December 18, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
The Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on Essential Health Benefits Proposed Rule

Dear Secretary Sebelius:

We, the undersigned, are health advocacy organizations representing millions of patients and their families who are committed to implementation of the Affordable Care Act (ACA). The manner in which the essential health benefits (EHB) are defined will directly impact how well health coverage works or does not work for approximately 23 million patients expected to be enrolled in the exchanges and the millions of enrollees in non-grandfathered individual and small group plans outside of the exchanges. We are writing to thank you for acknowledging our earlier concerns with the December 2011 EHB bulletin, and to comment on the proposed EHB rule issued on November 26, 2012. Specifically, we recognize the changes regarding prescription drug coverage, and now ask you to further consider our views as you finalize the rule in order to provide all patients with meaningful and affordable care and treatment.

**Prescription Drug Coverage**

We are pleased that you recognize the “one drug per class” minimum requirement was not workable for patients, particularly for those with serious complex chronic health conditions. The proposed language in the rule, “at least the greater of: 1) one drug in every category and class; or 2) the same number of drugs in each category and class as the EHB-benchmark plan” provides patients with greater access to medications. Unfortunately, it will inevitably fail to meet many patients’ needs and presents additional difficulties. Nevertheless, in the final rule, we urge you not to go below the proposed standard.

*Meeting a Target Number of Drugs:* Patients do not respond to a specific number of drugs but rather to specific drugs that best meet their needs as prescribed by their physician. The proposed rule merely requires plans to meet a target number of drugs within a specific class without regard to which drugs are covered. Under the standard described in the proposed rule, plans can choose not to include certain drugs that may have unique and important therapeutic advantages in terms of safety and efficacy, and still meet the requirements of EHB coverage just as long as they include a minimum number of drugs in the class. A system must be in place to review the adequacy and quality of each plan formulary; the quantity of medications must not be the only measure. EHB plans could exclude more effective therapies in some classes, which would violate the patient protections and non-discrimination policies in the law and would not be consistent with “typical” employer plans.
A robust formulary is necessary because not all patients respond to medicines in the same way. Physicians may need to change medicines over the course of an illness, patients may become resistant to or suffer adverse side-effects from a particular drug, some may need more than one medication from the same class at the same time, and patients taking multiple medicines need alternatives to avoid harmful interactions. Patients need access to a full range of medicines. If they are not able to access appropriate medications, patients may become ill, impacting healthcare spending in the long run.

State Variation in Drug Coverage: According to analysis conducted by Avalere Health, there exists a wide variation in the total number of drugs included in the state selected benchmark plans. While some states have over 1,000 drugs on their formulary, others have fewer than half of that amount. Although simply judging the quality of a formulary by the number of drugs covered is a poor measure of its adequacy, it is troubling that we see such significant variation across states. This perpetuates the fragmented system of health care in the country. To meet patients’ needs, we suggest that plans be required to cover all or substantially all drugs in each class.

Plan for New Drugs: The proposed rule does not discuss how plans must address new drugs that come onto the market during the course of a plan year. The standard described in the proposed rule appears to tie the EHB formulary requirements for 2014 and 2015 to the number of drugs offered by the benchmark plan in 2012 and does not include any requirements for plans to cover drugs approved after 2012. We would suggest that plans be required to update their formularies using methods similar to Medicare Part D and the private insurance market. For example, Part D requires that independent Pharmacy and Therapeutic (P&T) Committees make decisions on coverage of new products within 180 days of their approval. As part of the requirement to review newly approved drugs, patients in EHB plans should be able to remain on older therapies without the fear that their prescriptions will be taken off the formulary when a newer drug is added.

Drug classification system: HHS proposes to use the US Pharmacopeia (USP) system to classify the drugs in EHB formularies, but this system would require changes to be used for this purpose. The USP only updates their drug classification system every three years, which will cause delays in reflecting new medical innovations. USP also does not recognize combination products, which have been shown to improve adherence and have become the standard of care in some areas. The USP system is also very broad, which would allow plans to cover the same number of drugs in a class as the benchmark while exclude groups of drugs needed for patients with certain diagnoses. If changes are not made to the USP, we recommend that HHS consider alternative approaches.

Appeals Process for Drugs not on Formulary: While the proposed rule states that a plan “must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan,” such a process is not laid out and we are concerned the interests of patients will not be adequately protected. The proposed rule merely states that a plan has to have a process, but does not provide any standards or requirements for an appeal process. We would recommend that the procedures outlined in Medicare Part D, which calls for an expedited, time-limited process with emergency filling of prescriptions be required. Further, we believe that
HHS should adopt a standard of guaranteeing access to medically necessary pharmaceuticals through the appeals process.

