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December 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services (CMS)
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare $2 Dollar Drug List Model – Request for Information (RFI)

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) appreciates the opportunity to provide feedback on the Medicare $2 Dollar Drug List Model (M2DL Model) Request for Information (RFI). On behalf of approximately 37 million individuals living with chronic kidney disease (CKD) in the United States for whom medication adherence is essential to delay the progression of CKD, we request that CMS continue to develop the $2 Drug List Model.[1]

CKD is a public health crisis that is exacerbated by increasing rates of obesity, hypertension, and diabetes.[2] Approximately 13.5% of aged beneficiaries in traditional Medicare have a diagnosis of CKD, although the prevalence of CKD is almost certainly higher, as data from the National Health and Nutrition Examination Survey (NHANES) find that CKD prevalence among all aged and disabled Medicare beneficiaries exceeds 30 percent.[3] [4,] CKD confers high rates of morbidity and mortality on the health of Medicare beneficiaries through complications from the loss of kidney function and the interplay of cardiovascular and kidney disease. The result is that the risk of cardiovascular events increases as kidney disease progresses to kidney failure.[5] CKD can be prevented, and its progression slowed and stopped with a combination of lifestyle and pharmacologic interventions, however CKD is underdiagnosed and undermanaged.[6] The NKF works across healthcare payers and the public health systems to improve quality of CKD care by partnering with health plans and health systems to measure and close gaps in CKD identification and management.[7] Medicare policy can complement these efforts by targeting beneficiary-facing challenges in

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[1] Self-reported Medication Adherence and CKD Progression. Cedillo-Couvert, Esteban A.Appel, Lawrence J. et al. Kidney International Reports, Volume 3, Issue 3, 645 - 651
[2] Mallamaci F, Tripepi G. Risk Factors of Chronic Kidney Disease Progression: Between Old and New Concepts. J Clin Med. 2024 Jan 24;13(3):678. doi: 10.3390/jcm13030678. PMID: 38337372; PMCID: PMC10856768.
[3] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.
[4] Ibid.
[5] Borg, R., Carlson, N., Søndergaard, J., & Persson, F. (2023). The Growing Challenge of Chronic Kidney Disease: An Overview of Current Knowledge. *International Journal of Nephrology*, *2023*(1), 9609266. https://doi.org/10.1155/2023/9609266
[6] Risk of CKD Progression and Quality-of-Care Indicators in the Primary Care Setting. Yuen, Janet et al. American Journal of Kidney Diseases, Volume 81, Issue 2, 247 – 249.
[7] https://www.kidney.org/professionals/ckdintercept

medication adherence such as affordability, price transparency, and the need for simple to understand information about the Part D benefit through Innovation Center tests like the proposed Medicare $2 Dollar Drug List model. Stated simply, we agree with CMS that every quality improvement intervention we implement will not have the intended affect if the patients we set out to help do not find it easy to fill and take the medications they are prescribed.

The proposed Medicare $2 Drug List has special implications for individuals affected by kidney disease. The Part D benefit provides essential health coverage for beneficiaries with CKD and ESRD. For beneficiaries with CKD, enrollment in Medicare Part D follows general enrollment trends (74.7% of individuals with CKD and 71.4% of those without diagnosed CKD) but beneficiaries with CKD are more likely to be enrolled in the Low-Income Subsidy (LIS) (20.8% of Part D enrollees with CKD versus and 15.2% without CKD).[8] LIS eligible beneficiaries with CKD are disproportionately Black, Asian, and Hispanic.[9] These figures are similar for beneficiaries with ESRD, except that beneficiaries with ESRD are much more likely to be enrolled in the LIS than beneficiaries without (LIS; 59.6% versus 24.5%).[10] ***Of note for relevance of the $2 drug list for kidney patients, in 2022, over half of aged beneficiaries with CKD were prescribed statins, antibiotics, ACEi/ARBs, and beta-adrenergic blockers.***

Like all patients, kidney patients who cannot afford high out-of-pocket prescription copays face the consequences of poor health outcomes and increased morbidity and mortality.[11] Ensuring that kidney patients have every opportunity to access affordable, transparent, and comprehensible care is also essential for our patient population because many individuals who progress to kidney failure will interact with gatekeeping to optimal renal replacement therapy; i.e., therapy at home or a kidney transplant. Kidney patients who are not able to adhere to prescribed treatments may be labeled as "noncompliant" or "nonadherent." This classification can lead to significant consequences, such as the potential denial of access to the transplant waitlist for patients on dialysis who are hoping to receive a life-saving kidney transplant. Adherence to treatment is vital not only for health outcomes but also for eligibility for essential medical interventions, emphasizing the need to test novel approaches to helping beneficiaries access the medications they are prescribed.

