



December 21, 2015

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 2017 Proposed Rule*, CMS-9937-P

Dear Madame Secretary:

We, the 124 undersigned patient and community organizations representing millions of patients and their families are pleased to submit comments on the proposed rule, *Notice of Benefit and Payment Parameters for 2017 (80 FR, Dec. 2, 2015)*. At the outset, we respectfully wish to register our objection to the extremely short comment period. The proposed rule was released just prior to the Thanksgiving holiday and not published formally until December 2nd. For such an important matter that has great impact, the time for preparing and submitting comments from the patient community and others is unreasonably short. We urge the Department of Health and Human Services (HHS) in the future to provide longer comment periods for proposed rules relating to the Affordable Care Act (ACA).

The comments below are reflective of the experiences patients who we represent have encountered as they have utilized the qualified health plans (QHPs) over the past two years. We submit them for your consideration as we all work to improve upon the patient experience and health outcomes, particularly for those with serious and chronic health conditions. They focus on 1) proposed Standard Benefits Option; 2) protecting access to prescription drugs; 3) continuity of care; and 4) payments made to QHP enrollees on behalf of third parties.

1) Proposed Standard Benefits Option

We applaud HHS' intent to simplify patients' experience shopping for QHPs by proposing standardized benefits options (SBOs) in the federal Marketplace. We agree that, "standardized options will provide ... consumers the opportunity to make simpler comparisons of plans offered by different issuers within a metal level. Consumers will be able to focus their decision making on the providers in the plan networks, premiums, benefits, and quality, and will not be required to make complex tradeoffs among cost-sharing differences among a large number of plans.

Taken together, standardized options, EHB, AV and QHP certification standards can significantly simplify consumers' ability to compare plans and make informed choices.”

Standardized plans are being utilized in some states already and are proving to be useful for beneficiaries since they more clearly spell out patient cost-sharing. In designing a SBO, we generally support the basic four-tier structure HHS has proposed with four differing cost sharing amounts. However, **we are concerned with the use of the “Specialty Drug” tier**, which is not clearly defined and has become quite expansive over recent years. Insurers are placing more and more medications, especially those that are used to treat serious and chronic conditions, on this tier without any apparent cost justification, which results in higher costs to patients and a disincentive for them to enroll in the plan.

Also, we strongly believe that prescription medications should not be subject to a plan's deductible. This should be the case particularly for those plans that utilize extremely high deductibles, which sometimes are equal to the maximum out-of-pocket legal limit. If medications are included in the deductible, patients may not access them due to the potential high cost. We are pleased that HHS recognizes this and has proposed that for most of the SBOs in the various metal levels and proposed tiers, patient cost-sharing for prescription medications are not subject to a deductible. However, we are concerned that the cost-sharing for medications in the Bronze plans, except for generics, would be subject to a plan's deductible. **We urge HHS to make all medications not subject to a deductible in all metal levels and tier levels.**

We are also supportive of HHS' proposal that patient cost-sharing for most tiers and metal levels, except for the Bronze plans and the “Specialty Drug” tier, utilize reasonable co-pays. We agree with HHS that, “[r]esearch shows that consumers often prefer copayments to coinsurance because the former are more transparent and make it easier for consumers to predict their out-of-pocket costs.” The use of coinsurance totally defeats HHS' intended purpose to provide patients with greater clarity in a plan's design. In reviewing a plan that employs coinsurance, a beneficiary has no idea if their cost-sharing will be 50 percent of \$100 or 50 percent of \$2,000. While both have the same coinsurance level there is a big difference between \$50 and \$1,000. This inability to access the drug information prior to choosing a plan puts individuals who rely on prescription drugs to manage their chronic conditions at a significant disadvantage and can be characterized as discriminatory.

