

I AM ESSENTIAL

February 21, 2013

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 Proposed Rule “Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing”

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). As you implement the law through regulation and guidance, we urge you to guarantee that the needs of patients are met and that benefits and services are meaningful and affordable. Below we offer comments on the January 22 proposed rule that outlined how essential health benefits (EHB) for the expanded Medicaid population will be determined. The adequacy of the benefits in the Alternative Benefit Plans will directly impact how well health coverage works or does not work for approximately 17 million patients who can potentially be enrolled in the expanded Medicaid program. We also offer comments on patient cost sharing and the process to determine eligibility in the marketplace and the expanded Medicaid program, along with the eligibility appeals process.

Essential Health Benefits for Expanded Medicaid (Alternative Benefit Plans)

We have previously commented that the approach HHS is taking to determine how essential health benefits are defined is inadequate and perpetuates an uneven system of health care from state to state. Now, as you determine the process to develop essential health benefits for the expanded Medicaid population you propose basing coverage on a similar model to that created for the private market. States will participate in a two-step process in which they first select their Alternative Benefit Plan (ABP) from an existing Medicaid benchmark. Then, if the state ABP is not already an EHB option in the private market, the state will select a plan from the essential health benefits private market choices to supplement any additional benefits from that benchmark. While this methodology generally attempts to ensure robust coverage for this population, due to the quantitative limitations that states can impose on prescription drugs, as described below, instead of offering similar benefits, patients can, in fact, potentially receive a diminished drug benefit.

Scope of Benefits

Given that HHS is developing essential health benefits tied to existing benchmarks at least for the first couple years, we support the process laid out in the proposed rule that a state must select among four types of existing plans and then compare it with one of the essential health benefit plans for the private market in the state to supplement its adequacy.

We also support language in the preamble that states plans must cover all drugs by companies that participate in the Medicaid drug rebate program. However, this language is not included in the regulatory language and therefore, we request that it be incorporated into the final rule. Additionally, we are concerned that you allow states to place “limitations on amount, duration, and scope” and “adopt prior authorization and other utilization control measures, as well as policies that promote the use of generic drugs.” For people living with chronic conditions, use of utilization management techniques can have a detrimental impact and inhibit people from accessing lifesaving treatments. We also believe that these limitations can violate the non-discrimination requirements in the law.

Some states in the current Medicaid program limit the number of drugs and include other utilization control measures that are harmful to patients and deny them from the therapies that meet their health needs as prescribed by their physician. Some state Medicaid programs limit patients to 2 to 4 brand name drugs per month. Such limitations clearly do not meet patients’ needs and we urge you to not allow states to adopt them for the expansion population. Patients should be able to access the medications that they need as prescribed by their physicians. If they are not able to access appropriate medications, patients may become ill, impacting healthcare spending in the long run.

We seek clarification on what is being proposed in the rule’s recommendation regarding prescription drugs limits. While the rule proposes that the Alternative Benefit Plan has to meet the benefits in the state selected EHB for the private market, the rule separately appears to replace the Alternative Benefit Plan’s EHB drug benefit category with that described in Section 1927. In the final rule, we seek clarification on this matter and specifically on whether the ABP drug benefit is trumped by what is outlined in Section 1927, including with respect to any limitations. Furthermore, we are greatly concerned by the seemingly open-ended ability of states to impose limits. We recommend that quantity limitations not apply to the Alternative Benefit Plan.

Adequate Public Comment Period

In the rule, it is proposed that when a state submits or modifies its Alternative Benefit Plan as a State Plan Amendment that the public must be notified and there must be a reasonable opportunity to comment. Additionally, if a plan reduces benefits or increases cost sharing there must be a two week notice prior to the submission. While we appreciate the recognition that there should be an opportunity for public comment, we believe a state should provide at least 60 days for the public to review and comment on the plan before it is submitted. We believe this should be provided for all plan changes, not just those that are deemed to decrease benefits or increase cost sharing as the proposed rule posits. This will allow patients an opportunity to adequately analyze, develop positions, formulate comments and submit them on matters that will directly impact them.

Additionally, as HHS allowed all members of the public to review and comment on the essential health benefits selected for the marketplace for each state, we recommend that CMS publicly release all Alternative Benefit Plans selected and allow an opportunity for public comment to ensure plan adequacy.

