APhA
American Pharmacists Association

December 9, 2024

Elizabeth Fowler, Ph.D., J.D.
Deputy Administrator and Director of the Center for Medicare and Medicaid Innovation (CMS Innovation Center)
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare $2 Drug Model List Request for Information (RFI)

Dear Deputy Administrator and Director Fowler:

The American Pharmacists Association (APhA) is pleased to submit our comments to CMS' RFI regarding the "Medicare $2 Drug List (M2DL) Model," which would "enable Medicare Part D sponsors to offer a standard set of generic drugs at a fixed copayment of up to $2 for a month's supply (and up to $5 for a three-month supply) across all cost-sharing phases of the Part D prescription drug benefit (up to the out-of-pocket limit) for a beneficiary (including those enrolled in Low Income Subsidy (LIS) program) in a participating plan."[1] APhA supports CMS implementing plans that increase access to care by lowering the cost of medications. Providing patients with lower-cost medications should increase medication adherence and lead to improved health outcomes.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists, scientists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

[1] Medicare $2 Drug List Model – Request for Information (RFI). Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/m2dl-model-rfi.pdf.

Drug List Development Process

In developing the sample $2 Drug List, "CMS sought to include as many drugs used to treat common conditions as possible while balancing the cost of such drugs to encourage plan participation, thereby maximizing access for beneficiaries."[2] To do this, CMS reviewed covered outpatient generic drugs by utilizing multiple factors to determine which drugs would be included. After developing a list of drugs for potential inclusion, the drug list was reviewed by an external technical expert panel before being included in the $2 Drug List presented within the RFI. The current list includes 101 drugs that provide treatment options for 15 clinical categories and "represent a large proportion of Part D generic drug utilization."[3] APhA supports the sample $2 Drug List as a starting point, as it could result in millions of Part D beneficiaries receiving lower-cost drugs for their chronic conditions. APhA also supports the inclusion of pharmacists in the external technical expert panel, as pharmacists are medication experts and can provide a unique insight into the implementation of M2DL.

Maximizing Plan Participation

CMS states participation in the M2DL model would be voluntary. APhA supports voluntary participation in the M2DL model for Part D sponsors. Given that participation is voluntary, awareness of the M2DL model is essential in its success. APhA encourages CMS to educate pharmacists, prescribers, and beneficiaries of the utilization of the lower cost generic medications on the proposed $2 Drug List when appropriate to maximize plan participation. APhA urges CMS to utilize APhA to reach our nations over 300,000 pharmacists to maximize pharmacist and plan participation.

CMS Outreach Efforts

CMS states "[t]he M2DL Model will be most successful when prescribers, pharmacists, and beneficiaries are aware of the $2 Drug List." APhA agrees and generally supports the establishment of the M2DL model as the plan design is clear and provides patients with access to lower-cost medications. However, APhA encourages CMS to ensure that pharmacies are incentivized to participate in such a model and that pharmacists' full value is unlocked by also requiring coverage for counseling and medication management of the medications included on the list to meet the proposed model's goals to lower health care costs and increase access to lower-cost medications and pharmacist-provided patient care services. As stated earlier, APhA can also serve as a line of communication between CMS and our nations over 300,000 frontline

[2] Medicare $2 Drug List Model – Request for Information (RFI). Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/m2dl-model-rfi.pdf.
[3] Medicare $2 Drug List Model – Request for Information (RFI). Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/m2dl-model-rfi.pdf.

pharmacists and pharmacy technicians to effectively educate our members about the goals and implementation of CMS's plan and forward CMS feedback from those implementing the plan. Effective implementation of the M2DL model will ensure CMS can appropriately assess the plan's design and meet the proposed model's goals to lower drug costs and increase access.