Not only does coinsurance provide no transparency, it also results in higher patient costs since insurers are placing higher cost drugs on this tier. We are very concerned with the growing trend of increased patient cost-sharing for prescription medications. A recent study by researchers at Emory University found that chronically ill people enrolled in qualified health plans pay on average twice as much in out-of-pocket costs for prescription drugs than people covered through employer sponsored plans. Patients with at least one chronic condition pay on average \$621 out-of-pocket for prescription costs on mid-priced silver exchange plans compared to \$304 for those with employer coverage. Patients in the most-popular silver plans pay 46 percent of their total

drug spending on average, compared to 20 percent for patients in typical employer-sponsored plans.¹

We strongly oppose the use of coinsurance for the “Specialty Drug” tier across all metal levels and in all tiers (except for generics) in the Bronze plans. Using coinsurance might be more palatable if there were specific reasonable dollar level caps set, as some states have instituted in their standard benefit plans. Due to the use of coinsurance we believe the proposed tiering structure is significantly flawed and potentially discriminatory. The proposed options for Bronze, Silver and Gold plans all provide for coinsurance, ranging from 25 percent to 50 percent, for drugs placed on “Specialty Drug” tiers. Even the Silver plan with the most generous cost-sharing reductions (CSRs) would require patient coinsurance of 25 percent for “Specialty Drugs.”

The Bronze plan in effect has only two tiers – a \$35 copay for generics and 50 percent coinsurance for all other drugs. This violates the principles HHS has set out in the standard benefit design, which calls for four different tiers. For the Bronze plan, HHS has only identified, in effect, two tiers. For all medications, except for generics, patient cost-sharing would be an unaffordable 50 percent. Such a plan design would also violate HHS’ own definition of discriminatory plan design since all drugs to treat a certain condition that has no generics would automatically all end up on the highest 50 percent coinsurance tier. We believe that since more and more plans are placing all drugs to treat a certain condition on the highest cost tier, utilizing high coinsurance for all drugs on the “Specialty Drug” tier would result in discriminatory plan design.²

HHS recognized that such plans are potentially discriminatory in its 2016 *Letter to Issuers* cautioning issuers to “avoid discouraging enrollment of individuals with chronic health needs” in violation of EHB regulations. The letter further stated, “if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that plan design might effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions.”

Recommendation: If HHS proceeds with development of SBOs for the 2017 Marketplace, we strongly urge a final SBO design that protects patients from high cost-sharing and discriminatory plan designs. Specifically, SBO drug tiers should limit cost-sharing to reasonable copayment amounts, and not require coinsurance. In addition, all SBOs should provide that prescription drug coverage is not subject to deductibles.

We believe that issuers would not have to raise premiums unreasonably in order to design drug benefits without coinsurance. One recent study analyzed potential impacts of certain changes in drug benefit design, including various limitations on cost-sharing amounts. Overall results

¹ <http://khn.org/news/chronically-ill-pay-more-in-obamacare-plans-than-employer-coverage/>

² “Exchange Benefit Designs Increasingly Place All Medications for Some Conditions on Specialty Drug Tier” Avalere, February 11, 2015.

demonstrated that enrollee cost-sharing could be reduced significantly through these methods with minimal impact on total plan costs (less than 1 percent).³

2) Protecting Access to Prescription Drugs

We appreciate the effort in the proposed rule to clarify the formulary exceptions process for EHBs, and agree that strong federal protections should be applied, rather than weaker state protections. In the Notice of Benefit and Payment Parameters (NBPP), HHS solicits comments on future changes under consideration for the formulary exceptions process. Currently, EHB regulations require plans to have a process for considering requests in a timely manner when patients seek access to non-formulary drugs. If the exception is granted, patient costs for the non-formulary drug count toward the annual out-of-pocket cost limit. HHS is considering a change that would consider a plan to be in compliance with this rule if the plan complies with state provisions “that are more stringent than or are in conflict with” the federal standard. Proposed regulatory language is not offered in the NBPP. In general we support strong federal protections as a floor and would not oppose application of more stringent state regulation in the area of formulary exceptions.

