
# of observations	11,008	11,008	11,008	11,008	11,008	11,008

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the density of each species. "*Indepedent agencies*" refers to states with independent licensing agencies. "*Government agencies*" refers to those states whose licensing agencies are affiliated with the Department of Agriculture within state governments. There are 20 states and 709 counties with independent licensing agencies and 20 states and 1403 counties with affiliated agencies with governments. Standard errors are not clustered when using the Independent Agencies sample and are clustered by state when focusing on the Government Agencies sample. Standard errors are in parenthesis.

Table 3.6: Effects of Licensing on Livestock Density (by Board Composition, 1870-1930)

	dependent variable: density					
	mules	horses	cattle	cows	swine	sheep
Panel A: governors+prof						
$Licensing_s \times Post_t$	-0.001**	0.012***	0.370	0.014***	0.037***	0.062***
	(0.000)	(0.002)	(0.392)	(0.004)	(0.008)	(0.022)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.008	0.042	0.628	0.071	0.135	0.129
# of observations	3,384	3,384	3,384	3,384	3,384	3,384
Panel B: governors						
$Licensing_s \times Post_t$	0.002**	0.005**	0.116	0.009**	0.034**	0.110
	(0.001)	(0.002)	(0.103)	(0.004)	(0.013)	(0.121)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.031	0.093	0.044	0.151	0.135
# of observations	12,384	12,384	12,384	12,384	12,384	12,384

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the density of each species. "*Governors + professional association*" refers to those states in which board members are appointed by the governor (or department head in some instances), but an appointment must be made from a list submitted by an occupational association. "*Government agencies*" refers to those states whose board members are appointed by the governor without a statutory provision requiring appointment from a list submitted by the occupational association. Standard errors are not clustered when using the Independent Agencies sample and are clustered by state when focusing on the Government Agencies sample. Standard errors are in parenthesis.

Table 3.7: Effects of Licensing on Livestock Density (Great Plains, 1870-1930)

	dependent variable: density					
	mules	horses	cattle	cows	swine	sheep
Panel A: Great Plains						
$Licensing_s \times Post_t$	0.003***	0.020***	0.846	0.021***	0.058***	0.401***
	(0.001)	(0.003)	(0.621)	(0.006)	(0.012)	(0.144)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.040	0.470	0.055	0.126	0.148
# of observations	4,712	4,712	4,712	4,712	4,712	4,712
Panel B: Non Great Plains						
$Licensing_s \times Post_t$	0.001**	0.003*	0.085	0.008**	0.033***	-0.005
	(0.000)	(0.001)	(0.079)	(0.004)	(0.010)	(0.012)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.030	0.091	0.047	0.147	0.124
# of observations	13,392	13,392	13,392	13,392	13,392	13,392

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the density of each species. The Great Plains states include Colorado, Iowa, Kansas, Minnesota, Missouri, Montana, North Dakota, Nevada, New Mexico, Oklahoma, Texas, and Wyoming. Standard errors are not clustered when using the Great Plains Sample and are clustered by state when focusing on the non-Great Plains sample. Standard errors are in parenthesis.

Table 3.8: Effects of Licensing on the Supply of Veterinary Care (1870-1930)

	dependent variable: ratio		
	raw ratio	quartic root	inverse hyper sine
Panel A: all ages			
$Licensing_s \times Post_t$	0.766^{***}	0.062^{**}	0.216^{***}
	(0.228)	(0.027)	(0.076)
pre-treatment mean (1870)	1.341	1.341	1.341
Panel B: 18-35			
$Licensing_s \times Post_t$	0.189^{*}	0.009	0.124^{*}
	(0.105)	(0.030)	(0.071)
pre-treatment mean (1870)	0.310	0.310	0.310
Panel C: over 36			
$Licensing_s \times Post_t$	0.576^{***}	0.065^{***}	0.238^{***}
	(0.151)	(0.023)	(0.060)
pre-treatment mean (1870)	1.032	1.032	1.032
state FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
# of observations	329	329	329

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the full-count U.S. Decennial Census of Population (1870-1930). The sample includes all individuals with full literacy self-reported as veterinarians in the agricultural sector. The outcome is the number of such veterinarians per 100,000 residents in a state per year. Regressions are weighted by the number of people within a state and all standard errors are clustered at the state level. Standard errors are in parenthesis.

Table 3.9: Effects of Licensing on Livestock Density (western states, 1870-1930)

	dependent variable: density					
	mules	*horses*	*cattle*	*milch cows*	*swine*	*sheep*
$Licensing_s \times Post_t$	0.006***	0.003	0.103**	0.008	-0.010**	0.841**
	(0.001)	(0.004)	(0.040)	(0.009)	(0.004)	(0.383)
log(population)	0.000	-0.001	-0.015	-0.003	-0.006*	0.120**
	(0.001)	(0.002)	(0.010)	(0.006)	(0.003)	(0.048)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
state-specific time trends	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.011	0.046	0.157	0.084	0.370	0.054
# of observations	1,480	1,480	1,480	1,480	1,480	1,480

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the density of each species. All standard errors are clustered by state. Standard errors are in parenthesis.

Table 3.10: Effects of Licensing on Livestock Density (1870-1930)

	dependent variable: density					
	mules	*horses*	*cattle*	*milch cows*	*swine*	*sheep*
Panel A: w/ # of vet						
$Licensing_s \times Post_t$	0.001**	0.007**	0.383	0.016***	0.052***	0.087
	(0.001)	(0.003)	(0.244)	(0.005)	(0.013)	(0.080)
# of vets per 100,000 pop	-0.000	0.000***	0.002	0.000*	0.000	0.001***
	(0.000)	(0.000)	(0.002)	(0.000)	(0.000)	(0.000)
Panel B: baseline estimates						
$Licensing_s \times Post_t$	0.001**	0.007***	0.264	0.014***	0.050***	0.086
	(0.001)	(0.002)	(0.161)	(0.004)	(0.012)	(0.080)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
state-specific time trends	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.033	0.191	0.049	0.130	0.142
# of observations	13,578	13,578	13,578	13,578	13,578	13,578

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the density of each species. All standard errors are clustered by state. Standard errors are in parenthesis.

Table 3.11: Effects of Licensing on the Productivity of Milch Cows (1870-1930)

	(1)	*(2)*	*(3)*	*(4)*
$Licensing_s \times Post_t$	-0.095	0.053	0.054	-0.012
	(0.099)	(0.081)	(0.082)	(0.104)
county FE	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes
state-specific time trends	No	Yes	Yes	Yes
sample	all counties	all counties	rural counties	urban counties
pre-treatment mean (value, 1870)	0.006	0.033	0.191	0.049
# of observations	18,044	18,044	16,106	1,938

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the natural logarithm of the amount of butter produced per milch cow. All standard errors are clustered by state. Standard errors are in parenthesis.

The Cow-Doctor, an engraving from the American Agriculturist, *June, 1875.*

Figure A1: A Snapshot of Veterinarians in the History

Figure A2: Prominent urban veterinary colleges in the late nineteenth and early twentieth centuries. The dark triangles represent the location of the colleges and the gray circles represent the location of the largest cities in the year 1900. This figure is directly from Smith (2013).

Figure A3: Location of the first wave of land-grant veterinary colleges. The dark triangles represent the location of the colleges and the gray circles represent the location of the largest cities in the year 1900. This figure is directly from Smith (2013).

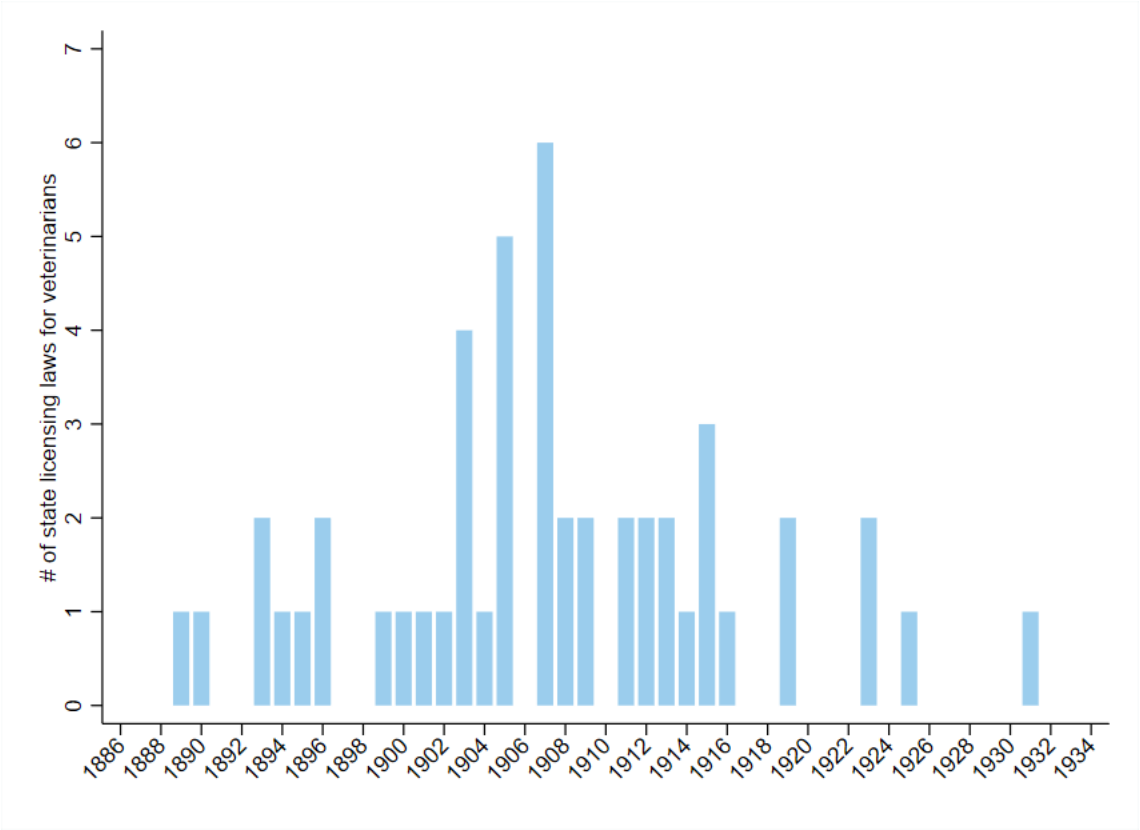


Figure A4: Evolution of State Licensing Laws (1890-1930)