APhA commends CMS for proposing benefit designs, such as the M2DL model that are clear and easy for patients and health care providers to understand. Pharmacies are often the next stop after a patient receives a prescription from their health care provider, particularly patients with common conditions among Medicare beneficiaries, such as high cholesterol and high blood pressure on the proposed $2 Drug List. However, pharmacists and pharmacy technicians are regularly tasked, but not compensated, with explaining plan benefits to patients. Clear information from Part D plans would also be vital to allow pharmacists and pharmacy technicians to easily and effectively educate their patients and providers on the benefits provided, which should enable patients to better utilize their prescription drug plans and providers to prescribe more affordable medications that are covered under their insurance that leads to improved patient outcomes. Additionally, APhA recommends that CMS take this opportunity to consider reimbursement for pharmacist-prescribed medications for those included on the proposed or future $2 Drug Lists. Currently, pharmacists in all states can prescribe through some mechanism, whether that be through independent prescribing under a standard of care model, collaborative practice agreements, or other statewide protocols, which increases access where there are often no other health care practitioners.[4] Accordingly, APhA encourages CMS utilize pharmacists as prescribers and allow them to practice at the top of their licenses to aid in reducing access issues in M2DL and other models to lower overall health care costs.

Part D Sponsor Outreach and Education Efforts for Beneficiaries

CMS wants to ensure that the outreach and education efforts it implements reaches "members of underserved communities including but not limited to beneficiaries in rural, tribal, and geographically isolated communities." Pharmacists are often the most accessible health care professional, as nearly 90% of Americans live within five miles of a community pharmacy.[5] As such, APhA encourages CMS to consider pharmacies and pharmacists as points of outreach and education for the details about a beneficiary's Part D plan to reach as many Americans as possible. APhA also urges CMS implement proper reimbursement mechanisms for pharmacies to ensure that Americans do not lose access to these critical health care access points.

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[4] Adams AJ, Weaver KK, Adams JA. Revisiting the Continuum of Pharmacist Prescriptive Authority. *Journal of the American Pharmacists Association*. 2023;63(5):1508-1514. doi:10.1016/j.japh.2023.06.025.

[5] Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I, Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis, Journal of the American Pharmacists Association (2022), doi: https:// doi.org/10.1016/j.japh.2022.07.003.

Assessment of Model Impact

APhA strongly encourages CMS to review how pharmacies will be reimbursed for dispensing the medications included in this model. As we learned from commercial pharmacies offering $4 generic drug lists, many of these lower-cost generics were offered below operating costs (~$8-$12/per fill), where pharmacies lost money filling them, but helped to get patients into pharmacies where they could also receive pharmacist-provided patient care services to lower costs and improve care. However, due to the low dollar amount, these models are not feasible for most pharmacies, particularly if drugs are sent through mail order. Generally, about 50% of generic drugs do not turn a profit.[6] Accordingly, APhA recommends that CMS ensure pharmacies receive fair, reasonable, and predictable reimbursement for drug acquisition costs in addition to a margin and equitable professional dispensing fees to cover all required pharmacy dispensing costs and associated services under the M2DL and other models. Adequate reimbursement is vital to keeping pharmacies open. Over the last four years, more than 2,200 community pharmacies have closed, including over 300 independent pharmacies in 2023 alone, leading to the creation of "pharmacy deserts" in many communities across the country.[7] Of the 88,930 community pharmacies operating between 2010 and 2020, new research has found that 29.4%, over 26,000, of them had closed by 2021, and those in Black and Latinx communities were at a higher risk of closure.[8] These closures impacted both rural and urban areas. At least 630 rural communities that had at least one community pharmacy in 2003 had zero community pharmacies by 2018.[9] Looking at urban areas, between 2009 and 2015, one in eight pharmacies closed due to Medicare and Medicaid reimbursements that were lower than costs of drug acquisition.[10] These reimbursement issues continue to force pharmacies to decide between dispensing medications to patients and keeping their doors open, as insurance companies and pharmacy benefit managers (PBMs) are paying community pharmacies dispensing fees far below the cost to acquire mediations from their wholesalers and to dispense medications – sometimes even at $0. Accordingly, APhA encourages CMS to establish protections for pharmacies to ensure that pharmacies receive appropriate dispensing fees, prompt payment, and cover under all its models so as not to exacerbate these pharmacy closures.

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[6] Swetlitz I. Why Are Generic Drugs Hard to Find? Because They're Not Profitable. Bloomberg.com. October 12, 2023. https://www.bloomberg.com/news/newsletters/2023-10-12/why-are-generic-drugs-hard-to-find-because-they-re-not-profitable.

