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THE EFFECT OF THE MEDICARE PART D DISCOUNT PROGRAM ON PRESCRIPTION DRUG UTILIZATION RATES

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ABSTRACT

After the national Medicare program was established in 1965, several decades passed until a prescription drug benefit was finally added to the program in 2003 as a result of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). The Medicare Part D prescription drug benefit generally helped reduce the financial burden of prescription drug costs on elderly beneficiaries. However, the beneficiaries who reached the coverage gap of the Part D plan benefit design structure continued to face significant out-of-pocket costs. The Patient Protection and Affordable Care Act (PPACA) of 2010 established discount and subsidy payment programs to gradually phase out the coverage gap by year 2020. The PPACA provisions began in 2011 with a 50% manufacturer discount on brand-name drugs in the coverage gap and a 7% plan subsidy on generic drugs in the coverage gap. Prior to the implementation of these provisions, several researchers were concerned that the large 50% discount on brand-name drugs would encourage beneficiaries to utilize more expensive brand-name drugs instead of cheaper generic alternatives. This thesis examines brand-name and generic drug dispensing and utilization rates of pharmacy benefit management companies from before and after the implementation of the PPACA provisions to determine if the researcher’s initial concerns actually occurred. Additionally, this thesis examines some of the possible reasons for the trends in dispensing and utilization rates over the last several years.
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Chapter 1
Introduction

A national health insurance program had been a desire of many American people since the early 20th century. After several decades of economic, social, and political challenges, a national health insurance program for the elderly finally became a reality when the Medicare and Medicaid programs were established in 1965. The Medicare program is a government insurance program that provides healthcare insurance coverage primarily to elderly individuals over the age of 65. The Medicaid program provides health insurance coverage to low-income individuals.

The Medicare program has evolved over the last several decades, but the most significant changes have occurred more recently. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act was signed into law, which finally added a long-awaited prescription drug benefit (Part D) to the Medicare program. The creation of a prescription drug benefit at this time was extremely important due to the increasing utilization and costs of prescription drugs among the elderly population. The Medicare Part D benefit reduced the financial burden of prescription drug costs for many elderly beneficiaries. However, out-of-pocket costs remained high for those who reached a component of the benefit design called the coverage gap. The Patient Protection and Affordable Care Act (PPACA) of 2010 established discount and subsidy provisions to gradually phase out the coverage gap by year 2020.

The PPACA provisions, which began in 2011, greatly reduced out-of-pocket costs for beneficiaries who reached the coverage gap. In 2011, enrollees who reached the coverage gap received a 50% manufacturer discount on brand-name drugs in the coverage gap and a 7% subsidy payment on generic drugs in the coverage gap. Prior to the implementation of these
provisions in 2011, several researchers felt that the large discount on brand-name drugs in the coverage gap had potential to encourage beneficiaries to utilize more expensive brand-name drugs rather than cheaper generic alternatives, ultimately increasing costs for the overall Medicare program.

The research question addressed in this thesis is: What impact did the brand-name drug discounts in 2011 have on prescription drug dispensing and utilization rates? Through the process of answering this question, this thesis will determine if researcher’s initial concerns actually occurred once the PPACA provisions were implemented. This thesis will begin with a comprehensive overview of the history of the Medicare program. This will be followed by a discussion of the Medicare Modernization Act and the Patient Protection and Affordable Care Act. Finally, this thesis will examine trends in dispensing and utilization rates before and after the implementation of the PPACA provisions as well as several factors contributing to these trends.
Chapter 2

History of Medicare

On July 30, 1965, President Lyndon B. Johnson signed House of Representatives Bill 6675 in Independence, Missouri in the presence of Harry S. Truman, a former advocate for major healthcare legislation. This bill, which established the national Medicare and Medicaid programs, ended a decades-long struggle for government health insurance for the elderly population. The initial Medicare program included two parts: Part A for hospital insurance and Part B for supplementary medical insurance. When Medicare coverage began on July 1, 1966, all individuals over the age of 65 were automatically enrolled in Part A and were able to sign up for voluntary Part B coverage. More than 19 million individuals were enrolled in the initial Medicare program in 1966. (Kaiser Timeline)

The Medicare program has evolved significantly over the last several decades since its inception in 1965. Today, the Medicare program provides insurance coverage to a larger subset of the U.S. population and covers a broader range of healthcare benefits and services. Medicare currently consists of four parts: Part A hospital insurance, Part B medical insurance for physician and outpatient services, Part C Medicare Advantage Plans, and Part D prescription drug coverage. Medicare Advantage Plans are Medicare-approved private health insurance plans that cover the benefits and services provided under Parts A, B, and D, and usually include some extra benefits and services not covered under Medicare for an additional cost. The Medicare program today provides health insurance coverage not only to elderly individuals over the age of 65, but also to certain disabled individuals under age 65 and individuals of any age with End-Stage Renal
Disease (Medicare Benefits). In 2012, there were over 49 million total Medicare beneficiaries in
the United States (State Health Facts).

This chapter will examine the major events leading up to the establishment of the
Medicare program, as well as the major events following the inception of the program that have
contributed to Medicare’s evolution to the present day. The first section of this chapter provides
information about the decades-long process leading up to the creation of the Medicare and
Medicaid programs and explains the many challenges and opposition that politicians faced along
the way. The second section of this chapter provides information about the history of Medicare
from its creation in 1965 until 2003. This section explains some of the cost related issues that
emerged after the implementation of the Medicare program, as well as some of the major cost
containment approaches that played a role in the evolution of the Medicare program. While there
are numerous sources that provide a comprehensive overview of the history of Medicare, the
events described in this chapter are primarily from Jennie Kronenfeld’s book Medical Issues
Today: Medicare. A brief timeline of Medicare history is presented in Appendix A.

2.1 History Prior to the Passage of Medicare in 1965

The idea of federal government-sponsored health insurance in the United States was not a
new idea when the Medicare program was created in 1965. Discussion surrounding government-
sponsored health insurance coverage and attempts at creating national social insurance programs
with health provisions began in the early 1900s. At the beginning of the 20th century, Americans
learned of mandatory sickness insurance programs for workers in Germany and England and
began to advocate for similar programs in the United States. In 1912, Theodore Roosevelt’s
Progressive Party supported a social insurance program that included sickness insurance;
however, Roosevelt was unsuccessful in his run for the presidency. Private groups that were also
advocating for similar sickness insurance programs around this time period experienced only initial success. One of these private groups was the American Association for Labor Legislation (AALL), which formed in 1906 and consisted of social scientists, physicians, businessmen, politicians, and lawyers dedicated to social reform (Corning). The AALL was successful in persuading states to adopt worker’s compensation legislation, and after this accomplishment the group shifted their efforts toward trying to get states to pass medical care insurance legislation. The American Medical Association (AMA), the main organization of physicians at this point in history, initially supported the AALL’s efforts, and as a result, medical care legislation was introduced in fifteen states and committees were formed in ten states to analyze the potential for state-sponsored health insurance. Despite initial success, progress toward ultimately passing formal legislation for a medical insurance program was stalled for numerous reasons. By 1920, the AMA had adopted a more conservative stance and officially declared opposition to a mandatory medical insurance program. After World War I and the Communist takeover of Russia, some members of the U.S. public no longer wanted to implement a socialized health insurance program similar to that of some European countries. Additionally, private insurance companies, pharmaceutical companies, and several groups in the American labor movement opposed the idea of a socialized health insurance program in the United States for fear of government control. (Kronenfeld)

Opposition to government health insurance programs continued until the Great Depression in the early 1930s. In response to the Great Depression and changes in the economic and political climate, President Franklin D. Roosevelt (FDR) advocated for social security legislation. In 1932, FDR introduced an economic security proposal and in 1934 a committee was formed to draft social insurance legislation with health insurance provisions. While the legislation originally intended to incorporate health insurance provisions, the economic extent of the Great Depression placed more emphasis on unemployment and old-age insurance. FDR
signed the Social Security Act into law in 1935 (Corning). This social insurance program ultimately dealt with the issue of economic security for the elderly by establishing a system where current workers would pay tax contributions while employed in order to ensure financial stability after retirement. As a result of the success of the Social Security insurance program, numerous politicians developed interest in working to introduce social health insurance legislation. In 1939, Senator Wagner from New York introduced a national healthcare bill into Congress, and worked directly with other senators and congressmen, including Senator Murray from Montana and Congressman Dingell from Michigan, to introduce additional legislation in subsequent years. The health insurance legislation introduced by Senator Wagner was unsuccessful in the early 1940s as the United States government was focused on World War II. (Kronenfeld)

Upon the end of World War II, President Harry S. Truman advocated for the creation of new healthcare policies. In 1948, President Truman became the first U.S. president to formally endorse national health insurance legislation when he endorsed the Wagner-Murray-Dingell Bill. When Congress did not act on the Wagner-Murray-Dingell Bill, Truman proposed his own health insurance plan. While the initial health insurance provisions in FDR’s social insurance legislation were viewed as a method of income protection and financial security, Truman’s plan took a different approach and viewed health insurance as a solution to the inequitable distribution of, and access to, healthcare services in the United States. Truman’s proposed plan covered all medical, dental, hospital, and nursing care expenses for a worker and his/her dependents. The program was intended to be financed through a 3% payroll tax split evenly between the employee and employer. In an attempt to prevent public fear of government control of healthcare, Truman’s plan allowed doctors and hospitals to choose whether or not to join the plan and patients would be able to choose their own doctors. (Kronenfeld)

