



January 24, 2019

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via <http://www.regulations.gov>

Re: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

The Partnership for Part D Access (the Partnership) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule titled, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" (the Proposed Rule).

CMS' work to address the affordability of prescription medications is critically important to Medicare Part D enrollees, and we want to ensure any proposals will result in the most appropriate care and outcomes for patients. Today, nearly three quarters of Medicare beneficiaries (43 million individuals) are enrolled in Part D plans. Many of these enrollees live with health problems, including multiple chronic conditions, cognitive impairments, and limitations in their activities of daily living, and many beneficiaries live on modest incomes. In 2018, over 12 million beneficiaries received a subsidy for their Part D coverage. Of these low-income individuals, nearly 8 million had very low income and were dually eligible for Medicare and Medicaid, including seniors and younger people with disabilities.¹ Individuals who are dually eligible tend to have more chronic conditions, as well as cognitive and functional limitations, than others on Medicare: more than half (58 percent) have a mental condition or cognitive impairment; one-third (37 percent) have five or more chronic conditions; and about one in six (18 percent) rate their health status as poor, more than three times the rate among other people on Medicare.²

The Partnership 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

¹ Kaiser Family Foundation analysis of CMS data files, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," May 17, 2018: <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/>

² Medicare Payment and Access Commission, *Report to Congress: Medicare and the Health Care Delivery System*, "Managed care plans for dual-eligible beneficiaries," June 2018: http://www.medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0

unique patient protections at section 1860D-4(b)(3)(G)(iv) (the “protected classes”). These medications are vital to the treatment of: (1) epilepsy; (2) mental illness; (3) cancer; (4) HIV-AIDS; and (5) organ transplants. The Partnership was founded to combat efforts to undermine consumer access to appropriate treatment by increasing policymaker awareness of the vulnerability of patients with these conditions and the potential impact of delayed or denied care. Given our mission, the Partnership is focusing its comments on the provisions in the Proposed Rule that expressly impact Medicare’s protected classes policy.

As we stated in our response to the Department of Health and Human Services’ (HHS) May 16, 2018, Request for Information, we appreciate the steps the Department is taking to develop ideas to address the cost challenges that threaten to limit patient access to prescription medications.³ We further appreciate Secretary Azar’s commitment to take a deliberate approach to finalizing any policy concerning the six protected classes.⁴ **However, we are very concerned with the Proposed Rule’s misunderstandings of both the congressional intent of the policy and the reality of how it is practically working for Medicare patients today.**

To this end, we are submitting with this letter a report the Partnership commissioned and released in November 2018. The report analyzes CMS’ Medicare Part D benefit design and formulary data from 2016, the most current year for which data is available. The analysis provides new insights into the tools plans are currently employing to manage utilization of drugs under Medicare’s six protected classes policy. As discussed in greater detail in the comments that follow, the findings suggest that plans have powerful negotiating tools that *already* allow them to exclude a significant number of drugs from their formularies and drive patients to fill prescriptions for drugs in the protected classes with lower-cost generic products.⁵ We do not believe CMS has considered these facts and the report’s specific findings in developing its rule.

Specifically, our primary concerns are summarized below:

New Impediments to Therapies for Chronically Ill Patients

- The agency has incorrectly assumed that the patient safeguards embedded in the protected classes policy first established by CMS through sub-regulatory guidance and later codified in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), are no longer necessary even though the Medicare Improvement and Patient Protection Act (MIPPA) and later the Affordable Care Act (ACA), codified the protected classes policy for all Medicare beneficiaries.
- Broadening prior authorization and step therapy policies within the protected classes, particularly for patients who are already stabilized on treatment regimes, will create barriers to prescription medications for Medicare patients with chronic conditions. As a result, this could undermine adherence to highly effective medication regimens, drive up

³ Available at: <http://www.partdpartnership.org/resources/partnership-submits-letter-on-hhs-drug-pricing-rfi>

⁴ Secretary Alex Azar statement at the National Ryan White Conference on HIV Care and Treatment, December 12, 2018: <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-2018-national-ryan-white-conference.html>

⁵ Partnership for Part D Access, “Medicare Part D’s Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs,” 2018: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf

medical costs for patients and the Medicare program, and erect unnecessary administrative hurdles for patients, their caretakers and providers.

- The proposed policies have a singular focus on lowering costs to the program and enrollees and are not supported by scientific evidence, clinical best practices, or analysis, particularly the policy allowing broader use of prior authorization and other utilization management tools.
- While we appreciate that CMS is attempting to limit additional patents on variations of an original drug, the policy as proposed could undermine patient access to truly innovative products. The agency has not specified how it will continue to ensure plans will cover innovative therapies designed to improve patient outcomes and adherence and reduce side-effects.
- CMS is over reliant upon its largely informal expectations for how Part D plans would design their formularies and the extent to which they would engage in negotiations with manufacturers of therapies within the protected classes. Further, the agency has not added specificity around the clinical criteria that will be applied to its revised formulary review or any additional oversight and monitoring that would be appropriate to ensure the well-being of Part D enrollees with chronic conditions.⁶

Ultimately, as written CMS' proposed changes will pit Part D sponsors against pharmaceutical manufacturers in hopes of bringing down the immediate price of a therapy without regard to the real-world impact on patients' experiences, outcomes, and total cost of care. Doing so comes at the expense of the most vulnerable Medicare beneficiaries and directly contradicts Congress' intent to ensure patients reliant upon medications from within these classes of medications can work with their providers to determine the therapy or therapies that work best for them and maintain their health.

The flaws in the proposed approach and the potential for significant harm to patients lead us to respectfully request the agency withdraw each of the three proposed exceptions. Enclosed, we provide additional information to support our request. In the event CMS moves to finalize any or all of these policies, we have endeavored to respond to the specific solicitations for comment with the goal of minimizing the adverse impact these exceptions are expected to present for patients.

I. The Proposed Rule Contradicts Congress's Intent to Protect Patients by Establishing and Strengthening the Classes of Clinical Concern

A. Legislative History Demonstrates Congressional Intent to Maintain Existing Classes

1. Initial Adoption of Protected Classes Demonstrates Rationale for the Policy

CMS crafted the protected class policy as a component of implementing the non-discrimination provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Those provisions require CMS to reject plans whose design and benefit structure (including formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals.⁷ CMS explained that it "instituted this policy because it was necessary to ensure that

⁶ 83 Fed. Reg. 62163-4.v

⁷ 83 Fed. Reg. at 62155.

Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”⁸ CMS reiterated this rationale in this Proposed Rule, consistent with the agency’s applicable proposed rule issued in January 2014.⁹ Consistent with that rationale, CMS policy protected access to: anticonvulsants (for epilepsy); antidepressants; antineoplastics to treat cancer; antipsychotics; antiretrovirals for HIV/AIDS; and immunosuppressants to prevent rejection of transplanted organs.¹⁰

When Congress established the Medicare Part D prescription drug benefit, it recognized that certain drug classes were vital to the beneficiaries whose lives, in many cases, depended on those drugs, and that their prescribers needed access to the full range of treatment options. For example, Congress expressed significant concern regarding the needs of Medicare beneficiaries with mental illness, as illustrated in the Conference Report that accompanied the MMA.¹¹ According to the Conference Report, CMS would be required to “ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression [and other conditions].”¹²

Like the Conference Report, a Senate colloquy that took place just before the MMA’s enactment emphasized that Part D would ensure broad coverage of medications to treat illnesses where access to the full array of therapeutic options is necessary to ensure patient safety.¹³ The colloquy pointed to the role of Part D’s non-discrimination provision in protecting beneficiaries with these types of illnesses. The exchange between these senators repeatedly emphasized the many layers of patient protections Congress had purposely built into Part D, including the fundamental protections available to beneficiaries “who need exactly the right medicine for them”:

Mr. BAUCUS, ranking member, Senate Finance Committee. . . . One of the things I am particularly proud about in this bill is the strong beneficiary protections You know, Senator Grassley, that there are certain diseases and conditions like AIDS, and epilepsy where having access to just the right medicine is especially important.

Mr. GRASSLEY, chairman, Senate Finance Committee. 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. ...

Mr. BAUCUS. Exactly. . . . [W]e require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry *all clinically appropriate drugs*.

Mr. GRASSLEY. I agree. And I am pleased with the backup protections in this bill. ...

⁸ Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

⁹ “Medicare Program; Contract year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (79 FR 1917) (hereinafter referred to as the January 2014 proposed rule)

¹⁰ 83 Fed. Reg. at 62155.

¹¹ U.S. 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.

¹² H.R. Rep. 108-391 at 770.

¹³ 149 Cong. Rec. S5882-03. 3

Mr. BAUCUS. These beneficiary protections are crucial for these vulnerable Medicare beneficiaries. . . . If a plan can't adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare. ...

We note no mention here – or anywhere else in any recorded legislative history of the MMA and subsequent legislation that we have been able to identify – that Congress in any way believed the need for these protections to be temporary, as CMS asserts in the Proposed Rule.¹⁴ All commentary in the legislative record prior to publication of the Proposed Rule reference the vulnerability of the relevant patient populations as the rationale for the protected classes policy.

2. The Medicare Improvement for Patients and Providers Act Strengthened the Protected Classes Policy and Established Two Criteria for Exceptions

Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) strengthened the protected classes policy by codifying it in the Part D statute, a strong congressional affirmation of the ongoing importance of these protections. Of greatest relevance, Congress rejected CMS' "substantially all" standard for Part D plan coverage of these classes by requiring that "all" such therapies be covered.¹⁵ This strong endorsement and enhancement of the policy occurred less than two years prior to enactment of the ACA and section 3307.

