AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

July 16, 2018

Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Room 600E
Washington, DC 20201

Re: Docket # CMS-2018-0075-0001 for "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs"

Dear Secretary Azar:

Aimed Alliance is a tax-exempt, not-for-profit organization that works to improve access to quality health care. Thank you for the opportunity to comment on the Department of Health and Human Services ("HHS") Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. As you are aware, many Americans cannot afford medical services and treatments due to high out-of-pocket costs, causing them to forego vital care or experience significant debt and even bankruptcy.[1] We commend the Administration for putting forth practical solutions that will reduce patients' financial burden; however, we also encourage HHS to ensure that new policies do not negatively impact access to lifesaving treatments.

## I. Increasing Competition

We commend the Food and Drug Administration ("FDA") for taking several significant steps to accelerate the approval of a record-breaking number of generic drugs, thereby increasing competition and providing patients with additional options for treatment.

### A. Access to Reference Product Samples

The FDA has taken several proactive steps in the past few months to evaluate and prevent drug manufacturers from using Risk Evaluation and Mitigation Strategies ("REMS") with restricted distribution to inhibit competition. As such, further action is not necessary.

In May 2018, the FDA published a list of companies that were the subject of reference listed drug ("RLD") access inquiries.[2] The website shows that the current REMS infrastructure is working efficiently. The FDA received a total of 164 inquiries regarding access to RLD

[1] *NCI Dictionary of Cancer Terms*, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/financial-toxicity (last visited May 9, 2018).
[2] U.S. FOOD & DRUG ADMIN, REFERENCE LISTED DRUG (RLD) ACCESS INQUIRIES (2018), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm.

samples.[3] Of those, the FDA only sent out 21 letters (roughly12 percent) regarding eight drugs. Of the eight drugs, most, if not all, have already shared samples for bioequivalence testing, thereby showing that generic manufacturers are able to access RLD samples for bioequivalence testing.[4] For the rest of the inquiries, the FDA determined that (1) the medication was not subject to REMS; (2) the requestor did not propose safety protocols comparable to those in the REMS for the RLD; (3) the requestor did not submit adequate information; or (4) the requestor otherwise did not qualify for a letter.[5]

Additionally, the FDA also issued two draft guidance documents in June to further streamline the REMS process by providing further clarity on developing single, shared REMS and waiving the single, shared REMS requirement.[6] Therefore, additional steps are not needed.

### B. Biosimilar Development, Approval, Education, and Access

Aimed Alliance supports the development and more efficient approval of biosimilars. Biosimilar products provide additional treatment options for patients with chronic conditions, such as cancer, rheumatoid arthritis, lupus, and multiple sclerosis, that require highly individualized care. Often, individuals living with chronic conditions try multiple medications before finding one that is well tolerated and effective.[7] Therefore, the more treatment options available, the better. Moreover, by increasing competition, biosimilars can also bring down the cost of care.

However, it is important that stable patients who are currently on a particular biologic or biosimilar medication be educated on the potential impact of switching to a different treatment given that large molecule biologic drugs are not identical in the way that small molecule brand and generic medications are.[8] Switches that are not based on medical reasons may trigger

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[3] *Id.*

[4] *See, e.g.*, Press Release, Evaluate, Sun Pharma Announces Absorica Patent Settlement (Oct. 5, 2015); Claravis (isotretinoin capsules, USP), https://www.tevagenerics.com/product/claravis-isotretinoin-capsules-usp (last visited July 13, 2018); Complaint at 5, Adverio Pharma GMBH et al. v. Teva Pharmaceuticals USA, Inc., No 1:18-cv-00112-UNA (D. Del. Jan. 19, 2018); Press Release, Quinn Emanuel Trial Lawyers, July 2017: Eve-of-Trial Settlement Victory in Hatch-Waxman Suit (July, 2017); Dana A. Elfin, *Actelion Sues to Block Two Generics of Orphan Drug*, BNA (July 13, 2018, https://www.bna.com/actelion-sues-block-n57982088342/); Press Release, Lannett And Celgene Enter Into Settlement And License Agreement Related To Thalomid (Oct. 30, 2017); Robert F. Leibenluft & Lauren E. Battaglia, *Actelion Settles REMS Dispute with Generic Drug Manufacturers*, HOGAN LOVELLS (Mar. 6, 2014), https://www.hoganlovells.com/en/blogs/focus-on-regulation/actelion-settles-rems-dispute-with-generic-drug-manufacturers.

[5] REFERENCE LISTED DRUG (RLD) ACCESS INQUIRIES, *supra* note 2.

