I AM (Still) ESSENTIAL

December 19, 2014

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: Comments on *Notice of Benefit and Payment Parameters for 2016 Proposed Rule*

Dear Madame Secretary:

We, the undersigned 279 patient and community organizations representing millions of patients and their families, are pleased to submit comments in support of many aspects of the proposed rule *Notice of Benefit and Payment Parameters for 2016 (79 FR 70673, Nov. 26, 2014)*. We thank you and your Department for listening to the voices of the patient community who wholeheartedly want the Affordable Care Act (ACA) to work, especially for those with chronic conditions. In the proposed rule, you have addressed many of the concerns we outlined in our July 28, 2014 letter to you that detailed some of the barriers to access enrollees have encountered in the Qualified Health Plans (QHPs).

The areas in which we have collectively focused and relayed to you in our July letter included discriminatory benefit designs that limit access, such as restrictive formularies and inadequate provider networks; high cost-sharing; and a lack of plan transparency. As outlined below, the proposed rule makes an effort to address each of these areas of concern. We realize that what have been proposed are just proposals. Therefore, we urge you to issue a final rule as soon as possible without diminishing any of the proposed improvements for patients and to implement these changes for the 2016 plan year. Patients should not wait another year for these modifications to occur; they need the ACA to work for them now. Additionally, we urge you to enforce the patient protections included in the law and in regulation, including the non-discrimination provisions that are critical to the ACA's success.

Essential Health Benefits Modifications

Benchmark Plans for 2017: We appreciate the recognition that benchmark plans used to determine the essential health benefits for each state need to be updated. Basing them on 2014 plans is an improvement. However, we would rather see a different process identified to determine essential health benefits, one that better meets patient needs and is more consistent across the country. Since an alternative approach is not being proposed at this time, and CMS is continuing to use the benchmark process to define essential health benefits for each state, we support using 2014 plans as the benchmark, but would like to see this implemented beginning for the 2016 and not the 2017 plan year.

Prescription Drug Benefits: We are extremely supportive of the proposal to replace the current system of determining the Essential Health Benefit's prescription drug benefit. The current process of relying on the greater of one drug per class or the number of drugs in each class in the state's benchmark based on the US Pharmacopeia (USP) classification system has many shortcomings. As described in the proposed rule's preamble, USP was designed for the Medicare Part D program, which is a different population than the qualified health plans. As we wrote to you in July, this has resulted in numerous drugs not being covered that are needed by patients, including newly approved medications, and plans removing necessary drugs mid-year. Moving to the American Hospital Formulary System (AHFS) as a standard for

classifying drugs is preferred to the USP system since it is more detailed, widely used and accepted, and more frequently updated. Utilizing Pharmacy and Therapeutic (P&T) committees that select what medications plans cover based on treatment guidelines and expert knowledge of specific health conditions and their treatment is also highly preferred. Requiring them to meet at least quarterly will help ensure newly approved drugs can be added to plan formularies. We agree with what was stated in the proposed rule's preamble, using a P&T committee process "will provide enrollees with a more robust formulary drug list." We also strongly support the proposed transparency requirements for the P&T committees included in the proposed rule.

We strongly support these improvements and urge CMS to move forward with retaining, as a minimum, the current greater than one drug or the number of drugs covered by the benchmark requirement using either the most recent AHFS or USP system, and using the most granular level of either counting system *in tandem* with the expert recommendations of the P&T committee.

Since plans already utilize P&T committees, we urge CMS to institute this process for plan year 2016 and not wait until 2017. If CMS uses the USP system in 2016, plans should be required to use USP Version 6.0 and not 5.0. Version 6.0 was finalized in February 2014 and is more current and reflective of today's FDA approved medications. For the AHFS to be used, it will have to be made accessible to the public.

Exceptions Process: We appreciate the federal standards that CMS has instituted regarding an "exceptions process" that requires plans to have for enrollees to access medications not on a plan's formulary and the timeframe in which they must act for an emergency health situation. We are also very supportive of the proposal to have such a standard exceptions process along with a secondary external review process. Adding both these measures will help patients access the medications prescribed for them by their provider. We believe implementation of these measures should occur in plan year 2016, as is proposed. Finally, we are extremely pleased that CMS is clarifying that patient cost sharing for excepted drugs count toward the maximum cost sharing limit.

