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ABSTRACT

The purpose of this dissertation is to investigate how regulation and deregulation impacts hospital performance, its persistence effect and the different impact on drug markets. The authorities designed programs and policies to regulate hospitals and pharmaceutical markets, aiming at improving hospital performance and control drug prices, while in reality, the programs and policies generate consequences, the effect varies across different types of the hospitals and drugs.

The dissertation consists of three essays. The first essay proposes a propensity score matching-difference in difference framework of program evaluation of Value Based Purchasing program. This framework first applies the propensity score matching method to find a treated group whose characteristics are comparable to our control group (hospitals in Maryland). Next, I used the difference in difference method to evaluate whether and how the VBP program impacts hospitals performance in terms of quality, satisfaction, safety and efficiency. Our empirical analysis using 5 years of hospital performance data from various sources. The results showed that, under the program of VBP, hospitals that are impacted did show improvements in patient experience, but in terms of experience dimensions, only pain control scores were improved significantly. Regarding safety, cost efficiency and conformance quality, the impacted hospitals did not show significant improvements. The sensitivity check supports our conclusion.

The second essay studies the state dependence effect of payment adjustments on hospitals to see whether the effect exist and how it varies across hospitals of different characteristics, socioeconomic factors and geo-locations. The program adjusts the payment as follows: First, the program reduces a portion of the hospital's Medicare payments in a specific fiscal year and then by the end of the same fiscal year, the amount of the payment reductions will be awarded to the hospitals based on the total performance score, thus the hospitals that do not receive the reward will lose the portion of money reduced by Medicare. In this essay, I apply the theory of state dependence and use the dynamic random effect probit model to estimate this effect. The results show that the hospital payment adjustment dynamics have a very significant state dependence effect (0.341), that means, hospitals that received a reward in previous year are 34.1% more probably to receive a reward this year than the ones that received a penalty in previous year. Meanwhile, I also find that the state dependence effect varies significantly across hospitals with different ownership (proprietary/government owned/voluntary nonprofit), the results show that voluntary nonprofit hospitals exhibit largest effect of state dependence (0.370), while government owned hospitals exhibit lowest effect of state dependence (0.293) and proprietary hospitals are in the middle. Among the factors that influence the likelihood a hospital receive a reward, I find that teaching hospitals with large number of beds (>400), are less likely be rewarded; in terms of ownership, I find that voluntary nonprofit hospitals are more likely be rewarded; in terms of are more likely be rewarded.

The third essay studies the effect of deregulation of price cap in pharmaceutical market. Price regulation (either through price cap or reference price) is common practice in pharmaceutical market but recently there are increasing voices calling for deregulation claiming that deregulation could help with lowering drug price and increase revenue of pharmaceutical firms. Upon those callings, Chinese government removed the price cap regulation in June 2015. In this essay, I applied the interrupted time series analysis (ITSA) on the sales revenue data of nine categories of both generic and branded drugs in China from March 2011 to August 2016 (the time frame includes both before and after of the initialization of the deregulation) and analyzed the effect of deregulation. The results showed that, whether the revenue of drugs will increase or decrease after the deregulation of price cap depends on the level of competition and the change of patterns of the branded and generic drugs are different. When HHI is sufficiently low (competition is high), revenue does not change as a result of deregulation, when HHI is moderately low (moderate competition), revenue from generic drugs will decrease significantly and revenue from branded drugs will increase significantly, when HHI is high (low competition), revenue from generic drugs will increase significantly and revenue from branded drugs will decrease significantly.

Three Essays on Regulation in Healthcare and Pharmaceutical Markets

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Dissertation

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CHAPTER ONE: OVERVIEW OF DISSERTATION INTRODUCTION

This dissertation consists of three essays about authorities' regulation and deregulation policies in face of performance shortfalls. Hospitals have long been criticized for ignoring patient experience and satisfaction, the payment model of healthcare also have long been blamed for focusing on quantity not on quality. In face of the critics and challenges, Center for Medicare & Medicaid Services (CMS) designed and launched the Hospital Value Based Purchasing (HVBP) program, which is the first nationwide pay-for-performance (P4P) program aiming at transforming the traditional payment model with a focus on quantity to a new payment model with a focus on quality, improving hospital performance four folds: conformance quality, cost efficiency, safety and patient experience. In 2003, CMS tested the Premier Hospital Quality Incentive Demonstration, a pay-for-performance pilot project involving more than 200 hospitals, which provided financial incentives to physician groups that performed well on quality and cost measures (Damberg et al. 2014). In 2005, it launched Hospital Compare database with public reporting of process measures of hospital quality, later extending this reporting to include clinical outcomes such as mortality rates too.

However, balancing different resource management strategies to improve performance is not an easy task for the hospitals. Inclusion of patient experience of care or patient satisfaction has led to a vigorous debate in the industry. Advocates for inclusion of patient satisfaction contend that it measures critical components of care that only patients can report, such as whether pain was addressed effectively or if patients received clear communication from physicians and nurses. This makes it an essential measure of how well a health care system function. In an industry where the patient should be the primary focus, the content of their experiences can help clinicians to better mobilize around their needs. This builds trust in the healthcare system from the perspective of the patient and promotes collaborative practices between clinicians and patients (Chatterjee et al. 2015). Prior studies in multiple healthcare settings have shown that poor patient satisfaction with the health care system is associated with slower recovery from illness and a lower likelihood of compliance with prescribed treatment regimens. Consequently, suboptimal patient experience has important implications not only for the health of patients but also for health care costs, which increase when patients use more health care services because of poor recovery and non-compliance (Chatterjee et al. 2012). When patients have a better experience, they are more likely to comply with treatments, return for follow-up appointments, and engage with the healthcare system by seeking appropriate care (Chatterjee et al. 2015).

Critics of including patient satisfaction in HVBP program argue that doing so is driving physicians to focus on the wrong priorities whereby hospitals end up behaving as hotels. Using patient satisfaction as a metric shifts provider attention away from delivering technically effective care to fulfilling patient expectations and demands (Chatterjee et al. 2015). By conflicting with the clinical practice guidelines higher patient satisfaction, in fact, may be associated with a higher rate of inpatient admissions, higher overall healthcare costs, and increased mortality. For example, providing a prescription may result in a satisfied patient but increase the cost of care and may contribute to ills such as antibiotic resistance and opioid crisis (Lindsay 2017).

Due to these concerns, Medicare stopped using pain management questions as inputs in its payment formula. I collected multi-year data from six diverse data sources, employed propensity score matching to obtain comparable groups, and estimated difference-in-difference models to show that, in fact, pain management was the only measure to improve in response to pay-for-performance system. No other input measure showed significant improvement. Thus, removing pain management from the formula risks rendering the entire program ineffective. I suggest two divergent paths for Medicare to make the program more effective.

Furthermore, I would like to analyze is there a state dependence effect in the payment adjustment for the HVBP program. In the second essay, I apply the theory of state dependence and use the dynamic random effect probit model to estimate this effect. The results show that the hospital payment adjustment dynamics have a very significant state dependence effect (0.341), that means, hospitals that received a reward in previous year are 34.1% more probably to receive a reward this year than the ones that received a penalty in previous year. Meanwhile, I also find that the state dependence effect varies significantly across hospitals with different ownership (proprietary/government owned/voluntary non profit), the results show that voluntary non profit hospitals exhibit largest effect of state dependence (0.370), while government owned hospitals exhibit lowest effect of state dependence (0.293) and proprietary hospitals are in the middle. Among the factors that influence the likelihood a hospital receive a reward, we find that teaching hospitals with large number of beds (>400), are less likely be rewarded; in terms of ownership, we find that voluntary non profit hospitals are more likely be rewarded; in terms of demographic factors, hospitals where the average household income are higher within the region are more likely be rewarded.

The third essay studies the opposite of regulation—deregulation effect. Price regulation is common practice in drug markets with the hope of containing drug price from increasing too rapidly. In terms of drug price regulation, two mechanisms are commonly used: reference pricing and price cap. According to a report by WHO (2015), 24 of 30 OECD countries and 20 of 27 European Union countries use the reference price regulation to control drug price. UK and China adopted the price cap regulation system. But since pharmaceutical spending continues to grow despite of price regulation, recently there are many callings to de-regulate. Since June 1st, 2015, Chinese government decided to remove price cap regulation in pharmaceutical market and offers us an opportunity to study the effect of de-regulation. In this essay, I applied an Interrupted Time Series Analysis (ITSA) approach to study the effect of de-regulation of price cap in China's pharmaceutical market. Data is obtained from Sinopharm Group, the largest distributor in China's pharmaceutical market. A total of nine categories of drugs were analyzed and the results showed a clear pattern between industry HHI and revenue change of the drugs. The results showed that, whether the revenue of drugs will increase or decrease after the deregulation of price cap depends on the level of competition and the change of patterns of the branded and generic drugs are different. When HHI is sufficiently low (competition is high), revenue does not change as a result of deregulation, when HHI is moderately low (moderate competition), revenue from generic drugs will decrease significantly and revenue from branded drugs will increase significantly, when HHI is high (low competition), revenue from generic drugs will increase significantly and revenue from branded drugs will decrease significantly.

CHAPTER TWO:

THE ROLE OF PATIENT SATISFACTION IN HOSPITALS` MEDICARE REIMBURSEMENTS

INTRODUCTION

In 1998, the Institute of Medicine formed The Committee on Quality of Health Care in America aimed at developing a strategy for its improvement. This committee prepared two reports that have driven many of the changes in healthcare in the past two decades. The first report, "To Err Is Human: Building a Safer Health System" published in 2000, aimed at improving the safety of healthcare provided in the US. The second report published in 2001, "Crossing the Quality Chasm: A New Health System for the 21st Century," outlined a framework for improving the quality of healthcare (Lindsay 2017). It highlighted the physician and hospital payment system as a big cause of quality problems in healthcare and a barrier to health reform. In the Medicare program, clinicians had perverse incentives to focus on doing more rather than doing better. Since this report, Centers for Medicare & Medicaid Services (CMS) has gradually moved in the direction of a more value-based pay-for-performance (P4P) system requiring hospitals to evaluate and demonstrate service delivery effectiveness (Lee et al. 2017).

In 2010, as a part of the Patient Protection and Affordable Care Act (ACA) CMS introduced the Hospital Value-Based Purchasing (HVBP) program. It connected the Medicare payment system directly to patient care delivery and perceived quality measures. The program's purpose was to reduce cost and improve healthcare quality. To do so, Medicare imposed reimbursement penalties or provided reimbursement bonuses based on a hospital's annual quality measures and actual healthcare outcomes in prior years (Lee et al. 2017). It went into effect in fiscal year 2013 and is mandatory for all acute-care hospitals, public and private, in the US except hospitals in Maryland which operate under a different all-payer model. Under HVBP program, Medicare withholds a percentage of its reimbursements (starting with 1 percent in 2013 and increasing by a quarter percent each year to reach the target of 2 percent in 2017) from hospitals that do not perform well on a set of pre-specified healthcare quality measures. Hospitals that do perform well receive reimbursement bonuses. It is a budget-neutral program such that the total amounts of the rewards and penalties are equal. In 2018, the HVBP funding pool held an estimated \$1.9 billion. (Lee et al. 2017).

Over the years, the program's emphasis gradually shifted from process-based quality measures toward outcome-based quality measures. In the first year of HVBP 70 percent of the measures were process measures, whereas now it rewards or penalizes hospitals based on their performance on multiple domains of care, including clinical processes, clinical outcomes (i.e., 30-day mortality rate), cost efficiencies (i.e., cost per discharge), and patient satisfaction (Figueroa et al. 2016b). The evidence for effectiveness of this program in improving the specified quality measures is mixed.

Patient satisfaction, which carries a weight of 25 percent in the HVBP payment formula, is obtained from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which is the first national, standardized, publicly reported survey of patients' experience of hospital care. Although inducted into the HVBP program in 2012 only, the survey data have been collected since 2006 and publicly reported since 2008 (Tefera, Lehrman, and Conway 2016).

The HCAHPS survey asks patients about their recent hospital stay and attempts to score their overall experience and eight specific dimensions of their experience of care. One of these dimensions is patient perception of the quality of pain care during hospitalization. Research has shown that managing patient expectations about pain during and after surgical procedures can reduce patients' distress, reduce the number of signs and symptoms, and improve their functional status. It can also result in positive emotional outcomes for patients such as a decrease in anxiety and depression and an increase in a sense of well-being (Glowacki 2015). However, many healthcare providers expressed concern about the questions on pain management in the survey saying that these questions wrongly equated pain management with prescription of a painkiller (Lowes 2016).¹ They reported feeling pressured to prescribe opioids to boost their hospital's survey scores and, in turn, their hospital's reimbursements. The American Hospital Association was among several prominent healthcare associations asking CMS to stop considering pain management questions in the HCAHPS survey when calculating payments under HVBP program (Dickson 2016). According to this school of thought incentivizing aggressive pain management has contributed to the overprescribing of opioids in the US and to the country's larger struggle with opioid addiction and overdose (Hall Render 2016).

In response to these concerns and to remove any perceived incentives of prescribing opioids, in July 2016 CMS announced that pain management questions of the HCAHPS survey will no more be considered in HVBP calculation. CMS has however stressed that robust pain control is an appropriate part of routine inpatient care and it is conducting research to see if the HCAHPS survey is indeed associated with the opioid epidemic. Depending on the findings, it may develop new questions to bring back pain dimension in HVBP calculation in future (Hall Render 2016).

In this paper, we utilized analytics tools to study the effectiveness of HVBP program at improving patient satisfaction. Most of the existing studies in this domain fail to account for wide heterogeneity of more than three thousand HVBP hospitals when comparing them to a small control group of less than fifty non-HVBP hospitals in Maryland. Furthermore, a large number of studies depend on one year of data only to observe changes in quality measures. We address both these limitations by collecting data over multiple years and employing propensity score matching to obtain a matched treatment group of HVBP hospitals before comparing them with the control group of hospitals in Maryland.

We integrated multi-year data from six diverse publicly available large data sources: patient satisfaction data from Hospital Compare database of CMS, clinical measures and clinical outcomes data from Medicare website, cost efficiency data from Hospital Inpatient Prospective Payment System (IPPS) of CMS, hospital characteristics from CMS Impact Files, and demographic data from the 2010 US census. Then we utilized difference-in-difference estimation framework to see if HVBP program actually led to improvement in patient satisfaction at the treatment group of hospitals compared with control group of hospitals. Our findings show that the only dimension of patient satisfaction that showed significant improvement is patient experience with pain management during hospitalization. After removal of this measure from penalty and bonus calculation, the HVBP program is essentially rendered ineffective at improving patient satisfaction, which is one of the key goals of the program.