[6] U.S. FOOD & DRUG ADMINISTRATION, WAIVERS OF THE SINGLE, SHARED SYSTEM REMS REQUIREMENT GUIDANCE FOR INDUSTRY (2018) https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf; U.S. FOOD & DRUG ADMINISTRATION, DEVELOPMENT OF A SHARED SYSTEM REMS GUIDANCE FOR INDUSTRY (2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609045.pdf.

[7] Leah L. Zullig & Hayden Bosworth, *Engaging Patients to Optimize Medication Adherence*, NEJM CATALYST (May 14, 2017 https://catalyst.nejm.org/optimize-patients-medication-adherence/).

[8] L. Zhao et al., *Clinical Pharmacology Considerations in Biologics Development*, 33(11) Act. Pharmacol. Sin. 1340 (2012).

adverse events or negatively impact individuals' quality of life.[9]

HHS should provide information and educational resources on the distinctions between a biosimilar product and an interchangeable product and the need for insurers and health systems to offer access to several biologics, biosimilars, and interchangeable product options. A biosimilar product is not interchangeable with its biologic reference drug product unless it receives official interchangeable designation from the FDA. Although it may not be appropriate for a patient to be switched from a biological drug to a biosimilar, some third-party payers are forcing stable patients to switch by making negative formulary changes, and some health systems are forcing the switch by refusing to carry biologics in their pharmacies in efforts to save money.[10] They erroneously argue that the drugs are interchangeable. Yet, the FDA has not certified any biosimilars as interchangeable with their reference biological drug product. Patients, providers, payers, and health systems need to be educated on the differences between these products and the detrimental effects switching a stable patient for non-medical reasons may have on patients' health.

## II. Better Negotiation

### A. Increased Transparency

Better negotiation policies and more transparency in the health system play a key role in reducing health care costs. The Administration should implement policies that increase the transparency of out-of-pocket costs in Medicare plans. Many Medicare Part D plan formularies contain a specialty tier in which beneficiaries must pay co-insurance rather than a flat copay.[11] In some instances, the coinsurance can be up to 50 percent.[12] Yet, without knowing the price of the medication, Medicare beneficiaries cannot calculate how much they will owe. Therefore, to increase transparency, plans should list the co-insurance rate along with the exact amount that beneficiaries will owe out of pocket for each medication for which co-insurance is required.

### B. Direct to Consumer Advertising

The blueprint proposes to require drug list prices in direct-to-consumer advertising. While this policy is worth exploring, the current rebate system masks the true price of a drug and can be misleading to consumers.[13] Some patients may be deterred from taking a medication that is most appropriate for them because they think they may be required to pay the full reference

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[9] E. Nguyen, et al., *Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review*, 32(7) CURR. MED. RES. OPIN. 1281 (2016).
[10] Judy Crespi-Lofton & Jann B. Skelton, *The growing role of biologics and biosimilars in the United States: Perspectives from the APhA Biologics and Biosimilars Stakeholder Conference*, 57 J. AM. PHARMACISTS ASS'N e15, e21 (2017).
[11] HENRY J. KAISER FAM. FOUND., THE MEDICARE PART D PRESCRIPTION DRUG BENEFIT (2017).
[12] *E.g.*, SILVERSCRIPT, 2018 FORMULARY (LIST OF COVERED DRUGS) (2018).
[13] CHARLES ROEHRIG, THE IMPACT OF PRESCRIPTION DRUG REBATES ON HEALTH PLANS AND CONSUMERS 4 (ALTARUM, APRIL 2018).

list price.[14] Yet, with rebates and caps on out-of-pocket costs, they may owe far less.[15] Conversely, some patients prefer to take the most expensive medication, assuming that the price is directly tied to superiority over other medications.[16] Therefore, before requiring list prices in advertisements, the rebate system must be reformed and consumers must be provided with a clear understanding of what the list price actually means for them.

### C. Value-Based Arrangements

The Administration's proposals regarding value-based pricing arrangements for Medicare and Medicaid is a novel approach to tackling rising drug prices, and we commend the Administration's willingness to try new approaches where traditional models have failed. Of the various forms of value-based arrangements, outcomes-based drug pricing models provide the most effective approach to lowering drug prices and ensuring that patients receive individualized care tailored to their needs. Outcomes-based pricing for medication can be structured so that drug manufacturers offer insurers or pharmacy benefit managers discounts if a medication turns out to be ineffective for individual plan beneficiaries. Outcomes-based pricing models allow for individualized care based on the value that the medication provides to the unique patient, and properly aligns incentives of the payer, drug maker, prescriber, and patient.[17]

### D. Indication-Based Payments

We do not support indication-based pricing arrangements, in which a drug that treats multiple indications is reimbursed at different rates based on the value provided for the particular indication,[18] because such arrangements may result in patient discrimination. Patients with one condition may have to pay more for the same drug than patients with another condition. Moreover, any projected cost savings from indication-based pricing arrangements might be swallowed by the administrative burden of managing these arrangements, and there is some evidence that indication-based pricing will actually increase overall drug spending, and manufacturer profits.[19]

### E. Part B to D

Aimed Alliance opposes the Administration's proposal to switch some medications from

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[14] Liz Szabo, *As Drug Costs Soar, People Delay or Skip Cancer Treatments*, NPR (July 13, 2018, https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments).

