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April 6, 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

**Re: Feedback on Draft Medicare Part D Legislation**

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

On behalf of the Medicare Rights Center, thank you for the opportunity to provide feedback on draft legislation to create an out-of-pocket maximum for Medicare Part D beneficiaries, and to make other recommendations to strengthen the Part D program.

The Medicare Rights Center is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Our organization provides services and resources to nearly three million people with Medicare, family caregivers, and health care professionals each year.

Based on this experience, we know that prescription drug affordability and access is an ongoing challenge. Every day on our National Consumer Helpline, we hear from older adults and people with disabilities who are struggling to obtain needed prescriptions. Given that many people with Medicare live on fixed or limited incomes that cannot keep pace with high and rising drug prices, the perennial nature of these calls is alarming, but not surprising.

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

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and less than \$14,550 in savings.<sup>1</sup> 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.<sup>2</sup> Out-of-pocket costs for prescription drugs represent a significant share of this amount, accounting for nearly one out of every five beneficiary health care dollars.<sup>3</sup>

With health-related expenses projected to consume a greater share of beneficiaries' income over time, if left unaddressed these affordability challenges will only worsen.<sup>4</sup> Already, it is not just lower-income beneficiaries who are affected by increases in prescription drug prices. In 2017, over 40% of Medicare Rights' Helpline callers who were screened for Part D assistance programs such as Extra Help did not qualify due to having income and assets in excess of the program's eligibility thresholds.<sup>5</sup> As the population ages and prices continue to rise, we are concerned that an ever-growing number of beneficiaries will find the cost of prescriptions, help paying these costs—or both—to be out of reach.

We therefore strongly support the draft legislation's cap on out-of-pocket (OOP) costs for all Medicare beneficiaries. Having this added protection would be a relief to many. When considering the appropriate liability for each payer in the post-cap period, we encourage Congress to ensure that both prescription drug plans and drug manufacturers have meaningful and proportional liability for each phase of the Part D benefit so that equitable, balanced incentives are structured in ways that will control costs for beneficiaries and the program. Ensuring that each of these parties has liability in each part of the benefit will help address the potential for unintended consequences even as Congress works to create a Part D structure with fewer incentives for high prices.

Some proposals to restructure the Part D benefit suggest that, in addition to changing the reinsurance liabilities above the catastrophic threshold and establish 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.

Medicare Rights strongly believes that capping Medicare Part D enrollees' OOP costs is important. We also encourage the committees to explore other opportunities to strengthen the Part D benefit, including by modernizing the Part D Low Income Subsidy (LIS) program,

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<sup>1</sup> 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/>.

<sup>2</sup> 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/>.

<sup>3</sup> 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/>.

<sup>4</sup> Cubanski, Juliette et al., Kaiser Family Foundation, "Medicare Beneficiaries Out-of-Pocket Health Care Spending a Share of Income Now and Projections for the Future," (January 26, 2018), available at: <https://www.kff.org/report-section/medicare-beneficiaries-out-of-pocket-health-care-spending-as-a-share-of-income-now-and-projections-for-the-future-report/>.

<sup>5</sup> Riccardi, Fred et al., Medicare Rights Center, "Medicare Trends and Recommendations: An Analysis of 2017 Call Data from the Medicare Rights Center's National Helpline," (April 2019), available at: <https://www.medicarerights.org/pdf/2017-helpline-trends-report.pdf>.

improving the Part D appeals process, and making the LI NET program permanent, as outlined below.

### **Eliminate the Asset Test & Expand Eligibility for LIS**

The LIS program is critical to ensuring Medicare beneficiaries with the lowest income and resources, including those who also have Medicaid, can access prescription drugs they need. However, many beneficiaries with limited incomes are not eligible or enrolled because of the strict thresholds, which limit assets as well as income.

