

September 10, 2019

The Honorable Richard Neal
Chairman
U.S. House of Representatives
Committee on Ways and Means

The Honorable Kevin Brady
Ranking Member
U.S. House of Representatives
Committee on Ways and Means

The Honorable Frank Pallone
Chairman
U.S. House of Representatives
Committee on Energy and Commerce

The Honorable Greg Walden
Ranking Member
U.S. House of Representatives
Committee on Energy and Commerce

Dear Chairman Neal, Ranking Member Brady, Chairman Pallone, and Ranking Member Walden:

The undersigned organizations share a commitment to improving the nation's drug pricing system in ways that will strengthen the health and economic security of current and future Medicare beneficiaries. We appreciate your attention to this matter and urge you to include needed reforms to the Part D benefit in any forthcoming prescription drug legislation.

Based on our work with people with Medicare and their families, we know that prescription drug affordability is an ongoing challenge. Our organizations frequently hear from older adults and people with disabilities who are struggling to cover their drug costs and obtain needed medications.

Many people with Medicare live on fixed or limited incomes and cannot keep paying ever-rising health and prescription drug costs. Currently, half of all Medicare beneficiaries—nearly 30 million older adults and people with disabilities—live on \$26,200 or less per year, while one quarter have incomes below \$15,250 and less than \$14,550 in savings.¹ At the same time, health care costs are taking up a larger and more disproportionate share of beneficiaries' limited budgets. In 2016, nearly 30% of Medicare households spent 20% or more of their income on health care, while only 6% of non-Medicare households did so.² Out-of-pocket costs for prescription drugs represent a significant share of this spending, accounting for nearly one out of every five beneficiary health care dollars.³

Accordingly, we respectfully ask that in any legislation to address the problem of high and rising prescription drug prices, you include updates to the Medicare Part D benefit structure, appeals process, and low-income programs, as outlined below. These long-overdue improvements would help older adults and people with disabilities better access and afford needed medications, as well as build and maintain their health and financial well-being.

¹ Jacobson, Gretchen et al., Kaiser Family Foundation, "Income and Assets of Medicare Beneficiaries, 2016-2035," (April 21, 2017) available at: <https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/>.

² Cubanski, Juliette et al., Kaiser Family Foundation, "The Financial Burden on Health Care Spending: Larger for Medicare Households than for Non-Medicare Households," (March 1, 2018) available at: <https://www.kff.org/medicare/issue-brief/the-financial-burden-of-health-care-spending-larger-for-medicare-households-than-for-non-medicare-households/>.

³ Kaiser Family Foundation, "10 Essential Facts about Medicare and Prescription Drug Spending," (January 29, 2019) available at: <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>.

Medicare Part D Benefit Structure

The Medicare Part D benefit structure is contributing to the affordability challenges facing many people with Medicare. In particular, the absence of a meaningful cap on beneficiary expenses and lack of an effective reinsurance scheme mean the program is unable to lower drug prices or protect enrollees from these rising costs. We urge you to revisit and improve the benefit's design. To that end, we recommend the following changes:

Establish an Out-of-Pocket Cap. While the Part D drug benefit does include an out-of-pocket (OOP) limit, it is not a hard cap. Instead, beneficiaries not receiving low-income subsidies (LIS) that help pay Part D premiums and cost sharing must pay 5% of their drug costs indefinitely once they reach the catastrophic coverage level—at which point they've already spent thousands of dollars out of pocket. In 2017, over 1 million non-LIS Part D enrollees had OOP spending above the catastrophic threshold, with average annual out-of-pocket costs exceeding \$3,200.⁴ A hard OOP cap would help reduce costs and enhance predictability for enrollees. As a further step to improve affordability, we seek a stop to the increase of the current \$5,100 threshold amount by \$1,250 up to \$6,350 at the end of this year, as prescribed in current law.

Ensure Proportional Liability Among Payers. When contemplating the appropriate liability for each payer in the post-cap period, we encourage you to ensure that both prescription drug plans and drug manufacturers have meaningful and proportional liability for each phase of the Part D benefit. Equitable, balanced incentives would help better control costs for beneficiaries and the program.