In promulgating this rule, CMS cited Section 176 as granting the Secretary authority to establish exceptions to the protected classes policy.¹⁶ Such exceptions may be granted to permit a Part D sponsor to exclude from its formulary a particular covered Part D drug in the protected classes of drugs or to otherwise limit access to such a drug, including through prior authorization or utilization management). The provisions of MIPAA state, and current CMS regulations and guidance specify, that any such exceptions must "(1) ensure[s] that any exception to such requirement is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV1-Infected Adults and Adolescents); and (II) includes a public notice and comment period."¹⁷

Through this Proposed Rule, CMS appears to meet one of the two criteria Congress specified in MIPAA (the requirement to provide a public notice and comment period). However, in clear violation of MIPAA and its own regulations, CMS has failed to document that the exceptions and additional flexibilities to the statutory requirements pertaining to the protected classes policy is based on scientific evidence and medical standards of practice, including in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV1-Infected Adults and Adolescents.

¹⁴ Ibid.

¹⁵ 42 U.S.C. § 1395w-104(b)(3)(G)(ii).

¹⁶ 42 U.S.C. § 1395w-104(b)(3)(G)(iii).

¹⁷ Ibid, CMS Medicare Prescription Drug Benefit Manual Chapter 6, Version (Rev. 18, 01-15-16), accessed January 10, 2018 at: Part D <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>

3. The Patient Protection and Affordable Care Act Reiterated Congress's Support for the Protected Classes while Giving CMS Authority to Improve Them

Section 3307 of the ACA continued Congress' clear support for the protected classes policy by updating the relevant provisions of MIPPA.¹⁸ After reiterating the requirement that Part D plans cover "all" drugs in a protected class, the ACA directed CMS to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern."¹⁹

Congress gave no indication, in the text of the ACA or in the accompanying body of legislative history, or as captured by related third party analysis, that it intended section 3307 be used to weaken the protected classes policy, including by making the protections temporary. A reading of section 3307 in the context of the policy's initial enactment and subsequent endorsement in MIPPA, less than two years prior to the passage of the ACA, can only conclude that the provision was a continuation of Congress' strong support for the protected classes policy. In scoring the policy, the Congressional Budget Office assigned no savings to the provision, a clear reflection that Congress had no intent that it be used to weaken the protected classes policy in an effort to cut costs.²⁰

Furthermore, Congress enacted section 3307 without modifying the Part D non-discrimination requirement in any way. Therefore, contemporaneous with passage of section 3307, Congress maintained the statutory provision that it and CMS both interpreted to require initiation of the protected classes policy in the first place. This is a clear signal that Congress intended that section 3307 serve as a platform for expanding and improving the baseline of protections initially effectuated under authority of the non-discrimination provisions of the MMA.

Ultimately, the clearest statement of Congress's intent in enacting section 3307 of the ACA comes from Congress itself. On February 5, 2014, every member of the Senate Finance Committee sent a letter to CMS Administrator Marilyn Tavenner rejecting the agency's approach to implementing the section. Finance Committee members stated that "Since the launch of Part D, Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medications" and the members went on to "strongly urge" CMS "to continue this important beneficiary protection as it exists today."²¹

On March 4, 2014, the House Energy & Commerce and Ways & Means Committees followed suit, with 50 of the committees' members sharply rebuking CMS' proposed implementation of section 3307. The committee members explain that section 3307 "reaffirm[ed]" Congress's determination that the existing six classes were appropriate for the protected classes policy before noting that CMS' proposal "will place harmful limits on Medicare beneficiaries' access to necessary medications."²²

While this Proposed Rule does not seek to directly eliminate one or more of the existing protected classes, taken together these proposed policies could have such a devastating impact on patient access to needed medications that that standard would be met. This is in conflict with Congress'

¹⁸ 42 U.S.C. § 1395w-104(b)(3)(G).

¹⁹ 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I).

²⁰ <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf>

²¹ U.S. Senate Finance Committee, Letter to Administrator Tavenner (February 5, 2014).

²² 15 U.S. House Ways & Means and Energy & Commerce Committees, Letter to Administrator Tavenner (March 4, 2014)

continued position that for certain types of conditions and therapies beneficiaries should have access to all available medications and CMS should not impose limits on these medications that would result in diminished access to these therapies, particularly for patients stabilized on current treatments.

B. Legislative Timeline Rebuts CMS Assertion that Circumstances Justifying Protected Classes Policy Have Changed

A linchpin of CMS' argument appears to be that circumstances for this vulnerable patient population have changed "dramatically" and that they are now fluent in navigating utilization management techniques, including denial of physician-prescribed drugs at the point of sale, coverage determinations, expedited exceptions, and the Part D appeals processes.

Unfortunately, Medicare beneficiaries afflicted with conditions addressed by the protected classes continue to have considerable difficulty in navigating Part D, even after the improvements that CMS has recently taken to assist Medicare beneficiaries with selecting a plan and navigating the appeals and grievance processes. Many patients with mental illness such as depression, for example, have cognitive difficulties and lack motivation to confront obstacles to their care.

Research has also clearly documented the interrelatedness among complicated illnesses and diseases. Studies have shown that close to 50 percent of individuals with HIV also have a mental illness. According to the American Cancer Society, 1 in 4 individuals with cancer has clinical depression. Further, studies have shown that persons with epilepsy have higher rates of depression and suicide. It is important that doctors have the ability to choose the right mix of medications for patients with such complicated health needs.

Sound clinical evidence and the clear intent of Congress is that the protected classes policy remain necessary to ensure safe, appropriate care for currently covered populations for the foreseeable future. While we carry hope for a breakthrough in treatment of any of these conditions, the fact that it is difficult for these patients to navigate the complex hurdles put in their way to comply with their treatment regimens is unlikely to change.

C. Purpose of Section 3307 is to Safeguard Classes of Clinical Concern, Not Cut Costs

CMS' pursuit of unsubstantiated claims regarding costs and utilization along with its apparent desire for comparability with the commercial market reflect a fundamental misreading of section 3307 of the ACA. CMS seeks to establish exceptions that would, among other things "...provide Part D sponsors with additional tools to negotiate as competitive a price as possible in order to provide drug pricing relief to Medicare Part D enrollees."²³ In pursuit of such goals, however, the agency fails to account for the overwhelming differences between the Medicare population and commercial market enrollees, which underlies Congress' intent in establishing the protected classes policy.

CMS has unduly tipped the scale heavily in favor of allowing Part D sponsors to drive price negotiations by limiting access to medications in the protected classes of drugs. This is evident when CMS' writes that "... we would predict future savings for both beneficiaries and the Part D program from both increased price competition as newly approved drugs come onto the market and more immediate savings if plans were able to remove some currently covered agents from their

²³ 83 Fed. Reg. at 62155.

formularies.”²⁴ There is no legislative history or support that Congress ever factored cost implications into its authorship of section 3307, which it understood would have no impact on the Federal budget at the time of passage.²⁵

II. The Proposed Rule Relies on Unsubstantiated Claims that Part D Sponsors Need New Tools to Negotiate Lower Costs for Drugs in the Protected Classes

A. CMS’ Savings Assumptions are Not Substantiated by the Reports Cited

In discussing its concerns that the protected classes policy limits Part D sponsors’ ability to negotiate with manufacturers, CMS states, “...many expert studies continue to demonstrate the role that the protected class policy plays in higher drug prices for protected class drugs in general.”²⁶ However, CMS appears to continue to rely upon the 2008 and 2011 studies it used in promulgating the agency’s 2014 proposal to develop the exceptions included in this Proposed Rule. While CMS does refer to its own internal analysis pertaining to rebate data, the explanation in the Proposed Rule lacks any meaningful or current detail to justify these changes, including aggregate rebate information broken down by the individual protected classes of drugs or products. As discussed in more detail later in our letter, the Proposed Rule also narrowly focuses on the rebates without incorporating implications on the total cost of care for Medicare patients as well as newer analysis of generic and brand utilization in the protected classes.

More specifically, three of the publicly available reports cited in the Proposed Rule do not present data establishing that protected class drugs have higher prices or lower Part D rebates than comparable drugs in non-protected classes. The 2011 HHS Office of Inspector General (OIG) report cited by CMS only repeats remarks of Part D plan representatives complaining about the rebates manufacturers paid on protected-class drugs.²⁷ These various “assertions” by Part D plan representatives are insufficient evidence to support putting patients at risk.

The 2008 Milliman report that CMS cites merely reflects the results of a survey the company conducted for the Academy of Managed Care Pharmacy (AMCP) asking for, again, the opinions of Part D plan representatives.²⁸ On its face, the survey instrument used for this “study” demonstrates clear bias, asking for the “opinions” of Part D plan sponsors on the “extent to which” (not “whether”) the protected classes policy prevents them from cutting costs, in part to build opposition to any expansion of the policy.²⁹ Furthermore, on page one, the report itself notes that, while clinical outcomes related to use of therapies covered by the protected classes policy “are of greatest importance,” it focuses only on the “simple costs” associated with “customary drug management practices.”³⁰

²⁴ 83 Fed. Reg at 62157.

²⁵ See CBO estimate for H.R. 3590 p. 8 (March 11, 2010), available at http://cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11307/reid_letter_hr3590.pdf.

²⁶ 83 Fed. Reg. at 62156.

²⁷ 83 Fed. Reg. at 62156.

²⁸ Ibid.

