The Six Protected Classes, Congress and Interest Groups: A Study

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Table of Contents

Thesis Statement	1
Chapter 1: Introduction	2
Chapter 2: Introduction to Health Policy as a topic, Medicare, Part D History, Formulary Design	8
Chapter 3: Legislative History of Six Protected Classes, The rule, The Debate, The Outcome	27
Chapter 4: Method of Inquiry	73
Chapter 5: Findings and Implications	78
Chapter 6: Conclusion	80
Appendix	83
Bibliography	84

Thesis Statement

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The purpose of this thesis is to examine why an effort by the Centers for Medicare and Medicaid Services (CMS) to update Medicare Part D prescription drug formularies failed so spectacularly. Additionally, it will examine the strong Congressional response and the role interest groups played in the defeat of this proposal. The unexpectedness of the rule is what garnered the response from Congress while the atomistic nature of modern interest groups allowed for coalition building and targeted lobbying efforts that further perpetuated the Congressional response. In conclusion, if any regulatory agency wants to undertake a controversial rulemaking they need to solicit appropriate feedback from relevant parties before doing so to prevent Congressional outrage. Even though interest groups have a more fractured message on most issues today due to their general atomization, they proved that they could still successfully coalesce around important policies to achieve a desired outcome.

Chapter 1: Introduction

In January of 2014 the Centers for Medicare and Medicaid Services (CMS) released a proposed rule titled 'Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.' It elicited an unusually passionate and unified reaction from both parties in Congress. A wide variety of interest groups were in staunch opposition to various proposals within the rule. Specifically they opposed changes to the six protected classes of drugs. In a rare move, CMS promptly rescinded the controversial potion of the proposed rule a mere three months later. CMS acted in response to the outpouring of concern and comments submitted by interested parties, but specifically Congress. They rescinded the rule far in advance of when the final rule was to be released in May 2014 and admitted defeat changing nothing about the existing program.

Rulemaking is an integral part of what CMS does as the regulatory agency that controls the Medicare and Medicaid programs. They are given this power directly in statute. The provision they were trying to change, that is the focus of this research, is referred to as the 'six protected classes. Drugs within the protected classes – antiretrovirals, antidepressants, antipsychotics, antineoplastics, immunosuppressants, and anticonvulsants – must be covered by prescription drug plans (PDPs) in the Medicare Part D program.[1] PDPs cannot subject a beneficiary to any sort of utilization management techniques such as step therapy or prior authorization before using these drugs. These classes and categories treat serious illness; cancer, AIDS, depression, mental illness,

[1] Please see appendix for further discussion on the six protected classes.

epilepsy, and are used to aid in suppressing the immune system of transplant patients to avoid organ rejection. These are expensive disease states.

Medicare is, and will remain for the foreseeable future, a pertinent topic. Eventually, if you live long enough in the United States, you will benefit from the Medicare program. If today it is not you, look to parents or grandparents as the policies discussed may impact their medical care at some point in their lives. Part D plays an ever-expanding role in the care provided to beneficiaries because of the increasing prevalence of prescription drugs in health care and the increasing cost associated with them. According to Duggan and Morton, "prescription drug expenditure represents the most rapidly growing component of health care spending, increasing from 5 percent of health care spending in 1980 to more than 10 percent by 2005."[2] Fundamentally, because we all pay for Medicare through our taxes, it is important to have an interest in what the government is doing to lower costs while maintaining access to important medications for beneficiaries. Nearly 60% of prescriptions filled in the United States are for a beneficiary of Medicare, Medicaid, or other government programs.[3] Additionally, coverage decisions made in Medicare tend to effect coverage decisions in the private insurance market and have an indirect impact on that marketplace as a whole. These protected classes, the debate surrounding them, and the final outcome of the proposed rule have far-reaching implications for the way health care policy is developed and how regulatory agencies interact with Congress when developing proposed rules.

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[2] Mark Duggan, Fiona Scott Morton. "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization." *The American Economic Review*, March 2010, 590.
[3] Ibid.

Research Question

The focus of this thesis is to determine why the six protected classes policy put forth in a January 2014 proposed rule received a uniquely strong backlash from Congress and interest groups. CMS issued the rule in the sixth year of President Obama's two terms in office. None of the rules issued in the first five years of the Obama Administration received such strong push back from Congress and interest group. This is not a case study of whether CMS had the authority to issue such a proposal through rulemaking. CMS clearly possesses the statutory authority to issue this type of rule and make changes to the Part D program. No one questioned their authority to make this change; they questioned CMS' policy intentions. What will be answered is why did this provision of the proposed rule receive such an impassioned reaction? Congressional letters, legislation and hearings are used to illuminate the response from Congress and the decade-long history of their involvement on this policy.

This rule and the actions taken against it were exceptional in a few ways and provide insight into what may happen during future interactions between CMS and Congress on similar issue areas. This information is useful to predict what may happen if other agencies propose policies under similar circumstances. Three notable things occurred as a result of this rule being issued. First, the Administration rescinded part of the proposed rule in the face of threatened legislation before the rulemaking process was complete. They rarely do as this as it can create legal issues stemming from the Administrative Procedures Act (APA) of 1946. Second, both Democrats and Republicans in Congress worked together to defeat this provision in the rule in a purportedly 'broken' political environment. Third, interest groups formed unusually influential coalitions in

opposition to the provision. Over the past thirty years interest groups have become more atomistic in nature, which lends itself to coalition building. Fragmentation and increasingly specific focus areas characterize the atomization of interest groups.

The six protected classes are an important policy issue for interest groups as well. PDPs see them as a barrier to negotiate effectively the cost of providing a prescription drug benefit; CMS adopted a similar rational in the rule. Beneficiary focused advocacy groups view the protected classes as a fundamental protection for those who are oftentimes the most vulnerable population to receive the Medicare Part D benefit. The beneficiary groups as well as many drug manufacturers stood in staunch opposition to the rule and mobilized the full force of their lobbying efforts against this provision.

Chapter 2

Chapter two provides an introduction to health policy and establishes its importance. The relevant actors; purchasers, insurers, providers, suppliers, the bureaucracy, interest groups, and Congress are all discussed. It also includes a history of both Medicare and the Medicare Part D program. A section is devoted to formulary design because it is fundamental to understanding why the six protected classes are important and how drastically different they are treated. A brief introduction to the dual eligible population is included as they are responsible for the genesis of the protected classes. This chapter is important because it sets up the framework within which the policy discussion at hand fits.

Chapter 3

Chapter three provides a retrospective look at the Congressional commitment to the six protected classes by examining the legislative history and the genesis of the provision with the dual eligible population's inclusion in Medicare Part D. This was a turning point for the policy. Once the dual eligibles entered the program, this protection had to be extended to everyone because there was no ways to limit the dual's plan choices. CMS' rationale and justification for their proposal are outlined. Next, the Congressional and interest group reactions are examined. The fallout surrounding the six protected classes provision was intense. It is in line with our modern ideas surrounding interest groups, in contrast to Congresses bipartisan and subsequently atypical reaction. The chapter ends with the outcome of the pushback against the proposed rule.

Chapter 4

Chapter four examines the method of inquiry used to find appropriate sources and the research behind the content. As an academic research topic this is unique and poses its own set of challenges because there are so few academic sources written on the six protected classes. It is a relatively new program having only existed for just under a decade. Proprietary claims data are needed to analyze the protected classes' impact on cost in the Part D program. Unfortunately, PDPs hold the claims information closely and are very resistant to sharing for fear of their competitors gaining access to this data. This makes the program extremely difficult to study. No similar program exists outside of Medicare Part D so there is no good comparison in the private insurance marketplace or from Medicaid. CRS became a major resource, easily accessed because of my job as a

Congressional staffer. Additionally, interviews with Congressional staff and access to interest group comments were more easily obtained because of my pre-existing working relationships.

Chapter 5

The findings and implications of chapters two and three are elaborated here. While this specific study looks at rulemaking from CMS, which handles government run health care programs, what makes this a relevant topic to discuss is that many agencies undertake rulemaking. A similar situation including a controversial rulemaking may one day occur even outside of the health care space and this case study could be used as a comparison. They are not only limited to health care rules. The implications of a lack of data and effective communication are far-reaching and can impede any policy process.

Chapter 6

Congress does not like to be surprised by the agencies to which they delegate authority. The expectation is that the agencies will communicate openly with Congress and do what Congress expects. But at times they do not and the results can be catastrophic and unproductive. Increased communication could prevent situations like this from occurring in the future. Congress came together in a uniquely bipartisan fashion because they were challenged in their authority by an agency. This rule came as a massive shock to Congress which is why they reacted the way they did.

Chapter 2 - Introduction to Health Policy as a topic, Medicare, Part D History, Formulary Design

Introduction to Health Policy – Importance and Relevant Actors

Before delving into the specifics on the six protected classes and the proposed rule, it is important to understand the landscape of health policy and health care in the United States. In this section, relevant players will be discussed. The importance of interest groups will be examined, as well as the size and scope of the health care industry. A history of the Medicare and Medicare Part D programs provides context for the discussion in Chapter Three of the proposed rule and the policy behind it.

Health care is one of the largest sectors of the American economy. The size of the health care industry and its importance in America are best illustrated by examining US health expenditures as a proportion of Gross Domestic Product (GDP). In 1980, the percentage of health care expenditure as a proportion of GDP was 9.2 percent.[4] In less than thirty years, it nearly doubled. In 2009 it was 17.6 percent of GDP.[5] The Centers for Medicare and Medicaid Services (CMS) predict it will reach 19.9% by 2022.[6] CMS also predicts that health care spending will grow more rapidly than GDP over the same time frame, by 1.0 percentage point faster on average.[7]

It is important to acknowledge that recently health care spending has slowed overall. The reasons for this vary depending on the source and no one has been able to prove causality. Some say it is because of the 'patent cliff' that occurred when

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[4] Thomas Bodenheimer and Kevin Grumbach, *Understanding Health Policy a Clinical Approach* (New York: McGraw Hill Medical, 2012), 130.
[5] Ibid., 91.
[6] "National Health Expenditure Projections 2012-2021," The Centers for Medicare and Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2012.pdf.
[7] Ibid., 1.

prescription drugs lost their profitable patents *en mass* and generic competitors entered the market place increasing competition and driving down costs. Others attribute it to cuts implemented in various budget reduction bills such as the Balanced Budget Act of 1997 or the Budget Control Act of 2011 that resulted in sequestration. Still others say reforms that have been implemented are resulting in less spending. Some attribute the slow growth in health care costs to a sluggish economy that has spared no sector. Growth in prescription drug use and subsequently cost is increasing rapidly even though overall health care spending estimates have decreased. CMS states that in 2012 prescription drug use was $260 billion of overall health care costs for the country.[8] This is nearly half of what is spent on the entire Medicare program that year, a huge number.[9] Ultimately, it is widely agreed that health care spending will gain momentum again and begin increasing at a steady rate with no plateau in sight.

Understanding Health Policy: A Clinical Approach discusses the four entities that make up 'health care' as an industry, understood as a portion of GDP.[10] These four comprise the world in which health policy exists on the practical, day-to-day level in terms of services provided to beneficiaries and payments made to providers. First, there are purchasers whose role is to supply funds for services or goods.[11] This can be an individual in the form of out of pocket costs they pay, insurance companies or the federal government. The two largest organized purchasers of health care are currently large businesses or corporations and the federal government. Second, insurers receive money from the purchasers and reimburse the third group, providers for services rendered or

[8] Ibid., 3.
[9] Ibid., 3.
[10] Bodenheimer and Grumbach, *Understanding Health Policy*, 201.
[11] Ibid., 201.

goods provided. Providers consist of hospitals, pharmacists, physicians, nurses and anyone else who is licensed to provide clinically appropriate care for patients. The fourth moving part is the suppliers. There are a variety of suppliers, but in this work, pharmaceutical manufacturers are the most important example as they supply the prescription drugs in question. The authors of *Understanding Health Policy* succinctly describe their interaction as follows, "Insurers, providers, and suppliers make up the health care industry. Each dollar spent on health care represents an expense to the purchaser and a gain to the health care industry."[12] These working parts provide and pay for care to patients and comprise the practical world of health care and represent health policy in action. The relevant purchaser here is the government by way of a PDP.

From the legislative affairs perspective, there is another relevant set of interested parties, those who create and implement health care policy. Specifically, they are the bureaucracy and interest groups. *Governing Health: The Politics of Health Policy* focuses on these two and both are extremely important. They comprise the framework, the world of policies, laws, rules, and guidance in which the purchasers, providers, insurers and suppliers exist.

James Madison in the Federalist Papers, specifically Federalist Ten, predicted the presence of what he called 'factions.'[13] He further defines factions as, "a number of citizens, whether amounting to a majority or a minority of the whole, who are united and actuated by some common impulse of passion, or of interest."[14] Today's interest groups

[12] Ibid., 201.
[13] James Madison, "Federalist 10," available from the Constitution website, http://www.constitution.org/fed/federa10.htm.
[14] Ibid.

are a modern expression of Madison's factions. While they can be mischievous as Madison predicted, more importantly they are influential and powerful.

In the 1980s interest groups in the health care space began to form and organize in earnest. Originally, health care policy decision-making was influenced by what was referred to as the 'iron triangle.'[15] This was comprised of congressional committees, interest groups, and bureaucrats.[16] The iron triangle was very cloistered and gave power over health care policy to a very small, select group of individuals. The interest groups were very large representing broad swaths of relevant parties. As the health care industry grew in both size and relevance, the interest groups from the iron triangle model evolved and went from being, "tightly knit, closely coordinated, impervious and closed to atomistic, uncoordinated, and highly permeable."[17] Since the 1990s, this shift has allowed for the rise of two important cohorts, the smaller more focused interest group that often has more targeted positions on certain issues and the subsequent coalitions formed by these smaller groups. The fragmentation of interest groups allows them to focus on more narrow issue areas that affect smaller numbers of individuals. Companies represent themselves individually and in various coalitions, which occurs in the debate over the six protected classes; the smaller more targeted interest groups were extremely active on this point as well. Temporary coalitions are a type of short-term alliance, "formed to work together on one issue or policy, only to disband when the issue dies or becomes law."[18] It benefits the interest groups to participate in these as well, because it saves time and effort

[15] Carol S. Weissert and William G. Weissert*, Governing Health: The Politics of Health Policy (*Baltimore: Johns Hopkins, 2002), 127.
[16] Ibid., 127.
[17] Ibid., 129.
[18] Ibid., 124.

to join in a united cause as opposed to developing their own policy positions independently. This is more efficient for them as they allocate resources. This sort of coalition will be discussed in Chapter Three.

