

June 6, 2019

The Honorable Richard Neal

Chairman

House Ways and Means Committee

The Honorable Frank Pallone

Chairman

House Energy and Commerce Committee

The Honorable Kevin Brady

Ranking Member

House Ways and Means Committee

The Honorable Greg Walden

Ranking Member

House Energy and Commerce Committee

## Re: Feedback on Draft Medicare Part D Legislation

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

Justice in Aging appreciates the opportunity to provide feedback on the bipartisan draft legislation to create an out-of-pocket maximum for Medicare Part D beneficiaries, as well as make other recommendations to improve the Part D program and the low-income subsidy.

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income beneficiaries, including those dually eligible for both programs.

Justice in Aging supports the draft legislation's cap on out-of-pocket costs for all Medicare beneficiaries. Having this added protection from high prescription drug costs would be a huge benefit to beneficiaries with chronic conditions, many of whom take multiple medications. While the low-income subsidy (LIS) program provides a backstop for those with very limited incomes, it does not reach many beneficiaries with very modest incomes. Therefore, without an out-of-pocket cap, they are exposed to unbearable financial risk.

The remainder of our feedback focuses on improvements to the LIS program and other recommendations to improve accessibility for low and moderate income Part D enrollees.

#### 1. Expand the Part D Low Income Subsidy.

Eliminate the Asset Test & Expand Eligibility

The LIS program is critical to ensuring Medicare beneficiaries with the lowest income and resources, including those who are dually eligible for Medicaid, can access prescription drugs they need. However, there are many Medicare beneficiaries with limited incomes who are not eligible or not enrolled because of the program's low eligibility thresholds that limit not only income, but also the assets a beneficiary can have. The asset test unfairly penalizes low-income beneficiaries for putting aside modest savings for retirement and emergency expenses, forcing them to spend down their assets.

#### **OAKLAND**

Asset tests also discourage beneficiaries from attempting to enroll. Even those who would qualify find that collecting information on assets is a challenge and many give up simply because of the paperwork burden, which can be especially challenging for beneficiaries who are ill or have disabling conditions. As a result, many Part D enrollees with minimal income remain ineligible for this crucial cost-sharing assistance. Eliminating the asset test would also simplify the LIS application processing burdens for the Social Security Administration, and thus reduce administrative costs.

To ensure that all seniors with limited income have access to LIS, we recommend Congress eliminate the program's asset test and extend \$0 premiums, \$0 deductibles and fixed copays to Medicare beneficiaries under 200% FPL, as outlined in the Medicare Extra Rx HELP Act (S. 691) introduced by Sen. Casey. We also support Congress taking interim steps to raise the asset limits and treat all retirement savings accounts the same as pensions, by counting the distributions as income but not counting the savings as assets.

Extend Automatic Enrollment in LIS to Individuals who Lose Medicaid Expansion Eligibility Turning 65

We also recommend expanding automatic enrollment in LIS to include individuals transitioning from expansion Medicaid to Medicare regardless of whether they are eligible for another category of Medicaid. Unfortunately, because of the difference in financial eligibility criteria, many seniors who are enrolled in expansion Medicaid lose their Medicaid eligibility when they turn 65 because their income and assets are too high to meet their state's aged/blind/disabled eligibility thresholds. While these individuals are most likely eligible for LIS, even under the current eligibility thresholds, they are not automatically enrolled because they are not eligible for Medicaid. Eliminating the necessity for these individuals to apply for LIS through the Social Security Administration would ensure that they get assistance with their Part D costs right away, and avoid unnecessary financial strain or delays in accessing prescription drugs.

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 a \$0 copay policy to all generics would both take the cost burdens off low-income beneficiaries and encourage adherence. Encouraging 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.

#### 2. 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 all Low-Income Subsidy (LIS) enrollees who have any premium liability the Chooser's Notice. This small change would ensure that



the LIS program works more efficiently, and give LIS enrollees the tools they need to choose the lowest cost plans, and thus decrease the financial burden for all stakeholders involved.

### 3. Translate the LIS Application into Additional Languages.

Currently, the LIS application forms are only available in English and Spanish. However, as noted in the 2017 Medicare Beneficiary Survey Early Look Data Brief, 12% of Medicare beneficiaries living in the community report that English is not their primary language. Other reports from the Office of Minority Health show 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. Translating the LIS application itself is necessary to address health disparities, empower beneficiaries with limited English proficiency to access this financial assistance, and is consistent with Title VI of the Civil Rights Act and Section 1557 of the Affordable Care Act.

Recently, Congressman Jimmy Gomez led a <u>letter</u> 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. We recommend that Congress take similar action to ensure the LIS application is translated into additional languages, including the most-requested languages at SSA for retirement claims.

### 4. 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. Furthermore, Part D enrollees are not provided individualized information or adequate education when refused a medication at the pharmacy counter, resulting in the 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 exception 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 the service because it is not authorized explaining the reason why.

Therefore, we recommend requiring a coverage determination to be provided automatically to a beneficiary at a point-of-sale refusal. Allowing the pharmacy counter refusal to serve as the coverage

<sup>&</sup>lt;sup>1</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; 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



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.

In the interim, we recommend requiring that the existing pharmacy counter notice explain the reason (i.e., prior authorization, step therapy, quantity limits, off-formulary, non-covered, etc.) that the beneficiary is being turned away at the pharmacy counter. This simple, straightforward 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.

# 5. Establish a Special Enrollment Period for Individuals Adversely Affected by a Significant Change in Co-Insurance Responsibility Mid-Year.

Part D plan designs have become increasingly complex, making it more and more difficult for consumers to understand and compare their real costs. Many plans have six drug tiers. An increasing number of tiers charge a percentage co-insurance based on the drug's retail price, rather than a set copay amount. Further, there are pricing tiers for preferred and non-preferred retail pharmacies and for preferred and non-preferred mail order pharmacies. Particularly problematic is the fact that plans are not required to maintain a drug's retail price throughout the year. They can adjust prices based on changed agreements with manufacturers. The result is that prices can rise mid-year, sometimes quite dramatically. Yet consumers affected by a major price hike by one plan have no Special Enrollment Period in which to move to a plan that better fit their needs, no transition protections, and no other recourse. Therefore, we recommend Congress work with CMS to establish a Special Enrollment Period for individuals adversely affected by a significant change in co-insurance responsibility mid-year.

# 6. 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 to 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 works and stabilizes 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 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 statutory language to deny coverage.

The problem is exacerbated by the fact that the compendia, which are encyclopedic on-line compilations, are very expensive, with some subscriptions costing thousands of dollars per year, 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 as follows:

"MEDICALLY ACCEPTED INDICATION.—The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia authorities described in subsection (g)(1)(B)(i)."

#### Conclusion

We appreciate your consideration of our feedback. If any questions arise concerning this submission, please contact Natalie Kean, Senior Staff Attorney, at nkean@justiceinaging.org.

Sincerely,

Jennifer Goldberg

orland fi

**Deputy Director**