Maintain Manufacturer Coverage Gap Discounts in the TrOOP Calculation. Some proposals to restructure the Part D benefit suggest that, in addition to changing the reinsurance liabilities above the catastrophic threshold and establishing an OOP cap, manufacturer coverage gap discounts should no longer count towards true out-of-pocket costs (TrOOP). We strongly oppose excluding manufacturer discounts from TrOOP costs. Even when combined with an OOP cap, this policy would increase costs for many beneficiaries by keeping them in the coverage gap longer.

Simultaneously Address the Root of the Problem. While we support capping OOP costs for Part D enrollees, there must also be efforts to address the underlying problem of high and rising prescription drug prices, such as exploring opportunities for bipartisan agreement on ways the Medicare program can negotiate prices with manufacturers. Consumers should not pay sky-high prices and neither should the Medicare program.

Medicare Part D Appeals Process

The Medicare Part D appeals process is an essential safety valve. For example, the process can allow access to prescription medications that are not on the plan's formulary, or are subject to high cost sharing, when formulary or lower-cost alternatives are not appropriate. However, we consistently observe that many Part D enrollees struggle to navigate this overly complex system, resulting in delays in access to needed prescription drugs, abandonment of prescribed medications, reduced adherence to treatment protocols, worse health outcomes, and higher costs. To alleviate these challenges, we encourage you to make the following improvements:

⁴ Cubanski, Juliette et al., Kaiser Family Foundation, "How Many Medicare Part D Enrollees Had High Out-of-Pocket Drug Costs in 2017?" (June 21, 2019) available at: <https://www.kff.org/medicare/issue-brief/how-many-medicare-part-d-enrollees-had-high-out-of-pocket-drug-costs-in-2017/>.

Streamline Medicare Part D Coverage Determinations and Appeals. Our organizations often hear from Part D enrollees who are struggling with appeals and coverage-related issues. Many were told at the pharmacy counter that their plan would not cover their medication—but not the reason why.

Pharmacists do not tend to have this information and can only direct enrollees to contact their plan for an explanation. As a result, affected enrollees may leave the pharmacy without their medication or a clear understanding of why it was denied. Many are also unaware of their right to appeal and do not know how to go about initiating the appeals process.⁵ Confused about what to do next, some may bypass the appeals process—knowingly or not—returning later to pay what they can out-of-pocket, or deciding to forego the medication altogether. Those who do take action must embark on a tedious fact-finding mission. This includes calling their plan to learn why the medication was refused and working with their physician to determine the best path forward, such as trying an alternative drug or appealing to the plan for coverage of the medication as prescribed.

Beneficiaries who decide to appeal must then re-engage with their plan to obtain a written denial that explains the plan’s reason for non-coverage—even though the plan has already issued a denial at the pharmacy counter, and even though the beneficiary has already contacted their plan to learn why. Only upon receipt of this “official” notice, known as a coverage determination, may a beneficiary request a formal appeal, termed a redetermination.

This multi-step, prolonged process proves burdensome and time-consuming for Medicare beneficiaries, pharmacists, plans, and prescribing physicians. These systemic inefficiencies can lead to delays in beneficiary access to needed prescriptions, abandonment of medications, reduced adherence to treatment protocols, worse health outcomes, and higher costs.

To meaningfully address these challenges, we recommend allowing a refusal at the pharmacy counter to function as the plan’s initial coverage determination. This one change—effectively initiating the appeals process at the time of the refusal—would serve the dual purpose of eliminating unnecessary steps within the current system while also expediting the appeals process for those who need it. We strongly support the bipartisan Streamlining Part D Appeals Process Act (S. 1861/H.R. 3924), which would accomplish these goals.