Transparency: We are also very supportive of the proposals to increase formulary and provider transparency. In order for patients to select the plans that best meet their individual health care needs, they must have access to easy-to-understand, detailed information about plan benefits, formularies, provider networks, and the costs of medications and services. While we have seen some transparency improvements with the 2015 plans, many plans still do not have a direct link to a plan's formulary on the "Summary of Benefits and Coverage" as required by the ACA. In order to find the formulary multiple searches must be conducted for some plans. The proposed rule reiterates the ACA requirement, and proposes that each plan publish up-to-date, complete formularies with tiering and any restrictions on accessing the drug. CMS is also seeking comment on whether formulary tiering information should include cost sharing information, including pharmacy deductible and cost-sharing. We are highly supportive of all these common sense proposals that help patients make the best decisions to meet their needs. Additionally, since plans are employing the use of co-insurance more frequently, plans should detail what the actual patient cost sharing will be in dollar terms. By not detailing this information, patients are left in the dark when it comes to how much they will have to pay for a drug or service.

We also are very supportive of the proposal to require plans to submit drug formularies and provider lists in machine-readable file. Currently, there is no standard formulary design and some have search capabilities while others do not. We would very much like to see an interactive web tool such as a plan finder or benefit calculator that matches an individual's prescriptions and provider needs with appropriate plans (such as the one utilized by the Medicare Part D program). Submitting information in a standard machine-readable format can assist in developing such tools.

Choice in Pharmacy Delivery: We are highly supportive of providing patients with the choice of how they receive their prescriptions and prohibit the practice of a mail-order only option. As the proposed rule describes, there are legitimate instances in which a patient may want to access a retail pharmacy and patients can benefit from interaction with a pharmacist. We see no reason why this option should be delayed until 2017 and believe it should be implemented in 2016.

Prohibition on Discrimination: We applaud CMS for including language in the proposed rule's preamble that remind plans they must not design plan benefits in a discriminatory manner, for example placing limits on or excluding services. We are particularly pleased that CMS singled out the needs of patients with chronic conditions by writing, "We also caution issuers to avoid discouraging enrollment of individuals with chronic health needs." CMS provided examples such as an issuer not covering a single-tablet drug regimen or extended-release product.

Another example of discrimination CMS identified was "if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, we believe that such plan designs effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions." We greatly appreciate the recognition of this increasingly used practice by some plans that design their benefit in such a way that harms patients, particularly those with pre-existing conditions. **We call on CMS and others to begin to enforce the ACA non-discrimination provisions and to issue regulations that further define what discrimination is**. Patient groups have pointed out these practices and are waiting for action by the federal government. As part of the plan review process for 2015, we thought there would be a better review of the plans for discrimination, but we are finding that the 2015 plans are utilizing the same practices as they did in 2014. **Again, we call upon CMS and others to enforce the law.**

Other Elements in the Proposed Rule: There are a number of other elements in the proposed rule that we are supportive of including efforts to better define habilitative services and strengthen provider networks, including essential community providers.

One critical element that was not addressed in the proposed rule but needs to be if the ACA and the qualified health plans will work for people with chronic health care conditions is the high level of co-insurance some plans are requiring for prescription medications. While enforcing the non-discrimination provisions can help, co-insurance as high as 40 or 50 percent make access to lifesaving medications out of reach for most people. It is very different for all drugs in one class to be placed on the highest tier with a nominal co-pay in one plan from another that places the same drugs on the highest tier with 50 percent co-insurance. We hope you will address this issue in the near future.

Again, thank you for addressing many of the issues patient groups have identified as needing attention if the ACA is to deliver on its promises for people with chronic health conditions. We look forward to finalization of this rule without any diminishment of the patient protections you have proposed and an early implementation of many of the outlined improvements.

Thank you very much.

Sincerely,

1 in 9: The Long Island Breast Cancer Action Coalition
AAFA New England
The ACCESS Network, Inc.
ACCSES
ADAP Educational Initiative
Addiction Professionals of North Carolina
Advocates for Responsible Care
Advocacy Center
African American Health Alliance