²⁹ “Potential cost impacts resulting from CMS guidance on ‘Special Protections for Six Protected Drug Classifications’ and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PL 110–275),” Milliman (2008), at 1, available at: <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279>.

³⁰ Ibid.

Finally, the study that CMS cites, which was published in the American Economic Review, only examines the first year of Part D (2005), and only focuses on “small” therapeutic classes, not the six protected classes per se. Further, its conclusion relating to price impacts are not statistically significant.³¹

B. The Proposed Rule Does Not Address the Significant Difference in Utilization Rates between Brand and Generic Drugs Across the Protected Classes

CMS also cites a study conducted by Milliman and published in 2018. This study, commissioned by America’s Health Insurance Plans (AHIP), focused on the rebates Part D sponsors negotiated for brand drugs in the protected classes.³² While this offers more recent data to inform the discussion on drug pricing, the study is limited in its relevance for justifying changes to protected classes of drugs because it narrowly focused on brand drugs. To support this point, we refer CMS to the November 2018 analysis performed by Avalere Health, in collaboration with the Partnership for Part D Access.

Avalere’s 2018 analysis of CMS benefit design and formulary data found that the majority of all prescriptions that Medicare beneficiaries fill for drugs in the protected classes are *already for generic products*. Across all protected classes, 35% of covered drugs are generic, yet 91% of prescriptions filled in 2016 were for generic products. Furthermore, generics represented more than 90% of the prescriptions filled within each of the categories for anticonvulsants (90%), antidepressants (97%), and antipsychotics (91%).³³

The extent of genericization hinges on the availability of such clinically equivalent products. However, once a generic market is established, this analysis shows that plans seek to incentivize use of generic products, including by placing generics on tiers that carry lower cost sharing obligations or that are subject to fewer clinical or administrative hurdles.

C. The Proposed Rule Does Not Account for Plan Benefit Designs that Already Exclude A Significant Percentage of Drugs in the Protected Classes

CMS repeatedly states that Part D sponsors must cover every drug, and reiterates its concern from 2014 that, “...an open coverage policy substantially limits Part D sponsors’ ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes.”³⁴ While Part D plans are required to cover all unique products in the protected classes, this requirement does not result in universal coverage of brands when clinically equivalent generic drugs are available. For example, if there is one brand product in a category and three generic products, the health plan sponsor may choose to cover just one of the four available drugs in this category.

According to the November 2018 Avalere analysis, across all classes Part D sponsors covered 67% of drugs (brand and generic combined) and 60% of brand drugs on average. In the class for

³¹ Duggan M, Morton FS, 2010. “The Effect of Medicare Part D on Pharmaceutical Prices and Utilization,” American Economic Review, American Economic Association, vol. 100(1), pages 590-607.

³² Prescription Drug Rebates and Part D Drug Costs: Analysis of historical Medicare Part D drug prices and manufacturer rebates.” July 2018. <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf>.

³³ “Medicare Part D’s Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs,” Partnership for Part D Access (2018), available at: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

³⁴ 83 Fed. Reg. at 62156

antidepressants, plans cover only 37% of brand name medications and for anticonvulsants they cover 46% of brand name products.³⁵

The analysis of CMS data demonstrates the majority of time, when there are multiple clinically equivalent drugs in a class, plans choose to cover one or more of the available lower cost generic products. This can allow plans to hold down costs and may enhance a plan sponsor's negotiating power with manufacturers. Yet, even with this protection, many patients must overcome layers of restrictive barriers that plans put in place to inhibit a patient's access to their needed medications.

D. The Proposed Rule Does Consider Plans' Current Use of Tier Placement as a Negotiating Tool

As previously discussed, the Proposed Rule relies upon reports of assertions from selected Part D sponsors, including assertions that "they received either no or minimal rebates for the drugs in these six classes," and that "there is little incentive for drug manufacturers to offer rebates for these six classes of drugs because they do not need to compete for formulary placement."³⁶ The November 2018 Avalere analysis directly contradicts these assertions, and thus the invalidates CMS' basis for changes to protected classes policy.

According to the November 2018 Avalere analysis, nearly three-quarters of all drugs in the six protected classes are placed in a non-preferred or specialty category, with 78% of branded products categorized as non-preferred or specialty and 66% of generics also subject to placement on the higher tiers.³⁷ Higher tier placement means patients are subject to higher cost sharing, additional authorization for coverage, and other requirements, which in turn allows plans to manage utilization and encourage greater use of lower-cost generic drugs. While 33 percent of protected classes drugs are categorized as specialty tier, these same drugs represent only 1 percent of filled prescriptions.

A separate analysis performed by Avalere on behalf of the National Kidney Foundation found that Part D sponsors are aggressively using utilization management and specialty tier placement for immune suppressant products. In fact, the analysis shows that Part D plans have *higher* rates of specialty tier placement than Exchange or employer plans, with 17 percent of Part D sponsors placing immune suppressants on specialty tier as compared to 1 percent of employers and 8 percent of exchange plans.³⁸

Similar to formulary placement, tiering can allow plans to hold down costs and may enhance a plan sponsor's negotiating power with manufacturers. The November 2018 Avalere analysis makes it clear that plans have the tools they need to drive patients to the plan's preferred medication and are aggressively using these tools. Therefore, the policies included in the proposed rule will serve to harm patients and increase rather than decrease overall Medicare costs.

³⁵ "Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs," Partnership for Part D Access (2018), available at: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

³⁶ 83 Fed. Reg. 62156.

³⁷ "Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs," Partnership for Part D Access (2018), available at: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

³⁸ "PlanScape® Review of Formulary Coverage: Prepared for NKF: Analysis of Selected Immune Suppressants" Avalere analysis prepared for the National Kidney Foundation, November 2015.

III. CMS Ignores Countervailing Costs Associated with Destabilizing Patient Care

The Partnership is very concerned that CMS' aggregate savings estimate did not assess the implications of the proposed Part D changes in their totality, i.e., by assessing potential cost-increasing and cost-shifting interactions within the broader Medicare program (Parts A and B), and to Medicaid. In previous CMS guidance, the agency has articulated that limiting access to the most appropriate medications will drive higher costs in Medicare Parts A and B by increasing admittance to inpatient hospital care and EDs due to the destabilization of patients' conditions. The agency also has stated that "factors described in our formulary guidance indicated that interruption of therapy in these [protected] categories could cause significant negative outcomes to beneficiaries in a short timeframe."³⁹

CMS states that future savings for both beneficiaries and the Part D program would manifest from "...both increased price competition as newly approved drugs come onto the market and more immediate savings if plans were able to remove some currently covered agents from their formularies."⁴⁰ This assessment appears contradictory to the rule's proposed exception which would limit access to single-source products and biologics.

Further, the corresponding savings estimated to stem from additional utilization management tools and the corresponding limits on access does not, however, quantify the beneficiary impact of such changes in modifying established treatment regimens, which may involve the weaning off of dosages and re-titrating to the therapeutic level; delays in filling the new prescription; issues with tolerability of the new prescription – including the presentation of new, unforeseen side effects – or other barriers affecting the beneficiary's propensity to adhere.

Additionally, limiting beneficiary access to vital medications will drive higher costs in Medicare Part A and Part B and Medicaid by increasing the need for inpatient care and emergency department visits due to the destabilization of patients' conditions. The costs associated with this care often is not borne by the Part D plan, but would increase overall costs to Medicare and Medicaid.

A study issued in 2015 and updated in April 2018 by researchers at Northwestern University's Kellogg School of Management and the University of Texas at Austin highlights how "profit-maximizing" Part D plans are incentivized to limit benefits or increase certain costs for which Part D plans are not responsible under Medicare (e.g. hospitalizations).⁴¹ As detailed in the study, Part D plans are explicitly encouraged to reduce drug spending without bearing financial responsibility for the holistic health of the patient. The authors conclude that in covering drugs less generously, Part D plans end up costing traditional Medicare \$475 million per year.⁴² Another study found that formulary restrictions within the Medicaid program appear to lead to worse outcomes for patients with major depressive disorder and increased the probability of an MDD-related hospitalization by

³⁹ CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?": <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf>

⁴⁰ 83 Fed. Reg. at 62157

⁴¹ Starc, A., and Town, R.J. National Bureau of Economic Research, Working Paper No. 21783. Externalities and Benefit Design in Health Insurance, Issued December 2015, revised April 2018, <http://www.nber.org/papers/w21783.pdf>

⁴² *Ibid.*

nearly 17 percent with no significant reductions to pharmacy or total spending. Importantly, there was no evidence that these restrictions resulted in any net savings for Medicaid.⁴³

Similarly, a June 2016 Working Paper published by the National Bureau of Economic Research (NBER) examines policies which may incentivize some Medicare Advantage plans to use drug formulary design to encourage enrollment by patients with medical conditions that are more profitable under traditional Medicare.⁴⁴ The researchers also find evidence that these plans more generously cover drugs that are likely to minimize health care costs, compared to standalone Part D plans. These studies reinforce the importance of Medicare's protected classes in limiting future medical complications, hospitalizations, and additional costs to the Medicare program.