Although public opinion of Truman’s plan was initially favorable, the legislation did not pass. While the Democrats held a majority of the seats in the House of Representatives, there
was a group of anti-Truman southern Democrats that joined with Republicans to block the bill. Additionally, public support for the bill decreased significantly when the AMA began a lobbying campaign that associated Truman’s plan with socialist ideals. Despite the defeat of his plan in 1949, Truman continued to push for health insurance legislation throughout his presidential term, but was continuously unsuccessful due to the controversial nature of health insurance at the time. (Kronenfeld)

After many failed attempts, proponents of health insurance legislation believed that a proposal aimed at a narrower subset of the population would have a greater chance to pass in Congress. Instead of health insurance coverage for the majority of the U.S. population, a new proposal was drafted in 1951 that would expand the Old Age and Survivors Insurance Program by providing health insurance to elderly beneficiaries receiving Social Security payments. Although this bill did not pass, the decision to shift the focus of government health insurance from the entire population to the elderly population was a significant step in the process of establishing the U.S. Medicare program. The idea of a health insurance program for the elderly was very attractive at this time in history. A health insurance program limited to the elderly reduced concerns of a giveaway program where health insurance would be provided to those who were not in need of assistance. The elderly population was deemed to be more deserving of assistance because this group was generally poorer, sicker, and less likely to be insured than younger Americans. By the 1950s, many workers received health insurance coverage through their employer, but lost these insurance benefits when they retired. Both the elderly and current workers, who would eventually receive the benefits when they retired, were in support of the new idea. (Kronenfeld)

Although the idea of a health insurance program for the elderly was slowly gaining support among the public, the possibility of passing legislation was stalled when Dwight Eisenhower was elected president in 1952 and the Republicans gained majorities in both the
House of Representatives and the Senate. Eisenhower had campaigned against socialized healthcare and opposed both Truman’s broad proposals and the more recent proposals restricted to the elderly population. In 1954, the Democrats regained control of the House of Representatives and the Senate, allowing for more discussion of healthcare policies. In 1956, legislation was passed that created disability insurance for workers over the age of 50 to provide greater economic security for older workers. This legislation was another significant step toward the creation of the U.S. Medicare program. (Kronenfeld)

In 1957, Representative Aime Forand from Rhode Island proposed a bill on health insurance for the elderly. The bill was influential in that it initiated a serious interest among member of Congress to develop a health insurance program for the elderly. In 1958, the Ways and Means Committee in the House of Representatives held a hearing on the Forand Bill, but Wilbur Mills, the chair of the committee, opposed the bill and did not let it pass through the committee. The congressional committee hearing caused the AMA to resume the lobbying campaign against health insurance legislation that they had started during the Truman era. Continuing their arguments from the late 1940s, the AMA criticized that the Forand Bill would cause an unwanted invasion of government into private healthcare and would be one of the first steps in creating national socialism. The AMA successfully convinced groups such as the American Hospital Association, the National Association of Blue Shield Plans, and the Life Insurance Association of America to oppose the idea of health insurance for the elderly. However, groups such as the American Nurses Association, the National Association of Social Workers, the American Geriatrics Society, and the American Association of Retired Workers continued to support the idea. (Kronenfeld)

In 1959, a special Senate subcommittee on aging was created under the leadership of Democratic Senator Pat McNamara from Michigan. The subcommittee hosted a series of public meetings in 38 cities around the country between 1959 and 1961 in order to raise public
awareness of issues facing the elderly, specifically the growing need for health insurance among members of this group of the population. The discussions resulted in two main approaches for health insurance for the elderly. One approach was a Social Security approach that would provide health insurance benefits to all elderly individuals who were covered under the Social Security program. The other approach was a welfare approach that would provide health insurance coverage to low-income elderly individuals whose financial resources were not enough to cover their medical expenses. The two approaches also differed in respect to the extent of coverage and funding mechanisms. The Social Security approach intended to cover hospitalization, nursing homes, and surgical procedures, while the welfare approach would cover hospital expenses, physician services, dental care, and prescription drugs. The Social Security approach proposed funding through additional Social Security taxes, while the welfare approach proposed funding through federal income tax revenues and matching funds given to states. The Social Security approach would be administered by the Social Security Administration on a national level, thus creating uniform national standards, while the welfare approach would result in varying standards administered at the state-level. (Kronenfeld)

Throughout the 1950s, the Eisenhower administration remained opposed to any health insurance legislation. Some Republicans, including current Vice President and potential Presidential candidate Richard Nixon, were worried that Republican opposition to health insurance legislation would give the party a disadvantage in the next presidential election. Therefore, several Republicans and conservative Democrats developed a new proposal for a health insurance program. The Kerr-Mills Bill, which was sponsored by Senators Robert Kerr of Oklahoma and Wilbur Mills of Arkansas, was based on the welfare approach and proposed expanding federal aid to states that were currently providing medical assistance to low-income elderly individuals. The AMA, along with other conservative groups, viewed the bill as a desirable alternative to the Social Security approach and decided to support the bill. The Kerr-
Mills Bill was passed in Congress and signed into law by President Eisenhower on September 13, 1960 (Corning). The passage of this bill was viewed by many Democrats as an important step toward even broader health insurance legislation in the future. Although the Kerr-Mills Act appeared to be a practical solution, the plan ultimately proved unsuccessful and was eventually replaced by the Medicaid program. By 1963, only eighteen states participated in the program and only four states offered the entire range of benefits and services outlined in the bill. By 1965, five states (California, New York, Massachusetts, Michigan, and Pennsylvania) were using nearly 90% of funds despite having only one-third of the elderly U.S. population. (Kronenfeld)

The recently enacted Kerr-Mills Act and health insurance for the elderly were controversial topics in the 1960 presidential election. Democratic presidential candidate John F. Kennedy made healthcare legislation a plank in the Democratic Party platform in order to distinguish himself from Republican opponent Richard Nixon. Kennedy was elected president and in his first State of the Union Address he announced a goal to pass healthcare legislation by the end of his first year as president. In February of 1961, Senator Clinton Anderson of New Mexico and Representative Cecil King of California proposed a new health insurance bill, called the King-Anderson Bill (Corning). Unlike the Kerr-Mills Act which only assisted low-income elderly, the King-Anderson Bill proposed coverage for all Americans over age 65. The plan would be financed by a 0.25% increase in Social Security taxes. The Kennedy administration supported the bill and used several methods, including campaigns, rallies, and nationally televised announcements, to increase public awareness and limit opposition. In spite of strong efforts to spread awareness and gain support for this legislation, the Kennedy administration faced several challenges. As was the case during Truman’s presidency, conservative southern Democrats joined with Republicans to block the new bill. In addition, Wilbur Mills, chair of the Ways and Means Committee, was concerned that the financing method for the new healthcare program would have severe consequences for the Social Security program. The AMA and other
conservative groups continued to oppose liberal healthcare proposals such as this one, claiming that it would lead to the spread of socialist ideology in the United States. (Kronenfeld)

Despite the Kennedy administration’s strong desire and continuous efforts to implement a new national health insurance program for the elderly, legislation was never passed. In November of 1963, President John F. Kennedy was assassinated and vice president Lyndon B. Johnson assumed the role of president. When Johnson ran for president in the 1964 election he aimed to continue Kennedy’s efforts toward improving healthcare for the elderly population. Johnson’s campaign platform focused on a variety of social reforms, including health insurance legislation. Johnson won the 1964 election and Democrats gained majorities in both the House of Representatives and the Senate. As a result of the election, the chance of passing health insurance legislation in the near future was practically guaranteed. (Kronenfeld)

Republicans and other opponents of previous attempts at health insurance legislation (i.e. AMA) acknowledged that the passage of some form of health insurance legislation was now unavoidable. These groups no longer wanted to block the process and shifted their efforts toward developing their own health insurance legislation in order to compete with the currently accepted King-Anderson bill that had been proposed a few years earlier during Kennedy’s presidency. Republican John W. Byrnes proposed a bill that would create a voluntary program where federal payments would subsidize private health insurance for the elderly. The Byrnes Bill would be a broader program than that proposed by the King-Anderson Bill and would provide coverage for doctor bills and prescription drugs. The AMA also developed a proposal, called Eldercare, which would be implemented on a state level and would include coverage for hospital and physician expenses, surgical fees, prescription drug costs, nursing home expenses, and services such as x-rays. (Kronenfeld)

By the beginning of 1965, there were three main proposals for health insurance legislation before Congress: the Democratic King-Anderson Bill, the Republican Byrnes Bill, and
the AMA Eldercare proposal. Congressional hearings were held for the King-Anderson Bill and there was serious discussion about passing this legislation. The Republicans, however, did not want the Democrats to take all of the credit for the passage of health insurance legislation and criticized the inadequacies of the Democratic King-Anderson Bill. The Republicans initiated congressional hearings for the Byrnes Bill and emphasized the main components of the bill that made it superior to the King-Anderson Bill. The Byrnes Bill was a voluntary program and covered doctor bills and prescription drug costs, which the King-Anderson Bill did not cover. (Kronenfeld)

