December 9, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via: https://surveys.cms.gov/jfe/form/SV_40iDHQWMNuVfyGq

Re: Medicare $2 Drug List Model – Request for Information

Administrator Brooks-LaSure:

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) greatly appreciate the opportunity to provide input to the Centers for Medicare & Medicaid Services (CMS) through its request for information (RFI) and look forward to a continued dialogue regarding the unique value pharmacies and pharmacists bring to advancing your goals to improve healthcare access, quality, and equity while controlling healthcare costs.[1] We look forward to continuing to explore opportunities for pharmacies to be leveraged in throughout the healthcare system to advance these goals.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Additionally, chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $94 billion healthcare marketplace, employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of concerns we have received from independent and LTC pharmacies.

We appreciate the opportunity to share critical feedback on the Medicare $2 Drug List Model (*hereafter referred to as "the model"),* launched in response to the President's 2022 Executive Order to lower drug costs

[1] *NACDS, 2021: Accelerating the Center for Medicare and Medicaid Innovation's Mission – Integrating Community Pharmacy Care into Value-Based Programs Amid COVID-19 Pandemic Recovery & Beyond. Available at:* https://www.nacds.org/news/new-nacds-report-demonstrates-how-leveraging-the-expertise-and-accessibility-of- pharmacists-will-help-support-broader-healthcare-transformation-to-advance-quality-and-value/

for Americans.[2] We appreciate CMS' efforts and share the agency's goal to support medication affordability and adherence for Medicare beneficiaries who use generic drugs for common chronic conditions. However, we are concerned that under this new model, where Part D plans would be encouraged to offer a standardized list of approximately 150 generic drugs with a maximum co-payment of $2 for a one-month supply, **pharmacy reimbursement, and patient access could be dramatically reduced without reasonable reimbursement guardrails to protect community pharmacies.** Pharmacies are currently facing significant challenges, such as declining reimbursement rates across the big three pharmacy benefit managers (PBMs), rising drug costs, PBMs steering patients to affiliated pharmacies, and vertical integration that only strengthens PBMs' market power over pharmacies.

Additionally, the model is silent on potential impacts to pharmacies that are contracted with a Part D plan that decides to offer the $2 drug list. In the current PBM-dominant marketplace, pharmacies have less leverage to negotiate fair terms in their contracts and this model would likely worsen this issue for pharmacies, since pharmacies are not direct participants in the program (nor has the impact to pharmacies been addressed). **Therefore, we call on CMS to consider incentives that would empower pharmacists and pharmacies to implement the model and require reasonable and relevant contract terms and conditions between the pharmacy and the plan sponsor, so pharmacies are not forced to shoulder the bill and at the wield of the plan sponsor or PBM.**

Within the model, we urge CMS to require Medicare Advantage, Part D plan sponsors, and PBMs to provide adequate reimbursement to pharmacies for the generic drugs on the standardized list. Specifically, payers and PBMs must ensure that **at a minimum, payment to pharmacies for drugs on the list should cover such pharmacy's costs to acquire and to dispense each covered part D drug on the $2 drug list,** so that a pharmacy may have the option to participate as a network provider and ensure continuity of care. Below-cost reimbursement already threatens public access to pharmacies today, and such lack of access will be a greater issue if reasonable reimbursement for pharmacies is not built into the model. **To help ensure the model is not implemented in a manner that harms beneficiary access to pharmacies, we strongly urge CMS to consider changes to the model, including requiring reasonable reimbursement for pharmacies within the model, reducing the number of drugs selected for the model, and delaying implementation until at least 2026. CMS also has the authority to waive certain program rules and enforce reasonable and relevant reimbursement guardrails under this program as well as future models related to drug pricing reforms.**

Specifically, to avoid unintended consequences on beneficiary access to pharmacy care, we encourage CMS to consider the following changes to the model:

1. **Ensure that pharmacies receive fair and transparent reimbursement for the generic drugs on the list,** based on the actual acquisition cost and cost associated with safely dispensing a patient's medication(s). The burden of compounding financial pressures on pharmacies is quickly becoming insurmountable. An alarming and ever-increasing number of pharmacies have closed permanently as a result of payers increasingly reducing reimbursement – in many cases to unconscionable levels that force pharmacies to dispense prescription drugs below cost. Reimbursement is further complicated by predatory PBM and payer tactics, such as retroactive (Direct and Indirect Renumeration) fees, which often occur as much as six months after a prescription is filled for a Medicare beneficiary and a payer decides to claw back funds from a

[2] https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription- drug-costs-for-americans/

pharmacy for so-called "quality measure" that are unknown, unpredictable, inconsistent, and completely outside of the pharmacies control. Simply stated, pharmacies across the nation are in crisis, facing unsustainable under-reimbursement by payers for the cost of buying and dispensing prescription drugs, threatening medically necessary and lifesaving access for all Medicare beneficiaries and healthcare consumers. CMS must explicitly state in the model that these drugs are not subject to retroactive clawbacks or any types of fees (e.g., DIR fees) imposed by the PBMs on pharmacies. If this model poses a serious downside risk to pharmacies, then this could negatively influence network adequacy and pharmacy access.

2. **Require plans and PBMs to include all pharmacies that offer the generic drugs on the list in their networks (where they must receive fair and transparent reimbursement) and prohibit any network restrictions or patient steering to a PBM affiliated pharmacy that would restrict beneficiary choice.**

3. **Require plans and PBMs to ensure reasonable and relevant contract terms and conditions** with pharmacies.

4. **Monitor the effect of the $2 drug model on pharmacy reimbursement and viability, beneficiary access and satisfaction, and adjust the model as needed** to protect the interests of pharmacies and the beneficiaries they serve. Provide a path or contact information for pharmacies to submit complaints regarding the effects of the model on patient access and pharmacy reimbursement.

5. **Delay the model's implementation until at least 2026** and/or start with a smaller subset of drugs commonly prescribed and dispensed generics to help the drug supply chain prepare and understand the downstream effects of the model on community pharmacies.

CMS should consider starting "low and slow" to allow pharmacy providers ample time to make administrative and financial adjustments that may be necessary due changes stemming from the Inflation Reduction Act (IRA) and address any new insurer/PBM contracting hurdles that may occur under this model to ensure a seamless transition for beneficiaries and fair reimbursement for pharmacies. **For example, CMS could start with 10 generic drugs and assess whether reasonable payment is flowing smoothly from the health plan to the pharmacy in the model and most importantly, to ensure systems are operationalized to appropriately reflect and effectuate the beneficiary's $2 copay.**

As you know, pharmacies are essential providers of medications and healthcare services. About 90% of Americans live within 5 miles of a pharmacy and pharmacies serve millions of Medicare beneficiaries every day, offering convenient access to essential medications, in addition to patient education, immunizations, medication therapy management and adherence programs, and other clinical services.[3] Pharmacies also play a vital role in supporting generic drug utilization, which saves the Medicare program and beneficiaries billions of dollars each year.

We appreciate your attention to our concerns and look forward to working with CMS on innovative ways to increase patient access, ensure patient affordability, and alleviate reimbursement concerns that have

[3] Berenbrok, L. A., Tang, S., Gabriel, N., Guo, J., Sharareh, N., Patel, N., Dickson, S., & Hernandez, I. (2022). Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. Journal of the American Pharmacists Association, 62(6) 1816-1822. Retrieved from https://www.sciencedirect.com/science/article/pii/S1544319122002333?via%3Dihub

spurred the pharmacy crisis in America. We also believe the proposed changes to the model would help preserve the future of pharmacies and their ability to continue serving Medicare beneficiaries as NACDS and NCPA work on comprehensive PBM reform in both Medicare and Medicaid.

Thank you for your consideration. If we can provide any additional information and/or schedule a future in-person meeting to learn more about the implementation and scope of this model, please do not hesitate to contact Dr. Christie Boutte, PharmD, NACDS Senior Vice President, Reimbursement, Innovation, and Advocacy, at cboutte@nacds.org and Ronna Hauser, PharmD, NCPA Senior Vice President, Policy & Pharmacy Affairs at ronna.hauser@ncpa.org.

Sincerely,

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National Association of Chain Drug Stores

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