Unintended Consequences of Reimbursement Schemes in Health Care

by

Luca Bertuzzi

Department of Economics
Duke University

Date: ______________________________
Approved:

____
Allan Collard-Wexler, Supervisor

____
David B. Ridley

____
James W. Roberts

____
Ryan C. McDevitt

Dissertation submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy
in the Department of Economics
in the Graduate School of
Duke University

2023

<u>ABSTRACT</u>

Unintended Consequences of Reimbursement Schemes in Health Care

by

Luca Bertuzzi

Department of Economics
Duke University

Date: ______________________________
Approved:

____
Allan Collard-Wexler, Supervisor

____
David B. Ridley

____
James W. Roberts

____
Ryan C. McDevitt

An abstract of a dissertation submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy
in the Department of Economics
in the Graduate School of
Duke University

2023

Abstract

The three essays in this dissertation explore the impact of various reimbursement structures and chain ownership in the context of U.S. health care.

In the first essay, I study how the moral hazard created by Medicare part D reimbursement structure affects coverage choices made by participating insurers. Using data on formularies for the universe of U.S. health insurance plans, I find that after rival entry non-Medicare plans reduce coverage of reference products by 20-25% more than Medicare plans. If Medicare Part D plans emulated non-Medicare plans, the federal government and patients could save around 6% annually. Finally, a 2018 policy change had only a small effect on the take-up of low-cost entrants.

In the second essay, co-authored with Paul J. Eliason, Benjamin Heebsh, Riley J. League, Ryan C. McDevitt and James W. Roberts, we study how health insurers game pay-for-performance reimbursement schemes. We use annual variation in Medicare's criteria for its Quality Incentive Program in dialysis to distinguish strategic patient dropping from the provision of higher-quality care. We find that patients whose characteristics would trigger penalties are 40% more likely to switch facilities, while along some dimensions facilities exert more effort to provide better care.

In the third essay, co-authored with Paul J. Eliason, Ryan C. McDevitt, James W. Roberts, Vincenzo Villani, Gabriel Butler, Nicole DePasquale, Christine Park and Lisa M. McElroy, we try to identify sociodemographic and facility characteristics associated with not receiving transplant information. We find that non-informed patients are more likely to be older, female, and on Medicare. Patients at chain facilities and independent facilities acquired by chains are more likely to receive information, but this does not translate into higher waitlist or transplantation rates. The chains' objective of profit maximization may bring facilities to disregard patient outcomes.

Contents

List of Tables

List of Figures

Acknowledgements

I am extremely greatful to my my main advisor Allan Collard-Wexler as well as members of my comittee David B. Ridley, James W. Roberts and Ryan C. McDevitt for their guidance and patience through my years at Duke. I am also thankful to Luca Maini for providing invaluable comments to strengthen my work. I am greatful to my coauthors Paul J. Eliason, Benjamin Heebsh, Riley J. League, Vincenzo Villani, Gabriel Butler, Nicole DePasquale, Christine Park and Lisa M. McElroy who I have worked with to produce the papers chapter 3 and 4 are based on. Finally, I want to thank my family for their love and support during my journey through graduate school.

Chapter 1

Introduction

United States healthcare spending has increased substantially in the past few years, from \$1.4 to \$4.3 trillion. Moreover, it has gone from 13.3 to 18.3 as a share of the nation's GDP[1]. Among the reasons for this increase in spending it is worth mentioning an increase in the share of the U.S. population age 65, the introduction of new, innovative treatments and technologies, as well as system complexity and consolidation[2].

In order to ensure access in light of increasing costs, multiple federally and state-administered programs have been introduced in the US. For example, in 2006, the federal government implemented a program that provides drug benefits to people 65 or older through approved commercial insurers (Medicare part D). The introduction of these programs has made health insurance provision fragmented into different segments (Dickstein et al., 2021), whose cost-sharing structures can vary substantially. Moreover, due to rising drug costs, health insurance plans are increasingly relying on the use of formularies to achieve cost containment goals. Mirroring in-network vs. out-network provider systems, formularies are lists of drugs that insurance plans decide to cover and make available for enrollees. Insurance plans can take advantage of the strong patient steering effects generated by these tools, and adjust the formularies to maximize their profits in light of the cost-sharing structures they face (Lavetti and Simon, 2018; Geruso et al., 2019). This means that formulary coverage choices can vary considerably across segments, with significant monetary and health consequences for patients and the government.

In Chapter 2, I study how moral hazard affects the coverage of reference biological drugs once a biosimilar becomes available. By employing a triple difference approach, I find that

[1]Centers for Medicare & Medicaid Services

[2]Peter G. Peterson Foundation

commercial plans are 20-25% less likely to cover a reference biological drug than Medicare plans after entry. Back-of-the-envelope calculations imply that Medicare patients and the federal government could save $7-39 million and $107-624 million respectively if Medicare plans reacted as aggressively as commercial plans to biosimilars' entry. The savings correspond to a reduction of about 2-10% of spending on biological drugs with a biosimilar available. I also find that Medicare plans are almost twice less likely to cover biosimilars relative to commercial plans after entry. These results are consistent with increasing evidence of sluggish take-up of biosimilars in Medicare part D (Socal et al., 2021). Moreover, I study the impact of a policy change in 2018 aimed at increasing biosimilars' penetration in Medicare part D. The policy equalized mandatory manufacturer discounts for biosimilars and reference biologics. I find only weak evidence of increased biosimilars coverage and reduced reference biologics coverage following the policy change. I also discuss a policy change recently implemented through the Build Back Better Act (2022), which comes with a higher potential for convergence in the take-up of biosimilars across Medicare and commercial plans.

Cost containment can be achieved not only through the implementation of drug formularies. In the past, healthcare providers were typically provided a flat rate for each medical service provided (fee-for-service). However, due to rising healthcare costs, public and private payers have increasingly tried to implement pay-for-performance schemes (James et al., 2012), which should avoid distortionary incentives for medical overuse from fee-for-service schemes.

For example, starting in 2011, Medicare provided dialysis facilities a single prospective payment (Zuber et al., 2012), which bundles dialysis services and all injectable drugs and biologics used in the treatment of ESRD (End stage renal disease). The introduction of a single prospective payment raised concerns that providers may cut costs and provide lower-quality care, so the legislation also mandated the development of the QIP, which links payments to performance by penalizing dialysis facilities that provide low-quality care, as determined each year by Medicare in its facility quality score. Although intended to give providers an incentive to exert more effort in caring for patients, pay-for-performance reimbursement schemes may also spur providers to avoid treating patients who would hurt their overall performance score.

Chapter 3 is based on joint work with Paul J. Eliason, Benjamin Heebsh, Riley J. League, Ryan C. McDevitt and James W. Roberts, and studies how dialysis facilities game the newly introduced payment scheme. To uncover whether facilities act strategically in this way, we use our claims data to classify patients as penalty-inducing when their diagnostic measures would lower their facility's QIP score in a given year. We then show that when a patient becomes penalty-inducing due to Medicare's annual change in QIP criteria, the probability that they switch facilities rises by 40%. We also find that penalty inducing patients are 37% more likely to switch facilities after being hospitalized. Because these penalty-inducing patients switch to lower-quality facilities in terms of mortality and hospitalization rates, we interpret the facility change as an involuntary one. Although the elevated rate of switching among penalty-inducing patients suggests some facilities respond to the QIP by strategically avoiding patients who might cause their reimbursements to fall, others may respond to the incentives created by the QIP by improving their quality of care, in keeping with the program's original intention. Two performance measures in particular illustrate this phenomenon. Dialysis facilities must regularly track the amount of toxins they clear from a patient's blood, with adequacy measured by either the patient's urea reduction ratio (URR) or Kt/V. These two measures are closely, but not perfectly, related. Initially, the QIP used URR as its performance measure for dialysis adequacy, but then switched to Kt/V in the program's fourth year. We use this abrupt change in metrics to cleanly identify facilities' strategic responses to performance pay. Patients who have good URR but bad Kt/V are more likely to switch facilities after QIP change its criteria (33%). In addition to dropping patients, however, facilities could also improve their adequacy scores by increasing the amount of time patients spend being dialyzed each session, although doing so comes with the opportunity cost of not using the station to treat another patient due to the fixed per-session payments from Medicare that do not adjust for longer run times. We show that patients with bad Kt/V who remain at the same facility after QIP begins penalizing low Kt/V scores start receiving longer run times, an increase in real effort.

Another factor which can contribute to suboptimal quality of care and patient outcomes is the ownership structure of healthcare providers. In the context of dialysis, two for-profit chains, DaVita and Fresenius, control well over 60% of facilities(United States Renal Data System, 2014; Baker, 2019; Eliason et al., 2020b). All patients starting dialysis should be informed of kidney transplant as a renal replacement therapy option, as required by the Centers for Medicare and Medicaid Services Form CMS-2728. Prior research has shown disparities in provision of this information (Finkelstein, 2008; Gander et al., 2018; Myaskovsky et al., 2012; Weng et al., 2005), but little emphasis has been put on facility characteristics and financial motives.

Chapter 4 is based on joint work with Paul J. Eliason, Ryan C. McDevitt, James W. Roberts, Vincenzo Villani, Gabriel Butler, Nicole DePasquale, Christine Park and Lisa M. McElroy, and aims to identify sociodemographic risk factors and dialysis facility characteristics associated with not receiving transplant information at the time of dialysis initiation, as well as the association of receiving transplant information with waitlist and transplant outcomes. We find that non-informed patients are more likely to be older, female, white, and on Medicare. Patients informed about transplant have a shorter time between end-stage renal disease onset and addition to the waitlist; they also spend a shorter time on the waitlist before receiving a transplant. Patients at chain facilities are more likely to receive information, but this does not translate into higher waitlist or transplantation rates. Patients at independent facilities acquired by chains are also more likely to be informed but less likely to be added to the waitlist post acquisition. This result is consistent with the fact that chain ownership comes with firm-wide standards (e.g., operation manuals that dictate treatment protocols) but also causes waitlist and transplant rates to fall. The chains' objective of profit maximization may bring facilities to disregard patient outcomes for higher reimbursements.

Chapter 2

The role of cost-sharing structures in the take-up of biosimilars

2.1 Introduction

Despite being a limited share of overall healthcare spending, drug spending has increased substantially in the past few years, from \$122 billion in 2000 to \$348 billion in 2020[1], with most of the increase due to new product entry (Hernandez et al., 2019). A good example of expensive treatments which were recently launched is given by HCV antivirals, which are highly efficacious Hepatitis C medications that can reach a list price of \$94,500 for a single course of treatment.

Due to rising drug costs, health insurance plans are increasingly relying on the use of formularies to achieve cost containment goals. Mirroring in-network vs. out-network provider systems, formularies are lists of drugs that insurance plans decide to cover and make available for enrollees. Figure 2.1 provides an example of a formulary for a major health plan in the US. For each category, insurance plans define drugs that are excluded and drugs that are included. Typically, an enrollee would have to pay the full list price charged by the manufacturer for an excluded drug. Instead, if a product is included, she would only have to pay a small share of the list price in the form of copayment (fixed amount) or coinsurance (% amount). Insurance plans can take advantage of the strong patient steering effects generated by this reimbursement structure.

[1]Peter G. Peterson Foundation

Drug Class	Excluded Medications	Preferred Alternatives
HEPATITIS Hepatitis C	LEDIPASVIR/SOFOSBUVIR, MAVYRET, SOFOSBUVIR/VELPATASVIR, SOVALDI	EPCLUSA, HARVONI, VOSEVI, ZEPATIER

Figure 2.1: Formulary structure for a major insurance plan

Moreover, to ensure access in light of increasing costs, multiple federally and state-administered programs have been introduced in the US. For example, in 2006, the federal government implemented a program that provides drug benefits to people 65 or older through approved private insurers (Medicare part D[2]). In some cases, the federal government, in addition to patients and the Medicare program itself, pays for the cost of prescription drugs. This raises a question: Are the cost-sharing structures of Medicare part D plans (Medicare plans henceforth) and non-Medicare commercial employer-sponsored plans (commercial plans henceforth) similar? As it turns out, they are not. In table 2.1, I compare the cost-sharing structures for two drugs: Crestor, which is a relatively "cheap" drug used to reduce cholesterol in the blood, with an annual cost of $2,600; and Harvoni, which is a relatively "expensive" drug used to treat Hepatitis C, with an annual cost of $94,500. For Crestor, the cost-sharing structures are very similar between Medicare and commercial plans. The latter are slightly more generous[3], but they both pay for most of the cost of the drug, leaving patients with a relatively small amount to pay out-of-pocket. For Harvoni, things appear quite different. While commercial plans pay for most of the cost of the drug, Medicare plans and patients pay a relatively small share of the overall cost. Above a certain spending threshold per patient ($7,050 in out-of-pocket spending in 2022[4]), the government provides very generous subsidies, called catastrophic phase subsidies. These subsidies generate a severe moral hazard issue on the part of plans when a cheaper alternative becomes

[2]https://www.medicare.gov/drug-coverage-part-d

[3]https://www.kff.org/report-section/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016-findings

[4]https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/

available. If a prescription for Crestor were filled with a product discounted by 30% off the list price, Medicare and commercial plans would generate similar savings. Instead, if a prescription for Harvoni were filled with a product discounted by 30% off the list price, Medicare plans would generate much lower savings than commercial plans. This moral hazard issue implies that Medicare plans may not have enough incentives to steer patients toward the cheaper alternative, particularly if the reference drug manufacturer[5] provides sizable discounts paid retrospectively to plans (i.e., rebates).

Table 2.1: Differences in cost-sharing between Medicare and commercial plans

	"Cheap" Drug		"Expensive" drug	
	Medicare	Commercial	Medicare	Commercial
Patient	\$420 (15.9%)	\$348 (13.4%)	\$7,213 (7.6%)	\$448 (0.5%)
Plan	\$2,220 (84.1%)	\$ 2,252 (86.6%)	\$15,888 (16.8%)	\$94,052 (99.5%)
Government	0	0	\$69,330 (73.4%)	0
Savings[a]	\$656	\$675	\$4,763	\$28,208

[a]Plan savings from a prescription filled with a drug 30% cheaper than the reference drug.

Moral hazard in Medicare part D is becoming increasingly important for two reasons:

- Catastrophic phase subsidies have increased substantially both in absolute and relative terms (as a share of total government transfers to plans) in the past years, according to CMS (see Figure 2.2)

- A considerable portion of catastrophic phase subsidies covers the cost of biological drugs, which are starting to face the competitive pressure of cheaper alternatives (i.e., biosimilars). A biosimilar is a biological drug that is highly similar to a reference product across several dimensions (e.g., purity) and does not exhibit clinically meaningful differences relative to a reference product[6].

[5]The reference drug is the product that the cheaper alternative tries to imitate and compete with. In table 1, the reference drugs are Crestor and Harvoni

[6]https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

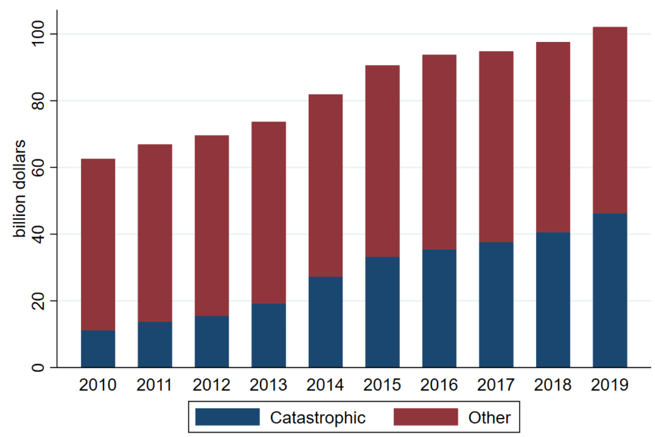

Figure 2.2: Evolution of federal subsidies to Medicare part D plans

In this article, I study how moral hazard affects the coverage of reference biological drugs once a biosimilar becomes available. By employing a triple difference approach, I find that commercial plans are 22.5% less likely to cover a reference biological drug than Medicare plans after entry. Back-of-the-envelope calculations imply that Medicare patients and the federal government could save $7-39 million and $107-624 million respectively if Medicare plans reacted as aggressively as commercial plans to biosimilars' entry. The savings correspond to a reduction of about 2-10% of spending on biological drugs with a biosimilar available. These results are consistent with increasing evidence of sluggish take-up of biosimilars in Medicare part D (Socal et al., 2021). Since biosimilars do not benefit from mandatory substitution laws (contrary to generics), they must gain space in formularies to compete effectively against reference biological products. However, I find that Medicare plans are almost twice less likely to cover biosimilars relative to commercial plans after entry.

Moreover, I study the impact of a policy change in 2018 aimed at increasing biosimilars' penetration in Medicare part D. Before the policy change, reference biologics manufacturers were required to provide mandatory discounts to insurance plans, while biosimilars manufacturers were not required to do so. The new policy equalized the requirements for these products. I find only weak evidence of increased biosimilars coverage and reduced reference biologics coverage following the policy change. One of the shortcomings of the policy change is that it did not substantially alter the cost-sharing structure in the program, which is the primary source of moral hazard. I also discuss a policy change recently implemented through the Build Back Better Act, which was signed into law on August 16 of this year. The law radically changes the reimbursement structure of Medicare plans, suggesting a higher potential for convergence in the take-up of biosimilars across Medicare and commercial plans. However, the law will come into effect only in 2025.

This study contributes to an expanding literature that analyzes the consequences of biosimilars' advent. Multiple papers in the medical literature have highlighted the benefits of biosimilars (see Braun and Kudrin, 2016; Jørgensen et al., 2017; Cohen et al., 2018). Other papers have focused on the limits of the current regulation of biologics, highlighting the failure of biosimilars to gain market share and the absence of a list price response by reference biologics (see Atteberry et al., 2019; Zhai et al., 2019; Trusheim et al., 2019). Extensive clinical testing requirements and high fixed costs from manufacturing are some of the reasons which may explain sluggish biosimilars take-up (Grabowski et al., 2007). Some studies have empirically tried to assess the take-up of biosimilars in the European (Scott Morton et al., 2018) and US markets (Maini et al., 2021). While procurement mechanisms across countries represent an important predictor of penetration, the latter paper proposes a theoretical model based on perceived quality differences that can explain differences in outcomes across reference biologics. In this study, I expand on previous results by documenting differences in the take-up of biosimilars across market segments in the US and by proposing differences in cost-sharing structures as a contributing factor to their slow adoption.

This paper also contributes to a growing literature on competition in pharmaceutical markets and formulary design. Some papers have focused on estimating rebates (generally secret information between manufacturers and PBMs/insurers) through moment inequalities (Hong, 2015; Olssen and Demirer, 2019). Other papers have focused on estimating the benefits of PBM contracting relative to costs introduced by an intermediary with an incentive to extract surplus (Feng and Maini, 2019; Ho and Lee, 2022). Moreover, there is growing literature on the strategic design of formularies (Geruso et al., 2019; Lavetti and Simon, 2018). The latter papers focus mainly on how insurance plans can design formularies to induce more financially desirable patients to enroll. Instead, my study analyzes how insurance plans choose drugs to include in their formularies based on different cost-sharing structures across market segments.

2.2 Background

2.2.1 Formularies

Formularies have grown in importance over the past three decades as drug-selection and cost-control tools[7]. Formularies are lists of drug products covered by insurance plans that steer patients towards the desired drugs by dividing medications into two to five tiers, each with a different level of patient cost-sharing.

Formularies convey substantial leverage to purchasers in negotiations with manufacturers. In the past years, insurers (or entities managing formularies on their behalf, called Pharmacy Benefit Managers) have increasingly relied on formulary exclusions to negotiate better prices with manufacturers and achieve higher cost savings[8] (See Figure 2.3). Formulary exclusions began in 2014. Since then, the number of drugs excluded from the formularies of the three major PBMs has grown substantially. This trend suggests that drug manufacturers need to gain access to formularies to effectively compete with each other and make profits, making drug coverage a good proxy for the intensity of competition in the pharmaceutical market.

[7]https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/

[8]https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html

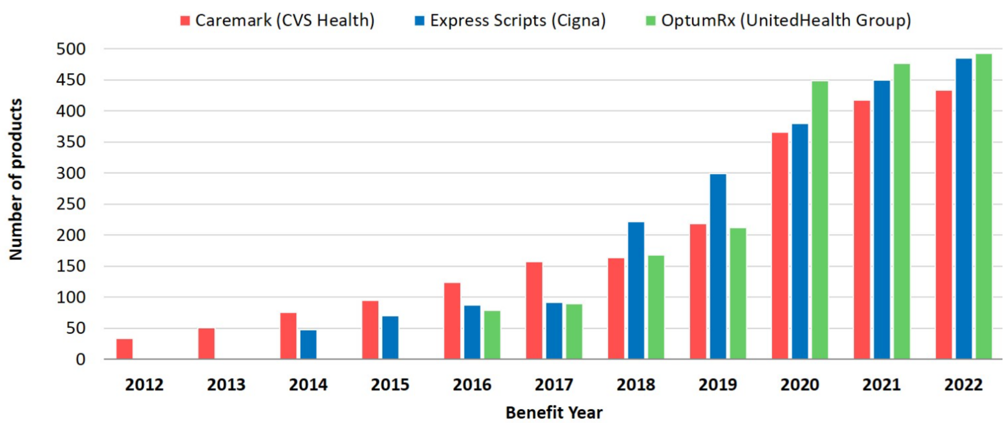

Figure 2.3: Evolution in the number of excluded drugs by top insurers/PBMs

2.2.2 Biologics and Biosimilars

Biological drugs or biologics are complex and large molecules isolated from a variety of natural sources. Examples of biological drugs include insulin, oncology drugs, and monoclonal antibodies. Since biologics cannot be reproduced precisely, they are fundamentally different from more classic, small-molecule products, which are often perfectly reproduced as non-branded generics once the original drug patent expires. However, it has recently become possible to generate a biosimilar version of a biological drug that is very similar to the reference product but may carry modest differences associated with the complexity of the production process[9].

Most existing legislation managing drug competition does not apply to biologics, due to their complex nature and impossibility of perfect replication. For example, generic drugs do not need to provide clinical trial data for approval. However, biosimilar drugs cannot apply through a simplified[10] process, and, until recently, had to submit data as entirely new drugs for approval. The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 attempted to address these issues by decreasing the burden that biosimilar manufacturers bear in order to gain approval, which is now dependant on submission of data exhibiting

[9] https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

[10] https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

that the drug is greatly similar and clinically equivalent to the reference product.

Although the BPCI Act makes it easier for biosimilars to come to the market, they still face 3 significant barriers to entry. First, the cost of developing a biosimilar is much higher than the cost of developing a generic (see Grabowski et al., 2016). Second, biosimilars suffer from a much higher risk of litigation, since biologics are typically protected by more patents than small-molecule products. Third, biosimilars do not benefit from regulation such as mandatory substitution laws, which apply to generic products.

2.2.3 Cost-sharing structures across market segments

Medicare part D plans

Medicare Part D is an optional United States federal government program with the objective of helping citizens who are 65 or older to pay for prescription drugs. Part D was enacted as part of the Medicare Modernization Act (2003) and became operational on January 1, 2006. Under the program, drug benefits are provided by private insurance plans who typically pay most of the cost for prescriptions filled by their enrollees, unless spending triggers the catastrophic phase of coverage. The Part D program runs both as a stand-alone benefit and as an addition to the Medicare Advantage program; Medicare Advantage plans operate like commercial insurance policies as they cover a comprehensive set of medical services.

Part D plans rely on tools used extensively by private plans, such as monthly premiums paid by patients. There is usually a deductible, and then enrollees pay a fraction of the cost of their medications. Plans adopt formularies to steer patients to the desired drugs which are placed in tiers that with lower patient cost-sharing amounts.

Table 2.2 provides a sketch of Medicare part D's current standard benefit. Notably, beneficiary spending is supposed to represent 25 percent of drug costs, with the plan covering 75 percent. Importantly, there are catastrophic coverage clauses for beneficiaries with considerable out-of-pocket expenses (above $7,050 in 2022). During the catastrophic benefit phase, enrollees pay 5 percent of the cost of prescriptions. Plans bear only 15 percent of the cost instead.

Table 2.2: Medicare part D current standard benefit

	Government	Plan	Member	Manufacturer
Deductible	0%	0%	100%	0%
Initial Coverage	0%	75%	25%	0%
Coverage gap	0%	5%	25%	70%
Catastrophic	80%	15%	5%	0%

Initially, the program included a gap between the initial coverage and catastrophic coverage, commonly known as the donut hole. When the Affordable Care Act passed in 2010, it included provisions for gradually shrinking the coverage gap each year. Members once paid the full costs in the gap, while now their share of costs is only 25%.

