



March 2, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Comments on *HHS Notice of Benefit and Payment Parameters for 2021* Proposed Rule,  
CMS-2020-0009-0002

Dear Administrator Verma:

On behalf of the undersigned organizations representing millions of patients and their families, I Am Essential appreciates the opportunity to submit comments on the proposed rule, *Notice of Benefit and Payment Parameters for 2021*.

**I Am Essential** is a broad coalition of patient and community organizations, that support access to quality and affordable health care, embedded with strong patient protections. The comments primarily focus on the needs of patients living with serious and chronic conditions with a focus on continuity of care and access to prescription medications, which are *truly essential* for patients' well-being.

**Section 156.130(h): Direct Support Offered by Drug Manufacturers**

CMS' decision to reverse the 2020 NBPP provision requiring issuers to count drug copayment assistance towards the annual limitation on cost sharing in the absence of a generic equivalent directly conflicts with the Affordable Care Act's (ACA) statutory intent to protect patients and promote affordable care.

**Copay Assistance Provides a Lifeline for Patients**

As a result of rising healthcare costs, copay assistance has become a necessity for many patients to afford their medications. In 2020, a plan with a deductible of at least \$1,400 is considered to be a high deductible health plan (HDHP); however, the average deductible for a silver-level qualified health plan this year is \$4,600. When such high deductibles are coupled

with coinsurance of 30-50 percent for a specialty drug placed on the highest formulary tiers, patients with chronic health care conditions who rely on specialty drugs are faced with the prospect of paying thousands of dollars at the outset of the plan year in order to fill their monthly prescriptions.<sup>1</sup> As proposed, this provision will unfairly burden the most vulnerable patients who have no option to select a lower cost drug, and who are already facing high out-of-pocket costs in their health care plan.

The administration made a commitment in 2018 to put “American patients first,” by reducing patient out-of-pocket costs.<sup>2</sup> As a result of rising costs, many patients cannot afford their medications and are forced to choose between adhering to their doctors’ treatment recommendations and other basic necessities. A Kaiser Family Foundation survey found that 20 percent of the patients who cited cost as a barrier to medication didn’t fill a prescription, while another 12 percent skipped doses or rationed pills.<sup>3</sup> There is a direct correlation between out-of-pocket costs and treatment adherence; when patient costs hit the \$250 mark, over 70 percent of new patients walk away from the pharmacy empty handed.<sup>4</sup> Delaying, rationing, or forgoing treatment for patients represented by IAE is likely to result in severe deterioration of their condition or even death. Copay assistance is a lifeline for patients who otherwise would not be able to afford their drugs because of the high out-of-pocket costs.

Moreover, the issuer’s decision not to count copay amounts paid via manufacturer copay assistance towards the deductible raises questions about whether issuers are collecting payments twice, effectively surpassing the maximum out-of-pocket threshold, and double-charging for the same copayments. Issuer’s copay accumulator adjustment programs accept manufacturer cost-sharing assistance in payment for prescription drugs. When they do not count that assistance towards the patients’ deductible and out-of-pocket limit, issuers are able to generate additional income for the same services, and beneficiaries lose the ACA’s cost-sharing limit protections.

Issuers that opt not to count a patient’s manufacturer copay assistance towards the deductible should be required to report this income in the same manner as other payments. As CMS has proposed to make changes to reporting requirements of pharmaceutical rebates as a deduction from the medical loss ratio, so too should manufacturer assistance be reported.

#### Copay Assistance Does Not Cause Market Distortion

In the proposed rule, HHS reiterates a concern that consumers who select a higher-cost brand name drug over an equally effective, generic drug cause market distortion. Such a concern is, by definition, an impossibility when no generic equivalent is available. In fact, in the 2020 NBPP, CMS agreed that manufacturer copay assistance used for a brand name drug without a generic

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<sup>1</sup> Robert Wood Johnson Foundation. March 2019. [Cost Sharing for Drugs Rises Sharply at Higher Tiers.](#)

<sup>2</sup> US Department of Health & Human Services. May 2018. [American Patients First: The Trump Administration blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.](#)

<sup>3</sup> Kaiser Family Foundation. February 2019. [Health Tracking Poll, Prescription Drugs.](#)

<sup>4</sup> IQVIA. May 2019. [Medicine Use and Spending in the US; A Review of 2018 outlook to 2023.](#)

equivalent would not distort the market, because there is no lower-cost option from which to steer patients. When that same rule was finalized HHS noted, “Where there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market.”<sup>5</sup>