The Democratic King-Anderson Bill and the Republican Byrnes Bill were initially presented as fully distinct plans. However, by March of 1965, Wilbur Mills proposed combining certain aspects of each of the two bills into a single proposal. While the Republicans did not favor this idea, the Democrats viewed it as an opportunity to incorporate Republican feedback and criticisms into the King-Anderson Bill and began considering possible combinations of the two proposals. The Democrats rejected Byrnes’ suggestion for prescription drug coverage outside of hospitals and nursing homes for fear of costs being too high. However, the Democrats did decide to include Byrnes’ financing approach for physician services which consisted of individual premium payments by current Social Security beneficiaries. Although the Democrats included some components from the Republican Byrnes Bill into the new proposal, the final vote from the House of Representatives Ways and Means Committee was a straight party vote of 17 Democrats in favor and 8 Republicans opposed. After some additional adjustments, the revised bill was finally passed by the House of Representatives on July 27, 1965 and by the Senate two days later. On July 30, 1965, President Lyndon B. Johnson signed the bill into law at a signing ceremony in Independence, Missouri, establishing the Medicare and Medicaid programs. The initial Medicare program included two parts. Part A covered hospital expenses and would be financed through a payroll tax. Part B was voluntary supplemental medical insurance that
covered outpatient physician services and would be financed through a monthly premium paid jointly by the federal government and enrollees (Kuttner). Medicaid is a federal-state program for low-income individuals and replaced the Kerr-Mills Act of 1960. (Kronenfeld)

2.2 History from 1965 to 2003

After more than half a century of deliberation and debate over health insurance legislation, the United States finally had a program of health insurance coverage for the elderly population. Implementation of the Medicare program did not begin until July 1, 1966, an entire year after the passage of the new legislation. In the interim, the Social Security Administration used national and local media sources to inform the public, and especially individuals over age 65, of the coverage, benefits, and premium payments under the two different parts (Parts A and B) of the new Medicare program. The efforts to educate the elderly appeared to be successful as 93% of the elderly population had enrolled in the voluntary Part B program by the end of the first year and enrollment continued to expand rapidly in the years following. (Kronenfeld)

Shortly after the implementation of the Medicare program in 1966, some of the complexities that were involved in managing and expanding such a large federal health insurance program began to emerge. During the early years of the Medicare program, unexpected increases in utilization and costs became significant issues. For the first few years of the program, costs exceeded the actuarial projections that had been made at the time the Medicare legislation was passed. Overall Medicare costs were difficult to predict as expenses varied based on the amount of healthcare services the elderly used, how much doctors and hospitals charged for this care, and by advancements in medical technology. The unexpected increase in costs at the start of the Medicare program was partially due to uncontrolled physician fees and hospital expenses. The initial Medicare legislation did not explicitly define the ‘reasonable’ fees that physicians could
charge their patients, and as a result, it is estimated that during the first several years of the Medicare program, physician fees increased 5% and physician incomes increased 11%. Additionally, the average daily hospital service charge increased approximately 22% during the first year of the Medicare program. When Medicare costs rose 40% in both 1968 and 1969, it became clear that the Medicare program had the potential to create a substantial strain on the federal budget. (Kronenfeld)

By 1970, government administrators and politicians realized that increasing Medicare costs were a major issue for the federal budget and therefore initiated discussions to find ways to control these rising costs. Sincere attempts for national healthcare reform were made in the early 1970s; however, none of the reform measures proved adequate enough to significantly control rising costs (Kronenfeld). Despite concerns over rising Medicare costs, the Medicare program continued to expand throughout the 1970s. On October 30, 1972, President Nixon signed the Social Security Amendments of 1972, which extended Medicare coverage to individuals under age 65 with long-term disabilities and to all individuals with End-Stage Renal Disease (Kaiser Timeline). Both of these expansions were significant in the history of Medicare because they extended Medicare beyond the elderly population to include people less than 65 years of age. While these expansions covered only a small subset of the population, they contributed to the rising costs of Medicare as the medical expenses for these individuals were generally quite high. (Kronenfeld)

In addition to the expansion of benefits, administration changes in the Medicare program also occurred during the 1970s. In 1977, Joe Califano, the Secretary of the Department of Health, Education, and Welfare, created the Health Care Financing Administration (HCFA). The administration of the Medicare program shifted from the Social Security Administration to the newly created Health Care Financing Administration (Kaiser Timeline). The HCFA, which was later renamed the Centers for Medicare and Medicaid Services (CMS) in 2001, became
responsible for the administration of both the Medicare and Medicaid programs. The decision to shift administrative responsibilities of both the Medicare and Medicaid programs to an agency that was dedicated to healthcare financing was driven by the need to reduce spending and control costs. The shift of administrative responsibilities also transformed Medicare from a social insurance program to a healthcare financing program and eventually weakened the connection between Medicare and Social Security. (Kronenfeld)

Despite the creation of the Health Care Financing Administration to control Medicare costs, costs for both the overall U.S. healthcare system and the Medicare program continued to rise. By 1980, medical care accounted for 8.9% of U.S. GDP, which was a 1.8% increase from a decade earlier. During the 1980s, President Ronald Reagan and his administration supported major changes in Medicare that primarily dealt with the issue of rising healthcare costs. Some of the changes that helped reduce Medicare costs during the 1980s were initiated by the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, the Medicare Prospective Payment System of 1983, and the Deficit Reduction Act (DEFRA) of 1984. (Kronenfeld)

The Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 attempted to control Medicare costs in several ways. First, TEFRA attempted to reduce Medicare spending and increase revenues by increasing Part B premiums to cover 25% of program costs. TEFRA also required all federal employees to begin paying the health insurance payroll tax and imposed a limit on the maximum amount Medicare would pay for a hospital discharge (Kaiser Timeline). In 1983, Congress established the Medicare Prospective Payment System, which replaced the old retrospective approach for hospital reimbursements with a new prospective approach. Under the old approach, a hospital would charge the Medicare program for the expenses incurred from treating a Medicare beneficiary. Under the new approach, the hospital would be paid in advance based on the expected length of stay and services used for a given diagnosis. The Prospective Payment System encouraged hospitals to provide healthcare services more economically and
initially helped to control the excessive growth of inpatient hospital costs. The Deficit Reduction Act (DEFRA) of 1984 and the Graham-Rudman-Hollins Act of 1985 placed additional limits on future increases in the prospective payments to hospitals and physicians, which helped to some extent to further control Medicare costs\(^1\). (Kronenfeld) (Kaiser Timeline)

In an attempt to control excessive costs during the first two decades, the Medicare program had not expanded benefits at the same rate as private health insurance plans. Upon successfully controlling Medicare costs during the 1980s, the Reagan administration faced increasing pressure to expand benefits under the Medicare program. One specific aspect of the Medicare program that was widely criticized was the lack of an outpatient prescription drug benefit. When the Medicare program was implemented in 1965, there was no coverage for prescription drugs that a physician or hospital may prescribe to a Medicare beneficiary. The initial lack of coverage for prescription drugs was not unusual because prescription drugs did not play a large role in healthcare in the 1960s. However, by the 1980s, large numbers of people were using prescription drugs to treat chronic health conditions. While Medicare beneficiaries could obtain prescription drug coverage through Medigap\(^2\) policies or employer retirement health insurance programs, many felt that the Medicare program should provide outpatient prescription drug benefits as well as other benefits that reflected changes in the healthcare industry. (Kuttner)

In the late 1980s, Otis Bowen, Secretary of Health and Human Services, convinced the Reagan administration to adopt his plan for expanding Medicare benefits. The Medicare Catastrophic Coverage Act (MCCA) was passed in 1988 and expanded many aspects of the Medicare program including hospitalization, hospice care, home health services, mammography

\(^{1}\) As a result of the reimbursement restrictions on inpatient hospital care, many hospitals began to shift more care to outpatient settings. The Balanced Budget Act of 1997 dealt with this shift from inpatient to outpatient treatments by expanding the prospective payment approach to home health agencies and skilled nursing facilities.

\(^{2}\) After the U.S. Medicare program went into effect, many private insurance companies developed policies that provided coverage for the costs and services that Medicare did not cover. These policies, which cover gaps in Medicare coverage, are called “Medigap” policies.
screening, and outpatient prescription drugs. The expansion of benefits under the MCCA was to be funded through a supplemental premium paid by the more affluent elderly. Despite the expansion of benefits, many elderly had negative reactions toward the MCCA and the bill was repealed within 16 months of implementation. The affluent elderly disapproved of the increased premiums and many others were dissatisfied by the lack of coverage for certain catastrophic situations such as nursing home care\(^3\). The repeal of the MCCA left many Medicare related issues, such as the outpatient prescription drug benefit, unresolved for many years. (Kronenfeld)

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\(^3\) Catastrophic situations are those with extremely large out-of-pocket expenses that impose serious financial burden.
Chapter 3

The Medicare Modernization Act of 2003

While the Medicare program has experienced many changes over the last several decades, one of the most significant changes to the Medicare program occurred more recently. After many years of political deliberation regarding the most appropriate structure and funding mechanisms for Medicare reform, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was signed into law by President George W. Bush in December of 2003. The Medicare Modernization Act made several important changes to Medicare including the establishment of a new income-related Part B premium and changes to the Part C Medicare + Choice HMO plans (currently called Medicare Advantage Plans). However, the most significant aspect of the MMA was the establishment of a long-awaited outpatient prescription drug benefit. The new prescription drug benefit is provided under Part D of the Medicare program and was fully implemented beginning in 2006 (Kronenfeld). This chapter explains the administration and implementation of Medicare Part D as well as the structure and cost-sharing mechanisms of the standard Part D benefit design.

