



October 25, 2022

The Honorable Xavier Becerra  
Secretary, U.S. Department of Health and Human Services  
200 Independence Ave SW  
Washington, DC 20201

Dear Secretary Becerra,

We, the undersigned members of the Consortium for Constituents with Disabilities (CCD) write regarding the implementation of the prescription drug provisions of the Inflation Reduction Act (IRA) of 2022 (PL 117-169). We look forward to the forthcoming beneficiary protections in the IRA and to working with the Centers for Medicare & Medicaid Services (CMS) and the rest of the Department to implement these protections.

CCD is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society. The CCD Health Task Force works to ensure access to high quality, accessible, affordable health care for people with disabilities and complex conditions of all ages that meets their individual needs and enables them to be healthy, live as independently as possible, and participate in the community. We work to promote access to comprehensive coverage and eliminate discrimination, disparities and inequities for people with disabilities within and across health care payers, providers, and systems. We recognize that racist and ableist structures, policies and practices have caused and continue to cause disproportionately worse outcomes for Black, Indigenous and other people of color with disabilities. And just as race and disability discrimination intersect, social determinants of health and compounding inequities related to age, size, national origin, immigration status, language, gender, gender identity, and sexual orientation, can further reduce access to care and community for people with disabilities. Our advocacy prioritizes recognizing such inequities and championing policies that will reduce and eventually eliminate them.

#### **Prescription Drug Price Negotiation**

The IRA gives Medicare the power to aggressively negotiate prices for a set number of prescription drugs covered by either Part D or Part B. We are pleased that Congress does not institute a national formulary or rely on restricting access to drugs in order to extract savings in price negotiation. We understand that the Department is not required to issue proposed rules for comment to implement this program; however, we urge you to do so. Engagement with stakeholders, including people with disabilities and complex conditions, will be essential to the success of the program.

The IRA lays out a formula for determining which drugs are eligible for negotiation, focusing on the costs to the Medicare program. When selecting drugs for negotiation within this framework, we urge the Secretary to consider the drugs with the highest burden on beneficiaries. The highest burden on

beneficiaries could be defined as either the highest cost share for an individual dose, course of treatment, or per year; the medications most often abandoned due to inability to pay;<sup>1</sup> or the medications subject to the most burdensome prior authorization or step therapy. The Secretary should seek, through the negotiation process, to achieve as much cost burden alleviation to beneficiaries as possible.

The IRA also provides detail on the information the Secretary shall consider in the negotiation process. This includes comparative effectiveness research, “taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.” When considering these effects, we urge CMS to work directly with the groups (and their representatives) listed by Congress to learn from them the effects of the drug and its therapeutic alternatives. Clinical trials often exclude people with disabilities or older people, and comparative effectiveness research may not have been conducted with a focus on the populations listed. People of color are also often under-represented in clinical trials. The Department should always include people with disabilities in programs that affect them, and in this case direct engagement may be the only source of the information that Congress has directed the Department to consider.

Regarding comparative effectiveness research, Congress also directed the Department that the Secretary “shall not use evidence...in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.” We believe that this language constitutes a prohibition on the use of Quality-Adjusted Life Years (QALYs), Disability-Adjusted Life Years (DALYs), and any other metric that discriminates against people with disabilities and older adults.<sup>2</sup> While this language refers to the use of comparative effectiveness research, we see no other place QALYs could potentially be used in the program. Based on this, Congress clearly banned the use of QALYs or similar metrics in the negotiation program.

During the deliberations of the IRA, Senator Bob Casey made a floor statement<sup>3</sup> that showed the expectation that the prescription drug negotiation process would include input from the people most affected.

*Mr. CASEY. Madam President, I am pleased that Democrats have come together to address the costs of prescription drugs and to lower Affordable Care Act health care premiums for Americans. I strongly support a negotiation process for prescription drugs that will enable the voices of affected stakeholders, especially older adults, patients and people with disabilities, communities of color, and other marginalized*

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<sup>1</sup> For an example of how to calculate abandonment, see Dusetzina, S. et al, Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions, Health Affairs, No. 4 (2022): 487–496

<https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01742>

<sup>2</sup> National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series (November 2019)

[https://ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf)

<sup>3</sup> Congressional Record, Vol. 168, No. 129, (August 2, 2022), page 27.

<https://www.congress.gov/117/crec/2022/08/02/168/129/CREC-2022-08-02.pdf>

*groups, to play an integral role and inform the development and oversight of Medicare drug negotiations.*

*The Department of Health and Human Services has the authority to ensure affected stakeholders provide input about the potential for drugs to achieve outcomes that improve their quality of life. I view the Inflation Reduction Act as an opportunity to put older adults, people with disabilities and patients in front of the process so those affected, especially those historically excluded from the data used to make decisions, are at the table as the Department of Health and Human Services negotiates prices and advances the health equity goals we all share.*

Senator Casey's words underscore the need for diverse stakeholder input in the establishment and operation of the negotiation program, especially from those most affected.