Asset tests unfairly penalize those who manage to put aside modest savings and create administrative burdens for both applicants and the program. To ease this burden and ensure that all limited-income people with Medicare have access to LIS, we encourage congress to eliminate the asset test and to extend 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 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 to all generics would both take the cost burdens off low-income beneficiaries and encourage 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 approximately 300,000 enrollees have reduced or identical premium liability compared to the previous year, but do not receive the notice. In 2019, this group will average about \$28 a month in premiums—a significant cost for individuals living on limited fixed incomes. 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.

## Examine Feasible Alternatives to Current LIS Assignment<sup>6</sup>

We remain concerned about the rate of reassignment and subsequent involuntary plan-switching LIS enrollees experience, as well as whether they are assigned to plans that best meet their needs. Every year, CMS re-calculates the benchmark for each region, often causing significant fluctuations as some plans lose benchmark status. Unless LIS enrollees at any time in the past chose their current plan, CMS randomly reassigns them to a new benchmark plan. As a result, low-income beneficiaries are forced to change plans more frequently than non-LIS enrollees. For example, between 2006 and 2010, 7 out of 10 LIS enrollees experienced one or more plan changes, compared to 3 out of 10 non-LIS enrollees.<sup>7</sup> This kind of churning contributes to instability and uncertainty for vulnerable LIS enrollees, and creates challenges for health plans.

Recent research suggests assigning LIS enrollees based on their individual prescription drug needs would be a better approach, with the potential to reduce enrollee OOP costs and Medicare spending. According to a June 14, 2104 *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.”<sup>8</sup> In 2007, the Congressional Budget Office scored an intelligent assignment provision in a bill passed by the House at \$1.2 billion in Medicare savings over 10 years.

Conducting a demonstration on such “intelligent” or “beneficiary-centered” assignment would be a useful way to examine feasible, cost-effective alternatives to random assignment.

## Streamline Medicare Part D Coverage Determinations and Appeals

The multi-step, prolonged Part D exceptions and appeals process proves onerous and time-consuming for Medicare beneficiaries, pharmacists, and prescribing physicians and can significantly delay access to necessary medications. To begin with, many Part D enrollees are unaware of their right to appeal and do not know how to go about initiating the appeals process.<sup>9</sup> Furthermore, Part D enrollees are not provided individualized information or adequate education when refused a medication at the pharmacy counter, resulting in the

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<sup>6</sup> 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 (<https://www.congress.gov/bill/110th-congress/house-bill/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>.

<sup>7</sup> See Figure 9 in Hoadley, Summer, et al. *To Switch or Be Switched: Examining Changes in Drug Plan Enrollment among Part D Low-Income Subsidy Enrollees*. Kaiser Family Foundation (July 2015).

<sup>8</sup> Zhang, Zhou, and Faik, *A Simple Change to the Medicare Part D Low-Income Subsidy Program Could Save \$5 Billion*. *Health Affairs* 33:6 June 2014).

<sup>9</sup> 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](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/MedPrescriptDrugApplGriev/Reconsiderations.html>.

individual and their physician spending hours trying to obtain this information in order to make a proper exceptions request.

Additionally, rather than being able to appeal the denial at the pharmacy counter, a beneficiary must formally make an exceptions request, which requires significant time and effort for both the patient and their physician. Only upon receipt of a written denial in response to this request, known as the coverage determination, is the beneficiary permitted to request a formal appeal, termed a redetermination.

Additional administrative efficiency could be gained by aligning the Part D exceptions process with the exceptions and appeals processes in Medicare Advantage (MA), Original Medicare, and Medicaid. In these each of these programs, a beneficiary automatically receives a notice of non-coverage after a service is received or prior to, if the service is not authorized.

Therefore, we recommend requiring a coverage determination to be provided automatically to a beneficiary at a point-of-sale refusal. Requiring the pharmacy counter refusal to serve as the coverage determination serves the dual purpose of removing a burdensome step for beneficiaries and their doctors while also expediting the appeals process for those who need it.

We note with interest a February 4, 2014 letter to then CMS Administrator Marilyn Tavenner, signed by every then-member of the Senate Finance Committee, stating in part: “We recommend improving the part D appeals process . . . For instance, we encourage CMS to explore ways 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.” It has been over five years since that bipartisan letter was sent. We urge Congress to address this longstanding need without delay.