A variety of published clinical studies document the adverse impacts that ensue when beneficiaries with mental illness, for example, experience delays or discontinuation of appropriate care. Research has found that mental health patients whose psychotropic medications are discontinued may relapse to more severe episodes and require psychiatric hospitalization.⁴⁵ Furthermore, disruptions in medication continuity among psychiatric patients are associated with high rates of symptom relapse or exacerbation, hospitalization, and other adverse consequences.⁴⁶ Patients who experienced an access problem were more likely to have an emergency department visit for the treatment of a psychiatric illness.⁴⁷

Furthermore, according to the American Society of Transplantation, inability to access proper immunosuppressive medications and combinations will lead to increased rates of chronic immune rejection characterized by organ injury, patient suffering and ultimately even death.⁴⁸ CMS' policy would also "dramatically increase the need and costs for constant drug level monitoring ... [and] the number of necessary patient visits to evaluate the changing therapies."⁴⁹

Additional research in the oncology space found that reduced use of necessary medicines increases the probability of having an ER visit and patients' health care costs.⁵⁰ Adding to the body of research, the Kaiser Family Foundation found, among other conclusions, that inadequate or lack of access to care often leads to adverse health outcomes.⁵¹

For example, the Kaiser piece stated:

A ... study of Medicare beneficiaries found that savings from increasing copayments for physician services and prescription drugs led to additional costs from increased

⁴³ Seabury, Seth, Lakdawalla, Darius, Walter, Deborah et al., "Patient Outcomes and Cost Effects of Medicaid Formulary Restrictions on Antidepressants," Forum for Health Economics and Policy, Volume 17, Issue 2, Pages 153–168, 2014.

⁴⁴ Lavetti K, Simon K. National Bureau of Economic Research, Working Paper No. 22338, "Formulary design in Medicare Part D plans," June 2016, nber.org/papers/w22338. Published. Accessed May 15, 2017.

⁴⁵ Smith, Kenneth J. et. al., Cost-Effectiveness of Medicare Drug Plans in Schizophrenia and Bipolar Disorder, 19:2 Am J Manag Care 55 (2013).

⁴⁶ Huskamp, Haiden A., PhD. et. al., Part D and Dually Eligible Patients with Mental Illness: Medication Access Problems and Use of Intensive Services, 60:9 Psychiatric Services (2009).

⁴⁷ *Ibid.*

⁴⁸ American Society of Transplantation, Letter to CMS (February 18, 2014)

⁴⁹ *Ibid.*

⁵⁰ Subramanian, S., 2011. Impact of Medicaid Copayments on Patients with Cancer: Lessons for Medicaid Expansion Under Health Reform. Medical Care, September, 49(9), p. 842–847.

⁵¹ Kaiser Family Foundation, Premiums and Cost-Sharing in Medicaid: A Review of Research Findings (Feb. 2013), available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/02/8417-premiums-and-cost-sharing-in-medicare.pdf>.

hospitalizations. For those in the worst health, the additional costs from increased hospitalizations were larger than the savings accrued from the increased copays for physician services and prescription drugs, with hospital spending increasing by nearly \$2 for every \$1 saved on other spending.”⁵²

In the case of antiretrovirals, there are few low-cost, generic options available. The lack of generic drugs, combined with fine-tuned individualized therapy, will not produce the large-scale cost-savings that the proposal anticipates. Furthermore, imposing step therapy and prior authorization goes against treatment guidelines and several studies have shown that prior authorization results in fewer prescriptions filled and lower rates of adherence.⁵³ These two factors not only pose threats to individual and public health, but will ultimately burden other parts of the Medicare program as a result of increased hospitalizations.

As part of its overall vision, CMS is taking significant steps to refocus its programs on patients and to reduce burden for providers. However, at a minimum, the proposal to expand the authority for plans to use prior authorization and utilization management could undermine progress toward these goals. Currently, many of the staff working in provider-based sites, including community mental health centers, do not have the clerical support to engage in disputes with insurance companies around the validity of a plan’s prior authorization requirement.

IV. The Proposed Rule Misrepresents the Limited Options Available to Medicare’s LIS Patients.

CMS’ proposal misunderstands the limited options available to Medicare patients who rely on the Low-Income Subsidy (LIS) to afford their medications. In Secretary Azar’s statement announcing this new policy proposal, he asserted that “... if seniors don’t like a plan that takes advantage of these new flexibilities, they are in the driver’s seat. They have the option to choose a different plan that better meets their needs.”⁵⁴

This misrepresents the reality of options that are available to low income Medicare beneficiaries, including those dually eligible for Medicare and Medicaid who receive the LIS. While patients do have the option to change plans during the annual open enrollment period, this does not mean patients can always choose a plan that better meets their medication needs at a cost they can afford.

First, the most vulnerable patients who are dually eligible for Medicare and Medicaid may enroll in any plan in their area, but they only receive the LIS that provides premium free coverage and reduced cost sharing from a designated set of Part D plans. The subset of these “benchmark plans,” which are premium-free for LIS eligible enrollees changes annually, which essentially forces the majority of beneficiaries to change plans.

When a plan no longer meets the benchmark criteria or will no longer offer coverage, CMS reassigns many of the LIS enrollees to a different premium free plan in their area. In 2018, Part D plans

⁵² *Ibid.*

⁵³ U.S. Department of Health and Human Services, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, available at <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/30/adherence-to-the-continuum-of-care>.

⁵⁴ Alex Azar, Secretary of the Department of Health and Human Services and Seema Verma, Administrator of the Centers for Medicare & Medicaid Services, statement, November 26, 2018: <https://www.hhs.gov/blog/2018/11/26/proposed-changes-lower-drug-prices-medicare-advantage-part-d.html>.

available to LIS enrollees with no premium decreased 6 percent from 2017 levels to 216 plans.⁵⁵ In 2018, nearly one million LIS beneficiaries — just over one in 10 LIS enrollees in standalone Part D plans — were enrolled in Part D plans that did not qualify as benchmark plans in 2019. In 2019, on average LIS beneficiaries have six benchmark plans available to them, or about one-fifth the average number of PDP choices available overall – the lowest number of benchmark plans since the Part D program began. In some regions, there are as few as two benchmark plans to choose from.

⁵⁶ The existing protected class policy has helped to ensure reassigned enrollees are able to enroll in a more affordable plan without disrupting their access to treatments that fall within the protected classes.

Further, patients, including dually eligible enrollees, may not always know the medication that works best for them at the time they are eligible to choose a plan. As a result, they find themselves in a situation where they enroll in a plan that covers a particular therapy and subsequently learn that a different product within the protected categories or classes of drugs is better able to address their care needs. Again, the current limitations on plans around prior authorization and utilization management provide a much-needed protection for Medicare patients who need treatments from among the protected categories and classes of drugs.

V. The Proposed Rule Exceptions Put Patients at Risk and Lacks Supporting Scientific Evidence.

A. Broader Use of Prior Authorization Hinders Access to Care

In the proposed rule, CMS would allow plans to use prior authorization as is currently allowed for all other drug categories and classes (except for antiretrovirals), including to implement step therapy for protected class drugs or to determine use for protected class indications or both, without distinguishing between patients initiating treatment and those who are already stabilized on treatment. The proposed rule would – for the first time, and contrary to federal treatment guidelines – allow prior authorization and step therapy for both new starts and existing treatments for people with HIV. This proposal subverts Congress’ clear intent to establish protections specific to Medicare patients who need the lifesaving treatments in the protected classes. Expanded authority to apply utilization management requirements placed on drugs in protected classes can add new access barriers for Medicare patients.

Notably, in proposing this policy, CMS fails to take into account the extent to which Part D plans can – and do – already use utilization management techniques such as prior authorization and step therapy for individuals newly starting treatment to promote lower-cost options in the protected classes. Across the six protected classes, plan sponsors employ utilization management tools at least 40 percent of the time. Plans apply utilization management policies for a majority of branded drugs (54 percent) in the protected classes. In particular, prior authorization is already required for nearly half of the brand drugs (49 percent) in the protected classes to ensure that treatments are being used for clinically appropriate purposes.

Furthermore, CMS does not provide detail for criteria they would use to evaluate impact to patients on existing stable therapies. In particular, provisions in the proposal that would allow step therapy and other potentially restrictive utilization management strategies could not only delay patient

⁵⁵ Medicare Payment and Access Commission, *Report to Congress*, “The Medicare prescription drug program (Part D): Status report,” March 2018: http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

⁵⁶ Kaiser Family Foundation, “Medicare Part D: A First Look at Prescription Drug Plans in 2019,” October 16, 2018.

access to proper treatments, they could potentially lead to irreversible disease progression and other significant patient health risks.

Moreover, CMS' proposal upends its long-standing, evidence-based policy which "...[I] ensures that any exception to such requirement is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents)..." The current US government HIV treatment guidelines state that prior authorizations for HIV drugs "result in fewer prescriptions filled and increased nonadherence.... and have substantially reduced timely access to medications." Step therapy is not a clinically acceptable practice in the treatment of HIV due to the danger of developing resistance to an entire class of drugs and potential side effects.

For these reasons, we strongly urge CMS to preserve the existing statutory and regulatory protection for patients established on a particular drug therapy rather than relying on CMS' expectation and annual review of plan submissions. As we have noted, the November 2018 Avalere analysis finds that plans already employ significant prior authorization and step therapy among protected class drugs for patients newly starting therapies.

CMS also sought input on specific patient population(s), individual patient characteristic(s), specific protected class drugs or individual protected drug classes that would require additional special transition or other protections and how such population(s) can be consistently identified. However, the statutory language already identifies specific patient populations and protected classes of drugs that require the very protections that would be subject to the exceptions. We request the agency remain in compliance with federal statute detailing existing protections, which were designed to ensure specific Medicare patients can access the therapies that work best for them.

B. Excluding Single-Source Drugs or Biological Products Would Limit Access to the Most Effective Treatments for Patients

The second new exception CMS seeks to add specifies that even if a new formulation of a single-source drug or biological product in the protected class becomes the only formulation available, Part D sponsors could exclude it from their formularies, except as required by the agency's other formulary requirements. CMS also notes that such changes would be subject to review and approval, as part of the agency' annual formulary review and approval process. CMS offers no rationale for this policy other than one related to cost.