Today, health care interest groups range from large organizations comprising the majority of an industry such as the American Hospital Association or America's Health Insurance Plans to much smaller more targeted organizations such as the Iowa Biotech Association. This diffusion allows for more focus when it comes to issue areas and naturally lends itself to coalition building. For example, an organization like the Iowa Biotech Association focuses only on a small area of the biotech world. This allows them to represent the narrow interests of organizations located in Iowa at the state and national level. If necessary they could mobilize and lobby in conjunction with the Biotechnology Industry Organization, or Bio, who represent biotech interests at the national level.

The health care industry has a distinct advantage over other industries when lobbying Members of Congress due to the critical role providers play in a Member's district taking care of their constituents, or the importance of a health insurance plan that insures 70,000 lives in the district. Members do not want to be seen as unsupportive of growing research or manufacturing interests in the health care space. Often times, the groups "target bureaucratic agencies through direct meetings, public comments on draft regulations, and messages sent through members of Congress that are important interest-group concerns to consider."[19] Interest groups successfully did these things in response to the proposed rule. They were able to successfully mobilize Congress as a means to an end in opposition to the bureaucracy.

[19] Ibid., 135.

Interestingly, the bureaucracy is not mentioned anywhere in the Constitution.[20] It is entirely a creation of the Legislative Branch. What is referred to as the 'administrative state' only came into existence during President Franklin D. Roosevelt's Administrations.[21] Congress passed the Administrative Procedures Act in 1946 in response to fear of the rapidly expanding Executive Branch. It is, "An act to improve the administrative justice by prescribing fair administrative procedure."[22] Congress passed this law to ensure they had not unintentionally delegated too much power to executive agencies in the administrative process. Rulemaking is a part of this process. Weissert and Weissert argue, "The single most important bureaucratic task in implementation is issuing rules and regulations for carrying out the law."[23] When bureaucrats implement legislation, they have enormous leeway over how to interpret the statute and implement it.[24] Congressional intent can only go so far. Due to the delegated authority, agencies have a large role to play in policy construction and implementation.[25]

Interest groups interact both directly and indirectly with the bureaucracy. It is comprised of Executive Branch agencies and their various subparts, such as CMS, which is housed under the Department of Health and Human Services (HHS). Bureaucracy is colloquially understood as "publicly funded agencies and offices."[26] Currently, Sylvia Burwell is the Secretary of HHS, a presidential appointee confirmed by the Senate. When

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[20] Ibid., 160.
[21] Ibid., 160.
[22] *Administrative Procedures Act,* US Code 5, http://www.justice.gov/sites/default/files/jmd/legacy/2014/05/01/act-pl79-404.pdf.
[23] Weissert and Weissert*, Governing Health:* 171.
[24] Ibid., 171
[25] Mark Rushefsky and Kant Patel, *Health Care Politics and Policy in America*, (New York: M.E. Sharpe, Inc., 2006), 8.

[26] Ibid., 160.

the rule was issued, the HHS Secretary was Kathleen Sebelius. She retired from the position in April of 2014. At CMS, Marilyn Tavenner was the administrator at the time of the rule's issuance. It is crucial for the outside groups to lobby public officials or 'bureaucrats' because their role in implementing policy is as important as that of Congress.

Congress is a relevant player. None of the bureaucracy would exist to implement regulations that are written based on legislation that the legislators write, if Congress had not legislated the bureaucracy into existence.

Interest groups lobby Congress to influence the executive branch and relevant agencies. Interest groups use their relationships with members to influence the questions they ask during a relevant hearing, work with them to send a letter on a specific policy issue to either the President or a relevant Secretary, or introduce legislation aligned with their priorities. It is equally important to consider what interest groups prevent from happening. Not every action or policy represents a positive change for every interest group. Running interference and preventing the introduction of an unfavorable piece of legislation should be considered a success. Preventing unfavorable actions is another important and undervalued measure of influence. Often times, lobbyists are more successful in what they can keep off of the agenda than with what they want put on it.[27] These are viewed "as a consequence of legislation (or in this case a regulation) rather than an impetus for it."[28] The proposed rule was a consequence of legislation and the ultimate goal of those in opposition to the rule was that it not be finalized and that nothing change.

[27] Ibid., 119.
[28] Ibid., 121.

The four sections of the health care industry described in *Understanding Health Policy,* the purchasers, insurers, providers and suppliers, comprise the interest groups in the *Governing Health* framework. The masses of industry, pharmaceutical companies, insurers and providers all have different incentives and come together in ways that meaningfully address their policy concerns. When well aligned, their lobbying of the bureaucracy and the Federal Government has the potential to affect major change in health care policy.

History of Medicare

The face of the insurance market changed dramatically with the creation of Medicare in 1965. For the first time the federal government put themselves at the center of health care policy. Medicare was created due to concern that only half of seniors had health care. It was intended primarily only for inpatient hospital care, which was deemed inadequate for most seniors.[29] Medicare was the American alternative to national health insurance, which was the direction much of Europe had taken at this time. Instead of covering everyone all at once, the federal government chose to cover a vulnerable subset of the population.[30]

At this time the Federal Government made the decision to cover the elderly in part because in the 1960s seniors were typically out of the workforce in their early sixties and losing any care their employer helped them acquire. Covering them for certain medical

[29] Patricia A. Davis, Scott R. Talaga, Cliff Binder, Jim Hahn, Suzanne M. Kirchhoff, Paulette C. Morgan, Sibyl Tilson, "Medicare Primer," *Congressional Research Service* (2014): 3.
[30] Rushefsky and Patel, *Health Care Politics and Policy in America,* 135.

services was easy and relatively inexpensive.[31] Originally, the program only had Part A and Part B coverage. These 'parts' covered hospital costs, post hospital services, doctor visits and other related medical services.[32] Hospitals incurred brick and mortar costs at rapidly increasing speed and provided care at a specific point of service that was becoming increasingly expensive as more and more elderly began to utilize their services. The main shift that occurred leading up to Medicare's creation is that seniors were no longer dying at home, but rather were going to hospitals to die and there was no one to pick up the bill. As a result, in the 1960s the hospitals needed this additional coverage almost more than the people who were being newly covered. This shifted uncompensated costs to the hospitals. They desperately needed financial assistance and it cam e in the form of Medicare.[33] According to the Congressional Research Service (CRS), "Medicare is considered a social insurance program and is the second largest such federal program, after Social Security."[34] Medicare passed as an amendment to the Social Security Act, and not as a stand-alone piece of legislation. In the mid-20th century as a nation we were setting up a social welfare system.

Medicare's finances are controlled through two trust funds, the Hospital Insurance and Supplementary Medical Insurance program. These are funded through a combination of general revenue, payroll tax, and beneficiary premiums.[35] Employers and employees pay 1.49% on employee's earnings, and those individuals who are self-employed pay a

[31] Rodney Whitlock, Health Policy Class Notes, Washington D.C., Summer 2013.
[32] Davis et al, "Medicare Primer," 3.
[33] Whitlock Class Notes.
[34] Davis et al, "Medicare Primer," 3.
[35] Ibid., 22.

tax of 2.9%.[36] It is important to note that 'there is no upper limit on earnings subject to the tax.[37] Additionally, beneficiary premiums, federal income taxes on Social Security benefits, and interest on federal securities that the trust fund holds, also provide funding for Part A.[38] Part B is financed through federal general revenues and from premiums.[39] Part D, which is the focus of this essay, is financed through a "combination of beneficiary premiums and federal government revenues."[40]

Medicare has not remained stagnant policy, undergoing various changes and updates. No large reforms relevant to this discussion were enacted during the 1970s or 1980s. Throughout the four decades of the program's existence, reform and expansion of the program first occurred in the 1990s when legislation was enacted to update the program. Medicare Part C, also known as Medicare Advantage, was created at that time. It allowed private companies to provide coverage for seniors and receive capitated payments from the Federal Government in compensation[41]. The next major reform occurred in the early 2000s when Congress created Medicare Part D.

Medicare Part D

When Medicare was created, prescription drugs did not play the same role in treatment regimes in the 1960s as they do now. Coverage for prescription drugs was not

[36] Ibid., 23.
[37] Ibid., 23.
[38] Ibid., 23.
[39] Ibid., 24.
[40] Ibid., 25.
[41] Ibid., 3.

included in the original benefit. Drugs' role in patient treatment was very minimal in the 1960s. Now it is expansive and dominates patient care.[42]

A 'biomedical revolution' occurred in the late 20th and 21st centuries that led to a boom in prescription drug use.[43] Drug manufacturers began to release new and improved therapies. The advent of new and innovative blockbuster drugs accompanied this. As the saying goes today, 'there is a pill for everything.' Seniors tend to be extremely heavy users of prescription medications. They often have chronic illnesses that are treated primarily with drugs. For example, heart disease or diabetes.[44]

In the late 1980s and the early 1990s the push for a prescription drug benefit for seniors began to swell. In the 1993 $50.6 billion was spent on prescription drugs in the United States.[45] In 2002 it had more than tripled to $162.4 billion and was projected to be $396.7 billion in 2010.[46] Prescription drugs were the most rapidly growing health care expenditure.[47] During this time period, drug manufacturers were increasing the prices of their drugs at double the rate of inflation, further increasing costs.[48] Seniors were concerned about how they would continue to afford these medications. In 2003 when the Part D program was created, a third of the nation's seniors did not have prescription drug coverage, and those who did have coverage did not always have robust or even adequate coverage.[49]

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[42] Whitlock Class Notes.
[43] Rushefsky and Patel, *Health Care Politics and Policy in America,* 162.
[44] Ibid., 163.
[45] Ibid., 58.
[46] Ibid., 59.
[47] Ibid., 58.
[48] Ibid., 59.
[49] Ibid., 62.

The political willingness of the Bush administration and a Republican controlled House and Senate, coupled with the drastically rising costs of drugs, pushed Congress to undertake a major addition to the Medicare program. This took the form of the Medicare Modernization Act (MMA). As stated by Patel and Rushefsky in *Health Care Politics and Policy in America,* "The politics surrounding that new law (MMA) and the policy implications of what that law has done represent the greatest change in Medicare since the 1997 Balanced Budget Act and possibly since the origin of Medicare itself."[50] Nothing is simple about making such a large policy change and there are varying opinions as to why Republicans supported the program. An interview with a Republican staffer, who spoke on the condition of anonymity and works for a committee of jurisdiction over the Medicare program, stated that the program was created as an act of hubris.[51] Democrats were in control of the White House, the House, and the Senate when they created Medicare in 1965. According to the staffer, many Republicans saw Part D as a way to leave a legacy and show that even though they were expanding an existing entitlement, Republicans did it on their own terms and designed it to be different; more efficient, than traditional Medicare.[52] Conversely, a senior Democratic staffer ascribed the willingness of the Republicans to create Part D to the fact that they were, "getting killed in the polls," on this issue. [53] Noting that nothing occurs in a vacuum in Washington.[54] There is likely some degree of truth to both of these assessments and it is important to acknowledge this political rational. It is often political pressure that leads to

[50] Ibid.,162.
[51] Republican Committee Staffer, Interview, Washington, D.C., February 6th, 2015.
[52] Republican Committee Staffer, Interview.
[53] Democrat Committee Staffer, Interview, Washington, D.C., February 6th, 2015.
[54] Ibid.

new programs being created or new policies being put into place. Congress is fundamentally a reactive body and typically does not get too far ahead on policy. They tend to act as late as possible on most issues.

The Medicare Modernization Act of 2003 created the prescription drug benefit known as Medicare Part D. It took effect on January 1, 2006.[55] The same eligibility requirements for traditional Medicare apply to Part D. However, there are notable additions to the eligible population that will be discussed later in this work. To deliver the benefit the federal government contracts with private companies called 'prescription drug plans' or PDPs.

This was not the first time certain drugs were covered for seniors under Medicare, but it was the most extensive coverage to date and in line with larger changes in the overall practice of medicine as it continues to shift to a reliance on more and more prescription drugs. Prior to Part D, Medicare covered immunosuppressives, oral anti-cancer drugs with the same active ingredient or indication as intravenous physician-administered drugs, clotting factor, and Erythropoietin for anemia.[56,57]

This arrangement has been enormously successful. Part D enjoys extremely high approval and satisfaction ratings. As a Medicare beneficiary, it is not mandatory to enroll

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[55] Suzanne M. Kirchhoff and Patricia A. Davis, "Medicare Part D Prescription Drug Benefit," *Congressional Research Service* (2014): 1.

[56] Jennifer O'Sullivan, "Medicare: Payments for Covered Prescription Drugs," in *Prescription Drugs: Pricing, Importance and Medicare Coverage,* ed. Charles B. Norton, (New York: Nova Science Publishers, Inc., 2004), 55.