Commercial plans

Commercial health insurance is the most frequent type of health insurance in the United States. It covers almost 2 out of 3 Americans, who commonly receive coverage through their employer.

Most employer-sponsored plans, along with most plans sold on the individual market, are comprehensive in the sense that they cover a wide variety of healthcare services and bear most of their cost. They are typically governed by state and federal requirements, among which the ones achieved by the Patient Protection and Affordable Care Act (ACA).

Employers typically require employees to pay a portion of the health plan premium, which is deducted from employees' paychecks. Moreover, employees need to share costs with employers at the time of service in the form of copayments, coinsurance rates and/or deductibles. Despite this, employers face a very high share of the healthcare costs borne by employees. In fact, employer sponsored-plans cover almost ten percentage points more of the cost of prescription drugs than they did ten years ago[11].

[11] https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-

2.3 Data

To evaluate the effect of biosimilar entry, I create a dataset including formulary placement, prices and Medicare spending for biological drugs. I do so by combining three different data sources.

The first data source comes from Managed Markets Insight and Technology (MMIT), a consulting firm that provides detailed information on formulary coverage for about 300 drugs from 2012 to 2020 at the drug-plan-quarter level. The data cover almost every health insurer in the US, spanning commercial insurance, Medicare, Medicaid, and the ACA health exchanges, reaching more than 300 million covered lives by the end of the study period (see Figure 2.4). As a point of comparison, the Kaiser Family Foundation reported an enrollment of 45.3 million patients in Medicare plans in 2019[12]. Instead, the sum of covered lives in the MMIT data results in a total enrollment of 42.8 million patients in the same year.

For each drug, the formulary data indicate if the drug is included and the tier in which it appears for that particular plan. Tier design varies across plans, but the majority of formularies includes at least two tiers. Drugs in the preferred tier have lower copays, while products in non-preferred tiers have higher associated copays or coinsurance rates. MMIT not only reports the original tiers on which drugs are placed, but also tries to harmonize tiering across different plans[13]. Additional information, such as prior authorization and step therapy, are also noted[14]. These data carry a limitation, which is that they do not include the monetary cost-sharing amounts associated with each tier. For my purposes this data

cost-sharing-for-families-with-large-employer-coverage/#Total20family health spending for large group enrollees, 2003-2018

[12]https://www.kff.org/other/state-indicator/total-population

[13]Plans can vary substantially by the tiering structure implemented in their formularies. MMIT takes these structures and synthesizes them into a universal structure. The unified tiers are created by internal specialists

[14]Prior authorization requires doctors to send a form to the insurance plan to confirm a prescription. Step therapy prevents patients from taking a drug before an alternative medication has been prescribed.

coding is acceptable, as it aligns with my research goal, which is to evaluate the inclusion and preferential placement of various drugs within plans, not monetary differences in cost-sharing across plans. The data also report the pharmacy benefit manager (PBM) working on behalf of each plan, the geographic coverage of the plan, and the number of lives covered. The number of lives covered allows me to compute the share of patients with access to each drug for each market segment (e.g., Medicare). It must be noted that in 2019 the top 10 plans represented 39% of the total enrollment in Medicare, which suggests that a handful of large plans will drive the results.

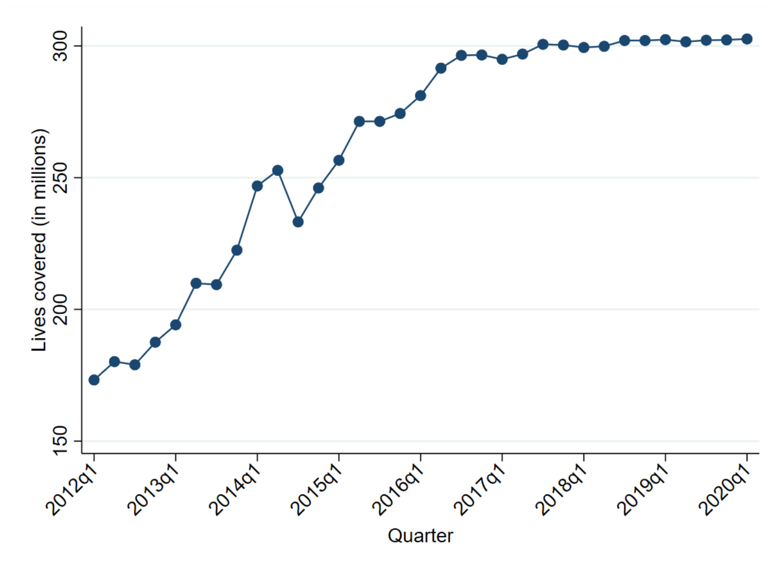

Figure 2.4: MMIT Lives covered

The second data source comes from SSR Health. The SSR Health database provides list prices, net prices, volume sales and net sales for roughly 1,000 brand drugs from 2007Q1 to 2020Q2. SSR Health collects net sales on a quarterly basis from SEC filings of publicly traded firms. In these filings, firms disclose net sales by drugs for their highest-selling drugs, which account for all discounts and rebates. In 2018, SSR Health covered about 90 percent of US invoice sales and about 80 percent of US net sales[15]. The main brand

[15] These numbers are based on a comparison of total spending in the SSR Health data against figures in a 2019 IQVIA report.

drugs not covered by the data are those belonging to privately-owned companies; these companies are not required to file public disclosures on net sales, so no data are available for them. However, the vast majority of pharmaceutical companies are publicly traded, so this restriction should not affect the interpretation of my results. SSR Health combines net sales data with invoice and volume sales from Symphony Health, a company that reports sales data from the pharmaceutical industry. SSR Health divides reported net sales by units sold to estimate net prices. This estimate reflects the manufacturer's average revenue for each unit of a drug sold. One drawback of this measure is that it includes coupons offered to patients (see Dafny et al., 2017).

Finally, I use publicly available Medicare part D data on spending by drug[16]. The Medicare Part D by Drug dataset presents information on spending for drugs prescribed to Medicare beneficiaries enrolled in Part D by physicians and other healthcare providers. Drugs prescribed in the Medicare Part D program are drugs patients generally administer themselves. Spending metrics are based on the gross drug cost, which includes ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees. These figures include amounts paid by the Medicare Part D plan and beneficiary payments. However, they do not reflect manufacturers' rebates, as such information cannot be publicly disclosed. These data can be used to obtain a proxy of Medicare Part D spending on biosimilars and their reference biological drugs. Moreover, I obtain biosimilar approval and launch dates from the FDA's website and announcements by pharmaceutical companies. The FDA's website also includes a complete list of biological drugs used to construct treated and control groups of drugs.

[16]https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug

2.4 Empirical Analysis

In this section, I exploit the staggered introduction of biosimilars to identify the effect of moral hazard on coverage choices made by health insurance plans (see Table 2.3 for the timing of first biosimilar entry for each reference drug).

Table 2.3: Timing of entry

Neupogen	Sep 2015
Remicade	Nov 2016
Lantus	Dec 2016
Humalog	Apr 2018
Neulasta	Jul 2018
Epogen	Nov 2018
Herceptin	Jul 2019
Avastin	Jul 2019
Rituxan	Nov 2019

I compare insurance plans belonging to the Medicare part D and the commercial employer-sponsored market segments, as these two segments present very different levels of exposure to moral hazard for biological drugs. As measures of formulary coverage, I compute for each drug and segment pair the share of patients whose plan offers any coverage (extensive margin), preferred coverage (intensive margin) and unrestricted coverage.

The entry of biosimilars over time allows separating drugs into two groups: drugs for which a biosimilar becomes available (treated group) and therefore face some degree of competition, and drugs for which a biosimilar is not launched (control group). In terms of the composition of these groups, I explore different choices. My preferred choice is to compare drugs for which a biosimilar is launched to drugs for which a biosimilar is approved by the FDA but not launched (11 drugs in total). The intuition for this preferred choice is that drugs for which a manufacturer seeked biosimilar approval should be similarly financially desirable. Note that almost every treated drug was subject to litigation by the incumbent (which was unsuccessful), which means that control drugs are not disproportionately affected by litigation relative to treated drugs (Van de Wiele et al., 2021, Lee et al., 2021, Sarpatwari et al., 2019).

I will also consider two other choices which serve as robustness checks. In the first robustness check, I compare drugs for which a biosimilar is launched to all other biological drugs (85 drugs in total). In the second one, I compare drugs for which a biosimilar is launched to all other biological drugs after excluding drugs that belong to Medicare part D protected drug classes (40 drugs in total). Table 2.4 provides the composition of treated and control groups of drugs under alternative choices.

Table 2.4: Composition of treated and control groups of drugs

	N Treated drugs	Control drugs	Total
Preferred specification	9	2	11
Robustness check - all biologics	9	76	85
Robustness check - protected drugs	5	35	40

2.4.1 Triple difference design and staggered DiD

I consider three empirical specifications. The first one is a triple difference design which generates three types of differences:

1. First difference: outcome of interest across biological drugs which witness biosimilars' entry, before and after entry
2. Second difference: outcome of interest across biological drugs for which a biosimilar is approved but not launched, before and after entry
3. Third difference: comparing the double difference generated by 1. and 2. between commercial and Medicare plans

The triple-difference estimate of exposure to biosimilars' entry is obtained from this equation:

$$\begin{aligned} y_{dst} = &\beta_0 + \beta_1 \times Post\_Entry_{dst} \times Biosim\_Availab_{dst} \times Comm_{dst} + \\ &\beta_2 \times Post\_Entry_{dst} \times Comm_{dst} + \beta_3 \times Biosim\_Availab_{dst} \times Comm_{dst} \\ &+ \beta_4 \times Post\_Entry_{dst} \times Biosim\_Availab_{dst} + \beta_5 \times Post\_Entry_{dst} + \\ &\beta_6 \times Biosim\_Availab_{dst} + \beta_7 \times Comm_{dst} + \epsilon_{dst} \end{aligned} \tag{2.1}$$

where y_{dst} is the outcome variable for drug d, segment s at time t; $Post\_Entry_{dst}$ is an indicator for post biosimilars' entry; $Biosim\_Availab_{dst}$ is an indicator for being a treated drug, and $Comm_{dst}$ is an indicator equal to 1 if the observation refers to the commercial segment. The parameter of interest is β_1 (the triple-difference estimate), while β_2 through β_7 are the coefficients associated with double interaction terms and linear terms. The standard triple difference design requires setting the same post-treatment date for all observations. In this case, I make a conservative choice by setting the treatment date equal to the first biosimilar's entry date (the first biosimilar launched was Zarxio in the last quarter of 2015). The estimates from this model should only be considered as indicative, since for all treated drugs but Neupogen entry occurs after the previously set date.

The second empirical specification is a staggered DiD framework where I allow for staggered treatment time, obtained by estimating the following equation:

$$y_{dst} = \gamma_{dt} + \lambda_{ds} + \eta_{st} + \beta_1 \times Entry_{dst} + \epsilon_{dst} \tag{2.2}$$

where y_{dst} is the outcome of interest corresponding to drug d, segment s at time t; $Entry_{dst}$ is equal to 1 if observation refers to commercial segment and for drugs which witness biosimilar entry — and only during periods t when the biosimilar is actually in the market; γ_{dt}, λ_{ds} and η_{st} are different combinations of fixed effects. The coefficient of interest is β_1

The staggered difference-in-differences regression estimator has come under criticism in very recent years, as under certain conditions it can produce biased estimates. It can be shown that the treatment effect estimate is equivalent to a weighted average of all pairwise 2x2 DIDs. A pairwise DID gets more weight if the event occurs around the middle of the study period, or if it includes more observations (see Goodman-Bacon, 2021). Some of the 2x2 DIDs use "already treated" observations as a control group. On its own, this would not generate biased estimates. However, if the treatment effect changes over time, the already treated observations do not follow the same trend as the treated observations, causing a violation of the common trend assumption. I provide an example of the violation of the common trend assumption in the context of my study. As previously described, some of the 2x2 DiDs contributing to the treatment effect estimate involve comparing later-treated drugs with earlier-treated drugs that have already received treatment. However, there might be phase-in effects: it might take some time for the entry of a biosimilar to produce measurable changes in behavior. This means that I may observe a bigger drop in coverage for earlier treated drugs (control group) than later treated drugs (treated group) in the period of interest. Hence, for the subset of 2x2 DiDs which use already treated drugs, I may find a treatment effect with a counterintuitive sign. In turn, this will generate some bias in the aggregate treatment effect estimate. In some cases, the bias is large enough to flip the sign of the treatment effect (see Baker et al., 2022).

Econometricians have identified multiple theoretical problems with staggered DiD estimators, and they have recently proposed different DiD estimation techniques to address them. In essence, each technique modifies the units that can act as effective comparison units to avoid comparing treatment units to inappropriate controls. Some estimators rely on first estimating the individual cohort-time-specific treatment effects, allowing for treatment effect heterogeneity, then aggregating them to produce measures of overall treatment effects (see Callaway and Sant'Anna, 2021 and Sun and Abraham, 2021). An alternative approach is a "stacked regression" (see Deshpande and Li, 2019 and Cengiz et al., 2019). The rationale for this approach is to create event-specific datasets, which include the event-specific treated units and all the other units that serve as controls (e.g., not-yet-, last-, or never-treated units). For each dataset, a specific identifying variable is generated. These event-specific datasets are then put together, and a DiD regression is estimated on the stacked dataset. Basically, this approach estimates a treatment effect from each of the event-specific datasets, then applies variance weighting to compute a consolidated treatment effect. In order to account for staggered difference-in-differences regression estimator issues, I estimate the following stacked regression:

$$\begin{aligned} y_{dste} = &\beta_0 + \beta_1 \times Post\_Event_{dste} \times Treated_{dste} \times Comm_{dste} + \\ &\beta_2 \times Post\_Event_{dste} \times Comm_{dste} + \beta_3 \times Treated_{dste} \times Comm_{dste} + \\ &\beta_4 \times Post\_Event_{dste} \times Treated_{dste} + \beta_5 \times Post\_Event_{dste} + \\ &\beta_6 \times Treated_{dste} + \beta_7 \times Comm_{dste} + \epsilon_{dste} \end{aligned} \tag{2.3}$$

where y_{dste} is the outcome of interest corresponding to drug d, segment s at time t and in the sub-experiment e; $Post\_Event_{dste}$ is an indicator for post biosimilars' entry; $Treated_{dste}$ is an indicator for being a treated drug, and $Comm_{dste}$ is an indicator equal to 1 if the observation refers to the commercial segment. The parameter of interest is β_1 (the triple-difference estimate), which should be free from previously described estimation biases.

2.4.2 Summary Statistics

Table 2.5 displays summary statistics on list prices and coverage between treated and non-treated drugs across grouping choices. In the preferred specification, list prices are pretty similar between treated and non-treated drugs. At the same time, formularies are slightly more generous for control drugs (as the treated drugs face biosimilar entry and may suffer a drop in coverage). In the robustness check with all biologics, there are sizable differences in list prices, and formularies become less generous for control drugs. The fact that biosimilars are more likely to compete with successful drugs appears to dominate the fact that these products may suffer a drop in coverage over time due to entry.

Table 2.5: Summary statistics for treated and control drugs

	Treated drugs		Control drugs	
	Mean	Median	Mean	Median
Preferred choice				
List price ($)	37,989	33,549	40,607	34165
Percent covered (%)	83	89	95	99
Percent preferred (%)	32	28	46	43
Percent unrestricted (%)	47	47	50	49
Robustness check - all biologics				
List price ($)	37,989	33,549	93,961	46,934
Percent covered (%)	83	89	74	79
Percent preferred (%)	32	28	22	15
Percent unrestricted (%)	47	47	46	42

Figure 2.5 exhibits trends in coverage for the set of 9 treated reference biologics between commercial and Medicare plans. While commercial plans are slightly more generous before entry in terms of coverage, they react more aggressively to entry than Medicare plans. In fact, the two lines converge around the time of the first biosimilar entry date, which is September 2015.

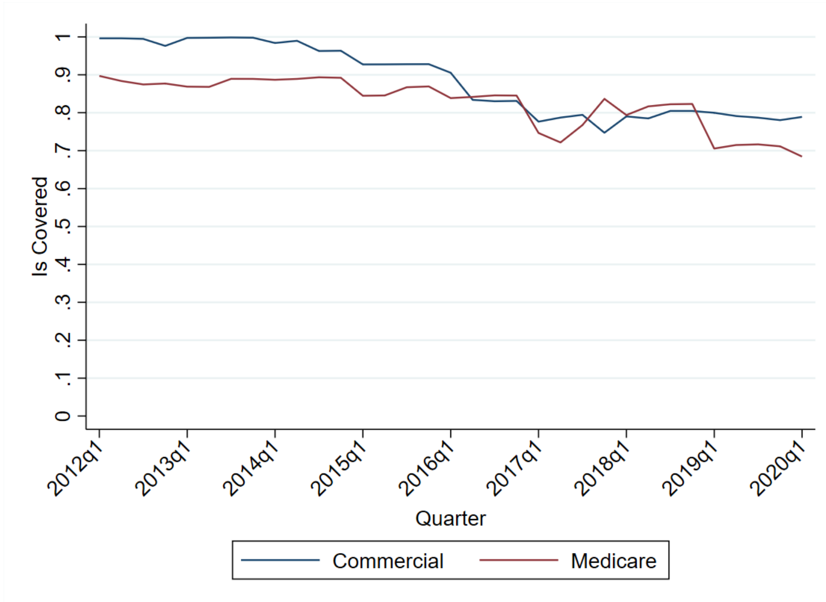

Figure 2.5: Trends in coverage of treated biologics by segment

2.4.3 Testing the parallel trend assumption

In a triple difference design, the coverage gap between treated and non-treated drugs should evolve similarly across commercial and Medicare plans in the absence of biosimilars' entry. Therefore, the identifying assumption in this class of models is that no other factors generate a difference in differential trends between the two defined groups (see Olden and Møen, 2022 and Muralidharan and Prakash, 2017). To verify this, I can test for parallel trends by estimating equation (2.1) and using the period before the first biosimilar entry (2012-2014). I do not reject the null hypothesis of parallel trends since the coefficient on the triple interaction term is close to zero and not statistically significant (see Table 2.6).

Table 2.6: Testing the parallel trends assumption

	Frac. Covered
Commercial	0.00731*
	(0.00381)
Biosim Available	-0.143*
	(0.0676)
Commercial x Biosim Available	0.147*
	(0.0659)
Quarter	-0.000667
	(0.000379)
Commercial x Quarter	0.000706
	(0.000408)
Biosim Available x Quarter	0.00200
	(0.00746)
Commercial x Biosim Available x Quarter	**-0.00492**
	(0.00749)
Constant	0.992***
	(0.00421)
R-squared	0.361
N	240

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

The parallel trends assumption can also be inspected graphically (see Figure 2.6). The difference in the likelihood of coverage between treated and non-treated drugs trends similarly between commercial and Medicare plans. The gap shrinks a bit as the first biosimilar entry date approaches, suggesting the presence of anticipatory effects. Nevertheless, the lines do not cross until the first biosimilar is available in the market.

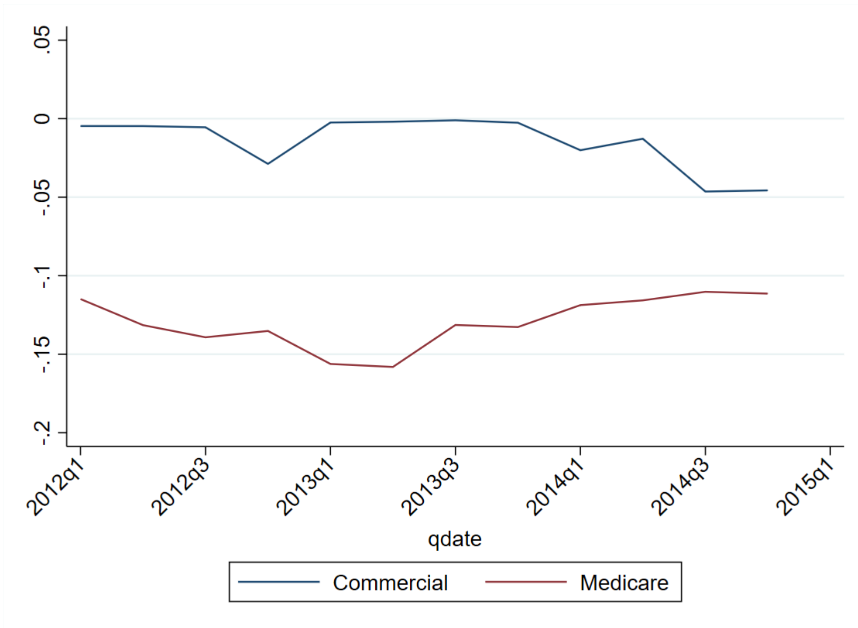

Figure 2.6: Graphical test of parallel trends

2.4.4 Results

Table 2.7 reports the triple-difference estimates of the effect of biosimilars' entry, based on equation (2.1). Adding drug and period fixed effects causes the variables which vary only across drugs or only across time to be omitted, but does not affect the triple interaction term estimates. The treatment effects presented should be interpreted as a decrease in the likelihood of reference drugs being covered after biosimilars entered of about 22.5% in commercial plans relative to Medicare plans. The estimates are somewhat noisy, as they are statistically significant only at 10% level. The clustering choice for standard errors has an impact on statistical significance. If I did not cluster standard errors at the drug level, the estimates would be statistically significant at 1% level. However, the outcome of interest is likely to be very correlated for groups of observations within drugs. The fact that standard errors increase substantially after clustering standard errors at the drug level indicates that the intra-class correlation is positive and substantial. Columns (3)-(4) in Table 2.7 use preferential coverage as the dependent variable. In this case, the treatment effect is 17.3%.

Table 2.7: Triple difference estimates - equation (2.1)

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Commercial	0.0255***	0.937***	0.839***
	(0.00450)	(0.00330)	(0.000663)
Biosim Available	-0.120***	0.220	0.255**
	(0.0362)	(0.122)	(0.113)
Commercial x Biosim Available	0.0940**	-0.573***	-0.304**
	(0.0396)	(0.113)	(0.123)
Post Entry	-0.115	-0.00153	-0.0430***
	(0.0994)	(0.00161)	(0.000581)
Commercial x Post Entry	0.109	-0.108***	-0.0561**
	(0.0991)	(0.0232)	(0.0251)
Biosim Available x Post Entry	0.0292	-0.0732	-0.0928*
	(0.115)	(0.0454)	(0.0457)
Commercial x Biosim Available x Post Entry	**-0.225***	**-0.173****	**-0.335*****
	(0.121)	**(0.0703)**	**(0.0953)**
Constant	0.974***	0.0538***	0.156***
	(0.00432)	(0.000414)	(0.000490)
R-squared	0.208	0.494	0.605
N	684	684	684

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Figure 2.7 plots the predicted coverage probability across groups before and after biosimilar's entry (using triple difference estimates). The graph suggests that Medicare plans reduce coverage of treated (Biosimilar available) and control drugs (Biosimilar not available) similarly. Instead, commercial plans show substantial divergence in coverage between the two groups following entry.

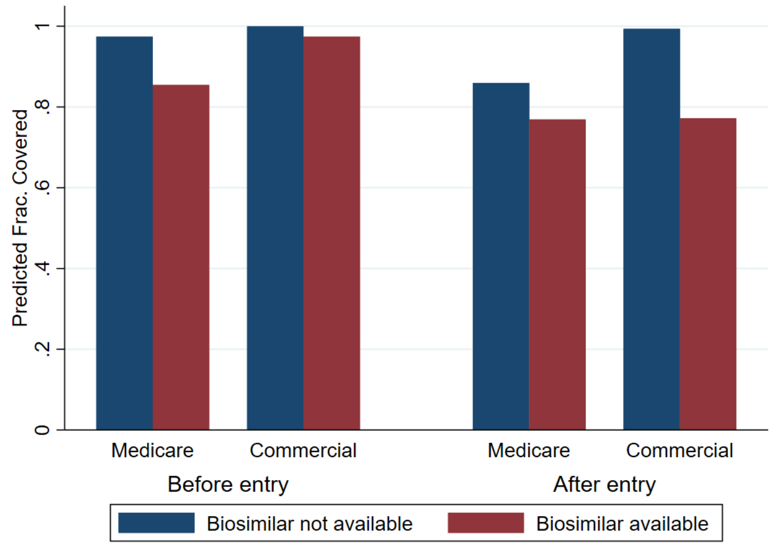

Figure 2.7: Graphical representation of triple difference estimates

Table 2.8 reports the staggered DiD estimates of the effect of biosimilars' entry, based on equation (2.2). For any coverage, the treatment effect is not substantially different from the one estimated with equation (1). Regarding preferential coverage, the estimate is about 10% higher in magnitude. The divergence in estimates may be due to equation (2.2) capturing more precisely the timing of biosimilar entry for each biological drug in the treated group.

