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Medicare $2 Drug List Model – Request for Information (RFI) – Responses Due December 9, 2024

This October marks two years since President Biden issued Executive Order 14087 "Lowering Prescription Drug Costs for Americans," which directed the Secretary of Health and Human Services to "select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access." The Secretary of Health and Human Services, in response, delivered a report to the White House in February 2023 outlining three selected models, all aimed at improving prescription drug affordability and access while also complementing the historic reforms in the Inflation Reduction Act of 2022 that are lowering prescription drug costs for Americans.

One of the three models proposed by the Secretary in the February 2023 report is the Medicare $2 Drug List Model ("the model"), which would allow Part D plan sponsors to offer a low, fixed (up to $2 for a month's supply) copayment across all cost-sharing phases of the Part D drug benefit (up to the out-of-pocket limit) for a standard Medicare-defined list of generic drugs. Further details on the model were also released in October 2023 in the "CMS Innovation Center's One-Year Update on the Executive Order to Lower Prescription Drug Costs for Americans" blog post.

In this Request for Information (RFI), **CMS is seeking input** from a broad range of interested parties to support continued development efforts for the model. CMS' **primary areas of interest include:**

- **Drug List Development Process;**
- **Maximizing Plan Participation;**
- **CMS Outreach Efforts;**
- **Part D Sponsor Outreach and Education Efforts for Beneficiaries;**
- **Assessment of Model Impact and;**
- **Drug List Modifications.**

CMS is interested in hearing from all stakeholders, including, but not limited to, Medicare beneficiaries, advocates, Medicare Part D plan sponsors, pharmacy benefit managers, prescribers, pharmacists, pharmacies, policy experts, researchers, drug manufacturers, wholesalers, distributors, and other interested parties.

Background on the Medicare $2 Drug List Model:
Affordability and limited price transparency are two of the primary reasons adults do not take prescribed medications.[1] In addition, an array of formulary designs, variations in preferred pharmacy networks, and other administrative requirements result in one in three Medicare beneficiaries reporting the Part D benefit is "difficult to understand" or "knowing little to nothing about what they need to know."[2]

The Innovation Center's Medicare $2 Drug List Model proposes testing whether a simplified approach to offering low-cost, clinically important generic drugs can improve medication adherence, lead to better outcomes, and improve beneficiary and prescriber satisfaction with the Part D benefit. The model aims to standardize cost sharing for low-cost generics through a new, easy-to-understand option for beneficiaries and their healthcare providers. Specifically, the model will 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

[1] Kaiser Family Foundation. (2022, October 20). Public Opinion on Prescription Drugs and Their Prices. https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
[2] Medicare Current Beneficiary Survey (MCBS) 2021 data. Internal analysis.

a participating plan.[3] The medications on the $2 Drug List target common conditions among Medicare beneficiaries, such as high cholesterol and high blood pressure, and would not be subject to utilization management requirements (except for safety-related requirements) at any network pharmacy. Participation in the model would be voluntary for Part D sponsors (including those offering both Medicare Advantage Prescription Drug (MA-PDs) plans and Standalone Prescription Drug plans (PDPs)).

Although most Part D sponsors can currently offer a similar benefit design, Innovation Center analyses note that in 2023, only 20% of Part D beneficiaries (or about 8 million beneficiaries) were enrolled in plans that offered generic drugs for $2 (or less) for a month's supply across all network mail and retail locations. Almost all these enrollees were in Medicare Advantage Prescription Drug Enhanced Alternative (EA) plans, likely due to EA plans having the flexibility to use supplemental dollars from Part C bids to subsidize beneficiary cost sharing in the Part D benefit.[4] Among the plans offering an equivalent or superior benefit, the drugs available varied significantly by Part D sponsor.

Standardized "drug lists" with pre-determined out-of-pocket costs are used by many beneficiaries and providers since large retail pharmacy and grocery chains with pharmacies successfully offer defined lists of prescription generic drugs at low, fixed prices. The Innovation Center's approach in the Medicare $2 Drug List Model is informed by this experience, building on the concept of a standardized list while tailoring the approach to the needs of Part D beneficiaries and plans.