Moreover, several analyses present evidence that the revision to this rule may be a disproportionate reaction to a perceived problem. When a lower-cost drug is available, providers and patients generally select that option, as evidenced by data showing that prescription purchases using copay assistance programs for drugs with generic equivalents represent less than half of 1 percent of the market.<sup>6</sup> Prescription payment claims analyzed by IQVIA from 2013 to 2017 revealed that of the total commercial market, copay cards for products that had lost exclusivity (meaning a generic equivalent exists) made up only 0.4 percent of the volume of claims. In two different analyses of copay assistance programs, by USC Schaeffer and IMS Institute for Healthcare Informatics respectively, both showed that the overwhelming majority (87 percent) of copay assistance programs are for drugs that have no generic equivalent.<sup>7,8</sup> The 67 drugs for which generic equivalent products were available, out of the 526 branded drugs IMS included in their review, accounted for only 0.05 percent of all prescriptions filled during the 12 month period of analysis. ***We strongly urge HHS to withdraw this proposal and leave in place the provision established in the 2020 NBPP*** which more accurately reflects the reality of the health care landscape for patients with serious and chronic conditions.

#### Revising the Definition of Cost Sharing Does Not Reduce Health Care Costs

At section 1302(c)(3)(A), CMS suggests that amounts paid via manufacturer copay assistance should be excluded from the definition of cost-sharing because the existence of manufacturer copay assistance reduces the patients’ cost-sharing obligation. We disagree with the reasoning HHS offers in this section; the existence of financial assistance does not change the patients’ cost-sharing obligation. Rather, it merely helps the patient meet that obligation, similar to a gift from a family member, income from a job, lottery winnings, or a tax refund. Given the exorbitant and increasing costs that patients with severe, chronic illnesses must pay for their health care, we urge CMS to focus its efforts – in furtherance with this administration’s stated goal – on reducing out-of-pocket costs for patients rather than limiting where patients are able to find the resources to pay for their care. *IAE urges CMS to reconsider revising §156.130(h) as proposed and uphold the patient protections intended by the law to ensure patients can afford their prescription medications without undue financial burden.*

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<sup>5</sup> Health & Human Services. April 2019. [Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2020.](#)

<sup>6</sup> IQVIA. Fact Sheet. [An Evaluation of Copay Card Utilization in Brands After Generic Competitor Launch](#)

<sup>7</sup> Van Nuys, K., Joyce, G., Ribero, R., Goldman, D.P. February 2018. [A Perspective on Prescription Drug Copayment Coupons. Leonard D Schaeffer Center for Health Policy & Economics.](#)

<sup>8</sup> IMS Institute for Healthcare Informatics. February 2014. [Patient Savings Program Use Analysis](#)

## Auto Reenrollment

I Am Essential strongly supports maintaining a consumer-friendly auto re-enrollment process for those who do not take action to select a new plan. Individuals who purchase their health insurance through the ACA have become accustomed to this practice which ensures continuous healthcare coverage, streamlines the health insurer process, and has also helped maintain a robust risk pool enrolled in the marketplace. In 2019, 3.4 million people were auto enrolled in coverage, representing 30 percent of all plan selection methods.<sup>9</sup>

## Undue Burden on Low-Income Patients

The proposed changes to the auto reenrollment process in the 2021 NBPP stands to harm thousands, if not millions, of patients who receive advance payments of the premium tax credit (APTC) amounting to a \$0 premium, and rely on auto reenrollment to maintain their health coverage. The main factor in the calculation of APTC is the enrollee's income; therefore, to qualify for enough APTC to cover the cost of a monthly premium payment would indicate an income lower on the federal poverty scale. Proposing to strip APTC from an enrollee who is eligible for a \$0 premium plan, requiring them to return to the exchange to select a plan places an undue burden on them relative to enrollees with somewhat higher income who qualify for less financial assistance. Furthermore, applying different rules to individuals who have lower incomes than for individuals with relatively higher incomes for the same process could be viewed as discriminatory.

If enrolled unsuspectingly in a plan for the full cost of the premium, or any amount more than \$0, the bill will undoubtedly come as a surprise to the patient, and is likely to result in them discontinuing coverage. To better utilize the outreach and education resources currently slated to alert patients to this new process, we recommend applying that assistance to encourage patients to return to the exchange to shop for new plans that best fit their needs.

## Proposed Changes Not Based on Eligibility

This proposal is also not based on information that large numbers of enrollees who qualify for the highest levels of APTC have experienced income changes that would reduce the amount of APTC for which they qualify. The statutory intent described in section 1104 of the ACA was to create an eligibility determination process that posed minimal burden on applicants and enrollees. The auto-renewal system currently in place was designed to avoid documented problems in other means-tested programs that cause people to lose coverage even when they have not experienced any life changes that make them ineligible for assistance. It relies on an intricate process of multiple data matching agreements and incorporates an income verification step, meaning that the enrollee's income level has been verified by the system for the future plan year. If they have been determined eligible for APTC, qualifying them for a \$0 premium, they should not be required to personally reverify and redetermine their eligibility.