Notably, H.R. 3924’s improvements have a strong history of bipartisan support. For example, a February 4, 2014 letter to Centers for Medicare & Medicaid Services (CMS) Administrator Marilyn Tavenner—signed by every member of the Senate Finance Committee—states, in part: “We recommend improving the Part D appeals process...to allow the beneficiary to initiate the appeals process at the pharmacy counter when he/she is first notified the drug is not covered by the part D plan.”⁶ Most recently, during the Senate Finance Committee’s July 25 Executive Session, Senator Cardin highlighted Committee

⁵ Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, “Part D exceptions and appeals” (September 2013), available at: http://www.medpac.gov/transcripts/part_d_exceptions_&_appeals.pdf; CMS, “Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011” (2011), available at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugAppGriev/Reconsiderations.html>.

⁶ Letter from the U.S. Senate Committee on Finance to CMS Administrator Tavenner (February 5, 2014) available at: <https://califsciences.org/wp-content/uploads/2015/06/Senate-Finance-Committee-Bipartisan-Letter-Opposing-Elimination-of-Six-Protected-Classes-of-Prescription-Drugs-from-Medicare-Part-D-February-5-2014.pdf>.

members' "strong bipartisan support" for the companion bill (S. 1861) and Ranking Member Wyden also expressed his agreement with this policy change.⁷

The need for this broadly supported legislation is likely only to grow more urgent. Part D plans are increasingly adopting utilization management strategies such as quantity limits, prior authorization, and step therapy in an effort to control costs.⁸ While these restrictions may be applied in ways that maintain enrollee access to appropriate medications, they often instead lead to medication delays or denials, forcing beneficiaries to then work through the deeply flawed appeals process in order to obtain needed therapies. Already, these controls are one of the most common reasons why a prescription is denied at the pharmacy counter.⁹ Such practices—and their effects—are likely to become more widespread if, as discussed above, the Part D benefit is restructured in ways that increase plan liability. While we strongly support those reforms, we recognize that plans may respond by imposing additional cost controls—pushing an ever-growing number of beneficiaries into a broken appeals system.

We urge you to address the long-standing need for a streamlined Part D appeals process without delay, by including H.R. 3924 in your forthcoming drug pricing package. These improvements are needed to ensure that people with Medicare can better access, understand, and manage the Part D appeals process—now and in the future.

Expand Tiering Exceptions. We also strongly support the establishment of a cost-sharing exception and appeal process for drugs included on the specialty tier. For all other plan formulary tiers, beneficiaries may request an exception from the plan, asking that the drug be placed on a lower cost-sharing tier—provided that the lower-tier medication is inappropriate for their specific medical needs. No such request is available for specialty tier drugs. At the same time, spending on these drugs has increased substantially in recent years. According to the Congressional Budget Office (CBO), Part D spending on specialty drugs rose from \$8.7 billion in 2010 to \$32.8 billion in 2015, accounting for about 30% of Part D spending on prescription drugs that year, up from 13% in 2010.¹⁰

Drugs on the specialty tier represent an increasing cost burden for beneficiaries. We encourage you to work with CMS to implement an exception and appeal process for the specialty drug tier at the earliest possible time.

Apply Medicare Part B and Medicaid Standards to Coverage Rules for Off-Label Prescription Drugs in Medicare Part D. When determining whether to cover an off-label use of an FDA-approved prescription drug, the Medicare Part B program, as well as many private insurance carriers and state Medicaid programs, include in their analysis a consideration of peer-reviewed literature, such as respected medical journals. The Medicare Part D program, however, does not permit reliance on peer-reviewed support at all. Instead, the program automatically denies coverage unless there is a supportive listing in one of three commercially-produced compendia. This inconsistency with standard practice of many

⁷ Transcript, Senate Committee on Finance, "Open Executive Session to Consider An Original Bill Entitled The Prescription Drug Pricing Reduction Act of 2019" (July 25, 2019) available at: <https://www.finance.senate.gov/imo/media/doc/7-25-19%20--%20RX%20Drug%20Pricing%20Reduction%20Act%20of%202019.pdf>.

⁸ Hoadley, Jack et al., Kaiser Family Foundation, "Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends, 2006-2015" (Oct. 5, 2015) available at: <http://files.kff.org/attachment/report-medicare-part-d-at-ten-years-the-2015-marketplace-and-key-trends-2006-2015>.