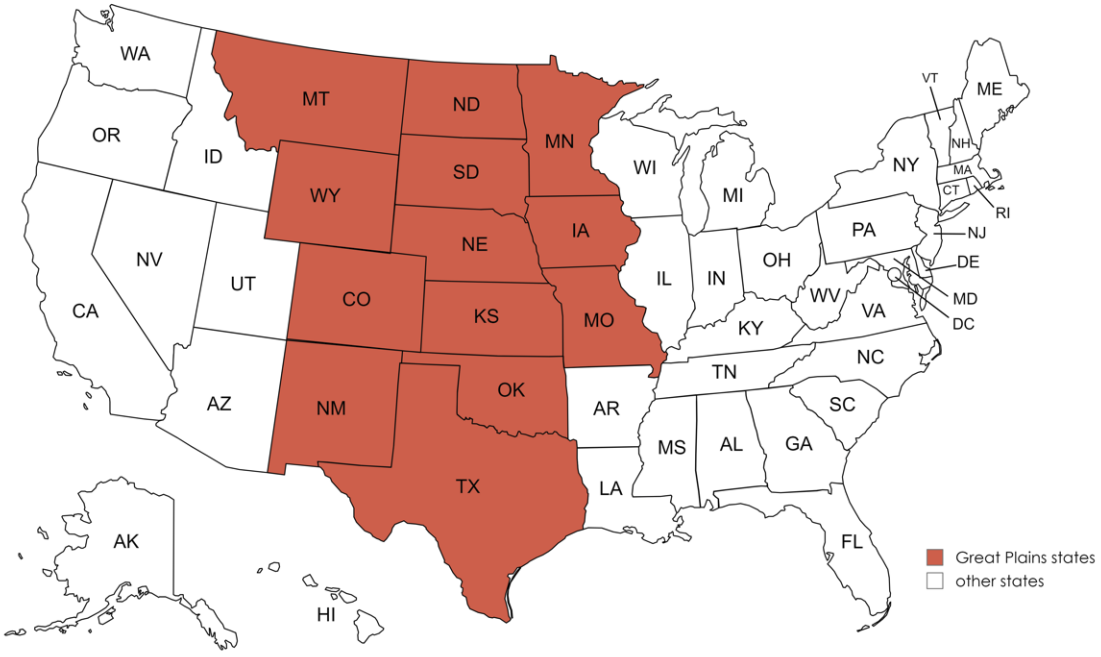


Figure A5: Great Plains

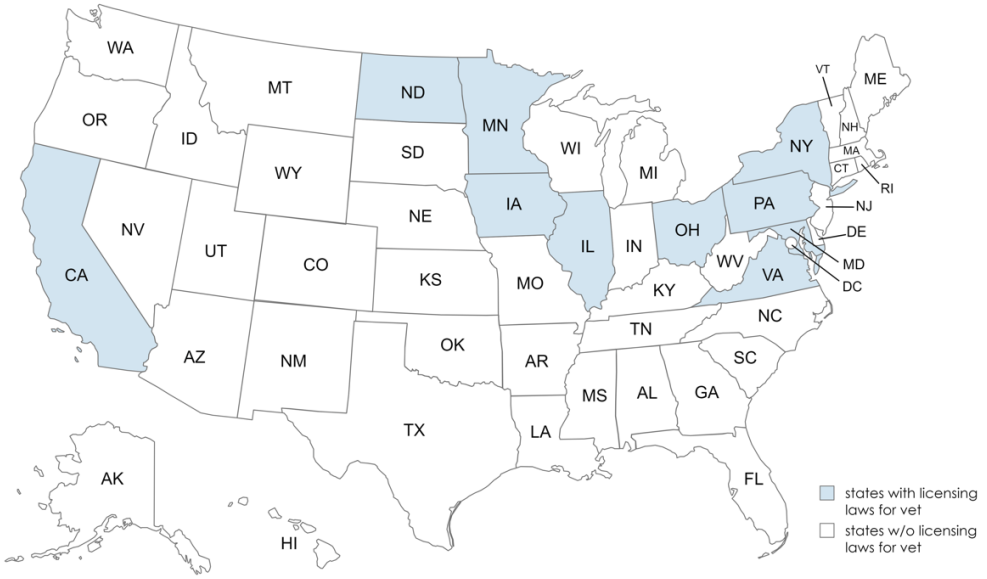


Figure A6: state licensing laws by 1900

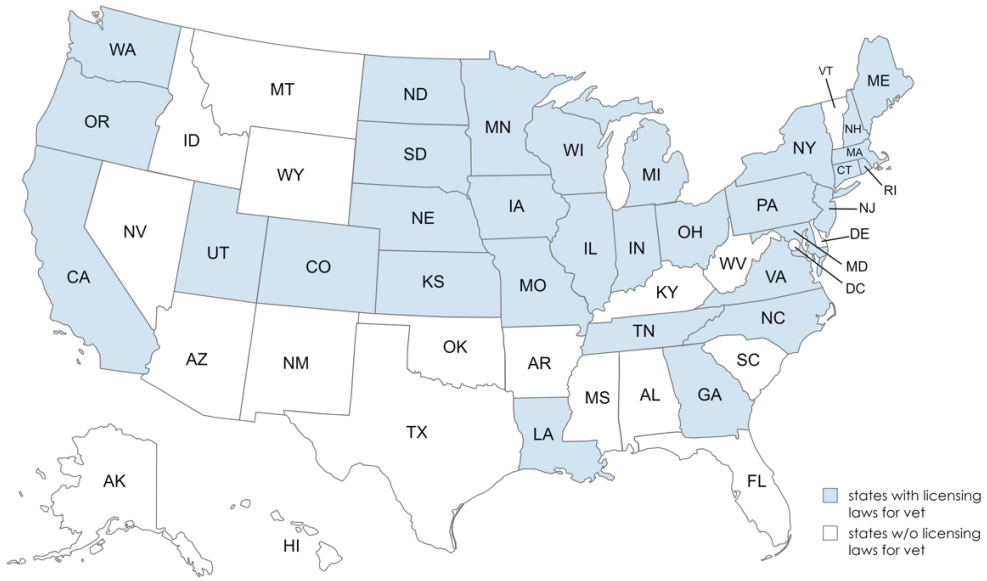


Figure A7: state licensing laws by 1910

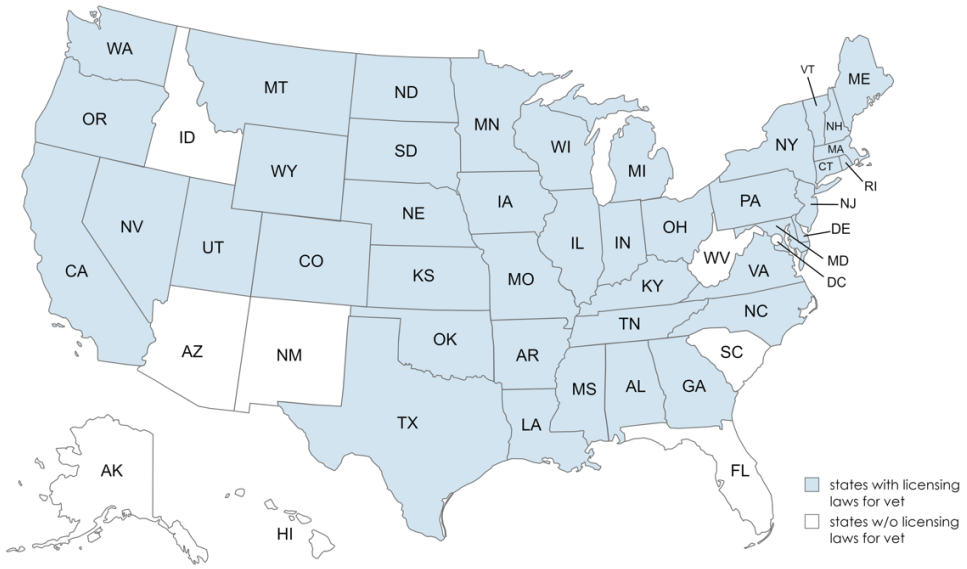


Figure A8: state licensing laws by 1920

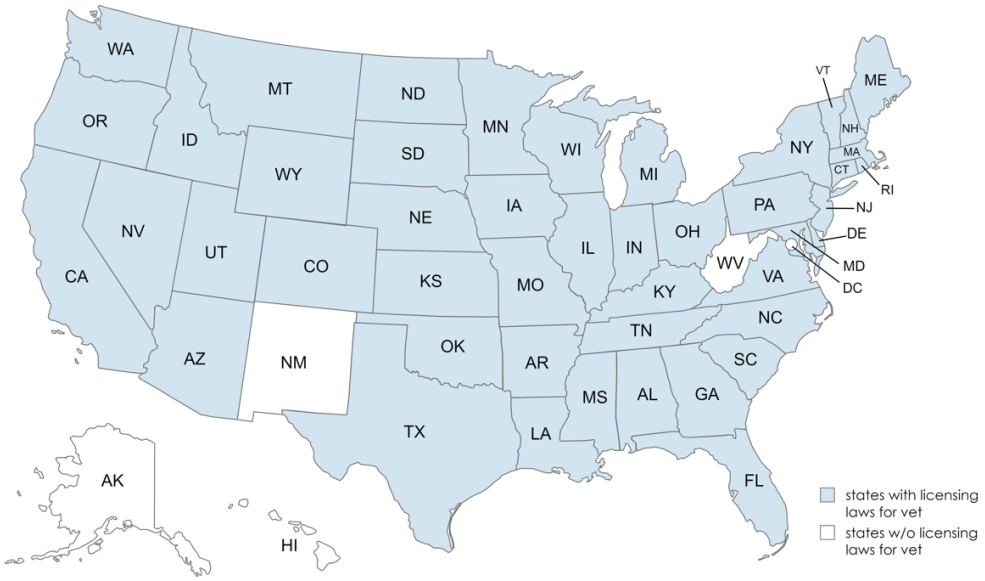


Figure A9: state licensing laws by 1930

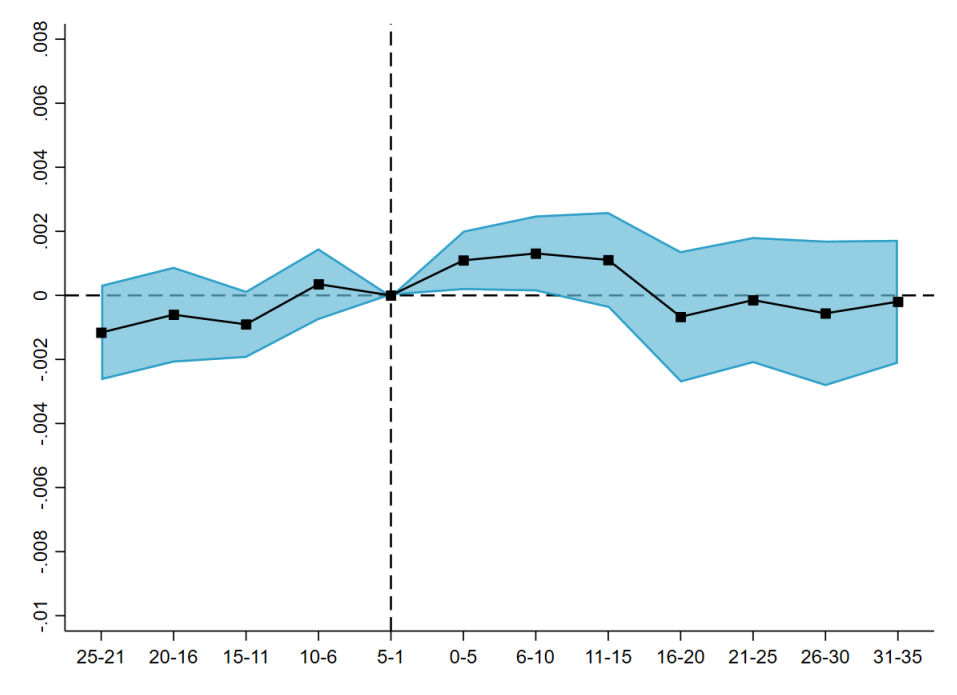


Figure A10: event-study estimates for the density of mules, rural counties

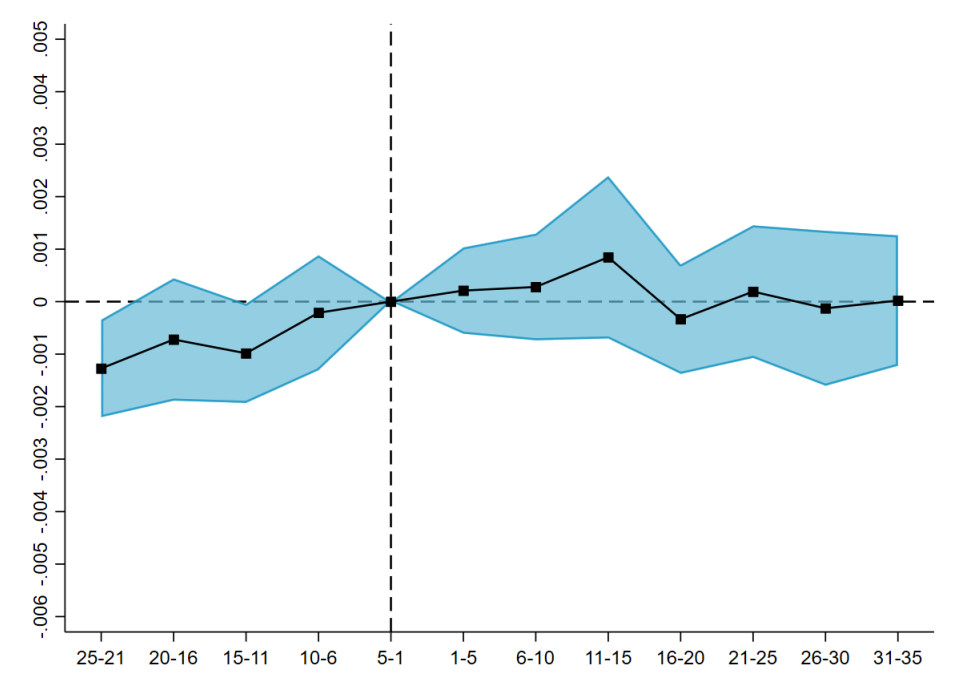


Figure A11: event-study estimates for the density of mules, urban counties

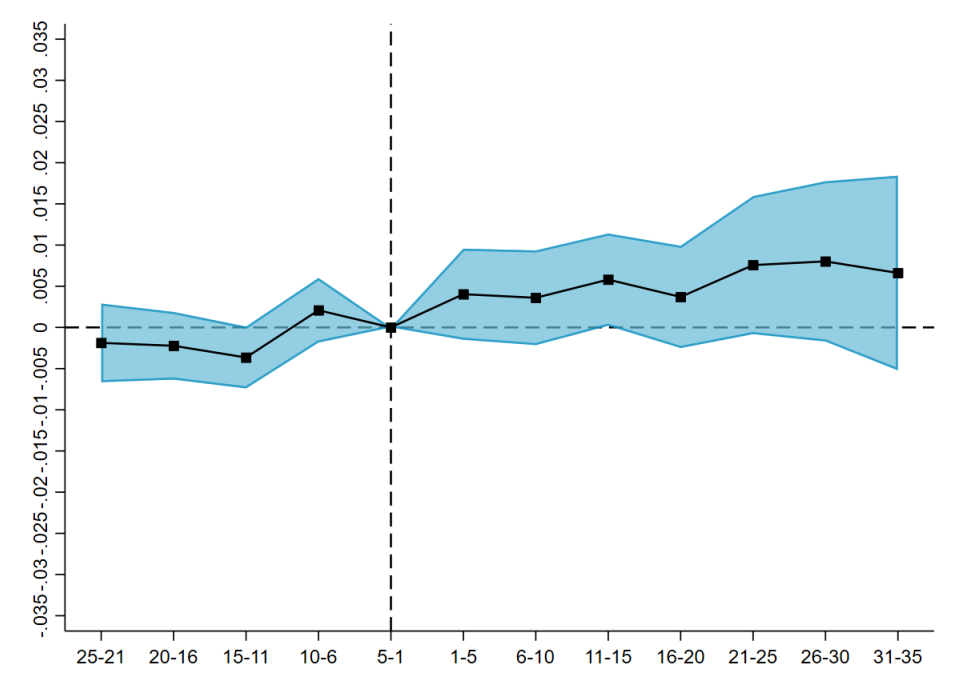