Here CMS again favors cost considerations over the well-being of patients who could benefit from truly innovative medicines that are introduced in the marketplace. For example, advances in cancer treatment have resulted in many therapies that are designed to target very specific conditions and oftentimes have no therapeutic equivalent. Allowing plans to cover just one drug per class or subclass could result in the exclusion of, for example many unique cancer therapies and innovative long-acting medications for schizophrenia, leaving patients unable to find a plan that will cover the only potentially lifesaving drug to treat their condition.

Further, while Congress clearly has recognized that patients who need medications from the protected classes are understood to have more complex health care needs that require additional safeguards, the proposed new standard would be more restrictive than the general policy

requirement in Part D that requires plans to cover at least two medications for each class and category of medication.

We also remain concerned with the lack of transparency around the criteria CMS will employ in its annual review process and whether this will be sufficiently clinically sound as to protect patients' access to effective therapies. If CMS proceeds with this policy, we request that the final rule clarify that true innovative advancements are not included in this policy.

C. Pricing Threshold for Protected Class Drug Formulary Exclusions

CMS's third proposed exception would allow Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. Similar to previously noted concerns, this exception is grounded solely in the cost of a therapy and fails to meet the statutory requirement to have a basis in scientific evidence and medical standards of practice. By allowing plans to completely exclude new formulations of drug therapies, this proposal denies patients access to innovative new medicines. The protected classes policy was designed to ensure providers could tailor treatment regimens to meet the needs of their patients.

Furthermore, we note that single source drugs comprise a small percent of the prescriptions filled across the protected classes. The November 2018 Avalere analysis found that a significant majority of all prescriptions filled for drugs in the protected classes are for generic products. In fact, only nine percent of scripts filled for drugs in the protected classes are for brand products. Since these single-source products comprise a small minority of scripts filled, it can reasonably be expected that this proposed exception would have minimal impact on the price of drugs in the protected classes and thus calls into question its likelihood of helping to achieve CMS cost cutting goal.

Should CMS refuse our request to rescind these proposals and instead proceed with this exception policy, we urge the agency to address the following issues. We believe these are critical to minimizing the harm to patients that could result from the proposed policy changes.

- 1) At a minimum, CMS should conduct further analysis of the patient impact associated with its proposed exception, including a total cost of care analysis by class of medications that incorporates the findings from the November 2018 Avalere analysis.
- 2) CMS proposes to use CPI-U to calculate the rate of inflation above the baseline price for a particular drug or product, but the agency offers no analysis of the projected impact on patient access to therapies in the protected classes, either based on historical impact or future modeling. We are concerned this threshold could give Part D plans license to design discriminatory benefit plans. We urge the agency to conduct analyses demonstrating the potential impact on coverage, including a comparative analysis with alternative pricing thresholds to the CPI-U.
- 3) CMS also proposes that, if the WAC for any NDC assigned to the drug increases faster than inflation, that the Part D sponsor can exclude from its formulary all NDCs assigned to that drug. In response to CMS' request for comment, in this situation, we oppose allowing Part D sponsors to exclude all NDCs assigned to that drug from the formulary.
- 4) We urge the agency to clearly state in the regulatory text that Part D plans can only effectuate permissible changes to drugs in a protected class or category through the

annual formulary submission process -- not throughout the entire plan coverage period. Patients with conditions that require treatment with therapies from among the protected classes require continuity in the drug treatment that is found to work best for them. While individuals who are dually eligible are permitted to change plans throughout the year, this is not permitted for the non-dual Medicare population who depend on therapies included in the protected classes. Allowing plans to selectively exclude drugs from within the protected classes at any point in the plan year would result in significant disruption in clinical care for patients.

- 5) CMS proposes that Part D sponsors would be responsible for monitoring price increases, determining the cumulative CPI-U increases for the corresponding applicable periods, and deciding whether they wish to submit a formulary that excludes protected class drugs with price increases that exceed the rate of inflation. Given the medical complexity of patients who benefit from the protected class policy, we request the agency provide additional detail on its oversight and monitoring strategy that will ensure the accuracy of plans' finding with respect to price increases.
- 6) While CMS stated the data demonstrate minimal growth in the allowed cost per day supply for non-protected class brand drugs, we note that CMS has chosen to only apply this policy to protected class brand drugs. We request the agency provide further explanation for selectively applying this exception to the protected classes policy.
- 7) In order to maximize the impact this exception policy would have on addressing high-cost drugs in protected classes, CMS solicited comment on a policy it considered to apply the price threshold exception to *all* drugs in the protected classes of a given manufacturer if *any one* of those drugs' WAC, when compared to the baseline WAC, increases beyond the cumulative rate of inflation. The agency also suggests allowing a Part D plan to exclude a protected class drug from its formulary for any future contract year once its WAC increased more rapidly than the cumulative increase in inflation. We oppose both proposals that CMS considered. These overly sweeping policies would add new, unjustified hurdles for patients needing access to medications within the protected classes as well as Medicare patients more broadly. Such a policy would further pit manufacturers against insurers at the expense of Medicare beneficiaries. Further, CMS has offered no clinical support for an exception policy that would limit access to particular therapies in the protected classes in perpetuity based on market conditions at a single point in time.

VI. Conclusion

The Partnership appreciates your consideration of our concerns and recommendation not to advance the proposed changes to the protected classes policy. We are committed to working with CMS on behalf of Medicare patients to advance proposals that help ensure uninterrupted access to treatments and maintain access to quality care.

Sincerely,

A handwritten signature in black ink that reads "Charles Ingoglia". The signature is written in a cursive, flowing style.

Chuck Ingoglia, MSW
Executive Director, Partnership for Part D Access
Sr. Vice President, Public Policy & Practice Improvement, The National Council

Enclosure:

“Medicare Part D’s Six Protected Classes Policy: A Balanced Approach to Provide Patients
Access to Medications While Allowing Powerful Tools to Control Costs”



Medicare Part D's Six Protected Classes Policy

*A Balanced Approach to Provide Patients
Access to Medications While Allowing
Powerful Tools to Control Costs*

Partnership for Part D Access

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EXECUTIVE SUMMARY

A new study performed by Avalere Health, a leading strategic advisory company, and sponsored by the Partnership for Part D Access provides new insights into the tools Medicare Part D plans are currently employing to manage utilization of drugs under Medicare’s six protected classes policy. The protected classes policy is designed to ensure that Medicare patients with some of the most serious health conditions — cancer, HIV, transplant recipients, epilepsy, and mental illness among others — have access to the full range of medicines recommended by their physician.

According to the Avalere analysis Part D plans are using formularies and employing a range of utilization management and other tools such as coinsurance and “fail first” policies to encourage Medicare beneficiaries to use lower-costing medications for both brand and generic medications across the protected classes. For example, nearly three-quarters of all drugs in the six protected classes are placed in a non-preferred or specialty category, with 78% of branded products categorized as non-preferred or specialty and 66% of generics also subject to placement on the higher tiers. Part D plans place drugs from the protected classes on high tiers (non-preferred or specialty) 73% of the time. For brand drugs, plans use this high tier placement 78% of the time and 66% of the time for generics.

Plans are using the wide regulatory authority granted to them to direct patients to the lowest cost option available. For the Medicare patients who need a particular formulation of a drug, the six protected classes policy is intended to ensure patients are able to access the medication their physician prescribes. Yet, even with this protection, many patients must overcome layers of restrictive barriers that plans put in place to access their needed medications.

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Part One

Overview of Medicare's Protected Classes Policy

When Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Senators repeatedly emphasized the role of protections, including the protected classes, available to beneficiaries who need “exactly the right medicine for them.”¹ During implementation of the MMA, which created the Medicare Part D drug program, the Centers for Medicare and Medicaid Services (CMS) issued sub-regulatory guidance directing prescription drug plans (PDPs), through contract provisions, to cover “all or substantially all” medications within six classes and categories that the agency identified.² These categories are: anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants (for the treatment of transplant rejection).

However, over time it became clear that adherence to the sub-regulatory guidance was uneven among plans. In 2008, Congress established under Section 176 of the Medicare Improvements for Patients and Providers Act (MIPPA), the Six Protected Classes of drugs under Medicare Part D. MIPPA codified CMS’ existing guidance. Specifically, it required Medicare Part D plan sponsors to include in their formularies access to all or substantially all drugs in the six identified classes and categories of priority. MIPPA also specified two statutory criteria that CMS had to use in identifying additional classes of clinical concern: (1) where restrictions on that class would have major or life threatening consequences; and (2) where there is a significant need for individuals which a disease or disorder treated by the drugs in the class to have access to multiple drugs within that class.

In the Affordable Care Act (ACA) Congress reaffirmed its reliance on the two-part test established under MIPPA. The ACA also codified the six existing protected classes and categories by name, and expanded coverage to include all drugs within these six classes and categories until such time as the Secretary makes changes. The regulations that have governed the policy allow for plans to cover one drug of clinical equivalence in each class.³ For example, if there is one brand product in a category and three generic products, the health plan sponsor may choose to cover just one of the four drugs in this category.

¹ 149 Cong. Rec. S5882-03.

² Centers for Medicare & Medicaid Services, “Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements” (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>

³ According to the 2016 iteration of the CMS’ “Medicare Prescription Drug Benefit Manual,” “substantially all” in this context means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with the following exceptions: multi-source brands of the identical molecular structure; extended release products when the immediate-release product is included; products that have the same active ingredient or moiety; and dosage forms that do not provide a unique route of administration.