In the interim, we recommend requiring that the existing pharmacy counter refusal notice explain the reason (i.e., prior authorization, step therapy, quantity limits, off-formulary, non-covered, etc.) why the beneficiary is being turned away. This simple, straightforward, much-needed information would better equip Part D enrollees and their providers to navigate the appropriate next steps, whether by requesting a coverage determination or pursuing an alternative medication.

### **Expand Tiering Exceptions**

We also strongly support the establishment of a cost-sharing exception and appeal process for drugs included on the specialty tier. Spending on specialty drugs has increased substantially in recent years. According to the Congressional Budget Office, 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.<sup>10</sup> Among Part D enrollees who

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<sup>10</sup> 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](https://www.cbo.gov/system/files?file=2019-03/55011-Specialty_Drugs_WP.pdf).

used a brand-name specialty drug and did not receive assistance with their cost sharing, the average OOP cost for such drugs (in 2015 dollars) increased from \$1,750 in 2010 to \$3,540 in 2015 and accounted for nearly 90% of their total Part D OOP costs.<sup>11</sup>

Thus, drugs on the specialty tier represent an increasing cost burden for beneficiaries. The issue remains extremely important for beneficiaries with conditions that have limited treatment options. For all other plan formulary tiers, beneficiaries may request an exception from the plan, asking for a drug to 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. We encourage Congress to work with CMS on implementing 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 and, instead, automatically denies coverage unless there is a supportive listing in one of three commercially-produced compendia. This inconsistency with standard practice of many other insurers has created serious barriers to access to effective and sometimes life-saving prescription drugs and has been a source of frustration for providers and beneficiaries alike.

We have heard of cases where physicians treating individuals with rare or difficult to manage conditions had, after much trial and error, come up with an approach that worked and stabilized the patient. The patient's Medicaid or commercial insurance had approved payment based on a review of the individual's medical condition and supporting peer-reviewed papers. But, when the patient turned 65 and qualified for Medicare, suddenly coverage stopped because the treatment did not appear in a compendium listing.

While rigorous review of proposed off-label use is appropriate for any insurer, including Medicare Part D insurers, the absolute and arbitrary denial of coverage because of the compendium listing requirement goes too far and impedes good medical practice. We have seen numerous Medicare Administrative Law Judge (ALJ) opinions in which the ALJ accepted the medical testimony that, without question, the proposed use of a prescription drug was medically appropriate for the beneficiary but the ALJ was constrained by the current regulatory interpretation of the statute and forced to deny coverage.

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<sup>11</sup> *Id.*

The problem is exacerbated by the fact that the compendia, which are encyclopedic on-line compilations, are very expensive and difficult to access. Most prescribing doctors do not use them in their day-to-day practice and many are totally unfamiliar with the publications.

Congress addressed these serious concerns in the context of drugs used in an anti-cancer regimen when it amended the Social Security Act to allow use of peer reviewed literature for those drugs. The issue remains, however, for drugs that do not fit into the cancer category. Therefore, we recommend Congress amend 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.

### **Make LI NET Permanent**

We are also supportive of proposals to make the Limited Income Newly Eligible Transition (LI NET) Program permanent, including H.R. 3029. 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.

Again, we appreciate this opportunity to share our perspective. We commend your thoughtful, bipartisan work on this complex issue and thank you for your leadership. We look forward to working together to improve the nation’s drug pricing system in ways that improve access and affordability for all people with Medicare.

For more information or if we can otherwise be of assistance, please feel free to contact Casey Schwarz, Senior Counsel, Education & Federal Policy at [cschwarz@medicarerights.org](mailto:cschwarz@medicarerights.org) or Lindsey Copeland, Federal Policy Director, at [lcopeland@medicarerights.org](mailto:lcopeland@medicarerights.org).

Sincerely,



Fred Riccardi  
President  
Medicare Rights Center