Figure A12: event-study estimates for the density of horses, rural counties

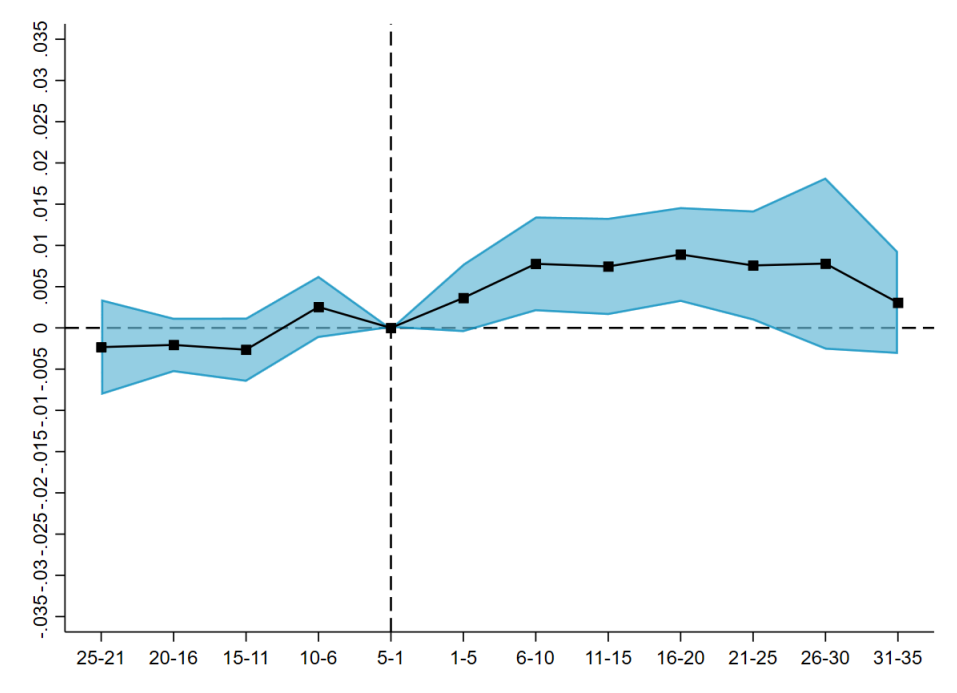


Figure A13: event-study estimates for the density of horses, urban counties

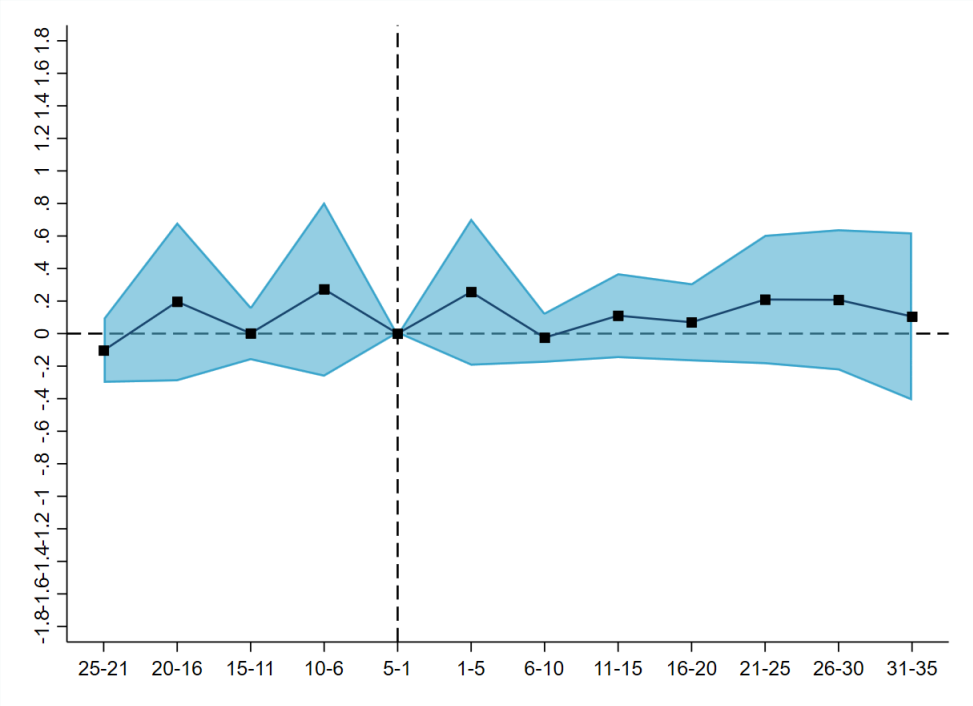


Figure A14: event-study estimates for the density of cattle, rural counties

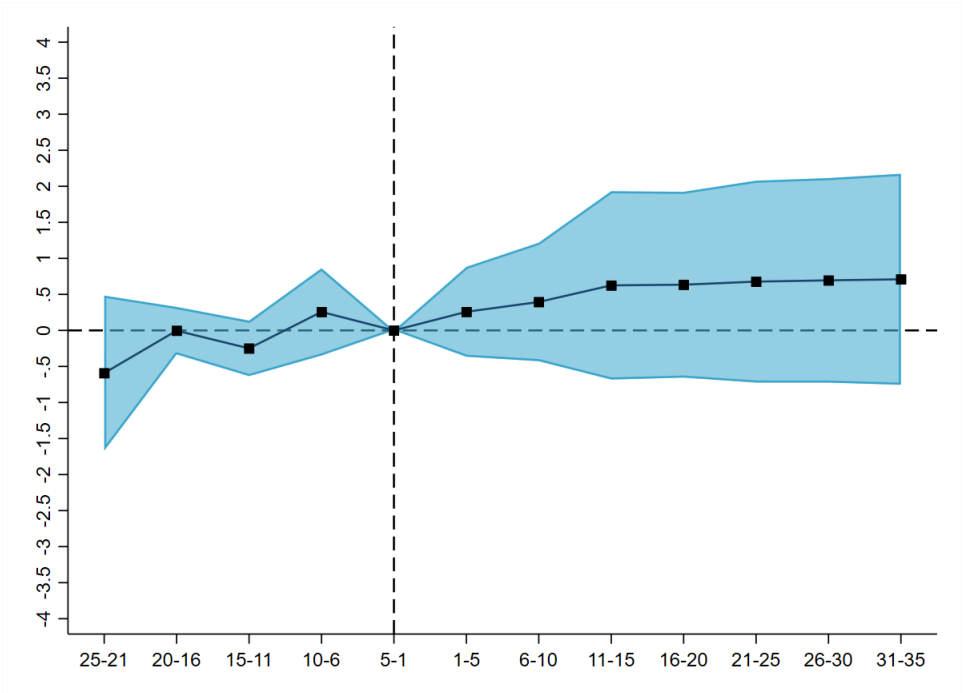


Figure A15: event-study estimates for the density of cattle, urban counties

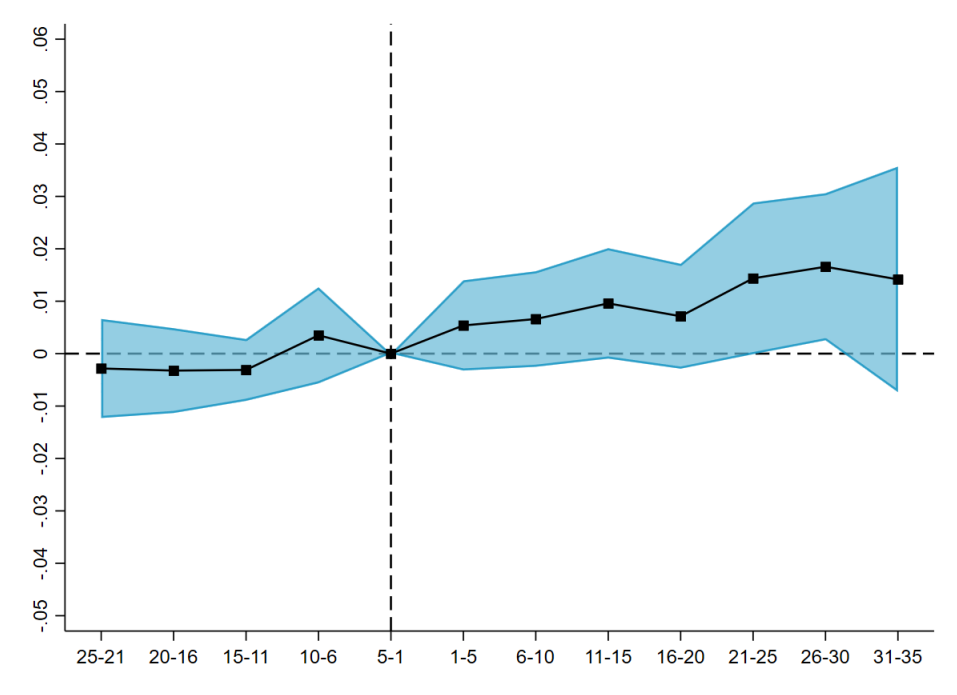


Figure A16: event-study estimates for the density of cows, rural counties

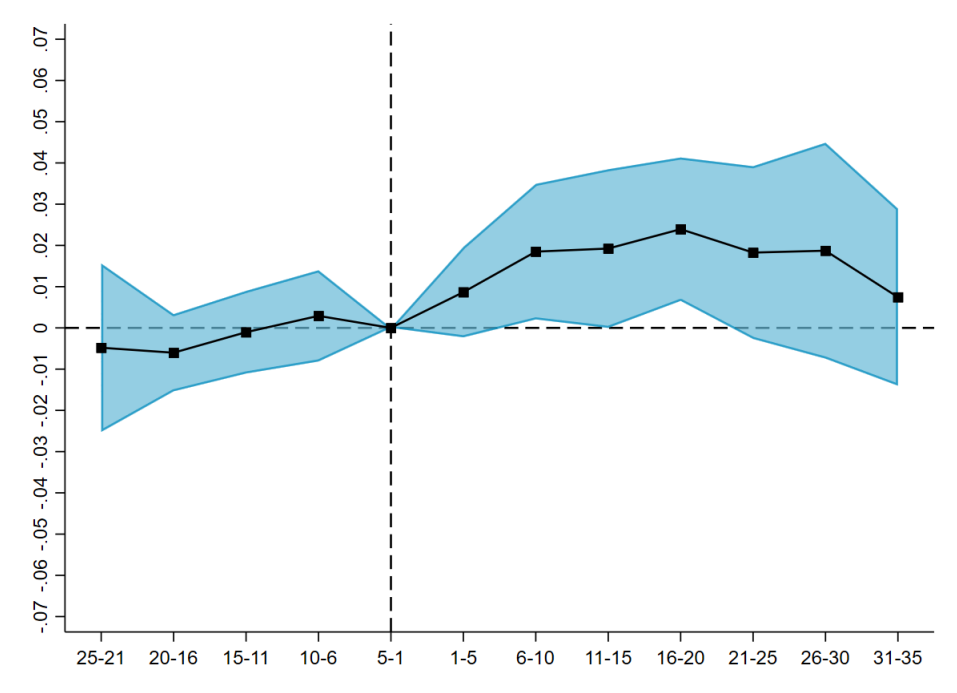


Figure A17: event-study estimates for the density of cows, urban counties

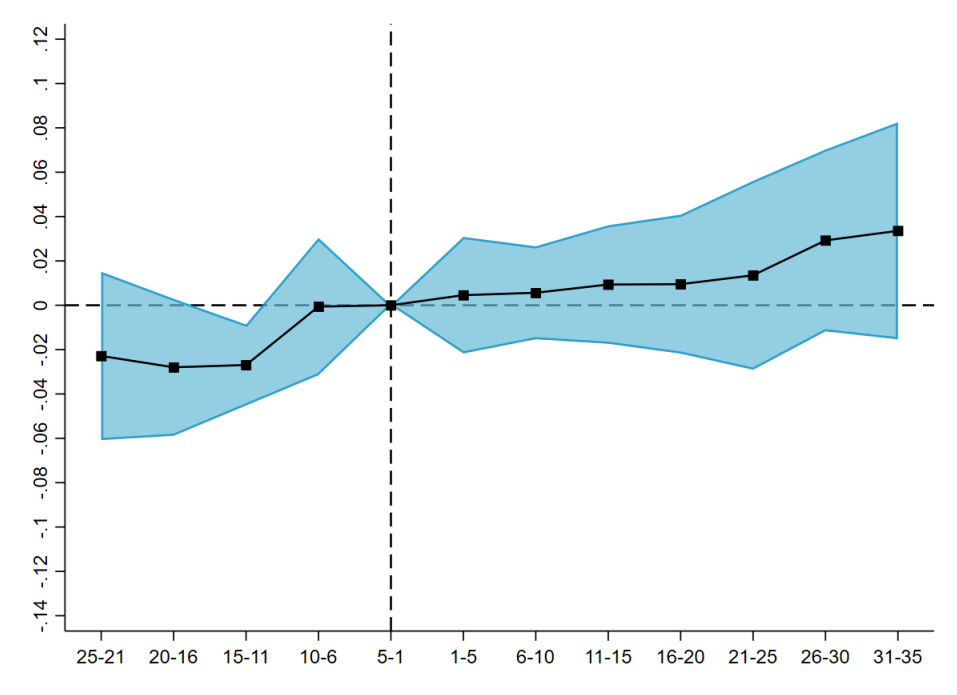