[15] JULIETTE CUBANSKI, TRICIAN NEUMAN, KENDAL ORGERA, & ANTHONY DAMICO, NO LIMIT: MEDICARE PART D ENROLLEES EXPOSED TO HIGH OUT-OF-POCKET DRUG COSTS WITHOUT A HARD CAP ON SPENDING (2017).

[16] Rebecca Waber, Baba Shiv, Ziv Carmon &Dan Ariely, *Commercial Features of Placebo and Therapeutic Efficacy*, AM. MED. ASS'N, 299(9), 1016-1017 (2008), https://jamanetwork.com/journals/jama/article-abstract/181562.

[17] Rachel Sachs, et al., Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule, 43(1) Journal of Health Politics, Policy and Law 5 (2018).

[18] Amitabh Chandra & Craig Garthwaite, *The Economics of Indication-Based Drug Pricing*, NEJM CATALYST (Sept. 11, 2017 https://catalyst.nejm.org/economics-of-indication-based-drug-pricing/).

[19] Amitabh Chandra & Craig Garthwaite, *The Economics of Indication-Based Drug* Pricing, NEJM CATALYST (Sept. 11, 2017 https://catalyst.nejm.org/economics-of-indication-based-drug-pricing/).

Medicare Part B into Medicare Part D. Switching medications into Part D from Part B would lead to higher out-of-pocket costs to beneficiaries, not lower costs, because tiered formularies could be used and benefit utilization management policies could be imposed.[20]

The switch could cause financial strain on health care practitioners in treatment centers because their reimbursement rates would likely be reduced. The last time practitioners' reimbursement rates were reduced, private oncology practices closed and consolidated with large hospital and health systems.[21] This resulted in fewer provider options, further reducing access to health care for the most vulnerable Medicare beneficiaries, along with increased out-of-pocket costs of obtaining needed medication through a Part D plan instead of Part B.[22]

Additionally, switching medications from Medicare Part B into Medicare Part D could be considered discrimination given that Part B medications are used primarily for individuals with cancer and autoimmune conditions.[23] Consequently, individuals with such conditions will be impacted far more than individuals with other conditions.

Therefore, Aimed Alliance recommends against switching medications from Medicare Part B into Medicare Part D.

### F. Fixing Global Freeloading

Aimed Alliance favors policies that will rectify the disparity of drug prices paid by American consumers versus foreign government buyers. Other nations, where government purchasing and price controls are more prevalent, impose below-market prices on U.S. pharmaceutical manufacturers, causing market prices in the U.S. to be higher than they otherwise would be under a more open global market.[24] Higher U.S. drug prices effectively subsidize pharmaceutical research and development costs for other developed nations.[25]

The U.S. government should enact trade policies that require other developed countries to

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[20] GRECIA M. MARRUFO, EMIL RUSEV, KRISTY PICCININI, ELIZABETH COOMBS, KEN UEDA, & ERICA SCHECTER, ESTIMATING THE EFFECTS OF CONSOLIDATING DRUGS UNDER PART D OR PART B (Acumen LLC, 2011).
[21] *Id*; R.M. Conti, et al., *The Impact of Provider Consolidation on Outpatient Prescription Drug-Based Cancer Care Spending*, Health Care Cost Institute (2015), http://www.healthcostinstitute.org/files/HCCI-Issue-Brief-Impact-of-Provider-Consolidation.pdf.
[22] COMMUNITY ONCOLOGY ALLIANCE, COMMUNITY ONCOLOGY PRACTICE IMPACT REPORT: THE CHANGING LANDSCAPE OF CANCER CARE (2014); Amanda Cassidy, *Site-Neutral Payments. Medicare uses different payment systems depending on where care is delivered. Recent proposals seek to eliminate this differential*, HEALTH POLICY BRIEF (July 13. 2018, https://www.healthaffairs.org/do/10.1377/hpb20140724.283836/full/healthpolicybrief_121.pdf).
[23] Letter from James C. Cosgrove, Director, Health Care, Government Accountability Office, to The Hon. Herb Kohl, Chairman, Special Committee on Aging, United States Senate * The Hon. Dick Durbin, United States Senate (Oct. 12, 2012) (on file with the United States Government Accountability Office).
[24] Ben Hirschler, How the U.S. Pays 3 Times More for Drugs, REUTERS (https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/).
[25] Jeanne Whalen, Why the U.S. Pays More Than Other Countries for Drugs, WSJ (Dec. 1, 2015), https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-fordrugs-1448939481