#### **Part D Benefit Reform and Out-of-Pocket Cap**

We were very pleased to see the simplification of the Part D benefit and creation of an out-of-pocket cap. This cap will relieve high costs for the 1.4 million Part D enrollees with annual out-of-pocket costs over \$2,000. The expansion of the low-income subsidy (LIS), will reduce costs even further for an additional 400,000+ beneficiaries who will be eligible to receive higher subsidies,<sup>4</sup> particularly helping people of color who make up a disproportionate share of Medicare beneficiaries with income below 150% FPL.<sup>5</sup>

In addition to the out-of-pocket cap, the IRA also restructures and simplifies the Part D benefit design, finally eliminating the coverage gap and creating a simplified structure with a deductible, coverage phase, and out-of-pocket cap. This change will make the benefit easier to understand and navigate for beneficiaries. To create this improvement, the IRA placed a greater liability on plan sponsors in the catastrophic coverage phase. While we support the redesign, we are concerned that this may create an incentive for new and more aggressive utilization management by plans, including increased use of prior authorization, step therapy, and other mechanisms designed to keep beneficiaries from filling high-cost prescriptions. While some utilization management may be medically necessary, most is driven by cost alone. People with disabilities are disproportionately harmed by utilization management due to the fact that they are more likely to need multiple high-cost drugs and often lack the resources to effectively appeal or apply for exceptions. Instead, utilization management can keep people from accessing needed therapies. We urge CMS to conduct oversight of the utilization management programs instituted by plan sponsors for their impact on beneficiaries and take any necessary steps to limit them.

We were also excited to see the option to spread out-of-pocket costs across the benefit year. We were particularly glad to see that the smoothing option is available to all, even to beneficiaries who will not

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<sup>4</sup> Kaiser Family Foundation, Explaining the Prescription Drug Provisions of the Inflation Reduction Act, <https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/>

<sup>5</sup> Kaiser Family Foundation, Medicare State Profiles: Part D Low Income Subsidy Demographics, <https://www.kff.org/interactive/medicare-state-profiles/?activeState=United%20States&activeCategory=part-d-low-income-subsidy-beneficiary-demographics>

hit the new out-of-pocket limit and those receiving LIS, and that beneficiaries can elect to join the program even after the benefit year has begun. We believe that this will reduce the number of Part D beneficiaries who are unable to fill their prescriptions due to cost.

We are concerned about the provisions regarding failure to pay. Clause (aa) says that an enrollee that misses a payment shall be terminated from the smoothing program and pay the cost-sharing otherwise applicable. In implementing this section, we urge CMS to institute a grace period of at least two months, a hardship exemption, and the ability to appeal the removal from the program. A beneficiary could miss a payment due to a move, lost mail, hospital stay, or other exigency of life. We believe that one missed payment, without the potential for explanation or appeal, is too low a threshold to remove someone from the program.

Similarly, clause (bb) states that a Part D plan sponsor or Medicare Advantage organization may preclude an enrollee from participation in the smoothing program in a subsequent plan year if they have previously missed a payment and been removed. We urge CMS to interpret this narrowly, allowing PDP and MA sponsors to preclude enrollment in only the next subsequent year, and only from the same Part D or MA plan the enrollee had been enrolled in. CMS should also make clear that plans are not required to preclude enrollees from opting-in to the smoothing option in the future. Finally, CMS should engage in beneficiary education about the program and consequences of missing a payment.

We urge CMS and the broader Department to engage in significant outreach and plan to educate consumers, especially about the out-of-pocket cap, smoothing option, and LIS expansion. While the negotiation program has garnered significant press attention, these three provisions are likely to result in savings for far more beneficiaries. However, two of them, LIS and the smoothing option, require the beneficiary to opt-in. There are already too many people eligible for LIS who are not enrolled.<sup>6</sup> The Department should work with the Social Security Administration and leverage subdivisions like the Medicare-Medicaid Coordination Office, the Administration for Community Living and the disability and aging networks to reach eligible enrollees.

Finally, we are looking forward to the improved coverage of vaccines. The IRA aligns vaccine coverage under Part B and Part D and eliminates cost-sharing and deductibles for vaccines covered under Part D, such as shingles. This means that people with Medicare will be able to receive all recommended vaccines without cost-sharing. The IRA also improves access to vaccines for adults with Medicaid by requiring coverage of all recommended vaccines, including administration, with no cost sharing and enhancing federal reimbursement to states. We urge CMS to do robust outreach and education on this expanded and simplified vaccination benefit, in combination with encouraging flu vaccination and COVID-19 boosters.

Thank you and we look forward to working with you to implement these important provisions. For more information contact Rachel Patterson, Senior Director of Federal Relations & Policy at the Epilepsy Foundation at [rpatterson@efa.org](mailto:rpatterson@efa.org).

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<sup>6</sup> National Council on Aging, Take-Up Rates in Medicare Savings Programs and the Part D Low-Income Subsidy (Sept.9, 2022), <https://www.ncoa.org/article/take-up-rates-in-medicare-savings-programs-and-the-part-d-low-income-subsidy>.

Sincerely,

Access Ready  
Allies for Independence  
American Association on Health and Disability  
Association of University Centers on Disabilities  
Autism Society  
Autistic Self Advocacy Network  
Autistic Women & Nonbinary Network  
Brain Injury Association of America  
Easterseals  
Epilepsy Foundation  
Family Voices  
Justice in Aging  
Lutheran Services in America  
National Alliance on Mental Illness  
National Association of Councils on Developmental Disabilities  
National Disability Rights Network  
National Health Law Program  
The Arc of the United States  
United Spinal Association

CC:

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Principal Deputy Administrator, Administration for Community Living