As strong advocates for drug affordability and for the availability of patient-facing materials that provide relevant medical information in a way that patients can process and use, we respectfully submit the answers below in response to the RFI:

$2 Drug List Development Process: Are there additional data sources, criteria, or considerations the Innovation Center should consider in developing future versions of the $2 Drug List?

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[8] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.
[9] *Ibid.*
[10] *Ibid.*
[11] Chisholm-Burns, M. A., & Spivey, C. A. (2012). The 'cost' of medication nonadherence: Consequences we cannot afford to accept. *Journal of the American Pharmacists Association, 52*(6), 823-826. https://doi.org/10.1331/JAPhA.2012.11088

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NKF broadly agrees with CMS' approach to developing the M2DL. We encourage the Innovation Center to evaluate important clinical practice guidelines in kidney disease, including those from Kidney Disease Improving Global Outcomes and the NKF's Kidney Disease Outcomes Quality Initiative (KDOQI). NKF would be pleased to nominate patient and/or professional members for future Technical Expert Panels (TEPs) supporting the ongoing development of the M2DL Model. The patient voice is a powerful lever that should be utilized as the Innovation Center develops future iterations of the $2 drug list.

<u>Maximizing Plan Participation:</u> 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, Medicare $2 Drug List Model – Request for Information (RFI) 5 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?

We agree with CMS that encouraging broad and balance participation in a voluntary model is a substantial challenge. Setting aside the immediate problem of needing a robust comparator for the proposed model's evaluation, we would note that, from NKF's perspective, any participation by MA-PD and PDP sponsors in the proposed M2DL Model would be meaningful as industry best practices can spread outside of direct policy incentives. Whether or not one believes that competition in the Part D market is robust, the Kaiser Family Foundation (KFF) reports that in 2024, the average Medicare beneficiary is choosing between 21 Medicare stand-alone drug plans and 36 Medicare Advantage drug plans.[12] We would hope that comprehensibility of plan materials and patient-facing information, which CMS could encourage through programs and models like the M2DL Model, could become a selling point in a market in which beneficiaries have their choice of drug plan.

In response to the specific question posed, we would not expect that the generic drugs proposed for inclusion on the M2DL are a cost center for a Part D sponsor or that projected savings or losses from including low-cost generic drugs at a fixed copay of $2 a month across all cost-sharing phases would the factor in determining whether to participate in the model. Rather, we expect participation will be a function of a plan sponsor's knowledge, interest, and capacity. As there is currently a great deal of interaction between CMS and Part D sponsors on a wide range of policy issues related to the implementation of the Inflation Reduction Act including the implementation of the Medicare Prescription Payment Plan and the Part D Redesign, we suggest considering the value of highlighting the development of the M2DL in outreach to and communications with Part D sponsors. CMS' leadership on its commitment to the model may be especially impactful given that we expect plan sponsors are looking for guidance and clarity from CMS on how to comply with CMS' expectations, regulations, and guidance on the future of Medicare Part D.

[12] https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2024-a-first-look-at-prescription-drug-plan-availability-premiums-and-cost-sharing/

<u>CMS Outreach Efforts:</u> What outreach activities would be most effective in reaching prescribers? What outreach activities conducted by CMS would be most effective in reaching beneficiaries and their caregivers? What outreach activities would best reach pharmacists, and how could their unique position support awareness of this model?

A growing body of literature supports the role of the pharmacist in identifying and managing medication-related problems, medication reconciliation, and adherence for individuals with CKD.[13] Patients with CKD have a substantial bill burden. One systematic review found a prevalence of polypharmacy of 82% and a pooled mean of 9.7 medications (95% confidence interval, 8.4 to 11.0) among all patients with CKD.[14] In CKD, polypharmacy is associated with worse clinical outcomes, more medication-related problems, and reduced quality of life.[15] Conversely, poor adherence to prescribed medications challenges optimal CKD management, a pillar of which is medications known to reduce CKD progression, comorbidities and associated cardiovascular risk. Medical management of individuals with CKD is further confounded by the implications of loss of kidney function, which affects how many drugs are absorbed, distributed in the body, and cleared.[16] Pharmacists are well positioned to manage these complex and competing patient needs.