Table 2.8: Stacked DiD estimates - equation (2.2)

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Entry	**-0.243***** **(0.0553)**	**-0.0516** **(0.0659)**	**-0.102** **(0.0774)**
Constant	0.880*** (0.00615)	0.365*** (0.00732)	0.503*** (0.00860)
Drug x Period FE	x	x	x
Drug x Segment FE	x	x	x
Segment x Period FE	x	x	x
R-squared	0.829	0.958	0.924
N	684	684	684

Standard errors (in parentheses) clustered at the drug level

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

As previously described, the staggered DiD treatment effect estimates may be biased. A way to address this issue is to estimate equation (2.3). The new treatment effect estimates are not substantially different (for what concerns any coverage), but slightly bigger in magnitude (see Table 2.9). This suggests that comparisons with already treated drugs generate some bias in the direction of finding no effect. The results from estimating equation (2.1), equation (2.2) and equation (2.3) with alternative treated and control groups can be found in Appendix A.

Table 2.9: Staggered DiD estimates - equation (2.3)

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Commercial	0.0655	0.453**	0.560***
	(0.0534)	(0.176)	(0.125)
Treated	-0.178	0.0884	0.0617
	(0.116)	(0.150)	(0.146)
Commercial x Treated	0.106	-0.285	-0.216
	(0.111)	(0.172)	(0.174)
Post Event	-0.0685**	-0.0257	-0.0356
	(0.0280)	(0.0247)	(0.0287)
Commercial x Post Event	0.0417	-0.0536**	-0.115*
	(0.0301)	(0.0234)	(0.0592)
Treated x Post Event	0.137*	0.0613	0.0673
	(0.0659)	(0.0618)	(0.0705)
Commercial x Treated x Post Event	**-0.262****	**0.00830**	**-0.0787**
	(0.102)	**(0.103)**	**(0.139)**
Constant	0.861***	0.133*	0.220**
	(0.0534)	(0.0629)	(0.0740)
R-squared	0.117	0.304	0.430
N	602	602	602

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

2.4.5 Biosimilars take-up

To make competition feasible, insurance plans need to add biosimilar products to their formularies as they become available in the market. Table 2.10 lists the number of launched biosimilars for each biological product. Note that not every biosimilar approved has been launched in the market yet (e.g., Humira).

Table 2.10: Number of biosimilars launched for each biologic

Reference Biologic	Number of biosimilars
Humalog	1
Lantus	1
Neulasta	3
Neupogen	3
Epogen	1
Avastin	2
Herceptin	2
Remicade	2
Rituxan	2
Total	17

Figure 2.8 shows that commercial plans are about twice more likely to cover a biosimilar once it enters the market relative to Medicare plans. Moreover, Figure 2.9 and Figure 2.10 show that commercial plans are more likely to cover a biosimilar regardless of whether the reference biological drug is excluded or included.

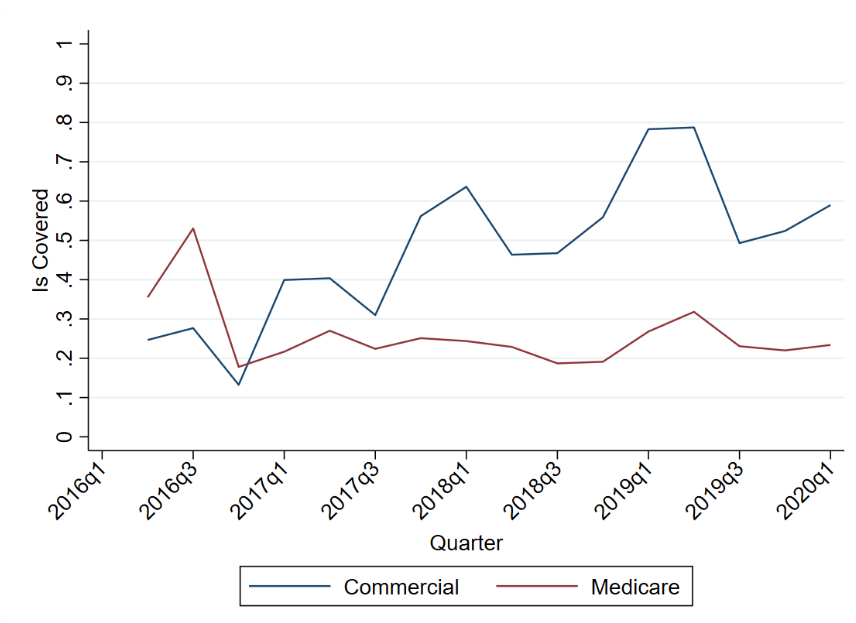

Figure 2.8: Probability of covering biosimilars

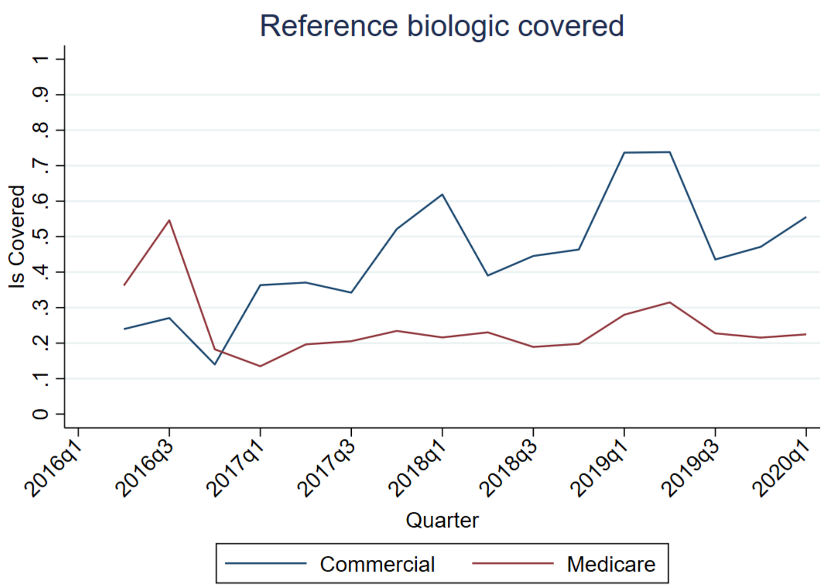

Figure 2.9: Probability of covering a biosimilar - reference drug covered

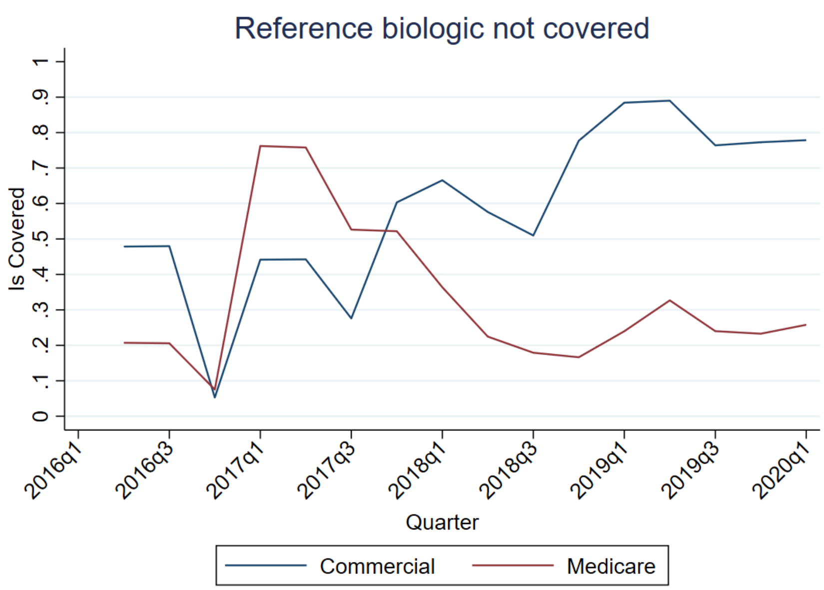

Figure 2.10: Probability of covering a biosimilar - reference drug not covered

To check for differences between commercial and Medicare plans in the coverage of biosimilars when the reference biologic is covered vs. not covered, I estimate the following equation:

$$y_{dst} = \beta_0 + \beta_1 \times Comm_{dst} \times Reference\_covered_{dst} + \beta_2 \times Comm_{dst} + \beta_3 \times Reference\_covered_{dst} + \epsilon_{dst} \tag{2.4}$$

where y_{dst} is the outcome variable for drug d, segment s at time t; $Reference\_covered_{dst}$ is equal to 1 when the corresponding reference biological drug is covered, and $Comm_{dst}$ is an indicator equal to 1 if the observation refers to the commercial segment. The coefficient of interest is β_1. Table 2.11 suggests that there is no substantial difference in coverage choices between market segments when the reference biological drug is excluded or included. For preferential coverage instead, the effect is stronger in commercial plans when the reference biological drug is excluded. This means that some commercial plans incentivize filling a prescription with a biosimilar not only by excluding the reference biological drug, but also by placing the biosimilar in a more favorable tier.

Table 2.11: Equation (2.4) estimates

	Frac. Covered		Frac. Preferred		Frac. Unrestricted	
	(1)	(2)	(3)	(4)	(5)	(6)
Commercial	0.293***	0.267***	0.254***	0.247***	0.228***	0.212***
	(0.0673)	(0.0700)	(0.0803)	(0.0810)	(0.0438)	(0.0453)
Reference Covered	-0.00540	0.00679	-0.0578	-0.0542	-0.107	-0.101
	(0.0744)	(0.0757)	(0.0621)	(0.0631)	(0.0718)	(0.0725)
Commercial x Reference Covered	**0.00422**	**0.0299**	**-0.0892***	**-0.0818***	**0.0225**	**0.0384**
	(0.0873)	**(0.0882)**	**(0.0461)**	**(0.0458)**	**(0.0643)**	**(0.0652)**
Constant	0.253**	0.253***	0.0836	0.0835	0.203**	0.203***
	(0.0897)	(0.0488)	(0.0645)	(0.0486)	(0.0858)	(0.0367)
Drug FE		x		x		x
Period FE		x		x		x
R-squared	0.153	0.567	0.158	0.467	0.151	0.551
N	480	480	480	480	480	480

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

2.5 Welfare effects

Coverage choices between Medicare and commercial plans vary substantially due to moral hazard. To draw some welfare implications, I make back-of-the-envelope calculations based on previous estimates and current spending on biological drugs in Medicare part D. The goal is to estimate the welfare effect of coverage of reference biologics going down in Medicare by as much as in the commercial segment. Based on CMS Medicare part D spending data, spending for reference biologics (with a biosimilar available) was $8.0 billion in 2020. Table 2.12 summarizes the effect of decreased reference biologic coverage on the federal government and patients. I use treatment effect estimates from previous sections, the fact that patients face a 5% coinsurance rate in the catastrophic phase, that the federal government provides an 80% subsidy in the catastrophic phase, and that the average discount from filling a prescription with a biosimilar is 29%. Lower and upper bound estimates are based on 90% confidence intervals from previous sections. The intervals are very wide, resulting in lower bound savings being close to 0. However, using mean estimates results in considerable savings for the government and patients, in the order of 6% of their current total spending. Moreover, the estimated savings are very conservative, since they are based on reference biologics for which a biosimilar is available until 2020. Several biosimilars are expected to be launched in the following years[17].

Table 2.12: Potential savings in Medicare part D

	Federal savings (million $)			Patient savings (million $)		
	LB	Mean	UB	LB	Mean	UB
Equation (3) estimate (Preferred choice)	107.2 (1.7%)	364.7 (5.7%)	623.6 (9.7%)	6.7 (1.7%)	22.8 (5.7%)	39.0 (9.7%)
Equation (3) estimate (All biologics)	201.8 (3.2%)	385.6 (6.0%)	567.9 (8.9%)	12.6 (3.2%)	24.1 (6.0%)	35.5 (8.9%)

In parentheses % savings

[17]https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars

2.6 Bipartisan Budget Act and Build Back Better Act

2.6.1 Bipartisan Budget Act

Medicare part D has been subject to multiple reforms over time. One policy change relevant to my paper is the Bipartisan Budget Act, which was signed into law in early 2018. This bill mandated the closure of the Part D coverage gap, as well as the requirement that biosimilars should pay coverage gap discounts since the start of 2019[18]. Table 2.13 summarizes how the Medicare part D benefit was modified due to the policy change. As it can be noticed, the policy change affected only the coverage gap phase. More specifically, manufacturer discounts increased from 50% to 70% for reference biological drugs, and 0% to 70% for biosimilars.

Table 2.13: Medicare part D standard benefit before and after BBA

	2018				2019			
	Gov.	Plan	Member	Man.	Gov.	Plan	Member	Man.
Deductible	0	0	100	0	0	0	100	
Initial Coverage	0	75	25	0	0	75	25	0
Coverage gap	0 (0)[a]	15 (56)	35 (44)	50 (0)	0	5	25	70
Catastrophic	80	15	5	0	80	15	5	0

[a]In parenthesis, the %s apply to biosimilars before the policy change.

To provide an example of the magnitude of the impact of the policy change, I calculate the cost of covering Neupogen (a reference biological drug) and Zarxio (its associated biosimilar) before and after the policy change (see Table 2.14). Neupogen has a list price of around $76,900, while Zarxio is sold at a 15% discount relative to Neupogen. While the plan cost of covering Neupogen barely changes between 2018 and 2019, the cost of covering

[18]https://www.centerforbiosimilars.com/view/budget-bill-contains-wins-for-biosimilars-effort-to-reduce-drug-costs-continues

Zarxio goes down by a few thousand dollars. It must be noted that the policy change does not directly address the source of moral hazard, which is federal catastrophic subsidies. However, requiring biosimilar manufacturers to provide discounts in the coverage gap phase should make their products more attractive to cover for Medicare part D plans.

Table 2.14: BBA example

	2018	2019
Neupogen (reference)	\$13,483 (17.5%)	\$13,115 (17.1%)
Zarxio (biosimilar)	\$15,256 (23.3%)	\$11,384 (17.4%)

To study the impact of the Bipartisan Budget Act, I estimate the following equation for reference biological drugs which witness biosimilar entry during the period of interest (9 drugs in total):

$$y_{dst} = \beta_0 + \beta_1 \times Policy_{dst} \times Entry_{dst} + \beta_2 \times Policy_{dst} + \beta_3 \times Entry_{dst} + \epsilon_{dst} \tag{2.5}$$

where $Entry_{dst}$ is equal to 1 for drugs that witness biosimilar entry — and only during periods t when the biosimilar is actually in the market, and $Policy_{dst}$ is equal to 1 for all observations starting in 2019. The coefficient of interest is β_1. Table 2.15 shows only weak evidence of a positive impact of the policy change. In fact, the coefficient associated with the interaction term goes down considerably in magnitude after adding period and drug fixed effects. Moreover, none of the estimated coefficients is statistically significant.

Table 2.15: Effect of policy change on coverage of reference biologics

	Frac. Covered		Frac. Preferred		Frac. Unrestricted	
	(1)	(2)	(3)	(4)	(5)	(6)
Policy Change	-0.0767		-0.102		-0.149*	
	(0.0840)		(0.0741)		(0.0700)	
Entry	0.0216	0.0999	0.104	0.0157	0.0528	0.00481
	(0.0493)	(0.0545)	(0.129)	(0.0145)	(0.125)	(0.0159)
Policy Change x Entry	**-0.103**	**-0.0529**	**-0.0153**	**-0.0419**	**0.0477**	**-0.0166**
	(0.116)	**(0.0806)**	**(0.0748)**	**(0.0291)**	**(0.0741)**	**(0.0408)**
Constant	0.859***	0.824***	0.153*	0.159***	0.260***	0.253***
	(0.0466)	(0.0125)	(0.0745)	(0.00574)	(0.0710)	(0.00504)
Drug FE		x		x		x
Period FE		x		x		x
R-squared	0.0961	0.633	0.0284	0.973	0.0312	0.955
N	309	309	309	309	309	309

Standard errors (in parentheses) clustered at the drug level

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

For what concerns coverage of biosimilars, Figure 2.11 exhibits the average probability that a Medicare part D plan covers a biosimilar before and after the policy change. There is a slight increase in the likelihood of coverage around the policy change, but the effect does not appear to be persistent.

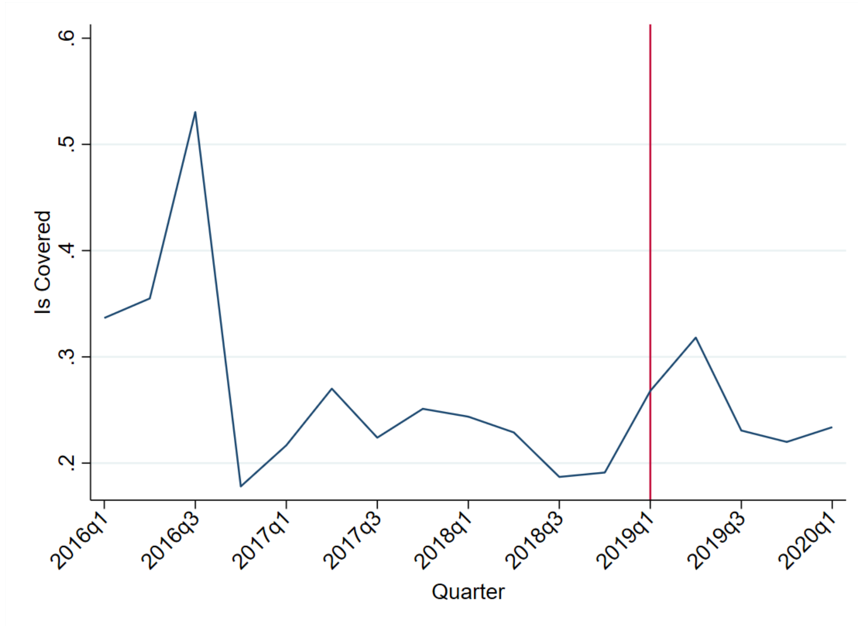

Figure 2.11: Probability of coverage of biosimilars in Medicare part D

2.6.2 Build Back Better Act

The Build Back Better Act is a bill that was signed into law on August 16, 2022. It includes several important provisions on Medicare part D. More specifically, the bill introduces the following changes to the standard benefit, that will become operational starting in 2025[19]:

- Member out-of-pocket costs are capped at $2,000 annually
- The current coverage gap phase of the benefit is eliminated
- Manufacturers cover 10% of a drug's gross cost in the initial coverage phase of the benefit and 20% of the drug's gross cost after a member surpasses the out-of-pocket maximum of $2,000
- The reinsurance amount paid by the federal government in the catastrophic phase decreases from 80% to 20%

[19]https://us.milliman.com/en/insight/the-build-back-better-act-medicare-parts-b-and-d-key-changes

Table 2.16 summarizes the Medicare part D benefit structure before and after the BBB Act. There is a substantial shift in the allocation of costs in the catastrophic phase. In fact, the cost percentages for the plan and the government are almost flipped, with the addition of manufacturer discounts which are only required in the coverage gap phase in the current benefit structure.

Table 2.16: Medicare part D benefit before and after the Build Back Better Act

	Current benefit				New benefit (2025)			
	Gov.	Plan	Member	Man.	Gov.	Plan	Member	Man.
Deductible	0%	0%	100%	0%	0%	0%	100%	0%
Initial Coverage	0%	75%	25%	0%	0%	67%	23%	10%
Coverage gap	0%	5%	25%	70%	No coverage gap			
Catastrophic	80%	15%	5%	0%	20%	60%	0%	20%

This policy change appears more promising than the Bipartisan Budget Act of 2018 for biosimilars' take-up in Medicare part D, as it directly addresses the moral hazard issue of plans. To provide an example of the potential impact of the policy change, I calculate the cost of covering Neupogen (a reference biological drug) and Zarxio (its associated biosimilar) before and after the policy change (see Table 2.17). The substantial reduction of federal subsidies in the catastrophic phase implies that after the policy change a plan would capture a higher share of the savings if a prescription were filled with Zarxio instead of Neupogen. In the current benefit, there is only a \$2,000 difference in the cost of covering Neupogen and Zarxio for a plan. This difference is set to grow considerably in 2025 to around \$7,000.

Table 2.17: Build Back Better Act example

	Current benefit				New benefit (2025)			
	Gov.	Plan	Member	Man.	Gov.	Plan	Member	Man.
Neupogen	53,778	**13,125**	6,118	3,893	13,942	**46,355**	2,000	14,618
	(69.9%)	**(17.1%)**	(8.0%)	(5.1%)	(18.1%)	**(60.3%)**	(2.6%)	(19.0%)
Zarxio	44,549	**11,395**	5,541	3,893	11,634	**39,432**	2,000	12,310
	(68.1%)	**(17.4%)**	(8.5%)	(6.0%)	(17.8%)	**(60.3%)**	(3.1%)	(18.8%)

The Build Back Better Act includes another important provision, which is that starting in 2025, the federal government could negotiate directly with manufacturers the price of certain drugs covered under Medicare Part B and Part D[20]. This clause represents an important novelty, as currently drug prices are negotiated between manufacturers and insurance plans (or pharmacy benefit managers on behalf of insurance plans). However, compared to previous proposals, the BBBA reduces the number of drugs eligible for negotiation as it sets out specific criteria for excluding drugs from the process. For example, the government could negotiate prices only for those drugs without generic or biosimilar competition. Therefore, the drugs which compose the treatment group in this article would not be subject to federal negotiation, as well as the other drugs which are expected to face biosimilars' entry in the coming years. Even if the government could negotiate prices for every drug, the issue of formulary steering by insurance plans would remain relevant.

2.7 Conclusion

In this article, I have examined how different cost-sharing structures across health insurance market segments generate moral hazard and affect coverage choices made by plans. I find that Medicare part D plans, which benefit from a generous federal subsidy for prescriptions filled with expensive biological drugs, are more likely to maintain coverage of a reference biological drug when a cheaper alternative becomes available. They are also less likely to cover the cheaper alternative relative to commercial plans. Back-of-the-envelope calculations suggest that the federal government and Medicare part D patients could realize substantial savings from coverage choices more aligned with commercial plans.

This analysis calls into question the sustainability of the current Medicare part D standard benefit. The rationale for the provision of a generous federal subsidy in the catastrophic phase of coverage was to maintain premiums low and accessibility to expensive drugs for

[20]https://www.kff.org/medicare/issue-brief/simulating-the-impact-of-the-drug-price-negotiation-proposal-in-the-build-back-better-act/

patients, but the program has witnessed a doubling of spending in the catastrophic phase of coverage between 2013 and 2017[21]. My analysis shows that preventing plan sponsors from bearing most of the financial risk for their enrollees' drug spending can lead to sub-optimal coverage choices, for example by hindering the take-up of cheaper and equally effective options to treat certain health conditions.

My results suggest that policymakers should find ways to make Medicare part D plans more financially responsible for drug spending. One of the Medicare part D policy changes implemented in 2018 did not achieve the desired goals as it did not substantially alter the plan coverage incentives. I suggest that the Build Back Better Act, recently signed into law, may have a stronger impact as it alters the cost-sharing structure faced by plans more radically.

My analysis carries some limitations. First of all, this paper focuses on coverage choices made by insurance plans and does not account for actual prescription choices made by doctor-patient pairs. However, coverage and spending generally have a strong relationship (Goldman et al., 2007). Secondly, my analysis does not consider rebates provided by drug manufacturers. In general, reference drug manufacturers offer higher discounts than cheaper alternative manufacturers, which may weaken the impact of policy changes aimed at increasing the take-up of biosimilars.

Additionally, I compare two market segments, Medicare part D and commercial, which do not operate in the same way and present significant differences in patient population. For example, one concern is that Medicare and commercial plans may make different coverage choices since Medicare targets the elderly, while commercial plans cover a younger population on average. Nevertheless, not every disease which is treated with drugs that trigger federal subsidies disproportionately affects the elderly population. For example, Hepatitis C infection rates are higher among young adults than the elderly[22]. Moreover, in 2018 adults

[21] https://www.commonwealthfund.org/publications/issue-briefs/2020/sep/catastrophic-coverage-medicare-part-d-drug-benefit

[22] https://www.cdc.gov/hepatitis/statistics/2019surveillance/Figure3.4.htm

ages 45 to 64 were more likely to receive a diagnosis of type 2 diabetes relative to other age groups[23], which implies that coverage choices for biologics such as Humalog and Lantus will have a strong impact not only on Medicare but also on commercial insurance spending. Another important distinction is that while in Medicare part D the downstream buyer is represented by the patient, in the commercial segment the downstream buyer is typically represented by the employer, an organization with varying size. Nevertheless, in the empirical section of the paper I show how differences in coverage of treated and control drugs trend similarly across Medicare and commercial plans before biosimilars' entry, while they diverge significantly after it. Therefore, I consider the moral hazard issue a higher-order driver of the results relative to differences in the downstream market structure of the two segments.