Figure A18: event-study estimates for the density of swine, rural counties

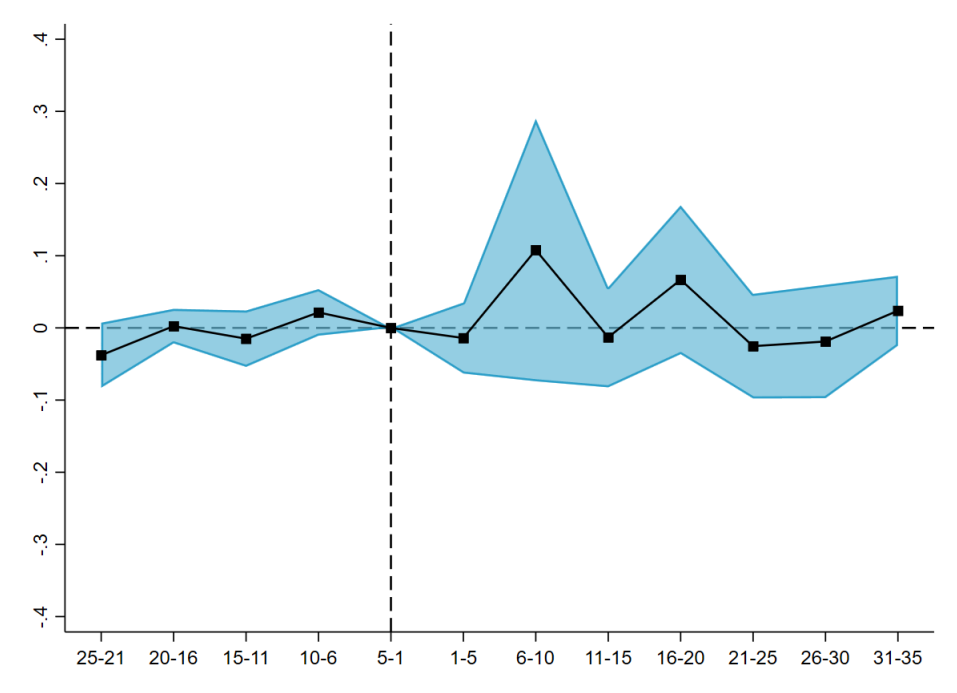


Figure A19: event-study estimates for the density of swine, urban counties

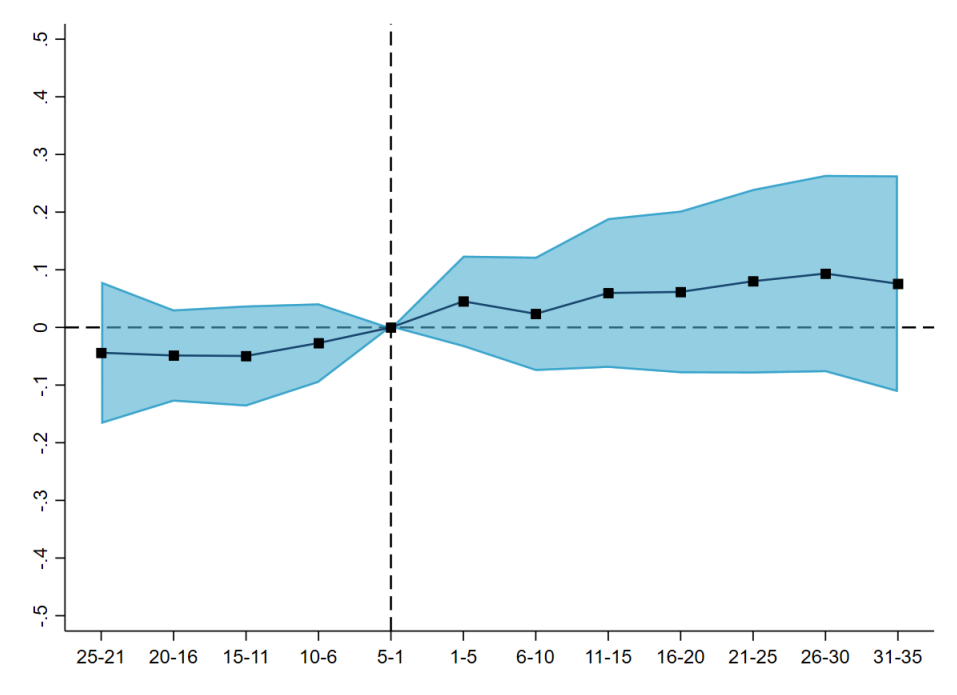


Figure A20: event-study estimates for the density of sheep, rural counties

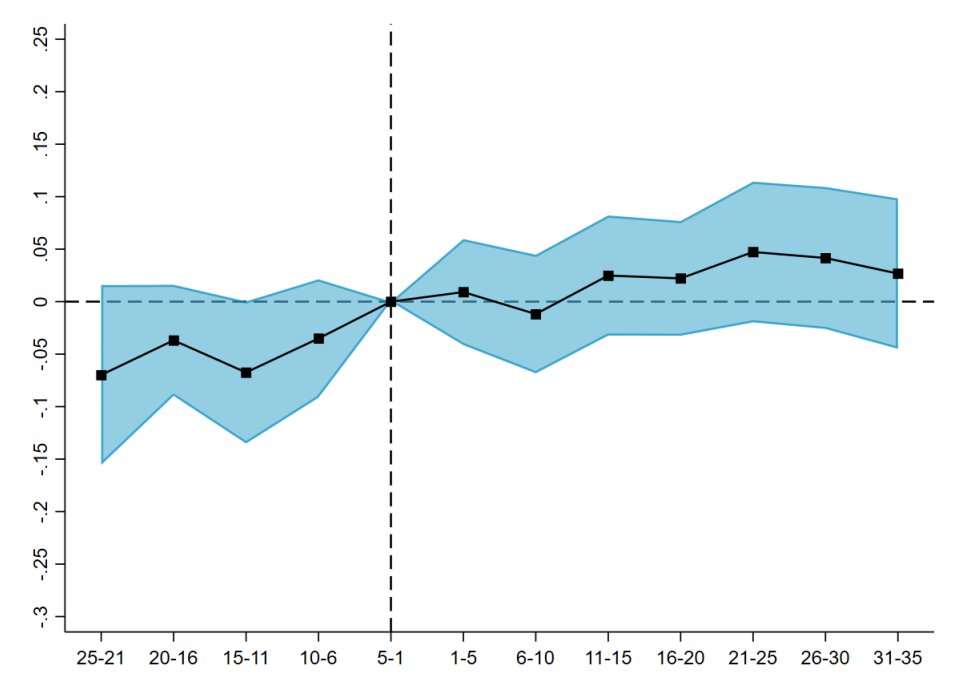


Figure A21: event-study estimates for the density of sheep, urban counties

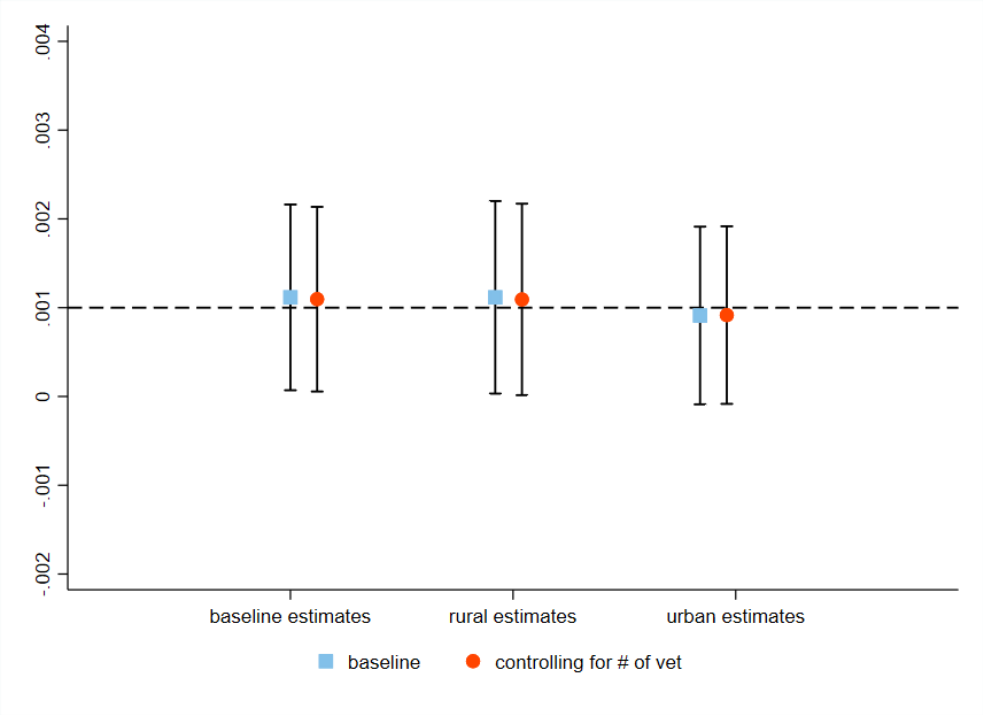


Figure A22: estimates for mules (with vs. without controlling for # of veterinarians)

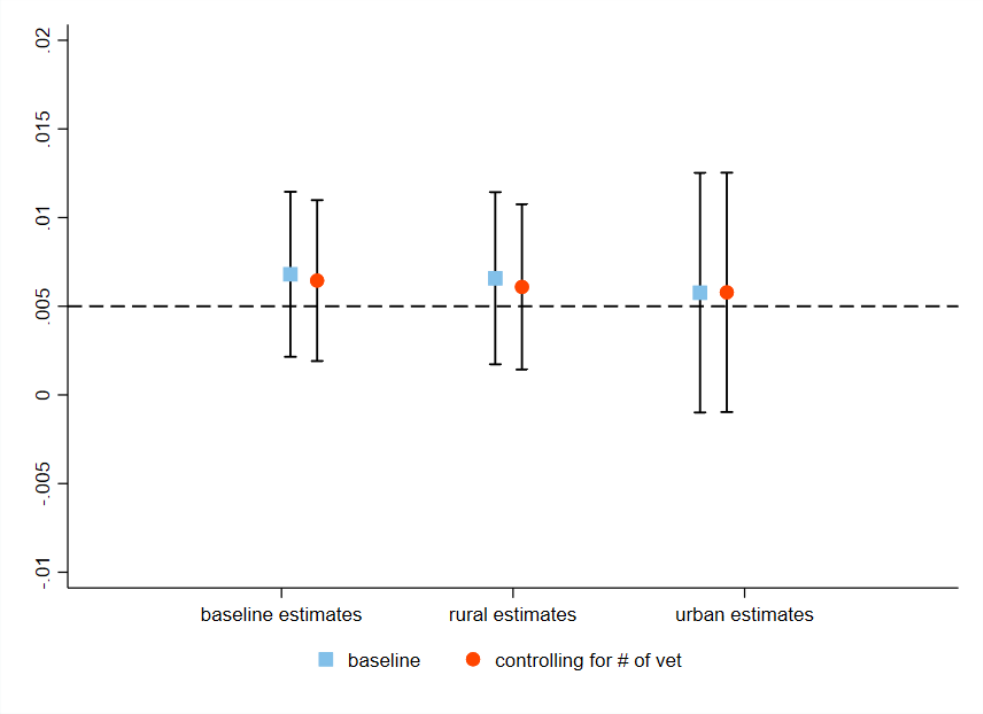


Figure A23: estimates for horses (with vs. without controlling for # of veterinarians)

