

September 26, 2018

Alex M. Azar II  
Secretary  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Azar:

The undersigned groups represent millions of Americans living with serious chronic conditions. We want to take this opportunity to share with you our thoughts on the Administration's proposals to reduce prescription drug spending. The individuals we represent rely on drug therapies to treat their diseases, to maintain their quality of life, prevent co-morbidities, and often to prevent recurrence or progression of their disease. Making prescription drug therapies more affordable is critical for our patient populations.

As the Administration continues to move forward with the recent policy change that would allow Medicare Advantage (MA) plans to use step therapy, we ask you to be mindful of the potential impact on beneficiaries and to implement further safeguards that will assure patient care is not negatively impacted. For many of the people we represent there are few therapeutically equivalent drugs for treating their conditions. Therefore, asking patients to take a drug that is not designed to treat their specific health circumstances could negatively impact care.

As the Administration proceeds with allowing step therapy for physician-administered drugs in MA plans we strongly urge you to accompany the policy with a set of patient protections including:

- **Adherence to evidence-based treatment guidelines:** CMS should require step therapy protocols follow clinical practice guidelines and best practices that have been vetted through the peer review process.
- **Protection for mid-treatment patients:** We understand that CMS is considering ensuring that patients who are currently using medication that has already been proven to work effectively would not be required to change medications. We support this approach. We appreciate your stated commitment to ensuring that these beneficiaries would not be required to change medications and urge CMS to engage in active monitoring and oversight to ensure plans comply with this requirement and have the correct, real-time information required to do so.
- **Recognized standard of care:** MA plans should be required to start step therapy with the recognized standard of care – even if that recognized standard is not the least

expensive drug. We ask that CMS work with stakeholder groups to make sure that plans do not deny coverage to patients for medically necessary services including:

- Requiring step therapy to be aligned with evidence-based clinical practice guidelines and appropriate clinical evidence;
  - Ensuring that beneficiaries with chronic conditions who may have prior experience with a given drug (even if that experience was in a prior plan year), are not required to undergo step therapy requirements; and
  - Ensuring that none of the policies or procedures implemented by plans are discriminatory.
- **A simple and expeditious exceptions & appeals process:** Treatment for patients who need a drug higher in the step protocol should not be delayed by a lengthy appeals process. While the new policy states beneficiaries can use the Part D exceptions process, CMS should closely monitor the extent to which exceptions are being sought to determine whether additional beneficiary protections (e.g., exemption of specific categories and classes of drugs) may be warranted.
  - **Full transparency and oversight:** Medicare beneficiaries should know in advance of enrolling whether an MA plan uses restrictive step therapy and understand what impact it may have on access to needed treatments. While CMS intends to require plans to notify beneficiaries through the Annual Notice of Coverage (ANOC), those newly entering the MA plan may not be provided advance notice of this policy. Therefore, the Medicare.gov plan finder should also convey this information. We also encourage CMS to establish a system that will ensure plans comply with patient and provider protections to prevent discrimination. We request CMS collect and provide to the public information on how many patients are seeking exceptions and appeals, and details of how many are granted.

Thank you again for the opportunity to share our thoughts with you. We look forward to the opportunity to continue a dialogue about these important issues, and the potential impact on patients. If you have additional questions, or would like to discuss any of the issues addressed please reach out to Keysha Brooks-Coley, Vice President, Federal Advocacy, American Cancer Society Cancer Action Network at [keysha.brooks-coley@cancer.org](mailto:keysha.brooks-coley@cancer.org) or Eric Gascho, Vice President, Policy and Government Affairs, National Health Council at [Egascho@nhcouncil.org](mailto:Egascho@nhcouncil.org).

Sincerely,

Academy of Medicine of Cleveland & Northern Ohio (AMCNO)  
Alliance of Dedicated Cancer Centers  
Alpha-1 Foundation  
American Academy of Allergy, Asthma & Immunology  
American Academy of Dermatology Association

American Association of Neurological Surgeons  
American Association on Health and Disability  
American Autoimmune Related Diseases Association  
American Cancer Society Cancer Action Network  
American Diabetes Association  
American Kidney Fund  
American Lung Association  
American Urological Association  
Arthritis Foundation  
Association of Oncology Social Work (AOSW)  
Beacon Charitable Pharmacy  
Bonnie J. Addario Lung Cancer Foundation  
CancerCare  
Caregiver Action Network  
Chronic Disease Coalition  
Congress of Neurological Surgeons  
Cystic Fibrosis Foundation  
Delaware Bioscience Association  
Delaware Ecumenical Council on Children  
Delaware HIV Consortium  
Diabetes Patient Advocacy Coalition  
Disability Rights Legal Center  
Epilepsy Foundation New England  
Epilepsy Foundation of Connecticut  
Fight Colorectal Cancer  
FORCE: Facing Our Risk of Cancer Empowered  
Global Healthy Living Foundation  
Global Liver Institute  
Hemophilia Association of the Capital Area  
Immune Deficiency Foundation  
International Myeloma Foundation  
Lung Cancer Alliance  
LUNgevity Foundation  
Lupus and Allied Diseases Association  
Lupus Foundation of America  
Lutheran Social Services  
Malecare Cancer Support  
Meals on Wheels of Wake County  
Medical Society of Delaware  
Mended Hearts  
Mended Little Hearts  
Men's Health Network  
Mental Health America  
Mental Health Association in New York State

Metastatic Breast Cancer Network  
National Alliance on Mental Illness  
National Blood Clot Alliance  
National Comprehensive Cancer Network  
National Consumers League  
National Eczema Association  
National Health Council  
National Hemophilia Foundation  
National LGBT Cancer Project  
National Multiple Sclerosis Society  
National Organization for Rare Disorders (NORD)  
National Patient Advocate Foundation  
National Psoriasis Foundation  
NC AIDS Action Network  
North Carolina Biosciences Organization  
Parent Project Muscular Dystrophy (PPMD)  
PKD Foundation  
Prevent Blindness  
Prevent Blindness Georgia  
Prevent Blindness Texas  
Prevent Blindness Wisconsin  
Prevent Blindness, Ohio Affiliate  
Prevent Cancer Foundation  
Pulmonary Hypertension Association  
Reach Out Free Clinic of Montgomery County Ohio  
Sjogren's Syndrome Foundation  
Survivors Cancer Action Network-Alabama  
Susan G. Komen  
Susan G. Komen Columbus  
The Asthma and Allergy Foundation of America  
Tourette Association of America  
US Pain Foundation  
Virginia Breast Cancer Foundation  
Virginia Hemophilia Foundation  
Wyoming Epilepsy Association  
ZERO - The End of Prostate Cancer