⁹ MedPAC, "Report to the Congress: Medicare Payment Policy" (March 2019), available at: http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0.

¹⁰ Anderson-Cook, Anna et al., Congressional Budget Office, "Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis" (March 2019) available at: https://www.cbo.gov/system/files?file=2019-03/55011-Specialty_Drugs_WP.pdf.

other insurers has created serious barriers to accessing effective and sometimes life-saving prescription drugs and has been a source of frustration for providers and beneficiaries alike.

We urge you to correct this misalignment and allow use of peer reviewed literature in Medicare Part D. Specifically, we support amending Section 1927(k)(6) of the Social Security Act (42 U.S.C. 1396r-8(k)(6)), the Part D definition of a “medically accepted indication,” to align the definition with that used in the Medicaid portion of the Social Security Act.

Medicare Part D Low Income Programs

The Part D Low-Income Subsidy (LIS), or Extra Help, was designed to address the needs of low-income Medicare beneficiaries, but the program has significant flaws that should be addressed. Congress should consider making the following changes to Extra Help and other low-income assistance programs in order to increase access and affordability:

Eliminate the Asset Test & Expand Eligibility for LIS. We support eliminating the asset test and extending the standard LIS benefit to all people under 200% of the federal poverty limit, as outlined in the Medicare Extra Rx HELP Act (S. 691). We also support interim steps to lessen the burden of the asset test, such as treating retirement savings accounts in the same manner as pensions are currently—with distributions counting as income but discounting the savings from assets.

Eliminate Cost-Sharing on Generics for LIS Beneficiaries. We also recommend eliminating cost sharing on generics for LIS beneficiaries. Even a minimal amount of cost sharing can be a barrier to access. While some plans do offer \$0 copay for some generics, applying this policy consistently to all generics would more effectively reduce financial burdens for low-income beneficiaries and increase medication adherence. Encouraging the use of generics should never come at a cost of limiting access to the full range of medications, however. It is important that reducing generic copays to \$0 not be accompanied by an increase in LIS cost sharing for branded drugs.

Notify All LIS Enrollees Who Have Premium Liability about \$0 Premium Plans. Currently, CMS sends the LIS “Chooser’s Notice” only to LIS enrollees with new or increased premium liability relative to the previous year. We are concerned that many LIS enrollees who will have reduced or identical premium liability year-over-year do not receive the notice, regardless of how high their new premium would be. We recommend requiring that CMS send the Chooser’s Notice to all LIS enrollees who have premium liability. This small change would help the LIS program work more efficiently and give LIS enrollees the tools they need to choose the lowest cost plans—thereby decreasing the financial burden for all stakeholders involved.

Index LIS Copayments and Deductibles for LIS Enrollees to the Social Security Cost of Living Adjustment (COLA). Under current law, LIS enrollees with incomes below 100% of the federal poverty level (FPL) have their prescription drug cost sharing increased according to the Consumer Price Index. For LIS enrollees with incomes between 100 and 150% of poverty, their cost sharing is increased according to the percentage increase in average per capita aggregate expenditures for covered Part D drugs. The Social Security COLA is the most accurate reflection of annual income increases for these fixed-income populations and is therefore likely the best index to use for each of these groups. The current indexing methodology for the 100-150% FPL group is particularly problematic since it increases out-of-pocket costs at a higher rate than increases in ability to pay and erodes the value of the LIS benefit over time.

Replace LIS Random Assignment with Intelligent Assignment. Rather than randomly assigning LIS enrollees into new plans, assigning them based on their individual prescription drug needs would reduce their out-of-pocket costs and Medicare program spending. A 2007 House bill, H.R. 3162, included a provision on intelligent assignment that CBO scored at \$1.2 billion in savings over 10 years.¹¹ Factoring in prior medication use, pharmacy preferences, and cost savings into the assignment process can improve access to needed drugs and save money both for beneficiaries and the Medicare program. According to a June 14, 2014 *Health Affairs* article: “We used an intelligent assignment algorithm and 2008-09 Part D drug use and spending data to match enrollees to available plans according to their medication needs. We found that such a reassignment approach could have saved the federal government over \$5 billion in 2009, for government savings of \$710 (median: \$368) per enrollee with a low-income subsidy.”¹²

