



July 16, 2018

The Honorable Alex Azar
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

I Am Essential commends the Administration's commitment to lowering prescription drug and out-of-pocket costs for patients in the United States. As a broad coalition of diverse patient and community organizations, representing millions of patients and their families, focused on ensuring access to quality and affordable health care through qualified health plans (QHPs) the cost of medications is of utmost importance. Access to drugs for patients with complex health needs such as mental health, epilepsy, HIV, cancer, arthritis, lupus, MS, hepatitis, and so many other conditions is critical. Medications allow individuals to maintain healthy and full lives, prevent and cure diseases, and keep patients alive.

We are pleased that the blueprint HHS has released, "**American Patients First**", not only focuses on ways in which prescription drugs prices can be lowered **but also addresses proposals to reduce patient out-of-pocket costs**. If patient cost-sharing is too high, patients will not be able to access their medications. Therefore, our comments focus on proposals contained in the [Request for Information](#) (RFI) that address efforts to reduce patient cost-sharing. For patients with serious and chronic health conditions, they often shoulder the heaviest cost burden and are looking forward to implementation of policies and proposals that could reduce their costs.

Importance of Coverage and Benefits

Before we focus on the importance of affordable patient cost-sharing, we must first stress the importance of insurance coverage and benefits. In order for patients to access their medications, they must have quality insurance coverage with comprehensive health benefits, including prescription medications. The Affordable Care Act (ACA) has sought to ensure just that; people have been able to purchase health insurance that include access to a broad array of health benefits and services as part of the essential health benefits (EHBs). Plans must offer meaningful and broad prescription formularies that do not discriminate against people with serious or chronic conditions and include new and innovative medications.

I Am Essential has expressed concerns about recent efforts taken by the Administration that weaken access to quality health insurance, including measures related to association and short-term health plans (See [association](#) and [short-term](#) comments). Neither of these insurance plan options include

patient protections that limit patient costs nor comply with the EHB requirements, meaning individuals may pay for health insurance without the guarantee of prescription drug coverage.

Health status is dynamic, and individuals cannot predict what prescriptions or services they might need in the future. If an individual were to become ill, and on one of these substandard plans, and the prescriptions they need are not covered, they would be forced to pay the full cost of the drug. This most likely will force the patient to forfeit care due to the unaffordable cost of the uncovered medication. Furthermore, even if a plan indicates it covers prescription drugs, the breadth of that benefit can fall short of what patients' need as they can place artificially low limits on the prescription medications covered and do not have to consider newly approved medications.

Patients will not be able to access their prescription drugs if they do not have quality health coverage and health plans that include comprehensive prescription benefits.

Shifting Cost-Sharing Responsibilities Increase Burden on Patients

In addition to increased premiums, patients, particularly those with serious and chronic conditions, are bearing a greater share of healthcare costs at the pharmacy. This is due to changes in plan benefit design by insurance companies that include high deductibles and high out-of-pocket maximums, along with rising copays and co-insurance.

Trends have shown a steady increase in plan deductibles overall and more high-deductible plans in the market. Today, 80 percent of the market is dominated by high deductible plans, and the average deductible for a silver-level QHP is \$4,000, up from \$2,600 in 2015.^{1,2} A report released by Families USA and Milliman Consulting firm indicates that beneficiaries with high deductibles are less likely to utilize healthcare, including medication and services to manage chronic conditions.³ Healthcare spending and service utilization data from a study by the National Bureau of Economic Research study revealed that when a large employer switched from offering completely free health coverage to a high deductible plan, overall healthcare spending was reduced, not as a result of selecting lower-cost alternatives, but directly connected to the reduction in beneficiaries' demand for services, even valuable preventive services that could help avoid high costs in the future.⁴

Even when patients have met their deductible, they are still responsible for a significant share of the cost of their prescriptions due to plans' greater use of co-insurance over a fixed-dollar copay. In 2016, 74 percent of silver plans had a co-insurance associated with specialty drugs and in 2017 that amount increased to 84 percent.⁵ Co-insurance can range upwards of 30 percent, and for the highest tiers it is not uncommon for plans to apply a 50 percent co-insurance. Gone are the days of three tier prescription formularies; according to the Kaiser Family Foundation 2017 Employee Health Benefit Survey, 49 percent of covered workers are enrolled in a plan that include four or more prescription tiers.⁶

Many of the prescriptions our patients rely on are specialty drugs often placed on the highest tier, and for which there are no generic alternatives. Adding insult to injury, the patient's portion of the co-