However, we have concerns about applying state regulations that are merely “in conflict with” federal regulations, and urge HHS to clarify the intent of any proposed changes. HHS should also clarify that costs of non-formulary drugs would count toward annual patient cost limits, even if state regulations are applied to the exceptions process. Additionally, we believe costs incurred by patients who rely on off-formulary medications should be included in the patient’s annual maximum out of pocket amount, even when the drug is not obtained via the exemption process but the physician determines it is the most appropriate treatment. Further, contrary to the suggestion in the NBPP, we believe that federal oversight authorities should determine whether state regulation is adequate in this area, not the state.

We are disappointed that HHS has not taken the opportunity this year to propose additional measures still necessary to ensure that enrollees can access the drugs they need. Despite HHS’ cautionary language in regulations and guidance for 2016 (noted above), patients enrolled in QHPs frequently encounter barriers. These barriers include lack of formulary coverage for prescribed medications, high cost-sharing and burdensome utilization management requirements such as extensive prior authorization requirements and step therapy, along with midyear formulary changes. We are concerned that EHB regulations and the proposed section 1557 nondiscrimination regulations do not go far enough to stop these practices. We urge HHS to codify the relevant language included in the preambles to the 2016 NBPP and *Letter to Issuers* and take further steps for 2017.

Recommendation: Issuers should be required by regulation to cover all medications recommended by current clinical guidelines for a given medical condition.

³ “Pharmacy Cost Sharing Limits for Individual Exchange Benefit Plans: Actuarial Considerations,” Milliman, March 5, 2015.

Recommendation: Issuers should be barred by regulation from placing all or almost all drugs in a certain class on the highest cost tiers.

Recommendation: Issuers should be prohibited from requiring prior authorization for all or most drugs in a class or all drugs that treat a certain condition.

Recommendation: HHS should further clarify uses of step therapy that are clinically appropriate and do not unreasonably restrict access.

Recommendation: HHS should include in regulation a prohibition on removing drugs midyear from plan formularies.

Recommendation: HHS should require issuers to provide patients with sufficient information to determine or estimate their out-of-pocket costs, including actual charges for applicable coinsurance.

3) Continuity of Care

Continuity of care is critical for managing serious and chronic conditions. We support the proposal that if a patient is in active treatment and his/her provider is terminated from the network without cause, the patient can continue treatment with that provider for up to 90 days.

Recommendation: HHS should extend continuity of care protections to transition fills for patients switching to a new health plan and also require, not simply urge, that plans provide 30 day transition fills for off-formulary medicines or medicines subject to utilization management.

4) Payments Made to QHP Enrollees on Behalf of Third Parties

We support the ability of third-party entities, including federal and state government and Indian tribes, to contribute to patient premiums and cost-sharing. To have this ability increases access to health care for patients in need of services and treatments, including prescription medications, who would not otherwise be able to afford them. We appreciate HHS' efforts to clarify the programs that would meet the definition of state and government programs to be more inclusive and include subdivisions and local governments. We also support that third party payments can be made by these government's grantees or sub-grantees. Finally, we strongly support the inclusion of not-for-profit, charitable organizations as entities that would be allowed to make payments for patient premiums and cost-sharing,

Recommendation: HHS should broadly permit state and local governments, and their grantees and sub-grantees, along with not for profit third party entities, to make payments on behalf of QHP enrollees.

We look forward to the many previously announced improvements to the Marketplace in 2017 that were included in previous regulation, including the establishment of Pharmaceutical and Therapeutics Committees to ensure that plans meet patients' treatment needs and the ability to add newly approved Food and Drug Administration (FDA) medications in a timelier manner.

We expect that additional information regarding the 2017 plans will be included in the forthcoming draft 2017 *Letter to Issuers*.

Finally, any law or regulation is useless if it is not enforced. We are deeply concerned that HHS and state insurance authorities are not adequately reviewing plans for discriminatory plan design and not taking action against those plans that are engaging in these practices that harm patients, particularly those with serious or chronic conditions. We urge HHS and the Office for Civil Rights to properly enforce the law now in order to ensure beneficiary rights are protected.

Thank you very much.

