

December 9, 2024

Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850

RE: Medicare \$2 Drug List Model

Dear Administrator Brooks-LaSure:

We appreciate the opportunity to comment on the <u>Medicare \$2 Drug List Model</u>. As health economists and policy researchers, we have studied pharmaceutical markets and the Medicare Part D plan design for nearly two decades.<sup>1</sup>

We support CMS' main aim of this model: to test whether a simplified approach to offering low-cost generic drugs can improve medication adherence, clinical outcomes and, ultimately, beneficiaries' health. Our research has documented how complex formulary structures can create confusion, thereby reducing medication use and needlessly increasing patient spending. Furthermore, there is growing evidence that U.S. consumers, including Medicare beneficiaries and taxpayers, are often overpaying for generics while pharmacy benefit managers and others in the distribution chain profit. <sup>2</sup>

### Background: U.S. Consumers Often Overpay for Generics Due to Distribution System Inefficiencies

Inefficiencies and misaligned incentives throughout the pharmaceutical distribution system have resulted in intermediaries retaining a larger share of the total net expenditures from generic drugs. For example, Schaeffer Scholars found that Medicare could have saved \$2.6 billion in 2018 on just 184 common generic drugs if they had been purchased at Costco cash prices instead of through Medicare Part D plans. The PBM and Part D plan sponsor increased average costs by 21%. While beneficiaries were largely shielded from these increased costs because of set copays, this research shows that plans and the

<sup>&</sup>lt;sup>1</sup> The opinions expressed in this document are solely those of the authors and do not necessarily reflect the views of the University of Southern California or the USC Schaeffer Center for Health Policy & Economics. <sup>2</sup> Trish, E., Van Nuys, K., & Popovian, R. (2022). US Consumers Overpay for Generic Drugs. *Schaeffer Center White Paper Series*, *10*, m589-2268.

<sup>&</sup>lt;sup>3</sup> Trish, E., Gascue, L., Ribero, R., Van Nuys, K., & Joyce, G. (2021). Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members. *JAMA Internal Medicine*, *181*(10), 1414-1416.

Medicare Part D program are not fully benefiting from negotiations happening between the PBM and the manufacturer.

In another example, Schaeffer experts found that in 2013, 28% of generic prescriptions in a commercial claims dataset involved a patient copay that exceeded the total cost of the drug to the PBM, with the PBM keeping the overpayment.<sup>4</sup>

Large, sudden spikes in the price of some common generic drugs have also gotten attention in recent years. Schaeffer experts have found these increases are primarily due to a lack of competition within a drug class rather than supply shortages. While patients' out-of-pocket costs tended to increase modestly following a sudden increase in generic drug prices, there was still an impact on premiums.<sup>5</sup>

Transparent, simple plan benefits like the \$2 Generic Drug List Model, as well as transparent cost structures throughout the system, have valuable impacts for the beneficiary and the potential to help align incentives throughout the distribution system.

# Most Generics Are Affordable for Medicare Beneficiaries, but Plan and Formulary Complexities Reduce Use

Although estimates vary on the total savings, other recent changes to the program spurred by the Inflation Reduction Act —including the elimination of the donut hole and introduction of a \$2,000 out-of-pocket cap in Part D starting in 2025 —may result in this model incurring only modest cost savings to beneficiaries and the Medicare program. However, the program will reduce variation in out-of-pocket costs across plans and largely eliminate financial barriers to obtaining the most widely prescribed generic drugs.

Schaeffer experts have found that while generic utilization has steadily increased over the past several decades, there is considerable variation in how generously these medications are covered, with some plans favoring higher cost brand-name drugs over their generic equivalents.<sup>6</sup>

For example, some widely prescribed generic drugs are increasingly being moved to non-preferred tiers or are subject to utilization management techniques. A study of Medicare Part D formularies found that 72% of formularies placed at least one branded product in a

<sup>&</sup>lt;sup>4</sup> Van Nuys, K., Joyce, G., Ribero, R., & Goldman, D. P. (2018). Overpaying for Prescription Drugs: The Copay Clawback Phenomenon. *USC Schaeffer Center for Health Policy & Economics: Los Angeles, CA*.