3.1 Administration and Implementation of Medicare Part D

The Medicare Part D benefit provides subsidized prescription drug coverage to eligible Medicare beneficiaries through government-approved plans offered by private insurance companies (Heiss). The method of administration for the new Medicare Part D benefit was innovative and unlike the approaches used by the other traditional parts of Medicare. The traditional Parts A and B are administered by the Medicare program. Medicare Part D is more
“privatized” than Parts A and B and is not directly administered by Medicare. The government agency called the Centers for Medicare & Medicaid Services (CMS) oversees the Part D program, creates standard plan rules, organizes the market competition, and enrolls beneficiaries into the program. The beneficiaries then choose specific government-approved drug plans sold by private insurers (Kuttner). There are two main sources of the prescription drug benefit. Beneficiaries can purchase stand-alone prescription drug plans (PDP) or they can purchase drug coverage through a Medicare Advantage Plan (MA-PD). Medicare Advantage Plans combine Parts A, B, and D into a single plan (Center for Medicare Advocacy, Part D). While this new approach for Medicare Part D contained many risks and concerns, it also had the potential to create significant benefits in the future.

There were several risks and concerns involved in the implementation of the Medicare Part D program. One initial concern was that private insurers would not enter the market and sponsor drug plans for the elderly. Other issues involved the complexity of the plan benefit design, the overwhelming number of plan options for beneficiaries to choose from, and adverse selection. The Part D program is voluntary and therefore individuals with higher expected costs have a greater incentive to enroll. In order for the implementation of the Part D program to be effective, enrollment from beyond just those individuals with high expected costs was necessary and educational outreach would be needed to help beneficiaries navigate the plan options and select plans specific to individual needs. (Kuttner)

In response to these initial concerns, the Medicare administration initiated an effective educational outreach campaign and the implementation of the Part D program proved to be more successful than many skeptics had anticipated (Kuttner). High enrollment rates were achieved with over 90% of eligible Medicare beneficiaries obtaining prescription drug coverage through Part D, or from another comparable source, within the first year of the program (Heiss). As of June 2006, 22.5 million Medicare beneficiaries were enrolled in Part D plans (Kaiser, Medicare
Data Update). Additionally, private insurers entered the market in all geographic regions of the country and overall program costs were less than Medicare actuaries initially predicted (Kuttner).

3.2 Structure and Cost-Sharing Mechanisms of the Part D Benefit

While many of the issues surrounding Medicare Part D were resolved during the implementation process, there were still a few major issues that remained and posed challenges for the Medicare program. The complexity of the standard benefit design\(^\text{4}\) was creating cost and coverage confusion among elderly beneficiaries. The original standard benefit design included four main components: an annual deductible, the initial coverage period, the coverage gap (also known as the doughnut hole), and the catastrophic coverage period (Center for Medicare Advocacy, Part D). Figure 1 on the next page shows the general structure of the original standard benefit which was in effect from 2006 to 2010. Under this structure, the beneficiary is first responsible for a monthly premium to be enrolled in a plan, and then the deductible, 25% of total drug costs within the initial coverage period, 100% of total drug costs within the coverage gap, and 5% of total drug costs above the catastrophic coverage limit.

\(^{4}\) Part D sponsors must offer plans with at least a “standard benefit.” Sponsors may offer plans that vary from the standard benefit, but these plans must be actuarially equivalent to the standard benefit. Sponsors can also offer enhanced plans that provide coverage and benefits beyond the standard benefit.
Prescription drug coverage is not free and comes at a cost to beneficiaries. In order to be enrolled in a Medicare Part D plan, beneficiaries must pay a monthly premium which is determined annually by plan sponsors and varies depending on the specific drug plan selected by the beneficiary. While premium amounts are determined by plan sponsors, Medicare sets the thresholds for the deductible, initial coverage limit, and catastrophic coverage limit (Center for Medicare Advocacy, Part D). The threshold amounts vary each year to reflect inflation. Table 1 on the next page shows the change in average monthly premiums, as well as the threshold amounts for the deductible, initial coverage limit, and the catastrophic coverage limit from 2006 to 2013. Table 1 also shows the total annual out-of-pocket expenses for a beneficiary whose drug costs reach the catastrophic limit. The total annual out-of-pocket expenses in Table 1 include the deductible, 25% coinsurance during the initial coverage period, and 100% coinsurance while in the coverage gap. Figure 2 graphically illustrates the threshold amounts from 2006 to 2013.
Table 1: Threshold Limits for Standard Part D Benefit, 2006 - 2013

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly Premium</td>
<td>$25.93</td>
<td>$27.39</td>
<td>$29.89</td>
<td>$35.09</td>
<td>$37.25</td>
<td>$38.29</td>
<td>$37.57</td>
<td>$40.18</td>
</tr>
<tr>
<td>Deductible</td>
<td>250.00</td>
<td>265.00</td>
<td>275.00</td>
<td>295.00</td>
<td>310.00</td>
<td>310.00</td>
<td>320.00</td>
<td>325.00</td>
</tr>
<tr>
<td>Initial Coverage Limit</td>
<td>2,250.00</td>
<td>2,400.00</td>
<td>2,510.00</td>
<td>2,700.00</td>
<td>2,830.00</td>
<td>2,840.00</td>
<td>2,900.00</td>
<td>2,970.00</td>
</tr>
<tr>
<td>Catastrophic Coverage Limit</td>
<td>5,100.00</td>
<td>5,451.25</td>
<td>5,726.25</td>
<td>6,133.75</td>
<td>6,440.00</td>
<td>6,447.50</td>
<td>6,750.00</td>
<td>6,955.00</td>
</tr>
<tr>
<td>Total Annual Out-of-Pocket Costs</td>
<td>3,600.00</td>
<td>3,850.00</td>
<td>4,050.00</td>
<td>4,350.00</td>
<td>4,550.00</td>
<td>4,550.00</td>
<td>4,772.50</td>
<td>4,971.25</td>
</tr>
</tbody>
</table>

1 Average monthly premium for Medicare Part D stand-alone prescription drug plans (PDP) weighted by yearly enrollment. 2006 – 2012 are actual premiums. 2013 is a projected premium.

2 Total Annual Out-of-Pocket Costs include all out-of-pocket costs up to the catastrophic coverage limit excluding the plan premium. This includes the deductible, 25% coinsurance in the initial coverage period, and 100% coinsurance while in the coverage gap.

Figure 2: Medicare Part D Standard Benefit Parameters, 2006 - 2013

1 As a result of coverage gap discounts in 2011 – 2013, the catastrophic coverage limits vary slightly for non-Low Income Subsidy and Low Income Subsidy enrollees. The catastrophic coverage limits shown for 2011-2013 are for non-Low Income Subsidy enrollees. The 2013 limit is an estimated value.

2 The Patient Protection and Affordable Care Act of 2010 established discounts and subsidies for brand-name and generic drugs in the coverage gap during 2011 – 2013.

As a result of high inflation in the healthcare industry in the early 2000s, many insurance companies began to incorporate more beneficiary cost-sharing mechanisms into insurance products as a means of effectively controlling costs and utilization (Rice). Several cost-sharing mechanisms were integrated into the initial Part D benefit design when it was established in 2003 by the MMA. Some of these cost-sharing mechanisms include deductibles, copayments, and coinsurance in the initial coverage period and coverage gap. The coverage gap is one of the more confusing and controversial cost-sharing features of the standard prescription drug benefit design. The coverage gap is a range of costs in the plan design where there is a gap or hole in coverage and the beneficiary is required to pay 100% of total drug costs out-of-pocket\(^5\). The initial justification for the coverage gap was that it would help to reduce costs and discourage unnecessary spending. Exposure to out-of-pocket costs in the coverage gap attempts to encourage beneficiaries to consider the high cost of their prescription drugs and therefore search for more cost-effective options, such as switching from more expensive brand-name drugs to cheaper generic alternatives. (Shrank)

Figure 3 on the next page compares total prescription drug spending and total out-of-pocket costs for a beneficiary with no prescription drug coverage and also for a beneficiary with Part D coverage during each of the first five years of the program. While the Part D benefit reduces overall out-of-pocket costs for a beneficiary in comparison to no prescription drug insurance, out-of-pocket costs and cost-sharing under the Part D benefit can still be quite large. For example, under the 2010 benefit structure, by the time an enrollee reaches the catastrophic limit of $6,440, he would have already paid a total of $4,550 in out-of-pocket expenses (this

\(^5\) Individuals that qualify for the Part D benefit Low-Income Subsidy (LIS) receive a subsidy from the Social Security Administration that helps cover the monthly premium, deductible, and coinsurance, as well as expenses in the coverage gap. Therefore LIS enrollees do not pay 100% of costs out-of-pocket in the coverage gap. (U.S. GAO) (Center for Medicare Advocacy, Part D)
includes the cost of the deductible, coinsurance in the initial coverage period, and expenses in the coverage gap), which is approximately 70% cost-sharing.

