PIPC Partnership to Improve Patient Care

October 20, 2017

Honorable Eric Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Secretary Hargan:

I am writing with regard to the MassHealth Section 1115 Demonstration Amendment Request. As Chairman of the Partnership to Improve Patient Care (PIPC), the author of the Americans with Disabilities Act (ADA), a long-time disability advocate and a patient with epilepsy, I have serious concerns about its implications for patients and people with disabilities, particularly Section 4b of the waiver which seeks to "exclude from the formulary drugs with limited or inadequate evidence of clinical efficacy." While PIPC also signed on to the attached letter providing an overview of concerns about the waiver, I wanted to communicate additional background to underscore our concerns.

Since its founding, PIPC has been at the forefront of applying principles of patient-centeredness in comparative effectiveness research (CER). Central to our mission is ensuring that the patient voice is heard in judgments about care value – whether in the context of comparative effectiveness research or emerging "value-based" payment incentives. From this experience, PIPC continues to work to bring the voices of patients, people with disabilities, and their families to the discussion of how to advance patient-centered principles throughout an evolving health care system. We understand the challenge of assessing value in health care in a manner that is centered on the characteristics, needs and preferences of the individual patient versus defining value based on what is cost effective for an "average" patient. Therefore, we have significant concerns regarding this proposed waiver policy.

As you know, the FDA's accelerated approval pathway is described by the FDA as, "Speeding the availability of drugs that treat serious diseases are in everyone's interest, especially when the drugs are the first available treatment or if the drug has advantages over existing treatments." The intent is to create access to these treatments for patients who may benefit from them. The policy outlined in Section 4b would allow Massachusetts to exclude such treatments from coverage, without any consideration of the value of that treatment for the individual patient, but instead relying on population data that reflects the average patient. The exceptions process is not a sufficient protection for patients that lack the resources to appeal, and are often facing dire health consequences and few, if any, alternative treatments. No patient is average.

PIPC is particularly concerned about the implications of health policy built on population-based value assessments on people with disabilities and patients with chronic conditions who may or may not be cured, but regardless are seeking access to treatments and health interventions that improve their quality of life. People with disabilities and patients with chronic conditions have a

long history opposing the use of cost effectiveness policies that lead to unnecessary and harmful limitations on access to care. Such simplistic average measures of value are perceived to reinforce the old paternalistic system of health care and work against the movement toward more personalized, individualized health care. By targeting treatments for exclusion based on their cost, Section 4b is in effect imposing a cost effectiveness analysis that tells impacted patients and people with disabilities they are not "worth" it.

Specifically, the proposal is very vague about the endpoints that would be used to determine that a treatment is not clinically effective. Instead, the state alludes to "its own rigorous review process" and partnership with the University of Massachusetts Medical School to make such determinations. There is no reference to a process that gives patients and people with disabilities a voice in determining whether a treatment is effective. There is no reference to the role of patients and people with disabilities in defining the endpoints that should be measured to determine effectiveness. And there is no description of the individual patient considerations that would need to be considered in order to qualify as an exception, and therefore achieve coverage. Ultimately, I have significant concerns about relying on ivory tower academics seeking to ration care based on short sighted cost effectiveness comparisons.

Alternatively, PIPC aims for policymakers to focus on health care payment and delivery reforms that activate and engage patients and people with disabilities and that support shared decision-making between them and their providers. We believe that solutions that center on patients and people with disabilities are the best approach to improving overall health care efficiency and quality. We are very excited about the work underway to develop alternative and more patient-centered methodologies for assessing value to the patient led by groups like the Patient-Centered Outcomes Research Institute, FasterCures, National Health Council and the National Patient Advocate Foundation.

We would propose that the State of Massachusetts look to entities such as PCORI for insights on how to measure comparative effectiveness of treatments in real world situations. The approval of breakthrough therapies by the FDA provides Massachusetts and all states an opportunity to collect data on the real-world effectiveness of treatments that could be invaluable to patients and their providers making tough decisions. We encourage states like Massachusetts to invest in the development of shared decision-making tools that reflect how treatments impact patients in real-world circumstances, so that patients are able to choose the treatment that is most effective for their individual needs. You have an opportunity to partner with patients and people with disabilities to determine the outcomes that matter most to them in their treatment, measure those outcomes, and translate that information into tools that ensure patients get the right care at the right time. If certain treatments do not work in real-world circumstances, that information can be shared with patients and providers so that alternative therapies can be pursued.

In this age of personalized medicine, we can reduce costs by better targeting treatments shown to work on patients with similar characteristics, needs and preferences, thereby avoiding the waste of valuable resources on care that patients do not value and that ultimately raise premiums. Providing patients with a pre-existing condition the first-line therapy early in their disease

process can prevent them from requiring more aggressive and expensive treatments in the future. Additionally, there are opportunity costs associated with *not* providing certain treatments that may be expensive. Overall, providing truly patient-centered care is cost effective at the population level. We also have to consider society's moral obligation to value the individual lives of patients and people with disabilities, and therefore not dictate the terms of the value debate solely based on a treatment's cost.

