

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 merely restates 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 and 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
RVL S.C.O.R.E. (RVL Spinal Cord Org for
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