October 6, 2016

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

Re: Comments on *HHS Notice of Benefit and Payment Parameters for 2018* Proposed Rule, CMS-9934-P

Dear Madame Secretary:

We, the 153 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 2018* (NBPP) (81 FR 61455, Sep. 6, 2016).

Our comments reflect the experiences beneficiaries we represent have encountered while shopping for and utilizing the Qualified Health Plans (QHPs) over the past three years. They focus on 1) Standardized Options approach for 2018; 2) revisions to the Risk Adjustment Program methodology; and 3) enhancing the Affordable Care Act's (ACA) important patient protections. We appreciate your consideration of our insights and concerns as we all work to improve the patient experience and health outcomes under the ACA, particularly for those with serious and chronic health conditions.

1) Standardized Options Approach for 2018

We are pleased that the Department of Health and Human Services (HHS) intends to extend the Standardized Options (Simple Choice plans) into 2018. Although we have yet to see how Simple Choice plans will work in practice, we believe that consumers will benefit from being able to more easily compare plans across issuers and having the protection of some added limits on cost-sharing, particularly for prescription medications. However, we do have concerns with some of the changes proposed and believe additional patient protections are necessary.

First, we believe issuers should be *required* to offer the standardized options so that all Marketplace beneficiaries can access these plan designs. The Simple Choice plans are designed to provide transparency with additional limits on cost-sharing that can both enhance access and

protect beneficiaries from medical bills they cannot afford. Therefore, **we recommend HHS require insurers to offer Simple Choice plans in 2018.**

As you recognize, some states have implemented successful standardized plans and other provisions to limit patient cost-sharing. **We support the proposed additional standardized options that allow issuers to offer Simple Choice plans while complying with state cost-sharing laws.** We believe that many of these state laws provide important patient protections, and by allowing these additional options, such laws would not interfere with issuers' ability to offer them.

Second, while we are pleased to see HHS' proposal to continue reasonable co-pays rather than co-insurance for most Simple Choices plans and tiers, **we reiterate our concern with the use of high co-insurance for all drugs on the "Specialty Drug" tier and in most bronze plan tiers**. The use of coinsurance amounts to a total lack of transparency. As beneficiaries cannot access drug price information prior to choosing a plan to calculate the dollar amount they will have to pay, such cost-sharing designs significantly disadvantage individuals who rely on prescription drugs to manage their chronic conditions during the plan selection process and can be characterized as discriminatory.

Co-insurance often results in high beneficiary costs that place medications out of reach for most patients and reduces medication adherence. Frequently, issuers place a high number of drugs to treat an individual health condition on the specialty tier.[1] This can result in discriminatory plan design. These plans that use adverse tiering are disproportionately forcing beneficiary cost sharing on prescription drug benefits and discourage beneficiaries with chronic conditions from enrolling. This is in violation of the strong non-discrimination provisions included in the ACA. Some issuers have successfully designed plans that limit patient cost-sharing to reasonable and affordable co-pays, and we encourage HHS to use the Simple Choice plans to lead issuers in this direction. Therefore, **we strongly oppose the use of co-insurance for the "Specialty Drug" tier across all metal levels and in all tiers (except for generics) in the Bronze plans.**

Third, we are pleased that most of the Simple Choice plans for 2017 exempt patient cost-sharing for prescription drugs from the deductible and suggest that be continued and expanded to bronze plans for 2018. **We strongly believe that prescription medications should not be subject to a plan's deductible at any metal level and especially for plans with very high deductibles near or even equal to the maximum allowable out-of-pocket limit**. Thus, we are disappointed that HHS is proposing to continue subjecting the cost-sharing for all medications except generics to the deductible in the Bronze Simple Choice plans. If medications are included in the Simple Choice bronze plan's $6,650 deductible, beneficiaries with limited income and resources will encounter cost barriers to accessing necessary medications. We are likewise concerned that HHS is proposing to remove the deductible exemption for specialty tier drugs at the Silver and 73 percent cost-sharing reduction (CSR) plans. Although the proposed addition of separate drug

[1] For example, Avalere Health's analysis of 2016 silver QHPs showed that 50 percent placed single-source multiple sclerosis drugs and 44 percent placed cystic fibrosis drugs on the specialty tier. Furthermore, the percentage of QHPs using greater than 40% co-insurance for all covered single-source antidepressants, atypicals and bipolar drugs increased in 2016. *PlanScape Review of Patient Access to Medicines in Exchange Plans*, Avalere Health, April 2016

deductibles at these levels provides some protection, it may actually increase patient cost-sharing. Furthermore, while we strongly support not applying the deductible at all to any tiers of drug coverage under the 87 percent CSR, 94 percent CSR, and Gold plans, we are concerned that listing a separate $0 Rx deductible for these plans adds confusion for beneficiaries.