pay more toward pharmaceutical research and development costs.[26] These policies should include exercising presidential authority under the Trade Act of 1974 to renegotiate trade agreements with other developed nations and China so that they contribute fairly to the costs of pharmaceutical research and development.[27]

## III. Creating Incentives to Lower List Prices

HHS should create new incentives that reward drug manufacturers that maintain or lower drug list prices. Such incentives should not be in the form of federal or state penalties or government-imposed mandate systems. State Medicaid pricing and formulary strategies that rely on closed formularies and negotiation of drug prices are state-imposed price controls.

Price controls stifle innovation, which can lead to a lack of access to lifesaving treatments.[28] Additionally, imposing penalties conflicts with the Administration's pro-market drug pricing stance and is inconsistent with the Administration's calls for foreign governments to ease the use of similar price control tactics.

### A. Fiduciary Duty for Pharmacy Benefit Managers

Aimed Alliance agrees that the pharmacy benefit management ("PBM") industry should be reformed. Aimed Alliance supports reforms that would prohibit PBMs from employing anti-competitive practices through their mail-order pharmacies, using gag clauses in pharmacy contracts, using "clawback" practices (*i.e.*, retaining the difference between a medication's cost and a higher consumer copay), and implementing mid-year negative formulary changes.[29] PBM reform should be the initial focus of the Administration's efforts to lower drug prices. As proposed in the blueprint, PBMs must owe a fiduciary duty to the entity they are working on behalf of.

Reforms that require PBMs to act solely in the interest of the entity for whom they are managing pharmaceutical benefits would ensure that insurers and patients actually see the benefit of drug rebates. Imposing a fiduciary duty on PBMs would align the incentives of PBMs, insurers, and consumers, resulting in a greater percentage of any rebates flowing to insurers, and to patients who pay insurance premiums and cost-sharing amounts. Without PBMs demanding high rebates for their own self-benefit, PBMs would instead have an incentive to negotiate for lower list prices on drugs.

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[26] AIMED ALLIANCE, COMMON-SENSE STEPS TO REDUCE THE COST OF HEALTH CARE IN THE U.S. PART I: FEDERAL GOVERNMENT (2018).

[27] There is a Better Way to Help U.S. Consumers: Pharmaceutical Price Controls Abroad: An Unfair Trade Policy, United States Senate Republican Policy Committee (Nov. 6, 2003), https://sites.hks.harvard.edu/m-rcbg/fellows/T_Christian_Study_ Group/Session%204/Republican_Policy_Committee.pdf.

[28] DARIUS LAKDAWALLA, DANA P. GOLDMAN, PIERRE-CARL MICHAUD, NEERAJ SOOD, ROBERT LEMPERT, ZE CONG, HAN DE VRIES, & ITALO GUTIERREZ, U.S. PHARMACEUTICAL POLICY IN A GLOBAL MARKETPLACE 3 (National Institutes of Health 2009).

[29] AIMED ALLIANCE, DRIVERS OF HEALTH COSTS IN THE U.S. PART II: UNDERSTANDING THE PHARMACY BENEFIT MANAGER'S ROLE (2017).

### B. Reducing the Impact of Rebates

Aimed Alliance supports rebate reforms that require PBMs to pass any cost-savings obtained by the PBMs to the consumers.

PBMs work as a "middle-man" between manufacturers and insurers to lower drug pricing for consumers. Yet, currently, PBMs use drug rebates they obtain from manufacturers as additional profit instead of passing the cost savings on to their insurance customers. This system leads to the perverse result of forcing drug companies to increase list prices as monopolistic PBMs demand larger rebates. Therefore, we propose that PBMs be prohibited from receiving any rebates from manufacturers; however, if rebates remain available to PBMs, then PBMs should be required to pass all or a portion of these rebates to consumers, via the insurer, at the point-of-sale.