AIDS Action Committee
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
The AIDS Institute
AIDS Project Los Angeles
AIDS Research Consortium of Atlanta
AIDS United
Alabaster
Alliance for Patient Access
Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)
Alpha-1 Foundation
Alzheimer's & Dementia Alliance of Wisconsin
Alzheimer's & Dementia Resource Center
American Academy of HIV Medicine
American Association of Colleges of Pharmacy
American Association on Health and Disability
American Autoimmune Related Diseases Association
American Behcet's Disease Association
American Kidney Fund
American Society for Metabolic and Bariatric Surgery
American Society of Bariatric Physicians
Analtech, Inc.
Aniz, Inc
APLA Health & Wellness
Arthritis Association of Louisiana
Asian & Pacific Islander American Health Forum
Association of University Centers on Disabilities
Batten Disease Support & Research Association
Behavioral Science Research
Bladder Cancer Advocacy Network
Blue Ribbon Advocacy Alliance
Boley Centers, Inc.
Borinquen Medical Centers
Brain Injury Association of America
California Asian Pacific Chamber of Commerce
California Chronic Care Coalition
California Council for the Advancement of Pharmacy
California Hepatitis C Task Force
Campaign to End Obesity Action Fund
CancerCare
Caregiver Action Network
Cascade AIDS Project
Catawba Care
The Cave Institute
Christie's Place
Colon Cancer Alliance
COLONTOWN
Combined Health Agencies
Community Health Action Network
Community Health Charities of Kentucky
Community Health Charities of Tennessee
Community Volunteers Association
Congenital Hyperinsulinism International
COPD Foundation
Crohn’s and Colitis Foundation
Dab the AIDS Bear Project
Delaware Ecumenical Council on Children and Families
The Desmoid Tumor Research Foundation
Diabetes Community Action Coalition, Inc.
Dysautonomia International
Easter Seals
Easter Seals Iowa
Easter Seals Massachusetts
Easter Seals UCP North Carolina & Virginia
East Georgia Cancer Coalition, Inc.
Elder Care Advocacy of Florida
ELLAS
Epilepsy Association of Oklahoma
Epilepsy Foundation
Epilepsy Foundation Central & South Texas
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation Louisiana
Epilepsy Foundation New England
Epilepsy Foundation North/Central Illinois, Iowa, Nebraska
Epilepsy Foundation Northwest
Epilepsy Foundation of Arizona
Epilepsy Foundation of Colorado
Epilepsy Foundation of Delaware
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Greater Cincinnati and Columbus
Epilepsy Foundation of Greater Los Angeles
Epilepsy Foundation of Greater Southern Illinois
Epilepsy Foundation of Hawaii
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Long Island
Epilepsy Foundation of Michigan
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Mississippi
Epilepsy Foundation of Missouri and Kansas
Epilepsy Foundation of Nevada
Epilepsy Foundation of New Jersey
Epilepsy Foundation of North Carolina

Epilepsy Foundation of Northeastern New York, Inc.
Epilepsy Foundation of San Diego County
Epilepsy Foundation of Southeast Tennessee
Epilepsy Foundation of the Chesapeake Region
Epilepsy Foundation of Vermont
Epilepsy Foundation of Western Ohio
Epilepsy Foundation of Western Wisconsin
Epilepsy Foundation Texas
Federation of Families for Children's Mental Health- Colorado Chapter
Filipino American Service Group, Inc. (FASGI)
First Step House
Florida Keys HIV Community Planning Partnership
Florida Partners in Crisis
Florida State Hispanic Chamber of Commerce
Friends-Together, Inc
The G.R.E.E.N. Foundation
GBS/CIDP Foundation International
Georgia Osteoporosis Initiative
GLMA: Health Professionals Advancing LGBT Equality
Global Colon Cancer Association
Global Healthy Living Foundation
Good Samaritan
Harm Reduction Coalition
HEALS of the South
HealthHIV
Healthy African American Families II
HealthyWomen.org
Hemophilia Alliance of Maine, Inc.
Hemophilia Association of the Capital Area
Hemophilia Federation of America
Hemophilia Foundation of Oregon
Hep C Connection
HIV Dental Alliance
HIV Prevention Justice Alliance
HIV/AIDS Services for African Americans in Alaska
Hope for a Brighter Day, Inc.
Human Rights Campaign
Immune Deficiency Foundation
International Foundation for Autoimmune Arthritis
International Institute of Human Empowerment
International Myeloma Foundation
Iowa State Grange
The Jewish Federations of North America
Kentucky Life Sciences Council
Latino Commission on AIDS
Latino Diabetes Association
Lifelong
Louisville Healthcare Navigators
Lupus Alliance of Upstate New York
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Lupus Foundation of America, DC/Maryland/Virginia Chapter
Lupus Foundation of America, Indiana Chapter
Lupus Foundation of America, Iowa Chapter
Lupus Foundation of Arkansas, Inc.
Lupus Foundation of Florida, Inc.
Lupus Foundation of Southern California
Lupus LA
Lupus Research Institute
Lupus Society of Illinois
Malecare
The Marfan Foundation
Marin County Pharmacists Association
Massachusetts Association for Mental Health, Inc.
MedTech Association (NY)
Men's Health Network
Mental Health America
Mental Health America of Franklin County
Mental Health America of Georgia
Mental Health Association of Connecticut, Inc.
Mental Health Association in New York State, Inc. (MHANYS)
METAvivor Research and Support
Michigan Positive Action Coalition (MI-POZ)
Molly's Fund Fighting Lupus
Myasthenia Gravis Foundation of Illinois
The Myositis Association
Nashville CARES
National Adrenal Diseases Foundation
National Alliance of State & Territorial AIDS Directors
National Alliance on Mental Illness
National Alliance on Mental Illness Beaufort County
National Alliance on Mental Illness Black Hawk County
National Alliance on Mental Illness California
National Alliance on Mental Illness Connecticut
National Alliance on Mental Illness Kansas
National Alliance on Mental Illness Minnesota
National Alliance on Mental Illness New Mexico
National Alliance on Mental Illness North Carolina