We suggest two divergent paths for CMS to address this. Either CMS should again start including pain management in the HVBP payment formula. To address the potential association between these questions and opioid prescriptions, it should separately track opioid prescriptions at each hospital. Alternatively, CMS should completely remove patient satisfaction measures from HVBP program. Doing so will allow hospitals to focus their resources and attention back on clinical processes and outcomes. It will also deliver cost savings for CMS by getting rid of administering the survey and gathering responses from more than three million patients every year.

BACKGROUND

Hospital Value-Based Purchasing (HVBP) Program

CMS took the next step in these efforts in 2010. As a part of the Affordable Care Act (ACA), it introduced the Hospital Value-Based Purchasing (HVBP) program to improve healthcare quality and reduce costs. The program went into effect in fiscal year 2013 and is mandatory for all acute care hospitals, public and private, in the US except hospitals in Maryland, which operate under a different all-payer model. In this program, Medicare imposes reimbursement penalties or provides reimbursement bonuses based on a hospital's performance on a set of pre-defined quality measures. Medicare withholds a percentage of its reimbursements (starting with 1 percent in 2013 and increasing by a quarter percent each year to reach the target of 2 percent in 2017) from hospitals that do not perform well and distributes this money as performance bonus to hospitals that perform well on its quality measures. Hence, it is intended to be a budget-neutral program.

The Total Performance Score (TPS), which is used as the basis for calculation of reimbursement bonus or penalty, comprises four dimensions of healthcare delivery: clinical processes, clinical outcomes (i.e., 30-day mortality rate), cost efficiencies (i.e., cost per discharge), and patient satisfaction. Half of the score is based on clinical measures with clinical outcomes contributing 40 percent to the total score and clinical processes contributing 10 percent. The rest of the score is obtained equally from cost efficiency and patient satisfaction (i.e., patient experience of care) with both contributing 25 percent each. Whereas other dimensions of care delivery are objective, patient satisfaction is obtained from a survey named the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). The survey is composed of 32 questions and is administered to a random sample of adult inpatients

between 48 hours and 6 weeks after discharge from short-term, acute care hospitals (Tefera and Lehrman 2017). It is the first national, standardized, publicly reported survey of patients' experience of hospital care. Each hospital in the program gets two sets of scores on each of the four dimensions – one for achievement (hospital's own performance compared with the 50th percentile of all hospitals' performance) and one for improvement (hospital's performance compared with its own performance in the previous period). The higher of the two scores on each dimension is utilized in the calculation of TPS which is a weighted average of the four dimensions.

Inclusion of patient experience of care or patient satisfaction has led to a vigorous debate in the industry. Advocates for inclusion of patient satisfaction contend that it measures critical components of care that only patients can report, such as whether pain was addressed effectively or if patients received clear communication from physicians and nurses. This makes it an essential measure of how well a health care system functions. In an industry where the patient should be the primary focus, the content of their experiences can help clinicians to better mobilize around their needs. This builds trust in the healthcare system from the perspective of the patient and promotes collaborative practices between clinicians and patients (Chatterjee et al. 2015). Prior studies in multiple healthcare settings have shown that poor patient satisfaction with the health care system is associated with slower recovery from illness and a lower likelihood of compliance with prescribed treatment regimens. Consequently, suboptimal patient experience has important implications not only for the health of patients but also for health care costs, which increase when patients use more health care services because of poor recovery and noncompliance (Chatterjee et al. 2012). When patients have a better experience, they are more likely to comply with treatments, return for follow-up appointments, and engage with the healthcare system by seeking appropriate care (Chatterjee et al. 2015).

Critics of including patient satisfaction in HVBP program argue that doing so is driving physicians to focus on the wrong priorities whereby hospitals end up behaving as hotels. Using patient satisfaction as a metric shifts provider attention away from delivering technically effective care to fulfilling patient expectations and demands (Chatterjee et al. 2015). By conflicting with the clinical practice guidelines higher patient satisfaction, in fact, may be associated with a higher rate of inpatient admissions, higher overall healthcare costs, and increased mortality. For example, providing a prescription may result in a satisfied patient but increase the cost of care and may contribute to ills such as antibiotic resistance and opioid crisis (Lindsay 2017).

Pain Management under HVBP and the Opioid Crisis

Within the broad criticism of including patient satisfaction, one item in particular has come under harsh scrutiny. The HCAHPS survey asks patients about their recent hospital stay and attempts to score nine dimensions of the experience of care they received. One of these dimensions is patient perception of the quality of pain management care during hospitalization.

In 2016, approximately 100 million people suffered from pain in the US out of which 9 to 12 million complained of chronic pain. Others reported short-term pain from injuries, diseases, or medical procedures (Stoicea et al. 2019). Not managing patient expectations about pain during and after surgical procedures can result in poorer clinical and psychological outcomes for the patients. Patients in pain also have negative perceptions of healthcare they receive. Egbert et al. (1964) reported that patients who received pain education required 50 percent fewer narcotics

during hospitalization and were discharged sooner than patients who did not receive pain education (cf. Glowacki 2015).

In 1996 the American Pain Society labeled pain as the "fifth vital sign" and developed a national quality improvement program emphasizing measurable patient outcomes of effective pain management such as decreased length of stay, reduced hospital costs, and increased patient satisfaction (Glowacki 2015). In 2000, the Joint Commission on Accreditation of Healthcare Organizations released new pain management standards that asserted that pain control was a patient's right, highlighted it as a perceived gap in clinician education and training, encouraged an aggressive approach to pain assessment, and emphasized safe pain management (Chidgey et al. 2019). The commission established that both acute and chronic pain were major causes of patients' dissatisfaction in the US health care system (Glowacki 2015).

In 2010, the HVBP program instituted reforms that included financial incentives for higher patient satisfaction scores. Patient satisfaction is strongly associated with their perspectives on management of signs and symptoms of their condition. They are more likely to experience dissatisfaction if they perceive a lack of validation in their pain experience or negative attitudes from their providers (Glowacki 2015). The HCAHPS survey contained three questions focused on pain management. Some physicians expressed concern that the questions wrongly equated pain management with prescription of a painkiller (Lowes 2016). These questions placed pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the survey (Hall Render 2016). Furthermore, patients complete the survey during a time when many are filling post-discharge opioid prescriptions. This timing could also inadvertently incentivize providers to overprescribe opioids after discharge to ensure satisfactory ratings (Lee et al. 2017). Although pain management may constitute only a small part of the survey but respondents do not necessarily separate out with which piece of the experience they were unhappy. If they were in pain and the hospital did not give them a painkiller despite their request, they may conclude that the hospital did not take good care of them. This can affect their responses to the whole HCAHPS survey (Tefera and Lehrman 2016). Thus, many physicians said they felt pressured to overprescribe opioids to boost their hospital's survey scores and, in turn, their hospital's reimbursements.

The Opioid Crisis

The current opioid crisis started taking shape in the 1990s. From the late 1990s until 2012, opioid prescriptions written each year in the US steadily rose to an annual peak of 225 million (Chidgey et al. 2019). Centers for Disease Control and Prevention reports that deaths attributable to prescription opioids more than tripled in the US during the 1999-2014 period (Dickson and Blesch 2016; Jena et al. 2016). Around 6 percent of the US population (15 to 64 years old) reported some type of opioid abuse in 2015, and more than 42,000 people died of opioid overdose in 2016 alone (Stoicea et al. 2019; Volkow et al. 2019).

Prescribing opioids at the time of discharge from an acute hospitalization represents an important but under-described potential avenue through which patients may develop long-term use of opioids. Use of opioids during and shortly after hospitalization is warranted in some clinical settings such as in patients undergoing surgery. Opioids are "powerful pain-reducing medications" which administered at appropriate doses are effective at not only eliminating pain but also further preventing its recurrence in long-term recovery scenarios (Stoicea et al. 2019). Failure to appropriately manage pain in such cases may delay discharge from the hospital, interfere in postoperative rehabilitation, and in general adversely affect patient's quality of life.

However, use of opioids is also associated with both short- and long-term risks including developing dependence (Jena et al. 2016).

Opioid overprescribing has been frequently identified as a major cause of the current opioid crisis (Chidgey et al. 2019). Overprescribing has been attributed to misinformation and outside pressure from both pharmaceutical companies and accreditation bodies such as the Joint Commission on Accreditation of Healthcare Organizations. Caught between regulatory requirements aimed at eliminating pain and aggressive marketing campaigns along with a shift in cultural beliefs about pain control, physicians became unwitting accomplices in the opioid crisis (Chidgey et al. 2019). In fact, the Promoting Responsible Opioid Prescribing Act of 2016 suggested that the pain management measure in HCAHPS survey could have incentivized both greater inpatient use of opioids and the prescribing of opioids at the time of discharge (Jena et al. 2016).

Another school of thought believes the evidence on the link between the HCAHPS survey and opioid prescription is inconclusive. For example, a study conducted in Michigan found no correlation between postoperative opioid prescribing and scores on HCAHPS pain measures (Lee et al. 2017). A coalition that included several pain-medicine societies such as the American Pain Society and the American Academy of Pain Medicine lobbied the CMS to retain the three questions; at least until better ones were drafted. They warned that in the absence of any conclusive evidence, eliminating pain-related questions would be a step back in proper pain management. It would deprive researchers of valuable data that could improve pain management (Lowes 2016).

CMS also offered defense of its decision to include patient perception of pain management in HCAHPS survey, and consequently in HVBP program. Historical data shows

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that the sharp increase in opioid prescription in mid-1990s coincided with the conceptualization of "Pain as the 5th Vital Sign" by the American Pain Society, and pharmaceutical industry's campaign to falsely detail opioid prescribing as safe, reasonable, and effective for chronic pain while downplaying the risks of opioid dependence, abuse, and overdose. The crisis thus began years before the HCAHPS Survey was launched in 2006. There is no noticeable acceleration in opioid prescription in 2006 or in 2008, when public reporting of hospital scores started (Tefera and Lehrman 2017).

Regarding the use of HCAHPS survey, CMS is not aware of any empirical evidence that physicians prescribe opioids to inpatients with an intention to obtain better scores on the pain management questions, or patients who receive opioids rate their hospital experience more positively than those who do not (Tefera and Lehrman 2016). Nothing in the survey suggests that opioids are a preferred way to control pain. In fact, good nurse and physician communication, a critical issue from the patient perspective, are strongly associated with better HCAHPS scores (Tefera, Lehrman, and Conway 2016). There is no evidence that experience with pain management dominates patients' overall assessment of their hospital experience. Moreover, the way HCAHPS survey contributes to HVBP makes the pain management dimension negligible as far as its impact on the overall payment to the hospital – it is one of the eight equally weighted dimensions of patient satisfaction and determines less than one-tenth of one percent of total payment to the hospital (Tefera and Lehrman 2016). In fact, patients diagnosed with substance abuse disorders are not included for the scoring of HVBP (Dickson and Blesch 2016).

Nonetheless, bowing to consistent criticism from healthcare providers, in July 2016 CMS announced the pain management questions of the HCAHPS survey will not be considered in HVBP to remove any perceived incentives of prescribing opioids. Given the complexity of the

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issue straddling two national challenges – of adequate pain management and opioid overprescribing – and the need for additional research, CMS will continue to survey patients about pain management and provide participating hospitals with valuable patient feedback. However, these pain dimension results are not a part of the HVBP calculation (Tefera and Lehrman 2017).

Empirical Evidence for Effectiveness of HVBP program

HVBP program was instituted with an intention to improve healthcare outcomes and patient experience and reduce costs. However, evidence about the effectiveness of the program to achieve these goals is mixed.

A study comparing data in HCAHPS surveys in 2008 and 2009 found improvements in all measures in patient experience except doctors' communication (Elliott et al. 2010). Staff responsiveness and whether patients received discharge information saw the largest improvements. Westbrook et al. (2014) used factor analysis to show that all dimensions of HCAHPS survey except discharge information significantly influenced patient satisfaction. However, the study was based on data from two hospitals only. A study using difference-indifference estimation methodology found that participating hospitals did not show significant improvement in any of the quality measures (Ryan et al. 2015). Some studies have compared participating hospitals in HVBP program with various control groups to see if the program made a relative difference in the quality of healthcare they deliver. A study comparing the participating hospitals to critical-care hospitals and hospitals in Maryland (these two categories of hospitals are not required to participate in HVBP) found no improvement in clinical outcomes as measured by 30-day mortality rates (Figueroa et al. 2016a). Another study comparing the participating hospitals to critical-care hospitals found no significant differences in the improvement in clinical processes and patient experience across the two groups (Ryan et al. 2017). Papanicolas et al. (2017) found only moderate improvement in patient experience among HVBP hospitals but even this improvement had occurred mostly before the intervention period.

Several other studies have compared groups of hospitals based on some underlying characteristics and demonstrated that while one group shows an improvement the other does not. For example, Jha et al. (2008) found substantial differences in the patients' experiences across different geographical regions which they attributed to the style of caregiving and organizational leadership. A study using data from 2009 to 2011 found that hospitals catering largely to older white female patients who underwent relatively fewer procedures did better under the program (Johnston et al. 2015). These hospitals were predominantly non-teaching smaller urban hospitals owned by the government or religious organizations. Another study comparing penalty or reward status of safety net hospitals' with other hospitals' using data from year 2014 found that safety-net hospitals were more likely to be penalized under the HVBP program (Gilman et al. 2015; Joynt, Zuckerman, and Epstein 2017).

A large number of these studies suffer from two limitations that could have biased their results. First, a number of them used data for a single year only which is not sufficient to capture the evolving dynamics in processes and outcomes of healthcare quality. Multiple years of data are required to capture any improvement. Second, most studies do not account for heterogeneity in HVBP hospitals when comparing them to a small control group of hospitals. Comparing more than three thousand hospitals under HVBP, which have a broad range of unique hospital and geo-locational characteristics with a small group of less than fifty hospitals all of which are located in Maryland can lead to biased results. Ideally, one should first obtain a matching sample of treatment group (i.e., hospitals participating in HVBP) before comparing them with the

control group so that one can minimize the role of hospital characteristics in any changes in their healthcare delivery quality.

In this study, we address both these limitations. We employ multiple years of data for model estimation and use propensity score matching to obtain a matched treated group of HVBP hospitals to compare with control group of hospitals in Maryland.