[7] Local Pharmacies on the Brink, New Survey Reveals. National Community Pharmacists Association. February 27, 2024. Accessed December 3, 2024. https://ncpa.org/newsroom/news-releases/2024/02/27/local-pharmacies-brink-new-survey-reveals#:~:text=NCPA%20sent%20a%20letter%20to,there%20were%20four%20years%20ago.

[8] Guadamuz JS, Alexander GC, Kanter GP, Qato DM. More US Pharmacies Closed Than Opened in 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk. *Health Affairs*. 2024;43(12):1703-1711. doi:10.1377/hlthaff.2024.00192.

[9] The Role of Pharmacy Benefit Managers in Prescription Drug Markets. House Committee on Oversight and Accountability. Accessed December 4, 2024. https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

[10] Ibid.

Pharmacies are essential health care hubs in many communities. Studies have shown that when pharmacies close patient adherence significantly declines.[11] In turn, medication nonadherence results in billions of dollars of avoidable health care spending due to worsening health outcomes and unnecessary hospitalizations.[12] As previously, mentioned pharmacy closures also create greater access issues, especially in minority and underserved communities, where localpharmacists may be the only accessible health care provider. .[13] In the spirit of CMS's goal of increasing access to care with M2DL, APhA also strongly recommends CMS take this opportunity to test a limited number of direct pharmacist billing codes for counseling and medication management of the medications within this initial drug list. APhA proposes the utilization of payment rates like those of the relative value units (RVUs) for counseling for remote patient monitoring or digital mental health treatments. CMS has tested new payment innovations in the "GUIDE Model" and "Enhancing Oncology Model." This proposed innovation would focus on the payment for direct care and services provided by pharmacists rather than only dispensing. Reimbursing pharmacists for the services they provide is crucial to keeping pharmacies open and ensuring patients retain access to their community pharmacies.

Drug List Modifications

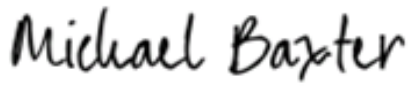
Regarding drug list modifications, APhA supports the current list of medications as a starting point and the multifactorial process used in selecting the drugs included on this list. APhA encourages CMS to continue to utilize the expertise of pharmacists on the external technical expert panel, as pharmacists are medication experts and can provide recommendations based on their experience working directly with patients and other health care providers. Additionally, the RFI states that CMS will routinely monitor "[n]ew generic drug launches, changing clinical indications, and trends in pricing" that could result in changes to the $2 Drug List.[14] APhA commends CMS for taking action to ensure that the list remains current and evolves with changes in the industry, so that beneficiaries can access the most beneficial medications at these lower price points.

APhA thanks CMS again for your work to create models that are clear and ensure greater patient access to medications. As previously mentioned, APhA also urges CMS to put

[11] Qato DM, Alexander GC, Chakraborty A, Guadamuz JS, Jackson JW. Association between pharmacy closures and adherence to cardiovascular medications among older US adults. *JAMA Network Open*. 2019;2(4). doi:10.1001/jamanetworkopen.2019.2606.
[12] Rohatgi KW, Humble S, McQueen A, et al. Medication Adherence and Characteristics of Patients Who Spend Less on Basic Needs to Afford Medications. *The Journal of the American Board of Family Medicine*. 2021;34(3):561-570. doi:10.3122/jabfm.2021.03.200361.
[13] Guadamuz JS, Alexander GC, Kanter GP, Qato DM. More US Pharmacies Closed Than Opened in 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk. *Health Affairs*. 2024;43(12):1703-1711. doi:10.1377/hlthaff.2024.00192.
[14] Medicare $2 Drug List Model – Request for Information (RFI). Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/m2dl-model-rfi.pdf.

reimbursement mechanisms in place to ensure that pharmacies are adequately reimbursed and consider testing a limited number of direct pharmacist billing codes for services related to those medications on the initial drug list. Please contact me at mbaxter@aphanet.org with any additional questions or to arrange a meeting with APhA on how CMS can unlock the full value of our nation's pharmacists.

Sincerely,



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