Studies demonstrate that issuers would not have to raise premiums unreasonably in order to exempt drug and other basic benefits from the deductible. A recent study by Families USA and Milliman found that the Simple Choice Silver QHPs in 2017 would have premiums comparable to current Silver QHPs and concluded that the Simple Choice plans could improve access by exempting basic health care services like medications from the deductible without driving up premiums.[2] Therefore, **we urge HHS to simply exempt all covered medications at all tier levels from the plan's deductible so that beneficiaries will understand they have first-dollar coverage**. Alternatively, we recommend that the separate drug deductible design proposed for the Silver and Gold plans be applied to the Bronze plans, as Bronze plan enrollees would greatly benefit from a lower Rx deductible.

2) Risk Adjustment

We commend you for proposing to update the HHS-Operated Risk Adjustment Model. **We strongly support HHS' proposal to add prescription drug data to the risk adjustment methodology beginning with the 2018 benefit year.** Despite the ACA's promise to end discrimination based on pre-existing conditions, many health insurance plans currently engage in practices, such as those mentioned above, that enable them to avoid patients with serious and chronic conditions. We agree that an effective risk adjustment program can help stabilize premiums. In addition, we believe that compensating issuers through mechanisms like risk adjusters for their enrollees who need and use higher-cost prescriptions will encourage issuers to take responsibility for caring for these patients, remove incentives for avoiding the sickest patients, and reduce discriminatory practices that prevent vulnerable populations from accessing care and treatment.

We agree that drug utilization data can be useful to impute missing diagnoses, indicate the severity of an individual's condition, and provide more timely and accessible information than medical claims. The classes of drugs HHS is proposing to include are well-suited for indicating severity of an enrollee's condition as well as, for most of the classes, imputing diagnoses. However, **we recommend that HHS add more drug classes to the risk adjustment model.** Many chronic and serious conditions are treated with prescription medications, and we believe that the risk adjustment model must take all of these into consideration in order to fairly compensate issuers for providing comprehensive and affordable coverage to beneficiaries regardless of their health status.

We also believe that some of the concerns HHS and stakeholders have raised are minimal and should not deter HHS from incorporating as many drug classes as possible. In particular, we believe the concern of providers over-prescribing to game the system is not an issue. As HHS

[2] "Federal Standardized Health Insurance Plans Could Improve Access without Raising Premiums," Families USA & Milliman, May 2016, *available at* https://shar.es/1xGOGL.

recognizes, choosing classes where treatment guidelines are well-established is one way to minimize any such risk. Furthermore, there is no direct relationship between the compensation a provider receives from an issuer and the cost of the medication. Therefore, we believe providers would have virtually no incentive to contribute to the issuer's risk adjustment score by overprescribing.

3) Enhancing the ACA's Important Patient Protections

We are disappointed that HHS has not taken the opportunity this year to propose additional regulations to strengthen the ACA's patient protections to ensure that beneficiaries can access the care and treatment they need. Despite HHS' cautionary language in regulations and guidance for 2016 and 2017, as well as the final 1557 nondiscrimination regulations, QHP beneficiaries continue to encounter barriers. These barriers include lack of formulary coverage for prescribed medications and adverse tiering; formularies not following widely accepted treatment guidelines; high cost-sharing and burdensome utilization management requirements such as extensive and/or unwarranted prior authorization and step therapy requirements; midyear formulary changes and requiring beneficiaries to switch medications for non-medical reasons; and having narrow provider networks that fail to include sufficient specialists to treat certain conditions.

We are concerned that current regulations and enforcement do not go far enough to stop these practices, and **strongly urge HHS to take further steps by codifying examples of discriminatory benefit design and strengthening enforcement during QHP review, building on Pharmacy & Therapeutics Committee requirements, and improving QHP transparency through tools such as HealthCare.gov's prescription drug lookup**.

a. Nondiscrimination

We believe more standards and parameters for benefit and plan design should be detailed in the final rule so that all QHPs are affirmatively prohibited from employing discriminatory practices with respect to any condition, not just those that are caught as outliers. Specifying what constitutes discriminatory design will also provide clarity to state and federal regulators now and in the future as they review and certify QHPs.