We do not support this waiver in its current form. We look forward to a dialogue about how to revise the waiver to put patients first, and urge you to request that the State of Massachusetts commit to a process of engaging patients and people with disabilities to positively shape a new waiver application that has support and buy-in from the impacted patient communities. Let patients and people with disabilities be partners in building a patient-centered health system for Massachusetts.

Sincerely,

Tony Coelho
Chairman, Partnership to Improve Patient Care

October 18, 2017

Eric D. Hargan
Acting Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: MassHealth Section 1115 Demonstration Amendment Request

Dear Acting Secretary Hargan:

The undersigned organizations collectively represent millions of patients who are currently battling or who have fought serious, chronic, and life-threatening diseases. We write to express our opposition to the proposal in the Massachusetts 1115 waiver amendment to potentially limit access to new and innovative drug therapies by imposing a closed formulary with as few as a single drug per therapeutic class in MassHealth, the state's Medicaid program.

Prescription drugs have different indications, different mechanisms of action, and different side effects, depending on the person's diagnosis and comorbidities. Restricting MassHealth's drug benefits to a closed formulary would limit the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving it to the state.

While we appreciate that the state will, when medically necessary, maintain an exceptions process to cover drugs not included on the formulary, the proposal fails to articulate the safeguards that will be put in place to ensure enrollees have access to the prescription drugs they need. Patients suffering from chronic, life-threatening conditions need a guarantee of uninterrupted access to the prescription drugs critical to maintaining or treating their disease. Disruptions in the treatment of serious and chronic conditions, including switching a patients' medication mid-treatment, could negatively impact their treatment and health outcomes.

Medicaid is a crucial source of coverage for thousands of Massachusetts residents with serious and chronic health care needs. This proposed amendment could severely restrict their access to critical therapies necessary to improve health outcomes. Therefore, we strongly urge the Centers for Medicare and Medicaid Services (CMS) to reject Massachusetts' 1115 demonstration amendment request in its current form.

On behalf of the millions of patients we represent, we stand ready to work with you to develop policies that will ensure individuals with serious and chronic conditions maintain access to innovative and medically necessary prescription drugs.

Thank you for your consideration of this important matter.

Sincerely,

American Cancer Society Cancer Action Network
Diabetes Patient Advocacy Coalition
National Blood Clot Alliance
Global Colon Cancer Association
US Pain Foundation
CancerCare
National Health Council
American Autoimmune Related Diseases Association
Lupus Foundation of America
Ecan.org
Multiple Sclerosis Foundation
Cooley's Anemia Foundation
Epilepsy Foundation
Tuberous Sclerosis Alliance
Fight Colorectal Cancer
Epilepsy Foundation New England
Arthritis Foundation
Digestive Disease National Coalition
The AIDS Institute
National Consumers League
Center for Health Law and Policy Innovation, Harvard Law School
Mental Health America
National Viral Hepatitis Roundtable
National Organization for Rare Disorders (NORD)
Lung Cancer Alliance
ADAP Advocacy Association
Community Access National Network
Bladder Cancer Advocacy Network (BCAN)
Georgia AIDS Coalition
National Comprehensive Cancer Network
Hispanic Health Network
Latino Commission on AIDS
Hep C Alliance
NASTAD
Global Healthy Living Foundation
Association of Asian Pacific Community Health Organizations (AAPCHO)
Immune Deficiency Foundation
Project Inform
Hospice and Palliative Nurses Association
National Patient Advocate Foundation
American Lung Association
Hope for Hypothalamic Hamartomas
National Alliance on Mental Illness
Ovarian Cancer Research Fund Alliance
Community Servings, Inc.
International Pain Foundation

Rare Disease United Foundation
American Medical Association
South Cove Community Health Center
International Myeloma Foundation
American Academy of HIV Medicine (AAHIVM)
Rush To Live
National Minority Quality Forum
Community Health Charities of Nebraska
Global Liver Institute
Caregiver Action Network
Southeastern Wisconsin Oncology Nursing Society
Central Florida Behavioral Health Network
Epilepsy Association of the Big Bend
Areawide Aging Agency, Inc.
Epilepsy Association of Central Florida, Inc.
United Partners for Human Services
NAMI Florida
NAMI Greater Des Moines and the Iowa Mental Health Planning Council
RAIN Oklahoma
Brain Injury Association of Kansas and Greater Kansas City
Cancer Support Community Central Ohio
Center for Healthcare Innovation
Iowa State Grange
Alzheimer's & Dementia Resource Center
Dana Farber Cancer Institute at South Shore Medical Center
American Autoimmune Related Diseases Association (AARDA)
Relapsing Polychondritis Awareness and Support Foundation Inc.
FORCE: Facing Our Risk of Cancer Empowered
Lupus Foundation of Florida
The Myositis Association
Cancer Support Community of Arizona
Lupus And Allied Diseases Association
Dysautonomia International
National Hispanic Life Sciences Society
Rheumatology Association of Iowa
AIDS Action Committee of Massachusetts
Mental Health America of Montana
Critical Mass: The Young Adult Cancer Alliance
U.S. Rural Health Network
National Hemophilia Foundation
Massachusetts Pharmacists Association
IFAA - International Foundation for Autoimmune & Autoinflammatory Arthritis
Epilepsy Foundation Heart of Wisconsin
EndHepCMA Coalition
Epilepsy Foundation of Alabama
Epilepsy Foundation of Connecticut
Arizona Myeloma Network