Figure 3: Total Prescription Drug Spending vs. Out-of-Pocket Costs

![Graph showing total spending vs. out-of-pocket costs](image)


While the general purpose of cost-sharing is to reduce costs and utilization, a key concern is that beneficiaries looking to lower their out-of-pocket expenses may forgo important health services or essential drugs that could adversely affect their health status (Kaiser, Understanding the Effects). Several studies have shown that while prescription drug coverage has generally had positive effects on overall drug utilization and out-of-pocket costs, there are unfavorable trends in specific parts of the benefit design including the coverage gap (Shrank) (Polinski). The Kaiser Family Foundation analyzed the behavior of Part D beneficiaries who reached the coverage gap
in 2008 and 2009. The study found that of the 27 million beneficiaries enrolled in Medicare Part D in 2009, nearly one in five (19%) had prescription drug expenses that were high enough to reach the coverage gap. The study also found that those who reached the gap were more likely to make unfavorable changes in their drug regimens, including switching, reducing, or completely stopping medications, than those who did not experience a full gap in coverage (i.e. Part D Low-Income Subsidy enrollees or elderly individuals with commercial drug insurance plans). Unfavorable changes in drug regimens while in the coverage gap could result in significant health consequences for individuals with chronic health conditions. Additional physician visits or medications to control these adverse health changes could ultimately lead to higher costs for both the elderly and the overall Medicare program (Kaiser, Understanding the Effects).
Chapter 4

The Patient Protection and Affordable Care Act of 2010

On March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act (PPACA). The purpose of PPACA is to expand health insurance coverage, control healthcare costs, and improve the healthcare delivery system in the United States (Kaiser, Summary of New Health Reform Law). This healthcare reform legislation includes several important provisions to Medicare Part D in order to eliminate the coverage gap and reduce the financial burden of prescription drugs on elderly Medicare beneficiaries (Kaiser, Explaining Health Care Reform). This chapter examines the PPACA provisions relating to Medicare Part D and presents some of the reactions to the PPACA provisions prior to implementation in 2011.

4.1 Patient Protection and Affordable Care Act Provisions

PPACA established two main provisions that gradually phase out the Medicare Part D coverage gap. First, PPACA created the Medicare Part D Coverage Gap Discount Program, which requires drug manufacturers, who wish to have their brand-name drugs covered under the Medicare Part D program, to provide a 50% discount on the price of brand-name drugs when beneficiaries reach the coverage gap. Second, PPACA included subsidies to help beneficiaries pay for both brand-name and generic drugs in the coverage gap (U.S. GAO). These provisions, which went into effect starting in 2011, no longer require beneficiaries to pay the full cost of their prescription drugs when in the coverage gap. As a result of the PPACA changes to Medicare Part D, enrollees, in 2011, were only responsible for 50% of brand-name drug expenses and 93% of generic drug expenses when they reached the coverage gap compared to 100% of both brand-
name and generic drug expenses in the coverage gap in years 2006 to 2010 (Hoadley). From 2011 until 2020, the PPACA provisions will gradually implement additional discounts and coverage for brand-name and generic drugs in the coverage gap, so that by 2020 the coverage gap will be completely eliminated and enrollees will only be responsible for the deductible and then 25% coinsurance up to the catastrophic coverage limit (The Department of Health & Human Services).

Figures 4 and 5 on the next page show the structure of the standard Medicare Part D benefit in 2011 under the provisions in PPACA. Figure 4 illustrates the benefit structure for generic drugs, while Figure 5 illustrates the benefit structure for brand-name drugs. The darker blue color in the figures represents the proportion of costs paid by the Medicare enrollee, while the lighter blue color represents the proportion of costs covered under the Part D plan. For generic drugs in the coverage gap in 2011, the enrollee was responsible for 93% of costs and a plan subsidy covered the other 7% of costs. For brand-name drugs in the coverage gap in 2011, the enrollee was responsible for 50% of costs and a manufacturer discount covered the other 50% of costs.
Figure 4: Standard Medicare Generic Prescription Drug Benefit, 2011


Figure 5: Standard Medicare Brand-Name Prescription Drug Benefit, 2011

Figure 6 shows the projected structure of the Part D benefit in the final year in the process of eliminating the coverage gap. In 2020, after the deductible is paid, the Medicare enrollee will only be responsible for 25% of costs for both brand-name and generic drugs up to the catastrophic coverage limit. It is important to compare Figures 4, 5, and 6 and notice how beneficiaries’ out-of-pocket costs in the coverage gap will be significantly reduced from 2011 to 2020.

Figure 6: Standard Medicare Prescription Drug Benefit, 2020

Figures 7 and 8 on the next page show brand-name and generic drug cost-sharing in the coverage gap from 2006 to 2020. Before PPACA was signed into law, enrollees were required to pay 100% of costs for both brand-name and generic drugs in the coverage gap. Figure 7 illustrates the cost-sharing structure for brand-name drugs in the coverage gap. The 50% manufacturer discount on brand-name drugs in the coverage gap, which began in 2011, is permanent and applies to all future years of the Medicare Part D program. Medicare Part D plan subsidies begin in 2013 in addition to the 50% manufacturer discount. In 2011, enrollees received the 50% manufacturer discount for brand-name drugs in the coverage gap and were responsible for the other 50% of costs in the gap. In 2013, the Medicare Part D plan subsidies cover 2.5% of brand-name drug costs and the manufacturer discount covers 50% of costs, for total coverage of 52.5% of brand-name drug costs in the gap. The remaining 47.5% of brand-name drug costs in the gap are paid for by the enrollee. After the Medicare Part D plan subsidies for brand-name drugs are implemented in 2013, they will gradually cover a larger percentage of costs over time so that by year 2020 and beyond, enrollees in the coverage gap will receive a 50% manufacturer discount, 25% plan subsidy, and will only be responsible for the remaining 25% of costs. The ultimate benefit structure in the gap for 2020 is consistent with original cost-sharing in the initial coverage period. Figure 8 illustrates the cost-sharing structure for generic drugs in the coverage gap, which is slightly different than that for brand-name drugs. The 50% manufacturer discount does not apply to generic drugs. The Medicare Part D plan subsidies for generic drugs began in 2011 with 7% coverage. The proportion of generic drug costs paid by an enrollee in the coverage gap decreases by an additional 7% each year through 2019. In 2020, an enrollee in the coverage gap will only be responsible for 25% of generic drug costs, while plan subsidies will cover the remaining 75% of costs. (U.S. GAO) (Kaiser, Explaining Health Care Reform)
Figure 7: Brand-Name Drug Cost-Sharing in the Coverage Gap, 2006 - 2020


Figure 8: Generic Drug Cost-Sharing in the Coverage Gap, 2006 - 2020

4.2 Reactions Prior to Implementation of PPACA Provisions

Prior to the implementation of the PPACA provisions in 2011, some researchers raised concerns regarding the significant change in coverage in the Medicare Part D coverage gap. Several researchers felt that the provisions, especially the large 50% discount for brand-name drugs in 2011, could potentially lead to increased utilization of more expensive brand-name drugs rather than cheaper generic alternatives, ultimately increasing overall costs for the Medicare program. According to the article, *Time to Fill the Doughnuts – Health Care Reform and Medicare Part D*, written by William Shrank and Niteesh Choudhry in February 2011, “discounting brand-name drugs by 50% at the outset while delaying the reduction of generic-drug prices was a step in the wrong direction…By disproportionately reducing the cost of brand-name medications, the legislation creates incentives for patients to use more expensive drugs and will leave the federal government on the hook for increased medication costs during the catastrophic-coverage period” (Shrank). A study analyzing the costs and consequences of the Medicare Part D coverage gap in 2008 and 2009 conducted by the Kaiser Family Foundation also addresses similar concerns as those raised by Shrank and Choudhry. According to the Kaiser Family Foundation study, “If the reduced size of the coverage gap leads Part D enrollees to give less attention to seeking appropriate generic alternatives, then overall program costs could rise, which could have significant spillover effects on both system costs and the premiums paid by beneficiaries” (Kaiser, Understanding the Effects).

If the large brand-name drug discounts in the coverage gap encourage Medicare beneficiaries to utilize more expensive brand-name drugs rather than cheaper generic alternatives, beneficiaries’ prescription drug expenses may accumulate more quickly causing the beneficiaries to advance more rapidly through the coverage gap and ultimately reach the catastrophic coverage period earlier in the calendar year. The Medicare program covers 80% of prescription drug costs
for beneficiaries in the catastrophic coverage period. If more beneficiaries reach the catastrophic coverage period and they reach it earlier in the calendar year, Medicare program costs could rise significantly.

From a health economics perspective, the concerns addressed in the article by Shrank and Choudhry, and also in the study conducted by the Kaiser Family Foundation, relate to the common economic and insurance concept of moral hazard. Moral hazard in the context of health insurance is the idea that people generally use more medical and health-related goods and services when insurance covers more of their costs than when it does not (Pauly). In regards to Medicare Part D, moral hazard relates to the idea that a significant increase in the proportion of prescription drug costs covered in the coverage gap may create incentives for beneficiaries to utilize more expensive brand-name drugs rather than cheaper generic alternatives.
Chapter 5

Prescription Drug Utilization Before and After PPACA

The PPACA provisions for closing the Medicare Part D coverage gap were implemented beginning in the 2011 calendar year and have now been in place for two years. This therefore raises the question of whether researcher’s initial concerns actually occurred and whether increased coverage in the gap led to greater utilization of more expensive brand-name drugs. In order to answer this question, this chapter will analyze and compare beneficiary prescription drug preferences from both before and after the implementation of the PPACA provisions. Gaining insight into beneficiary prescription drug behavior before and after the implementation of the PPACA provisions will enable researchers to evaluate recent and long-term effects of coverage gap discounts on drug utilization and costs.