Coverage of Preventive Services

We are highly supportive of the fact that the proposed rule clarifies that all Alternative Benefit Plans must cover all the preventive services that the plans in the marketplace must cover. This includes all “A” or “B” services recommended by the United States Preventive Services Task Force; Advisory Committee for Immunization Practices (ACIP) recommended vaccines; preventive care and screening for infants, children and adults recommended by HRSA’s Bright Futures program/project; and additional preventive services for women recommended by Institute of Medicine (IOM).

We also support the recommendation in Section 440.130 that expands the definition of who can provide preventive services to be in line with current statute, which defines “services...recommended by a physician or other licensed practitioner of healing arts within the scope of their practice under State law.” This should help increase the use of preventive services and reduce future health costs.

However, we are very concerned that you have proposed that cost sharing for preventive services be allowable for the Medicaid expansion population. We note that cost sharing is prohibited by plans in the marketplace, whose enrollees have a higher income level and can better afford to make contributions. The imposition of cost sharing for this population, who by definition is very poor, will certainly limit the utilization of preventive services and lead to poorer health outcomes and higher costs. We recommend that in the final rule preventive services in Alternative Benefit Plans be offered without cost sharing.

Definition of Medically Frail

We are very supportive of the proposal in Section 440.315(f) to revise the definition of “medically frail” to specifically include “individuals with disabling mental disorders (to include children with serious emotional disturbances and adults with serious mental illness), individuals with serious and complex medical conditions, individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform one or more activities of daily living, or individuals with a disability determination, based on Social Security criteria, or in states that apply more restrictive criteria than the Supplemental Security Income (SSI) program, as the state plan criteria.”

This should help ensure that all people with disabilities are included in the medically frail definition and therefore eligible for enrollment in the state’s traditional Medicaid program through the exemption process. We also support that individuals with a substance use disorder also be added to the definition of “medically frail.”

We seek clarification and further guidance on the enrollment and selection process for “medically frail” beneficiaries. It will be critical for those who qualify to be able to select the benefit plan that best meets their health care needs. Depending on the circumstance this could be either the traditional Medicaid package or the Alternative Benefit Plan but will depend on

individual need and state benefit designs. We want to ensure that “medically frail” beneficiaries will not be forced into a plan that provides fewer benefits than the ABP or the traditional Medicaid package.

Non-Discrimination Requirements

We are pleased that Section 440.347(e) of the proposed rule includes important non-discrimination protections for patients that states, “Essential health benefits cannot be based on a benefit design or implementation of a benefit design that discriminates on the basis of an individual’s age, expected length of life, an individual’s present or predicted disability, degree of medical dependency, or quality of life or other health condition.” However, the protections proposed for the Alternative Benefit Plans are not as inclusive of those proposed for the marketplace. We strongly urge that the two programs include the same and the richer of the two patient protects. Therefore, we propose the following anti-discrimination protections included in the law pertain to Alternative Benefit Plans: 1) EHB must “reflect an appropriate balance among the categories”; 2) The Secretary may “not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life”; and 3) EHB must “take into account the health care needs of diverse segments of the population, including women, children, [and] persons with disabilities.”

Patient Cost sharing

The level of patient cost sharing, particularly for the very poor, who by definition are the ones who will be enrolled in Medicaid expansion plans, will directly impact beneficiary access to health care services and medications. If it is too high, patients will not access those services that can lead to healthy outcomes and lower health care costs. Study after study has shown that even co-pays of a couple of dollars can deter beneficiaries from accessing services or medications and do not lead to overall program savings. Beneficiaries, particularly those with complicated or chronic health conditions, take multiple medications or access several outpatient services per month. Co-pays of \$4/drug or service multiplied by any factor can quickly add up and make access to health care or medications out of reach.

While the five percent cap on total out-of-pocket health spending is an attempt to shield this population from high costs, this is still insufficient. Several states now limit total monthly co-payments so that beneficiaries who need multiple medications to maintain their health or treat serious illnesses are not penalized or discriminated against. We suggest that such an additional cap be included in the final rule as a necessary protection for this vulnerable population. For example, Wisconsin has a cap of \$12 per month. We would recommend that CMS develop such a cap or some other nominal fee to take into consideration those low-income beneficiaries who access multiple medications, services, or providers to manage complex medical conditions.