Finally, insurance plans may use other formulary tools to steer patients to the desired drugs, such as Prior Authorization (Schwartz et al., 2021). I focus on coverage as it represents a stronger indicator of spending relative to formulary restrictions.

[23]https://www.healthline.com/health/type-2-diabetes-age-of-onset

Chapter 3

Gaming and Effort in Performance Pay

3.1 Introduction

Medicare and other health insurers routinely tie payments to providers' quality of care. Although intended to give providers an incentive to exert more effort in caring for patients, pay-for-performance reimbursement schemes may also spur providers to avoid treating patients who would hurt their overall performance score. Gaming quality benchmarks in this way not only undermines the integrity of pay-for-performance systems, it may also directly harm patients by disrupting their care and forcing them to seek out less-preferred providers. In this paper, we study the first federally mandated pay-for-performance scheme in the U.S. health care system, the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), to provide new evidence on how these payment models induce both effort and gaming among providers along with the resulting consequences for patients and payers.

Medicare started the QIP in 2012 following its move to a prospective payment system for dialysis treatments. In light of concerns that facilities would have little incentive to provide costly high-quality care under the new payment scheme, Medicare began assigning each facility an annual score based on a set of known quality metrics and reduced reimbursements to facilities with low scores by up to 2%. Because Medicare frequently updates the metrics it uses to evaluate facilities and compiles detailed data on each patient encounter, the QIP offers an ideal setting to identify how providers change their behavior in response to performance pay. We find that patients are much more likely to leave a facility when their characteristics would trigger a penalty that year, behavior consistent with anecdotes of dialysis facilities involuntarily discharging less-profitable patients.[1] Along some dimensions,

[1]https://www.theatlantic.com/magazine/archive/2010/12/-god-help-you-youre-on-

however, we find that facilities exert more effort to improve their quality of care in the years in which poor performance on that specific measure would be penalized. In short, performance pay leads to both real improvements in quality as well as strategic patient dropping to game Medicare's quality scores.

Facilities' motives for dropping penalty-inducing patients are clear-cut. A facility with the average load of 50 patients and at the bottom decile of QIP scores in 2010, for example, could move from the worst possible score to the best by dropping just three patients. This would be even less if the facility were to replace them with patients who do well in terms of the QIP parameters. To uncover whether facilities act strategically in this way, we use our claims data to classify patients as penalty-inducing when their diagnostic measures would lower their facility's QIP score below a penalty threshold in a given year. We then show that when a patient becomes penalty-inducing due to Medicare's annual change in QIP criteria, the probability that they switch facilities rises by 40%. We also find that penalty-inducing patients are 37% more likely to switch facilities after being hospitalized, a result consistent with facilities selectively refusing to take back patients who might harm their QIP score. Because these penalty-inducing patients switch to lower-quality facilities in terms of mortality and hospitalization rates, we interpret the facility change as an involuntary one.

Although the elevated rate of switching among penalty-inducing patients suggests some facilities respond to the QIP by strategically avoiding patients who might cause their reimbursements to fall, others may respond to the incentives created by the QIP by improving their quality of care, in keeping with the program's original intention. Two performance measures in particular illustrate this phenomenon. Dialysis facilities must regularly track the amount of toxins they clear from a patient's blood, with adequacy measured by either the patient's urea reduction ratio (URR) or Kt/V. Dialysis adequacy has been part of the QIP since its start, as patients with lower Kt/V and URR numbers have more health problems and a greater risk of death. These two measures are closely, but not perfectly, related: patients with an identical URR might have very different Kt/V measures, primarily due

dialysis/308308/

to differences in body weight. Initially, the QIP used URR as its performance measure for dialysis adequacy, but then switched to Kt/V in the program's fourth year. We use this abrupt change in metrics to cleanly identify facilities' strategic responses to performance pay.

Similar to our aggregate assessment of patient dropping that uses all QIP measures, patients who had good URR but bad Kt/V were more likely to switch facilities after QIP changed its criteria (33%), while patients with bad URR and good Kt/V were less likely to switch (13%). We do not find patients with good URR and bad Kt/V going to increasingly worse facilities after the rule change. In addition to dropping patients, however, facilities could also improve their adequacy scores by increasing the amount of time patients spend being dialyzed each session, although doing so comes with the opportunity cost of not using the station to treat another patient due to the fixed per-session payments from Medicare that do not adjust for longer run times. We show that patients with bad Kt/V who remain at the same facility after QIP begins penalizing low Kt/V scores start receiving longer run times, an increase in real effort that leads to better-quality care.

Given the importance of incentive systems in the provision of health care, there is a growing body of important work studying this topic to which our results contribute. Norton et al. (2018), for instance, find evidence that the Hospital Value-Based Purchasing Program led hospitals to improve their performance over time in the areas where they have the highest marginal incentives to do so, while Li and Norton (2019) find that agency-reported measures in the Home Health Value-Based Purchasing Program improved by approximately 1%, although these reported gains did not reflect true quality improvements because agencies manipulated their coding of patients in ways that inflated their performance. Also related to gaming, Lisi et al. (2020) suggest that pay-for-performance schemes that reward low mortality or readmission rates can either weaken or strengthen a hospital's incentive to provide high-quality care, depending on selection bias.

In more recent work closely related to our own, Gupta (2021) uses Medicare claims data to study the Hospital Readmissions Reduction Program (HRRP), the federal program that penalizes hospitals with high rates of re-hospitalization. Gupta finds that hospitals' responses to the penalty account for two-thirds of the decrease in readmissions over the study period, as well as a decrease in mortality for heart attack patients. Half of these gains come from quality improvements and the remainder from differences in the mix of returning patients.

Our paper builds on and complements this existing work in at least two important ways. First, the HRRP focuses solely on one quality dimension, whereas the QIP comprises a rich set of measures that varies over time, allowing us to use the changes in the measures Medicare uses to construct facilities' QIP scores to separately identify how facilities treat patients when their specific characteristics make them likely to trigger a penalty. Second, although Gupta is able to conduct some heterogeneity analyses about the effect of ownership (i.e., government hospitals are less responsive than private hospitals), the institutional details of dialysis allow us to document how facilities strategically shunt off their undesirable patients to competing facilities, such as chains sending penalty-inducing patients to nearby independent facilities.

Our paper also contributes to the literature on cream skimming and patient dropping in health care more generally. Policymakers typically view risk-adjusting reimbursements as a way to mitigate incentives for patient selection, but hospitals may game the payment scheme by choosing patients with poorly calibrated risk scores that make them more profitable to treat (Geruso et al., 2019; Brown et al., 2014). Alternatively, high-powered bonuses to decrease total treatment costs can lead hospitals to select healthier patients and identify low-cost patients within risk-adjustment groups (Alexander, 2020), and hospitals can game direct pricing changes for targeted patient categories (Dafny, 2005; Eliason et al., 2018). Similar patient selection efforts have been detected in the context of capacity constraints (Yang et al., 2020; Hackmann et al., 2020; Gandhi, 2019) and randomized field experiments (Werbeck et al., 2021).

Finally, our paper contributes to the literature focused more specifically on the impact of the QIP (Ajmal et al., 2020; Fink et al., 2002; Ajmal et al., 2019; Saunders et al., 2017), which has largely criticized the QIP for not including measures of patient satisfaction. Along with the contemporaneous work of (Kepler et al., 2022) examining facilities' location decisions, we believe our paper is the first to directly investigate the impact of the QIP on the strategic behavior of facilities, including patient dropping and investments in quality to improve patient outcomes.

3.2 Institutional Details and Data

3.2.1 Kidney Failure and the Dialysis Industry

Kidneys remove wastes and excess fluid out of the blood and produce erythropoietin, a hormone that stimulates the production of red blood cell. Chronic kidney failure occurs when kidneys no longer appropriately complete these tasks. Patients with ESRD (End-Stage Renal Disease) must either undergo surgery, where the failed kidney is replaced with a healthy kidney, or undergo dialysis, a procedure where wastes and excess fluid are removed artificially. Hemodialysis is the most prevalent type of dialysis, which employs a machine to mechanically filter and pass back blood into the body, and which can be performed at a patient's house or at a facility.

Dialysis patients pick their provider in the same way as they do for other healthcare procedure. Patients covered under Medicare can be treated at any facility that has an open slot. The are about 7,000 dialysis facilities in the country, where patients usually go thrice a week for a procedure that lasts 3/4 hours. These facilities are run by a mix of for-profit and non-profit firms, with the two largest for-profit chains, DaVita and Fresenius, controlling well over 60% of facilities and earning 90% of the industry's revenue (United States Renal Data System, 2014; Baker, 2019; Eliason et al., 2020b).

3.2.2 Medicare Payment Reform

Since 1972, Medicare is available to all patients with ESRD, not just the elderly. More specifically, dialysis and anemia treatment are reimbursed under Part B. Those enrolled in an employer sponsored plan when diagnosed with ESRD retain their commercial insurer as a primary payer for 33 months, during which time Medicare acts as a secondary payer (League et al., 2022).

From the early 1980s to 2011, providers were paid a flat rate for each dialysis session and a fee-for-service for any injectable drug dispensed during the visit. Such reimbursement schemes raised concerns that facilities may have an incentive for medical overuse, with negative consequences for federal finances and patients' health. This motivated policy makers to include ESRD in the Medicare Improvements for Patients and Providers Act (2008), which mandated bundling of dialysis services and all injectable drugs and biologics into a single prospective payment, starting in 2011.[2]

The transition to bundled payments raised concerns that facilities may then have an incentive to cut costs too aggressively, which led MIPPA to also mandate the introduction of the QIP, which links payments to performance by penalizing dialysis facilities that provide low-quality care, as determined each year by Medicare in its facility quality score. Facilities with low scores may have their Medicare payments reduced by up to 2%, depending on how far below a given threshold they fall. To construct the score, Medicare uses three time periods to measure performance, compares that performance to some baseline, and then implements any penalties.[3]

The performance measures used to construct the scores have changed over time, but

[2]Federal Register, Volume 74, Issue 187, (September 29, 2009). Eliason et al. (2022) study how this change in reimbursement policy affected the use of the most common of these drugs, EPO.

[3]The relevant years are (i) the "performance year" in which the performance of the facility is evaluated, (ii) the "comparison year" of two years before to which the performance year is compared, and (iii) the "payment year" two years after the performance year when facilities might receive payment reductions.

the basic scoring mechanism has remained constant. A facility's overall performance score is a weighted average of the facility's scores on each of the performance measures in the performance period, with Medicare changing the weights over time as well. A facility's scores on each performance measure are obtained by comparing the results in the performance year against either a national facility-level average or a facility's own past performance in the comparison year.

For example, reductions to Medicare reimbursements in 2012 were based on comparing a facility's performance in 2010 against its own performance in 2007 or the national benchmark in 2008, with the facility receiving the greater of the two scores.[4] To receive a full score on a measure, a facility that was previously above the national average needs only to remain above average, whereas a facility that was previously below average needs only to improve its own performance. Facilities just below the threshold have their payments reduced by 0.5% and those far below the threshold reduced by 2%, with facilities in between facing 1% or 1.5% reductions. Appendix B.1 provides more details on the QIP scoring system.

We use Medicare's changes to the measures and weights used in constructing the QIP to identify the impact of performance pay on facility behavior, as illustrated in Figure 3.1. In the first payment year, Medicare used only three equally-weighted performance measures focused on clinical outcomes: the percentage of patients with average hemoglobin values above 12, the percentage with average hemoglobin values below 10, and the percentage of patients with a median URR above 65. Medicare then updated its measures and weights in subsequent years and began assessing whether facilities reported certain results from patient surveys in 2014.

[4]The inaugural year is the only one in which the comparison year is more than two years before the performance year

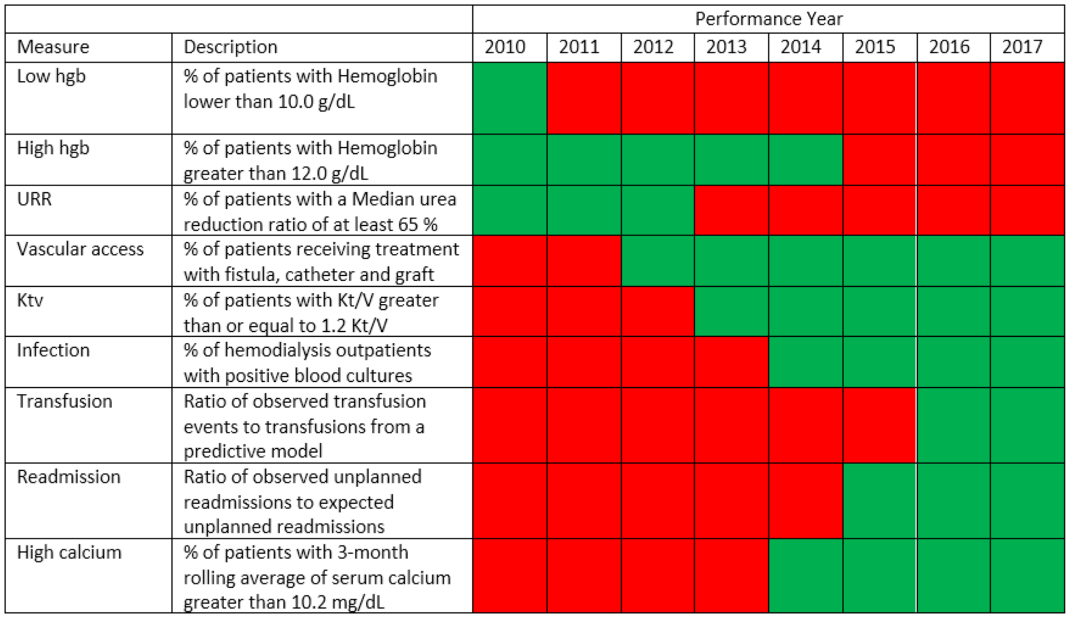

Figure 3.1: Introduction and dropping of QIP criteria

Medicare has changed its QIP measures for various reasons since its inception. For example, Medicare removed the anemia management measure of hemoglobin levels below 10 after the first year due to new medical evidence regarding the safety of a common treatment for anemia in dialysis patients.[5] Moreover, the increasing number of criteria contributing to the scoring mechanism over time reflects the desire to expand the breadth of the program and give more insights into the quality of care at dialysis facilities.

As will be important for our identification strategy below, the continuous update of QIP rules generates quasi-exogenous variation in the penalty-inducing status of patients. Because the new rules are typically proposed and finalized very close to the performance period — or even during the performance period for the first years of QIP — large numbers of patients abruptly become penalty-inducing solely due to changes in what Medicare evaluates rather than due to changes in their underlying health status, whereas others suddenly become compliant on all measures and no longer trigger a penalty.

[5]https://www.cms.gov/newsroom/press-releases/cms-announces-stronger-incentives-improve-esrd-treatment-outcomes

3.2.3 Data

The data for our analysis come from the United States Renal Data System, a national data system that collects and manages about chronic kidney disease and end-stage renal disease relevant to patients and providers. These data comprise of Medicare claims, treatment history files, patient characteristics, and facility surveys. Moreover, CMS Form 2728 includes information on the clinical characteristics of patients at the start of dialysis. Our sample includes 956,354 patients and 7,732 facilities.

As a first step to identify strategic patient dropping, we begin by identifying patients that switch facilities. On average, patients rarely switch facilities — about 0.8% per month — primarily because they must receive dialysis three times per week and strongly prefer a facility close to their homes. To avoid including temporary switches (e.g., if a patient receives dialysis while on vacation) in our analysis, we use only within-HRR switches for which a patient does not return to their original facility during the following six months. Although Medicare does not release systematic data on the reason a patient switches to a new facility, we will seek to uncover whether the switches appear to be involuntary by assessing how the likelihood of switching is affected by the QIP's criteria that determine whether a patient is penalty inducing and whether patients that switch go to facilities with better or worse overall care.

We use the QIP scoring rules to construct a measure of whether a patient is penalty-inducing. As we explain in the next section, our measures of whether a patient is penalty-inducing will take a value one if a patient-month has at least one QIP parameter that does not satisfy the QIP rules for that year, and we illustrate the robustness of our results to a continuous measure between 0 and 10 that is calculated by adding up dummies that take value one if the QIP parameter satisfies the QIP rules for the relevant year, weighted by the relative importance of the QIP parameter for the final QIP score. Table 3.1 provides summary statistics from our data, while Table 3.2 provides the share of patient-months that are penalty inducing each year.

Table 3.1: QIP, patient and facility characteristics

	Mean	Std. Dev.		Mean	Std. Dev.
QIP parameters			*Clinical characteristics*		
Penalty inducing (%)	33.1	47.0	Diabetic (%)	53.4	49.9
Desirability score	9.2	1.4	Hypertensive (%)	88.0	32.5
Low hgb (%)	17.8	38.3	BMI bin	24.2	8.4
High hgb (%)	17.7	38.1	GFR bin	6.0	4.7
Low URR (%)	4.9	21.6	Dialysis tenure	53.2	46.2
Catheter (%)	16.8	37.4	Dialysis tenure^2		
Graft (%)	20.2	40.2	Dialysis tenure^3		
Fistula (%)	62.9	48.3	HGB group	7.5	2.9
Low Kt/V (%)	2.9	16.8	High albumin (%)	63.2	48.2
Infection (%)	1.9	13.6	Cancer (%)	4.9	2.2
Transfusion (%)	0.7	8.2	Drug use (%)	1.3	1.1
Readmission (%)	0.4	6.1	Drinker (%)	1.4	1.2
High calcium (%)	2.6	16.0	Smoker (%)	6.3	2.4
Base Low hgb (%)	26.2	44.0	Needs assistance (%)	9.3	29.0
Base High hgb (%)	25.0	43.3	Chr. Obst. Pulm. Disease (%)	6.5	2.5
Base Low URR (%)	16.6	37.2	Athero. Heart Disease (%)	14.1	34.8
Base Catheter (%)	36.4	48.1	Peripheral Vasc. Disease (%)	10.7	34.8
Base Graft (%)	16.1	36.8	Ischemic Heart Disease (%)	8.1	27.3
Base Fistula (%)	47.4	49.9	Congestive Heart Failure (%)	27.5	44.6
Base Low Kt/V (%)	6.8	25.2	*Facility characteristics*		
Base Infection (%)	2.5	15.6	Facility age	16.2	10.0
Base Transfusion (%)	0.4	6.3	Facility age^2		
Base Readmission (%)	0.6	7.6	HRR		
Base High calcium (%)	4.2	20.0	Income bin	34,868.3	10,180.8
Patient demographics			Chain (%)	83.1	37.5
Male (%)	54.5	49.8	Freestanding (%)	95.2	21.4
Non hispanic white (%)	39.3	48.8	N. of fac. in Zip code	1.8	1.1
Black (%)	38.3	48.6			
Hispanic (%)	16.6	37.2			
Asian (%)	3.6	18.6			
Other Race (%)	3.7	18.9			
Age	63.2	14.6			
Age^2					
Age^3					

Table 3.2: % of penalty inducing patients over time

Year	Penalty ind.	Low hgb	High hgb	Low URR	Cath.	Graft	Low Kt/V	Inf.	Transf.	Read.	High calcium
2008	0.0	9.2	36.4	8.8				2.1	0.6	0.5	
2009	0.0	10.0	30.6	7.8				2.0	0.6	0.5	
2010	41.0	10.8	25.0	7.6	21.4	22.0		2.0	0.6	0.5	
2011	19.1	15.1	13.0	6.0	19.7	21.6		1.9	0.3	0.5	
2012	49.3	19.7	12.9	3.5	17.7	21.1	3.5	1.8	0.4	0.4	4.1
2013	47.2	21.0	12.4	3.5	16.0	20.5	3.1	1.8	1.1	0.4	3.4
2014	49.8	22.3	12.0	3.5	15.4	19.8	3.2	1.8	1.0	0.3	3.4
2015	40.6	22.5	12.6	3.4	15.7	19.3	3.0	1.8	0.9	0.3	2.5
2016	39.7	22.5	12.9	3.0	15.7	19.2	2.6	1.8	0.7	0.2	1.6
2017	38.8	21.6	13.8	2.8	15.6	19.2	2.1	1.8	0.6	0.2	1.4

3.3 Empirical Analysis

We use Medicare's exogenous changes to QIP measures to identify the causal effect of pay-for-performance on whether a patient switches facilities using the specification

$$Y_{ijt} = \beta f_t\left(PerformanceMeasures_{it}\right) + \alpha_1 PerformanceMeasures_{it} + \alpha_2 X_{ijt} + \varepsilon_{ijt}, \quad (3.1)$$

where Y_{ijt} is the response variable for patient i at facility j in month t and X_{ijt} includes a host of facility and patient controls in addition to year-month, HRR, and facility fixed effects. $PerformanceMeasures_{it}$ gives the patient's values on all performance measures prior to the start of the relevant performance period, while $f_t\left(\cdot\right)$ is a function mapping these characteristics to either (i) an indicator for whether the patient has at least one QIP parameter that does not satisfy the QIP rules for the relevant year or (ii) a continuous measure of the share of active performance measures the patient does not satisfy. By controlling for the health characteristics that are used to determine whether a patient is penalty-inducing, we identify the impact of being penalty-inducing solely using changes in which criteria are being evaluated by Medicare rather than comparing patients of different health statuses. Figure 3.2 shows that not only penalty inducing patients are more likely to switch, but the gap with non penalty inducing patients increases over time.

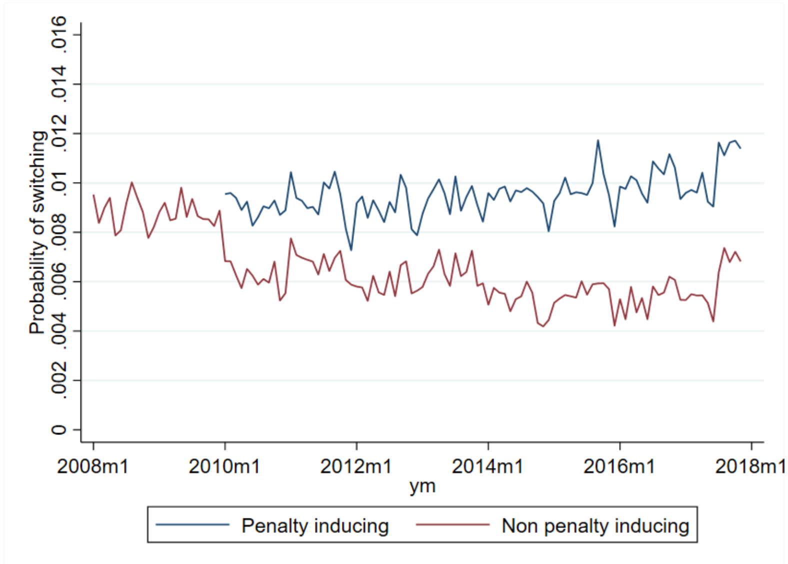

Figure 3.2: Switching by penalty-inducing status

Table 3.3 presents the results of estimating equation (3.1), with specification (3) suggesting that a penalty-inducing patient is 40% more likely to switch facilities, going from 0.66% to 0.92%. Using only patients discharged from a hospital, specification (9) shows that those who are penalty-inducing are 37% more likely to move to a new facility. As hospitalizations represent an opportunity for facilities to cut ties with a patient who might harm their QIP score by selectively not accepting back those with unfavorable characteristics, this result is again consistent with strategic patient dropping. Such estimates are even more relevant after considering that the average facility can completely eliminate its penalty under QIP by dropping just a handful of patients. For example, an average facility in terms of number of patients and well below average QIP performance (10th percentile) in 2010, can only drop 3 patients to change its score from 0 (the worst possible score) to 10 (the best possible score). Appendix B.2 provides estimation results using alternative definitions of penalty inducing status, which confirm the presence of strategic patient dropping.