Epilepsy Foundation of Arizona
Epilepsy Foundation of Greater Chicago
ZERO - The End of Prostate Cancer
Easter Seals Massachusetts
The Epilepsy Foundation of Greater Southern Illinois
United Ostomy Associations of America
Epilepsy Foundation of East Tennessee
Sickle Cell Disease Association of Florida
Bridge the Gap - SYNGAP1 Education and Research Foundation
Epilepsy Foundation Northwest
Coalitions of Texans with Disabilities
Mental Health Association in New York State
The Ohio Council of Behavioral Health & Family Services Providers
American Association on Health and Disability
Lakeshore Foundation
Lupus Foundation of Colorado
TexHealth
Colorado Gerontological Society
Massachusetts Gastroenterology Association
1in9 The Long Island Breast Cancer Action Coalition/Hewlett House
EDSers United
Colorado Cross-Disability Coalition
Survivors Cancer Action Network/Alabama
Long Term Care Community Coalition
AIDS Delaware
Hospice and Palliative Care Association of NY State
LUNGevity Foundation
Ohio Hematology Oncology Society
Kentucky Association of Medical Oncology
NAMI of Central Suffolk
National Association of Hispanic Nurses Houston Chapter
Multiple Sclerosis Resources of CNY, Inc.
Alpha-1 Foundation
Advocates for Responsible Care (ARxC)
Consumers for Quality Care
Epilepsy Foundation of Oklahoma
NAMI North Dakota
Epilepsy Foundation of Vermont
American Society of Clinical Oncology
Texas Healthcare and Bioscience Institute
Massachusetts Society of Clinical Oncologists
Scleroderma Foundation-Rocky Mountain Chapter
Susan G. Komen
Women In Progress Inc.
Cancer Support Community
HIV Medicine Association
BionorthTX
Rio Grande Valley Partnership

Texas Renal Coalition
Epilepsy Foundation of Delaware
SAGE Utah
Mature Gay Men Aloud
Utah Pride Center
Easterseals Central Texas
Dia de la Mujer Latina, Inc.
Centro de Mi Salud, LLC
Michigan Osteopathic Association
Rio Grande Valley Diabetes Association
National Alliance on Mental Illness (NAMI) Texas
Massachusetts, Maine and New Hampshire Rheumatology Association
National Association of Social Workers - Texas Chapter
American College of Rheumatology
First Step House
Arkansas Rheumatology Association
Florida Society of Clinical Oncology
NAACP New York State Conference
Bonnie J. Addario Lung Cancer Foundation
Texas Life Sciences Collaboration Center
South Carolina Rheumatism Society
Association of Idaho Rheumatologists
American Foundation for Women's Health / StopAfib.org
Rheumatology and Internal Medicine Associates, PC
Oregon Rheumatology Alliance
BioHouston Inc.
National Osteoporosis Foundation
The Leukemia & Lymphoma Society
Lupus of Nevada
Ohio Association of Rheumatology
NJ Mayors Committee on Life Sciences
Delaware Ecumenical Council on Children and Families
The National Adrenal Diseases Foundation
NAMI Nevada
ICAN-International Cancer Advocacy Network
Applied Pharmacy Solutions
BioNJ
Kentucky Life Science Council
Prevent Blindness Children's Vision Massachusetts
The Turnpike Partnership
Partnership to Improve Patient Care
National Association of Social Workers, North Carolina Chapter
Medical Society of Delaware
NAMI Huntington
New Jersey Association of Mental Health and Addiction Agencies, Inc.
Men’s Health Network
HealthCare Institute of New Jersey (HINJ)
Neuropathy Action Foundation

CNY HIV Care Network
Kentuckiana Rheumatology Alliance
American Kidney Fund
National Cervical Cancer Coalition - Arizona
Colorado BioScience Association
NMBio
Nashville CARES
National Association of Social Workers-MA
Tennessee Rheumatology Society
National Association of Hepatitis Task Forces
National Association of Hepatitis C Task Forces
National Coalition for LGBT Health
Rocky Mountain Stroke Center
National Infusion Center Association (NICA)
Wisconsin Rheumatology Association
Mississippi Arthritis and Rheumatology Society
California Rheumatology Alliance
National Coalition for Cancer Survivorship
NAMI New Mexico
NAMI Utah
Psychosocial Rehabilitation Association of New Mexico
SURVIVEiT®
Alliance for Patient Access
METAvivor Research and Support
MassEquality
California Chronic Care Coalition
Carrie's TOUCH
Dyson and Associates, LLC
New England Chapter American Association of Clinical Endocrinologists
Rheumatology Alliance of Louisiana
American Academy of Dermatology Association
Action CF
UsAgainstAlzheimers
Haystack Project