Co-pays for Non-preferred Drugs

We also are concerned with the proposed \$8 co-pay CMS is proposing to allow states to charge for each non-preferred drug. We do not believe it is a “nominal” level and it represents a doubling of the maximum co-pay for preferred drugs. Numerous studies have shown that increased co-pays are associated with lower medication adherence and poorer health outcomes across the entire population, and the impact of increasing cost sharing is particularly acute for low-income patients. While the cost sharing levels being proposed in the rule may seem

reasonable when compared to a commercial insurance plan, these co-pays will be a significant barrier for many very low-income beneficiaries.

Under section 1916A of the Social Security Act, the maximum cost sharing for non-preferred drugs for individuals with income at or below 150% of federal poverty level (FPL) cannot exceed a nominal amount. The proposed rule would set the “nominal” amount at \$4, but would set the non-preferred drug cost sharing at \$8. In our view, this would violate the law. Accordingly, CMS should reduce the proposed \$8 maximum cost sharing amount for non-preferred drugs to \$4, to match the nominal cost sharing for preferred drugs.

Not only does the proposed cost sharing increase for non-preferred drugs for individuals below 150% FPL violate the requirements of the law, the increase is unnecessary to achieve the policy goal of incentivizing the use of preferred drugs. Even with a \$4 maximum copayment for non-preferred drugs, a state could create a strong incentive for the use of preferred drugs by lowering the copayment for those drugs to \$1 or eliminating copayments on those drugs. This would meet both the requirements of the law and also provide states with the tools necessary to drive drug utilization towards preferred drugs.

The Use of Cost-effectiveness Standards

The proposed rule defines preferred drugs with respect to a cost-effectiveness standard. Specifically, preferred drugs are those “the State has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drugs within each therapeutically equivalent or therapeutically similar class of drugs.” Use of a cost-effectiveness standard as the basis for identifying preferred drugs in State Medicaid programs threatens access to needed treatment and would result in broad, one-size-fits-all policies that do not reflect important differences in individual beneficiary needs and circumstances. A cost-effectiveness standard should not be defined in Medicaid in a way that compromises access to needed care.

High Cost sharing is Discriminatory

The ACA’s anti-discrimination standards apply to all plans (including ABPs) required to provide Essential Health Benefits and was included to prevent plans from designing benefits that would discriminate against patients with significant health needs. This important beneficiary protection applies to any aspect of “benefit design.” Yet it is not reflected in the proposed rule’s provisions on cost sharing: a central feature of benefit design that often determines whether beneficiaries have affordable access to “covered” treatments. To meet the nondiscrimination requirements that govern Medicaid ABPs, CMS should require that these plans classify drugs as “preferred” or “non-preferred” drugs in a way that “[does not] discriminate on the basis of an individual’s age, expected length of life, or... present or predicted disability, degree of medical dependency, or quality of life or other health conditions.”

Meaningful non-discrimination protections will require a thoughtful and thorough review of preferred drug lists (PDLs). For example, PDLs should only be permitted to categorize a drug as non-preferred when there are genuine therapeutic alternatives classified as preferred. In addition, PDLs should allow for appropriate access to drugs needed for adherence to widely accepted treatment guidelines. Most importantly, medications used by particularly vulnerable Medicaid

beneficiaries should be largely available as preferred drugs, given the importance of avoiding medical complications and interruptions in therapy for individuals with those conditions.

Physician Determination

Finally, section 1916A explicitly requires that Medicaid provide preferred cost sharing on non-preferred drugs “if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual.” This is an important patient protection, and an explicit recognition that high cost sharing can be a complete barrier to access: the equivalent of not covering a drug at all. Further guidance should be provided to make sure that Medicaid providers are fully aware of this provision.

Cost Sharing for Inpatient Care

We note that some of the co-pays proposed for inpatient stays (50% of cost of first day of care for those with a family income less than 100% and 50% of cost of the agenda pays for the first day of care or 10% of total cost the agency pays for the entire stay) will be unattainable for families with these low income levels. Even for those proposed for families with an income level of more than 150% (including 20% of the cost an agency pays for a non-preferred drug) will be unattainable.