Table 3.3: Regression estimates - Probability of switching

	Probability of switching						Probability of switching at discharge					
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Penalty inducing	0.00255***	0.00277***	0.00263***				0.00394***	0.00502***	0.00480***			
	(0.0000562)	(0.0000585)	(0.0000585)				(0.000266)	(0.000269)	(0.000267)			
Low hgb				0.00148***	0.00149***	0.00143***				0.00103***	0.00105***	0.000915***
				(0.0000726)	(0.0000727)	(0.0000731)				(0.000261)	(0.000261)	(0.000264)
High hgb				0.000604***	0.000592***	0.000551***				-0.000518	-0.000543	-0.000553
				(0.0000843)	(0.0000844)	(0.0000849)				(0.000443)	(0.000443)	(0.000449)
Low URR				0.00310***	0.00309***	0.00296***				0.00359**	0.00364**	0.00335**
				(0.000358)	(0.000358)	(0.000359)				(0.00125)	(0.00126)	(0.00126)
Catheter				0.00297***	0.00297***	0.00276***				0.00244***	0.00237***	0.00225***
				(0.000118)	(0.000118)	(0.000119)				(0.000424)	(0.000424)	(0.000435)
Fistula				-0.0000944	-0.0000911	-0.0000565				0.000896*	0.000918**	0.00107**
				(0.0000833)	(0.0000833)	(0.0000847)				(0.000348)	(0.000348)	(0.000361)
Low Kt/V				0.00210***	0.00214***	0.00199***				0.00210	0.00203	0.00194
				(0.000402)	(0.000402)	(0.000405)				(0.00136)	(0.00136)	(0.00136)
Infection				0.00276***	0.00275***	0.00260***				0.00000565	0.0000102	0.0000120
				(0.000356)	(0.000356)	(0.000355)				(0.000411)	(0.000411)	(0.000414)
Transfusion				0.00131***	0.00135***	0.00143***				-0.000284	-0.000138	0.0000125
				(0.000362)	(0.000362)	(0.000361)				(0.000517)	(0.000517)	(0.000523)
Readmission				0.00415***	0.00415***	0.00402***				0.00243*	0.00238*	0.00224*
				(0.000784)	(0.000784)	(0.000782)				(0.000958)	(0.000960)	(0.000960)
High calcium				0.000937***	0.000986***	0.000950***				0.00246**	0.00251**	0.00246**
				(0.000172)	(0.000173)	(0.000173)				(0.000822)	(0.000823)	(0.000823)
Constant	0.0196***	0.0191***	0.00907***	0.0185***	0.0185***	0.00413	0.0286***	0.0264***	0.00343	0.0217***	0.0214***	0.00140
	(0.00113)	(0.00114)	(0.00136)	(0.00132)	(0.00132)	(0.00221)	(0.00531)	(0.00530)	(0.00600)	(0.00559)	(0.00559)	(0.00959)
Baseline QIP values	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Facility Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Month-Year FE	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Facility FE	No	No	Yes	No	No	Yes	No	No	Yes	No	No	Yes
R-squared	0.00181	0.00197	0.00794	0.00164	0.00174	0.00682	0.00362	0.00410	0.0212	0.00264	0.00293	0.0208
Observations	13112497	13112497	13112427	8178958	8178958	8178936	971108	971108	970988	546619	546619	546522
Mean Dep. Var.	0.00660	0.00660	0.00660	0.00557	0.00557	0.00557	0.0129	0.0129	0.0129	0.00789	0.00789	0.00788

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

To determine whether a switch is unlikely to be voluntary, we compare the mortality, hospitalization, and infection rates of the facility a patient leaves with his or her new facility as well as whether the new facility is located closer to the patient's home, with the intuition that a patient would not willingly move to a lower-quality, farther-away facility. We estimate the same regression as equation (3.1), where Y_{ijt} is now the difference in mortality rates, hospitalization rates, infection rates, and distance from the patient's home between the new facility and the previous facility.[6] The results in Appendix Table B.3 show that among patients that change facilities, penalty-inducing patients are more likely to switch to worse facilities than patients in similar health that are not penalty-inducing, with specification (3) implying they move to facilities with 0.3 p.p. higher mortality rates on a baseline of 7.8%, or 3.8% worse. Furthermore, penalty-inducing patients switch to facilities that are 0.3 miles farther away from home. This is highly suggestive that their moves are unlikely

[6] Note that in this specification, X_{ijt} includes only characteristics of the previous facility.

made for reasons of convenience since the average patient who switches facilities chooses a facility closer to them.

An alternative way to see this is to define voluntary and involuntary switches, and evaluate whether penalty inducing patients are more likely to undertake the latter switches. Table 3.4 shows that penalty inducing patients are slightly more likely to undertake involuntary switches than non penalty inducing patients. The results are robust across different definitions of involuntary switches (e.g. in specifications (1)-(3) a switch is defined as involuntary when a patient moves to a facility with higher mortality rate and further away from to home, while a switch is defined as voluntary if a patient moves to a facility with lower mortality rate and closer to home). Finally, we find no evidence that penalty-inducing patients switch to facilities that provide more intensive care, as conventional measures of care intensity including staffing ratios are similar or worse, as shown in Appendix Table B.4.

Table 3.4: Probability of involuntary switch

	Prob. of inv. switch (mort. rate + distance)			Prob. of inv. switch (hosp. rate + distance)			Prob. of inv. switch (inf. rate + distance)		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Penalty inducing	0.0165***	0.0177***	0.0210***	0.000600	0.00399	0.0141**	0.0115*	0.0122*	0.0207***
	(0.00464)	(0.00479)	(0.00476)	(0.00462)	(0.00477)	(0.00470)	(0.00461)	(0.00477)	(0.00470)
Constant	0.361***	0.358***	0.341***	0.404***	0.396***	0.262**	0.222*	0.210*	0.0835
	(0.0874)	(0.0875)	(0.0985)	(0.0859)	(0.0859)	(0.100)	(0.0874)	(0.0875)	(0.0991)
Baseline QIP values	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Facility Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Month-Year FE	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Facility FE	No	No	Yes	No	No	Yes	No	No	Yes
R-squared	0.0327	0.0370	0.271	0.0381	0.0450	0.289	0.0380	0.0428	0.287
Observations	46764	46764	46169	46658	46658	46072	46934	46934	46376
Mean Dep. Var.	0.441	0.441	0.440	0.414	0.414	0.413	0.430	0.430	0.428

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

As discussed in Section 4.1, Medicare changed its measure of dialysis adequacy from URR to Kt/V in 2013. The two measures are mathematically related, with the distinction that Kt/V also takes into account two additional factors: (i) urea generated by the body during dialysis and (ii) extra urea removed during dialysis along with excess fluid. Retrospective studies of mortality for ESRD patients suggest the odds of death increase progressively as the URR falls below 60–65% (Held et al., 1996; McClellan et al., 1998), with common barriers to dialysis adequacy including patient adherence to treatment, under-prescription of dialysis by the nephrologist, use of catheters for vascular access, and shortened treatment times (Tangri et al., 2011; Sehgal et al., 2002, 1998; Palevsky et al., 2000; Fishbane and Hazzan, 2012).

Medicare's rule change in 2013 introduces quasi-exogenous variation to the penalty status of patients, as patient who previously scored well on URR measures may suddenly become penalty-inducing with unsatisfactory Kt/V levels. Figure 3.3 summarizes the likelihood of patients switching out of a facility based on their current URR and Kt/V levels. The likelihood of switching for patients with good URR and bad Kt/V levels increases substantially after the QIP change, while the probability of switching for patients with bad URR and good Kt/V levels decreases. This indicates that changing the way the dialysis adequacy measure is calculated coincided with changes in the allocation of patients across facilities, despite these measures capturing the same underlying treatment quality.

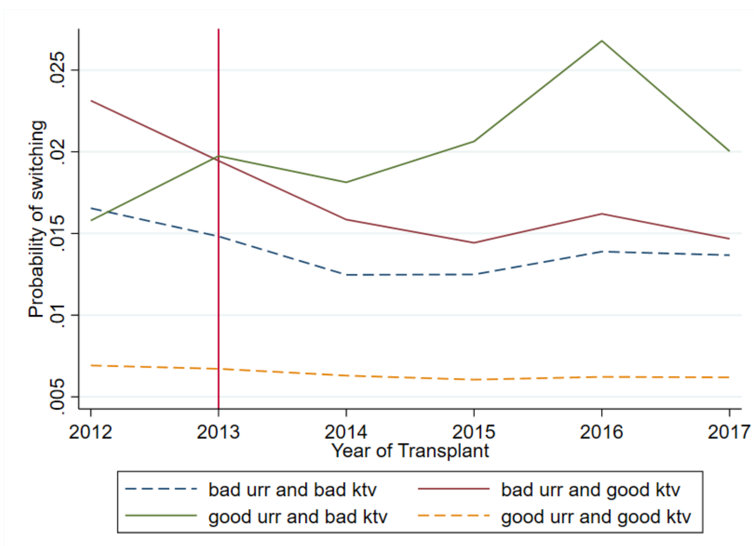

Figure 3.3: Switching by URR and Kt/V status

In addition to dropping patients with bad Kt/V readings, facilities could also improve their scores by increasing the amount of time patients with inadequate clearance levels spend getting dialysis. As shown in Table 3.5, patients with bad Kt/V readings receive 6.2 more minutes on dialysis, which becomes 7.0 minutes when Kt/V is included as a measure in the program. Note specifications (2)–(4) control for patients' URR levels, meaning that the switch in dialysis adequacy measures changed provider effort for the patients highlighted by the QIP, rather than just patients receiving inadequate dialysis more generally. Nevertheless, the effort undertaken by facilities to increase treatment time is relatively lower than the effort undertaken to drop penalty inducing patients. In fact, while treatment time increases by about 13%, the probability of switching for patients with bad URR and good Kt/V increases by about 33% at the rule change. This suggests that facilities strongly prefer changing the composition of their patient population instead of exerting effort to improve their patients' parameters, a more severe result than what can be found in the literature (e.g. Gupta (2021))

Table 3.5: Change in treatment time

	Δ treatment time			
	(1)	(2)	(3)	(4)
Low Kt/V=1	5.709***	6.160***	6.159***	6.225***
	(0.111)	(0.143)	(0.144)	(0.144)
Kt/V in QIP=1	0.0350***	0.0321***		
	(0.00693)	(0.00864)		
Low Kt/V $\times$ Kt/V in QIP	1.121***	0.722***	0.728***	0.741***
	(0.121)	(0.157)	(0.157)	(0.157)
Constant	-0.279***	-0.427***	-0.359***	-0.692***
	(0.00650)	(0.104)	(0.104)	(0.171)
Baseline QIP values	No	Yes	Yes	Yes
Patient Controls	No	Yes	Yes	Yes
Facility Controls	No	Yes	Yes	Yes
Month-Year FE	No	No	Yes	Yes
Facility FE	No	No	No	Yes
R-squared	0.00543	0.00529	0.00534	0.00573
Observations	11122986	6772549	6772549	6772538
Mean Dep. Var.	-0.0978	-0.0883	-0.0883	-0.0882

Standard errors in parentheses

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

3.4 Conclusion

Patients who would trigger a reimbursement penalty are much more likely to switch facilities after the introduction of pay-for-performance in dialysis. The switches appear to be involuntary, as penalty-inducing patients move to worse facilities that are farther from their homes.

One reason the QIP leads to gaming by facilities is misaligned financial incentives. Facilities can ensure adequate Kt/V by increasing treatment times, for instance, but this comes with the opportunity cost of treating fewer patients and receiving commensurately lower prospective payments. In such cases, facilities find it optimal to simply drop patients who would trigger QIP penalties rather than invest more effort to improve outcomes.

Chapter 4

Provision of Transplant Education for Patients Starting Dialysis: Disparities Persist

4.1 Introduction

For the nearly 1 million patients with end stage renal disease (ESRD) in the United States, kidney transplant has several advantages over dialysis, including longer patient survival and improved quality of life (Abecassis et al., 2008; Meier-Kriesche and Kaplan, 2002; Wolfe et al., 1999; McCullough et al., 2019). Patient education is an important component of making informed decisions about ESRD treatment options, as early access to nephrology care has been shown to result in improved patient satisfaction with ESRD treatment and higher rates of kidney transplant (Combes et al., 2017; Devins et al., 2003; Devins et al., 2005; Golper, 2007). Despite these benefits, a substantial number of patients with ESRD report limited discussions with their doctors about ESRD treatment options and a lack of knowledge about kidney transplant (Finkelstein, 2008; McPherson et al., 2019; Skelton et al., 2015).

For patients who lack early access to nephrology care, education about ESRD treatment options should occur at initiation of dialysis (Waterman et al., 2015a). The Centers for Medicare and Medicaid Services (CMS) requires the submission of a Medical Evidence Form (CMS-2728) for all patients with ESRD within 45 days of initiating dialysis. In 2005, the form was amended to include a question about the provision of kidney transplantation information; if information is not provided, the reason for not providing it must be specified. Prior research has found disparities in provision of information about kidney transplant based on social determinants of health including race, gender, and insurance status (Gander et al., 2018; Myaskovsky et al., 2012; Weng et al., 2005). Several important policy changes have occurred to improve patient education of CKD, ESKD, and transplant, including the 2019 Advancing American Kidney Health Initiative.

We hypothesized that despite 15 years since the modifications to Form 2728, persistent disparities remain in which patients are provided information about transplant at initiation of dialysis. We also hypothesized that a lack of early information about transplant contributes to disparities in kidney transplantation. The purpose of this study was to (1) quantify the provision of transplant information as indicated on the Medical Evidence Form, (2) identify sociodemographic risk factors for not receiving transplant information at the time of dialysis initiation, (3) determine the association of dialysis facility characteristics with provision of transplant information, and (4) determine the association of transplant information with waitlist and transplant outcomes.

4.2 Data

This was a retrospective analysis of patients aged 18 to 75 with a newly filed Medical Evidence Form during the study period between 1/1/2008 to 1/1/2019 using data from the United States Renal Data System (USRDS). Our sample consisted of 944,015 patients and 7,255 facilities. USRDS includes all patients in the United States who develop ESRD and require renal replacement therapy via either dialysis or a kidney transplant.

The primary outcome was provision of transplant information, as indicated on Medical Evidence Form 2728. For patients not informed at the time of dialysis, we collected the reason for not being informed (medically unfit, declined information, unsuitable due to age, psychologically unfit, not assessed, or other). Secondary outcomes were addition to the transplant waitlist and transplant rate.

Characteristics thought to be associated with the likelihood of receiving transplant education included the following: receiving nephrology care pre-ESRD, dialysis facility ownership, initial dialysis access, alcohol dependence, drug dependence, inability to ambulate, inability to transfer, and needing assistance with activities of daily living. The following dialysis facility characteristics were also considered: number of patients per registered nurse, number of patients per technician, and number of patients per social worker.

A complete list of characteristics can be found in the Appendix C.1. The models described below are estimated by controlling for all of these characteristics, while only major results/coefficients are reported in the Tables.

4.3 Empirical Analysis

4.3.1 Informed about transplant

Logistic regression models were constructed in which the dependent variable is whether the patient has not been informed of transplant options and each reason for which the patient has not been informed. The models for each reason were run on the subset of patients who have not been informed of transplant options. The reference variables to calculate the odds ratio were the following for their respective categories: cystic kidney for the variable "disease," arteriovenous fistula for the variable "vascular access," group (private) for the variable "insurance status," white for the variable "race," employed full time for the variable "employment", and Midwest for the variable "region".

4.3.2 Time to waitlist

We calculated Cox proportional-hazards model estimates for the time to waitlist after a patient's signature of the medical evidence form. We considered as study end date the latest addition date observed in the whole dataset (08/10/2018). For patients who did not reach the event of interest during the study observation period, we recorded when the patient was censored due to study end date or due to the occurrence of an event that prevents further follow-up of the patient (e.g., death) (Schold et al., 2021). We also restricted the dataset to patients whose medical evidence form was submitted by 12/31/2015 to account for the fact that those patients who started dialysis towards the end of the study period were not given an adequate opportunity to be waitlisted. A hazard ratio above 1 indicates a variable that is positively associated with the event likelihood (i.e., being added to the waitlist), and thus negatively associated with the time to waitlisting.

4.3.3 Time to transplant

We calculated Cox proportional-hazards model estimates for time to transplant after being added to the waitlist, which was conditional on being added to the waitlist. We considered as study end date the last time a transplant was observed in the dataset (08/10/2018). For patients who did not reach the event of interest during the study observation period, we recorded when the patient was censored due to study end date or due to the occurrence of an event that prevents further follow-up of the patient (e.g., death). Moreover, we restricted the dataset to patients whose medical evidence form was submitted by 12/31/2015 to account for the fact that those patients who started dialysis towards the end of the study period were not given an adequate opportunity to be transplanted. Pre-emptive transplant recipients were excluded from the analysis.

4.4 Results

4.4.1 Characteristics of non-informed patients

Between 2008 and 2019, 944,015 patients initiated renal replacement therapy. Provision of transplant information has increased over study time (see Figure 4.1).

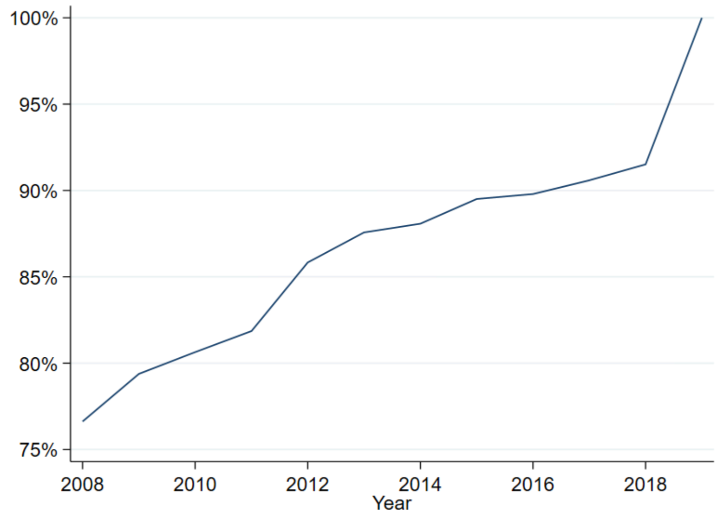

Figure 4.1: Trends in the proportion of patients being informed

Of all patients included, 133,414 (14.52%) did not receive information about kidney transplantation (see Table 4.1). Non-informed patients were more likely to be female (43 vs 42%, CIs [42.55;43.09] and [41.77;41.99]), white (52 vs 47%, CIs [51.96;52.49] and [46.89;47.11]), and obese (13 vs 12%, CIs [12.81;13.18] and [11.92;12.07]). Non-informed patients were about 3 years older than informed patients, on average. Socioeconomic characteristics were also associated with the provision of information: patients receiving information were more likely to be on private insurance (18 vs 10%, CIs [18.00;18.17] and [9.97;10.30]), and being employed full time (12 vs 5%, CIs [11.99;12.14] and [5.29;5.54]).

Etiology and medical management of ESRD were also associated with whether patients would be informed: informed patients were more likely to have hypertensive nephropathy as the cause of ESRD, more likely to have pre-dialysis access to nephrology care, and more likely to receive dialysis at chain-owned centers. Finally, patients who were informed were less likely to live in the West, to have alcohol dependence, substance dependence, and limited functional status (West region 20 vs 22%, CIs [20.05;20.22] and [21.90;22.35]; inability to ambulate 5 vs 12%, CIs [5.10;5.20] and [11.68;12.03]; inability to transfer 3 vs 7%, CIs [2.48;2.55] and [6.90;7.17]; needing assistance 10 vs 18%, CIs and [9.85;9.98] and

[18.09;18.51]).

Table 4.1: Medical and sociodemographic characteristics by transplant education

		Informed (%)	Not informed (%)
All patients		85.48	14.52
		[85.41;85.55]	
Gender	Female	41.88	42.82
		[41.77;41.99]	[42.55;43.09]
	Male	58.12	57.18
		[58.01;58.23]	[56.91;57.45]
BMI	≤ 40	88.01	87.01
		[87.93;88.08]	[86.82;87.19]
	> 40	11.99	12.99
		[11.92;12.07]	[12.81;13.18]
Race	Asian	3.78	3.11
		[3.74;3.83]	[3.02;3.20]
	Black	30.23	28.17
		[30.12;30.33]	[27.93;28.42]
	Hispanic	16.63	13.97
		[16.55;16.72]	[13.78;14.16]
	Other	2.36	2.52
		[2.33;2.39]	[2.44;2.61]
	White	47.00	52.22
		[46.89;47.11]	[51.96;52.49]
Insurance	Private	18.09	10.13
		[18.00;18.17]	[9.97;10.30]
	Medicare	16.65	18.12
		[16.57;16.73]	[17.91;18.32]
	Other	65.26	71.75
		[65.16;65.37]	[71.51;71.99]
Employment status	Employed full time	12.06	5.42
		[11.99;12.14]	[5.29;5.54]
	Homemaker or unemp.	29.71	28.88
		[29.61;29.82]	[28.63;29.12]
	Other	58.22	65.71
		[58.11;58.33]	[65.45;65.96]
Region	MW	20.03	21.02
		[19.94;20.11]	[20.80;21.24]
	NE	15.74	16.48
		[15.66;15.82]	[16.28;16.68]
	S	44.10	40.38
		[43.99;44.21]	[40.12;40.65]
	W	20.13	22.12
		[20.05;20.22]	[21.90;22.35]
ESRD case	Diabetes	51.25	50.54
		[51.13;51.36]	[50.27;50.82]
	Hypertension	26.79	25.15
		[26.69;26.89]	[24.91;25.39]
	Other	21.97	24.31
		[21.87;22.06]	[24.07;24.54]
Nephrology care pre ESRD	No	29.12	39.48
		[29.02;29.23]	[39.19;39.76]
	Yes	70.88	60.52
		[70.77;70.98]	[60.24;60.81]
Facility ownership	Chain	82.75	78.36
		[82.67;82.84]	[78.13;78.60]
	Independent	17.25	21.64
		[17.16;17.33]	[21.40;21.87]
Alcohol dependence	No	98.18	97.20
		[98.15;98.20]	[97.11;97.29]
	Yes	1.82	2.80
		[1.80;1.85]	[2.71;2.89]
Drug dependence	No	98.47	97.76
		[98.44;98.50]	[97.67;97.84]
	Yes	1.53	2.24
		[1.50;1.56]	[2.16;2.33]
Inability to ambulate	No	94.85	88.15
		[94.80;94.90]	[87.98;88.32]
	Yes	5.15	11.85
		[5.10;5.20]	[11.68;12.03]
Inability to transfer	No	97.49	92.97
		[97.45;97.52]	[92.83;93.10]
	Yes	2.51	7.03
		[2.48;2.55]	[6.90;7.17]
Needing assistance in ADLs	No	90.09	81.70
		[90.02;90.15]	[81.49;81.91]
	Yes	9.91	18.30
		[9.85;9.98]	[18.09;18.51]
Patients per registered nurse		17.05	16.36
		[17.03;17.07]	[16.31;16.40]
Patients per technician		12.68	12.26
		[12.65;12.70]	[12.22;12.31]
Patients per social worker		76.74	73.44
		[76.66;76.82]	[73.25;73.63]
Age		57.46	60.86
		[57.43;57.48]	[60.80;60.92]

4.4.2 Predictors of not being informed about transplant

Overall, the most common reasons for not providing information about transplant were "not assessed" (52%), followed by "medically unfit" (27%) (see Figure 4.2).

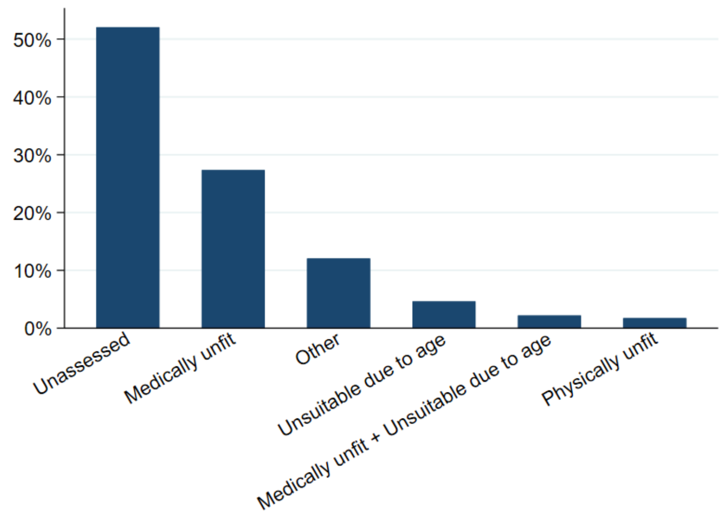

Figure 4.2: Frequency of reasons for not being informed

Table 4.2 provides estimates of logistic regressions in which we control for several patient characteristics (a complete list can be found in Appendix C.1). Characteristics that were strongly associated with being unassessed were race and chain ownership: American Indian, Black, and Hispanic (ORs 1.60 [1.02;1.32], 1.18 [1.14;1.22], 1.30 [1.24;1.37], respectively) patients and those undergoing dialysis at a chain facility (OR 1.45 [1.40;1.50]) were more likely to be uninformed for an unspecified reason (i.e., "not assessed"). Differences also appeared across geographic location, as patients in the South and West were more likely to be unassessed. Not receiving information about transplantation for being medically unfit was associated with BMI >40, having Medicare as insurance, alcohol dependence, impossibility to ambulate and to transfer, requiring help in activities of daily living, and being located in the Northeast (ORs 1.31[1.25;1.36], 1.16 [1.08;1.24], 1.48 [1.35;1.62], 1.91 [1.79;2.03], 1.55 [1.43;1.67], 1.74 [1.67;1.82] and 1.31 [1.25;1.37], respectively). Being considered psychologically unfit was associated with Black race, being unemployed, drug dependence, needing assistance, and being unable to transfer (ORs 1.11 [1.02;1.21], 2.54 [1.81;3.57], 2.29 [1.94;2.71], 2.90 [2.65;3.18], and 1.18 [1.01;1.38]). Being excluded from information due to advanced age was associated with being older, having Medicare, and being retired (ORs 1.31 [1.30;1.32], 1.40 [1.13;1.75] and 1.52 [1.16;1.99]), as expected, but also with Asian and Hispanic race (ORs 1.38 [1.19;1.60] and 1.60 [1.47;1.75]). Patients who declined to receive information were more likely to be white or American Indian, older than 70, retired, and to need assistance with activities of daily living.