In January 2014, based on a belief that plans did not have the tools to adequately manage the drug benefit, the Centers for Medicare and Medicaid (CMS) proposed changes that would have denied access to these vital medications. Under the proposal, CMS would have removed the protected status of antidepressants and immunosuppressants for the 2015 coverage year, and antipsychotics in 2016.

In response to strong congressional and stakeholder opposition, CMS eventually announced that the agency would not finalize the proposal to eliminate protected class status, although they acknowledged that they may look to advance these proposed changes “in future years.” More recently, in June 2016, the Medicare Payment Advisory Committee (MedPAC) renewed stakeholder concerns by again recommending that two of the protected classes be eliminated. And in May 2018, the Department of Health and Human Services (HHS) released a new Request for Information seeking further input on whether they should pursue additional changes to the protected classes policy.

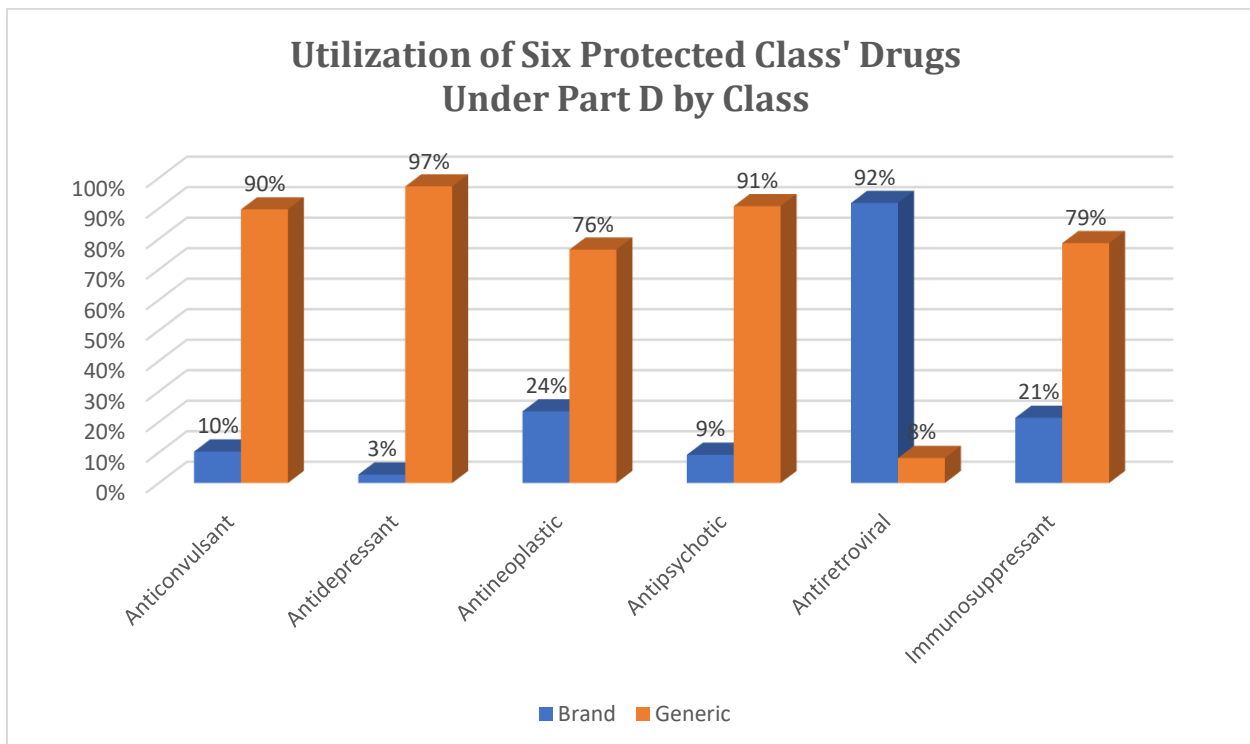
Part Two

Key Findings

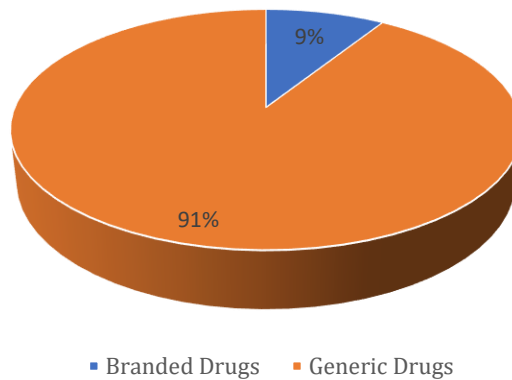
The following results from the Avalere study demonstrate that as currently implemented, Medicare’s six protected classes policy is “threading the needle” by ensuring access to a full range of drugs for patients who have specialized treatment needs while also providing plans with meaningful tools to manage front end access as well as overall costs.

A significant majority of all prescriptions filled for drugs in the protected classes are for generic products.

- Across all protected classes, 35% of covered drugs are generic, yet 91% of prescriptions filled in 2016 are for generic products.
- Generics represented more than 90% of the prescriptions filled within each of the categories for anticonvulsants (90%), antidepressants (97%), and antipsychotics (91%).



Utilization of Protected Classes Drugs Under Part D Overall



Key takeaway: Part D plan benefit design for drugs in the protected classes results in much higher utilization of generic drugs than brand drugs.

A small number of Medicare beneficiaries depend on medications that are on the highest tiers.

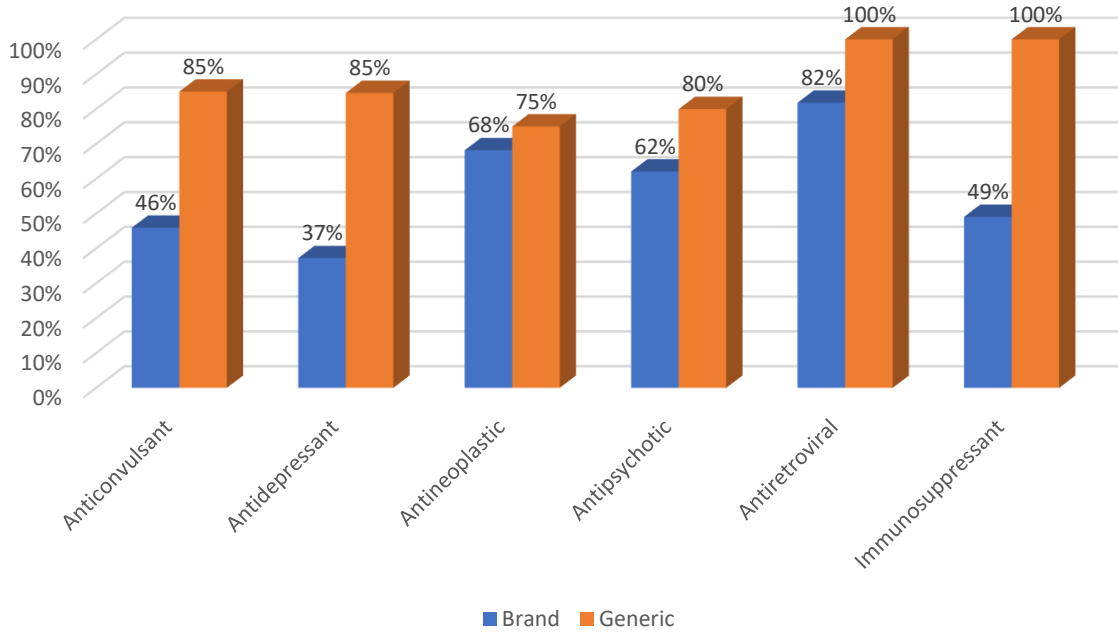
- Only 1% of all the prescriptions filled for drugs across the protected classes were for products that are always placed on high tiers — meaning the most difficult for patients to access.

Key takeaway: The protected classes policy ensures access to all unique medications and encourages the use of lower cost options.

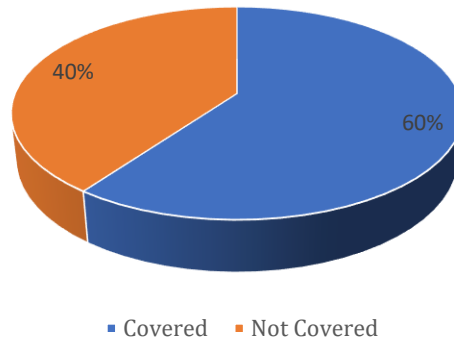
On average, plans cover just over two-thirds of drugs across all six of Medicare's protected classes.

- Across all classes, plans cover 67% of drugs (brand and generic combined) and 60% of the available brand name products, on average.
- In the class for antidepressants, plans cover only 37% of brand name medications and for anticonvulsants they cover 46% of the brand name products.