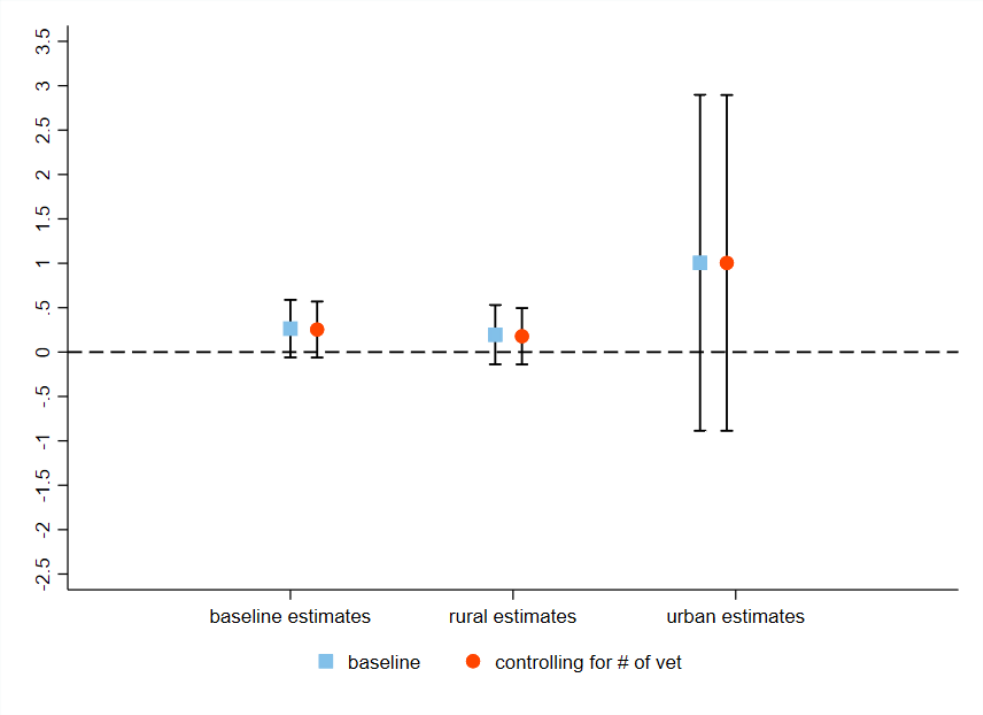


Figure A24: estimates for cattle (with vs. without controlling for # of veterinarians)

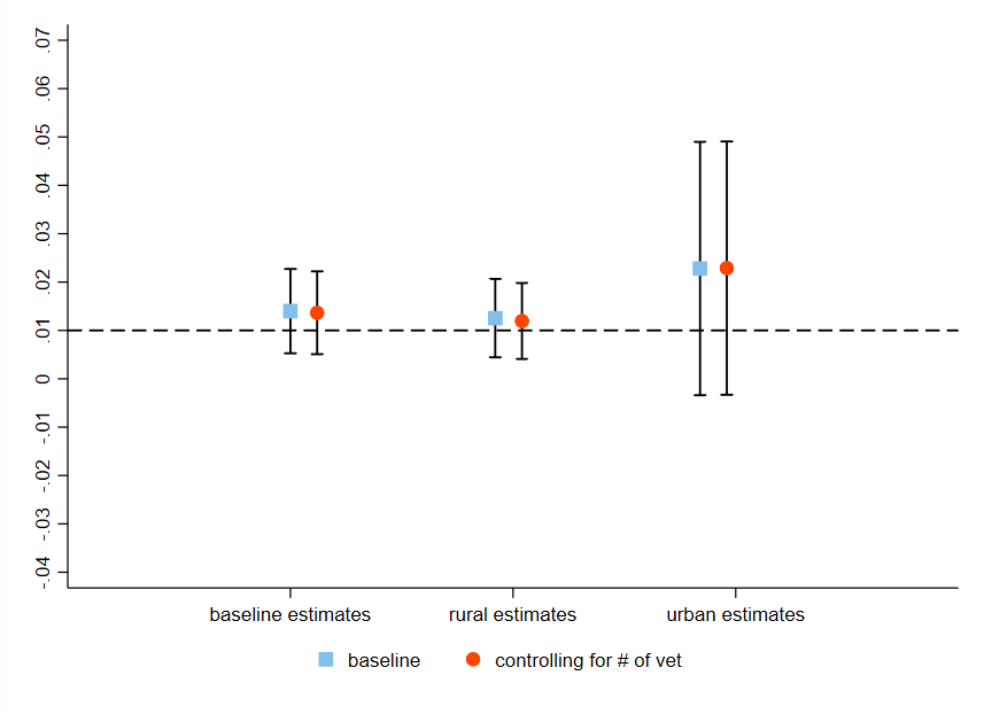


Figure A25: estimates for cows (with vs. without controlling for # of veterinarians)

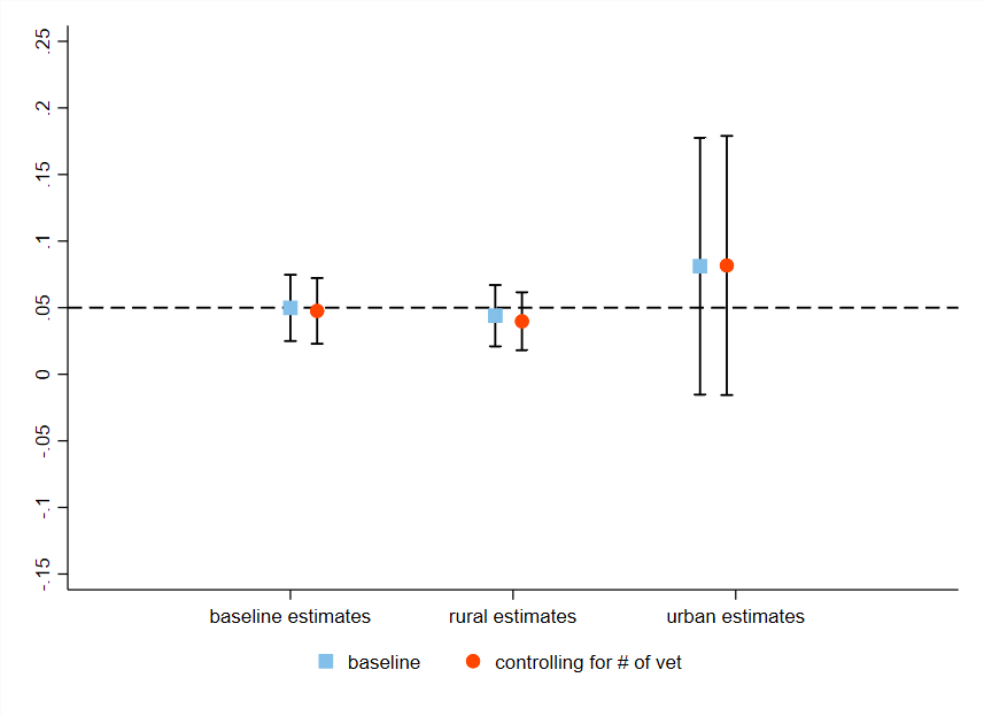


Figure A26: estimates for swine (with vs. without controlling for # of veterinarians)

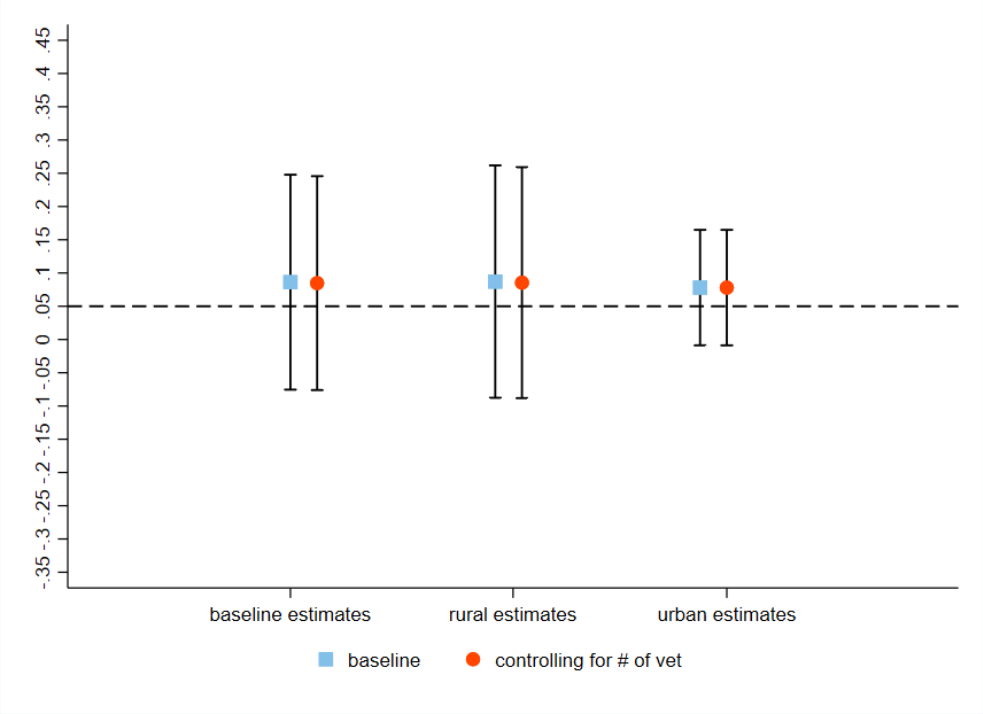


Figure A27: estimates for sheep (with vs. without controlling for # of veterinarians)

LOWNDES COUNTY.

Every Inspector and Agent working in Lowndes county was paid by the Federal Government. One Veterinarian the entire year and three agents worked from April last until Dec. 1st.

This work cost the Government about $3600.

Dr. H. E. Curry had charge of this county, W. N. Ray, J. A. Till and G. C. Marlette were the agents and inspectors.

When first inspected, 722 herds or 8556 cattle were found free and 85 herds of 1023 cattle were found infested. During the year 237 herds and 4477 cattle were quarantined. The turning out of cattle in the winter time has greatly retarded the work in this county.

MONTGOMERY COUNTY.

Dr. G. W. Browning had charge of Montgomery County from Jan. 1st to Sept. 1, 1909. Dr. R. L. McBreen, a Federal Veterinary Inspector had charge of the county in Sept. F. T. Dean worked as a State Inspector during March and April and was succeeded by T. H. Moore, who worked from June 1st to Dec 31, 1909. W. L. Dick worked as a State Inspector from April until Dec. 31, 1909. W. W. Smilie worked as a county Inspector from April until Dec. 31st. R. C. Rives worked as a State Inspector from Aug. 1st to Nov. 30th. Geo. W. Dickey worked as a county Inspector one month and two months as a State Inspector. L. A. Dick worked two months as a State Inspector.

The State spent in Montgomery County $3000
The County spent about 400
The Federal Government spent about 200

During the year 447 herds and 6802 cattle were quarantined. Most of these herds were inspected from four to ieght times during summer. Owing to violations of quarantine regulations and to the turning out of cattle in the winter, the county is not clean of ticks. The people of the county are now informed that all cattle must be hereafter kept up in the winter.

WILCOX COUNTY.

Dr. Sid Galt, Camden, Ala., Federal Veterinarian Inspector in charge of the County. J. K. P. Robson, S. M. Lambert and W. F. Spencer were Federal Agents working from March until Dec. 1st.

