



Comments from Public Citizen in Response to the Centers for Medicare & Medicaid Services' Request on the Medicare \$2 Drug List Model

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. As such, we and our members have a strong interest in improving affordable and stable access to vital medications for U.S. patients.

We commend the Centers for Medicare & Medicaid Services (CMS) for advancing the Medicare \$2 Drug List Model, which would encourage Part D plan sponsors (PDPs) to offer a low, fixed (up to \$2 per month supply) copayment across all cost-sharing phases of the Part D drug benefit (up to the out-of-pocket limit) for a standard list of generics at all network pharmacies. Though empirical research suggests median annual savings for Medicare beneficiaries may be modest (~\$11) under the model, the predictable and affordable prices at all network pharmacy locations will likely improve patient adherence and thereby improve clinical outcomes.¹ In this comment, we suggest that CMS (1) explore eliminating cost-sharing under the Model which may provide a larger magnitude of health benefit to enrollees for the minimal costs of covering the cost-sharing burden, (2) consider certain key outcomes for assessing the Model's impact, (3) use the modest costs of the Model to encourage PDP participation, and (4) consider including certain common generics that are currently omitted from the List.

First, we suggest that CMS consider eliminating the cost-sharing burden under the Model. Theories of cost-sharing to deter wasteful care are not borne out in practice, as patients decrease both beneficial and wasteful care.² Even limited cost-sharing can induce patients to underuse high-value care.³ A wealth of empirical research shows cost-sharing is specifically associated with harmful health outcomes for low-income populations and older adults, and in the context of

¹ Christopher L. Cai, Aaron Kesselheim, & Benjamin Rome, *Estimated Savings Under the Medicare High-Value Drug List Model*, 184 JAMA INTERNAL MED. 1390 (2024).

² Allison K. Hoffman, *Health Care's Market Bureaucracy* *Health Care's Market Bureaucracy*, 66 UCLA L. REV. 1926, 1974-77 (2019) (reviewing empirical research showing that cost-sharing does not improve use of healthcare and can be associated with worse health outcomes).

³ *Id.* (citing Katherine Baicker et al., *Behavioral Hazard in Health Insurance*, 130 Q. J. ECON. 1623, 1623 (2015)). Baicker highlights, "To take one particularly striking example, relatively small reductions in copayments even after an event as salient as a heart attack still produce improvements in adherence: providing post-heart attack medications for free (instead of roughly a \$10-\$25 copayment) increased adherence by about 5 percentage points (relative to a base of 35-50 percent), and this increase was associated with a reduced rate of subsequent major vascular events (Choudhry et al., 2011)." See Katherine Baicker et al., *Behavioral Hazard in Health Insurance*, NAT'L BUREAU ECON. RES., at 6 (2015).

prescription drugs, has been linked to higher rates of emergency department visits, hospitalizations, and mortality as well as poorer control of blood pressure, lipid levels, and glucose levels.⁴ One study underscores the benefit of free distribution of essential medicines. In a randomized clinical trial of 786 primary care patients providing free access to these medicines compared to unchanged access, free access increased patient adherence to medicines and reduced systolic blood pressure.⁵ Research that annual median cost-savings for beneficiaries could be approximately \$11 under the Model suggests that PDPs would expend limited financial resources per patient to adopt the \$2 Drug List.⁶ Therefore, the benefits to patient adherence and clinical outcomes when there are no cost barriers to these medicines may significantly outweigh the marginal cost of covering the \$2 financial burden for enrollees.

Second, we recommend that CMS collect data on savings to beneficiaries, patient adherence, and health measures in assessing the impact of the model. CMS could draw on outcomes used in studies of the consequences of cost-sharing burdens for prescription drugs, such as emergency department visits, non-elective hospitalization, nursing home admissions, mortality, and if possible, systolic blood pressure, LDL cholesterol, and indicators of glucose levels.⁷ Finally, CMS may wish to study premium increases that occur as a function of adopting the List to understand the net impact of the Model on beneficiaries, though as stated above, modest out-of-pocket savings projected by experts suggest that any such premium increases should be limited.

Third, we believe a factor that can help maximize PDP participation is research suggesting that the cost of adopting the List would be modest. That is, projections that the annual median cost-savings for beneficiaries would be \$11 suggest limited financial costs to PDPs for adopting the Model.⁸ Further research by CMS to illustrate costs to PDPs with the sample List could be beneficial. More PDPs may adopt the Model if CMS releases data that shows adoption of the \$2 Drug List is associated with less costly health interventions like hospitalizations and emergency department visits due to greater medication adherence, underscoring the importance of such data collection.

⁴ Hoffman, *supra* note 2, at 1976 (citing observational and quasi-experimental studies since 2001 showing that cost-sharing is associated with negative health outcomes for low-income and older populations, particularly in the context of prescription drugs); John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, 354 NEW ENG. J. MED. 2349, 2354–55 (2006); Tamblyn et al., *Adverse Events Associated With Prescription Drug Cost-Sharing Among Poor and Elderly Persons*, 285 JAMA 421, 426–27 (2001).

⁵ Navindra Persaud, Michael Bedard, & Andrew Boozary, *Effect on Treatment Adherence of Distributing Essential Medicines at No Charge*, 180 JAMA INTERN. MED. 27 (2020).

⁶ Christopher L. Cai, Aaron Kesselheim, & Benjamin Rome, *Estimated Savings Under the Medicare High-Value Drug List Model*, 184 JAMA INTERNAL MED. 1390 (2024).

⁷ John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, 354 NEW ENG. J. MED. 2349, 2354–55 (2006); Tamblyn et al., *Adverse Events Associated With Prescription Drug Cost-Sharing Among Poor and Elderly Persons*, 285 JAMA 421, 426–27 (2001).

⁸ Christopher L. Cai, Aaron Kesselheim, & Benjamin Rome, *Estimated Savings Under the Medicare High-Value Drug List Model*, 184 JAMA INTERNAL MED. 1390 (2024).

Finally, we urge CMS to consider adding more commonly used generic drugs to the List, including glipizide and omeprazole. If CMS does not add additional drugs to the list, we encourage that it clarify why glipizide and omeprazole are not included. The omission of omeprazole for gastroesophageal reflux disease is particularly concerning given data released by the Office of the Assistant Secretary for Planning and Evaluation showing that the drug often incurs costs greater than \$2 and is one of the top ten generic drugs used by volume among Medicare beneficiaries who do not receive the low-income subsidy.⁹

We commend CMS for advancing the \$2 Drug List Model which will improve access to vital prescription drugs, improve medication adherence, and benefit Medicare enrollees' health and wellbeing. Thank you for your commitment to patient access and your consideration of the public's interest.

Sincerely,
Public Citizen

⁹ YEVGENIY FEYMAN ET AL., OFF. ASS'T SEC. PLANNING & EVAL., DEP'T HEALTH & HUMAN SERVS., GENERIC DRUG UTILIZATION AND SPENDING AMONG MEDICARE PART D ENROLLEES IN 2022, at 28-29 (Mar. 7, 2024).