Coverage of Six Protected Class' Drugs Under Part D



Branded Drugs Covered Within the Protected Classes*

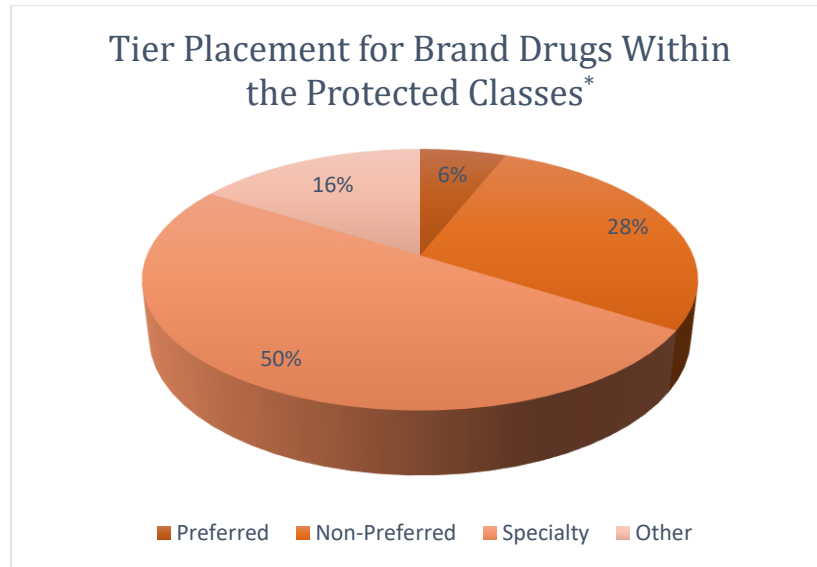


*Drugs reflect a count of unique drugs.

Key takeaway: While Part D plans are required to cover all unique products in the protected classes, this requirement does not result in universal coverage of brands when clinically equivalent generic drugs are available.

Tier placement is the primary tool plans use to manage access and utilization of medications in the six protected classes.

- The average Part D beneficiary is enrolled in a plan that places drugs from the protected classes on high tiers (non-preferred or specialty) 73% of the time.
- Specifically, branded products are placed on high tiers 78% of the time and generics 66% of the time — meaning they are subject to higher cost sharing, additional authorization for coverage, and other requirements.

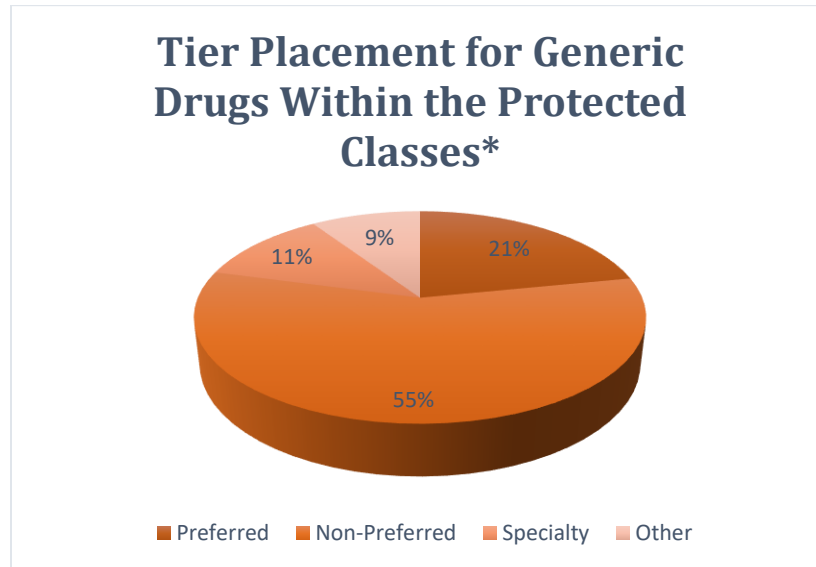


* Other tier types reflect "Injectable" and "Non-Medicare"

Key takeaway: Part D plans already can – and do – use tier placement to manage utilization and encourage greater use of generic drugs.

Generic products in the six protected classes are selectively placed on plan formularies as non-preferred or specialty products.

- Two-thirds (66%) of the covered generics in the protected classes are placed on non-preferred (55%) or specialty tiers (11%).
- Within the class of antidepressants, plans covered 85% of generic products, but the majority of these (57%) were still placed on non-preferred tiers, making them more difficult for patients to access.

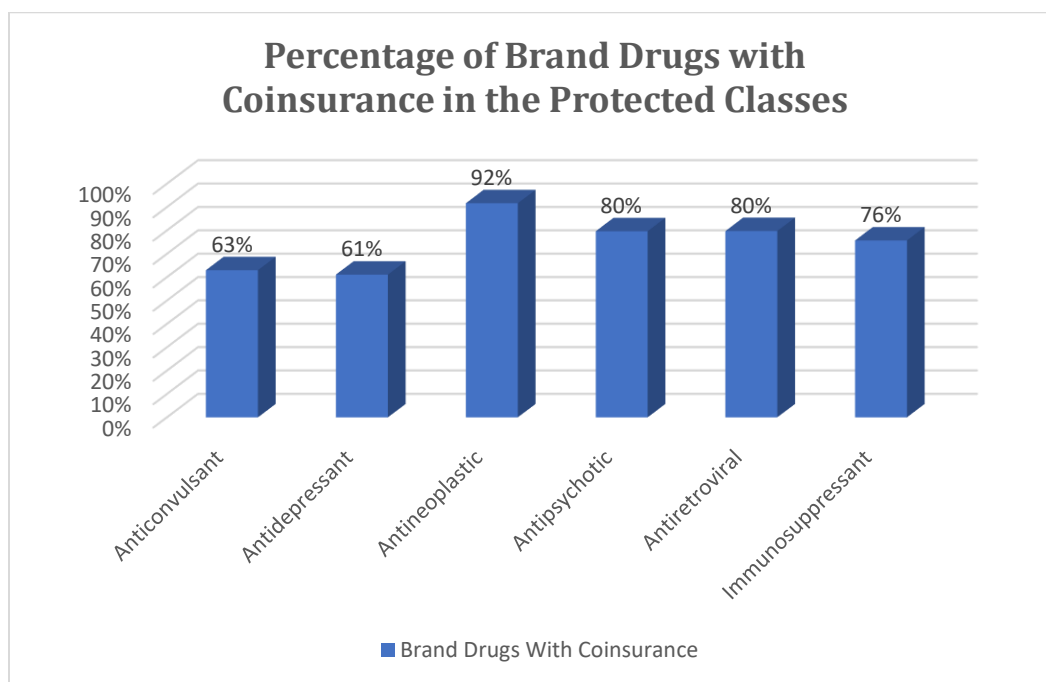


*Other tier types reflect "Injectable" and "Non-Medicare"

Key takeaway: Even with the safeguards that the six protected classes policy affords, patients still must overcome layers of restrictive barriers that plans put in place to access needed medications — ultimately driving patients to lower-cost options.

For the average Part D beneficiary, most drugs in the protected classes are placed on tiers that require coinsurance.

- Nearly 60% of the time, beneficiaries are enrolled in plans where drugs in the protected classes require coinsurance.
- Among brand name medications across the protected classes, patients are subject to a coinsurance payment for an overwhelming 80% of products.
- Plans apply a coinsurance for most of the brand antineoplastics (92%) and at least 60% of the brand products for antipsychotics (80%), antiretrovirals (80%), anticonvulsants (63%), antidepressants (61%) and immunosuppressants (72%).
- The average patient cost sharing amount for a brand name medication across the six protected classes was \$1,045 in 2016.⁴

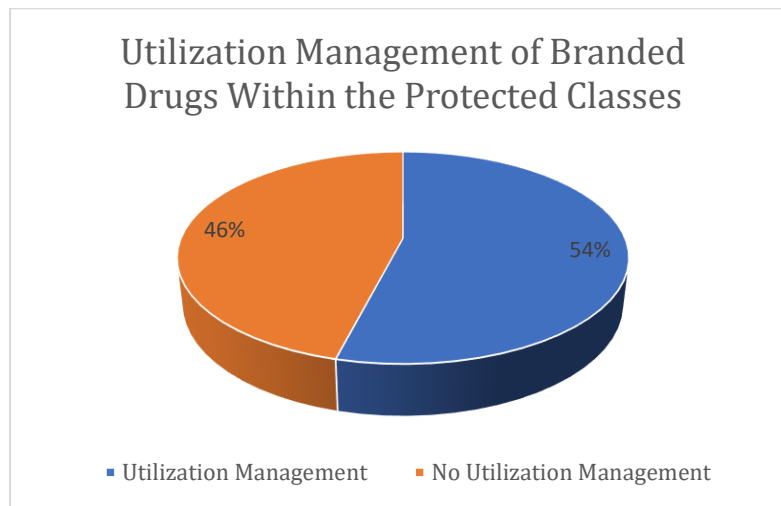


Key takeaway: When beneficiaries are subjected to coinsurance, which requires them to pay a percent of total costs, it may result in higher out-of-pocket expenses than when a copayment is assessed, depending on the benefit design.

⁴ Cost sharing is defined here as the share of costs covered by the health plan sponsor that is the responsibility of the Medicare Part D enrollee. This term generally includes deductibles, coinsurance, and copayments, or similar charges, but it doesn't include premiums, balance billing amounts for non-network providers, or the cost of non-covered services.

In addition to tier placement, plans frequently deploy other utilization management approaches to control patient access to drugs across all protected classes.

- Across the six protected classes, plan sponsors employ utilization management tools at least 40% of the time.
- Plans apply utilization management policies for a majority of branded drugs (54%) in the protected classes.
- Prior authorization (PA) is required for nearly half of the brand drugs (49%) in the protected classes.



Key takeaway: Utilization management requirements placed on drugs in protected classes can add access barriers for the Medicare Part D enrollees.

Part Three

Discussion

This study uncovered the range of strategies and tools that Medicare Part D plan sponsors employ to control spending for prescription drugs in the protected classes. As described below, these include strategic plan design and meaningful financial requirements as well as administrative hurdles that tend to favor patient use of lower cost generic alternatives wherever possible.