NKF encourages CMS to engage medical societies and organizations whose specialties involve prescribing medications listed on the $2 drug list to raise awareness of this model. The membership of the NKF includes over 100 pharmacists whom we would be pleased to involve in the further development of the model. NKF would also be glad to help CMS engage with the leadership of Advancing Kidney Health through Optimal Medication Management, which works to implement comprehensive medical management services, settings in which the M2DL could be tested and refined.[17] Outreach to CPESN, the American College of Clinical Pharmacy, and other organizations with a mission of connecting and educating pharmacists to inquire about the best ways to raise model awareness among the pharmacy community may also be worthwhile.

Given the spectrum of age, generations, health literacy, and other characteristics represented among Medicare beneficiaries, CMS should leverage multiple communication mediums to engage beneficiaries and their caregivers effectively. For CMS' part in general and though we understand that it is not in the remit of this model, the information on Medicare Plan Finder is not consistent with the general literacy level of the public, over half of which has basic literacy levels and some of it much less.[18] Terms like "drug tier," "coverage phase, "non-preferred drug," and "specialty tier" are not meaningful for most people interacting with the Medicare program. The simple term "Medicare $2

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[13] St Peter WL, Wazny LD, Patel UD. New models of chronic kidney disease care including pharmacists: improving medication reconciliation and medication management. Curr Opin Nephrol Hypertens. 2013 Nov;22(6):656-62. doi: 10.1097/MNH.0b013e328365b364. PMID: 24076556; PMCID: PMC4012859.

[14] Oosting, Ilse J.[1,2]; Colombijn, Julia M.T.[1,2]; Kaasenbrood, Lotte[1]; Liabeuf, Sophie[3,4]; Laville, Solène M.[3,4]; Hooft, Lotty[2,5]; Bots, Michiel L.[2]; Verhaar, Marianne C.[1]; Vernooij, Robin W.M.[1,2]. Polypharmacy in Patients with CKD: A Systematic Review and Meta-Analysis. Kidney360 5(6):p 841-850, June 2024. | DOI: 10.34067/KID.0000000000000447

[15] *Ibid.*

[16] https://www.aafp.org/pubs/afp/issues/2007/0515/p1487.html

[17] https://www.kidneymedicationmanagement.org/about

[18] https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2014008

Drug List" is, for example, a much easier term by which to understand the general concept of a formulary.

<u>Part D Sponsor Outreach and Education Efforts for Beneficiaries</u>: 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 the 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?

NKF appreciates CMS' intention to connect with specific underserved communities to create awareness of the proposed M2DL Model. We urge CMS to prioritize utilizing communication that is culturally appropriate and uses simple language to make any content easy to read, understand, and use. CMS should use a multipronged approach to outreach, deploying health technology through the EHR, CMS' communication channels (MLN, HCPLAN, etc.) and should encourage plan D sponsors to leverage the outreach already made to beneficiaries, particularly in the fall when advertising and outreach budgets should be substantial. To the extent CMS has the opportunity and resources to do so, the Innovation Center should engage with community-based organizations and trusted community leaders to identify the best way to engage and educate Medicare beneficiaries from specific communities on the $2 drug list. Learnings from testing innovative approaches to Medicare beneficiary outreach would not only benefit the Innovation Center but could complement and help CCIIO's outreach strategies grow in reach and impact. Michael McWilliams has described a paradigm in which traditional Medicare and Medicare Advantage should be robust competitors for one another for each program's leading edge to evolve.[19] This competition should extend beyond benefit designs to outreach & education. Traditional Medicare naturally cannot compete with MA on dollars spent on advertising but can compete with MA on how information is presented to beneficiaries and how outreach to beneficiaries is conducted.

Like many organizations that work for and with the patient community, we are hopeful that real-time benefit tools (RTBTs) will continue to stimulate cost-conscious conversations about drug costs. We are gratified by the efforts of Congress, CMS, and the Office of the National Coordinator (ONC) to facilitate the development, adoption, and integration of RTBTs into the electronic health record. We support the proposal described in the proposed rule of September 5, 2024, *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability*

[19] https://www.nejm.org/doi/full/10.1056/NEJMsb2313939

(89 FR 63498) to create a certification criterion to reduce fragmentation and technical barriers to the use of RTBTs in the healthcare setting. We hope to see this provision finalized.

