September 19, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

Subject: CMS Accountability and Transparency in the IRA Drug Price Negotiation Process

Dear Administrator Brooks-LaSure,

As CMS starts its Medicare price negotiation process with industry for the first 10 Part D drugs, the undersigned organizations urge 1) full transparency regarding how stakeholder input will be considered, and 2) the development of specific and strict guardrails against abuse of utilization management techniques by Part D plans for selected drugs. Currently, CMS has only pledged to be in "listening mode" with stakeholders rather than to dialogue with them; and to only "monitor" utilization management. The promise of the IRA was to reduce the price of prescription drugs at the pharmacy counter for older beneficiaries living with one or more major chronic conditions, not decrease the availability of them, and we expect CMS to make good on its promise.

Above all, CMS cannot interfere with the practice of medicine. Older individuals living with cancer, heart failure, atrial fibrillation, diabetes, chronic kidney disease, and arthritis meet with their health care providers, often alongside family caregivers, to discuss the benefits and risks of whether to take a drug or not. It is not the role of the Medicare program to insert barriers between the best judgment of patients and their doctors.

For some, access to a specific prescription drug prescribed by their care provider can be the difference between life and death or the mitigation of what would otherwise be an irrevocable loss of function. Innovative, FDA-approved treatments have transformed many diseases of aging from seriously debilitating or even deadly diseases to manageable chronic conditions. This has improved healthy aging and allows older people to be active members of society—working, spending time with family and friends, and appreciating leisure time, often in retirement.

The undersigned organizations represent a diverse group of patient advocates, caregivers, and providers who are deeply committed to advancing the well-being of older adults across diverse communities and ensuring equitable access to healthcare. We specifically want to bring attention to the following concerns:

- **The absence of specific and strict guardrails against abuse of utilization management techniques by Part D plans for selected drugs may result in "non-**

medical switching" in order for plans to reduce their costs further. If plans narrow access to certain medicines due to dynamics introduced by government price-setting, older patients who are stable on a given medication may lose access and be forced to switch to an alternative medicine that may not be optimal for their unique circumstances. CMS must install safeguards to prevent non-medical switching for drugs subject to negotiation and for which CMS deems it is paying a "fair price."

- **Several of the selected medications were selected based on volume rather than significant cost.** For example, oral anticoagulants (OACs) used to prevent stroke in people living with atrial fibrillation, coronary artery disease, and/or peripheral artery disease have been found to be cost-effective. CMS' top 10 list of Part D drugs includes multiple OAC drugs due to the sheer volume (in the millions) of beneficiaries being prescribed the medications by their providers, rather than excessive cost per capita.

- **CMS should refrain from using any metrics predicated on the discriminatory assessment that older adults have fewer life years to gain than younger individuals from using therapeutics.** CMS indicated in June 2023 guidance that it plans to use similar metrics to the quality-adjusted life year (QALY), including the evLYG. The agency also indicated it will use the non-pricing sections of reports that utilize QALYs. These measures are contrary to health equity goals, have discriminatory unintended consequences, and place a lower value on the lives and preferences of older adults and people with disabilities—the very populations that Medicare serves.

- **Due to drug price negotiations, new drugs and treatments may be delayed or not launched in the United States.** Negotiation and price setting models in other countries have typically led to significant access restrictions, with severe consequences for patients. One 2020 study of cancer drugs found that drugs reached the market an average of 242 days later in Europe than in the US, and the resulting delays in patient access to just two of these drugs may have led to a potential loss of more than 30,000 life years.

- **Public messaging from the agency must not exaggerate or conflate the impact of different policies.** Messaging around direct negotiation has repeatedly discussed how beneficiaries will experience reduced out-of-pocket (OOP) costs for negotiated drugs. However, this may not be true in any or all cases and will not impact beneficiaries' experience of drugs not subject to negotiation. We urge CMS to avoid overpromising regarding the OOP impacts of price negotiation, as it is likely to lead to confusion and beneficiary dissatisfaction with the broader IRA if the advertised impacts are not broadly experienced. CMS should also accurately attribute the most significant changes in OOP to implementing the Part D annual OOP cap and the Medicare Prescription Payment Plan flexibility.