METHODOLOGY

Data

Using analytics tools we integrated multi-year data from six diverse publicly available large data source: patient satisfaction data from HCAHPS, clinical measures and clinical outcomes data from Medicare website, cost efficiency data from Hospital Inpatient Prospective Payment System (IPPS) of CMS, hospital characteristics from CMS Impact Files, and demographic data from the 2010 US census.

Main variables of interest related to patient satisfaction in HCAHPS survey are obtained from the Hospital Compare data from years 2011 to 2015 available at CMS website. All shortterm, acute-care, non-specialty hospitals including hospitals in Maryland are required to participate in the survey. The survey is a 27-item tool administered after discharge to a random sample of adult inpatients, creating standardized, publicly reported measures that allow fair comparisons of patient experience in hospitals across the nation. The 9 HCAHPS measures derived from the survey reported on the Hospital Compare website assess physicians' and nurses' quality of communication, responsiveness of hospital staff to patient needs, quality of pain management, communication about medication, required information at the time of discharge, cleanliness and quietness of patient rooms, and overall rating (Lindsay 2017). The survey is administered by hospitals or their contracted vendors who send the data to the CMS, which validates, analyzes, and publicly reports the results. The scores that CMS reports reflect hospital-level patient experience during a 12-month period (Tefera and Lehrman 2017). The survey is widely used with more than 31,000 patients across 4,100 participating hospitals every day. After removal of ineligible patients, the survey has a 30 percent response rate that translates to 8,500 surveys completed daily. Meta-analyses have established that there is no nonresponse bias in the survey. Because HCAHPS adjusts for patient characteristics, the data provide statistically valid results that may help inform patient's choice of hospital and drive quality improvement at the hospital level. The official HCAHPS scores reported on the CMS Hospital Compare website are based on 3.1 million completed surveys each year (Tefera, Lehrman, and Conway 2016).

We obtained clinical measures and clinical outcomes data from Medicare website (medicare.gov). The dataset named "Complications and Deaths – Hospital" provides clinical outcomes as evaluated by the HVBP program – 30-day mortality rates for pneumonia, heart attack, and heart failure patients. The dataset named "Hospital Value-Based Purchasing (HVBP) – Clinical Care Domain Scores" provides clinical process scores.

Cost efficiency data are obtained from Hospital Inpatient Prospective Payment System (IPPS) of CMS. It provides a summary of hospital overall cost and total number of discharges from which cost per discharge was calculated.

Characteristics of hospitals such as the number of beds, the number of employees, resident-to-bed ratio, case mix index, number of discharges, and locational data are obtained from CMS Impact Files. According to CMS, the impact files are "generally prepared in the summer preceding the Federal fiscal year and are based on the best data available at the time. The files are used in estimating payment impacts of various policy changes to the IPPS proposed and finalized in the Federal Register."

Demographic data were obtained from the 2010 US census available at census.gov and matched with each hospital by 10-mile radius within the zip code.

To evaluate the effectiveness of HVBP program while also overcoming the limitations of existing research as mentioned earlier, we took several steps. We obtained data from 2011 to 2015, which was the last full year before CMS announced that pain management questions would no longer be used in HVBP calculations. Using multiple years of data allow us to capture improvement in various quality measures.

Propensity Score Matching

We used propensity score matching to obtain a matched treated group of HVBP hospitals to compare with control group of hospitals in Maryland.

Previous research has shown that various measures of hospital performance may be correlated with such factors as hospital characteristics and socio-economic characteristics in hospital's vicinity. For example, patients of different races or ethnicities tend to rate their satisfaction level toward a hospital very differently (Weech-Maldonado et al. 2003). Even aggregate patient characteristics such as gender, household income, and health status significantly affect the satisfaction rating of hospitals (Haviland et al. 2005; Weech-Maldonado et al. 2003). Clinical outcome measures such as mortality rates have been shown as significantly higher at for-profit hospitals (Hartz et al. 1989) and at major teaching hospitals while significantly lower at large urban hospitals (Keeler et al. 1992). Thus, comparing all the HVBP hospitals, which are heterogeneous with respect to these characteristics, with a small geographically concentrated control group can lead to biased findings. We used hospitals in Maryland as a control group because Maryland does not participate in HVBP program. The Medicare waiver (codified in Section 1814(b) of the Social Security Act) exempted Maryland from the Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) and allowed it to set rates for these services. Given the long-standing Medicare waiver for its own rate setting system, Maryland`s hospitals are exempted from the Medicare VBP program and operate on all-payer hospital rate regulation system. It thus allows for the most obvious choice as a control group for the purpose of comparison.

We used nearest-neighbor propensity score matching to obtain a group of HVBP hospitals comparable to hospitals in the control group. To avoid problem of endogeneity, we based this matching on a set of characteristics that are not subject to change due to participation in the HVBP program. These included hospital ownership (government owned, voluntary nonprofit, or proprietary), geo-location (large urban, other urban, or rural) and socio-economic characteristics within 10 mile radius of the hospital (white population, black population, Hispanic population, number of males and females, and average household income).

The dataset contains 45 hospitals from Maryland. However, five hospitals did not meet the minimum data requirement established by CMS for valid results; CMS requires a minimum of 100 surveys from patients of a hospital to report clinical quality measures. Five hospitals did not pass this threshold hence we used the remaining 40 hospitals in Maryland as our control group. We employed one-to-one nearest neighbor matching to form a treatment group of 40 HVBP hospitals. As figure 2.1 shows, overlap of control group's propensity scores is significantly better with scores of matched treated group of HVBP hospitals than with scores of all HVBP hospitals.

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[-----Figure 2.1 about here-----]

Figure 2.2 presents the comparison between the three groups of hospitals from 2011 to 2015 on clinical outcomes (30-day mortality rates), cost efficiency (cost per discharge), clinical process (conformance quality), and three dimensions of patient satisfaction namely overall experience, nurse communication, and pain experience. This comparison clearly demonstrates the bias that can afflict findings from studies comparing all the HVBP hospitals to a control group of hospitals.

[-----Figure 2. 2 about here-----]

Table 2.1 presents a detailed comparison of various characteristics of both treatment and control groups as well as all HVBP hospitals in FY 2011. This comparison further validates the importance of obtaining a matched group of hospitals before making the comparison with a control group of hospitals. Obtaining a matched treated group using propensity scores can help reduce the selection bias and strengthen causal arguments.

[-----Table 2.1 about here-----]

Model Estimation and Results

We perform a difference-in-difference estimation for the effectiveness of HVBP program using the data on 40 hospitals each from treated group and control group. We specify the following model:

$$\boldsymbol{y}_{it} = \alpha_i + \lambda_t + \beta D_{it} + \eta \boldsymbol{u}_{it} + e_{it}$$

where

 y_{it} is a vector of the average score of each performance measure for hospital *i* at time *t*, D_{it} is a dummy variable that equals 1 if time is after the institution of HVBP program (i.e., after 2013) and the hospital participates in the HVBP program, 0 otherwise,

 β is the coefficient for the D_{it} which indicates if there is a significant difference in the performance measures of hospitals belonging to two groups after the institution of the program,

 u_{it} is a vector of characteristics for each hospital *i* at time *t* controlled for in the model,

 α_i is the hospital unit fixed effects,

 λ_t is the time fixed effects,

 e_{it} is the error term.

We estimated this model to compare both the matched group of HVBP hospitals as well as the entire set of all HVBP hospitals with the control group. Results from both estimations show that patient perception of pain management is the only quality measure that showed consistent significant improvement in HVBP hospitals ($\beta_{Matched} = 1.46$; p < .01 and $\beta_{All} = .77$; p< .05) (see table 2.2). There is no significant difference in any other quality measure across the two groups of hospitals in matched samples.

[-----Table 2.2 about here-----]

Overall, our results suggest that out of four broad quality measures utilized in HVBP there was no significant improvement in clinical processes, clinical outcomes, or cost efficiency when compared with control group of hospitals located in Maryland which did not participate in the program. In patient satisfaction too, the only factor that showed significant improvement was patient perception of pain management during hospitalization.

Sensitivity Analysis

The key assumption behind diff-in-diff framework is: In the absence of treatment, the average change in the response variable would have been the same for both the treatment and control groups (parallel trends). As is pointed out by Ashenfelter (1978), one concern in diff-in-

diff study is that, there is often a "dip" in outcomes (earnings, employment, etc.) in the period before the treatment. For example, people lose their jobs just before joining the treated group and the people in the control group don't. A pre-treatment "dip" or "trend" that is special to the treated units would lead to biased estimates. To test this, I applied the method used by Autor (2003) by estimating treatment impacts at the timings before real treatment happens (including leads in the estimation framework), if the treatment effect is significant in previous years, it shows that there is a slope change for the units that are about to become treated and it is a sign of violation of the parallel trends assumption (sometimes called a modified "Granger Causality" test). Another extension I made here is to include lags of treatment. Lags are included to analyze whether the treatment effect changes over time after treatment.

$$y_{it} = \alpha_i + \lambda_t + \beta_{-1}D_{i,t-1} + \beta D_{it} + \beta_1 D_{i,t+1} + \eta u_{it} + e_{it}$$

where

 y_{it} is a vector of the average score of each performance measure for hospital *i* at time *t*,

 D_{it} is a dummy variable that equals 1 if time is the institution of HVBP program (i.e., 2013) and the hospital participates in the HVBP program, 0 otherwise,

 $D_{i,t-1}$ is a dummy variable that equals 1 if time is one year before the institution of HVBP program (i.e., 2012) and the hospital participates in the HVBP program, 0 otherwise,

 $D_{i,t+1}$ is a dummy variable that equals 1 if time is one year after the institution of HVBP program (i.e., 2014) and the hospital participates in the HVBP program, 0 otherwise,

 β is the coefficient for the D_{it} which indicates if there is a significant difference in the performance measures of hospitals belonging to two groups after the institution of the program,

 β_{-1} is the coefficient for $D_{i,t-1}$ which indicates if there is a significant difference in the

performance measures of hospitals belonging to two groups one year before the institution of the program (sign of violation of the parallel trend assumption),

 β_1 is the coefficient for $D_{i,t+1}$ which indicates if there is a significant difference in the performance measures of hospitals belonging to two groups one year after the institution of the program,

 α_i is the hospital unit fixed effects,

 λ_t is the time fixed effects,

 u_{it} is a vector of characteristics for each hospital *i* at time *t* controlled for in the model, and e_{it} is the error term.

We estimated this model to compare the matched group of HVBP hospitals with the control group. Results from estimations show that the estimation of patient perception of pain management is valid (β_{-1} is not significant).

[-----Table 2.3 about here-----]

Robustness Check

We tested for the robustness of our findings by obtaining matched groups of HVBP hospitals using other propensity score matching methods and re-estimating our models using these matched groups. The nearest neighbor matching method is a "greedy" method, in which the closest control unit for each treated unit is chosen one at a time, without trying to minimize the global distance measure. Hence, one could argue that the matched group of hospitals may still differ significantly from the control group in underlying characteristics.

We used two other propensity score matching methods – optimal matching and genetic matching – to obtain matched group of hospitals and re-estimated our model. Optimal matching method locates the matched units with the smallest average absolute distance across all the

matched pairs. It can be particularly useful when there may not be an appropriately matched control unit for a treated unit. Genetic matching, on the other hand, is a general multivariate matching method that automates the process of finding a good matching group. It is a generalization of propensity score and Mahalanobis distance matching. The idea is to use a genetic search algorithm to find a set of weights for the covariates to maximize the balance between matched treated and control units. The main advantage of this method is that it optimizes covariate balance directly. We used the same set of characteristics as in nearest neighbor method to match the groups in optimal and genetic matching too. Next, we used the two matched treated groups along with the control group of hospitals in Maryland to repeat difference-in-difference analysis using the same set of covariates. The results shown in table 2.4 are consistent in showing that the only measure that significantly differs between the two groups is patient perception of pain management.

[-----Table 2.4 about here-----]

CONCLUSION

In 2010, as a part of the Patient Protection and Affordable Care Act (ACA) CMS introduced a pay-for-performance system called Hospital Value-Based Purchasing (HVBP) program. The purpose was to reduce costs and improve healthcare quality by linking the Medicare payment system directly to a pre-defined set of quality measures. It went into effect in fiscal year 2013 and covered all acute-care hospitals except those in Maryland. The program calculates each hospital's bonus or penalty based on their performance on four domains of care: clinical processes, clinical outcomes (i.e., 30-day mortality rate), cost efficiency (i.e., cost per discharge), and patient satisfaction. Patient satisfaction, which carries a weight of 25 percent in the formula, is obtained from the HCAHPS survey. Besides other dimensions of patient
satisfaction, this survey captures patient experience with pain management during hospitalization. This pain management dimension has come under criticism because some physicians have reported feeling pressured to prescribe opioid painkillers to boost their hospital's survey scores and, in turn, their hospital's reimbursements. This is thought to have contributed to the overprescribing of opioids in the US and, consequently, to the opioid crisis. In response to this criticism and to remove any perceived incentives of prescribing opioids, in July 2016 CMS announced that pain management questions of the HCAHPS survey will no more be considered in HVBP calculation.

In this paper, we studied the effectiveness of HVBP program at improving patient satisfaction. Using analytics tools we collected data over multiple years and employed propensity score matching to obtain a matched treatment group of HVBP hospitals to compare with the control group of hospitals in Maryland. Then we utilized difference-in-difference estimation framework to see if HVBP program actually led to improvement in patient satisfaction at the treatment group of hospitals compared with control group of hospitals. Our findings show that the only dimension of patient satisfaction that showed significant improvement is patient experience with pain management during hospitalization. In fact, other components of the payment formula – clinical processes, clinical outcomes, and cost efficiency – also showed no significant improvement under HVBP program. These findings are broadly consistent with a number of other studies that have failed to show any improvement in quality measures after HVBP introduction.

After removal of this measure from penalty and bonus calculation, the HVBP program is essentially rendered ineffective at improving patient satisfaction, which is one of the key goals of the program. We suggest two divergent paths for CMS to address this. Either CMS should again start including pain management in the HVBP payment formula. In fact, the redesigned pain management questions that CMS used in 2019 seem suitable for re-inclusion in the formula: they have no apparent link to prescription of a painkiller.² This change can remove any perceived pressure on the physicians to prescribe opioids and allow them to choose the best option for a patient in their particular situation. That best option may be non-pharmaceutical, a non-opioid pharmaceutical, or even an opioid (Tefera and Lehrman 2016). Additionally, to lay at rest any potential suspect association between even these new questions and opioid prescriptions, CMS should separately track opioid prescriptions at each hospital. Given that the rates of fatalities due to opioid overdose vary markedly by state (Volkow et al. 2019), a one-size-fits-all decision of removing pain management anyway may not be optimal.

