

February 4, 2021

The Honorable Xavier Becerra  
Secretary Designee  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

**Re: CMMI Part D Payment Modernization Models**

Dear Secretary Designee Becerra:

The undersigned organizations represent millions of patients and consumers facing serious and chronic health conditions. We write in response to the new flexibilities for calendar year (CY) 2022 offered to Part D sponsors who participate in the Medicare Part D Payment Modernization models that were announced under the previous administration by the Center for Medicare & Medicaid Innovation (CMMI) on January 19, 2021. We believe the two new options – allowing for flexibility with respect to the six protected classes and allowing Part D plan sponsors to limit drug coverage to at least one drug per class – could jeopardize beneficiary access to medically necessary prescription drugs and harm patients with serious illness such as cancer, HIV/AIDS, epilepsy, mental health issues, and transplant patients. We strongly urge the current Administration to not move forward with these two new flexibilities and rescind the policy.

***Six Protected Classes Flexibilities***

The proposed policy change to the demonstration made by the former administration would permit Part D sponsors approved for participation to treat five of the six protected classes – anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they would any other Part D drug. For CY 2023 Part D sponsors participating in the Model would be permitted to treat antiretrovirals, the remaining protected class, as they would any other Part D drug.<sup>1</sup> In other words, Part D plans that are approved for participation in this model would no longer have to cover “all or substantially all” drugs within these classes.

The creation of this new flexibility contradicts the intent of the Part D program, and the six protected classes. As noted in the Part D manual the protected classes policy exists “because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”<sup>2</sup> Beneficiaries who rely on these drug therapies often have co-morbidities that could be negatively impacted by any potential change.<sup>3</sup>

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<sup>1</sup> Centers for Medicare & Medicaid Services Center for Medicare and Medicaid Innovation. Part D Payment Modernization Model Request for Applications for CY 2022. Available at <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22fs>.

<sup>2</sup> Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.

<sup>3</sup> See American Cancer Society, *Depression*, <https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/emotional-mood-changes/depression.html> (noting that one in four cancer patients is diagnosed with depression); Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White. Washington DC: National Academies Press. <http://www.iom.edu/Reports/2004/Public-Financing-and-Delivery-of->

The proposed policy change suggests this flexibility is necessary in order to give Part D sponsors greater ability to negotiate with manufactures. However, this justification fails to take into account that Part D plans already have more restrictive formularies for drugs covered under the six protected classes relative to commercial plans,<sup>4</sup> which suggest that the current policy does not prevent Part D Plan sponsors from effectively managing formularies within these drug classes. Part D generic utilization is high among drug classes within the six protected classes, with generic utilization for drugs within the six protected classes being higher than other drug classes (92 percent versus 84 percent).<sup>5</sup>

### ***One Drug Per Class Flexibility***

The former administration's proposal also offers an additional flexibility that would allow Part D sponsors to include on their formulary at least one drug per class, rather than the statutory requirement of at least two drugs per class. It is not clear from the information provided whether Part D sponsors would be able to meet this requirement by covering only a generic drug (if one exists) or whether the sponsor would be required to cover a branded drug.

We are deeply concerned this policy would limit Medicare beneficiaries' access to medically appropriate therapies. Part D sponsors already have a number of tools at their disposal to encourage beneficiaries to utilize lower-cost alternatives. They can create a formulary and exclude certain drugs from coverage, they can tier drugs to encourage the use of lower-cost alternatives, and they can impose utilization management edits on medications. These tools have been in place since the Part D program was first implemented in 2006 and the proposed policy change offers no justification as to why such a drastic change is needed at this time.

### ***Beneficiary Protections Are Insufficient***

The CMMI fact sheet notes that while the proposal intends to waive the six protected classes requirements and the one drug per class requirement, all other beneficiary protections would remain in place and provide sufficient protection to ensure beneficiaries have access to Part D drugs.<sup>6</sup> We strongly disagree.

*One or both flexibilities would jeopardize beneficiary access:* We are concerned that both policies to provide additional flexibilities would result in fewer covered Part D drugs for beneficiaries. This is a particularly serious problem for beneficiaries with serious chronic conditions who rely on specific medication therapies to treat their conditions. Beneficiaries who are not able to be stabilized on outpatient prescription drugs are more likely to require additional medical care which would increase health care expenditures under the Medicare Part A and B programs, not only costing the beneficiary

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[HIV/AIDS-Care-Securing-the-Legacy-of-Ryan-White.aspx](#) (finding that approximately half of those living with HIV have been diagnosed with a comorbid mental health condition).

<sup>4</sup> Kelly Brantley, Jacqueline Wingfield, and Bonnie Washington, "An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans," Avalere Health (2013), [http://avalere.com/research/docs/Anticonvulsants\\_in\\_Part\\_D\\_and\\_Commercial\\_Health\\_Insurance.pdf](http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf) (finding that on average commercial plans covered 80 percent of anticonvulsant drugs compared to Part D plans which covered on average 62 percent).

<sup>5</sup> The PEW Charitable Trusts, *Policy Proposal: Revising Medicare's Protected Classes Policy*, March 2018, <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicare-protected-classes-policy>.

<sup>6</sup> CMMI. Part D Payment Modernization Model Calendar Year (CY) 2022 Fact Sheet. Available at <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22fs>.

additional time and a decreased quality of life, but also needlessly increasing overall Medicare expenditures. We are also concerned that the limited information provided in the proposal would allow a Part D sponsor to seek approval for both the six protected classes and the one drug per class flexibilities.

