

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 or Eric Gascho, Vice President, Policy and Government Affairs, National Health Council at 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