Eligibility Determinations & Appeals Process

We support the framework you have proposed for the process to determine eligibility and the protocols developed for the eligibility appeals process. Both contain numerous consumer protections to ensure patients eligible under ACA will not go without health care. While we are disappointed that the eligibility process outlined in the proposed rule will not go into effect until 2015, we are pleased that you have proposed a process that will lead to coordination between the two. While you strive for beneficiaries to receive eligibility notices from one single entity in the future, during the first year you admit beneficiaries will most likely receive multiple notices from different entities. This could create confusion for many patients. In so much, we ask that great efforts be made to make notices clear and understandable to the vast majority of beneficiaries (including with respect to the outcome, next steps, appeals processes, and where to turn for help).

We are pleased that you are pursuing the “no wrong door” approach for eligibility appeals and there are several levels of appeals, including one involving HHS. We appreciate that there are hard time limits, beneficiaries will not lose benefits during an appeal, and an opportunity for expedited appeals if an appellant’s health is in jeopardy.

We thank you for your continued leadership in ensuring that more Americans will have access to quality and affordable health care free from discrimination. 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 final rule that will ensure quality and affordable health care for all as envisioned by the Affordable Care Act.

Thank you very much.

Respectfully,

AIDS Foundation of Chicago
The AIDS Institute
AIDS Project Los Angeles
AIDS United
Alzheimer's & Dementia Alliance of Wisconsin
American Autoimmune Related Diseases Association
Asian & Pacific Islander American Health Forum
Asthma and Allergy Foundation of America
Association for Behavioral Healthcare
California Hepatitis C Task Force
Caregiver Action Network
Coalition for Pulmonary Fibrosis
Committee of Ten Thousand
Crohn's & Colitis Foundation of America
Delaware Valley Chapter of NHF
Epilepsy Foundation
Epilepsy Foundation of Greater Chicago
Friends For Life
GBS-CIDP Foundation International
HealthHIV
Hemophilia Association of the Capital Area
Hemophilia Federation of America
Hemophilia Foundation of Maryland
Hemophilia of Georgia
Hemophilia of North Carolina
HERO House
Illinois Maternal and Child Health Coalition
Illinois Public Health Association
International Autoimmune Arthritis Movement
Jewish Board of Family and Children's Services
Latino Commission on AIDS
Lifelong AIDS Alliance
Lupus Foundation of America
Lupus Foundation of Florida, Inc.
Lupus Foundation of Genesee Valley NY, Incorporated
Lupus Foundation of Mid & Northern New York, Inc.
Lupus Research Institute
Mental Health Action
Mental Health America
Mental Health America of Colorado
Mental Health Association in New York State, Inc.
Michigan Association of Community Mental Health Boards
Minnesota AIDS Project
Nashville CARES
National Alliance of State & Territorial AIDS Directors
National Alliance on Mental Illness (NAMI)

National Alliance on Mental Illness (NAMI) - Greater Chicago
National Alliance on Mental Illness (NAMI) - Illinois
National Alliance on Mental Illness (NAMI) - Iowa, Inc
National Alliance on Mental Illness (NAMI) - New York State
National Alliance on Mental Illness (NAMI) - Ohio
National Alliance on Mental Illness (NAMI) - Washington State Chapter
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 Hemophilia Foundation
National Minority Quality Forum
National Organization for Rare Disorders
National Psoriasis Foundation
National Viral Hepatitis Roundtable
National Women and AIDS Collective (NWAC)
Neuropathy Action Foundation
New England Hemophilia Association
New York State Partners in Policymaking
Parkinson's Action Network
Prevent Cancer
Pulmonary Hypertension Association
Rocky Mountain Hemophilia & Bleeding Disorders Association
S.L.E. Lupus Foundation
Scleroderma Foundation
Society for Women's Health Research
The National Grange
UJA-Federation of New York
US Pain Foundation, Inc
Vasculitis Foundation
Veterans Health Council of Vietnam Veterans of America
Virginia Hemophilia Foundation
Washington State Clubhouse Coalition
Western Pennsylvania Chapter of the National Hemophilia Foundation