¹ <http://healthpolicy.usc.edu/improve-performance-health-care-markets.aspx>

² <http://avalere.com/expertise/managed-care/insights/plans-with-more-restrictive-networks-comprise-73-of-exchange-market>

³ https://familiesusa.org/sites/default/files/product_documents/ACA_Milliman%20Report_online.pdf

⁴ <http://www.nber.org/digest/dec15/w21632.html>

⁵ <http://avalere.com/expertise/life-sciences/insights/consumer-costs-continue-to-increase-in-2017-exchanges>

⁶ <https://www.kff.org/report-section/ehbs-2017-section-9-prescription-drug-benefits/>

insurance is based on the list price of the drug, whereas the plan and pharmacy benefit manager (PBM) have acquired the drug at a lower, negotiated price. These practices place an undue cost burden on patients.

High out-of-pocket costs have a detrimental impact on patient adherence, increasing medication abandonment which is harmful to patients' wellbeing and the overall healthcare system. Results from a 2017 survey by Consumer Reports Best Buy Drugs revealed that 14 percent of patients stated that an increase in out-of-pocket costs was the cause for not filling a prescription; 47 percent were deterred by as little as a \$20 increase.⁷

Proposals to Lower Out-of-Pocket Costs for Patients

In order to reduce the financial burden on patients as they access prescription medications we recommend the following policies that HHS should pursue:

- 1) **Encourage Plans to Keep Prescription Drugs Outside the Deductible:** People with serious and chronic conditions frequently rely on daily and consistent use of their medications and cannot afford to miss a dose. High deductibles act as a barrier to patients in accessing their medications, particularly at the beginning of each plan year. Removing this barrier would serve as an investment in both the individual's health and the healthcare system; patients who remain adherent and healthy are less likely to utilize emergency or high-cost services that will reduce healthcare costs in the future.

Applying first-dollar coverage for prescriptions will ensure patients have consistent access to the treatment they need to manage serious and chronic conditions and stay healthy, without raising premiums. Actuaries from Milliman performed an analysis of plans in three states that use these type of plans (and also limit copays) and found that the premiums were comparable between those that employed first-dollar coverage and those that did not, indicating that these types of plans could be offered without the risk of higher premiums. Error! Bookmark not defined.

As an alternative, insurers can establish a low drug deductible, separate from the plan's overall medical deductible. A separate drug deductible allows patients who rely on medications to more quickly meet the prescription out-of-pocket requirement after which the appropriate cost-sharing would apply. For example, one insurer offered on the Florida exchange offers a silver plan with a \$400 drug deductible with a separate \$4,950 individual medical deductible. Plan designs such as this helps guarantee patients afford and access their medications.

2. **Encourage Plans to Use Nominal Co-pays rather than Co-insurance:** Another option to reduce out-of-pocket costs and increase access to medications would be to encourage insurers to establish reasonable copays, rather than shifting more responsibility to patients through high co-insurance. Studies on adherence to specialty drugs have shown that \$250 is the tipping point for many patients to abandon their prescriptions at the pharmacy.⁸ When faced with a 50 percent cost-sharing responsibility on the full price of a drug, patients will undoubtedly have to make tough decisions, potentially leaving their prescriptions at the counter. Furthermore, the price of the drug is often obscured, which makes estimating what the cost the patient is responsible for and budgeting for healthcare expenditures impossible. Setting reasonable copay limits below the \$250 for specialty

⁷ <https://patientengagementhit.com/news/how-out-of-pocket-drug-costs-impact-patient-treatment-access>

⁸ <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2014.0497>

drugs threshold will help achieve the Administration's goals of reducing patient out-of-pocket costs while increasing access to healthcare and improving health outcomes.

Knowing that high co-insurance is a barrier to patients, particularly those with serious and chronic conditions, several states have passed legislation that places limits on patient cost-sharing for prescription drugs. For example, Delaware, Louisiana, and Maryland limit co-pays to only \$150 per month.

Other states, such as California, Vermont, and DC have established standardized benefit plans, which for the most part, exclude drugs from the overall deductible and require plans to utilize nominal copays. In California, actuaries estimate that capping copays across the board increase premiums by about one percent.⁹ That imperceptible increase seems like a reasonable tradeoff to ensure that patients who rely on medications to remain healthy and alive have reasonable copays and can actually access their medications.

HHS encouraged issuers to offer standardized plan options that had consistent deductibles, out-of-pocket limits, and cost-sharing across metal levels and highlighted them on the plan finder website for prospective shoppers. Utilizing and highlighting these plans was very helpful to beneficiaries. Unfortunately, for the 2019 plan year the administration will no longer be encouraging insurers to offer these plans or highlight them on the plan finder. We encourage you to reconsider this decision for the future.