We hope that the convergence of the Consolidated Appropriations Act of 2021, the forthcoming finalization of the (HTI-2) proposed rule and the continued development of the M2DL Model will encourage forward thinking Part D sponsors to deploy tools with capabilities beyond the minimum standards established by ONC, for example, the ability to implement separate education modules for prescribers and beneficiaries to provide targeted information about the availability of the $2 Drug List. CMS should embrace its leadership role and guide Part D sponsors to cultivate creative and innovative approaches to informing beneficiaries about generic drug options. For the purposes of the M2DL, this would manifest through conversations with Part D sponsors and benefit managers throughout model development. NKF's experience with the development of the Kidney Care Choices model revealed that potential participants are most creative during the model's ideation phase. As the model's framework is set and business decisions are made, potential participants become more concrete and less innovative. This experience suggests that this early period of model development is the best opportunity to leverage the possibilities of RTBTs with part D sponsors, especially as they are shopping for health IT vendors with whom to work to deploy them. In addition to price transparency, patient-facing modules could raise awareness of the different routes by which beneficiaries can access these medications. It is important to note that not all beneficiaries will have access to EHR systems, including aging populations and people living in areas with limited internet access. As its name suggests, the purpose of a RTBT is to galvanize conversations at the point of care. For some beneficiaries, counseling at the point of care will be most effective. Others may have the benefit of an engaged inpatient or outpatient pharmacist. Still others may access the $2 drug list on their own, a possibility that seems more likely considering the popularity of CostPlusDrugs among other approaches to simplifying a patient's interaction with their drug benefit. The variation in how beneficiaries may interact with the $2 drug list speaks to the need for a multipronged approach.

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?

As noted elsewhere in this letter, the most common prescriptions for beneficiaries with CKD are statins, antibiotics, ACEi/ARBs, and beta-adrenergic blockers, all classes of drugs that are low-cost generics included on the M2DL. We are interested in what the model's evaluation may teach us about how to improve equitable access and adherence to these commonly prescribed generic drugs. We expect that beneficiary behavior around access and adherence differs by generic and branded drug. To clarify, from our perspective, we are most interested in what the M2DL may reveal about beneficiary access and adherence to generic drugs. It is not appropriate to use the M2DL or policy interventions like it to drive beneficiaries with CKD away from branded products if the branded product is a first-

line therapy concordant with clinical practice guidelines and prescribed by a physician (for example, glucagon-like peptide-1 (GLP-1) agonists, for which under 15% of Part D beneficiaries with CKD with diabetes had a prescription, which is branded, and for which metformin would not be an appropriate substitution).[20] [21]

We hope that an evaluation of the model would characterize utilization by class of drug across beneficiary demographics, receipt of the LIS, and any other markers in pharmacy claims of structural disadvantage. To the extent it can be characterized using pharmacy claims, we also hope to learn whether the M2DL or approaches like it could improve adherence to prescribed therapy at the plan level and the beneficiary level. Qualitative studies that clarify generally how beneficiaries use the M2DL and other simplified formulary tools and specifically the value of consistent price transparency in filling an initial prescription and continuing to fill it would help the healthcare community understand how to better support patients. We would also be interested in what the evaluation of the M2DL Model might clarify about disparities in generic drug access, for example if the M2DL might have an impact on prescribing behavior i.e., does the availability of a simple generic drug formulary, particularly at the point of care, increase prescriptions for low-cost generic drugs. Looking at the impact of the MD2L on the prescriber behavior would also be of interest. For example, we would be curious about the impact of the M2DL on prescribing, access, and adherence across prescribers working in and beneficiaries who receive care in Federally Qualified Health Centers. Given the prevalence of CKD among Medicare beneficiaries, we would be appreciative if the evaluation of the model were to provide subgroup analysis of beneficiaries with a diagnosis of CKD in the medical record.

<u>Drug List Modifications:</u> 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?

The strategy for providing updates on the MD2L should be multi-pronged, including the model website, postal mail where feasible and appropriate, collaboration with Part D sponsors and benefit managers who are best suited to beneficiary outreach, and targeted communication to patient advocacy organizations and medical and pharmacy societies, such as the NKF Kidney Disease Outcomes and Quality Initiative (KDOQI), who can help disseminate updated information to their members. NKF is a steadfast proponent of transparency and urges CMS to communicate the reason

[20] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.

[21] KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease Stevens, Paul E. et al. Kidney International, Volume 105, Issue 4, S117 - S314.

for amendments to the drug list. We also recommend CMS establish a mechanism for prescribers and patients to communicate and offer feedback to CMS.

Regarding frequency, CMS should strive to provide advanced notice to stakeholders before any changes take place, particularly to prescribers and pharmacies to optimize care delivery and health outcomes.

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The National Kidney Foundation applauds CMS for taking measures to improve transparency, simplicity, and affordability for Part D beneficiaries. This is important for kidney patients as they strive to attain the best quality of life. We stand ready to offer our support to this endeavor. Please contact Jesse Roach, Senior Vice President of Government Relations, at Jesse.Roach@kidney.org.

Sincerely,

Kevin Longino
CEO and Transplant Patient

Kirk Campbell MD
President