Developing the $2 Drug List for the Model:
To develop the sample $2 Drug List (presented in Appendix 1), the Innovation Center evaluated covered outpatient[5] generic drugs across multiple factors including but not limited to:

- clinical role in therapy based on national treatment and medical society guidelines and public research;
- frequency of use among Medicare beneficiaries;
- cost of the drug (for the Part D sponsor) and associated financial impact of inclusion;
- rates of inclusion on Part D preferred generic formulary tiers;
- presence of prior authorization or step therapy requirements;
- inclusion on low-dollar retail and commercial formularies;
- inclusion on federal partner formularies (e.g., Veterans Affairs National Formulary);
- number of manufacturers and/or potential for supply interruptions; and
- presence on the American Geriatrics Society Beers Criteria®,[6] Drug Enforcement Administration (DEA) scheduled substances, or other safety related categorizations.

The Innovation Center structured and consolidated information using the above criteria for each generic drug, developing a prioritized list of drugs suitable for potential inclusion. The information was then reviewed with an external technical expert panel (TEP) of physicians, pharmacists, and health policy experts, and their individual recommendations informed the sample list of drugs presented in this RFI.

[3] The IRA eliminated the five percent coinsurance in the catastrophic coverage phase, effective January 2024. Starting in 2025, the IRA will institute a$2,000 out-of-pocket cap in Medicare Part D, to be indexed annually for inflation thereafter.
[4] CMS Blog Post - https://www.cms.gov/blog/cms-innovation-centers-one-year-update-executive-order-lower-prescription-drug-costs-americans
[5] Sec. 1860D-2. (e) "Covered drug"
[6] https://agsjournals.onlinelibrary.wiley.com/doi/10.1111/jgs.18372

The Sample $2 Drug List:

The sample $2 Drug List includes 101 drugs covering therapeutic uses across 15 clinical categories. The included drugs represent a large proportion of Part D generic drug utilization. Specifically:

- Of beneficiaries utilizing their Part D benefit in 2023, 95% (or ~40 million beneficiaries) filled a prescription for a drug on the sample $2 Drug List.
- Of prescriptions written for Part D beneficiaries in 2023, 80% of the time a drug included on the sample $2 Drug List could potentially have offered a treatment option.

The attached appendix specifies the 101 drugs at the level of RxCUI (RxNorm concept unique identifier), which uniquely identifies a drug with its active ingredient, strength, and formulation (e.g., atorvastatin 10mg tablets). In most cases, all available doses and formulations of a drug were included. But in some cases, it was necessary to exclude less common strengths or formulations with significantly higher prices and/or limited manufacturers. In all cases, 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. The table below summarizes the number of drugs included in the sample $2 Drug List, grouped into clinical categories.

Summary of Sample $2 Drug List by Clinical Categories:

Clinical Category	Count of Drugs
Blood Pressure/ Cardiovascular	35
Cholesterol	5
Diabetes	3
Substance Use	2
Mental Health	14
Neurological	7
Gastrointestinal	1
Thyroid	2
Hormone-Influencing Agents	3
Anti-Inflammatory	3
Eye Drops	4
Skin/ Topicals	3
Infections	12
Asthma and Inhalers	2
Other	5
Total	101

In addition, the image below summarizes the sample $2 Drug List grouping drugs by clinical category and consolidating them by active ingredient:

The Medicare $2 Drug List
SAMPLE & ILLUSTRATIVE
NOT FOR CLINICAL USE

Blood Pressure / Cardiovascular	
Amiodarone 200 mg	Tab
Amlodipine 2.5/5/10 mg	Tab
Amlodipine-Benazepril 2.5-10/5-10/5-20/5-40/10-20/10-40 mg	Cap
Atenolol 25/50/100 mg	Tab
Benazepril 5/10/20/40 mg	Tab
Carvedilol 3.125/6.25/12.5/25 mg	Tab
Chlorthalidone 25/50 mg	Tab
Cilostazol 50/100 mg	Tab
Clopidogrel 75 mg	Tab
Enalapril 2.5/5/10/20 mg	Tab
Fosinopril 10/20/40 mg	Tab
Furosemide 20/40/80 mg	Tab
Hydralazine 10/25/50/100 mg	Tab
Hydrochlorothiazide 12.5/25/50 mg	Tab
Hydrochlorothiazide 12.5 mg	Cap
Indapamide 1.25/2.5 mg	Tab
Irbesartan 75/150/300 mg	Tab
Irbesartan-HCTZ 150-12.5/300-12.5 mg	Tab
Isosorbide Mononitrate ER 30/60 mg	Tab
Lisinopril 2.5/5/10/20/30/40 mg	Tab
Lisinopril-HCTZ 10-12.5/20-12.5/20-25 mg	Tab
Losartan 25/50/100 mg	Tab
Losartan-HCTZ 50-12.5/100-12.5/100-25 mg	Tab
Metoprolol Succinate ER 25/50/100/200 mg	Tab
Metoprolol Tartrate 25/50/100 mg	Tab
Olmesartan 5/20/40 mg	Tab
Propranolol 10/20/40 mg	Tab
Quinapril 5/10/20/40 mg	Tab
Ramipril 1.25/2.5/5/10 mg	Cap
Spironolactone 25/50/100 mg	Tab
Triamterene-HCTZ 37.5-25/75-50 mg	Tab
Triamterene-HCTZ 37.5-25 mg	Cap
Valsartan 40/80/160/320 mg	Tab
Verapamil 40/80/120 mg	Tab
Warfarin 1/2/2.5/3/4/5/6/7.5/10 mg	Tab