[57] These drugs treated very serious diseases, but the medications were often used in conjunction with care provided by a physician in both inpatient and outpatient settings. These drugs tended to be different from other drugs that are included today in the six protected classes. Those covered prior to Part D were tied so closely to an inpatient procedure such as a liver transplant that a beneficiary would need immunosuppressives after their surgery to successfully sustain the transplant.

in a Part D plan, but in 2014, 75 percent of Medicare beneficiaries, roughly 41 million seniors, chose to enroll in a PDP.[58] Each plan varies slightly based on benefit design, differences in premium costs, drugs covered on the plan formulary, and beneficiary cost sharing.[59] Part D covers the following drugs; FDA approved outpatient prescription drugs used for a medically accepted indication, biologic products licensed under the Public Health Service Act, insulin and all related supplies, and vaccines licensed under the Public Health Service Act.[60] Today, almost 90% of Medicare beneficiaries are satisfied with their Part D coverage.[61] It was the culmination of years of momentum building within interest groups and Congress to provide this important benefit to seniors

Formulary Design

Formulary design is fundamental to understanding the proposed rule in question in the next chapter and the overall importance of the six protected classes. A formulary is, "A list of drugs that a plan chooses to cover and the terms under which they are covered… plans can choose to cover some, but not all, FDA-approved prescription drugs."[62] The prescription drug plans set their formulary based on negotiations they undertake with the drug manufacturer and requirements set forth by CMS in the case of Part D PDPs. For example, plans can negotiate a discounted rate for the drug in exchange for it receiving preferential placement on the PDPs formulary. As David J. Cantor states,

[58] Davis et al, "Medicare Primer," 19.
[59] Ibid., 19.
[60] Ibid., 27.
[61] "Nearly 90 Percent of Medicare Beneficiaries Satisfied with Medicare Part D Prescription Drug Coverage," *Medicare Today*, http://www.medicaretoday.org/Medicare%20Today%202011%20KRC%20survey%20release.pdf.
[62] Ibid., 28.

"Given the captive patient base of the large payers, the use of formularies enables these organizations to bargain intensively with the drug companies on the basis of price."[63] The United States Pharmacopeia Convention's (USP) provides lists of categories and classes for different drugs.[64] The USP is "a nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements."[65] A pharmaceutical and therapeutics committee also known as a P&T committee exists within each PDP and works to identify a clinically appropriate set of drugs to cover in all classes and categories the USP identifies. As defined by the USP, "a category is the broadest classification… and provides a high level formulary structure," and, "a class is a more granular classification, occurring within a specific USP category."[66,67]

PDPs must include at least two chemically distinct drugs in every category or class of medication provided on their formulary. In some instances, for a new or novel therapy, there is no alternative drug due to existing patent exclusivities and for a time all PDPs must cover that drug. For many classes or categories there are multiple drugs available due to the presence of generic competitors. The PDP then puts categories and classes of drugs onto different tiers within their formulary. There are often anywhere

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[63] David J. Cantor, "Prescription Drugs: Factors Influencing their Pricing," in *Prescription Drugs: Pricing, Importance, and Medicare Coverage,* ed. Charles B. Norton, (New York: Nova Science Publishers, Inc.,) 2004, 1.
[64] Ibid., 28.
[65] Ibid., 28.
[66] "USP Medicare Model Guidelines v6.0 and v5.0," available from the USP website, http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40.
[67] For example, 'metabolic agents' are a category of drugs. Within that category there are a multitude of classes. These classes treat different illnesses or have different mechanisms of action. In the metabolic agents category, there is an antigout class as well as a class for antiobesity agents.

from three to four tiers on average. The tiers are usually arranged based on price. The PDP can control beneficiary access to medications on different tiers in various ways. For example, a more expensive drug's class may be on a higher tier within the formulary, meaning it will cost the beneficiary more to take the drug. For a beneficiary to ultimately receive this drug, they must try other drugs such as a generic and have them be clinically unsuccessful for the higher tier medication, maybe a name brand, to then be covered. This is called step therapy. Another thing that plans may do is to increase beneficiary cost sharing for more expensive drugs to deter beneficiaries from selecting any drug that would leave them with higher out-of-pocket cost. That is often found in brand versus generic pricing because the brands typically cost the plan and the beneficiary more money. In this case brand drugs would be on a higher tier than generics. Drugs from a single class may fall onto different formulary tiers.

PDPs save the beneficiary money and earn a profit for themselves when they negotiate with drug companies on the placement of a drug on their formulary. Some plans will not cover one drug that for example, treats high cholesterol because they have already negotiated a lower cost with another drug company that has a clinically similar treatment. Fundamentally, "a formulary is a mechanism that allows a buyer to identify a therapeutically similar treatment as a viable substitute for a more expensive product. When bargaining with the seller of a patented product, the ability to shift demand to a substitute drug is a powerful negotiating tool."[68] The drug company benefits because of the increased volume of use they will experience for their medication in that plan which compensates for the drug being provided at a lower price. The plan benefits because they

[68] Duggan and Morton, "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization," 590.

successfully negotiated a lower price for a treatment saving them money that they then turn into a profit with savings passed along for the government and beneficiaries.

The major difference for the six protected class is that PDPs are required to include 'all or substantially all' drugs available in that class and are not allowed to steer beneficiaries away from these medications using utilization management techniques even though it would not affect them clinically.[69] For beneficiaries, this means that whatever Part D plan they choose, they will have access to 'substantially all' medications that are immunsuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. For the plans, this means that they cannot negotiate down the cost of these oftentimes very expensive drugs. Conversely, the drug manufacturers have no incentive to offer reasonable prices on these medications because they know they must be covered regardless of cost. The protected classes are treated much differently from the way formulary design otherwise works for drugs that are not in the six protected classes.

Dual Eligibles

There exists a special group of people it is important to discuss because of the role they played in shaping the six protected classes discussion. They are the 'dual eligibles,' also known as 'duals.' The duals are extremely low-income individuals that are eligible for a low-income subsidy through Medicare who are dually enrolled in both Medicaid and Medicare. Due to their financial situation, they are eligible for Medicaid. However duals currently receive their outpatient drug benefit exclusively through Part D due to a change made in the MMA. If a patient is Medicare eligible but also below the federal

[69] Ibid., 29.

poverty level (FPL) they qualify as a dual. To be considered a dual eligible you must, "have incomes below 135% of the federal poverty level, or $15,754.50 for an individual and $21,235.50 for a couple in 2014; and have resources below $8,660 for an individual and $13,750 for a couple in 2014."[70] The duals have a disproportionately high share of mental illness and other conditions that are treated primarily with drugs from the protected classes. They are the reason for the protected classes' existence. The next chapter elaborates on this point.

Other Considerations

Prescription drugs fall at the center of a number of very tense debates, where affordability and accessibility are juxtaposed with financial reward for development of new and innovative prescription drug therapies. Choosing how to deliver the benefit to seniors also highlighted a huge ideological divide between political parties. The argument fell between price controls on drugs and a government-provided benefit with free drugs for seniors, for which Democrats advocated. Or a competitive market where private companies contract with the federal government to provide the benefit for seniors which Republicans wanted. The latter option prevailed to create Medicare Part D as it exists today.

Another fear for some is the potential situation in which an excess of affordability in the prescription drug space would limit the potential for development. To elaborate, one must assume a company needs to make a profit on one drug to put back into the research and development to produce the next blockbuster, lifesaving drug. Without

[70] Kirchhoff and Davis, "Medicare Part D Prescription Drug Benefit," *Congressional Research Service*, 4.

decent profit, drug companies will not have the money to put back into meaningful research and development projects. David J. Cantor succinctly describes the issue as follows:

> The pricing of prescription drugs is also of concern more broadly to society as a whole. On the one hand is the ideal goal of insuring quality and affordable health care services to all persons. On the other hand is the need to provide adequate professional and financial incentives to all providers of health care services – including research-based pharmaceutical companies – to ensure their near-and long-term supply.[71]

Ultimately, what must be found is the delicate balance between allowing for innovation and profit for the drug manufacturers and maintaining access for the beneficiaries. Medicare Part D, formulary design, prescription drug plans, and the drug manufacturers are all integral pieces of the ever-evolving puzzle that continuously presents itself to policy makers.

[71] David J. Cantor, "Prescription Drugs: Factors Influencing their Pricing," in *Prescription Drugs: Pricing, Importance and Medicare Coverage,* ed. Charles B. Norton, 1.

Chapter Three - Legislative History of Six Protected Classes, the rule, the debate, the outcome

Congress and the Six Protected Classes – A History

In 2003, concerned Members of Congress informally established the idea of the six protected classes when Part D passed into law. Their concern initially arose because of the six million dual eligibles, who were having their prescription drug coverage moved from state Medicaid plans to the newly created Part D.[72] The duals are unique because they do not have to be over 65. They live in extreme poverty, have a lack of education, and have high rates of mental illness. Policy makers focused on protecting them as best they could because they were deemed particularly vulnerable. Nearly 50% of dual eligible Part D beneficiaries did not graduate from high school; for comparison, only 17% of non-dual eligible beneficiaries did not graduate high school.[73] 55% of duals report between 1-6 activities of daily living (ADL) limitations while only 25% of non-dual eligible Part D beneficiaries reported at least one ADL limitation.[74,75] Today, the six protected classes are comprised of antiretrovirals, antineoplastics, anticonvulsants, antipsychotics, antidepressants and immunosuppressants. These medications treat serious illnesses, ones that are often times life threatening. All or substantially all of these medications are required to be included on a Part D PDP's formulary. There is no ability

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[72] Department of Health and Human Services, Proposed Rule, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," *Federal Register* 79, no. 7 (January 10, 2014): 1936-1947, http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf, 1937.

[73] MedPAC, "Beneficiaries Dually Eligible for Medicare and Medicaid," http://medpac.gov/documents/data-book/january-2015-medpac-and-macpac-data-book-beneficiaries-dually-eligible-for-medicare-and-medicaid.pdf?sfvrsn=2, 33.

[74] Ibid., 33.

[75] There are six activities of daily living (ADLs). They are eating, bathing, dressing, toileting, transferring, and continence.

for a PDP to encourage the use of a "therapeutically similar treatment as a viable substitute instead of the more expensive product."[76] Because the duals utilize these drugs at higher rates than other Part D beneficiaries, and are more often cognitively impaired, they do not have the ability to navigate the tricky and imperfect Medicare appeals process for drug denials. To further illustrate this point, 60% of disabled dual eligibles and 20% of elderly dual eligibles have a mental disorder.[77] Another statistic from the Medicare Payment Advisory Commission states that 76% of dual eligibles under 65 have a behavior health condition; the rate is 40% in the over 65 population of duals.[78]

The dual eligible population is comprised of individuals, "who qualify for Medicaid based on income not necessarily age and assets (and they) are automatically deemed eligible for Medicare prescription drug low-income subsidies."[79] The low-income subsidies (LIS) in the Part D program help beneficiaries with cost sharing for their prescription copays and the premiums they pay to their PDPs each month. The concern for these six million individuals in 2003 was that the PDPs in the newly created Part D program would use drug utilization techniques that would be especially confusing to the dual eligible population. They never had been subjected to them before because the state Medicaid drug plans from which they were receiving the benefit have robust formulary designs and include the vast majority of drugs.[80] The concern was that when the duals went to fill their prescription at the pharmacy, they would be turned away

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[76] Duggan and Morton, "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization," 590.
[77] Julie M. Donohue, Haiden A. Huskamp, and Samuel H. Zuvekas, "Dual-eligibles with Mental Disorders and Medicare Part D: How are they faring?" *Health Affairs,* 2009, 1.
[78] MedPAC, "Beneficiaries Dually Eligible for Medicare and Medicaid," 35.
[79] Kirchhoff and Davis, "Medicare Part D Prescription Drug Benefit," *Congressional Research Service*, 4.

without a prescription with an explanation they did not understand.[81] This would result in a lapse of care that could be detrimental to a beneficiary's health and for the healthcare system at large due to subsequent increased hospital admissions and a lack of continuity of care. This would increase utilization of other parts of the health care system.

When the decision was made to cover the duals under Part D, an assortment of different provisions were put into place to make sure they were successfully enrolled in a Part D plan. Prior to Part D they did not have to actively elect a Medicaid drug plan. The dual population, if they do not autonomously do so, is auto-enrolled onto a PDP that offers coverage in the region where they live, if they are at or below the determined LIS subsidy level.[82] CMS chooses which plans to enroll the beneficiaries at random, so no one plan is overburdened with the duals. To allow beneficiaries who accidentally or unknowingly enroll in a plan that has a formulary that does not accommodate their medical needs, and to quickly switch to a more appropriate plan, dually eligible beneficiaries are allowed to switch their PDP monthly. For comparison, the rest of the non-LIS dual eligible population enrolling in Part D is able to select a plan once a year during open enrollment.[83] Because they can move so frequently in the program, in theory, they could be enrolled in a different PDP every month, up to twelve a year. Open and uniform formulary design becomes even more complicated and important for the dual eligible population.

[81] Ibid., 1937.
[82] Kirchhoff and Davis, "Medicare Part D Prescription Drug Benefit," *Congressional Research Service*, 12.
[83] Ibid., 12.

The dual eligible population was the genesis of the six protected classes. They are the reason the provision exists in the manner it does today. CMS stated in their 2005 policy memo that,

> We will reevaluate the formulary guidance for these categories for 2007, when we expect to have far fewer new transitions to Medicare coverage, and when further evidence may be available on effective formulary practices for achieving the statutory requirements of the MMA.[84]

The reason it extends to the entire Medicare population is because it is would be very difficult to justify carving out such a protection for one population from a policy perspective, especially when they are auto-enrolled onto plans and can change PDPs monthly. It would be very difficult for PDPs to adjust their formularies if that were the case. So, CMS extended the provision to all Medicare beneficiaries taking these drugs because it was easier to do so. Once CMS offered subregulatory guidance on this provision, the duals no longer became the focus of the provision and the efforts surrounding it. CMS acknowledges that the six protected classes were created for the benefit of Medicare-Medicaid population to "ensure a smooth transition," for the six million individuals coming from Medicaid.[85] As this provision was addressing a transitional concern, it stands to reason that this provision was never meant to be permanent as transitions are inherently temporary. As a result of its extension any group

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[84]CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" September, 2009. http://web.archive.org/web/20050923032302/http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf.

[85] Department of Health and Human Services, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 1937.

or Member of Congress with a vested interest in the Medicare program now came to care about the protected classes.