<sup>&</sup>lt;sup>5</sup> Joyce, G., Henkhaus, L. E., Gascue, L., & Zissimopoulos, J. (2018). Generic Drug Price Hikes and Out-of-Pocket Spending for Medicare Beneficiaries. *Health Affairs*, *37*(10), 1578-1586.

<sup>&</sup>lt;sup>6</sup> Buttorff, C., Xu, Y., & Joyce, G. (2020). Variation in Generic Dispensing Rates in Medicare Part D. *The American Journal of Managed Care*, 26(11), e355.

lower cost-sharing tier than its generic equivalent.<sup>7</sup> According to the same study, in 2020, more than 30% of generic-available compounds required prior authorization or step therapy or were excluded from coverage altogether.<sup>8</sup> Prohibiting prior authorization, formulary exclusions and other utilization management techniques on high-value generics will help improve adherence.

Complex plan designs contribute to beneficiary confusion and suboptimal decision-making. Schaeffer studies have shown most beneficiaries do not compare Part D plans during open enrollment and are rarely enrolled in their optimal plan.<sup>9,10</sup> Growth in preferred pharmacy networks, where copayments vary at preferred and non-preferred pharmacies, adds another layer of complexity that more often benefits plans than consumers.<sup>11,12</sup>

With successful implementation, including clear communication of the standardized drug list, this program has the potential to simplify and improve access to needed medications. To best leverage this feature, program information should be accessible to providers and beneficiaries in real-time to support prescriber decisions, and the list should be posted at all pharmacies.

# For the Most Impact, the \$2 Generic Drug List Should Be as Comprehensive as Possible

Gaps in adherence are related to a variety of factors: side effects, perceived efficacy of the prescription, forgetfulness and challenges with getting refills all rank higher than cost given the out-of-pocket price of most generic drugs is generally low.<sup>13</sup> Thus, the most valuable feature of the \$2 Generic Drug Model may be simplifying the benefit design for beneficiaries.

<sup>&</sup>lt;sup>7</sup> Socal, M. P., Bai, G., & Anderson, G. F. (2019). Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics are Available. *JAMA Internal Medicine*, *179*(6), 832-833.

<sup>&</sup>lt;sup>8</sup> Joyce, G., Blaylock, B., Chen, J., & Van Nuys, K. (2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011–20. *Health Affairs*, 43(3), 391-397.

<sup>&</sup>lt;sup>9</sup> Bruine de Bruin, W., Hodson, N., Rabinovich, L., Czarnowske, D., Heiss, F., Winter, J., ... & McFadden, D. (2024). Medicare Part D Beneficiaries' Self-Reported Barriers to Switching Plans and Making Plan Comparisons at All. *Health Affairs Scholar*, qxae141.

<sup>&</sup>lt;sup>10</sup> Heiss, F., McFadden, D., Winter, J., Wuppermann, A., & Zhou, B. (2021). Inattention and Switching Costs as Sources of Inertia in Medicare Part D. *American Economic Review*, *111*(9), 2737-2781.

 <sup>&</sup>lt;sup>11</sup> Xu J, Trish E, Joyce G. Medicare Part D Beneficiaries' Pharmacy Switching in Response to Preferred Pharmacy Networks. *Health Services Research*, March 17, 2022. <a href="https://doi.org/10.1111/1475-6773.13973">https://doi.org/10.1111/1475-6773.13973</a>
<sup>12</sup> Xu J, Trish E, Joyce G. Part D Beneficiaries' Incentives and Responses under Preferred Pharmacy Networks. *The American Journal of Managed Care*. 2023;29(4).

<sup>&</sup>lt;sup>13</sup> Goldman DP, Joyce GF, Zheng Y. "Prescription Drug Cost-Sharing: Associations with Medication and Medical Utilization and Spending, and Health". *Journal of the American Medical Association (JAMA)*. 2007; 29(1): 61-69.

To ensure the program is as impactful as possible, CMS administrators should work with health plans and providers to make the list of medications as comprehensive as possible. This is especially important in heterogenous classes such as mental health drugs, in which the effectiveness of different medications and formulations can impact patients differently. Developing a list that is as expansive as possible across all chronic condition categories will benefit beneficiaries.

#### CMS Should Also Set Costs for Plans, Pharmacies

The emergence of transparent pricing models, like Mark Cuban Cost Plus Drug Company (MCCPDC), highlights how distribution costs, not manufacturing costs, drive spending on generic drugs. For example, the widely prescribed statin rosuvastatin costs \$0.01-0.03 per pill to produce but \$10-15 to distribute, regardless of quantity or strength.