Alternatively, CMS should completely remove patient satisfaction measures from HVBP program. Doing so will allow hospitals to focus their resources and attention back on clinical processes and outcomes. It will also deliver cost savings for CMS by getting rid of administering the survey and gathering responses from more than three million patients every year. Critics have argued that HVBP program lacks design features of a successful pay-for-performance program. It should be focused on a small number of high-value measures to motivate clinicians to engage in good practice and have a simple enough design for hospitals and clinicians to know how they are doing. The clinical outcomes and patient's functional status are good choices for measures that can be included or retained in the payment formula (Jha 2017). Given its ineffectiveness at improving almost any health measure, HBVP should increase the stakes for hospitals by increasing the performance penalty/bonus amount to 5 to 10 percent of total Medicare payments of the hospital. That may be one way to focus hospital's attention at improving health measures (Jha 2017).

FIGURES AND TABLES FOR CHAPTER TWO

	All HVBP Hospitals	Matched HVBP Hospitals	Control Group
Number of hospitals	2912	40	40
Avg. number of hospital beds	200	282	268
Avg. number of hospital employees	1261	1835	1878
Avg. number of hospital discharges	9638	17786	16240
Percent of Medicare/Medicaid patients	49.5	54.2	53.5
Number of White residents ^a	17.39	14.14	14.91
Number of Black residents ^a	3.15	8.72	9.02
Number of Hispanic residents ^a	4.15	2.28	1.67
Number of males ^a	11.43	12.20	12.31
Number of females ^a	11.94	13.03	13.31
Avg. household income	44.90	55.92	55.89
Median age of males	33.06	33.60	32.48
Median age of females	35.38	35.85	34.84
Teaching status	.06	.07	.06
Avg. case mix index	1.45	1.43	1.42
Avg. overall patient experience score	70.6	69.6	66.1
Avg. nurse communication score	77.2	74.2	73.8
Avg. doctor communication score	80.2	78.4	77.4
Avg. staff responsiveness score	64.3	59.7	57.3
Avg. medicine explanation score	62.2	57.8	57.2
Avg. pain management score	69.6	67.0	66.6
Avg. discharge information score	84.5	79.7	82.3
Avg. cleanliness score	71.1	69.1	64.7
Avg. quietness score	58.5	55.6	55.1
Avg. 30-day mortality rate	12.7	12.2	12.4
Avg. cost per discharge	15441	15039	15279
Avg. clinical quality score	95.5	96.6	94.5

Table 2.1: Characteristics of Hospitals in Various Groups (FY 2011)

^aValues are in thousands.

	Matched HVBP Group		All HVB	All HVBP Group	
	vs Control Group		vs Contro	vs Control Group	
Performance measure	Coeff.	S.E.	Coeff.	S.E.	
Doctor communication	.64	.42	.01	.03	
Nurse communication	.93	.50	.36	.32	
Staff responsiveness	.91	.71	1.04**	.47	
Medicine explanation	.67	.61	.31	.47	
Pain control	1.46***	.62	.77**	.39	
Discharge information	35	.47	34	.29	
Cleanliness	1.14	.76	.68	.45	
Quietness	1.31	.87	.69	.46	
Mortality rate	03	.13	.07	.09	
Cost per discharge	-385.32	430.57	773.94	13788	
Conformance quality	.58	.64	1.06	1.07	

Table 2.2: Results from Difference-in-Difference Model Estimation

Note: ***p<0.01, **p<0.05

	Matched HVBP Group vs			
	Contr			
Performance measure	β_{-1}	β	β_1	
Doctor communication	52	.71	.36	
	(.53)	(.52)	(.56)	
Nurse communication	37	.94	.08	
	(.62)	(.62)	(.66)	
Staff responsiveness	20	1.46	.53	
	(.86)	(.85)	(.91)	
Medicine explanation	.28	.74	.63	
	(.90)	(.90)	(.96)	
Pain control	.13	1.76*	.42	
	(.78)	(.78)	(.83)	
Discharge information	.006	14	68	
	(.59)	(.59)	(.63)	
Cleanliness	15	.74	.76	
	(.96)	(.95)	(.1.01)	
Quietness	-1.14	.13	1.14	
	(.85)	(.85)	(.90)	
Mortality rate	.30*	.07	.05	
	(.13)	(.13)	(.14)	
Cost per discharge	386.76	390.37	28.8	
-	(379.76)	(378.72)	(402.29)	
Conformance quality	.13	.54	.25	
- •	(.60)	(.61)	(.61)	

Table 2.3: Results from Sensitivity Analysis

Note: ***p<0.01, **p<0.05

Table 2.4: Results from Difference-in-Difference Model Estimation	Using Matched
Treated HVBP Hospitals vs Control Group	

	Optimal Propensity Matching		Genetic Propensity Matching	
Performance measure	Coeff.	S.E.	Coeff.	S. E.
Doctor communication	.05	.52	.29	.59
Nurse communication	.06	.59	.21	.65
Staff responsiveness	.46	.92	1.46	1.02
Medicine explanation	.38	.67	.22	.73
Pain control	1.24***	.48	.90**	.42
Discharge information	47	.75	1.08	.76
Cleanliness	08	.81	.78	.89
Quietness	32	.84	.58	.93
Mortality rate	.06	.08	05	.12

Cost per discharge	360.64	3/1 75	272 51	372 76
Conformance quality	15	1.47	-373.31 .75	1.62
Note: ***p<0.01, **p<0.05				

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Notes:

HVBP hospitals are the Treated group and Maryland hospitals are the control group. Raw Treated group includes all HVBP hospitals; Matched Treated group includes 40 HVBP hospitals obtained using propensity score matching.



Figure 2.2: Comparison of Quality Measures Between Maryland Hospitals, Matched HVBP Hospitals, and All HVBP Hospitals

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CHAPTER THREE:

MEASUREING STATE DEPENDENCE EFFECT IN HOSPITAL PAYMENT ADJUSTMENT

INTRODUCTION

Since FY 2013, as a part of the Affordable Care Act (ACA) program, the Hospital Value-Based Purchasing (HVBP) program adjusts Medicare's payments to hospitals based on the total performance score of the hospital. First, the program reduces a portion of the hospital's Medicare payments in a specific fiscal year and then by the end of the same fiscal year, the amount of the payment reductions will be awarded to the hospitals based on the total performance score, thus the hospitals that do not receive the reward will lose the portion of money reduced by Medicare. In this research, the authors apply the theory of state dependence and use the dynamic random effect probit model to estimate this effect. The results show that the hospital payment adjustment dynamics have a very significant state dependence effect (0.341), that means, hospitals that received a reward in previous year are 34.1% more probably to receive a reward this year than the ones that received a penalty in previous year. Meanwhile, I also find that the state dependence effect varies significantly across hospitals with different ownership (proprietary/government owned/voluntary nonprofit), the results show that voluntary nonprofit hospitals exhibit largest effect of state dependence (0.370), while government owned hospitals exhibit lowest effect of state dependence (0.293) and proprietary hospitals are in the middle. Among the factors that influence the likelihood a hospital receive a reward, I find that teaching hospitals with large number of beds (>400), are less likely be rewarded; in terms of ownership, I find that voluntary nonprofit hospitals are more likely be rewarded; in terms of demographic factors, hospitals where the average household income are higher within the region are more likely be rewarded.

BACKGROUND

State dependence effect, proposed by Heckman (1981), refers to the phenomenon that the realization of an event affects the probability that the same event occurring in the future, it can be

caused by two reasons. The first explanation is that, through experiencing a past event, certain behavior, for example, preference of a consumer, R&D investment of a firm, are altered. In this explanation, the past experience has a genuine behavioral effect that will lead the individual to behave differently as opposed to the same individual who has not experienced that event. Heckman termed this as "true state dependence" or "structural state dependence". The second explanation is that, individuals may differ in unobserved factors (for example, lack of motivation, low level of capability) that affect their likelihood of experiencing an event (that has nothing to do with whether an individual has experienced that event in the past or not). Heckman termed this as "spurious state dependence". In his paper, he also proposed a model to distinguish between the true state dependence and spurious state dependence.

Heckman's paper has aroused a lot of attention in economics, finance, health care and other areas. Researchers studied this effect in labor force participation, unemployment persistence and poverty/low pay persistence, dynamics of health, persistence of R&D investment, etc. I list some phenomenon regarding state dependence effect studied before in this literature part.

Effect of the VBP Program

Since the introduction of the CMS VBP program, it has aroused a lot of attention both from practioners and researchers about the impact of the program. However, the results are mixed, and the impact on different perspectives of the program are different. Ryan (2015) studied the early effects of the VBP program, using a diff-in-diff framework, he compared the hospital performance in terms of clinical quality and patient experience in 2012 with the baseline period 2011 and found that, hospitals that are impacted by the VBP program show no improvement in both dimensions (clinical quality and patient experience), he conclude that, in the first implementation period (2011 to 2012), there is no improvement in hospital performance, the reason could be that, the low magnitude and complex design of financial incentive. However, this study suffers from the short study period (only 1 year), if the period is long enough, there could be more improvements in hospital performance.

Figueroa (2016) studied the impact of VBP program on patient mortality of three conditions (acute myocardial infraction, heart failure and pneumonia) using a total of 4267 acute care hospitals in US, among them 1348 were not eligible to participate in the VBP program (critical access hospitals and hospitals in Maryland). He found that, for the hospitals that were impacted by the program, the mortality rates decreased at 0.13% and for the hospitals that were not impacted by the program, the mortality rates decreased at 0.14%. The difference between the mortality trend of the impacted and the non impacted hospitals was not significant. He concluded that, there is a lack of evidence for that the VBP program will lead to a lower mortality rate and he suggested alternative models to achieve a lower mortality rate.

Ryan (2017) further studied the impact of the VBP program in the first four years since its introduction in terms of clinical quality, patient experience and mortality using a diff-in-diff framework, where the critical access hospital (not eligible to participate in the program) is used as a control group. The results show that the improvements on clinical care measures and patient experience measures were not significant comparing the hospitals exposed to the VBP program and the hospitals that are not exposed to the program. In terms of mortality rates, the reduction in mortality rate of heart failure or acute myocardial infarction is not significant, while the reduction in mortality of pneumonia is significant.

Bonfrer (2018) did an observational study comparing hospitals that volunteered to participate in the Premier Hospital Quality Incentive Demonstration (PHQID, the pilot program of VBP) and the hospitals whose incentives were implemented later in the VBP program. The sample of study include 214 hospitals that were impacted by the PHQID program since 2003 and 975 matched hospitals that were impacted by the VBP program since 2013. Their results showed that, early adopters and late adopters of the program did not differ significantly in terms of clinical quality or mortality. They concluded that, being impacted for a longer time in the program did not likely make the hospitals perform better.

Since the research on the effect of the VBP program largely show no or little improvements on hospital performance, researchers began to investigate why the VBP program is not effective, Markovitz (2017) reviewed the literature to assess whether area factors, organizational and structural factors play a role in hospital performance. Their results showed that, hospitals are not responding strategically to the incentives of the VBP program and the VBP program needs to increase the financial incentive while at the same time clarify the incentive structure. They also suggested that, although some heterogeneity across organization types may mask the main effect of the program, the variation is not sufficient enough to alter the conclusion that VBP program does not meet its original goal.

State Dependence, Unemployment and Poverty

A prominent example of the state dependence effect is unemployment persistence, whether past experience of unemployment affect the likelihood of future unemployment. Lynch (1985) examined the state dependence effect in youth unemployment and she found a significant state dependence effect that past unemployment duration has on future unemployment. She estimated that, a white male worker with mean values of expected income, given one week of unemployment, has a re-employment probability of 36.09% comparing with only 8.4% if this same individual has 10 weeks of unemployment experience. Narendranathan, Wiji, and Peter Elias (1993) studied whether there is a causal relationship between past unemployment experience and future unemployment, they used a sample of 4067 males born in 1958 and their employment history between the year 1974 and 1981 (seven years), duration of unemployment, and other socio-economic factors. The results showed a significant state dependence effect, the probability of becoming unemployed are 2.3 times higher for people who were unemployed last year than for people who were not unemployed. Among other factors, they found that the probability that an individual with a below average math score will be unemployed this year is 1.8 times higher compared to an individual who has an above average math score. With regard to reading scores, this figure is 1.6. Also, comparing to the people who are not married, the people who are married are less likely being unemployed.

Flaig, Licht and Steiner (1993) studied the state dependence effect in male unemployment behavior with the first six waves of the German Socio-Economic Panel through a dynamic random effect probit model. Their result showed a significant state dependence effect regarding both incidence and duration of unemployment controlling for observed and unobserved heterogeneity. The authors suggested a person`s previous unemployment history have a long term effect because it leads to a depreciation of human capital or acts as a screening device in future employers` hiring decisions.

Arulampalam, Booth and Taylor (2000) studied unemployment persistence with data from British Household Panel Survey through a dynamic panel model, the econometric issues of unobserved heterogeneity and initial conditions are discussed. They found a strong effect of state dependence—an individual`s previous unemployment experience has effect on his future unemployment. They suggested that policies reducing short term unemployment incidence will have long term effect on unemployment.

Later, Arulampalam (2001) further studied this effect and found that, not only did previous unemployment experience has state dependence effect on future unemployment, but also that previous unemployment experience will have an effect on wage received in the future. The author estimated that an incidence of unemployment will lead to a wage penalty of about 6% on re-employ in Britain, and three years later, they earned 14% less compared to what they would have received in the absence of past unemployment.

Another often studied phenomenon that exhibits state dependence effect is low wage employment and poverty persistence. Stewart and Swaffield (1999) studied the state dependence effect in low pay dynamics, they found that the probability of being low paid strongly depends on whether being low paid last year. In terms of econometric issues, they found that omitting the initial state will lead to overstatement of the effects of explanatory variables.

Cappellari and Jenkins (2004) studied low income transitions with data from a British panel survey, the results showed that there is substantial state dependence effect in poverty. They also estimated low income transition rates and the lengths of poverty for different person.

Later, Stewart (2007) examined the extent of state dependence in unemployment and low wage employment. He found that, previous experience of low wage employment and unemployment have almost as large effect on future prospects. He suggested that obtaining a high wage job will decrease the probability of repeated unemployment significantly.