Table 4.2: Predictors of reasons for patients not being informed

	(1) Not informed	(2) Medically unfit	(3) Declined	(4) Unsuitable due to age	(5) Unassessed	(6) Physically unfit	(7) Other
Alcohol dependence	1.121	1.478	1.269	0.938	0.785	1.694	0.721
	[1.069,1.176]	[1.348,1.620]	[0.907,1.775]	[0.716,1.227]	[0.718,0.859]	[1.428,2.011]	[0.611,0.851]
Drug dependence	1.313	1.222	1.157	0.853	0.693	2.288	1.235
	[1.245,1.385]	[1.096,1.363]	[0.749,1.787]	[0.503,1.447]	[0.626,0.766]	[1.935,2.706]	[1.059,1.439]
Inability to ambulate	1.341	1.906	1.147	0.960	0.632	0.857	0.862
	[1.296,1.387]	[1.794,2.026]	[0.933,1.410]	[0.858,1.075]	[0.594,0.672]	[0.747,0.984]	[0.760,0.976]
Inability to transfer	1.348	1.546	0.728	1.005	0.673	1.182	0.890
	[1.292,1.406]	[1.432,1.669]	[0.560,0.946]	[0.878,1.152]	[0.621,0.729]	[1.013,1.378]	[0.758,1.045]
Needs assistance	1.282	1.740	1.446	1.023	0.615	2.904	0.806
	[1.252,1.313]	[1.666,1.818]	[1.247,1.677]	[0.946,1.106]	[0.589,0.642]	[2.648,3.184]	[0.739,0.878]
Age at incidence	1.019	1.025	1.028	1.305	0.967	0.989	0.987
	[1.019,1.020]	[1.023,1.027]	[1.021,1.036]	[1.295,1.315]	[0.966,0.969]	[0.985,0.993]	[0.984,0.989]
Male	0.972	1.005	0.862	0.842	1.028	1.045	1.091
	[0.958,0.987]	[0.975,1.037]	[0.772,0.962]	[0.797,0.889]	[0.999,1.057]	[0.968,1.129]	[1.036,1.149]
BMI over 40	1.101	1.305	0.840	0.767	0.922	0.502	0.987
	[1.077,1.125]	[1.249,1.364]	[0.709,0.995]	[0.697,0.846]	[0.885,0.961]	[0.438,0.577]	[0.915,1.064]
Diabetes	1.511	1.672	1.051	1.026	0.707	0.655	1.204
	[1.412,1.616]	[1.397,2.001]	[0.603,1.831]	[0.755,1.393]	[0.611,0.819]	[0.465,0.923]	[0.933,1.554]
Glomerulonephritis	1.528	1.854	0.720	0.942	0.595	0.629	1.339
	[1.423,1.642]	[1.536,2.237]	[0.393,1.318]	[0.679,1.306]	[0.509,0.694]	[0.434,0.912]	[1.025,1.749]
Hypertension	1.466	1.443	0.974	1.030	0.736	0.825	1.228
	[1.369,1.569]	[1.203,1.730]	[0.556,1.706]	[0.757,1.401]	[0.635,0.854]	[0.584,1.165]	[0.949,1.589]
Other cause	2.294	3.574	0.815	0.681	0.349	0.548	1.468
	[2.140,2.458]	[2.979,4.289]	[0.461,1.441]	[0.498,0.933]	[0.300,0.405]	[0.385,0.780]	[1.132,1.903]
Other urologic	1.814	2.614	0.811	0.984	0.464	1.139	1.325
	[1.660,1.982]	[2.117,3.227]	[0.398,1.655]	[0.679,1.425]	[0.387,0.557]	[0.753,1.721]	[0.962,1.825]
Cath	1.347	1.297	0.943	0.894	0.890	0.828	1.020
	[1.317,1.377]	[1.235,1.363]	[0.799,1.113]	[0.828,0.965]	[0.852,0.929]	[0.732,0.936]	[0.940,1.107]
Graft	1.208	1.336	0.679	0.945	0.809	1.154	1.011
	[1.153,1.266]	[1.210,1.475]	[0.454,1.015]	[0.807,1.107]	[0.738,0.885]	[0.923,1.442]	[0.849,1.204]
Other	1.452	1.041	0.963	0.622	0.929	0.404	1.453
	[1.243,1.696]	[0.744,1.457]	[0.304,3.047]	[0.337,1.147]	[0.689,1.254]	[0.127,1.286]	[0.915,2.308]
Nephrologist care	0.752	0.989	0.878	1.085	1.035	0.759	0.869
	[0.741,0.764]	[0.957,1.022]	[0.782,0.987]	[1.022,1.152]	[1.004,1.067]	[0.700,0.823]	[0.823,0.917]
American Indian/Alaskan	0.923	0.829	1.428	0.999	1.159	0.753	1.053
	[0.864,0.986]	[0.721,0.953]	[0.933,2.185]	[0.737,1.352]	[1.019,1.317]	[0.508,1.116]	[0.848,1.308]
Asian	0.830	0.718	0.865	1.380	1.060	0.974	1.354
	[0.796,0.866]	[0.653,0.789]	[0.618,1.212]	[1.191,1.600]	[0.976,1.152]	[0.778,1.221]	[1.189,1.541]
Black	0.895	0.794	0.845	1.179	1.182	1.110	0.915
	[0.880,0.911]	[0.765,0.824]	[0.736,0.970]	[1.101,1.261]	[1.142,1.224]	[1.017,1.213]	[0.858,0.976]
Hispanic	0.772	0.558	0.981	1.601	1.303	0.708	1.270
	[0.754,0.790]	[0.529,0.589]	[0.821,1.173]	[1.466,1.747]	[1.244,1.365]	[0.619,0.809]	[1.178,1.370]
Other	1.181	1.029	1.000	1.310	1.401	0.685	0.402
	[0.965,1.444]	[0.680,1.557]	[1.000,1.000]	[0.621,2.765]	[0.942,2.085]	[0.212,2.220]	[0.148,1.094]
Pacific Islander	1.014	1.117	0.457	1.222	0.794	1.541	1.138
	[0.943,1.090]	[0.961,1.299]	[0.203,1.030]	[0.880,1.699]	[0.691,0.911]	[1.104,2.150]	[0.911,1.422]
Medicaid	1.226	1.154	1.056	1.335	0.777	2.723	1.028
	[1.187,1.266]	[1.073,1.242]	[0.808,1.381]	[1.024,1.741]	[0.728,0.829]	[2.176,3.407]	[0.923,1.144]
Medicare	1.135	1.156	0.895	1.404	0.764	1.812	1.007
	[1.100,1.170]	[1.080,1.238]	[0.697,1.148]	[1.126,1.751]	[0.718,0.813]	[1.442,2.278]	[0.903,1.121]
Medicare&Medicaid	1.396	1.267	0.769	1.437	0.702	3.766	0.903
	[1.352,1.442]	[1.182,1.359]	[0.593,0.996]	[1.149,1.796]	[0.659,0.748]	[3.023,4.690]	[0.807,1.010]
Medicare&Other	1.280	1.194	0.900	1.345	0.767	1.040	0.954
	[1.236,1.325]	[1.110,1.286]	[0.691,1.173]	[1.076,1.681]	[0.716,0.821]	[0.801,1.351]	[0.843,1.080]
Other	1.189	1.036	1.018	1.564	0.853	1.339	1.108
	[1.156,1.222]	[0.973,1.104]	[0.809,1.281]	[1.258,1.945]	[0.806,0.903]	[1.074,1.670]	[1.009,1.216]
Applying for Medicare	0.963	1.052	0.887	0.932	1.062	0.902	0.852
	[0.947,0.979]	[1.017,1.088]	[0.789,0.997]	[0.882,0.985]	[1.029,1.096]	[0.829,0.982]	[0.805,0.901]
Emp pt-time	1.031	1.241	1.222	1.384	0.779	1.017	1.258
	[0.968,1.098]	[1.061,1.451]	[0.710,2.105]	[0.946,2.024]	[0.682,0.889]	[0.555,1.866]	[1.040,1.522]
Med LOA	1.218	1.716	1.260	1.092	0.686	0.844	1.003
	[1.157,1.283]	[1.517,1.941]	[0.797,1.990]	[0.682,1.750]	[0.615,0.764]	[0.486,1.467]	[0.851,1.182]
Other	1.079	1.355	1.388	2.125	0.802	0.511	0.593
	[0.900,1.293]	[0.814,2.254]	[0.188,10.246]	[0.351,12.861]	[0.518,1.242]	[0.069,3.784]	[0.316,1.116]
Homemaker or Unemployed	1.396	1.505	1.057	1.124	0.706	2.542	1.113
	[1.347,1.447]	[1.373,1.651]	[0.756,1.478]	[0.849,1.489]	[0.654,0.763]	[1.809,3.571]	[0.991,1.249]
Retired	1.429	2.008	1.280	1.515	0.614	2.361	0.780
	[1.380,1.480]	[1.836,2.197]	[0.925,1.770]	[1.155,1.986]	[0.569,0.662]	[1.681,3.315]	[0.695,0.877]
Chain status	0.778	0.643	1.065	0.897	1.446	0.821	1.041
	[0.764,0.792]	[0.621,0.667]	[0.931,1.217]	[0.840,0.958]	[1.396,1.496]	[0.752,0.896]	[0.978,1.109]
NE	0.951	1.306	0.837	0.485	0.877	1.357	0.886
	[0.928,0.974]	[1.246,1.369]	[0.709,0.987]	[0.443,0.531]	[0.838,0.918]	[1.214,1.517]	[0.812,0.967]
S	0.954	0.797	0.746	0.901	1.249	0.818	1.001
	[0.935,0.973]	[0.766,0.830]	[0.649,0.858]	[0.842,0.966]	[1.203,1.298]	[0.738,0.907]	[0.933,1.073]
W	1.168	0.801	0.758	0.669	1.306	0.822	1.129
	[1.141,1.196]	[0.764,0.841]	[0.641,0.897]	[0.614,0.728]	[1.249,1.366]	[0.725,0.931]	[1.043,1.221]
Constant	0.026	0.029	0.004	0.000	19.463	0.029	0.174
	[0.024,0.028]	[0.023,0.037]	[0.002,0.008]	[0.000,0.000]	[16.069,23.574]	[0.017,0.049]	[0.127,0.239]
Observations	611211	91193	91074	91193	91193	91193	91193
chi 2	19851.5	13171.2	271.2	13634.0	11296.2	2415.9	1076.7
chi 2 type	LR	LR	LR	LR	LR	LR	LR

Exponentiated coefficients

4.4.3 Association between receiving information about transplant and time to waitlist and kidney transplantation

The goal of estimating Cox proportional-hazards models was to evaluate whether patients who receive transplant information get added to the waitlist or transplanted at a faster rate than non-informed patients while controlling for other relevant characteristics. Informed patients had a shorter time between ESRD onset and addition to the kidney transplant waitlist (hazard ratio 1.62 [1.58;1.65], see Table 4.3). This can be seen graphically in Figure 4.3, which depicts adjusted survival curves based on regression estimates and the average covariate values in the study group. For example, the probability of not being added to the waitlist from the time the medical form is signed to year 2 is 84% for someone who is informed and 90% for someone who is not informed, holding other characteristics at their mean values.

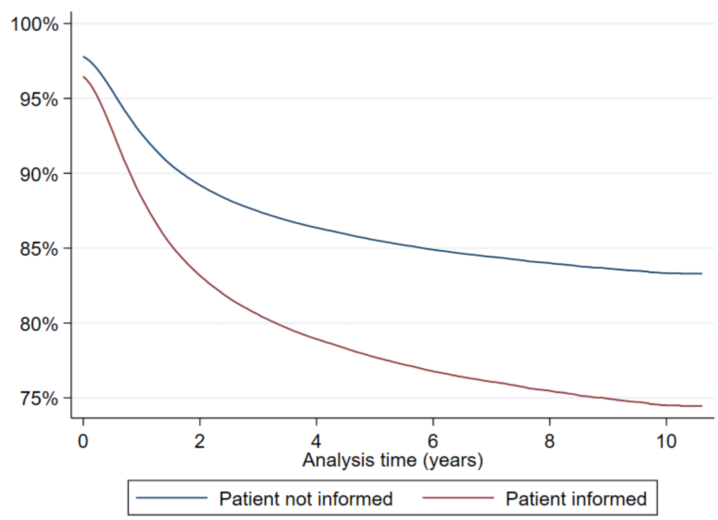

Figure 4.3: Probability of not being added to the waitlist by transplant information

To verify the proportional hazard assumption, we ran a statistical test on scaled Schoenfeld residuals (Grambsch and Therneau, 1994); the test suggested that we should reject the assumption of proportionality. A visual investigation of the Schoenfeld residuals shows that the cloud of residuals is negatively sloped at early time points (see Figure 4.4), or that the model underpredicts the marginal effect of transplant information at early time points. This implies that transplant information is especially important soon after it is received.

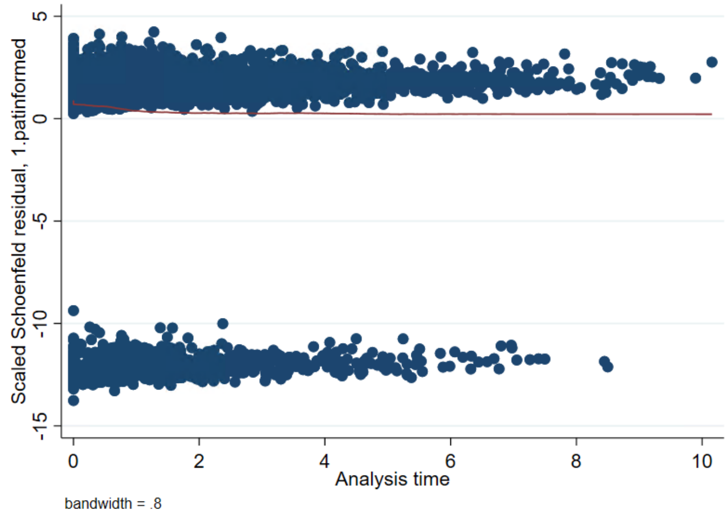

Figure 4.4: Testing PH assumption for the variable "Patient Informed"

Male, white, Hispanic, and Asian patients waited shorter times to be added to the waitlist relative to Black patients. Unemployed, retired, and homemakers waited longer to be added to the waitlist. The time from addition to the waitlist to transplant was shorter for patients who received transplant information (see Table 4.3), male patients, patients with alcohol dependence, and patients with glomerulonephritis. Again, the proportionality assumption is rejected for the variable ""Patient informed" after conducting a test on Schoenfeld residuals, implying that the relative importance of the variable changes over time. Minority patients had significantly longer times on the waitlist prior to transplant (Black 38%, Asian 33%, Hispanic 34%, Pacific Islanders 36% reductions in the hazard of receiving a transplant relative to white). Homemakers, unemployed, and retired patients had longer times from listing to transplantation. Similarly, patients on Medicare and/or Medicaid had longer times on the waitlist.

Table 4.3: Cox proportional-hazards estimates of time to waitlist and transplant

	(1) Time to waitlist	(2) Time to transplant
Patient informed	1.617	1.032
	[1.582,1.652]	[0.999,1.067]
Alcohol dependence	0.719	1.131
	[0.678,0.763]	[1.034,1.238]
Drug dependence	0.361	0.892
	[0.335,0.389]	[0.795,1.002]
Inability to ambulate	0.447	0.811
	[0.416,0.479]	[0.715,0.919]
Inability to transfer	0.678	1.170
	[0.603,0.763]	[0.958,1.429]
Needs assistance	0.603	0.894
	[0.582,0.625]	[0.842,0.949]
Age at incidence	0.965	0.984
	[0.965,0.966]	[0.983,0.985]
Male	1.138	1.024
	[1.124,1.152]	[1.005,1.043]
BMI over 40	0.428	0.782
	[0.418,0.438]	[0.754,0.811]
Diabetes	0.455	0.787
	[0.443,0.468]	[0.759,0.816]
Glomerulonephritis	0.664	1.050
	[0.644,0.684]	[1.011,1.091]
Hypertension	0.495	0.891
	[0.481,0.509]	[0.858,0.925]
Other cause	0.415	1.070
	[0.401,0.430]	[1.024,1.118]
Other urologic	0.454	0.888
	[0.427,0.483]	[0.819,0.963]
Cath	0.652	1.118
	[0.642,0.661]	[1.094,1.142]
Graft	0.805	1.038
	[0.776,0.835]	[0.983,1.095]
Other	0.750	1.241
	[0.667,0.842]	[1.062,1.451]
Nephrologist care	1.499	1.041
	[1.477,1.521]	[1.019,1.064]
American Indian/Alaskan	0.794	0.659
	[0.748,0.842]	[0.600,0.724]
Asian	1.476	0.672
	[1.436,1.517]	[0.645,0.700]
Black	0.943	0.616
	[0.929,0.957]	[0.603,0.630]
Hispanic	1.207	0.662
	[1.186,1.229]	[0.644,0.680]
Other	1.033	0.616
	[0.897,1.189]	[0.501,0.758]
Pacific Islander	0.943	0.639
	[0.888,1.002]	[0.580,0.704]
Medicaid	0.519	0.746
	[0.508,0.531]	[0.722,0.771]
Medicare	0.534	0.806
	[0.521,0.548]	[0.775,0.838]
Medicare&Medicaid	0.467	0.722
	[0.454,0.480]	[0.691,0.754]
Medicare&Other	0.727	0.915
	[0.706,0.749]	[0.875,0.956]
Other	0.700	0.868
	[0.688,0.713]	[0.847,0.888]
Applying for Medicare	1.032	1.038
	[1.017,1.047]	[1.016,1.061]
Emp pt-time	0.961	0.993
	[0.932,0.992]	[0.952,1.036]
Med LOA	0.838	0.888
	[0.816,0.859]	[0.857,0.920]
Other	0.743	1.040
	[0.695,0.794]	[0.959,1.128]
Homemaker or Unemployed	0.639	0.851
	[0.626,0.652]	[0.828,0.875]
Retired	0.636	0.877
	[0.623,0.649]	[0.853,0.902]
Chain status	0.973	0.948
	[0.959,0.988]	[0.928,0.969]
NE	1.340	0.794
	[1.315,1.366]	[0.773,0.816]
S	0.866	0.886
	[0.851,0.881]	[0.865,0.908]
W	1.007	0.753
	[0.987,1.027]	[0.732,0.775]
Observations	478746	109048

Exponentiated coefficients

4.4.4 Dialysis Center characteristics and access to information, waitlist, and transplantation

Dialysis center ownership was a significant contributor to delivery of information to patients. A dialysis center is defined as chain dialysis center if it is owned by one of the two largest for-profit dialysis chains (DaVita and Fresenius), or by smaller for-profit chains. Informed patients were more likely to receive ESRD care at a chain dialysis center than non-informed patients (83% vs 78% CIs [82.67;82.84] vs [78.13;78.60], see Table 4.1). Characteristics of the center itself were not associated significantly with whether patients would be informed, as a higher per-patient ratio of nurses, technicians, and social workers did not correspond to a higher number of patients informed. The effect of chain ownership also translated into a lower number of patients waitlisted and transplanted in patients undergoing dialysis at a private facility (patients at a chain center were 3% less likely to get listed and 5% less likely to get transplanted (see Table 4.3). These results were further corroborated by logit models estimated on the subset of independent facilities (see Table 4.4). In these models, the dummy variable “Acquired” takes value 1 after an independent facility is acquired by a chain. The odds ratios associated with this variable suggest that the average incident patient is more likely to be informed after acquisition, but also less likely to be added to the waitlist. The coefficients do not change substantially after adding facility and/or time fixed effects to the models, suggesting robustness of these results across different specifications.

Table 4.4: Logit model estimates conditional on independent facilities

	(1) Not informed	(2) Added to waitlist
Acquired	0.322	0.711
	[0.257,0.404]	[0.588,0.861]
Alcohol dependence	1.020	0.756
	[0.929,1.120]	[0.673,0.851]
Drug dependence	1.645	0.270
	[1.492,1.814]	[0.232,0.314]
Inability to ambulate	1.481	0.409
	[1.386,1.583]	[0.357,0.468]
Inability to transfer	1.339	0.508
	[1.235,1.452]	[0.409,0.632]
Needs assistance	1.263	0.543
	[1.206,1.323]	[0.507,0.582]
Age at incidence	1.018	0.948
	[1.017,1.020]	[0.946,0.949]
Male	0.980	1.177
	[0.950,1.010]	[1.141,1.215]
BMI over 40	1.085	0.372
	[1.037,1.134]	[0.352,0.393]
Cystic kidney	1.000	1.000
	[1.000,1.000]	[1.000,1.000]
Diabetes	1.655	0.292
	[1.435,1.907]	[0.268,0.318]
Glomerulonephritis	1.774	0.555
	[1.528,2.061]	[0.505,0.610]
Hypertension	1.564	0.346
	[1.354,1.807]	[0.317,0.378]
Other cause	2.845	0.248
	[2.460,3.289]	[0.225,0.273]
Other urologic	2.117	0.274
	[1.769,2.534]	[0.235,0.319]
Cath	1.381	0.523
	[1.317,1.447]	[0.503,0.543]
Graft	1.206	0.742
	[1.087,1.339]	[0.675,0.815]
Other	1.358	0.588
	[0.976,1.890]	[0.427,0.809]
Nephrologist care	0.752	1.627
	[0.727,0.776]	[1.570,1.687]
American Indian/Alaskan	0.964	0.736
	[0.859,1.081]	[0.646,0.838]
Asian	0.686	2.110
	[0.631,0.746]	[1.967,2.263]
Black	0.853	1.048
	[0.822,0.885]	[1.009,1.088]
Hispanic	0.681	1.495
	[0.649,0.716]	[1.428,1.564]
Other	0.841	1.531
	[0.555,1.274]	[1.056,2.219]
Pacific Islander	0.956	1.107
	[0.817,1.119]	[0.947,1.294]
Medicaid	1.202	0.427
	[1.122,1.287]	[0.404,0.452]
Medicare	1.238	0.455
	[1.158,1.324]	[0.427,0.484]
Medicare&Medicaid	1.423	0.380
	[1.331,1.523]	[0.356,0.406]
Medicare&Other	1.240	0.664
	[1.155,1.330]	[0.622,0.710]
Other	1.337	0.651
	[1.261,1.418]	[0.622,0.681]
Applying for Medicare	0.927	1.050
	[0.894,0.960]	[1.011,1.091]
Emp full-time	1.000	1.000
	[1.000,1.000]	[1.000,1.000]
Emp pt-time	1.114	0.876
	[0.984,1.262]	[0.804,0.955]
Med LOA	1.376	0.761
	[1.238,1.529]	[0.706,0.819]
Other	1.073	0.863
	[0.745,1.545]	[0.677,1.100]
Homemaker or Unemployed	1.496	0.512
	[1.388,1.613]	[0.485,0.540]
Retired	1.554	0.500
	[1.444,1.672]	[0.474,0.527]
Chain status	1.771	1.031
	[1.407,2.230]	[0.850,1.251]
NE	0.962	1.364
	[0.922,1.004]	[1.307,1.422]
S	0.797	0.783
	[0.765,0.831]	[0.750,0.816]
W	1.379	0.924
	[1.317,1.444]	[0.880,0.970]
Constant	0.023	59.517
	[0.019,0.028]	[51.989,68.135]
Observations	133888	133891
chi 2	7202.1	28885.0
chi 2 type	LR	LR

Exponentiated coefficients

4.5 Discussion

In our retrospective analysis of 944,015 patients who initiated dialysis between 2008 and 2019, we found that 14.52% did not receive information about kidney transplantation at the time of dialysis initiation. Of these, 52% were not assessed for an unknown reason, and 27% were deemed medically unfit by the nephrologist managing dialysis. Irrespective of receiving information about transplant options, racial and ethnic minorities, unemployed, and publicly insured patients had longer wait times to transplant. Patients who were informed about kidney transplantation were more likely to be added to the transplant waitlist (HR 1.62). Our findings demonstrate an improvement in the provision of transplant education since the work by Kucirka, who reported 69.9% patients were informed between 2005-2007 (Kucirka et al., 2012). Our results parallel the findings of Ku and colleagues, who recently reported that among ESRD patients, non-Hispanic Black and Hispanic patients had fewer medical contraindications to transplantation but were relatively less likely to receive a kidney transplant than non-Hispanic White patients (Ku et al., 2020).