Research has shown that plans and PBMs make a large margin on generic drugs while independent pharmacies often lose money from dispensing these low-cost prescriptions. <sup>14</sup> CMS should add a set fee paid to plans for administrative costs, as well as a set rate paid to pharmacies for dispensing the generic drug. This would ensure that plans and PBMs are not incentivized to favor generic products not on the list and that pharmacies are adequately reimbursed.

Achieving efficiencies in the generic drug market requires transparency and streamlined distribution. By making all costs transparent and consistent —not simply the copayment —CMS can ensure that beneficiaries receive the prescriptions they need.

#### **Evaluation of the Program Should Include Trends in Total Cost to CMS**

As mentioned in the previous section, capping out-of-pocket costs at \$2 doesn't mean the total cost of providing generic drugs to seniors will decrease. While cost-sharing at the point of sale will decline in most cases, premiums paid by the beneficiary and Medicare are likely to increase to offset the change, unless other measures are also taken. Transparent reporting and publicly available data would provide researchers and administrators with valuable information. Two reports would be of particular importance:

• Evaluate what the program is paying for these drugs overall and what each stakeholder in the distribution system is being paid, with particular attention given

<sup>&</sup>lt;sup>14</sup> Levitt, J., Bennett, S., and AJ Barbarito. (2022). A New World Order of Drastically Lower Pharmacy Reimbursement Series – Part 2: The Threatened Future of Independent Pharmacies. *Frier Levitt Attorneys at Law.* <a href="https://www.frierlevitt.com/articles/a-new-world-order-of-drastically-lower-pharmacy-reimbursement-part-2-the-threatened-future-of-independent-pharmacies/">https://www.frierlevitt.com/articles/a-new-world-order-of-drastically-lower-pharmacy-reimbursement-part-2-the-threatened-future-of-independent-pharmacies/</a>

- to PBMs, plans and independent and chain pharmacies. Comparing prices in Part D to outside suppliers such as MCCPDC is one possible benchmark.
- Analyze trends in prices and formulary placement for non-listed generics to ensure that patients taking these "non-protected" drugs are not adversely impacted.

In addition, CMS should monitor the generic supply chain and competition in the generic market more broadly. An analysis found that approximately 40% of generic drugs sold in the U.S. have just one manufacturer, and the share of markets supplied by just one or two manufacturers has increased over time. <sup>15</sup>

### **Future Opportunities for the Program**

Expanding the program to include more expensive generics with higher cost-sharing would further simplify benefit design and help beneficiaries make informed choices.

While we understand why the program is voluntary for plan participants, getting buy-in from all plans to participate would be ideal.

In conclusion, while cost-sharing reductions from \$6 to \$2 may yield modest adherence gains compared to larger copay differentials, standardizing coverage of essential generic drugs represents valuable benefit simplification. We appreciate CMS's evidence-based approach and commitment to improving Part D. We would welcome the opportunity to discuss our research findings in greater detail.

Sincerely,

Geoffrey Joyce, PhD

Senior Scholar, USC Schaeffer Center

Associate Professor, USC Mann School of Pharmacy & Pharmaceutical Sciences

Julie Zissimopoulos, PhD

Senior Scholar, USC Schaeffer Center

Co-Director, Center for Advancing Sociodemographic and Economic Study of Alzheimer's Disease and Related Dementias (CeASES ADRD) and USC RCMAR

Professor, USC Price School of Public Policy

<sup>&</sup>lt;sup>15</sup> Berndt, E. R., Conti, R. M., & Murphy, S. J. (2017). The Landscape of US Generic Prescription Drug Markets, 2004-2016 (No. w23640). National Bureau of Economic Research.

<sup>&</sup>lt;sup>16</sup> Trish, E., Kaiser, K., & Joyce, G. (2021). Association of Out-of-Pocket Spending with Insulin Adherence in Medicare Part D. *JAMA Network Open*, 4(1), e2033988-e2033988.

<sup>&</sup>lt;sup>17</sup> Joyce, G. F., Zissimopoulos, J., & Goldman, D. P. (2013). Digesting the Doughnut Hole. *Journal of Health Economics*, *32*(6), 1345-1355.