The drugs in the protected classes are very important and often times treat a similar, interconnected patient population. HIV is an extremely expensive disease to treat, and if not treated properly can result in a debilitating illness and eventually death. Antiretrovirals to treat HIV only really became available starting in the late 1990s, and have turned HIV from a death sentence into a more manageable chronic illness.[86] However, HIV can become drug resistant if medication adherence is not high and physicians need a full array of available medications to treat their patients.[87] Many of the same patients who have HIV also have co-morbid disease states. About half of those with HIV have mental illness requiring the use of antipsychotics for treatment; a large number of those with HIV also have Hepatitis C, which can result in a liver transplant where immunosuppressants would be needed to sustain the transplant.[88] One in four individuals with cancer have clinical depression.[89] This rule would affect cancer patients who need access to a broad array of antineoplastics but also would potentially affect their access to effectively treat a widespread issue, depression, if antidepressant treatment selections are

[86] The AIDS Institute, "Written Testimony of Charles Schmid, Deputy Executive Director, the AIDS Institute," "http://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-Wstate-SchmidC-20140226.pdf.
[87] Ibid., 3.
[88] Ibid., 3.
[89] National Alliance on Mental Illness, "Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4159-P). (Washington, DC, March 7, 2014), 9.

limited. Of the individuals who take anticonvulsants for epilepsy, 23% also have depression.[90] These disease states are overwhelmingly connected.

When Congress drafted the MMA they put beneficiary protections into place. For example, they included an appeals process for beneficiaries who wanted to petition for coverage of a drug their PDP formulary previously excluded. This would also serve a beneficiary who is looking to avoid step therapy or other utilization management techniques often times used before starting a new medication. According to CRS, "Part D enrollees have the right to appeal coverage determinations, file grievances against plan sponsors, and file complaints regarding quality of care."[91] There exists an extensive five-step appeals process that a beneficiary can undertake if they have an initial coverage decision come back unfavorably. The fifth step escalates all the way to the Federal District Court Level if necessary. Additionally, beneficiaries can appoint a representative to act on their behalf if they are unable or unwilling to traverse this complex process. In cases where a coverage decision may 'seriously jeopardize' the beneficiary's life, the plan must have a coverage decision back to them in 24 hours.[92] Even for those individuals who are not dual eligibles the process is difficult to take on. Various groups who were in opposition to the 2015 rule argued that if you were a part of this vulnerable patient population of dual eligibles, especially if you have mental illness for example, you would not be able to navigate the complex appeals process due to cognitive and other challenges.[93] This is especially true in the over 65 dual population where nearly 25% of

[90] Ibid., 3.
[91] Kirchoff and Davis, *Medicare Part D Prescription Drug Benefit,* 46.
[92] Ibid., 47.
[93] National Alliance on Mental Illness, "Comments on the Contract Year 2015 Policy and Technical Changes," 9.

beneficiaries have a cognitive impairment.[94] Even MedPAC, the Medicare Patient Advisory Committee concluded in a 2013 presentation that, "most beneficiaries are unaware of how the exceptions and appeals process works and physicians find the process frustrating."[95]

Due to these concerns, and the inclusion of the duals into the program, Senator Baucus (D-MT) and Senator Grassley (R-IA) took to the floor of the Senate in 2003 before the passage of the MMA to shed light on the importance of beneficiary protections that are enforced through non-discrimination provisions in the MMA. Senator Baucus began, "One of the things I am particularly proud about in this bill (MMA) is the strong beneficiary protections… You know, Senator Grassley, that there are certain diseases and conditions where having access to just the right medicine is especially important."[96] Senator Grassley responds, "I did know that, and I know that certain mental illnesses also fall in that category. This bill contains a number of protections for people *who need exactly the right medicine for them*."[97] This references the dual eligible population without naming them outright. The two Senators simultaneously shed light onto the intent of Congress and issued bipartisan statements of support for the idea that some need exactly the right medicine to treat specific illness and that their access should be protected.

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[94] MedPAC, "Beneficiaries Dually Eligible for Medicare and Medicaid," 35.
[95] MedPAC. "Part D Exceptions and Appeals," Available from the MedPAC website, September 12, 2013, http://www.medpac.gov/documents/september-2013-meeting-presentation-part-d-exceptions-and-appeals.pdf?sfvrsn=0.
[96] Partnership for Part D Access, "Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4159-P)," (Washington, DC, March 7, 2014), 3.
[97] Partnership for Part D Access, "Comments on the Contract Year 2015 Policy and Technical Changes," 3.

In spite of this bipartisan support, the protected classes were not included in the legislative language of the MMA. The conference report that was issued alongside the legislation formally outlined what would eventually become the six protected classes:

> "It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological disease resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes."[98]

This made congressional intent very clear. A conference report is not a piece of legislation that is passed into law, instead it is a document that travels with the legislation and elaborates on what congressional intent is on various parts of the bill. Often this is included if language is left ambiguous, or if it has the potential to be interpreted incorrectly by those implementing the legislation; in this case CMS. It also occurs with very long pieces of legislation or those creating new programs. This one paragraph represents the creation of the six protected classes. This combined with Senator Baucus and Senator Grassley's discussion on the Senate Floor, as well as other non-discrimination language inserted into the legislation resulted in CMS issuing sub-regulatory guidance in 2005, the year before Part D officially launched.

It is important to note the politics behind the six protected classes not being included in the MMA in 2003. Republicans created Part D. When the MMA passed,

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[98] U.S. Congress, House of Representatives. Report 108-391, *Medicare Prescription Drug Improvement and Modernization Act of 2003 (to accompany H.R. 1)*. (H.R. Rep 108-391). Washington: Government Printing Office, 2003 at pp. 769-770.

Republicans controlled the House, Senate and Presidency. One of the main elements of Part D is non-interference, the idea that, for example, the government will not negotiate prices for prescription drugs. Many interpret this to mean that Part D plans should have as much autonomy as possible to design how they will deliver the benefit. Something as prescriptive and limiting to the plans as the six protected classes would never have made it into statute at this time for political reasons.

The language being included in the conference report and the Baucus/Grassley exchange on the Senate floor were concessions to those members who felt that the inclusion of such a provision was important. The vote on the MMA was difficult so it was politically important to make these kinds of concessions.

As a result of the conference report that accompanied the MMA, CMS issued a policy memo in 2005, shortly before the program launched in 2006, that addresses why they were requiring 'all or substantially all' antidepressants, antipsychotics, anticonvulsants, anticancer, immunosuppressant and antiretroviral categories of drugs. They specifically cite the openness of the state Medicaid programs in allowing access to the drugs in these six categories, "even where the drugs are not included on the state's preferred drug list."[99] A preferred drug list is equivalent to a state formulary. They use this as the precedent behind this same type of protection being brought into the Medicare program. While they do not state it outright, this indicates that this is specifically being done for the benefit of the duals, much like the Grassley and Baucus exchange suggests. Seniors as a cohort were not coming from state Medicaid

[99] CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" 1.

programs, the duals were. The memo also sheds light on why Congress feared PDPs might be discriminatory in their practice towards the duals; "Diseases associated with these six categories of drugs have among the highest predicted drug costs and thus predicted payments in this model."[100] They are expensive. PDPs loose revenue and it is much more costly for them to provide the drug benefit when they have to pay for expensive drugs without employing utilization management techniques for the duration of the patients time spent enrolled in the drug plan. Some concern is valid.

One study done by the NIH found that, "the high expected drug spending of dual-eligibles with mental disorders creates incentives for PDPs to avoid enrolling them."[101] This is the discrimination that Congress and CMS were trying to avoid. These beneficiary's drug spend is high and sustained. Often their utilization of expensive medications will not decrease over time, as they tend to be afflicted with serious *chronic* conditions. For a PDP these frankly are the least desirable types of beneficiaries to enroll. The PDP might without these protections, offer a more closed formulary that would discourage the duals from enrolling in their plan due to a lack of medications that they need and use being available to them. This is currently happening in the small group private insurance market. A study from the New England Journal of Medicine published in January 2015 found that "insurers are resorting to tactics to dissuade high-cost patients from enrolling," specifically focusing on those drugs, antiretrovirals, that treat individuals

[100] Ibid., 1-2.
[101] Julie M. Donohue et. al., "Dual-Eligibles with Mental Disorders and Medicare Part D: How are they faring?" 3.

with HIV in the individual and small group markets.[102] The costs for those individuals who are enrolled in a plan with discriminatory formulary design pay three times more than other beneficiaries with HIV for the same drugs, $4,892 versus $1,615.[103] The fact that this is currently occurring grounds this concern in reality.

The memo CMS released in 2005 stated that if a beneficiary is clinically stable on a drug before entering the program the plan will not be permitted to use prior authorization or step therapy to control beneficiary utilization of that drug.[104] CMS closes the memo by saying that they had issued these requirements after they had reviewed plan formularies and that "the vast majority of formularies already meet this expectation."[105] Often this is used in the argument against the six protected classes; that all formularies meet these requirements anyway. More important is that enough plans did *not* meet this standard and CMS felt they had to act. Formularies are not permanently set and change year-to-year. While they appear acceptable in one contract year, the PDPs could drastically alter what they choose to cover on their formularies in bids to CMS for the next year.

This memo came as a last minute addition to the requirements for the PDPs who were already committed to participate in the program for it's first year. PDPs had submitted their bids and CMS already reviewed and approved them. After this process was complete, CMS released their memo. It is unlikely that CMS forgot to include this

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[102] Douglas B. Jacobs, Sc.B., and Benjamin D. Sommers, M.D., Ph.D., "Using Drugs to Discriminate – Adverse Selection in the Insurance Marketplace," *New England Journal of Medicine,* January 29, 2015, 1.
[103] Ibid., 401.
[104] CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" 2.
[105] Ibid., 2.

requirement initially and rather added it when they did because plans had no way to argue against it in earnest as they were already contractually obliged to offer the benefit. Another more innocent analysis of the somewhat suspicious timing is that maybe, CMS wanted to wait and see what the composition of plan formularies would be before this policy was introduced and to see if it was even necessary to include. Plans found themselves having to adjust.

Medicare's role as a payer changed drastically with the inclusion of the duals into the program. It suddenly became a large payer of psychotropic medications. A Health Affairs study quantifies this change in beneficiary populations. They analyzed the percentage of psychotropic medications paid for by Medicaid and Medicare for the dual-eligibles immediately before and immediately after the creation of Part D.

> "In 2005, Medicaid covered 70% of antidepressant, 84% of antipsychotic, and 82% of anticonvulsant spending for non-institutionalized dual-eligibles. In 2006, Medicaid's share of spending in these classes fell to 5%, 11% and 7%, respectively, as Medicare's share increased to 84%, 84% and 78%."[106]

With the influx of such high numbers of individuals with mental illness, depression and epilepsy coming into the program Members of Congress and CMS felt it was important to implement the six protected classes in order to establish an effective policy when it came to handling these beneficiaries and their needs. The protected classes and the way they were included were a product of this changing demographic but also a result of the political process of adding a new government benefit.

[106] Julie M. Donohue et. al., "Dual-eligibles with Mental Disorders and Medicare Part D: How are they faring?" 2.

MIPPA and the ACA

From 2006 to 2008 the Medicare Part D program continued without any further elaboration on the subregulatory guidance issued by CMS in 2005, nor did Congress legislate on the protected classes. Congress decided in 2008 it was time to make improvements to the entire Medicare program for both patients and providers. This resulted in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

MIPPA codified the six protected classes for the first time and made numerous other updates to the Medicare program. It put into statute that the Secretary should reevaluate and update if necessary the six protected classes of drugs. The statute reads as follows in Section 176:

> "The Secretary shall identify, as appropriate, categories and classes of drugs for which both of the following criteria are met. (I) Restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class. (II) There is significant clinical need for such individuals to have access to multiple drugs within a category of class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer. (ii) PDP sponsors offering prescription drug plans shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (I)."[107]

The inclusion of this language in MIPPA undoubtedly strengthened the Congressional commitment to the idea of the protected classes. This codified what had already been accomplished in subregulatory guidance. Since no formal rulemaking had taken place, CMS could do away with this policy at any time. Even though they had previously chosen not to do so, CMS did indicate that they would "reevaluate the formulary

[107] Medicare Improvements for Patients and Providers Act of 2008, http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf.

guidance for these categories" in the initial 2005 memo.[108] Congress got CMS to do what they wanted by legislating on the issue. While MIPPA was an appropriate vehicle to include this language, a very different Congress than the one that created Part D pushed for its inclusion. In 2008, Democrats controlled both the House and Senate, and President Bush was coming to the rocky end of his second term. Congress put numerous provisions into this bill that the President disagreed with to the point that he vetoed this legislation when it first came across his desk. However on July 15, 2008 Congress overrode the President's veto to successfully pass the legislation.[109] This bill addressed many issues both Democrats and Republicans felt needed to be addressed; the vote to override the veto split 383 to 41 in the Houses and in the Senate, 70 to 26.[110] The Democrats only held 50 seats in the Senate because two 'independent' Senators caucused with them, and 233 in the House. This was not solely a partisan override of the veto.[111] However, as the majority party in both chambers, Democrats were primarily responsible for what was included in the legislation. In a piece of legislation this large there are so many provisions that can garner animosity from various members. But if even one "must pass" item is included, the bill's chance of success is much higher.

Even though MIPPA directed CMS to do so, they did not pursue new rulemaking for the plan year of CY2010 and simply continued with the existing classes and criteria

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[108] CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" 2.
[109] Jean D. LeMasurier, Babette Edgar PharmD, MBA. *MIPPA: First Broad Changes to Medicare Part D Plan Operations*. Vol. 2. April/Mary 2009, 1.
[110] "Veto Override on Medicare Bill Marks Important Victory for Beneficiaries & Advocates," California Health Advocates, July 30, 2008, http://www.cahealthadvocates.org/news/basics/2008/veto.html.
[111] "109th United States Congress," available from Wikipedia, http://en.wikipedia.org/wiki/109th_United_States_Congress.

from their 2005 memo. They intended to reevaluate in 2010 for the CY2011 plan year, which they did by issuing a proposed rule. They were interrupted in the process.[112]

In 2009 the Affordable Care Act (ACA) provided another means for a Democratic Congress to demonstrate their commitment to the six protected classes and gave them the opportunity to legislate on the policy again. In 2009, Democrats controlled the House, Senate, and the Presidency and could essentially put whatever they wanted in statute, much like Republicans excluded whatever they wanted in 2003. The six classes were now enumerated in statute, unlike in MIPPA. Since the ACA followed so closely on the heels of MIPPA, Congress interrupted CMS in their rulemaking and they were subsequently unable to complete the reevaluation of the policy they had undertaken as a result of the "Secretary shall" language in Section 176 of MIPPA directing them to do. CMS issued a proposed rule in October 2009 that would have addressed the six protected classes further.[113] Before the final rule could be released in April of 2010, and in the midst of the comment process, the ACA passed into law and superseded the rulemaking. Section 3307 of the ACA directly amends the relevant MIPPA language:

> "A PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I). The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) or to otherwise limit access to such a drug, including through prior authorization or utilization management. The Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern. Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(II): anticonvulsants, antidepressants,

[112] Department of Health and Human Services, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 1937.
[113] Ibid., 1937.