One method of determining Medicare Part D enrollee drug preferences and behavior is to analyze brand-name and generic dispensing rates (GDR). These rates reflect the percentage of covered Medicare Part D brand-name or generic drugs filled by pharmacies (Filipek). More specifically, CMS defines generic dispensing rate as the number of fills for generic drugs divided by the total number of fills (Centers for Medicare & Medicaid Services – Dashboard Glossary) Figure 9 on the next page shows overall Medicare Part D brand-name and generic dispensing rates for each year from 2006 through 2010, the last year before the implementation of the PPACA provisions to eliminate the coverage gap6. Figure 9 shows that the mix of drugs dispensed under Medicare Part D plans has shifted significantly from brand-name to generic over this five year time period, suggesting that Medicare beneficiaries are using less brand-name drugs

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6 The dispensing rate information presented in Figure 9 was collected by CMS from Medi-Span and First DataBank. Medi-Span and First DataBank create and maintain databases of pharmaceutical industry market research including information about Medicare prescription drugs.
and more generic drugs. The brand-name drug dispensing rate decreased from approximately 40% in 2006 to almost 25% in 2010. The generic dispensing rate increased from about 60% in 2006 to about 75% in 2010. While the overall Medicare Part D generic dispensing rate increased from 2006 to 2010, the rate of increase from year to year was not steady. The yearly increase in the Medicare Part D generic dispensing rate was larger in earlier years of the program than it was in more recent years. The generic dispensing rate increased 4.2% from 2006 to 2007 and 5% from 2007 to 2008, while only increasing 2.4% and 2.9% from 2008 to 2009 and 2009 to 2010, respectively. This information suggests that the generic dispensing rate may soon reach a limiting value rather than continue to increase to 100%.

Figure 9: Overall Medicare Part D Brand-Name and Generic Dispensing Rates

Table 2 compares Medicare Part D generic dispensing rates with generic dispensing rates for commercial prescription drug insurance plans over the years 2006 through 2008. The generic dispensing rates for both populations increased over the three year period. In addition, the Medicare Part D generic dispensing rates were higher than the rates for commercial plans.

Table 2: Generic Dispensing Rates by Population, 2006 – 2008

<table>
<thead>
<tr>
<th>Population</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Part D</td>
<td>60.3%</td>
<td>64.1%</td>
<td>69.4%</td>
</tr>
<tr>
<td>Commercial Plans</td>
<td>49.7%</td>
<td>53.1%</td>
<td>59.2%</td>
</tr>
</tbody>
</table>


There are several factors that have contributed to both the overall increase in the generic dispensing rate and the higher generic dispensing rates for Medicare Part D than commercial plans. Some of these factors include popular brand-name drug patent expirations, increased public awareness of generic cost savings, cost-conscious behavior of the elderly population, and the cost-sharing structure in Medicare prescription drug plans (Filipek). As previously explained, the lack of coverage and exposure to out-of-pocket costs in the Medicare Part D coverage gap was designed to encourage beneficiaries to seek more cost-effective options, such as cheaper generic drugs, upon reaching the gap.

Although the Medicare Part D generic dispensing rate increased from 2006 to 2010, some researchers believed that this trend would not continue after the implementation of the PPACA provisions. Several researchers felt that the large discount for brand-name drugs in 2011 would encourage beneficiaries to utilize more expensive brand-name drugs rather than cheaper generic alternatives. In order to determine the extent of changes in beneficiary drug utilization patterns before and after the implementation of PPACA provisions, the overall Medicare Part D generic
dispensing rates illustrated in Figure 9 will be compared to Medicare Part D generic dispensing rates from 2011. Because CMS overall Medicare Part D generic dispensing rates for 2011 were not available at the time of publication, generic dispensing rates for the Medicare Part D line of business of several pharmacy benefit managers (PBM)\(^7\) will be used for comparison.

Table 3 shows generic dispensing rates for 2010 and 2011 for three pharmacy benefit management companies. The information in Table 3 was obtained from the 2011 Drug Trend Reports of the three companies. The Medicare Part D generic dispensing rate for Prime Therapeutics averaged 80.1% in 2011, which was a +2.4% increase from 2010 (Prime Therapeutics). The Medicare Part D generic dispensing rate for Express Scripts was 76.7% in 2010 and 78.9% in 2011, resulting in a +2.2% increase (Express Scripts, 2011). The Medicare Part D generic dispensing rate for SXC Health Solutions was 76.8% in 2011, which was a +4.3% increase from the prior year (SXC Health Solutions).

Table 3: Generic Dispensing Rates by Pharmacy Benefit Manager, 2010 - 2011

<table>
<thead>
<tr>
<th>Pharmacy Benefit Manager</th>
<th>2010</th>
<th>2011</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prime Therapeutics</td>
<td>77.70%</td>
<td>80.10%</td>
<td>2.40%</td>
</tr>
<tr>
<td>Express Scripts</td>
<td>76.70%</td>
<td>78.90%</td>
<td>2.20%</td>
</tr>
<tr>
<td>SXC Health Solutions</td>
<td>72.50%</td>
<td>76.80%</td>
<td>4.30%</td>
</tr>
</tbody>
</table>

In addition to generic dispensing rate information, the Express Scripts and SXC Health Solutions 2011 Drug Trend Reports also provided information regarding utilization trends. Utilization trend is defined as the extent to which members of a group use a particular service or prescription drug over a specified period of time (The Free Medical Dictionary). More specifically, Express Scripts defined utilization trend as the total number of 30-day prescriptions

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\(^7\)Pharmacy benefit managers negotiate contracts with pharmaceutical companies to dispense prescription drugs and other health-related products on behalf of insurance companies, government agencies, and corporations. (Gryta)
divided by total member years, which is the total number of months of eligibility of all members in the sample divided by twelve (Express Scripts, 2011). The utilization trend definition for SXC Health Solutions was comparable to that used by Express Scripts (SXC Health Solutions). The utilization trends are divided by traditional therapy drug class and specialty therapy drug class. The traditional therapy drug class includes medications for diabetes, high cholesterol, high blood pressure, depression, asthma, and pain, among many others. Specialty medications are used for more chronic and serious health conditions and this drug class includes medications for cancer, HIV, Hepatitis C, and transplants (Express Scripts, 2011). The utilization trends for Express Scripts and SXC Health Solutions are shown in Table 4. In 2011, Express Scripts experienced a +3.6% utilization trend for their traditional therapy drug class and a +8.4% utilization trend for their specialty therapy drug class (Express Scripts, 2011). SXC Health Solutions Medicare Part D line of business experienced a +2.0% utilization trend for their traditional therapy drug class and a +9.1% utilization trend for their specialty therapy drug class. Additionally, SXC Health Solutions experienced a +5.9% overall utilization trend for generic drugs and a -10.7% overall utilization trend for brand-name drugs (SXC Health Solutions).

Table 4: Utilization Trend by PBM Medicare Part D Line of Business, 2011

<table>
<thead>
<tr>
<th>PBM</th>
<th>Traditional</th>
<th>Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Express Scripts</td>
<td>3.6%</td>
<td>8.4%</td>
</tr>
<tr>
<td>SXC Health Solutions</td>
<td>2.0%</td>
<td>9.1%</td>
</tr>
</tbody>
</table>

The generic dispensing rates and utilization trends for the pharmacy benefit managers increased from 2010 to 2011. Despite large discounts on brand-name drugs in the coverage gap in 2011, the generic dispensing rate information and utilization trends from the three PBMs suggest that overall Medicare Part D beneficiaries did not increase utilization of
expensive brand-name drugs, but rather used generic drugs at slightly higher rates than those observed in previous years.
Chapter 6

Analysis of Prescription Drug Utilization Trends

There are several major factors that potentially contributed to the increase in the overall Medicare Part D generic dispensing rates and utilization trends from 2010 to 2011, despite the large discount on brand-name drugs in the coverage gap. Some of these factors include utilization management programs, the increase in the price of brand-name drugs relative to the price of generic drugs, brand-name drug patent expirations, the economic recession and slow recovery, and the cost-conscious nature of the elderly population. This section will address each of these factors and explain how each factor likely contributed to the Medicare Part D GDR and utilization trends.

One of the factors that likely contributed to the increase in the overall Medicare Part D generic dispensing rate and generic utilization trends from 2010 to 2011 was increased use of utilization management tools. Part D plan sponsors are required to establish reasonable drug utilization management programs that prevent over-utilization of prescription drugs and create incentives to reduce healthcare costs (Huskamp). These utilization management programs often make it more difficult for a beneficiary to obtain more expensive brand-name drugs when an appropriate generic alternative is available. Common utilization management tools include prior authorization, quantity limits, and step therapy. Prior authorization requires a beneficiary to obtain pre-approval before receiving coverage for particular drugs. Quantity limit techniques place limits on the number of doses of a particular drug that can be given in a certain period of time. Step therapy requires that a beneficiary must try certain drugs before being approved to take other drugs. An example of step therapy is that a beneficiary would first need to fail on a
generic or other low cost drug before being allowed to move to a more expensive brand-name
drug (Medpac, Data Book – 2011).