**Patient Cost-sharing:** In the development of health plans, it is also imperative that patient cost-sharing be limited so that patients can afford access to lifesaving medications and other health care services. We are concerned with HHS’ proposal that patient’s out-of-pocket spending on out-of-network treatments and services would not be counted as part of a patient’s cost-sharing. We are also concerned that HHS proposed not to factor these costs into the calculation of actuarial value. This appears to be contrary to the language in the Affordable Care Act, which limits the “cost-sharing incurred under a health plan.” HHS should revise its position and specify that copayments and coinsurance on covered out-of-network services will count towards the out-of-pocket maximum. This change will be particularly important given the likelihood that health plans offering essential health benefits will use narrow provider networks.

**Utilization Management Techniques:** It is critical that patients not be denied access to treatments through utilization management techniques such as step-therapy, prior authorizations, and quantity limits that impede quality care and treatment. Limits on these practices should be put in place along with a process for patients to appeal them.

**Physician Administered Medications:** The proposed rule does not address the scope of prescription drugs available via the medical benefits offered as part of the EHB. The final rule should confirm that these medications will be covered through the medical benefit, as is the case in employer sponsored health plans.

**Non-Discrimination Provisions**
According to the law, "the Secretary shall ensure that the scope of the essential health benefits … not make coverage decisions . . . that discriminate against individuals because of their . . . disability" and will "take into account the health care needs of diverse segments of the population, including . . . persons with disabilities." The proposed rule merelyrestates what is in the law relative to non-discrimination and provides no further guidance to the states and plans on how these requirements will be administered or enforced at the plan, state, or federal level. Frequently, plans place drugs on specialty tiers or deny patients certain necessary treatments or services. Additionally, plan sponsors may devise or market a plan that discourages enrollment of certain patients, particularly those with chronic health needs.

The final rule must better define how the state and the federal government will assess, monitor and enforce the law’s non-discrimination measures. There needs to be rigorous methods for assuring that plan benefit designs and formularies do not result in discouraging enrollment by individuals with significant health needs. We do not feel it is sufficient to allow all monitoring to rest at the state level. The processes CMS uses in the Medicare Part D and Medicare Advantage programs has been successful and would be an appropriate model for CMS to use for EHB plans.

**Access to Proper Care**
The proposed rule does not address the need for patients to access quality health care nor does it set any standards of care for patients. Patients need access to a comprehensive range of health care services and providers to ensure quality care and positive health care outcomes. Many patients need access to specialist care, particularly those with chronic conditions. The final rule
must allow for access to specialty care. There are tens of millions of Americans who are affected with serious chronic and/or rare diseases. For these patients, access to specialty physicians and other clinicians is essential for their diagnosis and treatment. Patients who do not have such access are at grave risk of having their condition reach crisis stages, increasing human suffering and requiring even more costly care, including hospitalization.

We thank you for your continued leadership in ensuring that more Americans will have access to health care. We realize that we are at a critical time in implementing ACA. Decisions that are made now will determine its success. On behalf of patients with many diverse chronic health conditions and disabilities, we look forward to a regulation that provides a more meaningful prescription drug benefit and a better explanation of the patient protections outlined in ACA.

Thank you very much.

Respectfully,

AGUILAS
Academy of Nutrition and Dietetics
AIDS Action Committee of Massachusetts
AIDS Foundation of Chicago
The AIDS Institute
AIDS Project Los Angeles
AIDS Resource Center of Ohio
AIDS Resource Center of Wisconsin
AIDS United
American Autoimmune Related Diseases Association
American Brain Coalition
American Dietetic Association
American Liver Foundation Allegheny Division
Arthritis Foundation
Asian & Pacific Islander American Health Forum
Asian Americans for Community Involvement (AACI)
Association for Behavioral Healthcare - Massachusetts
Asthma and Allergy Foundation of America
California Association of Addiction Recovery Resources (CAARR)
California Chronic Care Coalition
California Council of Churches
California Hepatitis C Task Force
California Senior Advocates League