Sincerely,

ADAP Advocacy Association
Adult Congenital Heart Association
Advocates for Responsible Care (ARxC)
ActionAIDS
AIDS Alabama
AIDS Alliance for Women, Infants,
Children, Youth & Families
The AIDS Institute
AIDS Resource Center Ohio
Alliance for the Adoption of Innovations in
Medicine (Aimed Alliance)
Alpha-1 Foundation
American Association on Health and
Disability
American Autoimmune Related Diseases
Association
American Behcet's Disease Association
Arthritis Foundation
Association of Maternal & Child Health
Programs
Autism Speaks
Bladder Cancer Advocacy Network
California Chronic Care Coalition
California Hepatitis C Task Force
Caregiver Action Network
Caring Ambassadors Program

Colon Cancer Alliance
Colorado Mental Wellness Network
Community Access National Network
(CANN)
COPD Foundation
D.C. Commission on Aging
Dab the AIDS Bear Project
Depression and Bipolar Support Alliance
Dystonia Medical Research Foundation
Easter Seals
Easter Seals Massachusetts
EPIC Long Island
Epilepsy Alliance of Utah
Epilepsy Association of Oklahoma
Epilepsy Foundation
Epilepsy Foundation Central & South Texas
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation Indiana
Epilepsy Foundation Louisiana
Epilepsy Foundation New England
Epilepsy Foundation North/Central Illinois,
Iowa, Nebraska
Epilepsy Foundation Northwest
Epilepsy Foundation Virginia
Epilepsy Foundation of Alabama
Epilepsy Foundation of Arizona

Epilepsy Foundation of Delaware
Epilepsy Foundation of East Tennessee
Epilepsy Foundation of Florida
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Greater Cincinnati
and Columbus
Epilepsy Foundation of Greater Los Angeles
Epilepsy Foundation of Hawaii
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Metropolitan New
York
Epilepsy Foundation of Michigan
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Missouri and
Kansas
Epilepsy Foundation of Nevada
Epilepsy Foundation of New Jersey
Epilepsy Foundation of North Carolina
Epilepsy Foundation of San Diego County
Epilepsy Foundation of Vermont
Epilepsy Foundation Texas
Epilepsy Foundation Western Ohio
Epilepsy Foundation of Western Wisconsin
Epilepsy-Pralid, Inc.
Federation of Families for Children's Mental
Health Colorado
Fight Colorectal Cancer
GBS|CIDP Foundation International
Global Colon Cancer Association
Global Healthy Living Foundation
Global Pneumonia Prevention Coalition
Hemophilia Federation of America
Hepatitis Foundation International
HIV Dental Alliance
HIV Medicine Association
Indiana Chapter of American Academy of
Pediatrics

International Foundation for Autoimmune
Arthritis
Kidney Cancer Association
Lakeshore Foundation
The Leukemia & Lymphoma Society
Lung Cancer Alliance
Lupus Foundation of America
Lupus Foundation of America, Indiana
Chapter
Lupus Foundation of America, Iowa Chapter
Lupus Foundation of Florida, Inc.
Lupus LA
Mental Health America
Nashville CARES
National Alliance of State & Territorial
AIDS Directors
National Alliance on Mental Illness
National Alliance on Mental Illness
Alabama
National Alopecia Areata Foundation
National Asian Pacific American Families
Against Substance Abuse
National Association of Hepatitis Task
Forces
National Association of Hispanic Nurses
National Association of Nutrition and Aging
Services Programs (NANASP)
National Fibromyalgia & Chronic Pain
Association
National Hemophilia Foundation
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
(NORD)
National Patient Advocate Foundation
National Psoriasis Foundation
National Viral Hepatitis Roundtable

Noah's Hope
Project Inform
Project SAFE
Pulmonary Hypertension Association
RAIN Oklahoma
RetireSafe
Rocky Mountain Bleeding Disorders
Association
Rush To Live Organization
Scleroderma Foundation
SisterLove

Southern AIDS Coalition
Sturge-Weber Foundation
The Marfan Foundation
The Veterans Health Council of Vietnam
Veterans of America
U.S. Hereditary Angioedema Association
Vasculitis Foundation
Virginia Hemophilia Foundation
Whitman-Walker Health
Wyoming Epilepsy Association