Cholesterol	
Atorvastatin 10/20/40/80 mg	Tab
Lovastatin 10/20/40 mg	Tab
Pravastatin 10/20/40/80 mg	Tab
Rosuvastatin 5/10/20/40 mg	Tab
Simvastatin 5/10/20/40/80 mg	Tab
Diabetes	
Metformin 500/850/1000 mg	Tab
Metformin ER 500/750 mg	Tab
Pioglitazone 15/30/45 mg	Tab
Substance Use	
Buprenorphine-Naloxone 2-0.5/8-2 mg	Sub. Tab
Naltrexone 50 mg	Tab
Mental Health	
Bupropion 75/100 mg	Tab
Bupropion ER 12Hr 100/150/200 mg	Tab
Bupropion ER 24Hr 150/300 mg	Tab
Buspirone 5/10/15 mg	Tab
Citalopram 10/20 mg	Tab
Escitalopram 5/10/20 mg	Tab
Fluoxetine 10/20/40 mg	Cap
Lithium 150/300/600 mg	Cap
Lithium 300 mg	Tab
Mirtazapine 15/30/45 mg	Tab
Risperidone 0.25/0.5/1/2/3/4 mg	Tab
Sertraline 25/50/100 mg	Tab
Trazodone 50/100/150 mg	Tab
Venlafaxine ER 37.5/75/150 mg	Cap
Neurological	
Carbidopa-Levodopa 10-100/25-100/25-250 mg	Tab
Divalproex DR 125/250/500 mg	Tab
Donepezil 5/10 mg	Tab
Lamotrigine 25/100/150/200 mg	Tab
Levetiracetam 250/500/750/1000 mg	Tab
Sumatriptan 25/50/100 mg	Tab
Tizanidine 2/4 mg	Tab
Gastrointestinal	
Metoclopramide 5/10 mg	Tab
Thyroid	
Levothyroxine 25/50/75/88/100/112/125/137/150/175/200/300 mcg	Tab
Methimazole 5/10 mg	Tab

Hormone-Influencing Agents	
Anastrozole 1 mg	Tab
Finasteride 5 mg	Tab
Tamoxifen 10/20 mg	Tab
Anti-Inflammatory	
Methotrexate 2.5 mg	Tab
Prednisone 2.5/5/10/20/50 mg	Tab
Sulfasalazine 500 mg	Tab
Eye Drops	
Brimonidine 0.2%	Solution
Latanoprost 0.005%	Solution
Polymyxin B-Trimethoprim 10,000U/ml-0.1%	Solution
Timolol 0.25%/0.5%	Solution
Skin / Topicals	
Mupirocin 2%	Ointment
Nystatin 100,000 units/g	Ointment
Nystatin 100,000 units/g	Cream
Infections	
Acyclovir 200 mg	Cap
Acyclovir 400/800 mg	Tab
Amoxicillin 250/500 mg	Cap
Azithromycin 250/500 mg	Tab
Azithromycin 250/500 mg	Pack
Cephalexin 250/500 mg	Cap
Fluconazole 150 mg	Tab
Isoniazid 100/300 mg	Tab
Metronidazole 250/500 mg	Tab
Penicillin V 250/500 mg	Tab
Sulfamethoxazole-Trimethoprim 400-80/800-160 mg	Tab
Terbinafine 250 mg	Tab
Asthma and Inhalers	
Albuterol (generic ProAir® HFA or Proventil® HFA)	Inhaler
Montelukast 10 mg	Tab
Other	
Alendronate 10/35/70 mg	Tab
Allopurinol 100/300 mg	Tab
Chlorhexidine 0.12%	Mouthwash
Hydroxyurea 500 mg	Cap
Tamsulosin 0.4 mg	Cap

The sample $2 Drug List shared in this RFI represents a starting point for the Innovation Center's development of the M2DL Model which, pending development, could start as early as January 2027. New generic drug launches, changing clinical indications, and trends in pricing will necessitate updates to the $2 Drug List both prior to launch and at regular intervals during the model. In addition to requesting input through this RFI, the Innovation Center intends to continue incorporating feedback from interested parties as part of this ongoing update process. The Innovation Center looks forward to obtaining feedback from a variety of sources to inform the development of the model that maximizes beneficiary access to low-cost generic drugs.