Mr. G. M. Pharr, of Catherine was employed by the State as a Live Stock Inspector from June until the last of

Figure A28: example of the annual report of veterinarians

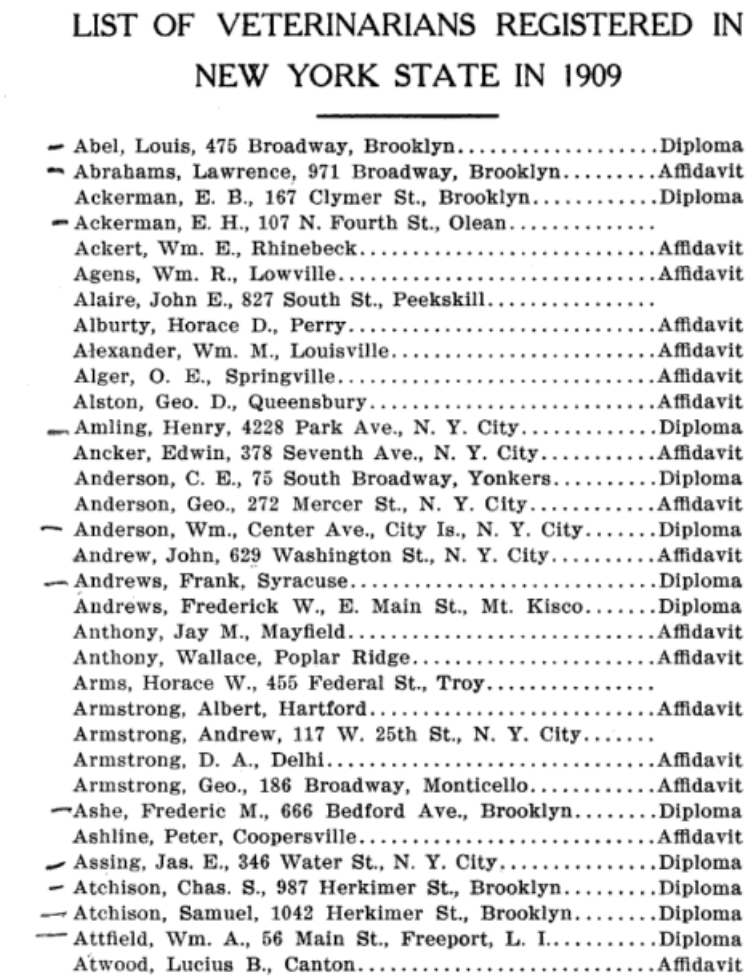
OFFICIAL REGISTER OF VETERINARIANS

HOLDING LICENSES FROM THE STATE VETERINARY MEDICAL BOARD OF THE STATE OF CALIFORNIA.

Eagan, W. F.	San Francisco
Burns, Peter*	San Francisco
Masoero, Cæsar	San Francisco
Skaife, F. W.	San Francisco
Neif, F. A.	San Francisco
Fitzgerald, J. D.	San Francisco
Claussen, H. H.	San Francisco
Creely, E. J.	San Francisco
Jacobsen, J.	San Francisco
Jones, W. H.	San Francisco
Bowhill, T.	San Francisco
Fabbi, H.	San Francisco
Robin, A.	San Francisco
Buckley, J. M.	San Francisco
Paterson, A.	San Francisco
Orme, T. W.	San Francisco
Westphal, C. H.	San Francisco
Buzzard, A. E.	San Francisco
O'Rourke, I. W.	San Francisco
Diete, C.	San Francisco
Archibald, R. A.	Oakland
Pierce, F. E.	Oakland
Hogarty, J. J.	Oakland
Simpson, G. W.	Oakland
Jackson, H. R.	Oakland
McCollum, A. M.	Sacramento
Fox, D. F.	Sacramento
Megowan, C. L.	Sacramento
Whittlesey, R. T.	Los Angeles
Blackenton, J. C.	Los Angeles
Edmons, J. A.	Los Angeles
Oliver, W. J.	Los Angeles
Morrison, W. E. D.	Los Angeles
Withers, R. J.	Los Angeles
Withers, S. A.	Los Angeles
Tourillon, H. P.	Los Angeles
Button, W. W.	Los Angeles
Twombly, S. S.	Los Angeles
Dodson, G. K.	Los Angeles
Spencer, H. A.	San José
Spencer, H. F.	San José
Schodde, B.	San José
Shaw, R. J.	San José
Orvis, C. B.	Stockton
Power, R. H.	Stockton
Eddy, J. H.	Stockton
Baldy, O. C.	Grass Valley
Lord, R. A.	Santa Ana
Gardner, J. H.*	Santa Ana
Rowland, W. B.	Pasadena
White, S.	Pasadena
Maclay, Thomas	Petaluma
Wadams, W. B.	Santa Clara
Parent, P. P.*	Hollister
Trullinger, J.	Bakersfield
Sawyer, F. N.	Bakersfield
Lemke, H.*	Bakersfield
Forrest, H. A.	Santa Cruz
Rowat, A. R.	San Francisco
Bergman, A.	Napa
Elliot, W. B.	Riverside
Clark, E. M.	Bishop
Gillen, J. R.	San Diego
Alexander, A. L.	Woodland
Streets, J. J.	Ventura
Matthews, G. E.	Fresno
Crandel, E. J.	Pico Heights
Davidson, R. D.	San Bernardino
Fleming, W. J.	Ontario
Cragan, H. B.	Pomona
Smith, A. O.	Pomona
Kelty, W. P.	Pomona
Blackentose, E.	Eureka
Graham, J.	Fresno
Forrest, F.	San José
Faulkner, G. F.	Salinas
Williams, A. S.	Marysville
Goulding, F.	Santa Barbara
Selleck, W.	Escondido
Wise, A. B.	San Bernardino
Carney, R. T.	Whittier
Davenport, P. C.	Stockton
Thompson, W. M.	Willows
Magor, J. F.	Redlands
Hester, J. H.	Pasadena
Carpenter, T.	Alameda
Summerfield, J. J.	Santa Rosa
Ramsey, F. A.	Pomona
Klench, J. P.	Petaluma
Tilton, E. W.	Santa Cruz
Richards, W. W.	San Diego

* Deceased.

Figure A29: example of historical records for licensed veterinarians in California



LIST OF VETERINARIANS REGISTERED IN NEW YORK STATE IN 1909

Abel, Louis, 475 Broadway, Brooklyn.....Diploma
Abrahams, Lawrence, 971 Broadway, Brooklyn.....Affidavit
Ackerman, E. B., 167 Clymer St., Brooklyn.....Diploma
Ackerman, E. H., 107 N. Fourth St., Olean.....
Ackert, Wm. E., Rhinebeck.....Affidavit
Agens, Wm. R., Lowville.....Affidavit
Alaire, John E., 827 South St., Peekskill.....
Alburty, Horace D., Perry.....Affidavit
Alexander, Wm. M., Louisville.....Affidavit
Alger, O. E., Springville.....Affidavit
Alston, Geo. D., Queensbury.....Affidavit
Amling, Henry, 4228 Park Ave., N. Y. City.....Diploma
Ancker, Edwin, 378 Seventh Ave., N. Y. City.....Affidavit
Anderson, C. E., 75 South Broadway, Yonkers.....Diploma
Anderson, Geo., 272 Mercer St., N. Y. City.....Affidavit
Anderson, Wm., Center Ave., City Is., N. Y. City.....Diploma
Andrew, John, 629 Washington St., N. Y. City.....Affidavit
Andrews, Frank, Syracuse.....Diploma
Andrews, Frederick W., E. Main St., Mt. Kisco.....Diploma
Anthony, Jay M., Mayfield.....Affidavit
Anthony, Wallace, Poplar Ridge.....Affidavit
Arms, Horace W., 455 Federal St., Troy.....
Armstrong, Albert, Hartford.....Affidavit
Armstrong, Andrew, 117 W. 25th St., N. Y. City.....
Armstrong, D. A., Delhi.....Affidavit
Armstrong, Geo., 186 Broadway, Monticello.....Affidavit
Ashe, Frederic M., 666 Bedford Ave., Brooklyn.....Diploma
Ashline, Peter, Coopersville.....Affidavit
Assing, Jas. E., 346 Water St., N. Y. City.....Diploma
Atchison, Chas. S., 987 Herkimer St., Brooklyn.....Diploma
Atchison, Samuel, 1042 Herkimer St., Brooklyn.....Diploma
Attfield, Wm. A., 56 Main St., Freeport, L. I.....Diploma
Atwood, Lucius B., Canton.....Affidavit

Figure A30: example of historical records for licensed veterinarians in New York State

In that time six meetings have been held, as follows: Los Angeles, July 18, 1903; Los Angeles, August 27, 28, 29, 1903; San Francisco, September 18, 1903; Los Angeles, March 4, 1904; San Francisco, September 14 and 22, 1904.

Number of applicants examined:

Applicants—graduates	47
Applicants—non-graduates	28
Total examined	75

Number of certificates issued:

To holders of diplomas	46
To non-holders of diplomas	18
Total certificates issued	64

FINANCIAL STATEMENT.

Receipts.

To balance on hand	$24.60	
Examining 47 graduates, @ $5	235.00	
Examining 28 non-graduates, @ $10	280.00	
Issuing 64 certificates, @ $5	320.00	
Total receipts		$859.60

Expenditures.

Incidentals, postage, rent, etc	$120.60	
Printing	26.50	
Per diem and traveling of members	697.50	
Total expenditures		$844.60
Balance on hand		$15.00

Figure A31: example of historical records for licensed veterinarians in California

Appendices

A1. Alternative Staggered DID Specification

Table 3.12: Effects of Licensing on Livestock Density (by Licensing Agency, 1870-1930)

	dependent variable: density					
	mules	horses	cattle	cows	swine	sheep
Panel A: independent agencies						
$Licensing_s \times Post_t$	0.008***	0.020***	0.064***	0.087**	-0.019***	0.679**
	(0.001)	(0.005)	(0.023)	(0.042)	(0.002)	(0.316)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.009	0.035	0.500	0.069	0.175	0.146
# of observations	5,392	5,392	5,392	5,392	5,392	5,392
Panel B: government agencies						
$Licensing_s \times Post_t$	0.000	-0.006***	-0.007***	-0.007***	-0.016***	-0.001
	(0.000)	(0.000)	(0.002)	(0.001)	(0.002)	(0.006)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.004	0.032	0.056	0.040	0.118	0.126
# of observations	11,008	11,008	11,008	11,008	11,008	11,008

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the natural logarithm of the density of each species, mule, cattle, and horse. "*Indepedent agencies*" refers to those states whose licensing agencies are independent. "*Government agencies*" refers to those states whose licensing agencies are affiliated with the Department of Agriculture within state governments. There are 20 states and 709 counties with independent licensing agencies and 20 states and 1403 counties with affiliated agencies with governments. Standard errors are not clustered when using the Independent Agencies sample and are clustered by state when focusing on the Government Agencies sample.

Table 3.13: Effects of Licensing on Livestock Density (Great Plains, 1870-1930)

	dependent variable: density					
	mules	horses	cattle	cows	swine	sheep
Panel A: Great Plains						
$Licensing_s \times Post_t$	0.009***	0.027***	0.329***	0.067*	-0.040***	0.703***
	(0.002)	(0.006)	(0.121)	(0.035)	(0.003)	(0.212)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.040	0.470	0.055	0.126	0.148
# of observations	4,712	4,712	4,712	4,712	4,712	4,712
Panel B: Non Great Plains						
$Licensing_s \times Post_t$	0.001***	-0.005***	-0.008***	-0.004***	-0.001	-0.009*
	(0.000)	(0.000)	(0.002)	(0.001)	(0.004)	(0.006)
county FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
pre-treatment mean (density, 1870)	0.006	0.030	0.091	0.047	0.147	0.124
# of observations	13,392	13,392	13,392	13,392	13,392	13,392

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the Census of Agriculture (1870-1930). The dependent variable of all regressions is the natural logarithm of the density of each species, mule, cattle, and horse. The Great Plains states include Colorado, Iowa, Kansas, Minnesota, Missouri, Montana, North Dakota, Nevada, New Mexico, Oklahoma, Texas, and Wyoming. Standard errors are not clustered when using the Great Plains Sample and are clustered by state when focusing on the non-Great Plains sample.

Bibliography

Acemoglu, Daron, and Joshua Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry." *The Quarterly Journal of Economics*, 119(3): 1049–1090.

Acharya, Viral V., Ramin P. Baghai, and Krishnamurthy V. Subramanian. 2013. "Labor Laws and Innovation." *The Journal of Law and Economics*, 56(4): 997–1037.

Adams, A. Frank, Robert B. Ekelund, and John D. Jackson. 2003. "Occupational Licensing of a Credence Good: The Regulation of Midwifery." *Southern Economic Journal*, 69(3): 659–675.

Aghion, Philippe, Nick Bloom, Richard Blundell, Rachel Griffith, and Peter Howitt. 2005. "Competition and Innovation: an Inverted-U Relationship*." *The Quarterly Journal of Economics*, 120(2): 701–728.

Akcigit, Ufuk, John Grigsby, and Tom Nicholas. 2017. "The Rise of American Ingenuity: Innovation and Inventors of the Golden Age." National Bureau of Economic Research Working Paper 23047.

Alexander, Diane. 2020. "How Do Doctors Respond to Incentives? Unintended Consequences of Paying Doctors to Reduce Costs." *Journal of Political Economy*, 128(11): 4046–4096.

