January 25, 2019

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-4180P – Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses
83 Fed. Reg. 62152 (November 30, 2018)

Dear Secretary Azar:

The undersigned organizations represent millions of patients and consumers facing serious and chronic health conditions. We write in response to the Medicare Part C and D proposed rule and urge you to not finalize the proposed changes to the Medicare Part D six protected classes.

Since its inception, the Medicare Part D program has identified six categories and classes of drugs of clinical concern (the so-called "six protected classes") – anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants – and requires Part D plan sponsors to cover "all or substantially all" of the drugs within these classes. This policy was put in place to ensure that vulnerable beneficiaries have access to medications needed to treat their conditions and to ensure that Part D plan sponsors' formularies do not discourage vulnerable beneficiaries from enrolling in their plans.

CMS' own manual clearly provides justification for the needed protection provided by the six protected classes policy, stating that "CMS instituted this policy 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."[1]

While the proposed rule would not eliminate the six protected classes, it does seek to make significant changes to the program that could harm beneficiary access to medically-appropriate therapies. We strongly urge CMS to proceed cautiously when considering any potential changes to the six protected classes. Beneficiaries who rely on these drug therapies often have co-morbidities that could be negatively impacted by any potential change.[2]

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[1] Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.

[2] See American Cancer Society, *Coping with Cancer: Anxiety, Fear, and Depression,* https://www.cancer.org/treatment/treatments-and-side-effects/emotional-side-effects/anxiety-feardepression.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-HIVAIDS-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).

Prior authorization requirements within the protected classes can be harmful to beneficiaries

The proposal would allow Part D plans to impose additional prior authorization requirements – like step therapy – on drugs within the six protected classes. We have serious concerns with this policy. Drugs within the same class – or even subclass – are often used to treat different diseases or conditions. For example, antidepressant medication impacts individuals differently and as such it can take time to find the right treatment that works for a given individual.

Part D plans already have more restrictive formularies for drugs covered under the six protected classes relative to commercial plans,[3] 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.[4] The Medicare Payment Advisory Commission (MedPAC) notes that the "protected status does not appear to affect plan sponsors' ability to encourage the use of generics."[5]

Imposing prior authorization requirements also increases administrative costs to providers. According to a 2017 survey of the American Medical Association, 92 percent of respondents reported care delays as a result of a private health plan's use of prior authorization requirements.[6]

Step therapy policies can lead to patients not filling their prescriptions or underutilizing medications,[7] which can have a negative impact on beneficiary adherence to medications. Prescription drug noncompliance can lead to poorer health outcomes for the beneficiary as well as increased costs to the Medicare program – as beneficiaries become sicker, they often use more physician (Part B) and/or hospital (Part A) services.

We appreciate CMS' intention to retain other formulary requirements. While CMS will retain the requirement that Part D sponsors cover at least two drugs per therapeutic category and class, we are concerned that this policy is not enough to ensure that beneficiaries have access to the treatments needed for their disease and condition, particularly as it pertains to a large category or class containing multiple drugs. While the Medicare appeals and exceptions process will be available to beneficiaries, this process is far from ideal. The Medicare Payment Advisory Commission (MedPAC) has noted that widespread frustration with this process exists among all stakeholders – beneficiary groups, prescribers, plan sponsors, and CMS – and that the process can be frustrating and burdensome for beneficiaries.[8]

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[3] 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 (finding that on average commercial plans covered 80 percent of anticonvulsant drugs compared to Part D plans which covered on average 62 percent).

[4] 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-medicares-protected-classes-policy.

[5] Medicare Payment Advisory Commission. Report to Congress: Medicare and the health care delivery system. Improving Medicare Part D (2016), at: 191.

[6] American Medical Association. 2017 AMA Prior Authorization Physician Survey. Available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf.

[7] Carlton RI, Bramley TJ, Nightengale B, Conner TM, Zacker C. Review of outcomes associated with formulary restrictions: focus on step therapy. Am J Pharm Benefits. 2010;2(1):50-58.

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

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.

CMS' proposal would impede beneficiary access to new drugs

CMS is proposing to allow Part D sponsors to exclude from their formularies a protected class single-source drug or biologic product for which the manufacturer introduced a new formulation with the same active ingredient or moiety that does not provide a unique route of administration. The proposal would allow Part D plans to exclude new formulations of a drug even if the manufacturer no longer makes the older version of the drug.

We are gravely concerned that this proposal would hinder beneficiary access to the latest medical breakthrough products. For example, prescription drugs that are "extended release" differ quite substantially from an "immediate-release" version of the same drug, particularly as it relates to beneficiary adherence.

CMS' price indexing proposal is misguided

The proposal would also allow Part D sponsors to exclude from their formularies any single-source drug or biological product within the protected classes whose price increases beyond the rate of inflation. While we appreciate the Administration's interest in making prescription drugs more affordable for beneficiaries, we believe this proposal may be misguided.

Medicare beneficiaries need access to medically-appropriate prescription drugs to treat their diseases and conditions. Allowing Part D sponsors to remove drugs from their formularies because pharmaceutical manufacturers' prices increased beyond an arbitrary threshold could result in harm to beneficiaries who need access to these medications. If drugs are no longer covered under this policy, Medicare beneficiaries who have a medical need for these products will have to pay out-of-pocket for these products (which can be beyond the means of most beneficiaries) or fail to fill their prescription.

Given the potential harm to the populations we serve, we urge the Department to not finalize the Part D six protected classes policy changes in the proposed rule. These changes could result in cost-shifting to beneficiaries and could jeopardize vulnerable beneficiaries' access to medically-necessary prescription drugs. Thank you for the opportunity to comment on this proposed rule. We 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, ACS CAN at Keysha.brooks-coley@cancer.org or 202-661-5720.

Sincerely,

American Cancer Society Cancer Action Network
ADAP Advocacy Association
Addario Lung Cancer Medical Institute
Advocates for Responsible Care
Alliance for Patient Access
American Association on Health and Disability
American Autoimmune Related Diseases Association
American College of Surgeons Commission on Cancer
American Heart Association
American Kidney Fund

American Lung Association
American Medical Association
American Society for Radiation Oncology
American Society of Clinical Oncology
Asbestos Disease Awareness Organization
Association of Oncology Social Work
Bonnie J. Addario Lung Cancer Foundation
Bridge the Gap - SYNGAP Education and Research Foundation
Cancer Support Community
Caregiver Action Network
Caregiver Voices United
Colorectal Cancer Alliance
Community Access National Network
Deadliest Cancers Coalition
Debbie's Dream Foundation: Curing Stomach Cancer
Disability Rights Legal Center
Epilepsy Foundation
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Global Healthy Living Foundation
Global Liver Institute
Hemophilia Federation of America
ICAN, International Cancer Advocacy Network
International Myeloma Foundation
Lakeshore Foundation
Lung Cancer Alliance
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
National Alliance on Mental Illness
National Blood Clot Alliance
National Brain Tumor Society
National Consumers League
National Hemophilia Foundation
National Infusion Center Association
National Organization for Rare Disorders
National Ovarian Cancer Coalition
Neuropathy Action Foundation
Oncology Nursing Society
Ovarian Cancer Research Alliance
Pennsylvania Prostate Cancer Coalition
Survivors Cancer Action Network
Susan G. Komen
The AIDS Institute
U.S. Rural Health Network