> antineoplastics, antipsychotics, antiretrovirals, immunosuppressants for the treatment of transplant rejection."[114]

The ACA differs from MIPPA in that it lists which categories and classes of drugs are to be protected; anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection, until the Secretary chooses to undertake rulemaking.

It is worth noting that during the proposed rulemaking from 2008 and 2009 that was never completed, different associations and organizations still submitted comments to CMS. One such comment was from the Pharmaceutical Care Management Association (PCMA), which represents a majority of America's pharmacy benefit managers (PBMs). PCMA member PBMs, "administers prescription drug plans (PDPs) for more than 210 million Americans with health coverage."[115] They wrote comments expressing their extreme concern with the proposed rulemaking and the underlying statute. They stated that, "the protected classes provision of last year's MIPPA statute is arbitrary, offers no proven ability to increase access, and, according to CMS, will increase drug costs by $4.2 billion over 10 years."[116] This is representative of one organization with a very large interest in doing away with the protected classes. However, it is important to demonstrate how controversial this provision was before CMS released the proposed rule in January 2014. This upset groups at the time. However, PCMA later joined a very different coalition in the face of the 2014 proposed rule. Over the next four years, CMS did not

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[114] *Affordable Care Act,* 42 US Code, Sec. 18001, https://www.law.cornell.edu/wex/patient_protection_and_affordable_care_act_of_2010.
[115] Pharmaceutical Care Management Association, "CMS-4138-IFC4," (Washington, DC, March 17, 2009,) 1.
[116] Pharmaceutical Care Management Association, "CMS-4138-IFC4," 1.

choose to initiate any rulemaking and the six protected classes remained as they were listed in the ACA.

It is the Legislative Branch's prerogative to decide how much power they yield to the bureaucracy when they write legislation. They also decide how strongly they feel about their law or a provision being acted upon. For example, the difference between the words 'may' and 'shall' in legislative language is important to understand. In MIPPA and the ACA the statue reads, "The Secretary shall..." meaning the Secretary has no choice but to do what is instructed in the language. If "may" were to be used, the Secretary has more of a choice in how, or if, they interpret the legislative language. They can choose whether they want to act or not. The Congress must decide if they want to 'hardwire' or 'softwire' the process affecting how much control the agencies have.[117] The language in both MIPPA and the ACA is strong in that it uses 'shall' in their directive. It is ironic that Congress mandated CMS to reevaluate the six protected classes, but it backfired when Congress did not anticipate the direction of the reevaluation. CMS upset Congress when they also included language on prior authorization in the proposed rule. This gets to a point made in *Governing Health the Politics of Health Policy.* It is important that Congress is aware of how much discretion they are giving to the agencies when it comes to policy decisions. After the reaction to the January 2014 proposed rule, it is easy to look back and see that Congress simply assumed how the Secretary would use this new directive. They assumed incorrectly that she would only use the directive to expand, not do away with, parts of the six protected classes. Congress opted to rely on what they

[117] Weissert and Weissert, *Governing Health the Politics of Health Policy*, 179.

deemed adequate congressional intent. This confusion and the ambiguity in the rule could have been easily avoided if Congress had been clearer in their legislative language.

An interview with a Democrat Congressional staffer who also worked briefly at CMS, further sheds light on the issue of delegating power to the agency when it comes to implementing legislation through rulemaking. Her opinion is that the agency needs to be as expansive as possible in its rulemaking because they are the ones to whom the difficult decisions are often times left.[118] Democrats typically tend to be more comfortable with a larger government, while Republicans want smaller, less pervasive government. She also believes that Congress should simply set up the framework for how programs should be created. The agency is the appropriate place for real innovation and forward thinking to occur. They are the one body that can afford to look towards the future unencumbered by elections, process and procedure, and constituents.[119] Her concern lies primarily with how slowly Congress moves. An issue as important as medicine, that develops and changes so rapidly, is not appropriately managed through legislation.[120] Congress is too reactive of a body and should focus on laying out the general structure of health policy rather than being over-prescriptive in statute. If a mistake is made or if a bad policy is put into place using statutory language, it is much harder to undo than if an agency offers guidance or goes through the rulemaking process. Congressional mistakes must be re-legislated which is a laborious and unwieldy undertaking. Even the best laid plans and policies can have flaws when put into practice.

[118] Democrat Committee Staffer, Interview.
[119] Ibid.
[120] Ibid.

CMS and the Rule

In January 2015 CMS decided to reevaluate the six protected classes, as directed in the statute.[121] What began as a straightforward and commonsense reevaluation of a policy turned into a major fight among the Administration, Congress and various interest groups. The issue came down to the newly developed criteria for determining the protected classes and how CMS proposed to use it to determine what drugs were included or excluded. Ultimately the proposed rule proposed a much more restrictive interpretation of what drugs needed to be protected than Congress had anticipated or intended. It would have done away with three of the six protected classes in 2015 and 2016 with plans to reevaluate the other three in the future. It did not include any new categories or classes to be protected.

By the time of the proposed rule, the use of drugs in the protected classes was substantial. In 2010, approximately 40% of Medicare beneficiaries used a drug in the protected classes.[122] The protected classes are no longer important only to the dual eligible population alone, even though they were the genesis of the policy. Today, these drugs represented 13% of all prescriptions in Part D, and 18% of the Part D drug spend.[123]

An important function of CMS, as part of the bureaucracy and as a regulatory agency is to go through the rulemaking process on various policy areas over which they have statutory authority. They issue proposed rules and release them as a discussion draft

[121] This occurred in the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule.
[122] Kirchoff and Davis, *Medicare Part D Prescription Drug Benefit*, 29.
[123] Ibid.

of sorts as mandated by the APA. The agency receives public comment for a set period of time. They then consider the feedback they have received and issue a final rule that incorporates other ideas and viewpoints; or at the very least addresses them. The agency may make changes based on this public feedback. Alternately, they may continue without it. Any changes are incorporated in the final rule, which is published at a later date. This proposed rule followed this process, and CMS exercised the statutory authority Congress gave them in the ACA.

In the rule issued on January 10, 2014, CMS proposed, "Revising the criteria the Secretary will use to identify drug categories and classes of clinical concern…We also propose to specify drug categories or classes that would meet the proposed criteria and explain the process we used for making these determinations."[124] The statute directed the Secretary to not only establish criterion but to actively apply them to the protected classes. CMS justified moving forward with new more restrictive criteria because they felt that there were other, "adequate beneficiary protections," that would help seniors procure needed drugs.[125] They go on to cite the protections that they already have in place to insure that beneficiaries receive the drugs they need. CMS cites provisions on formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals process.[126] For example, the formulary transparency takes place in the form of the 'plan

[124] Department of Health and Human Services, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 1936.
[125] Ibid., 1938.
[126] Ibid., 1938.

finder' website that CMS created to help beneficiaries find plans that provide coverage for all of their prescription drugs.[127] This also includes the five-step appeals process.

CMS developed criteria in accordance with statute to evaluate the six protected classes. It would determine if a class or category needed to be included or excluded. They also proposed using these criteria for future determinations of six protected class drugs. The first criterion states:

> "In the case of a typical beneficiary who has a disease or condition treated by drugs in the following category or class, hospitalization, persistent or significant incapacity or disability, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription of the drug was presented to the pharmacy to be filled. By typical beneficiary, we mean, for a given disease or condition, an individual who has the average clinical presentation of the relevant disease or condition."[128]

The second criterion reads as follows:

> "More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations."[129]

Criteria one is straightforward. It is a measure based on what would happen to a beneficiary who was not receiving care for seven days with the necessary medications. If it would end in incapacity, disability, or death, then the category or class should be protected. While criteria two is more difficult to understand and apply than the first, it is stating that a formulary can exclude drugs but it simultaneously can provide adequate coverage for various disease states. A formulary does not have to be completely open to

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[127] Plan finder is a website that CMS maintains that helps beneficiaries search for PDPs in their region that cover the drugs that they are currently taking. CMS often cites it as a way they have increased transparency for beneficiaries and made it easier for them to select a plan. Beneficiaries often find the sight confusing and difficult to use.
[128] Ibid., 1941.
[129] Ibid., 1942.

provider meaningful clinical care to a beneficiary. This is how drugs are treated that do not have the formulary requirements of the six protected classes. The category or class of drugs would be of concern if CMS "cannot establish that a formulary would include sufficient drugs needed to treat the diseases or conditions."[130] Sufficient is the key word. 'Sufficient drugs needed to treat' does not mean every drug needs to be covered. CMS is allowing for a more closed formulary here because they do not believe it would have a negative impact on beneficiary health or care. They did not want to hyper-regulate formulary design. It would be inappropriate for them to do so as the Medicare Part D program is built around market-based principles such as competition. It is this competition that allows PDPs to provide the Part D benefit at competitive prices.

In developing the criteria, CMS assembled a 'consensus panel' of their staff pharmacists and the Chief Medical Officer for Medicare. The panel examined the six protected classes and evaluated them to see which still needed to be protected under the new criteria. The panel found that only three of the six were still appropriate to protect. They were anticonvulsants, antineoplastics, and antiretrovirals. The consensus panel concluded that for antiretrovirals, drug resistance could occur if treatment is delayed for seven days, which can result in death. The panel found that immunosuppressants for transplant rejection, antidepressants, and antipsychotics do not meet *both* of the proposed criteria but they may have met one. This consensus panel was an important step for CMS to make in their rulemaking. They hoped that it showed they had put considerable thought into the proposed rule. A panel that included pharmacists with a background in

[130] Ibid., 1942.

formulary design was important in validating their decision-making. CMS utilized this to lend credibility to their decision-making.

CMS looked to other health insurance programs for comparison this. They state in the proposed rule, "We are not aware of any other U.S. government programs, or commercial private health plans having a similar requirement."[131] The government programs include the Federal Employee Health Benefit Plans, the Veterans Association, or Medicaid.[132] There was no finding of a need for such protections in other plans.

Prior to this, CMS operated under the previously established criteria. That "interruption of therapy in these categories could cause significant negative outcomes to beneficiaries in a short timeframe."[133] This is a broad definition and is largely left up to interpretation. However, it previously validated the six protected classes' existence, so it did serve an important purpose. With the six protected classes playing such a prominent role in beneficiary care with so many Part D recipients receiving them, an updated criteria that provided more clarity to plans and advocacy groups should have been welcome.

The primary motivations for proposing these changes are cost saving incentives and the belief that the appeals process is adequate to compensate for any issues beneficiaries may have as a result of losing protected class status. CMS stated, "We are concerned that requiring essentially open coverage of certain categories and classes of drugs presents both financial disadvantages and patient welfare concerns for the Part D

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[131] Ibid., 1946.
[132] Ibid., 1945.
[133] CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" 1.

program as a result of increased drug prices and overutilization."[134] If the protected class drugs have to be covered on a formulary, there is absolutely no incentive or reason for the drug companies that are negotiating with the drug plan to offer a competitive price. This also played a role in the development of the second criteria they used to evaluate the protected classes. They state they should not over regulate the formularies because that would impede the competition that drives Part D.

In the proposed rule CMS stated that all drugs should be subject to normal formulary and price competition only if access to drugs cannot be ensured for beneficiaries in the face of every other beneficiary protection in place.[135] Fundamentally, because CMS contracts with the plans that are providing the Part D benefit, it follows that they would be concerned about drug pricing specifically in these protected classes because any increased cost to the plan results in a subsequent increased cost to the beneficiary and the federal government. In a worst case scenario it could potentially impact the contracting process with the Part D plans in the future. This would make it harder for CMS to provide the benefit if prices increased rapidly. For these reasons it is important that CMS weigh not only the beneficiary perspective but also the plan side of every issue they face because those are the two most important entities they deal with and both, together, make up the Part D program.

The rule also proposed to make prior authorization of protected class drugs appropriate when there are questions surrounding the "presence of a medically-accepted

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[134] Department of Health and Human Services, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 1937.
[135] Ibid., 1938

indication."[136] This is a major change from what they stated in their 2005 memo when they introduced this formulary requirement to plan sponsors. They had previously stated that, "utilization management tools are generally not employed in widely used, best practice formulary models," for this cohort of medications, specifically HIV/AIDS medication.[137] This provision would have impacted all protected classes, which, if the rule were finalized, would include antineoplastics, antiretrovirals and anticonvulsants but additionally could be used for all accepted Part D drugs, which could potentially increase the use of prior authorization. This was due to the concern stated previously that CMS had over beneficiaries being over prescribed antipsychotics, in particular, as a result of their protected status. If an instance arose where there was not a clear medically accepted indication for the drug's usage, a plan could use prior authorization to review medical records and prescribing patterns. CMS assumed that prior authorization would only be used in a very small number of instances, where a drug being prescribed has a unique or narrow indication.[138]

CMS predicated their claims on the financial benefit of removing the protected classes on two widely cited studies in this space. The first was, an actuarial study done by the firm Milliman in 2008. The second was the Duggan and Morton article "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization," cited earlier in this work.[139] These two studies were, unfortunately two of the only studies ever done on the protected

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[136] Ibid., 1943.
[137] CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" 2.
[138] Department of Health and Human Services, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 1943.
[139] Ibid., 1938.

classes. The Milliman study states that, "It should be noted that any additional protected classes would result in lower rebates which would result in higher claims costs, which would likely be reflected in higher member premiums and or government liabilities."[140] CMS additionally relied on anecdotal evidence from the HHS Office of the Inspector General. CMS did not undertake any additional research on the six protected classes in the proposed rule. This is unfortunate because if CMS was certainly in a position to produce an in depth study on this issue. The literature on this proposal is very thin, but CMS cited it as their rationale for moving forward.