Figure 10 on the next page shows utilization management tools used by Part D plan
sponsors from the years 2007 through 2011. In 2010, the average beneficiary in a stand-alone
prescription drug plan (PDP) experienced some form of utilization management for 28% of the
drugs listed on a plan’s formulary, compared with 24% for the average beneficiary enrolled in a
Medicare Advantage prescription drug plan (MA-PD) (Medpac, Data Book – 2010). In 2011, the
average beneficiary in both stand-alone prescription drug plans and Medicare Advantage
prescription drug plans faced utilization management techniques on a larger portion of the drugs
on the plan formulary than in 2010. In 2011, the average beneficiary in a stand-alone prescription
drug plan experienced utilization management for 32% of drugs on the plan’s formulary, a 4%
increase from the prior year. Beneficiaries enrolled in Medicare Advantage prescription drug
plans experienced utilization management for 28% of drugs on the plan’s formulary, also a 4%
increase from 2010. Of the utilization management techniques used by Part D plan sponsors, the
most common is quantity limits, followed by prior authorization, and then step therapy. All three
of these utilization management techniques increased from 2010 to 2011 for Medicare Advantage
prescription drug plans, while only quantity limits and prior authorization techniques increased
Another factor that potentially contributed to the increase in the overall Medicare Part D generic dispensing rate and generic utilization trends from 2010 to 2011 was the increase in the brand-name prescription drug prices during this time period. Pharmacy benefit manager Express Scripts tracked overall price inflation for a fixed market basket of commonly used brand-name and generic drugs from 2008 to 2012 and found that the price of brand-name prescription drugs increased more than the inflation rate, while the price of generic prescription drugs decreased compared to the inflation rate. Figure 11 on the next page summarizes the results of Express Scripts’ drug price analysis. From 2010 to 2011, the price of brand-name drugs increased 13.3%, while the price of generic drugs decreased almost 22%. According to Figure 11, a brand-name drug that cost $100 in 2008 would cost $163.08 in 2012 (in 2008 dollars), while a generic drug that cost $100 in 2008 would only cost $60.96 in 2012 (in 2008 dollars). This compares to the national Consumer Price Index which increased from $100 in 2008 to $109.06 in 2012 (in 2008
dollars). The increase in brand-name drug prices and the decrease in generic drug prices may have encouraged price-sensitive Medicare Part D enrollees to utilize more generic drugs than brand-name drugs from 2010 to 2011. (Express Scripts, 2012) (Thomas)

Figure 11: Brand-Name and Generic Drug Price Inflation, 2008 - 2012


One reason for the significant decrease in generic drug prices from 2010 to 2011 may be due to brand-name drug patent expirations. When a new brand-name prescription drug is manufactured by a pharmaceutical company, the company is granted a patent by the U.S. Food and Drug Administration (FDA) in order to compensate for the time and expenses incurred in the research and development of the new drug. The average patent can range from 11 to 20 years and during this time period the brand-name drug is marketed with very limited direct competition (Schondelmeyer). When a brand-name prescription drug patent expires, pharmaceutical companies may develop and market generic versions of the drug to compete with the original
brand-name drug. Multiple generic versions of a brand-name drug typically enter the market, creating significant competition and driving down overall drug prices. This competition can result in generic drug prices that average 85% lower than the brand-name drug price prior to patent expiration, as well as reduce the brand-name drug’s market share from 100% to 10% (Schondelmeyer). Therefore, a 50% brand-name drug discount may not be enough to reduce a brand-name drug price to that of generic alternatives. Over the last several years, there has been a considerable number of patent expirations for major brand-name drugs developed in the 1990s. These patent expirations have allowed generic versions to enter the market, and therefore lower generic drug costs for Medicare beneficiaries. Additional patent expirations in the coming years are ultimately expected to create enormous cost savings for the American public. (Schondelmeyer)

Another reason for the significant increase in brand-name prescription drug prices from 2010 to 2011 may be due to the discounts in the Medicare Part D coverage gap. Prescription drug manufacturers may have increased prices for brand-name drugs in order to offset the 50% discount that they are required to provide to Medicare Part D beneficiaries who reach the coverage gap. In order to gain an understanding of the effect of the Medicare Part D discount program on brand-name drug prices, the U.S. Government Accountability Office (GAO) interviewed pharmacy benefit managers (PBMs), drug manufacturers, and insurance company plan sponsors. Six of the seven plan sponsors and two of the three PBMs interviewed by the GAO believed that the Medicare Part D discount program was a contributing factor in the rising prices of brand-name drugs based on their own analysis and observations of drug pricing data. The remaining plan sponsor and PBM observed increases in brand-name drug prices but did not believe that the price increase was attributable to the discount program. While the majority of the plan sponsors and PBMs interviewed by the GAO felt that the discount program affected brand-name drug prices, the drug manufacturers had opposite opinions. Six of the eight drug
manufacturers interviewed by the GAO believed that their brand-name drug prices have not been affected by the discount program. One of the remaining drug manufacturers mentioned that they considered the discount program when determining drug prices, but that there were other factors such as market competition that had greater influence on pricing. The other remaining drug manufacturer indicated to the GAO that they were still evaluating the effects of the discount program and could not determine if it has or will affect their brand-name drug prices in the future. Although drug manufacturers cannot specifically target and raise drug prices for Medicare beneficiaries that reach the coverage gap, they may have been more likely to increase prices of brand-name drugs that were used most often by beneficiaries who reached the gap in prior years. The results of this interview suggest that the Medicare Part D discount program may have contributed to the increase in brand-name drug prices from 2010 to 2011. (U.S. GAO)

In addition to utilization management programs, increases in brand-name drug prices, and brand-name drug patent expirations, other factors that potentially contributed to the increase in the overall Medicare Part D generic dispensing rate and generic utilization trends are the financial circumstances of elderly Medicare beneficiaries and current economic conditions. Most elderly Medicare beneficiaries live on low or modest incomes and have little retirement savings. Figure 12 on the next page shows the overall median income among Medicare beneficiaries in 2010. In addition, Figure 12 shows the distribution of income of Medicare beneficiaries divided by race, age, and marital status. In 2010, 35% of elderly had incomes less than twice the poverty threshold ($20,916 for single individuals) (Komisar). The median income among Medicare beneficiaries was only slightly higher than twice the poverty level at $21,183 (Smith). When out-of-pocket medical expenses and other factors that reduce disposable income were taken into account, the percentage of elderly that had incomes less than twice the poverty threshold in 2010 was 49% (Komisar). In regards to retirement savings, half of all Medicare beneficiaries have less than $2,100 in retirement accounts such as IRAs and half of all Medicare beneficiaries have less
than $31,000 in other financial assets including savings accounts, stocks, and bonds (Smith).

Figure 13 on page 47 illustrates the distribution of retirement savings and financial assets of Medicare beneficiaries in 2010. As a result of limited income and financial savings, the elderly population may be more likely to select cheaper generic prescription drugs if available, rather than expensive brand-name drugs despite a discount on the brand-name drugs.

Figure 12: Median Income among Medicare Beneficiaries, 2010


Between 2007 and 2009, the United States experienced one of the worst economic recessions since the Great Depression, resulting in a slowdown in economic activity, decline in GDP, high unemployment rates, and strain on incomes and financial assets. Although this most
recent economic recession has officially ended, economic growth and recovery has been slow (Special Series: Economic Recovery Watch) (The Recession of 2007 – 2009). As premiums and out-of-pocket costs increased and the ability to pay for healthcare-related expenses decreased during the economic recession and slow recovery period over the past several years, it is likely that Medicare beneficiaries sought cheaper generic drugs rather than expensive brand-name drugs (Lau) (Rucker).

Figure 13: Financial Assets & Retirement Savings of Medicare Beneficiaries, 2010

Chapter 7

Conclusion

Despite some initial concerns that the PPACA provisions to phase out the Medicare Part D coverage gap would lead to higher utilization of more expensive brand-name drugs, analysis of generic dispensing rates and utilization trends suggest that this may not have actually been the case. Although there was a large discount on brand-name drugs in the coverage gap in 2011, pharmacy benefit managers’ Medicare Part D line of business experienced higher overall generic dispensing rates and utilization trends than they had in the past. The large discount on brand-name drugs appears to have been offset by several other factors including utilization management programs, increases in brand-name drug prices, brand-name drug patent expirations, the economic recession and slow recovery, and the cost-conscious nature of the elderly population.

This research suggests that the PPACA provisions appear to have been effective at controlling healthcare costs and creating cost savings for both beneficiaries who reach the coverage gap and the overall Medicare program. This research, in conjunction with future research, will hopefully enable actuaries and other researchers to further evaluate the long-term effects of the PPACA provisions and coverage gap discounts on beneficiary prescription drug behavior. As more data becomes available in future years, it will be interesting to continue to analyze the effect of brand-name drug discounts on generic dispensing rates (GDR) and utilization trends. Instead of looking at overall GDR that covers the entire Part D benefit, as was done in this thesis, researchers may be able to gain a better understanding of the effect of the brand-name drug discounts by analyzing brand-name and generic dispensing rates solely within the coverage gap. The brand-name drug discounts apply only to the coverage gap so GDR within
the coverage gap may vary slightly from overall GDR. However, GDR information specific to the coverage gap may be more difficult to obtain as it would require pharmacy benefit managers to monitor not only prescription drug fills but also when beneficiaries enter and leave the coverage gap.