Allen, Bennett, Michelle L. Nolan, and Denise Paone. 2019. "Article Commentary: Underutilization of Medications to Treat Opioid use Disorder: What Role does Stigma Play?" *Substance Abuse*, 40(4): 459–465. PMID: 31550201.

Anderson, D. Mark. 2010. "Does information matter? The effect of the Meth Project on meth use among youths." *Journal of Health Economics*, 29(5): 732–742.

Anderson, D. Mark, Ryan Brown, Kerwin Kofi Charles, and Daniel I. Rees. 2020. "Occupational Licensing and Maternal Health: Evidence from Early Midwifery Laws." *Journal of Political Economy*, 128(11): 4337–4383.

Andrews, Christina, Amanda Abraham, Colleen M. Grogan, Harold A. Pollack, Clifford Bersamira, Keith Humphreys, and Peter Friedmann. 2015. "Despite Resources From The ACA, Most States Do Little To Help Addiction Treatment Programs Implement Health Care Reform." *Health Affairs*, 34(5): 828–835. PMID: 25941285.

Andrews, Michael J. 2021. "Historical patent data: A practitioner's guide." *Journal of Economics & Management Strategy*, 30(2): 368–397.

Arrow, Kenneth J. 1978. "Uncertainty and the Welfare Economics of Medical Care." In *Uncertainty in Economics*. 345–375. Elsevier.

Atal, Juan Pablo, Jose Ignacio Cuesta, and Morten Sæthre. 2022. "Quality Regulation and Competition: Evidence from Pharmaceutical Markets." Working Paper.

Athey, Susan, and Armin Schmutzler. 1995. "Product and Process Flexibility in an Innovative Environment." *The RAND Journal of Economics*, 26(4): 557–574.

Babina, Tania, Asaf Bernstein, and Filippo Mezzanotti. 2020. "Crisis Innovation." National Bureau of Economic Research Working Paper 27851.

Barbara Andraka-Christou, Olivia Golan, Rachel Totaram Maggie Ohama Brendan Saloner Adam J. Gordon, and Bradley D. Stein. 2023. "Prior authorization restrictions on medications for opioid use disorder: trends in state laws from 2005 to 2019." *Annals of Medicine*, 55(1): 514–520. PMID: 36724766.

Bena, Jan, Hernán Ortiz-Molina, and Elena Simintzi. 2022. "Shielding Firm Value: Employment Protection and Process Innovation." *Journal of Financial Economics*, 146(2): 637–664.

Berkes, Enrico. 2018. "Comprehensive Universe of U.S. Patents (CUSP): Data and Facts." Unpublished Working Paper.

Birnbaum, Philip H. 1984. "The Choice of Strategic Alternatives Under Increasing Regulation in High Technology Companies." *Academy of Management Journal*, 27(3): 489–510.

Brot-Goldberg, Zarek C, Samantha Burn, Timothy Layton, and Boris Vabson. 2023. "Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare." National Bureau of Economic Research Working Paper 30878.

Budish, Eric, Benjamin N. Roin, and Heidi Williams. 2015. "Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials." *American Economic Review*, 105(7): 2044–85.

Buera, Francisco J., and Yongseok Shin. 2013. "Financial Frictions and the Persistence of History: A Quantitative Exploration." *Journal of Political Economy*, 121(2): 221–272.

Burns, A. J., M. Eric Johnson, and Peter Honeyman. 2016. "A Brief Chronology of Medical Device Security." *Commun. ACM*, 59(10): 66–72.

Byrski, Dennis. 2021. "From Scientific Research to Healthcare Markets: Empirical Essays on the Economics of Pharmaceutical Innovation." *working paper*.

Caggese, Andrea. 2019. "Financing Constraints, Radical versus Incremental Innovation, and Aggregate Productivity." *American Economic Journal: Macroeconomics*, 11(2): 275–309.

Callaway, Brantly, and Pedro H.C. Sant'Anna. 2021. "Difference-in-Differences with multiple time periods." *Journal of Econometrics*, 225(2): 200–230. Themed Issue: Treatment Effect 1.

Carpenter, Christopher. 2007. "Heavy Alcohol Use and Crime: Evidence from Underage Drunk-Driving Laws." *The Journal of Law and Economics*, 50(3): 539–557.

Carpenter, Daniel, Justin Grimmer, and Eric Lomazoff. 2010. "Approval regulation and endogenous consumer confidence: Theory and analogies to licensing, safety, and financial regulation." *Regulation & Governance*, 4(4): 383–407.

Carr, Carey J.A., Jiangmin Xu, Cristina Redko, D. Timothy Lane, Richard C. Rapp, John Goris, and Robert G. Carlson. 2008. "Individual and system influences on waiting time for substance abuse treatment." *Journal of Substance Abuse Treatment*, 34(2): 192–201.

Carroll, Sidney L., and Robert J. Gaston. 1981. "Occupational Restrictions and the Quality of Service Received: Some Evidence." *Southern Economic Journal*, 47(4): 959–976.

Chen, Jiafeng, and Jonathan Roth. 2023. "Logs with Zeros? Some Problems and Solutions*." *The Quarterly Journal of Economics*, 139(2): 891–936.

Chernew, Michael, and Harrison Mintz. 2021. "Administrative Expenses in the US Health Care System: Why So High?" *JAMA*, 326(17): 1679–1680.

Clemens, Jeffrey, and Joshua D Gottlieb. 2014. "Do physicians' financial incentives affect medical treatment and patient health?" *American Economic Review*, 104(4): 1320–1349.

Clemens, Jeffrey, and Parker Rogers. 2022. "Environmental Catastrophe and the Direction of Invention: Evidence from the American Dust Bowl." *Working Paper*.

Clemens, Michael A., Ethan G. Lewis, and Hannah M. Postel. 2018. "Immigration Restrictions as Active Labor Market Policy: Evidence from the Mexican Bracero Exclusion." *American Economic Review*, 108(6): 1468–87.

Crampes, Claude, and Abraham Hollander. 1995. "Duopoly and quality standards." *European Economic Review*, 39(1): 71–82.

Currie, Janet, Jeffrey Grogger, Gary Burtless, and Robert F. Schoeni. 2001. "Explaining Recent Declines in Food Stamp Program Participation [with Comments]." *Brookings-Wharton Papers on Urban Affairs*, 203–244.

Currie, Janet, Wanchuan Lin, and Juanjuan Meng. 2014. "Addressing antibiotic abuse in China: An experimental audit study." *Journal of Development Economics*, 110: 39–51. Land and Property Rights.

Cutler, David M. 2020. "Reducing administrative costs in US health care." *The Hamilton Project Policy Proposal*, 9: 3–25.

Dafny, Leemore S. 2005. "How Do Hospitals Respond to Price Changes?" *American Economic Review*, 95(5): 1525–1547.

Dave, Dhaval, and Swati Mukerjee. 2011. "Mental health parity legislation, cost-sharing and substance-abuse treatment admissions." *Health Economics*, 20(2): 161–183.

Dechezleprêtre, Antoine, David Hémous, Morten Olsen, and Carlo Zanella. 2019. "Automating Labor: Evidence from Firm-Level Patent Data." *Available at SSRN 3508783*.

Deshpande, Manasi, and Yue Li. 2019. "Who Is Screened Out? Application Costs and the Targeting of Disability Programs." *American Economic Journal: Economic Policy*, 11(4): 213–48.

Dicks, Michael R. 2013. "A Short History of Veterinary Workforce Analyses." *Journal of the American Veterinary Medical Association*, 242(8): 1051–1060.

Dimitri, Carolyn, Anne Effland, and Neilson C Conklin. 2005. "The 20th century transformation of US agriculture and farm policy."

Dunn, Abe, Joshua D. Gottlieb, Adam Hale Shapiro, Daniel J. Sonnenstuhl, and Pietro Tebaldi. 2021. "A Denial a Day Keeps the Doctor Away." University of Chicago, mimeo. Available online at `https://users.nber.org/~jdgottl/BillingCostsPaper.pdf`.

Dunn, Abe, Joshua D. Gottlieb, Adam Hale Shapiro, Daniel J. Sonnenstuhl, and Pietro Tebaldi. forthcoming. "A Denial a Day Keeps the Doctor Away." *Quarterly Journal of Economics*.

Farronato, Chiara, Andrey Fradkin, Bradley Larsen, and Erik Brynjolfsson. 2020. "Consumer Protection in an Online World: An Analysis of Occupational Licensing." National Bureau of Economic Research Working Paper 26601.

FDA. 1975. "X Rays: Focusing on Patient Protection." *FDA consumer*, 9(5): 8—11.

Finck, Bruce Alan. 1974. "U.C.D. Law Review." *U.C.D. Law Review*, 7: 293.

Finkelstein, Amy. 2004. "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry." *The Quarterly Journal of Economics*, 119(2): 527–564.

Finkelstein, Amy, and Matthew J Notowidigdo. 2019. "Take-Up and Targeting: Experimental Evidence from SNAP*." *The Quarterly Journal of Economics*, 134(3): 1505–1556.

Friedell, Hymer L. 1971. "The Radiation Control for Health and Safety Act of 1968." *Radiology*, 99(3): 584–588. PMID: 5578706.

Friedman, Milton, and Simon Kuznets. 1945. *Income from Independent Professional Practice.* National Bureau of Economic Research, Inc.

Galasso, Alberto, and Hong Luo. 2021. "Risk-Mitigating Technologies: The Case of Radiation Diagnostic Devices." *Management Science*, 67(5): 3022–3040.

Galasso, Alberto, and Hong Luo. 2022. "When Does Product Liability Risk Chill Innovation? Evidence from Medical Implants." *American Economic Journal: Economic Policy*, 14(2): 366–401.

Garella, Paolo G., and Emmanuel Petrakis. 2008. "Minimum Quality Standards and Consumers' Information." *Economic Theory*, 36(2): 283–302.

Gaynor, Martin, Rodrigo Moreno-Serra, and Carol Propper. 2013. "Death by Market Power: Reform, Competition, and Patient Outcomes in the National Health Service." *American Economic Journal: Economic Policy*, 5(4): 134–166.

Goldin, Claudia, and Lawrence F. Katz. 2016. "A Most Egalitarian Profession: Pharmacy and the Evolution of a Family-Friendly Occupation." *Journal of Labor Economics*, 34(3): 705–746.

Goodman-Bacon, Andrew. 2021. "Difference-in-differences with variation in treatment timing." *Journal of Econometrics*, 225(2): 254–277. Themed Issue: Treatment Effect 1.

Grennan, Matthew, and Robert J. Town. 2020. "Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices." *American Economic Review*, 110(1): 120–61.

Grennan, Matthew, Charu Gupta, and Mara Lederman. 2020. "Spillovers Across Product Categories in the Medical Device Industry." *Available at SSRN 3266574*.

Griffith, Rachel, and Gareth Macartney. 2014. "Employment Protection Legislation, Multinational Firms, and Innovation." *The Review of Economics and Statistics*, 96(1): 135–150.

Gross, Daniel P. 2023. "The Hidden Costs of Securing Innovation: The Manifold Impacts of Compulsory Invention Secrecy." *Management Science*, 69(4): 2318–2338.

Gruber, Jonathan, and Maria Owings. 1996. "Physician Financial Incentives and Cesarean Section Delivery." *The RAND Journal of Economics*, 27(1): 99–123.

Haines, Michael, Fishback Price, and Paul Rhode. 2005. "Historical, Demographic, Economic, and Social Data: The United States, 1790-1970." *Inter-university Consortium for Political and Social Research*.

Haines, Michael, Fishback Price, and Paul Rhode. 2018. "United States Agriculture Data, 1840 - 2012." *Inter-university Consortium for Political and Social Research*.

Hale, Adeline B, and Arthur B Hale. 1978. *The medical and healthcare marketplace guide*. International Bio-medical Information Service.

Hall, Bronwyn H, Adam B Jaffe, and Manuel Trajtenberg. 2001. "The NBER Patent Citation Data File: Lessons, Insights and Methodological Tools." National Bureau of Economic Research Working Paper 8498.

Hamersma, Sarah, and Johanna Catherine Maclean. 2021. "Do expansions in adolescent access to public insurance affect the decisions of substance use disorder treatment providers?" *Journal of Health Economics*, 76: 102434.

Hardenbergh, John G. 1936. "Veterinary Service in the Control of Dairy Products." *American Journal of Public Health and the Nations Health*, 26(6): 597–605.

Harris, Matthew C., Yinan Liu, and Ian McCarthy. 2020. "Capacity constraints and time allocation in public health clinics." *Health Economics*, 29(3): 324–336.

Hemenway, H.B. 1916. *Essentials of Veterinary Law. Veterinary medicine series*, American journal of veterinary medicine.