Ultimately, CMS saw this as an opportunity to return some of the market-based principles of Part D to these protected classes and to begin to address the issue of overutilization of the antipsychotic class of drugs. CMS believed that the beneficiary protections that are currently in place are sufficient to protect all beneficiaries, even the most vulnerable. This was an attempt to do away with a policy that was meant to address a transitional need. With the recommendations of the consensus panel, CMS felt they had developed two acceptable criteria. Beneficiaries were still being protected by the appeals process and overprescribing of antipsychotics was being addressed.

The Reaction

The response from Congress and interest groups to the proposed rule was swift and strong. As one journalist stated, "It is worth sitting up and taking notice when

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[140] Richard A. Kipp M.A.A.A., Carol Ko. *Potential Costs Impacts Resulting from CMS Guidance on "Special Protections for Six Portected Drug Classifications" and Sections 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275).* Washington, DC: Milliman, 2008.

everyone seems to hate what you are doing."[141] In this section various interest group comments in opposition to the proposed rule will be discussed. The outcry against the rule was much more loudly heard and more strongly coordinated than any that supported the change to the six protected classes. This is due in part to coalition building that occurred to defeat the rule as a whole. The only groups supporting the proposed changes were the prescription drug plans and health plans. But neither of these have the same clout with Congress as beneficiary groups. They got swept aside in a tide of advocacy group anger. Primarily, groups communicated with the Administration about the protected classes through comments they submitted to CMS. Additionally, and equally important, interest groups lobbied and mobilized members of Congress and committees of jurisdiction.

Congress has the unique ability to shine a spotlight on hot topics of the day in the form of a hearing, which is exactly what they did. Mr. Jonathan Blum the Principal Deputy Administrator of CMS testified before Congress at the hearing entitled "Messing With Success." He used the hearing to examine the agencies attempt at explaining their rationale and to justify their actions. Part of what made this so fascinating is that Republicans and Democrats both felt passionately about this rule and specifically this provision. Overall, the reaction to the rule was zealous and a fascinating study in the way interest groups, Congress, and the administration interact to create or , alter or eliminate policy.

[141] Ian Spatz, "Medicare Part D Proposed Rule: Where Did Things Go Wrong?" *Health Affairs*, March 6, 2014.

Congress' reaction is examined first. This occurred primarily through multiple letters that were written to CMS from various members and the hearing the Energy and Commerce Committee held in late February 2014. During the 113th Congress, Democrats were in the majority in the Senate and Republicans were in the majority in the House. This Congress was factious and more partisan than almost any that came before it, making the multiple bipartisan letters even more powerful than they would have been relative to other Congresses. A range of letters was written, some from individual members and others that were both bipartisan and bicameral in nature.

The Congressional Response

On February 5th, 2014 all twenty-four members of the Senate Finance Committee, the committee that has sole jurisdiction over Medicare in the Senate, wrote a letter to Marilyn Tavenner, the Administrator of CMS. This letter was one of the first sent, and written specifically on the six protected classes. They state,

> "We are writing to express our concern over the recent proposal to reduce the number of "protected classes" under the Medicare prescription drug benefit known as Part D, and strongly urge the Centers for Medicare and Medicaid Services (CMS) to continue this important beneficiary protection as it exists today."[142]

Their intent for sending the letter is clearly spelled out. The letter goes on to note that while they appreciate the effort to reduce unnecessary spending, they are concerned that vulnerable beneficiary populations, specifically those with mental health problems, will

[142] United States Finance Committee. "Letter on Proposed Rule." Washington, DC, February 5, 2014, 1.

be left without access to their medications.[143] The Committee was also concerned by the lack of data CMS provided as the rationale behind their decision-making. Senators Baucus and Grassley, who in 2003 went to the Senate floor to initially advocate for special protections on this issue, also signed the letter. It is remarkable that every member of this committee signed on. It speaks to how strongly they felt about this policy. The membership of Senate Finance in the 113th Congress ranged from Senator Maria Cantwell, a Democrat from Washington State, one of the more liberal states in the Union, to Senator John Cornyn, a very conservative Republican from Texas, one of the most conservative states. This speaks volumes to the bipartisanship that was achieved to defeat this policy.

Three short weeks later the Senate Finance Committee sent another letter, on February 28th, 2014. Eighteen members of the committee signed this letter, eight Democrats and ten Republicans. Less bipartisan consensus was achieved on this letter because it was not specifically on the six protected classes like the February 28th letter. The scope of the letter however was wider. The discontent with the rule was reiterated, "Given this remarkable success we are perplexed as to why the Centers for Medicare and Medicaid Services would propose to fundamentally restructure Part D."[144] Republicans were more critical of the rule as a whole because in their minds it directly challenged the heart of the program they created a mere decade earlier. Democrats were most passionate about the six protected classes provision but they did like other aspects of the rule as well. This could be why all of the Democrats signed the February 5th letter with its more

[143] *Finance Committee Members Express Bipartisan Concerns Over Proposed Medicare Rule.* Washington, DC, February 28, 2014, 1.
[144] Ibid.,1.

narrow focus. While not a member of the Senate Finance Committee, Congressman Pallone's remarks at the Energy and Commerce hearing held on February 24, 2014 are representative of the way Democrats felt about the proposed rule. He stated, "There are many positive provisions in this proposed rule that, even if it's not perfect, I do not agree with the naysayers who have called for its dismissal outright."[145] The one provision he specifically discusses and says he is concerned about is the six protected classes.

On February 19th, the lead Republicans, Chairman Fred Upton, Chairman Dave Camp, and Ranking Member Hatch, of the three committees of jurisdiction over Medicare in the House and Senate; The Energy and Commerce Committee, the Committee on Ways and Means, and the Senate Finance Committee all sent a letter to both the Secretary of the Department of Health and Human Services at the time, Kathleen Sebelius and Administrator Tavenner. The six protected classes are not mentioned but referred to as, "important protections that ensure appropriate access to vital medicines."[146] They note that they believe the success of Part D comes from the lack of 'Washington interference.'[147]

Democrats and Republicans who sit on both the House Ways and Means Committee and the House Energy and Commerce Committee signed a bipartisan letter that went out to CMS and HHS on March 4, 2014. Not every member of these two committees signed the letter, but 58 members did which is a very respectable percentage of the committee. It specifically focuses on the six protected classes, which is likely why

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[145] Rep. Pallone, Opening Statement, Energy and Commerce Committee Hearing, Transcript, pg. 9, http://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-Transcript-20140226.pdf.
[146] Fred Upton, Dave Camp, Orrin Hatch. "Letter on Proposed Rule." Washington, DC, February 19, 2014, 2.
[147] Ibid., 1.

it had such widespread bipartisan support. The members were concerned that the proposed rule, "Relies upon what is widely known to be ineffective exceptions, appeals, and grievance processes to ensure sick individuals enjoy timely access to necessary medications."[148] There is a line in the letter that attacks the agency over the 'significant challenges' CMS and HHS face in implementing healthcare reform and questions why they would attempt to undertake another difficult change simultaneously.[149] Democrats who signed the letter had to agree with this point. You cannot sign a letter and pick and choose what you agree and disagree with. Typically, members approve a letter in its entirety. This shows that both parties were upset with CMS for promulgating this proposed rule. The letter also states, "The six classes of medications were deemed by Congress to be correct classes for inclusion in 2008 and the position was reaffirmed in 2010."[150] Congress reiterated their support for the provision numerous times over the years and that CMS was undercutting their authority.

This gets to the concerns brought up by the Senior Democratic Staffer interviewed; that this sort of decision-making should fundamentally be left to the agency and not a reactive body like Congress. Ultimately, it is often times both impossible and unwise for Congress to write a law with such a level of clarity that it can be instantly implemented without any sort of rulemaking or agency interpretation.[151] The agency can

[148] House Energy and Commerce Committee and House Ways and Means Committee. "Bipartisan Letter on Proposed Rule." Washington, DC, March 4, 2014.
[149] Ibid.
[150] Ibid.
[151] Weissert and Weissert, *Governing Health*, 169.

responded more quickly than Congress; "It is easier for administrators to change or revise a troublesome provision than for Congress to reconsider the matter."[152]

In addition to the letters that were sent out by the different committees of jurisdiction and their membership, individual members of Congress and more focused groups of concerned Members signed onto other letters as well. On February 14, 2014 five members including, Dr. Burgess (R-TX) signed a bipartisan and bicameral letter that highlighted the impact that this proposed rule would have on access to immunosuppressants. The focus of this letter is to, "protect organ transplant recipients," specifically.[153] All the members who signed had worked extensively on this issue and had been champions for advocacy groups who advocate for individuals who need these protected medications. For example, the American Society of Transplant Surgeons named Dr. Burgess one of the signers of the letter, as a, "longtime champion of the transplant community."[154] Dr. Burgess had previously worked on issues related to transplantation in the Medicare program so he was a natural lead on this issue for immunosuppressants.

Dr. Murphy (R-PA), who chaired the Oversight and Investigations Subcommittee on the Energy and Commerce Committee, had been an advocate for those with mental illness throughout his career. As a practicing psychologist before coming to Congress, he witnessed firsthand the barriers those with mental illness face when trying to receive appropriate care. He sent his own oversight letter on January 28, 2014 in which he requests that the agency respond to various questions he poses. They include request to,

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[152] Ibid., 169.
[153] Congressman Burgess and Senator Durbin, "Immuno Letter," February 14, 2014.
[154] "ASTS Applauds CMS for Continuing Immunosuppressant Protected Class Status," Available from the American Society of Transplant Surgeons, March 12, 2014, http://asts.org/news-and-publications/asts-news/article/2014/03/12/asts-applauds-cms-for-continuing-immunosuppressant-protected-class-status.

"Describe the Agency's current rationale for designating therapeutic categories of medications as "protected classes.""[155] His main concern was ensuring beneficiary access to important antipsychotic medications. As Chair of the Oversight Subcommittee, this is the expected emphasis for a letter from him. His priority was mental health legislation that he wrote and introduced in the 113th Congress that among other things further codified protected class status for antidepressants and antipsychotic medications. Mental health is particularly important because depression is a co-morbidity for many of the other diseases that the six protected classes treat like cancer and HIV. In the February hearing the Energy and Commerce Committee held, Dr. Murphy calls the six protected classes reevaluation, "an unscientific, callous and anti-medical decision."[156]

These letters all demonstrated the breadth of the Congressional response. Not only was it bipartisan and bicameral, but also several members signed multiple targeted letters. These provided an opportunity for Congress to make its voice heard.

The Administration had the opportunity to testify at a hearing that was held in February of 2014 by the Health Subcommittee of the Energy and Commerce Committee. The hearing focused on the proposed rule. In the majority committee memo released in advance of the hearing, there is no mention of the six protected classes outright. It provided a high level view of the Part D program and how CMS pays for its implementation. In the minority memo, the six protected classes are more thoroughly discussed. It focused specifically on the concerns that advocacy groups raised and the new criteria that CMS developed to reassess the protected classes. The hearing was on

[155] Dr. Tim Murphy, "Mental Health Letter," January 28, 2014, 2.
[156] Energy and Commerce Committee Hearing Transcript, "Messing With Success," http://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-Transcript-20140226.pdf, 77.

the entirety of the proposed rule, but for many members it was solely about the protected classes.

Jon Blum, who was the Principal Deputy Administrator and Director at CMS, did not address the agency rational for removing the protected classes from the proposed rule. He instead stated that, "It would be a mistake to assume that any current medications, especially brand-name medications, would no longer be broadly available on beneficiaries' current Part D plans as a result of our proposed policy change."[157] This assessment is based on what CMS had seen historically in the program concerning drugs that were not in the six protected classes. For these categories and classes CMS claimed a 79% inclusion rate.[158] Additionally, Mr. Blum stated, "Once the requirement to cover all drugs in a class was removed, we would expect manufacturers to negotiate for their products to remain on many formularies in order to retain as much market share as possible."[159] The expectation from CMS was that drug manufacturers would lower their costs of these drugs to retain market share on various PDPs. This does not acknowledge that PDPs may not be as keen to keep as many expensive drugs on their formulary. In his written statement, Blum states that they propose doing away with this provision because it inhibits competition, leading to higher costs.[160] The Administration also pointed to "insights obtained through practical experience with the programs – not only our experience but also that of stakeholders."[161]

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[157] Blum, Jon, *Opening Statement*. February 26, 2014, 6.
[158] Ibid., 6.
[159] Ibid., 6.
[160] Ibid., 4.
[161] Ibid., 5.

This did nothing to ease concerns over a lack of data. Many of those in opposition to the rule did not accept this as valid evidence on which to predicate such a significant change. The two studies CMS cited in the proposed rule are outdated and have limited data sets. One is limited to data from the first year of Part D only. That, coupled with CMS using anecdotal evidence to make such a drastic policy change, further undercut their attempts at justify the elimination of the protected classes.

During the hearing Dr. Gingrey, a Republican, responded passionately to the proposed rule, when he asserted, "You (the Administration) are trying to kill a gnat by torching a village."[162] He also accuses the Administration of trying to bring down costs and alter the Part D program in ways that benefit CMS but that hurt the beneficiary. As a member who was in Congress when the MMA passed in 2003, he was especially upset at the fact that CMS ignored Congressional intent and in his opinion, incorrectly reinterpreted the legality of their actions in the rule.

On the other side of the aisle, Dr. Christensen a Democrat from the Virgin Islands revealed inadequacies in the panel that was chosen to review the protected classes under the new criteria. Specifically, she asks if there was a transplant surgeon who served on the panel, and Mr. Blum said, "I don't believe so, but again, CMS proposed these changes in an open, transparent way."[163] There are few combinations more odd in Congress than Dr. Gingrey and Dr. Christiansen. Politically, demographically, and ideologically they differ on most aspects. On this point though, they wholeheartedly agreed. All of the member's questions came back to one main point; they just wanted to

[162] Energy and Commerce Committee Hearing Transcript, "Messing With Success," 124.
[163] Ibid., 79.

understand what CMS thought they were doing when they put this provision in the proposed rule.