Policy initiatives implemented during the study period may account for the improvement in access to information about kidney transplant at dialysis initiation. It is possible that increased insurance coverage following the implementation of the Affordable Care Act in 2010 may have decreased barriers related to insurance status. Despite this, we found that patients with Medicare and/or Medicaid were less likely to be informed about transplantation, and patients with private insurance were more likely to receive information about kidney transplant and access to the waitlist and transplantation (while controlling for several socioeconomic characteristics) (Johansen et al., 2012; Keith et al., 2008; Patzer et al., 2012). Older and female patients as well as racial and ethnic minorities spent a longer time on the waitlist, demonstrating that for some minorities the barriers to transplantation are complex and not entirely overcome by gaining access to the waitlist (Vranic et al., 2014).

It is important to note how the persistent disparities in access to information mostly result from providers' choices, as only a small percentage of patients (less than 2% in all groups) declined information about kidney transplantation. Although some groups were more likely to decline information (female, white, retired), their overall percentage remained small, indicating that a lack of information does not reflect an intentional decision by patients, but rather stems from providers' assessments of perceived barriers to transplantation. Still, gender, age, employment status, type of insurance, type of dialysis center, and predialysis nephrology care were all associated with the receipt of information about kidney transplant, as indicated on the 2728 form. The fact that most patients were excluded from receiving information for a "not assessed" reason suggests that the decision not to inform patients may have been taken after a superficial "gestalt" evaluation. Even when a reason for exclusion was specified, it did not necessarily stem from an accurate evaluation of the patient. For example, of patients who were unable to ambulate, only 30.1% were not informed because they were deemed medically unfit. These findings suggest that there may be significant provider-driven bias when assessing eligibility for transplantation. Another explanation for the high rate of non-assessment is lack of time, and prior studies have found that nephrologists treating predominantly Black, elderly, and Medicaid-insured patients report insufficient time as the primary barrier to transplant education (Balhara et al., 2012). To ensure fairness in the referral process and to decrease provider bias, some authors have proposed an opt-out referral model as a solution, although this is a subject of debate (Huml et al., 2021).

We also found that dialysis center ownership was associated with provision of information about transplantation to ESRD patients. Patients undergoing dialysis at chain facilities were more likely to receive information compared to patients treated at independent facilities, but this did not lead to higher rates of waitlisting and transplantation. Moreover, independent facilities acquired by chain facilities change their practices considerably, as patients become more likely to be informed but less likely to be added to the waitlist after acquisition. Our finding suggests that, rather than differences in patient populations, for-profit units provide a lower quality of transplant education, as our analysis controls for several medical and socioeconomic patient characteristics. This result, that chains are more likely to inform patients of transplant options but less likely to place patients on the waitlist, is consistent with prior work that found chain ownership comes with firm-wide standards (e.g., operation manuals that dictate treatment protocols) but also causes waitlist and transplant rates to fall; for-profit chains' explicit mandate to maximize profits may lead them to sacrifice patient outcomes in favor of higher reimbursements (Eliason et al., 2020a). Of note, patients who received information were treated in facilities with a slightly lower number of nurses and social workers when compared to patients who did not receive information, as well as higher patient-to-nurse and patient-to-technician ratios. These results are in contrast to a recent publication indicating that a lower patient-to-staff ratio is more likely to be associated with transplant education (Koch-Weser et al., 2021).

Our study has several additional policy implications. With very limited exceptions, all patients with ESRD should receive access to information about kidney transplantation. Ideally, this would occur well before initiation of dialysis, as pre-emptive transplant is the most ideal renal replacement therapy offered. The purpose of the expanded reimbursement for transplant education and the accompanying change to the CMS-2728 form was to ensure patients are educated about their options for managing ESRD. These options include transplantation, and provision of education about transplant as an option does not require—and we argue should not include—an assessment of whether the patient is a suitable candidate for transplantation, as initiation of renal replacement therapy is not the appropriate setting for a specialized screening. This is especially important considering a recent study showing that dialysis providers themselves had limited knowledge of barriers to transplantation (Waterman et al., 2015b). Ideally, information about transplant as a treatment option for ESRD would be provided well before initiation of dialysis. It is likely, then, that the 2728 falls short of its intended purpose—to ensure timely receipt of information about transplant for patients. One key component of the Advancing American Kidney Health Initiative is the performance payment adjustment, a positive or negative payment adjustment based on home dialysis rate and transplant rate. The Center for Medicare & Medicaid Innovation additionally will provide financial incentives for improved rates of home dialysis and kidney transplant and expand the use of the kidney disease education benefit to CKD stage 5.

These initiatives lend weight to the previously established idea that progression of kidney disease occurs over time and that education about options for renal replacement therapy, including transplantation, should happen at an earlier stage in the disease process. Although our research focused on Form 2728 as a way to quantify delivery of information about transplantation and the disparities associated with it, the time point associated with it (45 days after initiation of dialysis) is probably not the most appropriate. Information about transplantation should ideally happen at an earlier time point, although this would require a shift from the current policy system, where Form 2728 is the latest checkpoint at which all patients should be informed about transplantation. Moreover, our analysis sheds light on differences in attitudes towards transplant information between chain and independent facilities. In fact, policy actions should account for facility ownership differences and ensure that chain protocols do not impede higher information rates to translate into higher waitlist and transplantation rates.

Some limitations apply to our study. This was an observational analysis based on the CMS-2728 Form as part of the USRDS and is therefore subject to the limitations of large registry data reporting. Moreover, there may be inaccuracies in the way in which certain variables on the CMS-2728 Form are coded (Bowling et al., 2015). We limited our focus to documenting which patients received information about kidney transplantation—and did not study directly which patients received access to kidney transplant—based on the assumption that every patient with ESRD should be informed, and that the evaluation and candidacy determination should be managed by transplant centers. In addition, the concept of receiving education about kidney transplantation is vague, and there may be differences in what information is provided to patients, as well as what information is actually retained by them. In fact, a recent study found that a significant proportion of patients informed about kidney transplant by their physicians did not recall receiving the information (Salter et al., 2014). Moreover, we did not assess disparities in pre-emptive listing, and it is also likely that patients may receive information about transplantation from sources other than CMS-2728.

4.6 Conclusion

All patients starting dialysis should be informed of kidney transplant as a renal replacement therapy option, as required by the Centers for Medicare and Medicaid Services Form CMS-2728. Prior research has shown disparities in provision of this information. In this study, we aimed to identify sociodemographic risk factors and dialysis facility characteristics associated with not receiving transplant information at the time of dialysis initiation. We additionally sought to determine the association of receiving transplant information with waitlist and transplant outcomes.

We found that eighteen percent of patients did not receive information about transplantation. Non-informed patients were more likely to be older, female, white, and on Medicare. Patients informed about transplant had a shorter time between end-stage renal disease onset and addition to the waitlist; they also spent a shorter time on the waitlist before receiving a transplant. Patients at chain facilities were more likely to receive information, but this did not translate into higher waitlist or transplantation rates. Patients at independent facilities acquired by chains were more likely to be informed but less likely to be added to the waitlist post acquisition.

These results suggest that disparities continue to persist in providing information about transplantation at initiation of dialysis. Patients who are not informed have reduced access to the transplant waitlist and transplantation. Maximizing the number of patients informed could increase the number of patients referred to transplant centers, and ultimately transplanted. However, policy actions should account for differences in protocols stemming from facility ownership.

Chapter 5

Conclusions

This dissertation focuses on the impact of various reimbursement structures and chain ownership in the context of U.S. health care.

Chapter 2 shows that moral hazard is a serious issue in the Medicare part D reimbursement mechanism. Medicare part D plans, which benefit from a generous federal subsidy for prescriptions filled with expensive biological drugs, are more likely to maintain coverage of a reference biological drug when a cheaper alternative becomes available. They are also less likely to cover the cheaper alternative relative to commercial plans. Back-of-the- envelope calculations suggest that the federal government and Medicare part D patients could realize substantial savings from coverage choices more aligned with commercial plans. This analysis calls into question the sustainability of the current Medicare part D standard benefit. The rationale for the provision of a generous federal subsidy in the catastrophic phase of coverage was to maintain premiums low and accessibility to expensive drugs for patients, but the program has witnessed a doubling of spending in the catastrophic phase of coverage between 2013 and 201721. The analysis shows that preventing plan sponsors from bearing most of the financial risk for their enrollees' drug spending can lead to sub-optimal coverage choices, for example by hindering the take-up of cheaper and equally effective options to treat certain health conditions. Policymakers should find ways to make Medicare part D plans more financially responsible for drug spending. One of the Medicare part D policy changes implemented in 2018 did not achieve the desired goals. The Build Back Better Act, recently signed into law, may have a stronger impact as it alters the cost-sharing structure faced by plans more radically.

Chapter 3 shows that gaming of pay-for-perfomance arrangements is prevalent in the context of dialysis. Patients who would trigger a reimbursement penalty are much more likely to switch facilities after the introduction of such arrangements. The switches appear to be involuntary, as penalty-inducing patients move to worse facilities that are farther from their homes. One reason the QIP leads to gaming by facilities is misaligned financial incentives. Facilities can ensure adequate Kt/V by increasing treatment times, for instance, but this comes with the opportunity cost of treating fewer patients and receiving commensurately lower prospective payments. In such cases, facilities find it optimal to simply drop patients who would trigger QIP penalties rather than invest more effort to improve outcomes.

Finally, Chapter 4 shows that chain ownership of dialysis facilities is associated with higher rates of transplant information at dialysis initiation, but it is also associated with lower rates of addition to the waitlist and surgery. The same result applies to independent facilities acquired by chain facilities during the study period. While chain ownership may be beneficial for patients through economics of scale and the application of firm-wide standards (e.g., operation manuals that dictate treatment protocols), it may also lead to a drop in quality of care associated with the chains' explicit mandate to maximize profits. This may induce chain facilities to impede patients from getting added to the waitlist and undergoing transplant surgery. Therefore, policy actions should account for facility ownership differences and ensure that chain protocols do not impede higher information rates to translate into higher waitlist and transplantation rates.

Appendix A

Appendix for Chapter 2

A.1 Robustness checks

A.1.1 All biological drugs

In the following subsection, I expand the set of control drugs used in the analysis. More specifically, the control group expands from including only the drugs Humira and Enbrel to including all biological drugs for which a biosimilar has not been launched in the market to date. The tables below report the estimates using the updated control group for equations (2.1), (2.2) and (2.3). The estimated treatment effect for equation (2.1) is about half of what was obtained in the previous section and not statistically significant, but still sizable in magnitude. Instead, the treatment effect from equation (2.2) is much larger and statistically significant.

Table A.1: Equation (2.1) estimates - all control drugs

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Commercial	0.289***	0.328***	0.606***
	(0.0455)	(0.0502)	(0.0441)
Biosim Available	0.181**	0.143	0.0673
	(0.0571)	(0.121)	(0.116)
Commercial x Biosim Available	-0.170**	0.0357	-0.0701
	(0.0590)	(0.119)	(0.125)
Post Entry	-0.0970**	-0.00382	-0.0780*
	(0.0347)	(0.0228)	(0.0320)
Commercial x Post Entry	-0.0185	-0.196***	-0.366***
	(0.0346)	(0.0363)	(0.0421)
Biosim Available x Post Entry	0.0115	-0.0709	-0.0578
	(0.0658)	(0.0490)	(0.0541)
Commercial x Biosim Available x Post Entry	**-0.0979**	**-0.0851**	**-0.0253**
	(0.0742)	**(0.0731)**	**(0.0973)**
Constant	0.674***	0.131***	0.343***
	(0.0457)	(0.0325)	(0.0439)
R-squared	0.221	0.185	0.394
N	4376	4376	4376

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table A.2: Equation (2.2) estimates - all control drugs

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Entry	**-0.178****	**-0.0952**	**-0.0885**
	(0.0628)	**(0.0560)**	**(0.0533)**
Constant	0.759***	0.239***	0.469***
	(0.00109)	(0.000972)	(0.000926)
Drug x Period FE	x	x	x
Drug x Segment FE	x	x	x
Segment x Period FE	x	x	x
R-squared	0.884	0.916	0.910
N	4376	4376	4376

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table A.3: Equation (2.3) - all control drugs

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Commercial	0.229***	0.102***	0.258***
	(0.0317)	(0.0320)	(0.0252)
Treated	0.0705	0.101	0.0123
	(0.117)	(0.131)	(0.121)
Commercial x Treated	-0.0577	0.0663	0.0862
	(0.0818)	(0.0986)	(0.112)
Post Event	-0.0455***	0.00902	-0.00983
	(0.0120)	(0.00641)	(0.00869)
Commercial x Post Event	0.0563***	0.0536***	-0.0131
	(0.0146)	(0.00996)	(0.0130)
Treated x Post Event	0.114**	0.0266	0.0415
	(0.0502)	(0.0405)	(0.0462)
Commercial x Treated x Post Event	**-0.277***	**-0.0989**	**-0.180***
	(0.0791)	**(0.100)**	**(0.0982)**
Constant	0.612***	0.121***	0.270***
	(0.0350)	(0.0221)	(0.0306)
R-squared	0.171	0.0710	0.136
N	7956	7956	7956

Standard errors (in parentheses) clustered at the drug level

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

A.1.2 Excluding protected drug classes

One limitation of the analysis so far is that it disregards protected drug classes in Medicare part D. At the start of the program, the Centers for Medicare and Medicaid Services (CMS) identified six "categories and classes of clinical concern", commonly known as the "six protected classes". Then, it required Part D plans to cover "all or substantially all drugs" within each of the classes. These six protected classes include: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants[1]. In the previous section, I demonstrated how this policy is not strictly enforced since a considerable number of Medicare patients do not have access to drugs that belong to the above-mentioned categories. Nevertheless, I extend the analysis to remove treated and control drugs that

[1]https://www.fightcancer.org/

belong to these categories. In the estimation, this approach shrinks the number of drugs to 5 treated drugs and 35 control drugs. The tables below exhibit the results from estimating equations (2.1), (2.2) and (2.3) with the updated treated and control groups. The estimated coefficients of interest do not vary considerably from the previous subsection.

Table A.4: Equation (2.1) estimates - no protected drugs

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Commercial	0.270***	0.263**	0.562***
	(0.0639)	(0.0757)	(0.0673)
Biosim Available	0.141	0.183	0.0991
	(0.0754)	(0.182)	(0.175)
Commercial x Biosim Available	-0.134	0.00228	-0.117
	(0.0795)	(0.174)	(0.184)
Post Entry	-0.132*	-0.0106	-0.0860
	(0.0494)	(0.0376)	(0.0507)
Commercial x Post Entry	0.00540	-0.109*	-0.269***
	(0.0512)	(0.0526)	(0.0627)
Biosim Available x Post Entry	-0.0124	-0.0682	-0.0481
	(0.0926)	(0.0667)	(0.0798)
Commercial x Biosim Available x Post Entry	**-0.172**	**-0.0754**	**-0.0308**
	(0.102)	**(0.0869)**	**(0.137)**
Constant	0.685***	0.183**	0.379***
	(0.0661)	(0.0553)	(0.0699)
R-squared	0.222	0.128	0.350
N	2170	2170	2170

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table A.5: Equation (2.2) estimates - no protected drugs

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Entry	**-0.210***	**-0.137**	**-0.123**
	(0.0970)	**(0.0892)**	**(0.0707)**
Constant	0.743***	0.294***	0.519***
	(0.00241)	(0.00222)	(0.00176)
Drug x Period FE	x	x	x
Drug x Segment FE	x	x	x
Segment x Period FE	x	x	x
R-squared	0.871	0.912	0.896
N	2170	2170	2170

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table A.6: Equation (2.3) estimates - no protected drugs

	Frac. Covered	Frac. Preferred	Frac. Unrestricted
Commercial	0.260***	0.115**	0.336***
	(0.0483)	(0.0448)	(0.0331)
Treated	0.111	0.134	0.0804
	(0.146)	(0.190)	(0.170)
Commercial x Treated	-0.0195	0.120	0.0971
	(0.102)	(0.130)	(0.133)
Post Event	-0.0127	0.0202	0.0126
	(0.0176)	(0.0132)	(0.0153)
Commercial x Post Event	0.00962	0.0436***	-0.0480**
	(0.0231)	(0.0159)	(0.0219)
Treated x Post Event	0.122*	0.0436	0.0480
	(0.0666)	(0.0579)	(0.0669)
Commercial x Treated x Post Event	**-0.294*****	**-0.106**	**-0.181**
	(0.101)	**(0.151)**	**(0.137)**
Constant	0.568***	0.156***	0.283***
	(0.0501)	(0.0378)	(0.0466)
R-squared	0.165	0.0707	0.181
N	2994	2994	2994

Standard errors (in parentheses) clustered at the drug level
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Appendix B

Appendix for Chapter 3

B.1 Computing TPS scores

The following tables provide some insights on the QIP scoring mechanism for a hypothetical facility. The first shows how the TPS score is computed from the QIP subscores, the second one provides the TPS score thresholds which define payment reductions, while the last one shows how a QIP subscore (Dialysis Adequacy) is computed starting from claims data.

PROJECTED PAYMENT REDUCTION PERCENTAGE:	NO REDUCTION
TOTAL PERFORMANCE SCORE	
Facility Total Performance Score: 27 (out of 30)	
PERFORMANCE MEASURE SCORES	
Anemia Management Percent of patients with hemoglobin less than 10 grams per deciliter (g/dL)	**8** (out of 10)
Anemia Management Percent of patients with hemoglobin greater than 12 g/dL	**10** (out of 10)
Dialysis Adequacy Percent of patients with urea reduction ratio (URR) of at least 65%	**10** (out of 10)

Note: The Total Performance Score is based on a *weighted average* of the measure scores:

Hemoglobin less than 10 g/dL represents 50% of the total weighted score.
Hemoglobin greater than 12 g/dL represents 25% of the total weighted score.
URR of at least 65% represents 25% of the total weighted score.

Total Performance Score	Payment Reduction	
26 to 30	No reduction	←**This facility**
21 to 25	0.5%	
16 to 20	1.0%	
11 to 15	1.5%	
0 to 10	2.0%	
No score calculated	No reduction	

	Facility Rate Calculation for 2007	
7a	Number of patients with URR of at least 65%	49
7b	Total number of patients included in calculation	50
7c	Percent of patients with URR of at least 65% *Divide 7a by 7b and round*	**98%**
	Performance Standard Determination	
7d	Facility comparison rate for 2007 (from 7c)	98%
7e	National average in 2008	96%
7f	Performance standard applied *Apply the lesser (worse) of 7d or 7e*	**2008 national average 96%**
	Facility Rate Calculation for Performance Period (2010)	
7g	Number of patients with URR of at least 65%	34
7h	Total number of patients included in calculation	35
7i	Percent of patients with URR of at least 65% *Divide 7g by 7h and round*	**97%**
	Performance Measure Score Calculation	
7j	Facility performance rate in 2010 (from 7i)	97%
7k	Performance standard (from 7f)	96%
7l	Does the facility meet or exceed the standard?	Yes
7m	Difference between facility rate and performance standard	Meets or exceeds
7n	**Performance Measure Score** *Compare 7m to Table 3*	**10**

Figure B.1: Example of TPS score calculation

B.2 Robustness checks with alternative definitions of penalty inducing status

The following tables provide a set of robustness check using an alternative definition of penalty inducing status.

Table B.1: Regression estimates - Probability of switching

	Probability of switching			Probability of switching at discharge		
	(1)	(2)	(3)	(4)	(5)	(6)
Desirability score	-0.000678***	-0.000755***	-0.000714***	-0.000491***	-0.000835***	-0.000783***
	(0.0000196)	(0.0000205)	(0.0000205)	(0.0000821)	(0.0000825)	(0.0000830)
Constant	0.0255***	0.0260***	0.0154***	0.0296***	0.0309***	0.00685
	(0.00112)	(0.00113)	(0.00135)	(0.00518)	(0.00518)	(0.00587)
Baseline QIP values	Yes	Yes	Yes	Yes	Yes	Yes
Patient Controls	Yes	Yes	Yes	Yes	Yes	Yes
Facility Controls	Yes	Yes	Yes	Yes	Yes	Yes
Month-Year FE	No	Yes	Yes	No	Yes	Yes
Facility FE	No	No	Yes	No	No	Yes
R-squared	0.00162	0.00179	0.00784	0.00307	0.00368	0.0220
Observations	12885608	12885608	12885548	935592	935592	935469
Mean Dep. Var.	0.00623	0.00623	0.00623	0.0115	0.0115	0.0115

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table B.2: Likelihood of switching - moving average of penalty inducing status

	Probability of switching			
	(1)	(2)	(3)	(4)
Ever Penalty inducing	0.00466***	0.00251***	0.00296***	0.00277***
	(0.0000470)	(0.0000614)	(0.0000662)	(0.0000669)
Always penalty inducing	0.00134***	0.00116***	0.00102***	0.000938***
	(0.0000620)	(0.0000873)	(0.0000890)	(0.0000900)
Constant	0.00437***	0.0187***	0.0192***	0.00876***
	(0.0000382)	(0.00130)	(0.00130)	(0.00166)
Baseline QIP values	No	Yes	Yes	Yes
Patient Controls	No	Yes	Yes	Yes
Facility Controls	No	Yes	Yes	Yes
Month-Year FE	No	No	Yes	Yes
Facility FE	No	No	No	Yes
R-squared	0.000481	0.00183	0.00201	0.00791
Observations	19154484	10729558	10729558	10729479
Mean Dep. Var.	0.00774	0.00694	0.00694	0.00694

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

B.3 Do patients move to better facilities?