Prowse (2012) studied the effect of previous employment outcomes on future employment by distinguishing full time and part time employment, considering unobserved heterogeneity, children and education. The results showed variation in effect of children and education. The author found that, comparing temporary part time employment and full time employment, the part time employment has a higher state dependence effect in future employment than full time employment.

State Dependence, R&D, and Innovation

The persistence of innovation refers to the influence of past innovation activities on current and future innovation behavior and success. State dependence theory suits well into the research on persistence of innovation and it has been studied since 1990s. Flaig and Stadler (1994) studied the product and process innovations of private firms with a dynamic random effects probit model. They found that, firms` probability of innovation depend on market structure, unobserved heterogeneity, and realized innovations in the previous year. The positive significant effect of past innovation on future innovation suggested there is strong state dependence.

Cefis and Orsenigo (2001) examined the persistence of innovative activities with panel data from six different countries in the period of 1978-1993. By applying a transition probability matrix approach, they found evidence of persistence in innovative activities and they also found that, the effect of persistence declined as time passes. They also suggested that, both innovators and non-innovators have a high persistence to remain in their state.

Peters (2009) investigated firms` innovative behavior from 1994 to 2002 with a panel of German manufacturing firms. He found that the persistence at the firm level is significant in both manufacturing firms and service firms by applying a dynamic random effect model. Moreover,

he found that among the factors of firms, the knowledge provided by skilled employees is the most important factor in explaining the innovative behavior of the firms.

Ganter and Hecker (2013) studied persistence of technological and organizational types of innovation with moderating effects of firm level characteristics and evaluated the sources of state dependence. The results showed that, For organizational innovation, the model shows the firm's propensity to adopt technological innovations significantly increases with previous adoption of technological innovation, firm size, and public support in financing innovations; while organizational innovations does not show the same pattern. The authors suggested that, in terms of technological innovation, there is a strong state dependence effect, past success of innovation will have an impact on the adoption of new technological innovation, however, organizational innovation does not show the same effect.

Triguero and Corcoles (2013) studied persistence of innovation with a panel of manufacturing firms from Spain in the period of 1990-2008. They applied a dynamic random effects probit model controlling for initial conditions and unobserved heterogeneity. The results showed that both R&D and innovation have strong persistence at the firm level. Regarding specific factors, firm size and outsourcing have positive effects on R&D and innovation.

Pere Arque-Castells (2013) measured the state dependence in R&D based on a panel of Spanish manufacturing firms from 1998 to 2009. The results showed positive significant state dependence effect. Moreover, they found that R&D subsidies can generate on average 9% of inducement effects and this effect varies from small to large firms, they concluded that the amount of subsidies needed to generate the same inducement effects for small firms are larger.

State Dependence and Marketing

The state dependence effect has been studied by marketing scholars since 1990s.

Conventionally, marketing scholars tend to believe that brand choice behavior of the majority of consumers were consistent with the zero-order process, meaning that there is no significant causal relation between past purchase and current purchase (Bass 1974, 1984). In applying state dependence theory, Michael Keane (1997) first studied the persistence in brand choice and found a substantial state dependence effect using Nielsen data after controlling for heterogeneity. Also he concluded that this effect tend to decline as time passes, suggesting that the long term effect of promotion is positive but small.

Seetharaman, P. B., Andrew Ainslie, and Pradeep K. Chintagunta (1999) investigated the household state dependence effect across different categories through a Bayesian variance component approach. The results showed that household exhibited strong state dependence effect in four of the five categories studied (one category does not show effect). The authors found that, sensitivity to marketing mix and category expenditure variables are associated with greater state dependence while household demographics such as family size or income did not have an influence on state dependence.

Seetharaman, P. B (2004) proposed a new utility theoretic brand choice model with different sources of state dependence effect incorporated: structural state dependence (effect of previous brand choice), correlated error terms in random utility function (effect of habit type 1), correlations between utility maximizing alternatives (effect of habit type 2) and carryover effects (effect of previous marketing mix variables). By using scanner data, the author showed that structural state dependence to be the most important effect among the four proposed effects. Meanwhile, the author showed that lagged promotions have carryover effects on habit persistence.

Che, Hai, K. Sudhir, and P. B. Seetharaman (2007) investigated the pricing behavior of manufacturers and retailers with a demand that is state dependent. They estimated the effect with household level scanner data and found that, omission of state dependence in demand will lead to biased inference of firm behavior and observed retail prices are consistent with a pricing model where both manufacturers and retailers are forward looking, based on this, they suggested that even a myopic pricing model with state dependence effect accounted in demand will be a reasonable approximation.

Dubé, Jean-Pierre, Günter J. Hitsch, and Peter E. Rossi (2010) studied the phenomenon of consumer inertia with an explanation from state dependence theory. They found significant structural state dependence using data from margarine and refrigerated orange juice purchase. The authors suggested three economic explanations for the state dependence, preference change due to the loyalty, search and learning induced by past purchase experience, the data used by the authors supported the loyalty explanation.

Pavlidis, Polykarpos, and Paul B. Ellickson (2017) explored the importance of parent brand state dependence effect on pricing outcomes of forward looking multi product firms. Through numerical simulation, the authors found that loyalty to the parent brand lead to decreased prices and reduced profits of the joint profit maximization relative to sub brand profit maximization and state dependence effect to the sub-brand will mediate this.

State Dependence and Health

While the state dependence theory have been well applied in unemployment dynamics, income dynamics, innovation dynamics and brand choice dynamics, the application in health is less well established. With the first paper came out in 2000s. Contoyannis, Paul, Andrew M.

Jones, and Nigel Rice (2004) studied health dynamics using British Household Panel Survey (BHPS) data from 1991 to 1998. The authors applied both static and dynamic panel probit models allowing for both state dependence effect and unobserved heterogeneity. The results of dynamic panel probit models showed significant positive state dependence effect.

Halliday (2008) studied the persistence in the evolution of health over the life cycle and two sources of persistence are allowed: unobserved heterogeneity and state dependence. The author used data from PSID (Panel Study of Income Dynamics) and the main variables used are self reported health status, age and gender. The results showed modest level of state dependence in half the population and for the other half the state dependence is found to be near unity. The author explained that this could be due to the large number of people who never exit healthy states. Among the factors that influence an individual`s health, the authors concluded that the early adulthood health and before have a far reaching effect.

Contoyannis, Paul, and Jinhu Li (2011) studied the health outcome persistence from childhood to adolescence using data from Canadian National Longitudian Survey of Children and Youth. The authors suggested that positive significant state dependence exist in health dynamics of children and further ,the results showed that children living in poorer/lower education level neighborhoods tend to experience poor health status for longer, and children tend to experience health drops living in neighborhoods where more families headed by lone-parents living in rental accommodations.

Roy and Schurer (2013) examined the persistence in mental health problems using a panel data from Australia applying different approaches including GMM and correlated random effects. Their results showed that, an individual who had a problem of depression before is five times more likely to experience depression a year later, indicating a strong evidence of state dependence. Among the factors, low income is a significant factor for depression for both men and women.

Carro and Traferri (2014) examined the persistence in self reported health status using a dynamic ordered probit model with two fixed effects controlling for unobserved health status and reporting behavior. The authors found strong state dependence effects in self reported health status. A small but significant effect of income on health status is found among other socioeconomic variables.

Hospital Value Based Purchasing (VBP) Program and Payment Adjustment

Established by Section 1886 of the Social Security Act, the HVBP program is the first national pay for performance (P4P) program implemented and administrated by CMS (Center for Medicare & Medicaid Services). The quality of care are evaluated in four domains: safety, efficiency, clinical care and patient experience. Different measures are used to evaluate the performance on the four domains (detailed measures of the four domains are in the appendix). CMS assesses the hospital`s performance by comparing the hospital`s achievement points (awarded by comparing a hospital`s rates during the performance period with all hospitals` rates during the baseline period) and improvement points (awarded by comparing a hospital`s rates during the performance period with the hospital`s self rates during the baseline period). The greater of the two (achievement point and improvement point) is used to calculate the total performance score (TPS). The weight of the four domains are adjusted from year to year.

For example, the total performance score for FY 2015 is calculated as:

And the total performance score for FY 2016 is calculated as:

TPS₂₀₁₆ = 0.10 * Clinical Care Score + 0.25 * Patient Experience Score + 0.25 * Efficiency Score + 0.40 Safety Score

The program will first reduce a portion of the hospital's Medicare payments and then distribute this portion of money to the hospitals based on the quality of care provided to patients. For FY 2013, the portion is 1 percent of total Medicare payments and the percent will increase 0.25 each subsequent year. For FY 2017 and later, the portion is set at 2 percent. In terms of total amount of money distributed by the program, for FY 2013, it is \$963 million and for FY 2017, it is \$ 1.8 billion.

METHODOLOGY

To model this type of state dependence effect, we apply the following model:

$$y_{it} = x'_{it}\beta + ry_{ij-1} + \alpha_i + u_{it}$$

where y_{it} is the binary outcome of whether a hospital receive a reward (equals 1) or a panelty (equals 0), y_{it-1} is whether the hospital receive a reward or panelty last year (lag of dependent variable), x_{it} is the vector of observed hospital characteristics, α_i captures the unobserved heterogeneity and u_{it} is the error term. The null is there is no state dependence (γ =0). The estimate of parameter γ is the average state dependence over time and is our focus.,Several assumptions are contained in the equation. First, the dynamics are first order, i.e. y_{ij-2} does not have an effect on y_{ij} ; Second, x_{it} are appropriately strictly exogenous, conditional on unobserved heterogeneity. The assumptions are the same as Wooldridge (2005).

Given the two assumptions (dynamics are first order; x_{it} are strict exogenous), let $f_t(y_t|x_t, y_{t-1}, \alpha; \beta)$ be the correctly specified density, then the density of $(y_{i1}, ..., y_{iT})$ is

$$\prod_{i=1}^{N} \prod_{t=1}^{T} f_t(y_{it} | x_{it}, y_{it-1}, \alpha_i; \beta_0)$$

To get an estimate of parameter β , we need to face the fact that it depends on unobservables, α_i . To solve this, we can treat α_i as parameters to be estimated, this leads to the maximization of the log likelihood function

$$\sum_{i=1}^{N} \sum_{t=1}^{T} \log f_t(y_{it} | x_{it}, y_{it-1}, \alpha_i; \beta)$$

As is pointed out by Hsiao (1986), the initial conditions will not be a problem if T is large, unfortunately in our dataset comparing with i, T is small. So we need to endogenize and model the initial condition to obtain consistent estimate. In previous research, three ways have been proposed to solve the problem of handling the initial conditions in dynamic nonlinear models, as is summarized by Hsiao (1986, section 7.4), the first one is to treat the initial conditions for each unit as nonrandom, however this requires very strong assumptions that the initial condition y_{i0} is independent of unobserved heterogeneity.

The second approach, proposed by Hsiao (1986, section 4.3) is to use the joint distribution of outcomes on the response condition on unobserved heterogeneity and observed variables and allow the initial condition to be random. The main difficulty in this approach is to specifying the distribution of initial condition based on unobserved heterogeneity. The last one is to approximate the conditional distribution of the initial condition, as is proposed by Heckman (1981) but it is more difficult computationally to obtain estimate of parameters and average effects.

Here we apply the Wooldridge (2005) approach to handle this problem, which is to model the distribution of unobserved heterogeneity conditional on observed exogenous variables and initial values (use the density of $(y_{i1}, ..., y_{iT})$ conditional on (y_{i0}, x_i) , i.e., specifying $f(\alpha | y_{i0}, x_i)$). Under this approach, assume $h(c | y_0, z; \delta)$ is a correctly specified model for the density of $D(c_i | y_{i0}, z_i)$, the density of $(y_{i1}, ..., y_{iT})$ given $(y_{i0} = y_0, x_i = x)$ is:

$$\int_{\mathbb{R}^{J}} \left(\prod_{t=1}^{T} f_{t}(y_{t}|x_{t}, y_{t-1}, \alpha; \beta_{0}) \right) h(\alpha|y_{0}, x; \delta_{0}) \eta(d\alpha)$$

Which leads to the log-likelihood function conditional on (y_{i0}, x_i) to be:

$$l_{i}(\beta,\delta) = \log \left[\int_{\mathbb{R}^{J}} \left(\prod_{t=1}^{T} f_{t}(y_{t}|x_{t},y_{t-1},\alpha;\beta) \right) h(\alpha|y_{i0},x_{i};\delta) \eta(d\alpha) \right]$$

After this we sum up the log-likelihood function with respect to i = 1, ..., N and maximize with respect to β , δ , we get estimate of β_0 , δ_0 . The result conditional MLE is \sqrt{N} consistent and asymptotic normal under standard regularity conditions.

To obtain the estimate of partial effect, let $q(y_t)$ be a scalar function of y_t , then the average partial effects across the distribution of α_i is:

$$\mu(\mathbf{x}_t, \mathbf{y}_{t-1}) = \mathbf{E}[\mathbf{m}(\mathbf{x}_t, \mathbf{y}_{t-1}, \alpha_i; \beta_0)]$$

where

$$\begin{split} m(x_t, y_{t-1}, \alpha_i; \beta_0) &= E[q(y_{it}) | x_{it} = x_t, y_{i,t-1} = y_{t-1}, \alpha_i = \alpha] \\ &= \int_{R^G} q(y_t) f_t(y_t | x_t, y_{t-1}, \alpha; \beta_0) v(dy_t) \end{split}$$

A consistent estimator can be obtained by

$$\hat{\mu}(x_{t}, y_{t-1}) = N^{-1} \sum_{i=1}^{N} r(x_{t}, y_{t-1}, x_{i}, y_{i0}; \hat{\beta}, \hat{\delta})$$

Where $r(x_t, y_{t-1}, x_i, y_{i0}; \beta_0, \delta_0) = E[m(x_t, y_{t-1}, \alpha_i; \beta_0)|y_{i0}, x_i]]$

The entry probability is $e_{it} \equiv \Pr(y_{it} = 1 | y_{it-1} = 0, x_{it}) = \Phi[(x'_{it}\beta)(1-\rho)^{0.5}]$

The persistence probability is

$$s_{it} \equiv \Pr(y_{it} = 1 | y_{it-1} = 1, x_{it}) = \Phi[(\gamma + x'_{it}\beta)(1 - \rho)^{0.5}]$$

Where Φ [] is the standard normal cumulative distribution function and ρ is the fraction of variance that attributes to the variation in the time-invariant individual effects.