As discussed in Chapter Two, interest groups and their structure have changed drastically in the past thirty years. They are now atomistic in nature. This lends itself to coalition building around certain issue areas as coalitions become necessary since interest groups are now so narrowly focused.[164] The Partnership for Part D Access is, "a coalition of healthcare stakeholders committed to maintaining access to medications under Medicare Part D, especially the categories and classes of drugs identified for unique patient protections."[165] The Partnership is made up of various stakeholders who have a vested interest in maintaining the six protected classes, such as The AIDS Institute, Alkermes, the National Alliance on Mental Illness, and Sunovian to name a few. The coalition represents both industry and interest groups. For example, Alkermes and Sunovian are pharmaceutical companies that each has a range of drugs that treat mental illness. The members of the coalition are diverse and wanted all of the six protected classes' provision rescinded. This was not the only coalition that formed to defeat the proposed rule. These coalitions narrowed the focus of much of what was being said on the rule as a whole by interest groups.

The Partnership also drew attention to the fact that in the proposed rule CMS does not use data to back up their claims that patients can now traverse the complex utilization management techniques and appeals process. CMS included no evidence that beneficiaries could handle this any better than they could in the past. They wrote, "CMS

[164] Weissert and Weissert, *Governing Health: The Politics of Health Policy* 129.
[165] Partnership for Part D Access, "Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," 1.

offers no evidence to support this proposition other than the passage of time."[166] They also state that the reports CMS used to argue that these categories and classes cost money, "fail to support the agencies conclusion; not one of the three reports actually presents data establishing that protected class drugs have higher prices."[167] The Partnership is a good example of how modern interest groups now come together to bring about change. This is done through a vast array of groups working together in a way unseen previously. They also highlight many of the key points that upset both Congress and interest groups about the proposed rule; primarily the lack of meaningful evidence from CMS.

In addition to the Partnership for Part D Access there was another unnamed coalition that was even larger. The coalition was comprised of 379 different organizations encompassing an even broader swath of the health care world than the Partnership for Part D Access. They wrote a letter to all of the relevant committee Chairman and Ranking Members. It was organized in opposition to the rule as a whole, and did allude to the six protected classes provision, "The rule would significantly reduce beneficiaries' choice of plans and medicines and lead to disruptions in care."[168] The organizations that joined the letter disliked the rule primarily because of the six protected classes provision. But because this was such a powerful coalition and it focused on the rule as a whole, it attracted strange bedfellows. PCMA who had in 2009 written comments expressing their disdain for the protected classes provision, joined this larger coalition that supported keeping the protected classes. It was comprised of smaller, more narrowly focused

[166] Ibid., 5.
[167] Ibid., 6.
[168] "Coalition Group Letter." *Medicare Today.* March 7, 2014. http://www.hlc.org/wp-content/uploads/2014/02/cmsletter.pdf.

interest groups as well as larger interest groups that would have fit into the iron triangle model. Also, drug companies who have a financial stake in keeping the six protected classes participated in these coalitions as well. They could participate more openly when partnering with relevant patient groups as the messages they put forth were bolstered by one another. Patients were advocating for access to drugs, and the drug companies were highlighting the important role they play in their patient's lives. It would have been odd to do so otherwise; it would not win them many friends. The discussion was safely steered away from the economic benefits the drug companies receive by having universal formulary coverage of their drugs.

The Medicare Payment Advisory Commission is, "a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program."[169] They were created by the Congress to provide advice on all issues relating to Medicare. Their comments are important to consider because MedPAC does not have one beneficiary group in mind, nor are they concerned with increase plan profits. They look objectively at the Medicare program and provide comments that balance all of these considerations. They stated, "In general, we support CMS's approach in applying objective criteria to determine drug categories or classes of clinical concerns, while balancing the goals of beneficiary access and welfare."[170] They expressed concern, however, over the way CMS was proposing to handle the antipsychotic class; that excluding antipsychotics from the protected classes due to concerns surrounding overutilization would not actually do away with this phenomenon. It would put more

[169]MedPAC Bio, Available from the MedPAC Website, http://www.medpac.gov/.
[170] MedPAC. "Request for Comments on the Medicare Program; Contract Year 2015 policy and technical changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, proposed rule." Washington, DC, February 28, 2014, 2.

individuals in the throes of the imperfect appeals process trying to gain access to their needed medications. Members of Congress also echoed this concern during the relevant hearing. Chairman Murphy sent a letter to this point as well. MedPAC approved of CMS' objective criteria to reevaluate the protected classes but warned them to proceed with caution. MedPAC's comments on this provision are only two paragraphs and are not as strongly worded as other comments. They are unique in that they are some of the only comments that support CMS in their decision-making. They were one of the few commenters able to achieve a rational balance between beneficiary access and the high cost of providing these drugs. It is also important to include due to MedPAC's position as a valued and trusted advisor to Congress.

The National Alliance on Mental Illness (NAMI) is a member of the Partnership for Part D Access. They also wrote and submitted their own comments that are specific to those who would be affected by change in their antipsychotics or antidepressants in particular. Interestingly there is some over-lap in the comments both organizations submitted. However, they focus more on the secondary issues related to individuals with mental illness that do not have access to their drugs. If for instance someone with a major psychiatric disorder comes off of their medications for even the seven-day period that CMS uses in their criterion, this can have huge consequences in the quality of care they receive and the quality of their life. NAMI states that, "these may include: loss of employment, hospitalizations, homelessness, criminal justice involvement, or even death."[171]

[171] National Alliance for Mental Illness, "Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule," 1.

NAMI bolstered their argument against the rule by including findings that demonstrate that psychiatric medication is not interchangeable. They cite multiple studies to make the point that, "formulary-driven medication switches," are extremely complicated and that it can take up to a year to find the right medicine for some patients.[172] This is contrary to how CMS interpreted clinical standards for mental health in the proposed rule. NAMI points out how beneficiaries would be unable to navigate the complicated beneficiary appeals process, and criticize CMS on the point that, "No data is provided suggesting that the exceptions process works."[173]

The appeals process has been a point of contention for CMS and the beneficiary groups since the start of Part D. With MedPAC expressing their concerns with the appeals process and CMS claiming them as adequate, the conversation is likely to be unproductive. Advocacy groups base their arguments on anecdotal information that shows how hard the system is to traverse. CMS defended the system they put into place and subsequently ran.

The American Medical Association (AMA) looked at the issue in their comments highlighting the burden this will add to physicians and how this could potentially translate into poorer quality care for patients. They state, "Part D utilization management policies and appeals processes translate into additional physician, patient, and staff hours expended to obtain medically necessary treatment."[174] The physician plays a role in helping beneficiaries navigate the complex appeals process, but often it cuts into time

[172] Ibid., 1 and 10.
[173] Ibid., 11.
[174] American Medical Association, "Medicare Program Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," March 7, 2015, 3.

they can spend with them or other beneficiaries. Again, this is anecdotal evidence but the AMA uses it as very powerful leverage.

A majority of these comments are predicated on the fact that beneficiary protections are first, important, but that second, the appeals process does not work and is extremely difficult to navigate. CMS states outright in the proposed rule that, "The formulary exceptions and appeals requirements facilitate obtaining any medically necessary Part D drug that is not on the formulary or that is otherwise subject to utilization management requirements."[175] "Facilitate" implies that it is easy to obtain drugs through and navigate the appeals process. CMS goes on to say, "We believe these requirements are comprehensive enough that additional access safeguards are needed only in those situations where a Part D beneficiary's clinical needs cannot be efficiently met."[176] It is clear that the beneficiary groups strongly believe clinical need cannot be 'efficiently met' for the six protected classes in their entirety.

It is hard to discern if CMS issued this proposed rule to be provocative or controversial in their actions, or if they simply did not realize the backlash their proposal would receive. They were trying to do away with an arguably superfluous policy that was only meant to be temporary by CMS from the beginning. Often times the agency works so hard on a proposal internally that they do not always think about what the consequences may be or what outside groups may think of their work when it is released. Even though CMS received such a strong response from Congress and interest groups, it

[175] Department of Health and Human Services, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 1941.
[176] Ibid., 1941.

does not necessarily mean that something was fundamentally wrong with what they were trying to do; only that they disagreed with CMS' objective.

The Outcome

The rule surprised Congress and interest groups. This was a theme that ran through all of the comments submitted and at the Congressional hearing. No one expected this proposal to be included by CMS. Congress, not wanting this proposed rule to move forward, reacted how they know best, by introducing legislation. Representative Renee Ellmers (R-NC), a nurse by training and a member of the Energy and Commerce Health Subcommittee, introduced H.R. 4160, "Keep the Promise to Seniors Act of 2014." She introduced the bill on March 6th and House Leadership planned a vote on the bill for the following week. The legislation would, "Prohibit the Secretary of Health and Human Services from taking any action to implement any provisions of the proposed regulation."[177] The prohibition in the bill encompassed the entirety of the rule, not just the six protected classes.

Republicans liked this legislation because it stopped all of the provisions from being acted upon, including the protected classes, and Democrats did not mind it because it would stop the protected classes from being changed. In a surprising turn of events, however, the vote on the legislation never took place.

CMS announced on March 10th, 2014, four days after the legislation was introduced and two months in advance of when the final rule came out in May, only a day before the vote on H.R. 4160 was to take place, that they would not move forward on the

[177] H.R. 4160, "Keeping the Promise to Seniors Act of 2014," https://www.congress.gov/bill/113th-congress/house-bill/4160.

six protected classes provision. In a letter they sent to members who expressed their concern CMS stated, "Given the complexities of these issues and stakeholder input, we do not plan to finalize these proposals at this time. We will engage in further stakeholder input before advancing some or all of the changes in these areas in future years."[178] In the final rule released in May of 2014, only one sentence addressed the six protected classes, "We are not finalizing any new criteria and will maintain the existing six protected classes."[179] There was no discussion of the comments they had received or any further explanation of the agency's rationale. In the letter they left their revisiting the rule as a possibility, but did not go so far in the final rule.

As mentioned in the prior section, CMS seriously undermined their own efforts to affect change in a variety of ways. When they attempted to include overutilization as part of their rationale to exclude antipsychotics from the protected classes, they confounded the issue at hand and upset the entire patient population impacted by the six protected classes. The role of Medicare changed dramatically when CMS became such a large payer for psychotropic medications. Initially they were seen as drugs utilized primarily by the dual eligibles. However as the Part D program aged, it became clearer that there was a problem with the over prescription of antipsychotics and, in particular, prescriptions for those individuals who are in nursing homes. CMS attempted to use the rulemaking process as an inappropriate vehicle to address this issue. Restricting access to medication is one way to lower its usage, but this will not stop bad actors from simply

[178] Secretary Marilyn Tavenner Letter to Congressman Henry Waxman, March 10, 2014.
[179] Department of Health and Human Services. "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule." *Federal Register* 79. No. 100 (May 23, 2014): 42 CFR 417, 422, 423 et al. http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf., 29847.

prescribing incapacitated nursing home seniors a different, covered antipsychotic or misdiagnosing them with disease states they do not have. Dr. Murphy addresses that in his letter to the agency, "The rationale is made without a factual basis, but even if it were to be true, eliminating Medicare beneficiary access to medication is not the solution to this problem."[180]

CMS cited 'insights obtained through practical experience' with their stakeholders that were not rooted in valid studies examining issues surrounding access of the six protected classes. Practical experience is not easily replicated, nor does it provide data to be shared with interested stakeholders. CMS did not formally study the issue before they felt the need to propose changes to the policy. This could have been as simple as issuing a report from their actuaries validating their position. To propose such a radical overhaul without solid quantitative information was a mistake. CMS relied on old, inadequate studies. They also provided no data or a compelling argument to counter the argument that the appeals process does not work. CMS did not attempt to address MedPACs assertion that the appeals process is flawed. This lack of data did not gain them support. It only made their arguments easily dismissible.

Due to legal restrictions, notably the Administrative Procedures Act, agencies cannot discuss issues surrounding a proposed rule with interested stakeholders before the rule is finalized and after the proposed rule has been released. However, there are no legal restrictions that would prohibit them from speaking about policies that may be considering. CMS did not do this before they released the proposed rule and left many, most importantly the relevant committees, feeling blindsided. Even though they had

[180] Dr. Murphy Letter, 2.

initiated rulemaking in 2008 and 2009, never finished, it was not enough of an indicator that this proposed change was being considered. CMS had not released any data or reports on the protected classes nor had they brought it up in other venues such as hearings or briefings prior to January of 2014. No one had any notice that a massive change was on the horizon, nor did they feel like they had been made privy to the rationale behind its inclusion. This was truly the major mistake by CMS and the six protected classes changes they proposed. No one expected it.

Carl Schmid, the Deputy Executive Director for the AIDS Institute addressed this point in his written testimony during the "Messing With Success" hearing on February 27, 2014. He stated, "One would think that if the Administration was contemplating any changes, the criteria for class review would be developed first with adequate public comment before it was applied."[181] He continued, "Instead a very arbitrary criterion was developed in secret and then arbitrarily applied at the same time."[182] This is how most everyone felt when CMS released the rule. CMS neglected to approach anyone outside of the agency prior to releasing the proposed rule leading them to state in their retraction letter, "We will engage in further stakeholder input," before moving on this issue again.[183] Clearly this is something that they should have done in advance. They may never have the opportunity to revisit the policy soon, because it has become so politically charged.

The consensus panel CMS assembled did not go far enough to protect beneficiaries. Interest groups felt that the establishment of the consensus panel and the

[181] The AIDS Institute, "Written Testimony of Charles Schmid, Deputy Executive Director, the AIDS Institute," 2.
[182] Ibid. 2.
[183] Tavenner Letter to Waxman.

development of the two criterion for inclusion should have been open to the public from the start. Instead, interest groups were left feeling that an anonymous and under-qualified panel arbitrarily decided the fate of the protected classes. CMS incorrectly thought that the panel was a suitable alternative to public comment.