Table B.3: Quality of care measures

	Δ mortality rate			Δ hospitalization rate			Δ infection rate			Δ distance		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Penalty inducing	0.00260***	0.00233***	0.00300***	0.00232	0.00133	0.00402***	0.00192*	0.00154*	0.00352***	0.388***	0.312***	0.286***
	(0.000560)	(0.000562)	(0.000531)	(0.00143)	(0.00137)	(0.00121)	(0.000764)	(0.000760)	(0.000696)	(0.0705)	(0.0720)	(0.0715)
Constant	-0.0135	-0.0132	-0.0152	-0.0172	-0.0160	-0.0231	-0.0383**	-0.0381**	-0.0247	-0.731	-0.351	0.455
	(0.00980)	(0.00982)	(0.0114)	(0.0280)	(0.0270)	(0.0287)	(0.0134)	(0.0133)	(0.0149)	(1.273)	(1.278)	(1.366)
Baseline QIP values	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Facility Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Month-Year FE	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Facility FE	No	No	Yes	No	No	Yes	No	No	Yes	No	No	Yes
R-squared	0.0210	0.0255	0.285	0.0302	0.0470	0.333	0.0231	0.0287	0.301	0.0202	0.0239	0.186
Observations	57588	57588	57101	57588	57588	57101	57588	57588	57101	57135	57135	56606
Mean Dep. Var.	-0.000594	-0.000594	-0.000667	-0.0128	-0.0128	-0.0130	-0.00261	-0.00261	-0.00265	-0.292	-0.292	-0.303

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table B.4: Staffing measures

	Δ nurse per tech.	Δ nurse per pat.	Δ nurse per employee	Δ employee per station	Δ pat. per station	Δ nurse per station	Δ tech. per station	Δ pat. per employee
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Penalty inducing	0.00525	-0.0200	-0.00135	0.0172**	0.0870***	0.00480*	0.00341	0.0392
	(0.00710)	(0.0233)	(0.00102)	(0.00563)	(0.0243)	(0.00194)	(0.00228)	(0.0266)
Constant	-0.0204	-0.485	0.00289	-0.0290	0.686	-0.00569	0.00406	0.370
	(0.151)	(0.354)	(0.0240)	(0.122)	(0.475)	(0.0446)	(0.0536)	(0.559)
Baseline QIP values	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Facility Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Month-Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Facility FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
R-squared	0.301	0.0550	0.350	0.684	0.674	0.701	0.694	0.274
Observations	53628	46272	54720	56718	46387	56718	56718	44462
Mean Dep. Var.	0.0207	0.0216	0.00320	-0.00635	-0.209	0.000181	-0.00929	-0.300

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

B.4 URR - Kt/V regressions

Table B.5: URR - Kt/V regressions

	Probability of switching			
	(1)	(2)	(3)	(4)
Low URR and good Kt/V	0.00658***	0.00811***	0.00813***	0.00825***
	(0.00115)	(0.00159)	(0.00159)	(0.00158)
Good URR and low Kt/V	-0.000755	-0.000216	-0.000189	-0.000160
	(0.000966)	(0.00131)	(0.00131)	(0.00131)
Good URR and good Kt/V	-0.00962***	-0.00866***	-0.00868***	-0.00843***
	(0.000502)	(0.000663)	(0.000663)	(0.000661)
Kt/V in QIP	-0.00325***	-0.00315***		
	(0.000547)	(0.000722)		
Low URR and good Kt/V × Kt/V in QIP	-0.00412***	-0.00579***	-0.00573***	-0.00593***
	(0.00122)	(0.00167)	(0.00167)	(0.00166)
Good URR and low Kt/V × Kt/V in QIP	0.00798***	0.00741***	0.00740***	0.00712***
	(0.00117)	(0.00158)	(0.00158)	(0.00157)
Good URR and good Kt/V × Kt/V in QIP	0.00253***	0.00279***	0.00284***	0.00291***
	(0.000550)	(0.000726)	(0.000726)	(0.000723)
Constant	0.0165***	0.0315***	0.0286***	0.0139***
	(0.000499)	(0.00148)	(0.00135)	(0.00212)
Baseline QIP values	No	Yes	Yes	Yes
Patient Controls	No	Yes	Yes	Yes
Facility Controls	No	Yes	Yes	Yes
Month-Year FE	No	No	Yes	Yes
Facility FE	No	No	No	Yes
R-squared	0.000485	0.00179	0.00194	0.00718
Observations	15464192	9315901	9315901	9315853
Mean Dep. Var.	0.00666	0.00633	0.00633	0.00633

Standard errors in parentheses

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Appendix C

Appendix for Chapter 4

C.1 List of patient and facility characteristics

Table C.1: List of patient and facility characteristics

Variables	Subcategories
Age	
Gender	M
	F
BMI	>40
	<=40
Race	Black
	White
	Asian
	American Indian/Alaskan
	Pacific Islander
	Hispanic
Current insurance	Private
	Medicaid
	Medicare
	Medicare&Medicaid
	Medicare&Other
	Other
Applying for Medicare	Yes
	No
Employment status	Employed full-time
	Emp part-time
	Homemaker or Unemployed
	Medical Leave of absence (LOA)
	Other
	Retired
ESRD case	Cystic Kidney
	Diabetes
	Glomerulonephritis
	Hypertension
	Other urologic
	Other cause
Nephrology care pre ESRD	Yes
	No
Facility ownership	Chain
	Independent
First access	Arteriovenous Fistula
	Indwelling catheter
	Arteriovenous Graft
	Other
Region	NE
	MW
	S
	W
Alcohol dependence	Yes
	No
Drug dependence	No
	Yes
Inability to ambulate	No
	Yes
Inability to transfer	No
	Yes
Needing assistance in ADLs	No
	Yes
Patients per registered nurse	
Patients per technician	
Patients per social worker	

Bibliography

Michael Abecassis, Stephen T Bartlett, Allan J Collins, Connie L Davis, Francis L Delmonico, John J Friedewald, Rebecca Hays, Andrew Howard, Edward Jones, Alan B Leichtman, et al. Kidney transplantation as primary therapy for end-stage renal disease: a national kidney foundation/kidney disease outcomes quality initiative (nkf/kdoqi™) conference. *Clinical Journal of the American Society of Nephrology*, 3(2):471–480, 2008.

Fozia Ajmal, Janice Probst, John Brooks, James Hardin, and Zaina Qureshi. Association between freestanding dialysis facility size and medicare quality incentive program performance scores. *American journal of nephrology*, 49(1):64–73, 2019.

Fozia Ajmal, Janice C Probst, John M Brooks, James W Hardin, Zaina Qureshi, and Tazeen H Jafar. Freestanding dialysis facility quality incentive program scores and mortality among incident dialysis patients in the united states. *American Journal of Kidney Diseases*, 75(2):177–186, 2020.

Diane Alexander. How do doctors respond to incentives? unintended consequences of paying doctors to reduce costs. *Journal of Political Economy*, 128(11):4046–4096, 2020.

Preston Atteberry, Peter B Bach, Jennifer A Ohn, and Mark Trusheim. Biologics are natural monopolies (part 1): why biosimilars do not create effective competition. *Health Affairs Blog*, 15, 2019.

Andrew C Baker, David F Larcker, and Charles CY Wang. How much should we trust staggered difference-in-differences estimates? *Journal of Financial Economics*, 144(2): 370–395, 2022.

Sam Baker. The U.S. Health Care System is Full of Monopolies. *Axios*, 2019.

Kamna S Balhara, Lauren M Kucirka, Bernard G Jaar, and Dorry L Segev. Disparities in provision of transplant education by profit status of the dialysis center. *American Journal of Transplantation*, 12(11):3104–3110, 2012.

C Barrett Bowling, Rebecca Zhang, Harold Franch, Yijian Huang, Anna Mirk, William M McClellan, Theodore M Johnson, and Nancy G Kutner. Underreporting of nursing home utilization on the cms-2728 in older incident dialysis patients and implications for assessing mortality risk. *BMC nephrology*, 16(1):1–10, 2015.

Jürgen Braun and Alex Kudrin. Switching to biosimilar infliximab (ct-p13): evidence of clinical safety, effectiveness and impact on public health. *Biologicals*, 44(4):257–266, 2016.

Jason Brown, Mark Duggan, Ilyana Kuziemko, and William Woolston. How does risk selection respond to risk adjustment? new evidence from the medicare advantage program. *American Economic Review*, 104(10):3335–64, 2014.

Brantly Callaway and Pedro HC Sant'Anna. Difference-in-differences with multiple time periods. *Journal of Econometrics*, 225(2):200–230, 2021.

Doruk Cengiz, Arindrajit Dube, Attila Lindner, and Ben Zipperer. The effect of minimum wages on low-wage jobs. *The Quarterly Journal of Economics*, 134(3):1405–1454, 2019.

Hillel P Cohen, Andrew Blauvelt, Robert M Rifkin, Silvio Danese, Sameer B Gokhale, and Gillian Woollett. Switching reference medicines to biosimilars: a systematic literature review of clinical outcomes. *Drugs*, 78(4):463–478, 2018.

G Combes, K Sein, and K Allen. How does pre-dialysis education change? findings from a qualitative study with staff and patients. *Nephrology Journal*, 2017.

Leemore Dafny, Christopher Ody, and Matt Schmitt. When discounts raise costs: the effect of copay coupons on generic utilization. *American Economic Journal: Economic Policy*, 9(2):91–123, 2017.

Leemore S Dafny. How do hospitals respond to price changes? *American Economic Review*, 95(5):1525–1547, 2005.

Manasi Deshpande and Yue Li. Who is screened out? application costs and the targeting of disability programs. *American Economic Journal: Economic Policy*, 11(4):213–48, 2019.

Gerald M Devins, David C Mendelssohn, Paul E Barré, and Yitzchak M Binik. Predialysis psychoeducational intervention and coping styles influence time to dialysis in chronic kidney disease. *American Journal of Kidney Diseases*, 42(4):693–703, 2003.

Gerald M Devins, David C Mendelssohn, Paul E Barré, Kenneth Taub, and Yitzchak M Binik. Predialysis psychoeducational intervention extends survival in ckd: a 20-year follow-up. *American Journal of Kidney Diseases*, 46(6):1088–1098, 2005.

Michael J Dickstein, Kate Ho, and Nathaniel D Mark. Market segmentation and competition in health insurance. Technical report, National Bureau of Economic Research, 2021.

P Eliason, Benjamin Heebsh, R League, R McDevitt, and James Roberts. The effect of bundled payments on provider behavior and patient outcomes: evidence from the dialysis industry. *Work. Pap., Duke Univ., Durham, NC*, 2022.

Paul J Eliason, Paul LE Grieco, Ryan C McDevitt, and James W Roberts. Strategic patient discharge: The case of long-term care hospitals. *American Economic Review*, 108(11): 3232–65, 2018.

Paul J Eliason, Benjamin Heebsh, Ryan C McDevitt, and James W Roberts. How acquisitions affect firm behavior and performance: Evidence from the dialysis industry. *The Quarterly Journal of Economics*, 135(1):221–267, 2020a.

Paul J Eliason, Benjamin Heebsh, Ryan C McDevitt, and James W Roberts. How acquisitions affect firm behavior and performance: Evidence from the dialysis industry. *The Quarterly Journal of Economics*, 135(1):221–267, 2020b.

Josh Feng and Luca Maini. Demand inertia and the hidden impact of pharmacy benefit managers. *Available at SSRN 3316430*, 2019.

Jeffrey C Fink, Min Zhan, Steven A Blahut, Michael Soucie, and William M McClellan. Measuring the efficacy of a quality improvement program in dialysis adequacy with changes in center effects. *Journal of the American Society of Nephrology*, 13(9):2338–2344, 2002.

FO Finkelstein. Story k firanek c barre p takano t soroka s mujais s rodd k mendelssohn d perceived knowledge among patients cared for by nephrologists about chronic kidney disease and end-stage renal disease therapies. *Kidney Int*, 74:1178–1184, 2008.

Steven Fishbane and Azzour Hazzan. Meeting the 2012 qip (quality incentive program) clinical measures: strategies for dialysis centers. *American journal of kidney diseases*, 60 (5):S5–S13, 2012.

Jennifer C Gander, Xingyu Zhang, Laura Plantinga, Sudeshna Paul, Mohua Basu, Stephen O Pastan, Eric Gibney, Erica Hartmann, Laura Mulloy, Carlos Zayas, et al. Racial disparities in preemptive referral for kidney transplantation in georgia. *Clinical transplantation*, 32(9):e13380, 2018.

Ashvin Gandhi. Picking your patients: Selective admissions in the nursing home industry. *Available at SSRN 3613950*, 2019.

Michael Geruso, Timothy Layton, and Daniel Prinz. Screening in contract design: Evidence from the aca health insurance exchanges. *American Economic Journal: Economic Policy*, 11(2):64–107, 2019.

Dana P Goldman, Geoffrey F Joyce, and Yuhui Zheng. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *Jama*, 298(1):61–69, 2007.

Thomas A Golper. Predialysis nephrology care improves dialysis outcomes: now what? or chapter two, 2007.

Andrew Goodman-Bacon. Difference-in-differences with variation in treatment timing. *Journal of Econometrics*, 225(2):254–277, 2021.

Henry Grabowski, Genia Long, Richard Mortimer, and Ani Boyo. Updated trends in us brand-name and generic drug competition. *Journal of medical economics*, 19(9):836–844, 2016.

Henry G Grabowski, David B Ridley, and Kevin A Schulman. Entry and competition in generic biologics. *Managerial and Decision Economics*, 28(4-5):439–451, 2007.

Patricia M Grambsch and Terry M Therneau. Proportional hazards tests and diagnostics based on weighted residuals. *Biometrika*, 81(3):515–526, 1994.

Atul Gupta. Impacts of performance pay for hospitals: The readmissions reduction program. *American Economic Review*, 111(4):1241–83, 2021.

Martin B Hackmann, R Vincent Pohl, and Nicolas R Ziebarth. Patient versus provider incentives in long-term care. 2020.

Philip J Held, Friedrich K Port, Robert A Wolfe, David C Stannard, Caitlin E Carroll, John T Daugirdas, Wendy E Bloembergen, Joel W Greer, and Raymond M Hakim. The dose of hemodialysis and patient mortality. *Kidney international*, 50(2):550–556, 1996.

Inmaculada Hernandez, Chester B Good, David M Cutler, Walid F Gellad, Natasha Parekh, and William H Shrank. The contribution of new product entry versus existing product inflation in the rising costs of drugs. *Health Affairs*, 38(1):76–83, 2019.

Kate Ho and Robin Lee. Contracting over rebates: Formulary design and pharmaceutical spending. 2022.

Jason Hong. The threat of exclusion in bargaining: Evidence from medicare part d. 2015.

Anne M Huml, John R Sedor, Emilio Poggio, Rachel E Patzer, and Jesse D Schold. An opt-out model for kidney transplant referral: The time has come. *American Journal of Transplantation*, 21(1):32–36, 2021.

Julia James, C Damberg, A Ryan, et al. Pay-for-performance. *Health Affairs*, 34(8):1–6, 2012.

Kirsten L Johansen, Rebecca Zhang, Yijian Huang, Rachel E Patzer, and Nancy G Kutner. Association of race and insurance type with delayed assessment for kidney transplantation among patients initiating dialysis in the united states. *Clinical Journal of the American Society of Nephrology*, 7(9):1490–1497, 2012.

Kristin K Jørgensen, Inge C Olsen, Guro L Goll, Merete Lorentzen, Nils Bolstad, Espen A Haavardsholm, Knut EA Lundin, Cato Mørk, Jørgen Jahnsen, Tore K Kvien, et al. Switching from originator infliximab to biosimilar ct-p13 compared with maintained treatment with originator infliximab (nor-switch): a 52-week, randomised, double-blind, non-inferiority trial. *The Lancet*, 389(10086):2304–2316, 2017.

Douglas Keith, Valarie B Ashby, Friedrich K Port, and Alan B Leichtman. Insurance type and minority status associated with large disparities in prelisting dialysis among candidates for kidney transplantation. *Clinical Journal of the American Society of Nephrology*, 3(2):463–470, 2008.

John D Kepler, Valeri V Nikolaev, Nicholas Scott-Hearn, and Christopher R Stewart. Quality transparency and healthcare competition. *Available at SSRN 3963418*, 2022.

Susan Koch-Weser, Thalia Porteny, Dena E Rifkin, Tamara Isakova, Elisa J Gordon, Ana Rossi, Geri Lynn Baumblatt, Jennifer St Clair Russell, Kelli Collins Damron, Shennon Wofford, et al. Patient education for kidney failure treatment: a mixed-methods study. *American Journal of Kidney Diseases*, 78(5):690–699, 2021.

Elaine Ku, Brian K Lee, Charles E McCulloch, Garrett R Roll, Barbara Grimes, Deborah Adey, and Kirsten L Johansen. Racial and ethnic disparities in kidney transplant access within a theoretical context of medical eligibility. *Transplantation*, 104(7):1437, 2020.

Lauren M Kucirka, ME Grams, Kamna S Balhara, Bernard G Jaar, and Donny L Segev. Disparities in provision of transplant information affect access to kidney transplantation. *American Journal of Transplantation*, 12(2):351–357, 2012.

Kurt Lavetti and Kosali Simon. Strategic formulary design in medicare part d plans. *American Economic Journal: Economic Policy*, 10(3):154–92, 2018.

Riley J League, Paul Eliason, Ryan C McDevitt, James W Roberts, and Heather Wong. Variability in prices paid for hemodialysis by employer-sponsored insurance in the us from 2012 to 2019. *JAMA Network Open*, 5(2):e220562–e220562, 2022.

ChangWon C Lee, Mehdi Najafzadeh, Aaron S Kesselheim, and Ameet Sarpatwari. Cost to medicare of delayed adalimumab biosimilar availability. *Clinical Pharmacology & Therapeutics*, 110(4):1050–1056, 2021.

Jun Li and Edward C Norton. Pay-for-performance and long-term care. In *Oxford Research Encyclopedia of Economics and Finance*. 2019.

Domenico Lisi, Luigi Siciliani, and Odd Rune Straume. Hospital competition under pay-for-performance: Quality, mortality, and readmissions. *Journal of Economics & Management Strategy*, 29(2):289–314, 2020.

Luca Maini, Josh Feng, Thomas Hwang, and Jacob Klimek. Biosimilar entry and the pricing of biologic drugs. *Available at SSRN 3760213*, 2021.

William M McClellan, J Michael Soucie, and W Dana Flanders. Mortality in end-stage renal disease is associated with facility-to-facility differences in adequacy of hemodialysis. *Journal of the American Society of Nephrology*, 9(10):1940–1947, 1998.

Keith P McCullough, Hal Morgenstern, Rajiv Saran, William H Herman, and Bruce M Robinson. Projecting esrd incidence and prevalence in the united states through 2030. *Journal of the American Society of Nephrology*, 30(1):127–135, 2019.

Laura J McPherson, Reem E Hamoda, and Rachel E Patzer. Measuring patient knowledge of kidney transplantation: An initial step to close the knowledge gap. *Transplantation*, 103(3):459, 2019.

Herwig-Ulf Meier-Kriesche and Bruce Kaplan. Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A paired donor kidney analysis: 1. *Transplantation*, 74(10):1377–1381, 2002.

Karthik Muralidharan and Nishith Prakash. Cycling to school: Increasing secondary school enrollment for girls in india. *American Economic Journal: Applied Economics*, 9(3): 321–50, 2017.

Larissa Myaskovsky, Donna Almario Doebler, Donna M Posluszny, Mary Amanda Dew, Mark Unruh, Linda F Fried, Galen E Switzer, Sunghee Kim, Chung-Chou H Chang, Mohan Ramkumar, et al. Perceived discrimination predicts longer time to be accepted for kidney transplant. *Transplantation*, 93(4):423, 2012.

Edward C Norton, Jun Li, Anup Das, and Lena M Chen. Moneyball in medicare. *Journal of health economics*, 61:259–273, 2018.

Andreas Olden and Jarle Møen. The triple difference estimator. *The Econometrics Journal*, 25(3):531–553, 2022.

Alexander L Olssen and Mert Demirer. Drug rebates and formulary design: Evidence from statins in medicare part d. In *Massachusetts Institute of Technology Working Paper*. 2019.

Paul M Palevsky, Margaret S Washington, Judy A Stevenson, Jeffrey M Rohay, Nancy J Dyer, Rhonda Lockett, and Shane B Perry. Barriers to the delivery of adequate hemodialysis in esrd network 4. *Advances in renal replacement therapy*, 7(4 Suppl 1):S11–20, 2000.

Rachel E Patzer, Jennie P Perryman, Stephen Pastan, Sandra Amaral, Julie A Gazmararian, Mitch Klein, Nancy Kutner, and William M McClellan. Impact of a patient education program on disparities in kidney transplant evaluation. *Clinical Journal of the American Society of Nephrology*, 7(4):648–655, 2012.

Megan L Salter, Babak Orandi, Mara A McAdams-DeMarco, Andrew Law, Lucy A Meoni, Bernard G Jaar, Stephen M Sozio, Wen Hong Linda Kao, Rulan S Parekh, and Dorry L Segev. Patient-and provider-reported information about transplantation and subsequent waitlisting. *Journal of the American Society of Nephrology*, 25(12):2871–2877, 2014.

Ameet Sarpatwari, Rachel Barenie, Gregory Curfman, Jonathan J Darrow, and Aaron S Kesselheim. The us biosimilar market: stunted growth and possible reforms. *Clinical Pharmacology & Therapeutics*, 105(1):92–100, 2019.

Milda R Saunders, Haena Lee, and Marshall H Chin. Early winners and losers in dialysis center pay-for-performance. *BMC health services research*, 17(1):1–9, 2017.

Jesse D Schold, Sumit Mohan, Anne Huml, Laura D Buccini, John R Sedor, Joshua J Augustine, and Emilio D Poggio. Failure to advance access to kidney transplantation over two decades in the united states. *Journal of the American Society of Nephrology*, 32 (4):913–926, 2021.

Aaron L. Schwartz, Troyen A. Brennan, Dorothea J. Verbrugge, and Joseph P. Newhouse. Measuring the Scope of Prior Authorization Policies: Applying Private Insurer Rules to Medicare Part B. *JAMA Health Forum*, 2(5):e210859–e210859, 05 2021. ISSN 2689-0186. doi: 10.1001/jamahealthforum.2021.0859. URL `https://doi.org/10.1001/jamahealthforum.2021.0859`.

Fiona M Scott Morton, Ariel Dora Stern, and Scott Stern. The impact of the entry of biosimilars: evidence from europe. *Review of Industrial Organization*, 53(1):173–210, 2018.

Ashwini R Sehgal, Richard J Snow, Mendel E Singer, Saeid B Amini, Peter B DeOreo, Marcia R Silver, and Randall D Cebul. Barriers to adequate delivery of hemodialysis. *American Journal of Kidney Diseases*, 31(4):593–601, 1998.

Ashwini R Sehgal, Janeen B Leon, Laura A Siminoff, Mendel E Singer, Lisa M Bunosky, and Randall D Cebul. Improving the quality of hemodialysis treatment: a community-based randomized controlled trial to overcome patient-specific barriers. *Jama*, 287(15): 1961–1967, 2002.

Stacy L Skelton, Amy D Waterman, LaShara A Davis, John D Peipert, and Anne F Fish. Applying best practices to designing patient education for patients with end-stage renal disease pursuing kidney transplant. *Progress in Transplantation*, 25(1):77–90, 2015.

Mariana P Socal, Ijeamaka Ezebilo, Ge Bai, and Gerard F Anderson. Biosimilar formulary placement in medicare part d prescription drug plans: A case study of infliximab. *American Journal of Health-System Pharmacy*, 78(3):216–221, 2021.

Liyang Sun and Sarah Abraham. Estimating dynamic treatment effects in event studies with heterogeneous treatment effects. *Journal of Econometrics*, 225(2):175–199, 2021.

Navdeep Tangri, Hocine Tighiouart, Klemens B Meyer, and Dana C Miskulin. Both patient and facility contribute to achieving the centers for medicare and medicaid services' pay-for-performance target for dialysis adequacy. *Journal of the American Society of Nephrology*, 22(12):2296–2302, 2011.

MR Trusheim, Preston Atteberry, Jennifer A Ohn, and Peter B Bach. Biologics are natural monopolies (part 2): A proposal for post-exclusivity price regulation of biologics. *Health Affairs Blog*, pages 10–13, 2019.

United States Renal Data System. 2014 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2014.

Victor L Van de Wiele, Aaron S Kesselheim, and Ameet Sarpatwari. Barriers to us biosimilar market growth: Lessons from biosimilar patent litigation: Article examines barriers to us biosimilar market growth. *Health Affairs*, 40(8):1198–1205, 2021.

GM Vranic, JZ Ma, and DS Keith. The role of minority geographic distribution in waiting time for deceased donor kidney transplantation. *American Journal of Transplantation*, 14(11):2526–2534, 2014.

Amy D Waterman, Marie Morgievich, David J Cohen, Zeeshan Butt, Harini A Chakkera, Carrie Lindower, Rebecca E Hays, Janet M Hiller, Krista L Lentine, Arthur J Matas, et al. Living donor kidney transplantation: improving education outside of transplant centers about live donor transplantation—recommendations from a consensus conference. *Clinical Journal of the American Society of Nephrology*, 10(9):1659–1669, 2015a.

Amy D Waterman, John D Peipert, Christina J Goalby, Katrina M Dinkel, Huiling Xiao, and Krista L Lentine. Assessing transplant education practices in dialysis centers: Comparing educator reported and medicare data. *Clinical Journal of the American Society of Nephrology*, 10(9):1617–1625, 2015b.

Francis L Weng, Marshall M Joffe, Harold I Feldman, and Kevin C Mange. Rates of completion of the medical evaluation for renal transplantation. *American journal of kidney diseases*, 46(4):734–745, 2005.

Anna Werbeck, Ansgar Wübker, and Nicolas R Ziebarth. Cream skimming by health care providers and inequality in health care access: Evidence from a randomized field experiment. Technical report, National Bureau of Economic Research, 2021.

Robert A Wolfe, Valarie B Ashby, Edgar L Milford, Akinlolu O Ojo, Robert E Ettenger, Lawrence YC Agodoa, Philip J Held, and Friedrich K Port. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. *New England journal of medicine*, 341(23):1725–1730, 1999.

Ou Yang, Marc K Chan, Terence C Cheng, and Jongsay Yong. Cream skimming: Theory and evidence from hospital transfers and capacity utilization. *Journal of Economic Behavior & Organization*, 173:68–87, 2020.

Mike Z Zhai, Ameet Sarpatwari, and Aaron S Kesselheim. Why are biosimilars not living up to their promise in the us? *AMA Journal of Ethics*, 21(8):668–678, 2019.

Kim Zuber, Jane Davis, and Dana V Rizk. Kidney disease education one year after the medicare improvement of patients and providers act: a survey of us nephrology practices. *American Journal of Kidney Diseases*, 59(6):892–894, 2012.

Biography

Luca Bertuzzi is a PhD candidate at Duke University and will complete his doctoral degree in May 2023. His research interests relate to Industrial Organization and Health Economics. Luca also holds a Master's and Bachelor's degree from the University of Bologna.