By comparing the raw persistence and predicted persistence, we can derive the percentage of the raw persistence explained by the state dependence effect is

$$\Pr(y_{it} = 1 | y_{it-1} = 1, x_{it}) - \Pr(y_{it} = 1 | y_{it-1} = 0, x_{it}) / \Pr(y_{it} = 1 | y_{it-1} = 1) - \Pr(y_{it} = 1 | y_{it-1} = 0)$$

DATA

The data are obtained from three main sources: characteristics of hospitals (for example number of employees, number of beds, number of discharge) are obtained from CMS Impact File and payment adjustment data come from Hospital Inpatient Prospective Payment System (IPPS), demographics data within 10 miles radius come from the Census Bureau.

Number of hospitals participating in the program, average adjustment factor, number of hospitals received award/penalty are shown in the Table 3.1:

[Table 3.1 about here]

Total number of hospitals vary from year to year because CMS has established a minimum data requirement for number of cases, measures, surveys, etc. For example, for the patient experience domain, hospital must report at least 100 patient surveys in order to receive a score for this domain. Inclusion of data that do not meet the requirement could skew the results and further impact the calculation of total performance score.

CMS do not publish the exact amount of money that are awarded or penalized for each hospital, only in FY 2016, they published the distribution in Table 3.2 and 3.3:

[Table 3.2 about here]

[Table 3.3 about here]

Here I construct a balanced panel with 2471 hospitals from year 2013 to 2018, total 14826 observations. As is mentioned in the theory part of state dependence, there are two reasons that the realization of an event affects the probability that the same event occurring again in the future. The first one is that, the experience has a genuine behavioral effect that will lead the hospital to behave differently as opposed to the same hospital who has not experienced that event (i.e. true state dependence). The second one is individuals may differ in unobserved factors (unobserved heterogeneity or spurious state dependence).

Since I have the data of whether the hospitals get reward through the six years (2013 to 2018), I can calculate the conditional probabilities of a hospital that receive a reward this year, conditional on last year's reward status. If there is no difference on the two conditional probabilities, then there is model free evidence that last year's reward status has no effect on this year's status. Table 3.4 shows the conditional probabilities:

[Table 3.4 about here]

Comparing Column 3 and 4 of the Table 3.4, I can see that, if in the previous year, a hospital got rewarded, then next year, its probability of receiving a reward again is about twice of

the hospital who got a penalty last year. So I can see that there is a considerable state dependence in hospitals` payment adjustment by HVBP program.

In Table 3.5 I summarize the dependent variable and explanatory variables used in this study, with their mean value and standard error.

[Table 3.5 about here]

RESULTS

In Table 3.6 I show results of estimates based on simple pooled probit estimator, random effects probit estimator and the Wooldridge estimator. The hospitals in the category of rural/proprietary/lowest CMI/none teaching/lowest bed capacity of New England are used as the benchmarking ones.

[Table 3.6 about here]

The lag of dependent variable (reward t-1) is positive significant across the three estimators, suggesting there is a positive significant state dependence.

The preferred model (Wooldridge model) gives an average marginal effect of 0.341, which means that hospitals that received a reward in previous year are 34.1% more probably to receive a reward this year than the ones that received a penalty in previous year. This explains 77.1% of the persistence observed in the data.

For other explanatory variables, some hospital characteristics are significantly associated with the likelihood of receiving a reward from CMS, for example, number of employees show a significant positive effect, number of beds show a significant negative effect, teaching status show a significant negative effect, percent of Medicare/Medicaid discharge show a moderate negative effect. Comparing with proprietary hospitals, voluntary nonprofit and government owned hospitals are more likely to receive a reward.

Among demographic variables, I observe a moderate significant negative effect from number of black and Hispanic population, household income shows a significant positive effect on the probability of a hospital receive a reward, and competition show a moderate significant positive effect.

For geographic factors, I do observe that, comparing with hospitals located in rural area, hospitals located in urban areas are less likely to receive a reward, comparing with hospitals located in New England area, the hospitals located in Mid Atlantic, West South Central show a significant less likelihood of receiving a reward, the hospitals located in East South Central show a moderate significant less likelihood of receiving a reward, while hospitals located in other areas do not show a significant difference.

Above are the estimates from the three estimators based on the whole sample. I controlled for the hospital ownership and located areas with a set of dummy variables. However, this state dependence effect may differ over the different ownership and geographic areas. So I analyzed the interaction terms between lag of reward status and dummy variables of hospital ownership and geo location. A test of equality of coefficients is performed to examine if the state dependence effect across different ownership/geographic areas are the same or not. If the state dependence effect is different across those, then there is evidence to suggest the policy design across different kind of ownership and different geographic areas should be different. By performing the Wald test, I obtained the results in Table 3.7:

[Table 3.7 about here]

The test of equality of coefficient shows a chi-2 value of 8.98 and a p value of 0.011, which means that the state dependence effect are significantly different between large urban/other urban/rural hospitals.

I further performed pair wise comparison test to see if the effect is equal between pairs of large urban/other urban, large urban/rural, other urban/rural hospitals, the results of the chi-2 and p value can be found in the last two rows of Table 3.8, I can see that among the three pairs, the state dependence effect differ significantly between hospitals located in large urban areas and other urban areas, for other pairs, it is not significantly different.

[Table 3.8 about here]

The test of equality of coefficient shows a chi-2 value of 7.34 and a p value of 0.026, which means that the state dependence effect are significantly different across hospitals of different ownership. For pair wise comparison, I found that, the state dependence effect is significantly different between voluntary nonprofit hospitals and proprietary hospitals, also, for voluntary nonprofit hospitals and government owned hospitals, it is also significantly different, for other pair wise comparison, I don't found a significant difference.

Analysis of Hospitals that are Penalized or Rewarded every year

In this section, I considered only the hospitals that were penalized or rewarded every year from 2013 to 2018 and built a model to find out if there is a relationship between the hospital characteristics and the amount of penalty or reward.

For the hospitals that were penalized every year from 2013 to 2018, there are 280 hospitals (out of the total number 2471). I estimate the following model:

$$P_{it} = x'_{it}\delta + \lambda_i + \epsilon_{it}$$

where P_{it} is the extent of penalty paid by the hospital i in year t (between 0 and 1, larger P_{it} equals more penalty paid), x'_{it} is the same hospital characteristics I used in previous section, λ_i is the hospital specific random effect and ϵ_{it} is the individual specific random effect.

Also, I considered the hospitals that received a reward from the program every year from 2013 to 2018, there are 345 hospitals in total. Again, I estimated the same model as above with the extent of reward received as the dependent variable. The results of the two model estimates are in the following table:

[Table 3.9 about here]

From the results I can see that, among the hospitals that were penalized every year, number of employees, number of discharges and competition play a key role: number of employees shows a negative significant effect, meaning that, for the hospitals that received a penalty each year, the larger the number of employees, the smaller the amount of penalty; number of discharges has a positive significant effect, meaning that, for the hospitals that received a penalty each year, the smaller the number of discharges, the smaller the amount of penalty; competition (measured by the number of people per hospital in the 10 miles radius) has a negative significant effect, meaning that, the smaller the competition, the smaller the penalty. Other factors do not show a significant effect.

Among the hospitals that were rewarded every year, the factors that have a significant effect are: number of employees, number of discharges, number of white people, number of household income, bed capacity, case mix index and geo-regions. For number of employees I found a positive significant effect, meaning that for hospitals that received a reward each year, the larger the number of employees, the larger the amount of reward; for number of discharges I found a negative significant effect, meaning that for hospitals that received a reward each year, the smaller the number of discharges, the larger the amount of reward; For socio economic factors, I found that the larger the number of white people, the smaller the amount of reward, the larger the number of household income, the larger the amount of reward; For patient characteristics, I found the more the clinical complexity, the larger the amount of reward; For geo-region factors, I found that comparing with hospitals located in rural area, the hospitals located in urban areas received a smaller amount of reward; comparing with hospitals in New England area, hospitals located in Mid Atlantic and East South Central received a smaller amount of reward.

CONCLUSION

Hospital Value Based Purchasing (HVBP) program, launched and administrated by CMS (center for Medicare and Medicaid Services), is the first national level p4p program for hospitals in US. Although some research suggests moderate to none improvement in hospital quality, how the payment adjustment decision is made, whether the payment adjustment has a long last effect (other than just immediate effect) on hospital has not been studied. In this research, I applied a dynamic probit random effects model to analyze the state dependence effect in hospital payment adjustment. I ask the question that, does hospitals' payment adjustment status depends on last year's status, and what are the factors that influence the hospitals' likelihood of receiving a reward in this program. The results showed a positive significant state dependence effect across the three different models I estimated and is significant with hospitals located in different geo areas (large urban/other urban/rural) and with hospitals of different ownerships (government owned/voluntary non profit/proprietary).

For the factors that impact the likelihood that a hospital receive a reward from the HVBP program, I found that number of employees show a significant positive effect, suggesting that as the number of employees get larger, hospitals have more labor resources, and can manage to improve upon the quality measures to reach a reward; number of beds and discharges show a significant negative effect, suggesting that as patient volumn get heavier, hospitals become unable to meet the quality criteria, suggesting there is a potentially a negative network effect. Teaching status show a significant negative effect, this makes sense because residents in hospitals are still in their training stage and may not be able to perform in a quality level that is required by the program. Percent of Medicare/Medicaid discharge show a moderate negative effect. Comparing with proprietary hospitals, voluntary non profit and government owned hospitals are more likely to receive a reward.

Among demographic variables, I observe a moderate significant negative effect from number of black and Hispanic population, household income show a significant positive effect on the probability of a hospital receive a reward, and competition show a moderate significant positive effect.

For geographic factors, I do observe that, comparing with hospitals located in rural area, hospitals located in urban areas are less likely to receive a reward, comparing with hospitals located in New England area, the hospitals located in Mid Atlantic, West South Central show a significant less likelihood of receiving a reward, the hospitals located in East South Central show a moderate significant less likelihood of receiving a reward, while hospitals located in other areas do not show a significant difference.
FIGURES AND TABLES FOR CHAPTER THREE

Year	No of Hospital Penalized	No of Hospital Awarded	Total Number of Hospital	Min Adjustment Factor	Max Adjustment Factor
2013	1426	1557	2984	0.991	1.008
2014	1473	1255	2728	0.989	1.007
2015	1375	1714	3089	0.987	1.021
2016	1235	1806	3041	0.983	1.024
2017	1343	1612	2955	0.982	1.032
2018	1211	1597	2808	0.983	1.030

Table 3.1: Number of Hospitals Awarded and Penalized

Change of Payment	Number of Hospitals
>\$150,000	284
\$120,001 to \$150,000	103
\$90,001 to \$120,000	172
\$60,001 to \$90,000	217
\$30,001 to \$60,000	366
\$1 to \$30,000	652
\$0 to \$0	0
\$-30,000 to \$-1	391
\$-60,000 to \$-30,001	182
\$-90,000 to \$-60,001	138
\$-120,000 to \$-90,001	98
\$-150,000 to \$-120,001	73
<=-\$150,000	349

Table 3.2: Distribution of Change of Payments for FY 2016

Table 3.3: Distribution of Percentage Change of Payments for FY 2016

Change of Percentage of Payment	Number of Hospitals
1.0% < x	316
$0.9\% < x \le 1.0\%$	77
$0.8\% < x \le 0.9\%$	92
$0.7\% < x \le 0.8\%$	94
$0.6\% < x \le 0.7\%$	108
$0.5\% < x \le 0.6\%$	123
$0.4\% < x \le 0.5\%$	174
$0.3\% < x \le 0.4\%$	194

$0.2\% < x \le 0.3\%$	194
$0.1\% < x \le 0.2\%$	212
$0.0\% < x \le 0.1\%$	210
0.00%	0
$-0.1\% < x \le 0.0\%$	222
$-0.2\% < x \le -0.1\%$	227
$-0.3\% < x \le -0.2\%$	197
$-0.4\% < x \le -0.3\%$	162
$-0.5\% < x \le -0.4\%$	133
$-0.6\% < x \le -0.5\%$	85
$-0.7\% < x \le -0.6\%$	105
$-0.8\% < x \le -0.7\%$	42
$-0.9\% < x \le -0.8\%$	37
$-1.0\% < x \le -0.9\%$	13
x ≤ -1.0%	8

Table 3.4: Conditional and Unconditional Probabilities that a Hospital Receive a Reward

Year	Unconditional	Awarded at t-1	Penalized at t-1
	$(\boldsymbol{P}_{it}=1)$	$(\boldsymbol{P}_{it} = 1 \boldsymbol{P}_{it-1} = 1)$	$(\boldsymbol{P}_{it}=1 \boldsymbol{P}_{it-1}=\boldsymbol{0})$
2014	0.467	0.677	0.246
2015	0.516	0.675	0.377
2016	0.553	0.786	0.285
2017	0.511	0.717	0.257
2018	0.548	0.815	0.268

Table 3.5: Summary of Dependent and Explanatory Variables

Variable Name	Description	Mean	SD
Dependent Variable			

Reward Status	Whether a hospital was	0.518	
	rewarded (binary variable)		
Explanatory Variable			
Geographic			
Characteristics			1
New England	CT, ME, MA, NH, RI, VT	0.048	
Mid Atlantic	NJ, NY, PA	0.129	
East North Central	IL, IN, MI, OH, WI	0.174	
West North Cenral	IA, KS, MN, MO, NE, ND, SD	0.082	
South Atlantic	DE, FL, GA, MD, NC, SC, VA, DC, WV	0.178	
East South Central	AL, KY, MS, TN	0.084	
West South Central	AR, LA, OK, TX	0.120	
Mountain	AZ, CO, ID, MT, NV, NM, UT, WY	0.065	
Pacific	AL, CA, HI, OR, WA	0.140	
Large Urban Area	Hospital located in a large urban area	0.418	
Other Urban Area	Hospital located in other (small) urban area	0.339	
Rural Area	Hospital located in a rural area	0.243	
Demographic Characteristics			
White Population	Number of white residents in the zip code (in thousands)	18.21	10.81
Black Population	Number of black residents in the zip code (in thousands)	3.21	4.64
Hispanic Population	Number of Hispanic residents in the zip code (in thousands)	4.16	7.43
Household Income	Average Household income in the zip code (in thousands)	45.70	19.77
Competition	Number of people per hospital in 10-mile radius of a hospital (in thousands)	5.23	7.11
Hospital Characteristics			
Ownership			1
Government Owned	Hospitals owned by government	0.154	