Recommendation: In the final 2018 NBPP rule, HHS should codify what constitutes discriminatory benefit design through the following provisions:

- Require issuers to cover all medications recommended by current clinical guidelines for a given medical condition.
- Prohibit issuers from excluding coverage of combination or extended release products that are customarily prescribed and/or recommended in treatment guidelines.
- Prohibit issuers from placing all or almost all drugs in a certain class on the highest cost tiers.
- Prohibit issuers from requiring prior authorization for all or most drugs in a class, or all drugs that treat a certain condition.

- Require that any use of step therapy or quantity limits be based on clinical protocol and not unreasonably restrict access.
- Prohibit issuers from removing drugs midyear from plan formularies.
- Require issuers to provide patients with sufficient information to estimate their out-of-pocket costs, including dollar amounts for applicable co-insurance.

In order to enforce the existing nondiscrimination rules and our above proposed additions, **we encourage HHS to develop more plan review tools to ensure that issuers proposing QHPs with discriminatory benefit designs are identified and required to bring their QHPs into compliance with the law and regulations *before* selling them on the Marketplaces**. We also request that HHS pay particular attention to plans' compliance with nondiscrimination, cost-sharing and access, transparency, and Pharmacy & Therapeutics Committee requirements when undertaking compliance reviews. Along these lines, we support the proposal in the NBPP to specify HHS' authority to impose authorized remedies where an issuer is non-responsive or uncooperative with compliance reviews.

b. Pharmacy & Therapeutics Committees

Beginning with the 2017 plan year, HHS is requiring QHPs to use Pharmacy & Therapeutics Committees (P&T Committees). We believe this is a critical step forward in ensuring QHPs use thorough and transparent processes and provide more comprehensive drug coverage. While the current rules regarding P&T Committee are a good foundation, **we encourage HHS to strengthen these requirements and remind QHPs of their obligations in the 2018 NBPP and *Letter to Issuers***.

Recommendation: HHS should issue further regulation and guidance on the operation of P&T Committees including:

- establishing a mandatory time frame to review newly approved medications;
- requiring the use of advisory committees or expert panels so that specialists with relevant expertise are consulted;
- requiring that meeting time and place, meeting minutes, written documentation of decisions along with data and materials considered in reaching those decisions, and results of the annual formulary review be available and easily accessible to the public; and
- creating a process for beneficiaries and patient advocates to provide input.

c. Prescription Drug Lookup Tool

Finally, we are thankful that HHS implemented the HealthCare.gov prescription drug lookup tool for 2016. While it is helpful to consumers to be able to filter their QHP options by those that cover their drug, we believe that the tool itself should provide more information about the coverage, including tiering, cost-sharing, and any utilization management restrictions. Therefore, we **urge HHS to improve the tool and require issuers to submit the necessary information in machine-readable format to allow beneficiaries to determine the tiering, cost-sharing (in a dollar amount), and utilization management restrictions for a given drug.**

We are looking forward to the many previously announced improvements to the Marketplaces in 2017 that were included in previous regulation, particularly enforcement of the final 1557 nondiscrimination regulations, addition of Simple Choice plans, and implementation of P&T Committees. We expect that additional information regarding the 2018 plans will be included in the forthcoming *Letter to Issuers.*

Thank you very much for your consideration of our comments. Should you have any questions, please contact: Carl Schmid, Deputy Executive Director, The AIDS Institute, cschmid@theaidsinstitute.org; Beatriz Duque Long, Senior Director, Government Relations, Epilepsy Foundation, bduquelong@efa.org; or Andrew Sperling, Director of Federal Legislative Advocacy, National Alliance on Mental Illness, asperling@nami.org.