Federal legislation has also been proposed that the Administration can support that would set cost-sharing limits for health plans that cover prescription drugs. Specifically, the Patients' Access to Treatment Act would not permit plans to impose copayments or coinsurance for specialty drugs higher than for other prescriptions in a non-preferred brand tier. We believe this will help patients with chronic, disabling, and life-threatening conditions access innovative drug therapies.

Colorado and Montana insurance commissioners explored several of the approaches mentioned above as ways to manage patient out-of-pocket expenses related to prescription drugs and reduce barriers to access. Guidance issued in both states require plans sold on the exchange to offer a minimum number of plans with a fixed-dollar copay, no prescription drug deductible, and no co-insurance.¹⁰ The results of a Milliman study of the changes implemented in the two states showed that these policies did not disrupt the markets, such as causing premium increases above the market trend, which make the case to expand these practices nationally.

- 3. Enforce Nondiscrimination Protections:** The ACA includes strong patient protections, including nondiscrimination provisions that prohibit insurers from discriminating against a person with a pre-existing condition, disability or health status. Additionally, essential health plan benefits must not be designed that discriminate against people based on their health status. Unfortunately, insurers are not always following these laws and regulations and federal and state governments are not doing enough to monitor plan design and take action against insurers for discriminatory plan design.

For example, CMS has identified the practice of placing all drugs from a certain class on the highest tier as an example of discriminatory plan design. A 2016 review by Avalere discovered there were

⁹ <https://www.managedcaremag.com/archives/2018/7/small-changes-or-big-ones-case-limits-prescription-drug-copayments-california>

¹⁰ <http://us.milliman.com/uploadedFiles/insight/2017/Impact-Prescription-Drug-Copay-Guidance-CO-MT.pdf>

still cases of plans permitting this formulary design; with 10 percent of silver plans placing all covered Anti-HIV protease inhibitors, 31 percent of all covered multiple sclerosis agents, and 50 percent of all covered antiangiogenic agents on the specialty tier.¹¹ Adverse tiering practices such as these can cost patients thousands of dollars in out-of-pocket costs. Ensuring plans adhere to the law and regulations is one way the administration can ensure patients are not faced with unnecessary out-of-pocket expenses and will be able to access their medications.

4. **Ensure Patient Use of Copay Cards:** In order to afford the high level of cost-sharing insurers are now burdening patients with, which include high deductibles and co-insurance, many patients rely on manufacturer copay assistance cards to access their medications. Copay cards are critical for insured patients, serving as a means of access to medications due to high patient cost-sharing. We strongly support the use of co-pay cards as a way in which patients can access their medications in absence of other protections like nominal co-pays.

A recent IQVIA analysis concluded that copay cards have helped reduce the burden patients face as a result of increasing cost-sharing. When the challenge of affordability is reduced, so is patient abandonment and discontinuation. According to the study, abandonment rates are 50 percent lower with the assistance of a copay card compared to when no copay card is used.¹²

Copay cards do not lead to higher drug prices, they merely assist patients afford their medications. The insurers still collect the same amount of money whether it is from the patient or the manufacturer. It also does not steer patients to using more expensive drugs. Another study recently conducted by IQVIA examined a large sample of branded prescriptions in the commercial market that had at least one generic equivalent showed that of 2.1 billion prescription purchases, only 0.4% were purchased utilizing a copay card.¹³

We also encourage HHS to look into a new practice that many insurance plans and pharmacy benefit managers (PBMs) are instituting, often called copay accumulators, that prevents copay assistance contributions from counting towards a beneficiary's deductible and maximum out-of-pocket spending limits. Implementation of these practices, often unbeknownst to the beneficiary, results in thousands of dollars in additional costs to the patient. This leads to patients not picking up their medications, putting them at risk for jeopardizing their health and wellbeing. On top of it, since the insurers still collect the money associated with the copay cards and the patient cost-sharing, they are actually collecting more money for each drug a patient receives under this new practice.¹⁴

Since plans are instituting these policies without proper notice to beneficiaries and are hiding them in the small print of plan contracts, we ask HHS to look into this matter in order to determine if insurers and PBMs are violating transparency and other requirements. In any event, this is a perfect example of how insurers are increasing patient cost sharing which can jeopardize patients' health.