	(district/local/state/federal)		
Voluntary non-profit	Voluntary non profit	0.655	
	hospitals owned by		
	churches or other private		
	entities		
Proprietary	Proprietary hospitals	0.191	
Bed Capacity	Number of beds in a	226.34	191.41
	hospital		
Small	Hospitals with<100 beds	0.251	
Medium	Hospitals with 100 to 399	0.611	
	beds		
Large	Hospitals with >400 beds	0.138	
Teaching Status	resident-to-bed ratio in a	0.072	0 166
Touching Status	hospital	0.072	0.100
None	Hospitals with no	0.636	
ivone	residents	0.050	
Vory Minor	Hospitals with resident to	0.100	
very winor	had ratio between 0.001	0.109	
	and 0.040		
		0.155	
Minor	Hospitals with resident-to-	0.155	
	bed ratio between 0.050		
	and 0.249		
Major	Hospitals with resident-to-	0.07	
	bed ratio between 0.250		
	and 0.599		
Very Major	Hospitals with resident-to-	0.03	
	bed ratio≥0.600		
Case Mix Index	diversity, clinical	1.539	0.266
	complexity, and the need		
	for resources in a		
	hospital		
Quartile 1	Hospitals with CMI≤1.254	0.131	
Quartile 2	Hospitals with CMI	0.255	
	between 1.255 and 1.446		
Quartile 3	Hospitals with CMI	0.298	
_	between 1.447 and 1.645		
Quartile 4	Hospitals with CMI≥1.646	0.316	
Number of Employees	Number of total paid	1460.53	1861.51
	employees in a hospital		
Number of Discharges	Total number of	10986.35	10541.99
	discharges in a year for a		
	hospital		
Percent of	The ratio of	0.470	0.132
Medicare/Medicaid	Medicare/Medicaid	0.170	
Discharge	discharge over total		

number of discharge	

	Pooled Probit	RE Probit	Wooldridge
reward t-1	1.087 (0.025)***	0.973 (0.033)***	0.867 (0.035)***
reward 0			0.248 (0.035)***
No of Employees t-1	0.073 (0.039)***	0.079 (0.017)***	0.085 (0.018)***
No of Discharges t-1	-0.008 (0.003)*	-0.009 (0.004)*	-0.009 (0.004)*
Percent of	0.019 (0.118)	-0.038 (0.135)*	0.074 (0.140)*
Medicare/Medicaid			
Discharge t-1			
Bed Capacity Medium	-0.296 (0.039)***	-0.331 (0.045)***	-0.329 (0.047)***
t-1			
Bed Capacity Large t-	-0.421 (0.071)***	-0.464 (0.082)***	-0.467 (0.086)***
1			
CMI Q2 t-1	0.034 (0.045)	0.051 (0.050)	0.042 (0.052)
CMI Q3 t-1	0.021 (0.049)	0.044 (0.056)	0.033 (0.058)
CMI Q4 t-1	0.009 (0.055)	0.034 (0.062)	0.024 (0.064)
Government Owned	0.072 (0.043)	0.075 (0.051)	0.104 (0.054)*
Voluntary non-profit	0.209 (0.034)***	0.226 (0.040)***	0.260 (0.042)***
Very Minor Teaching	-0.121 (0.043)**	-0.139 (0.049)**	-0.143 (0.052)**
t-1			
Minor Teaching t-1	-0.134 (0.039)**	-0.154 (0.045)**	-0.145 (0.047)**
Major Teaching t-1	-0.171 (0.059)**	-0.195 (0.068)**	-0.204 (0.070)**
Very Major Teaching	-0.162 (0.088)	-0.190 (0.101)	-0.173 (0.106)
t-1			
White Population	0.001 (0.001)	0.002 (0.002)	0.002 (0.002)
Black Population	-0.008 (0.003)*	-0.009 (0.003)*	-0.009 (0.004)*
Hispanic Population	-0.005 (0.002)*	-0.006 (0.003)*	-0.006 (0.003)*
Household Income	0.004 (0.001)***	0.005 (0.001)***	0.005 (0.001)***
Competition	0.003 (0.001)*	0.003 (0.001)*	0.003 (0.001)*
reward t-1*LURBAN	-0.033 (0.063)	-0.056 (0.067)	-0.057 (0.068)
reward t-1*OURBAN	0.138 (0.066)	0.131 (0.070)	0.126 (0.072)
reward t-	-0.085 (0.070)	-0.106 (0.074)	-0.113 (0.076)
1*Government Owned			
reward t-1*Voluntary	-0.164 (0.063)**	-0.178 (0.067)**	-0.172 (0.068)**
Non Profit			
Large Urban Area	-0.150 (0.044)***	-0.163 (0.051)***	-0.175 (0.054)***
Other Urban Area	-0.158 (0.039)***	-0.173 (0.046)***	-0.190 (0.048)***
Mid Atlantic	-0.281 (0.068)***	-0.310 (0.079)***	-0.314 (0.084)***
East North Central	-0.023 (0.067)	-0.015 (0.078)	-0.038 (0.083)
West North Cenral	0.016 (0.074)	0.024 (0.086)	0.017 (0.091)
South Atlantic	-0.025 (0.068)	-0.016 (0.078)	-0.037 (0.083)

Table 3.6: Results of Model Estimates of State Dependency

East South Central	-0.183 (0.075)*	-0.192 (0.088)*	-0.210 (0.092)*
West South Central	-0.194 (0.072)**	-0.208 (0.083)**	-0.234 (0.088)**
Mountain	-0.149 (0.079)	-0.172 (0.092)	-0.184 (0.096)
Pacific	-0.071 (0.072)	-0.087 (0.084)	-0.067 (0.088)
Average Partial Effect	0.427	0.381	0.341
(***p<0.01, **p<0.05, *p<0.1)			

Table 3.7: Comparison of State Dependence Effect across Different Geo-area

	Large Urban Hospitals	Other Urban Hospitals	Rural Hospitals
reward t-1	0.749 (0.053)***	0.962 (0.061)***	0.935 (0.069)***
number of hospitals	1033	838	600
number of	6198	5028	3600
observations			
estimated state	0.297	0.375	0.365
dependence effect			
test of equality of			
coefficient			
chi-2		8.98	
p value		0.011	
pair wise	LURBAN/OURBAN	OURBAN/RURAL	RURAL/LURBAN
comparison			
chi-2	8.84	3.47	0.70
p value	0.003***	0.06	0.40

^{(***}p<0.01, **p<0.05, *p<0.1)

Table 3.8: Comparison of State Dependence Effect across Different Ownership

	Government Owned Hospitals	Voluntary non profit Hospitals	Proprietary Hospitals
reward t-1	0.648 (0.091)***	0.953 (0.043)***	0.752 (0.076)***
number of hospitals	380	1618	473
number of observations	2280	9708	2838
estimated state dependence effect	0.265	0.371	0.293
test of equality of coefficient			
chi-2		7.34	
p value		0.026	
pair wise comparison	G/V	V/P	P/G
chi-2	8.42	6.39	2.23

p value	0.001***	0.01*	0.14			
(***p<0.01, **p<0.05, *p<0.1)						

·	1	/	1	/	1	/	

	Extent of Reward	Extent of Penalty
No of Employees t-1	0.04 (0.03)*	-0.02 (0.01)**
No of Discharges t-1	-0.01 (0.005)***	0.007 (0.002)***
Percent of	-0.4 (0.1)*	-0.02 (0.08)
Medicare/Medicaid		
Discharge t-1		
Bed Capacity Medium	-0.1 (0.03)***	0.04 (0.04)
t-1		
Bed Capacity Large t-1	-0.0009 (0.09)	0.07 (0.05)
CMI Q2 t-1	0.1 (0.03)***	0.008 (0.04)
CMI Q3 t-1	0.2 (0.04)***	0.03 (0.04)
CMI Q4 t-1	0.2 (0.04)***	0.08 (0.05)
Government Owned	-0.06 (0.04)	0.05 (0.03)
Voluntary non-profit	-0.01 (0.04)	0.02 (0.02)
Very Minor Teaching t-	-0.01 (0.04)	-0.008 (0.02)
1		
Minor Teaching t-1	0.06 (0.04)	-0.004 (0.02)
Major Teaching t-1	-0.05 (0.06)	-0.02(0.03)
Very Major Teaching t-	0.04 (0.1)	-0.01 (0.04)
1		
White Population	-0.003 (0.001)***	-0.0002 (0.001)
Black Population	0.004 (0.005)	0.001 (0.001)
Hispanic Population	-0.0002 (0.003)	0.001 (0.001)
Household Income	0.002 (0.0008)***	-0.0007(0.0005)
Competition	0.0001(0.001)	-0.002 (0.0008)***
Large Urban Area	-0.2 (0.04)***	-0.01 (0.03)
Other Urban Area	-0.1(0.03)***	-0.009 (0.03)
Mid Atlantic	-0.1 (0.07)*	0.06(0.04)
East North Central	-0.04 (0.06)	0.02 (0.03)
West North Cenral	0.01 (0.06)	-0.04 (0.05)
South Atlantic	-0.07 (0.06)	0.02 (0.05)
East South Central	-0.1 (0.07)*	0.04 (0.05)
West South Central	-0.1 (0.06)**	-0.02 (0.05)
Mountain	-0.1(0.07)	-0.04 (0.05)
Pacific	-0.02 (0.07)	-0.01 (0.05)

^{(***}p<0.01, **p<0.05, *p<0.1)

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CHAPTER FOUR: EFFECT OF DEREGULATION ON DRUG MARKET

INTRODUCTION

Pharmaceutical industry impacts the health of a population and economics of a nation significantly. U.S. pharmaceutical spending grows by 2.5% in 2019, reaching \$370 billion. Fitch Solutions (2019) estimates that by 2023, pharmaceutical spending will reach \$420 billion, account for nearly 1.7% of the national GDP. This growth in pharmaceutical spending has exceeded GDP growth in United States as well as many other countries (Schumock 2019). Due to the prominence of the pharmaceutical industry, it is highly regulated and deeply impacted by public policies from approval of new drugs, drug pricing to drug distribution, among others.

In terms of drug price regulation, two mechanisms are commonly used: reference pricing and price cap. According to a report by WHO (2015), 24 of 30 OECD countries and 20 of 27 European Union countries use the reference price regulation to control drug price. UK and China adopted the price cap regulation system. But since pharmaceutical spending continues to grow despite of price regulation, recently there are many callings to de-regulate. Since June 1st, 2015, Chinese government decided to remove price cap regulation in pharmaceutical market and offers us an opportunity to study the effect of de-regulation.

In this research, we applied an Interrupted Time Series Analysis (ITSA) approach to study the effect of de-regulation of price cap in China`s pharmaceutical market. Data is obtained from Sinopharm Group, the largest distributor in China`s pharmaceutical market. A total of nine categories of drugs were analyzed and the results showed a clear pattern between industry HHI and revenue change of the drugs.

The rest of the chapter is organized as follows. We started with a literature review on branded drugs/generic drugs competition, reference price regulation, price cap regulation and their effects. After this, we described the China`s pharmaceutical market, our data and methodology. Then we presented the analysis and the results for the nine categories of drugs after price cap deregulation. Lastly we conclude with discussions, implications of the price cap deregulation in terms of government price regulation as well as the drug company pricing practice.

BACKGROUND

Competition between Branded Drugs and Generic Drugs

Generic drugs are copies of branded drugs that have the same dosage, intended use, effects, side effects, risks, safety, and strength. In other words, their pharmacological effects are the same as those of their branded counterparts. Branded drugs come with patent protection, or so called "exclusivity period", which protects the branded drugs from the competition of generic drugs. The length of exclusivity period varies from 3 years to 7 years, according to U.S. Food & Drug Administration (2018), depends on the level of innovation of the branded drugs. After the exclusivity period, the production of generic drugs is allowed thus bring competition to branded drugs.

This competition from generic drugs to branded drugs arouse many attentions from academia and industry. Aronsson (2001) analyzed how market shares for brand name drugs are affected by generic competition. They used data for twelve different branded drugs, which are all subject to generic competition. For five of these drugs, they find that the price of the branded drugs relative to the average price of the generic ones significantly affects the market share of the branded drug. Lexchin (2004) studied whether brand-name manufacturers compete on price once generic competitors become available in the market. He identified 81 brand-name drugs that lacked generic competition in July 1990 but had acquired generic competitors by December 1998. He compared and analyzed the price changes, the results showed no statistically significant change in brand-name prices when generic competition started. Gonzalez (2008) studied how physician characteristics and prescribing decisions impact competition among branded drugs of a therapeutic class once generic drugs enter the market. They found that generic entry in the analyzed category would not only lead to the decrease in the prescription of the branded drugs bioequivalent to the generics, but also lead to increase of non-bioequivalent branded drugs as detailing-sensitive physicians switched from the contested drugs to these other branded alternatives. Vandoros (2014) studied whether there is a switch in total (branded and generic) consumption after generic entry from molecules that face generic competition towards other molecules of the same class, which are still in-patent. Data from six European countries for the time period 1991 to 2006 are used to study the cases of angiotensin-converting enzyme inhibitors and proton pump inhibitors. Empirical evidence shows that patent expiry led to a switch in total (branded and generic) consumption towards other in-patent angiotensin-converting enzyme inhibitors, whereas patent expiry of omeprazole led to a switch in consumption towards other proton pump inhibitors.

Regulation on Drug Prices and the Effect

Pharmaceutical markets are regulated heavily. Most countries regulate manufacturer prices for pharmaceuticals either through price cap regulation or reference price regulation. As is stated by Danzon (2006), the rationale for drug price regulation derives from pervasive insurance or third party payment, which makes patients insensitive to prices, hence creating incentives for suppliers to charge higher prices than would occur without insurance. To counteract this supplier moral hazard that applies to all insured health services, including drugs, both private and public insurers limit the prices that they will pay for all insured health services.

Price cap regulation refers to the practice that under which, the regulatory body sets a maximum price that can be charged for a drug. The price cap may be based on cost plus a profit margin, prices for the same product in other countries, or prices for therapeutic alternatives. Previous research on the effect of price cap regulation has focused on the price of the drugs, sales of drugs and how this regulation undermines or increase competition. Dalen (2006) used monthly data over the period 1998–2004 for the six drugs in Norwegian pharmaceutical market that were included in the price cap regulation, a structural model was estimated to examine the impact of the regulation on both demand and market power. The results suggested that under the price cap regulation, the market shares of generic drugs were increased, price competition between generic and branded drugs were increased. Stremersch (2009) used 84 months of sales data of newly introduced medicine and found that, manufacturer price controls, has a positive effect on drug sales. The effect of manufacturer price controls is similar for newly launched and mature drugs. Brekke (2015) used a dataset of monthly sales and price data of 165 on-patent substances. Their findings suggested that, stricter price cap regulation reduces competition from parallel imports, and has no (strictly negative) effect on producer profits in the presence (absence) of parallel imports.