Key Questions for Interested Parties:

$2 Drug List Development Process: The Innovation Center considered various criteria (bulleted list in previous section) to develop the sample drug list. Are there additional data sources, criteria, or considerations the Innovation Center should consider in developing future versions of the $2 Drug List?

Maximizing Plan Participation: Given participation in the M2DL Model would be voluntary on the part of Part D sponsors, what factors may inform the decision by Part D sponsors to participate (or not participate) in this model? To maximize beneficiary, prescriber, and pharmacist awareness of and use of these low-cost generics when appropriate,

are there other policies the Innovation Center should consider to encourage broad and balanced (i.e., MA-PD and PDP) Part D sponsor participation in the M2DL Model?

CMS Outreach Efforts: The M2DL Model will be most successful when prescribers, pharmacists, and beneficiaries are aware of the $2 Drug List. In addition, prescribers having the ability to easily reference the list will help facilitate increased beneficiary access to these low-cost drugs when clinically appropriate. To achieve this level of awareness, CMS intends to conduct outreach and education that would complement existing plan communications. Additionally, we are interested in outreach by other external parties that may help raise awareness of the model. What outreach activities would be most effective to reach prescribers? What outreach activities conducted by CMS would be most effective to reach beneficiaries and their caregivers? What outreach activities would best reach pharmacists, and how could their unique position support awareness of this model?

Part D Sponsor Outreach and Education Efforts for Beneficiaries: We are seeking information about the best practices used by Part D sponsors' communications and marketing efforts to prescribers, beneficiaries, and their caregivers about the details of a given Part D plan, especially details on gaining access to low-cost drugs. Please provide examples of specific marketing elements or techniques that have either been effective or ineffective at helping beneficiaries, and their prescribers navigate their Part D plan options. Are there specific marketing or outreach elements that have either been effective or ineffective with low-income populations? How could these examples be applied to the M2DL Model being developed?

How might outreach and educational efforts be most impactful for helping to reach members of underserved communities including but not limited to beneficiaries in rural, tribal, and geographically isolated communities to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes?

Additionally, Part D sponsors are required to implement one or more electronic real-time benefit tools and comply with a standard adopted by Office of the National Coordinator for Health Information Technology by 2027. How can Part D sponsors utilize the real-time benefit tools to educate prescribers and beneficiaries about the $2 Drug List?

Assessment of Model Impact: The Innovation Center intends to study a broad range of outcomes when evaluating the M2DL Model, including metrics assessing utilization and beneficiary and provider satisfaction. What outcomes and metrics will be most important for the Innovation Center to monitor and evaluate for this model? Beyond CMS's existing administrative data, what data sources might help to evaluate the impact of this model? Given the sample drug list as proposed and timeframe of the model test, what health-related outcomes should the evaluation consider measuring?

Drug List Modifications: The ease of beneficiaries, pharmacists, and prescribers using the $2 Drug List is improved if the list is static. But with changes to the generic drug landscape and the dynamic nature of associated scientific evidence, updates to the list may be necessary. How could future changes to the $2 Drug List be best communicated to beneficiaries, prescribers, pharmacies, and plans? How could changes to the $2 Drug List complement existing formulary update processes? With what frequency should the list be updated to balance both consistency with the need to respond to dynamic changes?

Process for Parties to Submit Responses:
Resources to submit comments can be found on the Model webpage. Comments must be submitted by **December 9, 2024, 11:59 PM PST** and will only be accepted through the survey portal.

Special Note to Commenters:
Whenever possible, respondents are asked to draw their responses from objective, empirical, and clinically actionable evidence and to cite this evidence within their responses.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. In addition, this RFI does not commit the U.S. Government to any policy decision and CMS will follow established methods for proposing future policy changes. We note that not responding to this RFI does not preclude participation in any future procurement or rulemaking, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

CMS may choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this RFI are not offers and cannot be accepted by the U.S. Government to form a binding contract. Information obtained as a result of this RFI may be used by the U.S. Government for program and/or model planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur costs for which payment would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

Appendix 1: Machine Readable File

Sample $2 Drug List for the M2DL Model in machine readable format (.csv) with drug names and associated RxCUI information.