¹¹ <http://avalere.com/expertise/managed-care/insights/2016-exchange-plans-improve-access-to-medicines-used-to-treat-complex-disease>

¹² <https://www.iqvia.com/-/media/iqvia/pdfs/us-location-site/market-access/patient-affordability-part-three---the-implications-of-co-pay-cards.pdf>

¹³ https://www.iqvia.com/-/media/iqvia/pdfs/us-location-site/market-access/fact-sheet-evaluation-of-copay-card-utilization-post-loe.pdf?_af=1518638195185

¹⁴ <https://www.drugchannels.net/2018/06/hidden-policies-search-for-copay.html>

I Am Essential appreciates the Administration's commitment to helping patients access their medications by exploring ways to lower drug pricing and reduce their out-of-pocket costs. We hope you will consider the proposals we have offered. We believe they will help lower patient cost sharing and at the same time improve access to necessary medications and help improve the health and wellbeing of beneficiaries.

Should you have any questions or comments, please contact: Carl Schmid, Deputy Executive Director, The AIDS Institute, cschmid@theaidsinstitute.org; Abbey Roudebush, Government Relations Manager, Epilepsy Foundation, aroudebush@efa.org; or Andrew Sperling, Director of Federal Legislative Advocacy, National Alliance on Mental Illness, asperling@nami.org. Thank you very much.

Sincerely,

ADAP Advocacy Association
Adult Congenital Heart Association
Advocates for Responsible Care (ARxC)
AIDS Alliance for Women, Infants, Children,
Youth & Families
The AIDS Institute
Aimed Alliance
Allergy & Asthma Network
Alliance for Aging Research
Alpha-1 Foundation
American Association on Health and Disability
American Autoimmune Related Diseases
Association
American Behcet's Disease Association (ABDA)
American Bone Health
Arthritis Foundation
Asthma and Allergy Foundation of America
California Chronic Care Coalition
California Hepatitis C Task Force
Caregiver Action Network
Caregiver Voices United
Caregivers of New Jersey
Chronic Disease Coalition
Coalition on Positive Health Empowerment
Community Access National Network (CANN)
COPD Foundation
Crohn's & Colitis Foundation
Diabetes Patient Advocacy Coalition
Easter Seals Massachusetts
EF Greater Southern Illinois
EPIC Long Island
Epilepsy Foundation
Epilepsy Foundation Central & South Texas
Epilepsy Foundation Eastern Pennsylvania
Epilepsy Foundation Greater Dayton Region
Epilepsy Foundation Greater Los Angeles
Epilepsy Foundation Heart of Wisconsin

Epilepsy Foundation Maryland
Epilepsy Foundation Metropolitan Washington
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Epilepsy Foundation Nebraska
Epilepsy Foundation New England
Epilepsy Foundation Northwest
Epilepsy Foundation of Alabama
Epilepsy Foundation of Arizona
Epilepsy Foundation of Colorado
Epilepsy Foundation of Connecticut
Epilepsy Foundation of Delaware
Epilepsy Foundation of East Tennessee
Epilepsy Foundation of Florida
Epilepsy Foundation of Georgia
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Indiana
Epilepsy Foundation of Iowa
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Metropolitan New York
Epilepsy Foundation of Michigan
Epilepsy Foundation of Middle & West
Tennessee
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Mississippi
Epilepsy Foundation of Missouri & Kansas
Epilepsy Foundation of Nevada
Epilepsy Foundation of New Jersey
Epilepsy Foundation of North Carolina
Epilepsy Foundation of Oklahoma
Epilepsy Foundation of Southeast Tennessee
Epilepsy Foundation of Texas - Houston/Dallas-
Fort Worth/West Texas
Epilepsy Foundation of Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation of Virginia
Epilepsy Foundation Rochester-Syracuse-
Binghamton

Epilepsy Foundation Southeast Wisconsin
Global Colon Cancer Association
Global Healthy Living Foundation
HealthyWomen
Hemophilia Federation of America
Huntington's Disease Society of America
International Association of Hepatitis Task
Forces
International Pain Foundation
International Pemphigus and Pemphigoid
Foundation
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Men's Health Network
Mental Health America
Multiple Sclerosis Foundation
National Alliance on Mental Illness
National Association of Nutrition and Aging
Services Programs (NANASP)

National Black Women's HIV/AIDS Network
National Council for Behavioral Health
National Hemophilia Foundation
National Kidney Foundation
National Patient Advocate Foundation
New Jersey Association of Mental Health and
Addiction Agencies, Inc.
Partnership to Fight Chronic Disease
Prevent Blindness
Susan G. Komen
The Hepatitis C Mentor and Support Group-
HCMSG
The Veterans Health Council of Vietnam
Veterans of America
TRACKtech LLC
U.S. Pain Foundation
United Spinal Association
Vietnam Veterans of America
Virginia Hemophilia Foundation
Wyoming Epilepsy Association