Reference price regulation refers to the practice that under which, the reference price is the maximum reimbursement for a group of drugs. According to a report by WHO (2015), 24 of 30 OECD countries and approximately 20 of 27 European Union countries use the reference price regulation to control drug price. This regulation regime also arouses many attentions. Ekelund (2003) used a data set consisting of all new chemical entities (NCEs) launched in Sweden between 1987 and 1997, the ratio of launch price to the average price of existing branded substitutes and the same ratio four years later are used as the dependent variable. Their results showed that, reference pricing regulation leads to higher launch price and faster decline of real price. Moreno-Torres (2009) studied the effect of reference pricing on number of entries of generic firms in Spanish pharmaceutical market. He used dummies for reference pricing, number of generic firms in the market, number of branded competitors in the market, revenues and age of product as explanatory variables. The results showed the system of reference pricing restrains generic entry. Brekke (2011) studied the effect of reference pricing using off-patent prescription drugs within the 40 largest therapeutic groups from 1st of January 2001 to 31st of December 2004. The results showed that reference pricing significantly reduces both brand-name and generic prices, and results in significantly lower brand-name market shares. Kaiser (2014) studied the effect of reference pricing 2003 to 2007 in Denmark where the reference price became effective in 2005. They found that the reference pricing led to substantial reductions in drug prices as well as decreases in overall producer revenues and health care expenditures.

Chinese Pharmaceutical Market and Regulation Practice

Chinese pharmaceutical market is the second largest (following United States as the largest one) in the world, with over 122 billion value in USD by the year 2017 and it projected to reach 180 billion value in USD by the year 2020. From 2010 to 2015 the compound annual growth rate is about 15.5 percent and from 2016 to 2020, the compound annual growth rate is about 8 percent (IMS Institute 2015). Although in recent years the growth slows down but it continues to be above the growth of GDP.

Historically, government healthcare payments are lower than personal payments. Since the public insurance plan named New Co-operative Medical Scheme (NCMS) was launched in 2003, the government payments has been growing and it exceeded private payments. In 2015, the total government healthcare expenditure reached 1422.5 billion in RMB (about 330.3 billion in USD), that equals about 330.3 USD per capita and 4.98% of total GDP according to World Health Organization (WHO 2016). Although the government expenditure on healthcare is projected to grow but comparing to OECD countries, the number is still low. The NCMS plan now covers about 96 percent of people in 2019 according to the latest news release by the National Health Commission of China.

Generic drugs are the mainstay of Chinese pharmaceutical industry, according to a report by Deloitte (Deloitte 2015), in 2015, the sales of generic drugs reached about 614 billion in RMB (about 88 billion in USD), representing about 85% of the total pharmaceutical sales. The compound annual growth rate of sales of generic drugs is projected around 14%. In 2015 the total sales of branded drugs is 112.7 billion in RMB (about 16.1 billion in USD, representing about 15% of the total pharmaceutical sales) and compound annual growth rate of sales of branded drugs is projected around 25%. While the government relys upon widespread prescription of generics in the public insurance plan to control the overall healthcare expenditures, the growth of economy and household income, Chinese customers will likely to switch from the domestic generic drugs to imported branded drugs.

China has used price cap regulation set by the NDRC (National Development and Reform Commission) for many years (Mossialos 2016). Research about this price cap regulation in China are rare, and the results are mixed. Han (2013) studied the impact of price cap regulation of the Chinese government on pharmaceutical expenses. They used the data for systemic antibiotics of 12 hospitals in Beijing from 1996 to 2005 and analyzed the effect on price change and the volume change. The results showed that the price cap regulation lowered the prices, but the expenditure on antibiotics was raised because more expensive drugs in the same therapeutic category were prescribed. Wu (2015) used a macro-level data between 1997 and 2008 to evaluate the effects of China's pharmaceutical price cap regulations. The results showed that the regulations have short-run effects on pharmaceutical price indexes, reducing them by 0.5 percentage points. The price regulations fail to reduce household health expenditures and the average profitability of the pharmaceutical industry was not impacted.

DATA AND METHODOLOGY

The data came from Sinopharm Group, the largest distributor of Chinese pharmaceutical market. In 2015, the company`s revenue reached 227 billion in Chinese RMB (about 35 billion in USD). The company provided us with the sales data to 535 hospitals in Jinlin Province from March 2011 to August 2016, a total of 66 monthly sales data. Since June 1st, 2015, Chinese government decided to remove price cap regulation in pharmaceutical market. There are 14 months data after the deregulation policy, 52 months data before the deregulation policy. Our price data were extracted from db.yaozh.com, a database that contains price data of the Chinese pharmaceutical market. Our data consists of nine categories of drugs, each categories of drugs include both branded and generic drugs in it.

Method

We used interrupted time-series analysis (ITSA) method for each drugs (both generic and branded) of each category to assess the change in sales associated with the deregulation of the price cap. ITSA is a quasi-experimental design useful to evaluate the longitudinal effects of interventions occurring at a fixed point in time on a population level, such as the regulation/deregulation of a policy. The date of removal of the price cap in the pharmaceutical market (June 1st, 2015) was regarded as the intervention time point for ITS analyses.

The estimation framework is as follows:

$$Y_t = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t T_t + \epsilon_t$$

 Y_t is the outcome variable that measures the sales in month t, X_t the time is the dummy variable representing the intervention (equals 1 if the time is after the intervention, equals 0 if the time is before the intervention), and X_tT_t is the interaction term, ϵ_t is the error term.

 β_0 represents the intercept or starting level of the outcome variable, β_1 is the slope or trend of the outcome variable until the introduction of the intervention. β_2 represents the change in the level of the outcome that occurs in the period immediately following the introduction of the intervention. β_3 represents the difference between pre-intervention and post-intervention slopes of the outcome. Thus, a significant P value in β_2 is an indicator of immediate treatment effect and a significant P value in β_3 is an indicator of a treatment effect over time.

RESULTS AND DISCUSSION

We analyzed a total of nine categories of drugs, I listed the detailed results of antidiabetics and oncology drugs, the results for this estimation analysis are presented in Table 3.1 and 3.2.

[Table 3.1 about here]

[Table 3.2 about here]

As we can see, the trend change are different, depends on what kind of drugs it is, whether it is branded or generic. We further calculated each categories` Herfindahl-Hirschman Index (HHI) to see whether this is related to the level of competition. The HHI is calculated as follows:

$$HHI = s_1^2 + s_2^2 + s_3^2 + \dots + s_n^2$$

where s_n is the market share percentage of firm n expressed as a whole number.

According to the U.S. Department of Justice (2018), a market with an HHI of less than 1,500 is considered a competitive marketplace, an HHI of 1,500 to 2,500 is considered a moderately concentrated marketplace, and an HHI of 2,500 or greater is considered a highly concentrated marketplace. The higher the HHI is, the lower the level of competition. The results of the trend change and the respective HHI are listed in Table 3.3.

[Table 3.3 about here]

The results of our estimation framework show that, when HHI is relatively low (competition is high), after deregulation of the price cap, the revenue of drugs does not show a significant change (as in the case of antibiotics and gastrointestinal medications); as HHI increases (competition becomes lower), we observe that, after deregulation of the price cap, the revenue of generic drugs show a significant decrease (as in the case of oncology, cardio medications, immunosuppressant, immunostimulant and eye condition medications) and the revenue of branded drugs show a significant increase; when HHI grows really high (competition is low), we observe an increase in the revenue of the generic drugs, however, the revenue of branded drugs will decrease (as in the case of antidiabetics and antithrombotics). Upon price change, when HHI is relatively low (competition is high), price change is not significant; when HHI is high (competition is low), branded drugs will increase the price and generic drugs will lower the price.

Discussions and Implications

Previous studies on price regulation of pharmaceutical industry usually focus on how different price regulation regime will affect drug prices and how the effect of price regulation differ between generic and branded drugs (Brekke 2009, Kaiser 2014), with only a few others studied the effect of price regulation on market share (Podnar 2007), corporate R&D investment (Eger 2014) and physician`s prescribing behavior (Han 2015). With only one paper talking about pharmaceutical revenue (Neeraj 2008), but the paper`s focus is on national level of pharmaceutical revenue, not on level of drugs. In this paper, we obtained data from Sinopharm Group on revenues of different categories of drugs from 2011 to 2016 and thus applied a natural policy experiment study on the deregulation of price cap starting from June 2015. A direct relation between level of competition (represented by HHI) and revenue of drugs was found.

The deregulation of price cap in China's pharmaceutical market is a unique policy practice since most countries are regulating price instead of de-regulating and thus it provides us with some unique implications. First, competition does help with shaping the market characteristics. In our results, when HHI is low (meaning competition is high), for the two categories of drugs (antibiotics, gastrointestinal medications), after price cap deregulation, we don't observe a significant change both in drug price and revenue, suggesting that the competition itself plays the role of regulation; Second, after price cap was removed, for the other seven categories where competition is not as high as antibiotics and gastrointestinal medications, branded drugs will increase the price and generic drugs will decrease the price, suggesting that branded drugs have more confidence in their pricing power comparing with generic drugs, generic drugs will lower their price with the hope of increasing the quantity; Third, although branded drugs have more confidence in their pricing power and thus increase their price, they don't always end up with an increase in revenue, for the two categories (antithrombotics and antidiabetics) where HHI is high (meaning competition is low), they raise the price more than 10% and at last suffer from a decrease in revenue; while on the contrary, the generic drugs gain an increase in revenue.

FIGURES AND TABLES FOR CHAPTER FOUR

Table 4.1: Estimates of Changes in Revenue for Antidiabetics Following the Deregulation of

Price Cap

	β	SD	P Value	Branded/Generic	Price
					change
Recombinant Insulin	37324.65	17013.99	0.032	G	-6.27%
Glargine Injection					
Baseline level					
Baseline trend	10057.47	999.54	0.000		
Level change	-2249.81	74073.24	0.976		
Trend change	15070.25	7340.79	0.044**		
Mixture Recombinant	820.67	4030.36	0.839	G	-3.11%
Human Insulin					
Injection 50 R					
Baseline level					
Baseline trend	1973.77	200.95	0.000		
Level change	-25413.66	9250.59	0.008***		
Trend change	2471.07	867.08	0.006***		
Humulin NPH 70/30	84992.35	20921.10	0.000	В	+8.56%
Baseline level					
Baseline trend	14056.01	717.87	0.000		
Level change	-117664.6	48859.96	0.019**		
Trend change	-21659.64	4362.71	0.000***		
Mixture Recombinant	-12532.07	4732.04	0.010	G	-9.17%
Human Insulin					
Injection R					
Baseline level					
Baseline trend	2094.81	241.47	0.000		
Level change	14821.86	18552.61	0.427		
Trend change	3139.08	1550.58	0.047*		
Humalog Mix50 Baseline level	-7046.32	5466.26	0.202	В	+5.28%
Baseline trend	4708.50	291.39	0.000		
Level change	-13635.79	21448.34	0.527		
Trend change	-5230.03	1622.26	0.002***		

Repaglinide Tablets	19437.78	7386.97	0.011	В	+8.62%
Baseline level					
Baseline trend	3161.81	338.82	0.000		
Level change	-20927.98	16744.86	0.216		
Trend change	-4679.34	1305.31	0.001***		

^{(***}p<0.01, **p<0.05, *p<0.1)

Table 4.2: Estimates of Changes in Revenue for Oncology Drugs Following the Deregulation

	0	CD	DY		D .
	ß	SD	P Value	Branded/Generic	Price
					change
Pharmorubicin	291309	38359.33	0.000	В	+7.06%
Baseline level					
Baseline trend	1870.87	1608.40	0.249		
Level change	-124538.7	61750.98	0.048**		
Trend change	13932.4	5624.9	0.016**		
Oxaliplatin	305583.2	66531.84	0.000	В	+3.32%
Baseline level					
Baseline trend	8730.21	2504.19	0.001		
Level change	-61612.82	117144.5	0.601		
Trend change	31832.04	14316.37	0.030**		
Irinotecan	113697.5	14346.94	0.000	G	-2.49%
Hydrochloride for					
Injection					
Baseline level					
Baseline trend	3332.28	630.80	0.000		
Level change	-10341.76	26747.65	0.700		
Trend change	-7086.19	2871.34	0.016**		
Hydroxycamptothecin Baseline level	112180.6	17302.41	0.000	G	-1.15%
Baseline trend	-60.53	764.66	0.937		
Level change	42652.07	27414.63	0.125		
Trend change	-4630.35	1650.08	0.007***		
Capecitabine Baseline level	60078.88	22192.46	0.009	G	-6.16%

of Price Cap

Baseline trend	8178.39	1383.25	0.000		
Level change	39184.26	101936.1	0.702		
Trend change	-26051.72	8149.62	0.002***		
Icotinib Hydrochloride Tablets Baseline level	182593.7	35938.62	0.000	В	+3.99%
Baseline trend	3984.15	1450.76	0.008		
Level change	-275451.4	51875.56	0.000***		
Trend change	11542.01	4845.82	0.021**		

^{(***}p<0.01, **p<0.05, *p<0.1)

Table 4.3: Estimates of Changes in Revenue and Price for the Nine Categories of Drugs

	R _G	R _B	P _G	P _B	HHI
Antibiotics	no change	no change	no change	no change	385.47
Gastrointestinal Medications	no change	no change	no change	no change	675.54
Oncology	-	+	-11.33%	+5.89%	730.58
Cardiac Medications	-	+	-10.53%	+6.54%	1007.49
Immunosuppressant	-	+	-13.44%	+6.18%	1206.16
Eye Condition Medications	-	+	-11.9%	+7.88%	1273.17
Immunostimulant	-	+	-12.88%	+7.01%	1304.87
Antithrombotics	+	-	-6.15%	+11.36%	1955.62
Antidiabetics	+	-	-6.34%	+14.24%	2338.10



Figure 4.1: Recombinant Insulin Glargine Injection (G)



Figure 4.2: Mixture Recombinant Human Insulin Injection (G)



Figure 4.3: Mixture Recombinant Human Insulin Injection R (G)



Figure 4.4: Humulin NPH (B)



Figure 4.5: Humalog Mix 50 (B)





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