***IAE strongly discourages finalizing this proposed change to the auto reenrollment process*** that will confuse consumers, increase coverage losses, and risk interrupting care for low-income patients for whom access to healthcare is essential.

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<sup>9</sup> CMS. March 2019. [Health Insurance Exchanges 2019 Open Enrollment Report](#)

## **Other Proposals in the 2021 NBPP**

### **Section 153.720(g)(2) and (3) Prescription Drug Rebates under MLR**

*IAE supports the proposal to require insurers to count the amount of money they receive in prescription drug rebates and price concessions in the medical loss ratio (MLR) calculation.*

Requiring insurers to report and deduct prescription drug rebates and price concessions from incurred claims under the MLR is appropriate, as these amounts that are received by the insurer and pharmacy benefit managers (PBMs) may artificially inflate what the issuer reports to be spending on health care claims. The MLR requirement is designed to ensure that insurers are accountable to enrollees by spending 80 or 85 percent (depending on whether the plan covers individuals and small business or large groups) of premiums on the delivery of health care, rather than administration, marketing, or profit. Requiring insurers to count the value of rebates and negotiated discounts for prescription drugs, which amount to billions of dollars annually, is in line with the purpose of the ACA's MLR provision to ensure that insurance companies spend the bulk of the income they gain from or on behalf of enrollees on care instead of profits.

Like proposals that promote passing through the savings of rebates to patients, this requirement has the potential to directly benefit patients.

### **Premium Adjustment Percentage**

*IAE opposes the proposed changes to the premium adjustment calculation, and urges CMS to withdraw this proposal.*

Reiterating our concerns raised in response to the 2020 NBPP, IAE believes that the changes to the premium adjustment percentage calculation will raise costs for millions of consumers, including the annual out-of-pocket limit. As previously stated, patients are being continuously burdened by increasing costs through no fault of their own, making it harder to afford their healthcare and gain access to lifesaving medicines. Such changes run contrary to the purpose of the Affordable Care Act and the administration's patient-focused efforts, and should not be finalized.

### **Section 155.420 Special Enrollment Period for those Newly Ineligible for CSRs**

*IAE supports the proposed new special enrollment period for people who lose eligibility for cost-sharing reduction payments in the middle of a plan year.*

People with incomes low enough to qualify for cost-sharing reduction payments (CSR) at the time of their application for premium tax credits likely make decisions about which plan to purchase based on their qualification for CSRs. Even if they experience an increase in income during the year that disqualifies them for CSRs, they may not be able to afford the monthly premium for a silver-level plan. We appreciate CMS' recognition of this hardship in its proposal to allow a special enrollment period (SEP) for such individuals along with the option to change plans to a metal-level above or below their existing plan. This will ensure that enrollees are able to find a plan that best fits their health and financial needs. We support this proposal, and urge CMS to finalize it as written.

**I Am Essential** is committed to working with CMS, bringing the voice of those who rely on Healthcare.gov and their state-based exchanges to the table and to provide insight on how the implementation of these policies will impact their ability to access healthcare and live healthy lives. Thank you very much for your consideration of our comments. Should you have any questions, please contact: Rachel Klein, Deputy Executive Director, The AIDS Institute, [rklein@taimail.org](mailto:rklein@taimail.org); Laura Weidner, Vice President, Government Relations and Advocacy, Epilepsy Foundation, [lweidner@efa.org](mailto:lweidner@efa.org); or Andrew Sperling, Director of Federal Legislative Advocacy, National Alliance on Mental Illness, [asperling@nami.org](mailto:asperling@nami.org).

Sincerely,

ADAP Advocacy Association  
AIDS Alliance for Women, Infants, Children, Youth & Families  
Allergy & Asthma Network  
ALPHA-1 FOUNDATION  
American Association on Health & Disability  
Arthritis Foundation  
American Autoimmune Related Diseases Association (AARDA)  
California Chronic Care Coalition  
Caregiver Action Network  
Center for Independence of the Disabled, NY  
Community Access National Network  
Epilepsy Foundation  
Epilepsy Foundation of Colorado  
Epilepsy Foundation of Vermont  
Global Healthy Living Foundation  
Global Justice Institute, Metropolitan Community Churches  
Hemophilia Association of the Capital Area  
International Foundation for Autoimmune & Autoinflammatory Arthritis (headquartered in St. Louis)  
Lakeshore Foundation  
Lupus and Allied Diseases Association, Inc.  
Men's Health Network  
Mental Health America  
National Alliance on Mental Illness  
National Association of Nutrition and Aging Services Programs (NANASP)  
National Hemophilia Foundation  
National Multiple Sclerosis Society  
Prevent Blindness  
Susan G. Komen  
The AIDS Institute  
Virginia Hemophilia Foundation

cc: Randy Pate/CCIIO