UTILIZATION OF GENERIC PRODUCTS

Medicare Part D plan sponsors are overwhelmingly advancing strategies that lead patients to fill generic products. The extent of genericization hinges on the availability of such clinically equivalent products. However, once a generic market is established, plans seek to incentivize use of generic products, including by placing generics on tiers that carry lower cost sharing obligations or that are subject to fewer clinical or administrative hurdles.

COVERAGE WITHIN THE PROTECTED CLASSES

While Medicare's protected classes policy precludes plans from entirely excluding a drug, plans do avail themselves of existing authority that permits exceptions to this coverage requirement.^{5,6,7,8} In practice, this means plans are varying the scope of coverage for drugs in a class or category. The study results demonstrate that plans are using this flexibility to exclude brand medications within some of the protected classes. The majority of time, when there are multiple clinically equivalent drugs in a

⁵ The protected classes policy requires Medicare Part D drug plans to include in their formularies access to all drugs in the six identified classes and categories of priority. The latest version of the CMS "Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements", last revised in 2016 identifies specific exceptions where plans may exclude a drug from a formulary. These exceptions are for multi-source brands of the identical molecular structure; extended release products when the immediate-release product is included; products that have the same active ingredient or moiety; and dosage forms that do not provide a unique route of administration.

⁶ Within the categories of protected classes, Congress has provided additional protections. Specifically, Part D plans are required to cover *all* approved antiretrovirals (ARVs) used in treatment for Medicare patients with HIV. There may be some exceptions in coverage, such as medications with the same active ingredient. See: <https://medicare.com/health/hiv-and-aids-treatment-options/>

⁷ CMS' Medicare manual also advises Part D plan sponsors that for HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models. See: <https://medicare.com/health/hiv-and-aids-treatment-options/>

⁸ Plans may be limited in their ability to direct patients to generic alternatives for antineoplastics used to treat cancer since there are a limited number of alternatives and treatments typically follow specific clinical protocols.

class, plans choose to cover one or more of the available lower cost generic products. This can allow plans to hold down costs and may enhance a plan sponsor's negotiating power with manufacturers.

TIER PLACEMENT

Non-preferred and specialty drugs are placed on higher tiers, which serves as a first line check to identify patients who might not otherwise need a higher cost medication. Medicare Part D plan sponsors plans can – and do – place drugs in the protected classes on higher tiers. Higher tiers generally require a greater financial contribution from the patient and are subject to additional layers of review by plan administrators.

The data support that higher tier placement may lead to a low rate of utilization for these products, as evidenced by the low rate of patient utilization for brand medications. This preferential tier placement serves to redirect patients away from higher cost to lower cost medications, when these options are available. For example, the vast majority of patients needing antidepressants and antipsychotics are using generic medications. Formulary placement is a primary tool plans utilize to secure favorable pricing during negotiations with drug manufacturers.

UTILIZATION MANAGEMENT TOOLS

While the protected classes policy provides additional safeguards for Medicare patients with certain complex health conditions, health plans have significant control to design plan structure and the ability to employ a range of utilization management tools, including prior authorization, cost-sharing, step therapy, coinsurance, and others that drive patients to low cost, preferred medications. Taken together, these flexibilities add to the suite of tools plans employ to direct patients to use lower cost medications, when they are available. In particular, prior authorization is a frequent tool employed by health plans for patients that request brand medications. This additional layer is designed to further limit the number of Medicare patients that access the higher-cost products within the protected classes.

COST SHARING

Plans also design cost-sharing and coinsurance policies to direct patients to lower-cost alternatives. A clear majority of beneficiaries are enrolled in Part D plans where protected classes medications require coinsurance. Plans are particularly consistent in applying a significant coinsurance for brand medications across the protected classes, which presents another hurdle for patients seeking higher-cost medications.

Part Four

Conclusion

This study provides new information regarding the impact Medicare’s protected classes policy has on patient access to prescription drugs and Part D plans’ ability to manage prescription drug costs. The results demonstrate that the safety valve of Medicare’s protected classes is working as intended to provide a balanced approach for Medicare Part D enrollees with complex medical conditions to access the medications that work best for them.

The majority of Part D enrollees may not necessarily need a particular formulation of a medication, and those patients are already choosing lower-cost generic alternatives within the protected classes, even when there are several brand options available in a protected class. The findings also provide evidence that the protected classes policy ensures that patients who need a particular formulation of a drug are able to access it. These patients, however, must still overcome additional layers of restrictions that plans put in place to further manage utilization.

Additionally, the findings provide new evidence that health plans are employing a range of utilization management and other tools such as selective formularies, coinsurance, and prior authorization to maximize use of lower-costing medications for both brand and generic medications across the protected classes.

The Medicare population is comprised of individuals over age 65, who often have multiple chronic conditions, and individuals with significant disabilities. The protected classes policy is designed to reflect Medicare enrollees’ unique and challenging health characteristics. Limiting access to the most appropriate medications would drive higher costs in Medicare Part A and Part B and Medicaid by increasing admittance to in-patient care and emergency departments due to the destabilization of patients’ conditions. The costs associated with this care otherwise would not be incurred by Medicare or Medicaid.

Part Five

Study Design

COMPARISON OF PART D BENEFIT DESIGN AND FORMULARY PLACEMENT

This study analyzes Part D benefit design and formulary data from 2016 to assess coverage and management of drugs under six protected classes. Specifically, for each protected class and in aggregate, Avalere used its proprietary database of formulary and benefit design data, PlanScape, to analyze:

- Drug tier placement
- Cost sharing type (copay vs coinsurance)
- Average cost sharing amounts
- Utilization management restrictions, especially prior authorization and step therapy requirements

ASSESSMENT OF UTILIZATION OF BRAND AND GENERIC DRUGS IN PART D PROTECTED CLASSES

The study also is designed to provide a side-by-side comparison of brand and generic drug utilization for the six protected classes and insights to the classes where generic use is more prevalent. This analysis uses data from Inovalon's Medical Outcomes Research for Effectiveness and Economics Registry (the MORE2 Registry®), which includes access to comprehensive Medicare Fee-for-service (FFS) Parts A/B claims data, Part D prescription drug event (PDE) data, Medicare Advantage claims data, Medicaid managed care plan claims data, and commercial health plan claims data. The registry also includes some clinical data, such as laboratory results, for certain populations.

DATA ANALYSIS

Across the Part D plans there is variation in the level of coverage within a category of drugs in the protected classes. Avalere looked across all Part D plans to calculate the average level of coverage. The findings presented for each class reflect enrollment-weighted averages across all Part D plans analyzed in the 50 states and DC. The results of the analysis are stratified by generic versus brand drugs.

The coverage, cost-sharing, and utilization management analysis was conducted using publicly available and proprietary databases to identify approximately 18,000 national drug codes (NDCs) on the market in 2016 for the six protected drug classes under Medicare Part D (Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antiretrovirals and Immune Suppressants). This database combines and analyzes the Centers for Medicare & Medicaid Services (CMS) 2016 Public Use Files (PUF) data on Part D enrollment, plan benefit and formulary design, and negotiated drug

prices. Avalere then identified a subset of approximately 1,200 NDCs on Part D plan formularies spanning individual months in 2016. Avalere excluded Cost plans, demonstration plans, and Programs of All-Inclusive Care for the Elderly (PACE) plans from the analysis due to the unique benefit design of those plans that would not be representative of the Part D market.

If an NDC of a drug was placed on different tiers across months for the same plan, Avalere captured the highest tier for that NDC in the analysis. In addition, among all drugs analyzed, Avalere identified a subset of 228 NDCs across all 6 protected classes (76 unique drugs) that were predominantly placed on high tiers (non-preferred or specialty) by plans in 2016 (i.e., at least 90% of Part D beneficiaries were enrolled in plans that placed those drugs on high tiers on their formularies).

To assess the utilization of brand and generic drugs in Part D protected classes Avalere analyzed the 2016 Part D prescription drug event (PDE) data from Inovalon's Medical Outcomes Research for Effectiveness and Economics Registry (MORE2 Registry®). For each protected class, Avalere calculated the volume of scripts overall and segmented by total brand versus generic drugs. The analysis of the generic and brand utilization used the subset of approximately 1,200 NDCs identified in the 2016 Part D plan formulary files to assess utilization using PDE data from 2016.

Per the data use agreement (DUA) with CMS, the final study cohort cannot comprise more than 20% of Medicare beneficiaries for any given year. The number of beneficiaries prescribed drugs from the antidepressants class exceeded the 20% threshold, so Avalere restricted the brand/generic analysis timeframe for this specific drug class. The restriction includes only beneficiaries with a prescription of interest in the 11 of 12 months of Part D coverage in 2016 which met the 20% threshold. Avalere also performed a utilization assessment specific to a subset of 228 NDCs identified as being predominately placed on high tiers by Part D plans in 2016.

TERMS AND DEFINITIONS

For this analysis the Medicare definition of a covered drug was used.⁹ The study uses the brand/generic indicator assigned to drugs in the formulary data as well as claims data.

Plans name and define their tiers in a variety of ways. For consistency this analysis aggregated different names into five tier categories: Brand, Generic, Preferred, Non-Preferred, and Specialty. In this context, "non-preferred tier" refers to instances where plans choose to place drugs for which they don't have agreements with manufacturers and/or the drug cost is high, and therefore cost-sharing on non-preferred tier is higher than on preferred tier. The specialty tier is designed for high-cost drugs whose prices exceed a certain threshold set by CMS: \$670 for a one-month supply at an in-network retail pharmacy.

⁹ See: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PartDDrugsPartDExcludedDrugs.pdf>