Additional future research could examine GDR trends over time. Overall Medicare Part D generic dispensing rates increased each year from 2006 to 2011. However, it is uncertain as to whether GDR will continue to increase or if it will continue to increase at similar rates as in the past. It may be interesting to analyze Medicare Part D GDR trends and determine if GDR will eventually reach 100% or if it will reach a limiting value less than 100%.

Further research related to this thesis could also include more in-depth analysis of the factors that may have offset the brand-name drug coverage gap discounts such as inflation in brand-name drug prices. As described in this thesis, there was evidence to suggest that drug manufacturers may have increased brand-name drug prices to offset the 50% brand-name drug discount that is provided to beneficiaries who reach the coverage gap. However, it may be interesting to analyze the extent to which brand-name drug discounts have affected manufacturer drug prices in the past or how further discounts may affect prices in the future.
Appendix A

Timeline of Medicare History

1932: President Franklin D. Roosevelt introduces his economic security proposal.

1934: President Roosevelt forms a committee to draft social insurance legislation with health insurance provisions.

1935: The Social Security Act is signed into law by President Roosevelt. Although the program originally intended to incorporate health insurance, the focus of the new program is on economic security.

1939: Senator Wagner introduces a national healthcare bill into Congress, but the government’s focus is on World War II.

1948: President Harry S. Truman endorses the Wagner-Murray-Dingell Bill, but Congress fails to act on the bill.

1951: A new proposal of health insurance for elderly beneficiaries receiving Social Security payments is introduced. Although this proposal did not pass, the decision to shift the focus of health insurance from the entire population to the elderly was a significant step in the establishment of the Medicare program.

1956: Legislation creates disability insurance for workers over age 50.

1957: Representative Aime Forand proposes the Forand Bill for health insurance for the elderly, but the bill is defeated.

1959: A Senate subcommittee on aging is formed and hosts a series of public meetings across the country between 1959 and 1961 to raise awareness of issues facing the elderly population.

1960: The Kerr-Mills Bill is signed into law by President Dwight Eisenhower. The Kerr-Mills Act expanded federal aid to states providing healthcare assistance to low-income elderly. The program was ultimately replaced with the Medicaid program.

1961: Senator Clinton Anderson and Representative Cecil King introduce the King-Anderson Bill, which proposes expanding health insurance to all individuals over the age of 65.

1964: Republican John W. Byrnes proposes the Byrnes Bill and the AMA proposes a program called Eldercare to compete with the Democratic King-Anderson Bill.

1965: In March of 1965, Wilbur Mills proposes combining certain aspects both the King-Anderson Bill and Byrnes Bill into a single bill. In July, President Lyndon B. Johnson signed H.R. Bill 6675 into law creating the Medicare and Medicaid programs.

1972: President Nixon signed the Social Security Amendments of 1972 into law. This extended Medicare coverage to individuals under age 65 with long-term disabilities and to all individuals with End-Stage Renal Disease.

1977: The administration of the Medicare program shifts from the Social Security Administration to the newly created Health Care Financing Administration.

1982: The Tax Equity and Fiscal Responsibility Act attempts to reduce Medicare spending and increase revenues by increasing Part B premiums, requiring federal employees to pay the health insurance payroll tax, and placing limits on hospital reimbursements.

1983: Congress develops the Medicare Prospective Payment Approach, which reimburses hospitals in advance instead of after providing treatment to Medicare beneficiaries.

1988: The Medicare Catastrophic Coverage Act is passed in an attempt to expand benefits under the Medicare program; however, negative reactions to the new act cause it to be repealed within 16 months.

2003: President George W. Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act into law, establishing prescription drug coverage.


2010: President Barack Obama signed the Patient Protection and Affordable Care Act into law. This law includes discount and subsidy provisions for closing the Medicare Part D coverage gap.
Appendix B

Glossary of Terms

**Beneficiary** – an individual who receives health insurance benefits through the Medicare or Medicaid programs

**Brand-Name Drug** – a drug under a trade name and protected by patent

**Catastrophic Coverage** – coverage that begins when a beneficiary’s Part D drug costs exceed a maximum limit set by Medicare

**Centers for Medicare & Medicaid Services (CMS)** – the federal government agency within the U.S. Department of Health and Human Services that runs the Medicare and Medicaid programs, as well as the Children’s Health Insurance Program (CHIP)

**Coinsurance** – a cost-sharing mechanism, after the deductible has been paid by the beneficiary, where a percentage of costs are paid out-of-pocket by the beneficiary and the remaining portion of costs is covered by insurance

**Consumer Price Index (CPI)** – measures the change in prices of consumer goods and services

**Copayment** – a cost-sharing mechanism where a beneficiary pays a fixed amount (rather than a percentage of costs as in coinsurance) for a medical service, such as a doctor’s visit or prescription drug

**Cost-Sharing** – the amount a beneficiary pays out-of-pocket for health services and prescription drugs; cost-sharing mechanisms include deductibles, copayments, and coinsurance

**Coverage Gap** – a gap in Part D insurance coverage where beneficiaries pay 100% of costs out-of-pocket; also known as the doughnut hole

**Coverage Gap Discount Program** – a program created by the Patient Protection and Affordable Care Act that provides manufacturer discounts on brand-name drugs in the coverage gap

**Deductible** – an amount that a beneficiary must pay before insurance coverage begins

**End-Stage Renal Disease (ESRD)** – permanent kidney failure that requires dialysis or kidney transplant; people with ESRD are eligible to receive Medicare benefits before age 65

**Formulary** – a list of prescription drugs covered by a prescription drug plan

**Generic Dispensing Rate (GDR)** – the percentage of generic drugs to total drugs filled by a pharmacy

**Generic Drug** – a prescription drug that has the same active-ingredient formula as a brand-name drug and is as safe and effective as brand-name drugs, but usually costs less; allowed to be issued to the market when the brand-name drug patent expires
Health Maintenance Organization (HMO) – a type of Medicare Advantage Plan; most HMOs require physician referrals and only allow beneficiaries to visit certain doctors, specialists, or hospitals on the plan list expect in an emergency

Initial Coverage Period – Part D coverage that begins after the deductible has been paid; the beneficiary pays 25% of costs and the plan pays 75% of costs during this period

Low-Income Subsidy (LIS) – a subsidy administered by the Social Security Administration and given to low-income beneficiaries to help cover premiums, deductibles, and other prescription drug expenses; individuals that do not receive the low income subsidy are often referred to as Non-Low Income Subsidy (Non-LIS) enrollees

Medicaid – a federal-state program that provides healthcare assistance for low-income individuals

Medicare – a federal health insurance program for people over age 65, people below age 65 with certain disabilities, and people with End-Stage Renal Disease

Medicare Advantage Plan (MA or MA-PD) – a Medicare-approved private health insurance plans that covers the benefits and services provided under Parts A, B, and D, and usually includes some extra benefits and services not covered under Medicare for an additional cost; a plan that combines the benefits of Medicare Parts A and B is considered an MA plan, and a plan that combines Parts A, B, and D is considered an MA-PD plan; Medicare Advantage Plans are included under Medicare Part C

Medicare Modernization Act (MMA) – federal law signed in 2003 by President Bush that improved the Medicare program by adding or enhancing benefits including the Medicare Part D prescription drug program

Medigap – insurance, sold by private insurers, that fills gaps in traditional Medicare coverage

Moral Hazard – the idea that people will generally use more medical and health-related goods and services when insurance covers more of their costs

Out-of-Pocket Costs – costs that a beneficiary must pay on their own because they are not covered by Medicare or other insurance

Part A (Hospital Insurance) – covers costs associated with inpatient hospital care, skilled nursing facilities, hospice services, and some home healthcare

Part B (Medical Insurance) – covers costs associated with physician services, outpatient care (laboratory, x-ray, etc), medical equipment, and preventative services

Part C – Medicare Advantage Plans

Part D (Prescription Drug Insurance) – covers costs associated with outpatient prescription drugs through private plans approved by Medicare
Patient Protection and Affordable Care Act (PPACA) – a federal law signed by President Obama in 2010 to expand health insurance coverage, control healthcare costs, and improve the healthcare system in the U.S.; includes specific provisions for eliminating the Medicare Part D coverage gap by 2020

Pharmacy Benefit Manager (PBM) – negotiates contracts with pharmaceutical companies to dispense prescription drugs on behalf of insurers, government agencies, and employers

Prescription Drug Plan (PDP) – one of the two sources of the Medicare Part D benefit that provides coverage for prescription drugs; also known as stand-alone plans because other benefits are not included as they are in MA-PD plans

Utilization Management – a set of tools established by Medicare Part D plan sponsors to prevent over-utilization of prescription drugs and create incentives to reduce prescription drug costs; includes prior authorization, quantity limits, and step therapy

Utilization Trend – the extent to which members of a group use a particular service or prescription drug in a specified period of time
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- Enhanced workers compensation indication workspace through the inclusion of a stochastic component that developed variability around point estimate trends, loss development factors, and indicated rate changes
- Assessed the Erie Secure Home product rating system to identify potential issues during the upcoming automated policy renewal process
- Conducted demographic analysis for the Erie Personal Auto Rate Lock product

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- Reviewed the pricing of Centers for Medicare & Medicaid Services (CMS) actuarial bids for participation in the 2012 Medicare Part D Plan program
- Ensured reasonableness of bids through detailed inspection of base period experience and contract year projections, as well as other evaluation components of the bid review and bid pricing systems
- Identified bid issues and documented resolutions in CMS Health Plan Management System
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