Center for Independence of the Disabled, NY
Center for Public Policy Priorities
Chemung Valley Rural Health Network
Chula Vista Elementary School District
Clinical Social Work Association
Coalition for Pulmonary Fibrosis
Columbia County Department of Human Services
Community Access National Network
County Alcohol and Drug Program Administrators Association of California
Crohn's & Colitis Foundation of America
Delaware HIV Consortium
The Delaware Valley Chapter of NHF
Dept. of Drugs and Alcohol, Addiction Medicine Treatment, County of Santa Clara, CA
Diabetes Foundation of Mississippi
Down East AIDS Network
Easter Seals
Epilepsy Foundation
Epilepsy Foundation of Central & South Texas
Epilepsy Foundation of Greater Chicago
Faces & Voices of Recovery
Frannie Peabody Center
Gay Men's Health Crisis
Global Healthy Living Foundation (GHLF)
Graves' Disease and Thyroid Foundation
Health & Disability Advocates  
HealthHIV  
Healthy Start  
Hemophilia Association of the Capital Area  
Hemophilia Federation of America  
Hemophilia Foundation of Maryland  
Hemophilia of Georgia  
Hemophilia of North Carolina  
Huntington's Disease Society of America  
Illinois Psychiatric Society  
Immune Deficiency Foundation  
Interfaith Worker Coalition  
The International Autoimmune Arthritis Movement  
International Myeloma Foundation  
Intracranial Hypertension Research Foundation  
Keville & Associates  
Latino Commission on AIDS  
Legal Action Center  
Lifelong AIDS Alliance  
Louisville Healthcare Navigators  
Lupus Foundation of America  
Lupus Foundation of Florida, Inc.  
Lupus Foundation of Mid and Northern New York, Inc.  
Lupus Foundation of Southern California  
Lupus Research Institute, National Coalition  
Massachusetts Health Council  
Mary M. Gooley Hemophilia Center  
Massachusetts Association for Mental Health  
Massachusetts Association of Behavioral Health Systems  
Massachusetts Pharmacists Association  
MassBio  
Men's Health Network  
Mental Health America  
Mental Health America of Colorado  
Mental Health America of Illinois  
Mental Health America of Indiana  
Mental Health America of San Diego  
Mental Health Association of Michigan  
Mental Health Association of New York State, Inc.  
Mental Health Systems  
Michigan Lupus Foundation  
Minnesota AIDS Project  
Minority Health Institute, Inc.  
National Alliance of State & Territorial AIDS Directors  
National Alliance on Mental Illness  
National Alliance on Mental Illness Alabama  
National Alliance on Mental Illness California  
National Alliance on Mental Illness Delaware  
National Alliance on Mental Illness Illinois  
National Alliance on Mental Illness Iowa  
National Alliance on Mental Illness Massachusetts  
National Alliance on Mental Illness Greater Chicago  
National Alliance on Mental Illness Ohio  
National Alliance on Mental Illness Washington  
National Alliance on Mental Illness Will-Grundy  
National Alopecia Areata Foundation  
National Asian Pacific American Families Against Substance Abuse  
National Association of County Behavioral Health and Developmental Disability Directors  
National Association of Hepatitis Task Forces  
National Association of Hispanic Nurses (NAHN)  
National Association of Social Workers, California  
National Association of Social Workers, Washington State  
National Council for Community Behavioral Healthcare  
National Family Caregivers Association  
National Fibromyalgia & Chronic Pain Association  
The National Grange  
National Hemophilia Foundation  
National Kidney Foundation  
National Marfan Foundation
National Minority Quality Forum
National Psoriasis Foundation
National Spasmodic Dysphonia Association
National Viral Hepatitis Roundtable
National Women ad AIDS Collective
    (NWAC)
New England Hemophilia Association
New York Association of Psychiatric
    Rehabilitation Services
New York State Partners in Policymaking
New Yorkers for Accessible Health
    Coverage
Ohio AIDS Coalition
Parkinson's Action Network
Pharmacists Society of the State of New
    York
Prevent Cancer Foundation
Pulmonary Hypertension Association
Rehabilitation and Pain Management
    Associates, Baltimore, MD
RetireSafe
Rocky Mountain Hemophilia Association
    Regaining Excellence)
San Diego Center for Patient Safety, UCSD
    School of Medicine
Sjogren's Syndrome Foundation
Society for Women's Health Research
Sound Mental Health
State Associations of Addiction Services
State of Texas Kidney Foundation
The Sturge-Weber Foundation
Thresholds
Toledo Area Jobs with Justice
Tremor Action Network
UJA-Federation of New York
Urbana Human Services Organization
Veterans Health Council
Vietnam Veterans of America
Virginia Hemophilia Foundation
Washington Community Mental Health
    Council
Western Pennsylvania Chapter of the
    National Hemophilia Foundation