A 2021 Morning Consult poll found that seventy-six percent of older adults are concerned that there is no guarantee that patients will save money because of the drug price negotiations, while seventy-four percent fear that medications covered could be decided based on the 'value' of a patient's life by looking at their medical conditions and age. This underlines the concerns shared in this letter and shows that CMS needs to be transparent about how the price negotiations will take place, what metrics CMS will use, and how they will weigh stakeholder input in the drug price negotiation process.

We support CMS's efforts to have meetings with patients and stakeholders starting in October. We ask that the agency clearly lay out the purpose and potential outcomes that may occur because of these meetings. Our recommendations include:

1. **Provide information publicly about the goals of CMS stakeholder meetings.** Currently, it is unclear if stakeholder meetings will solicit information on endpoints that are important to beneficiaries that may be incorporated into the calculation of the maximum fair price (MFP) or if, because of these meetings, a drug may even be reconsidered for inclusion on the list of negotiated drugs. As beneficiaries and groups engage, it is essential that these meetings be able to impact CMS policy meaningfully.

2. **Incorporate multiple beneficiaries with the condition, as well as patient advocacy groups.** Patient engagement efforts must include multiple representatives of beneficiaries with the disease impacted, including from communities of color and rural areas for whom access issues may occur with greater frequency. Additionally, we encourage CMS to include participation from disease-specific advocacy organizations that work with Medicare beneficiaries and are well-equipped to respond to technical as well as experiential questions on behalf of patients.

3. **Follow up with publicly available post-event information summarizing key takeaways.** A public record of themes and notable messages from the meeting will help provide context and information as MFPs and negotiated rates for selected drugs are established. The impact or incorporation of information from stakeholder meetings should also be reflected in future guidance around prices established during the negotiation process.

Our organizations expect CMS to take action to ensure that patient advocates, caregivers, and providers are heard in the drug price negotiation process and that their concerns—including those addressed in this letter—are taken seriously, as reflected by CMS publicly responding to and reporting on stakeholder input.

Please reach out to Sue Peschin, President & CEO at the Alliance for Aging Research, at speschin@agingresearch.org, and Michiel Peters, Director at the Global Coalition on Aging, at mpeters@globalcoalitiononaging.com, with any questions on the concerns shared in this

letter. We are happy to engage in conversation with CMS to ensure that patient advocates, caregivers, providers, and other stakeholders' concerns are heard.

Sincerely,

ACMCRN Arachnoiditis and Chronic Meningitis Collaborative Research Network
ADAP Advocacy
Alliance for Aging Research
American Academy of Allergy, Asthma & immunology
American Association on Health and Disability
American Foundation for Women's Health/StopAfib.org
AnCan Foundation
Association of American Indian Physicians
Autistic Women & Nonbinary Network
Bladder Cancer Advocacy Network (BCAN)
Cancer Support Community
Caregiver Action Network
CaringKind, The Heart of Alzheimer's Caregiving
Children with Diabetes
Chronic Care Policy Alliance
Community Access National Network
Davis Phinney Foundation for Parkinson's
Derma Care Access Network
Genetic Alliance
Global Coalition on Aging Alliance for Health Innovation
HFC
International WAGR Syndrome Association, IWSA
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
National Minority Quality Forum
NBIA Disorders Association
NTM Info & Research
Organic Acidemia Association
Partnership to Advance Cardiovascular Health
Partnership to Fight Chronic Disease (PFCD)
Patients Rising
RASopathies Network
RetireSafe
RUNX1 Research Program
SYNGAP1 Foundation
The Coelho Center for Disability Law, Policy and Innovation
The Latino Coalition
The Mended Hearts, Inc.
The National Association of Directors of Nursing Administration (NADONA)