American Hospital Association™
Advancing Health in America

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Submitted Electronically

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

Dear Administrator Brooks-LaSure,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations; our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to share our comments regarding the Centers for Medicare & Medicaid Services (CMS) Medicare $2 Drug List (M2DL) Model request for information (RFI).

We support the intent of this model, which is to make drugs more affordable and provide greater drug price transparency for Medicare beneficiaries. We also recognize that the skyrocketing cost of drugs continues to be a barrier to treatment adherence for many. Indeed, an unaffordable drug is not a lifesaving drug. For example, recent data from the Kaiser Family Foundation indicate that approximately 30% of adults report not taking medication as prescribed in the past year because of cost, and 37% of adults taking four or more prescription drugs say they have difficulty affording medication.[1]

Providing low, fixed copayments for common generic drugs, as CMS proposed, could help increase medication adherence and improve health outcomes. This model would standardize cost sharing for certain drugs for beneficiaries with Medicare Part D enrolled in a participating plan and their health care providers. Specifically, this model would allow Part D plan sponsors to offer a low-cost fixed copayment (up to $2 for a month's supply) for a standard Medicare-defined list of common generic drugs. Our detailed comments follow.

[1] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

LIST OF DRUGS

CMS utilized several factors when determining the initial sample list of $2 drugs for the model including:

- 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 of 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.
- Presence on the American Geriatrics Society Beers Criteria®, six Drug Enforcement Administration (DEA) scheduled substances, or other safety-related categorizations.

The RFI states that CMS developed the M2DL for the model "taking into consideration the number of manufacturers and/or potential for supply interruptions." That said, we recommend the agency carefully monitor the supply of the selected $2 generic drugs and temporarily remove a drug from the list if it is included on the Food and Drug Administration drug shortage list for as long as it remains in shortage.

Generic drugs are prone to shortages for a variety of reasons. One key reason is they are often offered at very low prices and thus have smaller margins, making their production less profitable for the manufacturers. If generic drug manufacturers leave the market, there is an overreliance on a small number of manufacturers. Thus, we are concerned that the reduced copayment under the model could tip the balance for the remaining manufacturers, causing decisions to exit the market or resulting in a drop in quality that could cause a shortage.

MAXIMIZING PLAN PARTICIPATION

The AHA supports the model's voluntary participation for Part D sponsors and stand-alone prescription drug plans. The prescription drug classes under consideration are important for Medicare beneficiaries' health and wellness, including for chronic condition management, and removing barriers to access could improve health outcomes. Maintaining a voluntary program enables plan sponsors to differentiate their products from other plans and incentivizes sponsors to do outreach to Medicare beneficiaries, prescribers, pharmacists and other stakeholders.

We encourage CMS to leverage plans' experiences with nominal coinsurance requirements in Medicaid. Specifically, in the Medicaid program, states can opt to charge a nominal copayment for prescription drugs for certain beneficiaries. We acknowledge two key differences between Medicaid and the M2DL program in this respect: the M2DL would be more limited in scope and plan participation in the M2DL model would be voluntary. However, despite these differences, the experience of administering the program among key stakeholders could inform CMS' work to engage with plans and conduct outreach to Medicare beneficiaries.

ASSESSMENT OF MODEL IMPACT

The AHA appreciates CMS' interest in carefully evaluating whether the potential model would lead to better patient outcomes and better experiences for health care providers. To strike an appropriate balance of burden and value, we encourage the agency to fully leverage its available data to assess a range of population-level outcomes for providers and patients who participate in the model before asking participating providers to report data. At a minimum, CMS could use its claims data to evaluate hospital admission and readmission rates and emergency department visits rather than requiring hospital reporting. In addition, the agency should consider assessing such metrics by clinical condition. For example, CMS could monitor these statistics for behavioral health patients who are prescribed one of the substance use disorder drugs and separately monitor these statistics for cardiac patients who are prescribed one of the blood pressure or cardiovascular drugs.

CMS also should explore approaches to measuring prescription adherence. For example, it could consider using claims data to determine the frequency with which drugs on the $2 medication list are obtained at the pharmacy. While this measure would not necessarily reflect whether patients took their drug regimens precisely as prescribed, it would indicate whether one of the most critical barriers to treatment adherence — affordability — is being addressed successfully. We also encourage CMS to use its available data to assess the extent to which the model helps to reduce inequities. For example, CMS could consider stratifying data on whether prescriptions are obtained by dual-eligible status, participation in the Part D low-income subsidy, or demographic data where available.

Lastly, we encourage CMS to obtain both patient and provider feedback on the model. Provider feedback could be obtained through voluntary focus groups or CMS-administered surveys. CMS also could use focus groups to obtain patient feedback. In addition, it could consider including optional questions on existing Medicare Advantage and Part D plan Consumer Assessment for Healthcare Providers and Systems surveys to obtain quantitative feedback on participation in the model.

DRUG LIST MODIFICATIONS

Although we can appreciate that a static $2 drug list would provide simplicity for the model, this would not support the flexibility required to adapt to changing scientific evidence and new generic drugs which may be released to market during the model implementation timeframe. As such, we recommend that the agency provide an opportunity for routine public input on the $2 Drug List so stakeholders can recommend additions, deletions or other updates. At a minimum, we recommend this be done annually through public rulemaking.

We thank you for considering our comments. Please contact me if you have questions, or feel free to have a member of your team contact Jennifer Holloman, AHA's senior associate director of payment policy, at jholloman@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development