*Part D appeals process provides an insufficient safeguard:* While the proposal intends to retain the current Part D appeals process, we are concerned that the existing appeals process is confusing and complex and in need of improvements.<sup>7</sup> The Medicare Payment Advisory Commission has noted the appeals process can be time consuming, frustrating, and burdensome for some beneficiaries.<sup>8</sup>

The policies under consideration will likely result in a significant increase in the number of appeals and exceptions, which can further burden the existing process. This is particularly concerning given that in announcing the flexibilities the proposal does not address any additional CMS resources (such as additional staff or appropriations) to ensure that beneficiaries who need access to drugs within the protected classes are able to obtain their medications in a timely manner.

*Part D transition supply policy provides insufficient safeguard:* The proposal suggests that Part D sponsors who have been approved to implement the formulary flexibilities (e.g., the six protected classes flexibility) will be required to provide an enhanced transition process for drugs in the protected classes, including both proactive outreach to current enrollees and an extended transition supply that provides for “multiple” temporary fills.<sup>9</sup> While we appreciate that the proposal attempts to mitigate the damage caused to beneficiaries by its six protected class flexibility, we do not believe this extended transition policy is sufficient. The transition supply would provide for temporary fills within the first 120 days of the calendar year. It is unclear whether all Part D sponsors approved to participate in the six protected classes flexibility model would be subject to the same number of temporary fills, and whether CMMI or the Part D sponsor determines the appropriate number of fills.

### **Conclusion**

Given the potential harm to the populations we serve, we urge the Department to not move forward with either of these new flexibilities and rescind the proposed policy change by the previous administration. These changes could result in cost-shifting to beneficiaries and could jeopardize vulnerable beneficiaries’ access to medically necessary prescription drugs for patients with serious illness such as cancer, HIV/AIDS, epilepsy, mental health issues, and transplant patients.

Thank you for the opportunity to provide feedback on these proposed policy changes put forward during the last days of the prior administration. We would welcome the opportunity to meet with you to discuss our concerns in more detail. If you have any questions or would like to discuss our comments further, please contact Keysha Brooks-Coley, VP Federal Advocacy and Strategic Alliances, American Cancer Society Cancer Action Network at [Keysha.brooks-coley@cancer.org](mailto:Keysha.brooks-coley@cancer.org) or 202-661-5720.

Sincerely,

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<sup>7</sup> American Cancer Society Cancer Action Network. The Medicare Appeals Process: Reforms needed to ensure beneficiary access. Nov. 17, 2020. Available at <https://www.fightcancer.org/policy-resources/medicare-appeals-process-reforms-needed-ensure-beneficiary-access>.

<sup>8</sup> Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, status report on the Medicare prescription drug program (Part D), March 2017 at 421.

<sup>9</sup> CMMI Fact Sheet at 2.

American Cancer Society Cancer Action Network  
Alliance for Aging Research  
ADAP Advocacy Association  
Alliance for Patient Access  
American Autoimmune Related Diseases Association  
American Brain Coalition  
American Kidney Fund  
American Liver Foundation  
American Lung Association  
American Psychiatric Association  
American Society of Consultant Pharmacists  
Association for Clinical Oncology  
Association of Community Cancer Centers (ACCC)  
Association of Oncology Social Work  
Be The Match/National Marrow Donor Program  
Cancer Support Community  
*CancerCare*  
Children's Cancer Cause  
College of Psychiatric and Neurologic Pharmacists  
Colorectal Cancer Alliance  
Community Access National Network (CANN)  
Depression and Bipolar Support Alliance  
Epilepsy Foundation  
Fight Colorectal Cancer  
FORCE: Facing Our Risk of Cancer Empowered  
Global Liver Institute  
GO2 Foundation for Lung Cancer  
HealthHIV  
Hematology/Oncology Pharmacy Association  
Hemophilia Federation of America  
HIV + Hepatitis Policy Institute  
Hope for ULD

International Myeloma Foundation  
KidneyCAN  
Livestrong  
LUNGevity Foundation  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Lymphoma Research Foundation  
Melanoma Research Foundation  
Men's Health Network  
Metastatic Breast Cancer Network  
METAvivor  
National Alliance on Mental Illness  
National Association of Chronic Disease Directors  
National Association of Epilepsy Centers  
National Brain Tumor Society  
National Cancer Registrars Association  
National Coalition for LGBT Health  
National Comprehensive Cancer Network  
National Council for Behavioral Health  
National Health Council  
National Hemophilia Foundation  
National Kidney Foundation  
National Organization for Rare Disorders  
National Pancreas Foundation  
National Patient Advocate Foundation  
Oncology Nursing Society  
Ovarian Cancer Research Alliance  
Phelan-McDermid Syndrome Foundation  
Prevent Cancer Foundation  
Ring14 USA  
Sarcoma Foundation of America  
Schizophrenia and Related Disorders Alliance of America

Susan G. Komen

The AIDS Institute

The Kennedy Forum

The Leukemia & Lymphoma Society

The NORSE Institute

Transplant Recipients International Organization

Transplant Support Organization

Triage Cancer

Tuberous Sclerosis Alliance

Wishes for Elliott/DEE-P Connections

ZERO - The End of Prostate Cancer