Sincerely,

Action Wellness
ADAP Advocacy Association
ADAP Educational Initiative
Adult Congenital Heart Association
AIDS Action Baltimore, Inc.
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
The AIDS Institute
AIDS Resource Center of Wisconsin
AIDS United
Alliance for Prostate Cancer Prevention
Alpha-1 Foundation
Alzheimer's & Dementia Resource Center
American Association on Health and Disability
American Autoimmune Related Diseases Association
American Behcet's Disease Association
American Lung Association
Arthritis Foundation
Asian & Pacific Islander American Health Forum
Asian Pacific Health Foundation
Association of Asian Pacific Community Health Organizations
Association of Black Cardiologists
Asthma & Allergy Foundation of America, New England Chapter
Autism Family Services of New Jersey
Big Bend Cares of Florida
California Chronic Care Coalition
California Hepatitis C Task Force
Caregiver Action Network
Center for Independence of the Disabled of New York
Central Florida Behavioral Health Network
Choices: Memphis Center for Reproductive Health
Cholangiocarcinoma Foundation
Chronic Disease Coalition
Community Access National Network
COPD Foundation
COPE: Coalition on Positive Health Empowerment
Debbie's Dream Foundation: Curing Stomach Cancer
Depression and Bipolar Support Alliance
Dysautonomia International
Dystonia Medical Research Foundation
Easter Seals Massachusetts
Easterseals
Epilepsy Association of the Big Bend
Epilepsy Foundation
Epilepsy Foundation Central & South Texas
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation New England
Epilepsy Foundation Northwest
Epilepsy Foundation of Alabama

Epilepsy Foundation of Arizona
Epilepsy Foundation of Connecticut
Epilepsy Foundation of East Tennessee
Epilepsy Foundation of Florida
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Greater Cincinnati and Columbus
Epilepsy Foundation of Hawaii
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Long Island
Epilepsy Foundation of Louisiana
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/Central Illinois, Iowa, Nebraska
Epilepsy Foundation of Northeastern New York
Epilepsy Foundation of Oklahoma
Epilepsy Foundation of Southeast Tennessee
Epilepsy Foundation of Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation of Virginia
Epilepsy Foundation of Western Ohio
Epilepsy Foundation of Western Wisconsin
Epilepsy Foundation Western/Central Pennsylvania
Epilepsy Pralid Inc.
Fight Colorectal Cancer
Florida CHAIN (Community Health Action & Information Network)
Florida State Hispanic Chamber of Commerce
Friends-Together, Inc.
GBS|CIDP Foundation International
Genetic Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
H.E.A.L.S. of the South
HealthHIV
Hemophilia Federation of America
Hep C Alliance
Hep C Allies of Philadelphia
Hepatitis Foundation International
HIV Medicine Association
Hope for a Brighter Day Inc.
IFAA (International Foundation for Autoimmune Arthritis)
Intercultural Cancer Council
Lakeshore Foundation
Let's Talk About Change
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Lupus Foundation of Florida
Lupus Foundation of Southern California
The Marfan Foundation
Men's Health Network
Mental Health America LA
Metachromatic Leukodystrophy Foundation
NAMI Alabama
NAMI New Mexico
Nashville CARES
National Alliance of State & Territorial AIDS Directors
National Alliance on Mental Illness
National Alliance on Mental Illness North Carolina
National Alopecia Areata Foundation
National Association of Hepatitis Task Forces
National Association of Hispanic Nurses
National Association of Nutrition and Aging Services Programs (NANASP)
National Eczema Association
National Hemophilia Foundation
National Hispanic Medical Association
National Kidney Foundation
National Medical Association
National Minority Quality Forum
National MS Society
National Organization for Rare Disorders
National Stroke Association
National Viral Hepatitis Roundtable
NephCure Kidney International
Neurofibromatosis Tumor Foundation
New Jersey Association of Mental Health and Addiction Agencies, Inc.

New Orleans Council on Aging
New Yorkers for Accessible Health Coverage
One in Four Chronic Health
Pennsylvania Prostate Cancer Coalition (PPCC)
Platelet Disorder Support Association
Prevent Cancer Foundation
Pulmonary Hypertension Association
PXE International
Relapsing Polychondritis Awareness and Support Foundation, Inc
RetireSafe
Rush To Live
Scleroderma Foundation
Sickle Cell Disease Association of Florida
Society for Women's Health Research
Susan G. Komen
Tourette Association of America
U.S. Hereditary Angioedema Association
U.S. Pain Foundation
United Cerebral Palsy
Usher 1F Collaborative
The Veterans Health Council of VVA
Vietnam Veterans of America
Virginia Hemophilia Foundation
Wellness and Education Community Action Health Network (WECAHN)
WomenHeart: The National Coalition for Women with Heart Disease