Make LI NET Permanent. We are also supportive of proposals to make the Limited Income Newly Eligible Transition (LI NET) Program permanent, including as provided for in the Beneficiary Education Tools Telehealth & Extenders (BETTER) Act of 2019 (H.R. 3417) and in the Senate Finance Committee’s drug pricing bill as considered on July 25. This program acts as an important safety net for beneficiaries who are eligible for LIS but not yet receiving Part D coverage. It allows beneficiaries immediate access to covered Part D drugs at the point-of-sale during the period that begins on the first day of the month a person is determined to be eligible for LIS. This prevents beneficiaries from experiencing a lapse in access to their prescription drugs.

Improve Language Access for Part D Beneficiaries. U.S. Census data estimates that in 2017, over 10 million older adults over age 60 speak a language other than English at home and 6 million speak English less than “very well.” Furthermore, the 2017 Medicare Beneficiary Survey Early Look Data Brief shows that 12% of Medicare beneficiaries living in the community report that English is not their primary language. Other reports from the Office of Minority Health estimate that almost 2 million beneficiaries speak languages other than English or Spanish, including over 200,000 beneficiaries who speak Chinese, over 150,000 who speak Vietnamese, and over 140,000 who speak Tagalog.

Currently, important Part D notices and other Medicare information are sent to most of these limited English proficient (LEP) beneficiaries in English (or Spanish). Moreover, beneficiaries can only submit the LIS application in English or Spanish. While the Social Security Administration has made translations of the LIS application available in multiple languages, those translations only serve as guides. LEP beneficiaries must transcribe their information to the English or Spanish version of the application in order to submit it.

We recommend requiring that CMS translate important Part D notices, including notices of disenrollment and coverage denials, into all languages spoken by either 1,000 individuals or 5% of the population in the service area, whichever is lower. CMS’s current 5% threshold, used alone, results in most documents only being translated into Spanish. Similarly, we recommend directing the Social Security Commissioner to allow individuals to directly submit LIS applications in the 18 languages

¹¹ See Sec. 218 of Rep. Dingell’s Children’s Health and Medicare Protection (CHAMP) Act – H.R. 3162, passed the House on 8/1/07, available at: <https://www.congress.gov/bill/110th-congress/housebill/3162/text?q=%7B%22search%22%3A%22HR+3162%22%7D&r=1&s=1> and scored by CBO as saving \$1.2 billion over 10 years: <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/hr316200.pdf>.

¹² Zhang, Zhou, and Faik, *Health Affairs*, “A Simple Change to the Medicare Part D Low-Income Subsidy Program Could Save \$5 Billion” (June 2014) available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.1083>.

already translated.¹³ Finally we recommend requiring CMS to translate the Medicare & You Handbook into additional languages beyond Spanish and English. This document provides vital information on all aspects of Medicare, including Part D.¹⁴ All of these translations are necessary to address health disparities, empower beneficiaries with limited English proficiency to access this financial assistance, and are consistent with Title VI of the Civil Rights Act and Section 1557 of the Affordable Care Act.

Thank you for your consideration. We look forward to continued collaboration on efforts to improve prescription drug access and affordability for all people with Medicare.

Sincerely,

Center for Medicare Advocacy
Justice in Aging
Medicare Rights Center
National Committee to Preserve Social Security and Medicare
National Council on Aging

¹³ Social Security Administration, "Application for Extra Help with Medicare Prescription Drug Plan Costs" available at: <https://www.ssa.gov/benefits/medicare/prescriptionhelp/other-languages.html>.

¹⁴ Recently, Congressman Jimmy Gomez led a [letter](#) signed by 62 Members of Congress to CMS Administrator Verma encouraging Medicare to translate key materials such as the Medicare & You Handbook into additional languages. See: https://gomez.house.gov/uploadedfiles/medicare_language_access_final.pdf.