Ho, Kate, and Robin S. Lee. 2017. "Insurer Competition in Health Care Markets." *Econometrica*, 85(2): 379–417.

Hornbeck, Richard. 2010. "BARBED WIRE: PROPERTY RIGHTS AND AGRICULTURAL DEVELOPMENT." *The Quarterly Journal of Economics*, 125(2): 767–810.

Hornbeck, Richard. 2012. "The Enduring Impact of the American Dust Bowl: Short- and Long-Run Adjustments to Environmental Catastrophe." *American Economic Review*, 102(4): 1477–1507.

Hornbeck, Richard, and Pinar Keskin. 2014. "The Historically Evolving Impact of the Ogallala Aquifer: Agricultural Adaptation to Groundwater and Drought." *American Economic Journal: Applied Economics*, 6(1): 190–219.

Hullova, Dusana, Paul Trott, and Christopher Don Simms. 2016. "Uncovering the Reciprocal Complementarity between Product and Process Innovation." *Research Policy*, 45(5): 929–940.

Johnson, Matthew S, Kurt J Lavetti, and Michael Lipsitz. 2023. "The Labor Market Effects of Legal Restrictions on Worker Mobility." National Bureau of Economic Research Working Paper 31929.

Jones, Christopher M., Melinda Campopiano, Grant Baldwin, and Elinore McCance-Katz. 2015. "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment." *American Journal of Public Health*, 105(8): e55–e63. PMID: 26066931.

Jones, Susan D. 2003. *Valuing animals: Veterinarians and their patients in modern America.* JHU Press.

Jones, Susan Dorothy. 1997. *Animal value, veterinary medicine, and the domestic animal economy in the United States, 1890-1930.* University of Pennsylvania.

Karlsson, Martin. 2007. "Quality Incentives for GPs in a Regulated Market." *Journal of Health Economics*, 26(4): 699–720.

Kessler, Daniel P, and Jeffrey J Geppert. 2005. "The Effects of Competition on Variation in the Quality and Cost of Medical Care." *Journal of Economics & Management Strategy*, 14(3): 575–589.

Kitchens, Carl, and Price Fishback. 2015. "Flip the Switch: The Impact of the Rural Electrification Administration 1935–1940." *The Journal of Economic History*, 75(4): 1161–1195.

Klein, Benjamin, and Keith B. Leffler. 1981. "The Role of Market Forces in Assuring Contractual Performance." *Journal of Political Economy*, 89(4): 615–641.

Kleiner, Morris M. 2000. "Occupational Licensing." *Journal of Economic Perspectives*, 14(4): 189–202.

Kleiner, Morris M., Allison Marier, Kyoung Won Park, and Coady Wing. 2016. "Relaxing Occupational Licensing Requirements: Analyzing Wages and Prices for a Medical Service." *The Journal of Law and Economics*, 59(2): 261–291.

Kleiner, Morris M., and Robert T. Kudrle. 2000. "Does Regulation Affect Economic Outcomes? the Case of Dentistry." *The Journal of Law Economics*, 43(2): 547–582.

Klerman, Daniel. 2011. "Personal jurisdiction and product liability." *S. Cal. L. Rev.*, 85: 1551.

Knowles, Matthew T. 2022. "How access to addictive drugs affects the supply of substance abuse treatment: Evidence from Medicare Part D." *Health Economics*, 31(8): 1649–1675.

Koch, Nicolas, Erasmus K.H.J. zu Ermgassen, Johanna Wehkamp, Francisco J.B. Oliveira Filho, and Gregor Schwerhoff. 2019. "Agricultural Productivity and Forest Conservation: Evidence from the Brazilian Amazon." *American Journal of Agricultural Economics*, 101(3): 919–940.

Kogan, Leonid, Dimitris Papanikolaou, Amit Seru, and Noah Stoffman. 2017. "Technological Innovation, Resource Allocation, and Growth*." *The Quarterly Journal of Economics*, 132(2): 665–712.

Krawczyk, Noa, Caroline E. Picher, Kenneth A. Feder, and Brendan Saloner. 2017. "Only One In Twenty Justice-Referred Adults In Specialty Treatment For Opioid Use Receive Methadone Or Buprenorphine." *Health Affairs*, 36(12): 2046–2053. PMID: 29200340.

Lamoreaux, Naomi R., and Kenneth L. Sokoloff. 2001. "Market Trade in Patents and the Rise of a Class of Specialized Inventors in the 19th-Century United States." *American Economic Review*, 91(2): 39–44.

Lamoreaux, Naomi R., Kenneth L. Sokoloff, and Dhanoos Sutthiphisal. 2008. "The Reorganization of Inventive Activity in the United States during the Early Twentieth Century." *Understanding Long-Run Economic Growth: Geography, Institutions, and the Knowledge Economy*, 235–274. University of Chicago Press.

Lange, Fabian, Alan L. Olmstead, and Paul W. Rhode. 2009. "The Impact of the Boll Weevil, 1892–1932." *The Journal of Economic History*, 69(3): 685–718.

Law, Marc T., and Sukkoo Kim. 2005. "Specialization and Regulation: The Rise of Professionals and the Emergence of Occupational Licensing Regulation." *The Journal of Economic History*, 65(3): 723–756.

Leland, Hayne E. 1979. "Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards." *Journal of Political Economy*, 87(6): 1328–1346.

Magerman, Tom, Bart Van Looy, Bart Baesens, and Koenraad Debackere. 2011. "Assessment of Latent Semantic Analysis (LSA) text mining algorithms for large scale mapping of patent and scientific publication documents." *FBE Research Report MSI_1114*.

Marco, Alan C, Amanda Myers, Stuart JH Graham, Paul D'Agostino, and Kirsten Apple. 2015. "The USPTO patent assignment dataset: Descriptions and analysis."

Maresova, Petra. 2023. "Impact of Regulatory Changes on Innovations in the Medical Device Industry: Comment on" Clinical Decision Support and New Regulatory Frameworks for Medical Devices: Are We Ready for It?-A Viewpoint Paper"." *International Journal of Health Policy and Management*, 12.

Marette, Stéphan. 2007. "Minimum Safety Standard, Consumers' Information and Competition." *Journal of Regulatory Economics*, 32: 259–285.

Markowitz, Sara, E. Kathleen Adams, Mary Jane Lewitt, and Anne L. Dunlop. 2017. "Competitive effects of scope of practice restrictions: Public health or public harm?" *Journal of Health Economics*, 55: 201–218.

Miravete, Eugenio J., and Jose C. Permoas. 2006. "Innovation Complementarity and Scale of Production." *The Journal of Industrial Economics*, 54(1): 1–29.

Moien, Mary. 1974. *Patient Charges in Short-stay Hospitals, United States, 1968-1970.* National Center for Health Statistics.

Newman, Mark EJ. 2014. "Prediction of highly cited papers." *Europhysics Letters*, 105(2): 28002.

Newman, M. E. J. 2009. "The first-mover advantage in scientific publication." *Europhysics Letters*, 86(6): 68001.

Nguyen, Thuy D, Kao-Ping Chua, Barbara Andraka-Christou, W David Bradford, and Kosali Simon. 2022. "Trends in buprenorphine coverage and prior authorization requirements in US commercial formularies, 2017-2021." Vol. 3, e221821–e221821, American Medical Association.

Nicholas, Tom. 2010. "The Role of Independent Invention in U.S. Technological Development, 1880–1930." *The Journal of Economic History*, 70(1): 57–82.

of State Governments, Council. 1952*a*. *Occupational Licensing Legislation in the States.* Council of State Governments.

of State Governments, Council. 1952*b*. *Occupational Licensing Legislation in the States. HeinOnline: Subject compilation of state laws*, Council of State Governments.

Olmstead, Alan L., and Paul W. Rhode. 2001. "Reshaping the Landscape: The Impact and Diffusion of the Tractor in American Agriculture, 1910-1960." *The Journal of Economic History*, 61(3): 663–698.

Olmstead, Alan L., and Paul W. Rhode. 2004. "An Impossible Undertaking: The Eradication of Bovine Tuberculosis in the United States." *The Journal of Economic History*, 64(3): 734–772.

Pacula, Rosalie L., David Powell, Paul Heaton, and Eric L. Sevigny. 2015. "Assessing the Effects of Medical Marijuana Laws on Marijuana Use: The Devil is in the Details." *Journal of Policy Analysis and Management*, 34(1): 7–31.

Pakes, Ariel, and Zvi Griliches. 1980. "Patents and RD at the firm level: A first report." *Economics Letters*, 5(4): 377–381.

Pelc, Norbert J. 2014. "Recent and future directions in CT imaging." *Annals of biomedical engineering*, 42: 260–268.

Peltzman, Sam. 1973. "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments." *Journal of Political Economy*, 81(5): 1049–1091.

Petralia, Sergio, Pierre-Alexandre Balland, and David Rigby. 2016. "HistPat Dataset."

Pietzsch, Jan B, Marta G Zanchi, and John H Linehan. 2012. "Medical device innovators and the 510 (k) regulatory pathway: implications of a survey-based assessment of industry experience."

Pietzsch, Jan B., Marta G. Zanchi, and John H. Linehan. 2013. "Medical Device Innovators and the 510(k) Regulatory Pathway: Implications of a Survey-Based Assessment of Industry Experience—Part 2: Medical Device Ecosystem and Policy." *Journal of Medical Devices*, 7(2): 021003.

Popovici, Ioana, Johanna Catherine Maclean, and Michael T French. 2017. "Health Insurance and Traffic Fatalities: The Effects of Substance Use Disorder Parity Laws." National Bureau of Economic Research Working Paper 23388.

Powell, David, Rosalie Liccardo Pacula, and Mireille Jacobson. 2018. "Do medical marijuana laws reduce addictions and deaths related to pain killers?" *Journal of Health Economics*, 58: 29–42.

Rogers, Parker. 2023. "Regulating the Innovators: Approval Costs and Innovation in Medical Technologies." *Working Paper*.

Ronnen, Uri. 1991. "Minimum Quality Standards, Fixed Costs, and Competition." *The RAND Journal of Economics*, 22(4): 490–504.

Sarada, Sarada, Michael J. Andrews, and Nicolas L. Ziebarth. 2019. "Changes in the demographics of American inventors, 1870–1940." *Explorations in Economic History*, 74: 101275.

Schmookler, Jacob. 1966. *Invention and Economic Growth.* Cambridge, MA and London, England:Harvard University Press.

Shapiro, Adam, and Daniel Wilson. 2019. "Taking the Fed at its Word: Direct Estimation of Central Bank Objectives using Text Analytics." *Federal Reserve Bank of San Francisco, Working Paper Series*, 01–67.

Shapiro, Adam Hale, Moritz Sudhof, and Daniel J. Wilson. 2022. "Measuring news sentiment." *Journal of Econometrics*, 228(2): 221–243.

Shapiro, Carl. 1986. "Investment, Moral Hazard, and Occupational Licensing." *The Review of Economic Studies*, 53(5): 843–862.

Shepard, Lawrence. 1978. "Licensing Restrictions and the Cost of Dental Care." *The Journal of Law Economics*, 21(1): 187–201.

Smith, Donald F. 2013. "Lessons of history in veterinary medicine." *Journal of Veterinary Medical Education*, 40(1): 2–11.

Stern, Ariel Dora. 2017. "Innovation under Regulatory Uncertainty: Evidence from Medical Technology." *Journal of Public Economics*, 145: 181–200.

Stigler, George J. 1971. "The Theory of Economic Regulation." *The Bell Journal of Economics and Management Science*, 2(1): 3–21.

Sun, Liyang, and Sarah Abraham. 2021. "Estimating dynamic treatment effects in event studies with heterogeneous treatment effects." *Journal of Econometrics*, 225(2): 175–199. Themed Issue: Treatment Effect 1.

Tran, Vivi. 2006. "The Radiation Control for Health and Safety Act of 1968: History, Accomplishments, and Future." *working paper*.

Turner, Ani, George Miller, and Samantha Clark. 2019. "Impacts of Prior Authorization on Health Care Costs and Quality." *Center for Value in Health Care*.

Udall, Morris K. 1984. *Federal Policies and the Medical Devices Industry.* US Government Printing Office.

United States. Department of Health, Education, and Welfare. 1973. *Radiation Control for Health and Safety: Message from the President of the United States Transmitting the 1972 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968.* U.S. Government Printing Office.

Viscusi, W. Kip, and Michael J. Moore. 1993. "Product Liability, Research and Development, and Innovation." *Journal of Political Economy*, 101(1): 161–184.

Weber, E. 2020. "Spotlight on legislation limiting the use of prior authorization for substance use disorder services and medications." *Legal Action Center. May.*

Wooldridge, Jeffrey M. 2023. "Simple approaches to nonlinear difference-in-differences with panel data." *The Econometrics Journal*, 26(3): C31–C66.