National Alliance on Mental Illness Ohio
National Alliance on Mental Illness Oregon
National Alliance on Mental Illness Rhode Island
National Alliance on Mental Illness Washington
National Alopecia Areata Foundation
National Asian Pacific American Families Against Substance Abuse
National Association of Hepatitis Task Forces
National Association of Hispanic Nurses (NAHN)
National Association of Nutrition and Aging Services Programs (NANASP)
National Association of Social Workers, North Carolina Chapter
National Black Gay Men's Advocacy Coalition
National Black Nurses Association
National Black Women's HIV/AIDS Network, Inc.
National Council for Behavioral Health
National Grange
National Hemophilia Foundation
National Hispanic Medical Association
National Kidney Foundation
National LGBT Cancer Project - Out With Cancer
National LGBTQ Task Force
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Osteoporosis Foundation
National Patient Advocate Foundation
National Psoriasis Foundation
National Spasmodic Dysphonia Association
National Transitions of Care Coalition (NTOCC)
National Viral Hepatitis Roundtable
National Women and AIDS Collective
Neurofibromatosis, Inc. Mid-Atlantic
Neuropathy Action Foundation
New England Hemophilia Association
New Jersey Association of Mental Health and Addictions Agencies, Inc.
New York City Hemophilia Chapter
New Yorkers for Accessible Health Coverage
Noah's Hope Batten Disease Fund
North Carolina Psychological Association
Northeast Kidney Foundation
Obesity Action Coalition
The Obesity Society
Ohio Association of County Behavioral Health Authorities
Old North State Medical Society
One in Four Chronic Health
Ovarian Cancer Coalition
Ovarian Cancer National Alliance
OWL-The Voice of Women 40+
Palmetto AIDS Life Support Services
Parkinson's Action Network (PAN)
Parkinson's Association
Patient Services Inc.
The Philadelphia Center
Plaza Community Services
Prevent Blindness
Prevent Blindness Ohio
Prevent Blindness Wisconsin
Project Inform
Pulmonary Hypertension Association
Racial and Ethnic Health Disparities Coalition
Relapsing Polychondritis Awareness and Support Foundation
RetireSafe
Rocky Mountain Hemophilia & Bleeding Disorders Association
Rocky Mountain Stroke Center
Rush To Live
S.L.E. Lupus Foundation
Salud USA
San Francisco AIDS Foundation
Sangre de Oro, Inc.
Scleroderma Foundation
The Senior Citizens Council
Society for Women's Health Research
Solidarity Project Advocacy Network
South Carolina HIV Task Force
Southern HIV/AIDS Strategy Initiative (SASI)
State Grange of Minnesota
The Sturge-Weber Foundation
Substance Use Disorder Federation
Treatment Access Expansion Project (TAEP)
United Spinal Association
US Pain Foundation
Utah Support Advocates for Recovery Awareness
Vasculitis Foundation
Veterans Health Council
Vietnam Veterans of America
Vietnamese Social Services of Minnesota
Virginia Hemophilia Foundation
The Wall Las Memorias Project
The Well Project
West Virginia Parkinson's Support Network
Wound Care Clinic - ESU