CMS confounded their predicament in a multitude of ways. First they did not build their case with any new data on the six protected classes and chose instead to rely on dated and inadequate sources. Their concern with the over prescription of antipsychotics clouded their messaging even though many groups, including MedPAC, agreed that it was a problem. If CMS presented the antipsychotic issue separately, they may have been able to garner real support for reform for that class of drugs. Instead they faced significant opposition from groups like NAMI. Finally, the unexpectedness of the proposal took everyone by surprise. CMS gave no advanced notice that this proposal was being considered. The lack of prior warning and socialization of the idea, among the other issues listed before, led to well organized and impassioned response from interest groups. Republicans and Democrats were both so upset by the proposal that they worked across the aisle, as a Congress and not as different parties, to defeat the rule.

Chapter 4 – Findings and Implications

The unexpectedness of the proposed rule elicited a strong, knee-jerk response from Congress and the interest groups. Prior to January of 2014, CMS did not publically question the validity or necessity of the six protected classes in any forum, congressional or otherwise. They released no studies or data indicating that this was an issue they were actively examining. They did not raise the issue with Congress at other hearings on the Part D program in recent years. CMS did not attempt to undertake a 'demo' within the Medicare program in an attempt to see what their proposed changes would look like when implemented. Demos are frequently used to assess the necessity, value, and merit of newly proposed policies within Medicare and Medicaid. Oftentimes demos are performed to gather data that is used to further aid CMS in its decision-making. Congress was woefully unaware that CMS even viewed the protected classes as problematic.

It is rare that a proposed rule receives such pushback from Congress and interest groups. After extensively researching rulemaking under the Obama Administration, there were no rulemakings that elicited a similar response. However, towards the end of President George W. Bush's second term a proposed rule on intergovernmental transfers in the Medicaid program received a similar, if not more passionate response. Intergovernmental transfers in Medicaid allow for funds to flow to public hospitals and nursing homes that serve primarily vulnerable and poor populations.[184] When CMS proposed doing away with the transfers, there was a massive outcry against the policy, even more extreme than the six protected classes. They actually passed legislation, H.R.

[184] "CMS Proposes Elimination of Medicaid Intergovernmental Transfers," January 24, 2007, accessed from the Arent Fox Website, http://www.arentfox.com/newsroom/alerts/cms-proposes-elimination-medicaid-intergovernmental-transfers#.VPNXaVPF9_Q.

5613, Protecting the Medicaid Safety Net Act, to block the policy from going into effect even though the administration had put it in their final rule. A Democratic House and a Democratic Senate passed H.R. 5613 in opposition to a very unpopular Republican Administration. This step was not taken with the six protected classes in 2014, but the House still demonstrated how seriously opposed the proposal were by introducing legislation to block the rule and scheduling a floor vote. In both situations the proposals were unexpected and Congress ultimately deemed them unacceptable.

At times, it is advantageous for agencies to get ahead of Congress when it comes to innovative thinking and new ideas. That may be especially true in the world of medicine. But doing so without communicating with Congress at all is inherently dangerous. In the case of the six protected classes, a lack of communication rendered a sound policy proposal unpalatable because Congress felt blindsided. As the Democratic health care staffer pointed out in her interview, CMS should have and could have done a much better job reaching out to Congress in advance of the proposed rule. Specifically, she recommended briefings for the committees of jurisdiction before the release of the proposed rule. This would ensure that they were at least aware that such a large change was being considered. This could have tempered the Congressional response and paved the way for a more constructive and meaningful conversation.

While issuing a proposed rule is the agency indicating they want public feedback on a policy or an idea, it is not the time to socialize such a controversial policy change. This is a nuanced but important distinction between wanting feedback and socializing an idea. Socializing an idea allows Congress and interest groups to react in a meaningful manner when there is no imminent threat of action. Instead, if the administration drops a

controversial policy is into a proposed rule with no warning, they risk getting initial, frenetic responses instead. A proposed rule leads to a final rule, and final rules are codified in the Code of Federal Regulations. Rulemaking is an integral part of the policy process. As former Supreme Court Justice Holmes once said, "a rule is the skin of a living policy … its issuance marks the transformation of a policy from the private wish to public expectation."[185]

Congress is slow to react in most cases, and is often factious and divided in their response. But when taken by surprise they tend to act like an animal cornered by a predator, lashing out with a large amount of force and emotion. In the future a similar response can be expected in the face of a highly controversial, unsocialized, and poorly researched proposed rule from a regulatory agency. This is not unique to the health care space, as rulemaking occurs throughout the Executive Branch.

Interest group participation was unique in that so many groups came together under various coalitions to defeat the rule. Their atomistic nature allowed them to coalesce around defeating the proposed rule. This would not have happened thirty years ago in the health sector based on the way interest groups were arranged at that time. They were dominated by a few major groups and comprised a third of the 'iron triangle.' Interest groups today "understand bureaucracy to be another avenue for achieving policy goals."[186] Their goal was to block this proposed rule. They went after the agency with their full force expertly capitalizing on the situation to, "promote their narrow private interests using the rhetoric of the common good."[187] Many of the patient populations

[185] Weissert and Weissert, *Governing Health*, 171.
[186] Ibid., 172.
[187] Patel and Rushefsky, *Health Care Politics and Policy in America*, 29.

treated with drugs from the six protected classes are extremely small relative to the number of individuals in the Medicare Part D program. For example, immunosuppressants are utilized in a very limited population. Transplant patients and surgeons capitalized on the rhetoric that this would harm seniors and limit access for beneficiaries writ large to gain a more favorable policy outcome for themselves. They played their role as expected within the framework that was set up in Chapter Two.

The implications of these findings are broad and can be applied to every area of the federal government with a regulatory agency. If the administration wants to make a large or controversial change through rulemaking, they should only move forward if they have already socialized their proposal. This is important especially if the proposal has the potential to be particularly controversial. Education and outreach should occur in advance of the proposed rule being published for a move favorable outcome. This should also spur more meaningful conversations on proposed policies. It should be noted that this does not have to occur in a public forum. It could be done, for example, through closed briefings with relevant committee staff. It is also important to reiterate that legally, this would not create any problems for the agency under the APA.

In September 2014, six months after CMS rescinded the proposed rule, the issue was still on the minds of Members of Congress. In a hearing that month, Representative Mark Meadows (R-NC) asked the CMS Administrator point blank about the rescinded six protected classes provision, "Do I have your word that you will not put forth a rule that is similar in nature to the one that was pulled back."[188] Administrator Tavenner

[188] Amy Lotven and Michelle Stein. "Tavenner Says She's 'Not Interested' in Second Look At Part D Policies." *Inside Health Policy*. Washington, DC, September 23, 2014.

responded, “I’m not interested in bringing back the pieces that we pulled.”[189] Congress reigned successful.

[189] Ibid.

Chapter Five – Method of Inquiry

I initially began my research in a traditional academic sense looking for books and articles on the six protected classes. This yielded information on the Medicare program and Part D in particular, but the protected classes were rarely mentioned. There was one journal article, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, from the American Economic Review. This article utilizes data from only the first year of the Part D program. There was a second report, but it was commissioned and is not from academia. The actuarial firm McMillan executed the study, but again it had limited data as it was published only two years after Part D began. There is much to be desired in the academic literature on the protected classes. These are the articles CMS cited extensively in the proposed rule. It is beguiling that an entire policy discussion can be grounded in only two woefully inadequate studies and a plethora of speculation and anecdotal evidence.

After adjusting my strategy, I began to utilize the Congressional Research Service for more up-to-date and relevant information on Part D and in particular the six protected classes. No source possessed a full history of the protected classes. Most contained only a cursory nod to the policy's origin in the Medicare Modernization Act of 2003 but none went further. I attempted to construct a comprehensive history of the six protected classes in this work to fill this void in the literature.

The issue area is relatively new, having only existed for a decade. It is the lack of relevant data that makes it so difficult to study. The pricing information that would be necessary for substantive analysis is propriety and companies will not share it with researchers. This results in anecdotal evidence dominating the conversation on this topic.

The interviews with Congressional staffers are extremely important to include even though all of the staff spoke on the condition of anonymity. When working as a staffer, you develop your own personal thoughts and opinions on a whole host of topics, ideas, and policy proposals. However, staffers work for a member who has their own priorities and views on specific policies that may differ from those of staff. Because of this constant dichotomy, staffers often speak about various policy areas, but on the condition of anonymity. This should not discount their opinions or the inclusion of their perspective into this research. They provide some of the best insights and perspectives.

The Energy and Commerce Committee record proved useful when researching the hearing that was held in February. The transcript provided the quotes from members. The administration's testimony was also kept as part of the record.

The comment letters from the various organizations were collected from both the Internet through Google searches of the relevant organization's websites, some were sent to me from various individuals with whom I have professional relationships. Additionally, all documents from CMS were collected from the Internet and through searching the Federal Register.

The debate surrounding this policy proposal between the Administration, Congress, and interest groups was in no way an informed one, it was passionate. The fact that so little data existed on this topic was a major hindrance to working out an effective solution. What instead ensued was a panicked response from Congress fueled by anecdotal evidence. It is unfortunate that CMS cited, "stakeholder feedback," as the primary motivation for the changes proposed. In other instances CMS did not cite anything.

Chapter 6 - Conclusion

Congress does not like surprises. According to Weissert and Weissert, "The assumption is that agencies will do whatever Congress asks and do it well."[190] This is often the case. But when the agency goes down their own path that Congress does not like or does not see coming, they get upset. While it is true that there are many entities who help develop policy, Congress is ultimately where the 'primary policymaking responsibility lies,' when it comes to health care.[191] The first line of implementation is Congress. They are the genesis of all new health policy for programs the Federal Government runs. The reason Republican and Democrats worked so well together on this by intentionally signing bipartisan letters and unintentionally by agreeing to the same points during the Energy and Commerce hearing, was because Congress as a whole was slighted by an agency, not one political party over the other, but Congress.

Since the 1990s a shift occurred and had allowed for the rise of two important cohorts, the smaller more focused interest group that often has more targeted positions on certain issues and the subsequent coalitions formed by these smaller groups. Based on this shift and the atomization of interest groups it is expected to see coalitions form around issues such as this. This is exactly what happened on the protected classes issue and they ended up being wildly successful. The coalitions were also able to manage the messaging surrounding the proposed rule. Those who were in favor of the policy change proposed by CMS were kept quiet.

Interest groups were also successfully in keeping this off of CMS' agenda- extremely important measure of success if you are a lobbyist. Additionally, interest

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[190] Weissert and Weissert, *Governing Health*, 172.
[191] Patel and Rushefsky, *Health Care Politics and Policy in America*, 17.

groups successfully mobilized Congress in opposition to the rule. That is demonstrated clearly through the interaction between Dr. Burgess and the American Society for Transplant Surgeons. They personally thanked him in their press release on the issue after he had sent a targeted letter to the Administration on the drugs that affect their patients the most, immunosuppressants. This is no coincidence, only effective and targeted lobbying. It is this type of mobilization that led to the rule being rescinded.

As quoted on page five, prescription drugs represent the most rapidly growing costs for health care in the United States. The Wall Street Journal recently reported that, "Prescription-drug spending rose more than 12% last year in the U.S., the biggest annual increase in over a decade."[192] This is attributed to the presence of drugs like Sovaldi, a cure for Hepatitis C that entered the market last year. It costs an astounding $84,000 per course of treatment. With these increased costs and revolutionary drugs, Sovaldi completely changed how Hepatitis C is treated. An increase in utilization management techniques can be expected. The discussion over access, and especially unquestioned access for those that are very sick to expensive medications is not going away, it is only going to become more complicated. Formulary design will only grow in importance.

This is an incredibly important issue area. The idea that classes of medication need to be 'protected' can have major ramifications for how a prescription drug benefit is delivered to millions of Americans. No equivalent exists outside of the protected classes in the Medicare Part D program. But based on issues that have arisen with discriminatory formulary design on certain small group marketplace plans, the issue of drugs needing

[192] Joseph Walker, "Expensive Hepatitis C Medications Drive Prescription-Drug Spending," *The Wall Street Journal*, March 10, 2015, accessed March 10, 2015, http://www.wsj.com/articles/expensive-hepatitis-c-medications-drive-prescription-drug-spending-1425960214.

protection may shift the discussion outside of the Medicare Part D program. The conversations that occurred surrounding the six protected classes provision will no doubt set the stage for these future conversations and will remain relevant even outside of CMS promulgating any rules in the future.

Appendix

The six protected classes of drugs are antiretrovirals, antineoplastics, anticonvulsants, antipsychotics, antidepressants, and immunosuppressants. Antiretrovirals treat the HIV/AIDS virus. The regiment of drugs is complex. Patients take multiple drugs at one time to treat the virus and achieve viral suppression. If a treatment regiment is not adhered to, the virus can become resistant to treatment and nearly impossible to treat. Antineoplastics are used in the treatment of cancer, they are colloquially known as chemotherapy drugs. These drugs are extremely expensive and can be downright toxic. Antineoplastics are used in a variety of combinations. Often times drugs must be quickly switched in the treatment of cancer to combat new growth. Anticonvulsants treat seizures. Patients often try a variety of anticonvulsants before they find one that can effectively stop their seizures. Some patients never find a drug that works. Antipsychotics and antidepressants are used to treat mental illness, anxiety, and depression. These are complicated diseases to treat and often patients have more than one interrelated mental illness, such as anxiety and depression, or bipolar disorder. Patients with mental illness often do not stick to their medication regiment, making it even harder to effectively treat the illness. Additionally, it may take years of trial and error for someone with schizophrenia, for instance, to find a drug that reduces their symptoms effectively. Drugs will stop working or never work at all for some patients with mental illness. The final category of immunosuppressants is used to suppress a patient's immune system. They are most frequently used in transplant cases when the immune system must be suppressed so the body can accept the new organ. There are a limited number of drugs for physicians to use and these are a crucial part of making transplantation possible.

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