In addition, to reduce costs, rebates also should not be used in Medicare programs. Ideally, Medicare Part D should prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers and require these contracts to be based only on a fixed price for a drug over the contract term. This change would align the incentives of all stakeholders to compete for market share by lowering list prices. It would also increase transparency of the true price of drugs, which will allow for fair competition between manufacturers, distributors, PBMs, and payers. Alternatively, if rebates are to be used, there must be a mechanism in place to ensure that they are passed on to plan beneficiaries.

### C. The 340B Drug Discount Program

We support the proposed reforms to the 340B drug pricing program, including measures to enhance program integrity to ensure the program is fulfilling its purpose of providing medication to needy patients. The 340B program is used too often as a profit generator, as some hospitals purchase discounted medication under the program and then obtain high reimbursements from commercial insurers, instead of using the discount to subsidize treatment of needy patients.[30] As a result, drug manufacturers increase their list prices for other government and commercial payers to compensate for the required 340B discounted prices paid by participating hospitals. This further distorts the market.

The Centers for Medicare and Medicaid Services rule that reduced the 340B discount and took effect at the start of 2018 was a good first step in correcting this market distortion. We encourage the Administration to enact further reforms to the 340B drug pricing program to reduce patient out-of-pocket spending, increase access to treatment for the intended patient population, and increase transparency.

[30] 340B Facilities and Charity Care, Alliance for Integrity and Reform, (Oct. 2017), http://340breform.org/wp-content/ uploads/2017/10/AIR340B-Designed_340B_CharityCare_FINAL. Pdf; Sunita Desai & J. Michael McWilliams, Consequences of the 340B Drug Pricing Program, The New England Journal of Medicine, (Feb. 2018), http://www.nejm.org/doi/full/10.1056/ NEJMsa1706475

## IV. Reducing Patient Out-of-Pocket Spending

Patient out-of-pocket spending for drugs has increased markedly in recent years because of escalating cost-sharing provisions in insurance and increasing drug prices. The Administration's proposal to create an annual cap for Medicare beneficiaries' out-of-pocket drug costs would provide needed certainty and security for beneficiaries and fulfill the intended purpose of such insurance, which is to protect beneficiaries from unexpectedly high medical costs.

### A. Federal Preemption of Contracted Pharmacy Gag Clause Laws

Aimed Alliance supports federal preemption of pharmacy gag clauses that prohibit pharmacists from informing customers of their best option to purchase medication at the point-of-sale.

### B. Inform Medicare Beneficiaries with Medicare Part B and Part D about Cost-Sharing and Lower-Cost Alternatives

Certain health plans and PBMs have devised tools to inform Medicare beneficiaries about various formulary options, expected cost-sharing responsibilities, and lower-cost alternatives designed to reduce beneficiary out-of-pocket spending. These cost-sharing tools and the information provided may be helpful to some beneficiaries, but the interests of patients must remain paramount in determining which medications are prescribed by a treating physician. Part D plans and PBMs should provide such information to health care practitioners and encourage practitioners to discuss lower-cost options if such options are medically appropriate.

## V. Additional Feedback: Medicare Part D Modernization Plan

President Trump's proposal to modernize the Medicare Part D program was outlined in his fiscal year 2019 budget, which would require Part D plans to share any manufacturer rebates with beneficiaries at the point of sale, modify Part D reimbursement structures to discourage manufacturer use of rebate strategies, and place an annual cap on beneficiary out-of-pocket spending. Aimed Alliance supports these portions of the Part D modernization plan.

However, the following proposals in the Part D modernization plan would have detrimental consequences for patients. Allowing Part D plans to adjust formularies by reducing medication options to a single drug per category or class and allowing plans to drop medications from the formulary during the plan year could harm patients who count on having access to prescribed medication through their Part D plan. Additionally, narrowing formularies could result in a patient switching medication solely because of cost concerns rather than obtaining the medication deemed the best treatment option by the patient's physician.

Beneficiaries select Part D plans that cover their prescribed medications. Reducing choices for beneficiaries through narrower Part D plan formularies, or worse, allowing plans to drop coverage for medications during a plan year, would put the health of Medicare beneficiaries at risk. We do recommend that Part D plans be allowed to add medications to a formulary during

a plan year, however, so that Part D plans may expand medication options without having to wait for a new plan year to begin.

Similarly, leveraging Medicare Part D negotiating power for the benefit of Part B drugs would not be in the best interests of patients long term. Implementation of this proposal would lead to increased benefit utilization management by Part D plans, such as preauthorization requirements and the removal or exclusion of medications from plan formularies. Such practices impose barriers to patients' access to medications that have been prescribed to them based on their providers' medical knowledge and individualized assessments. Delays or interruptions to effective care can place the health of Medicare beneficiaries at risk.

Additionally, we recommend against eliminating cost-sharing for generic drugs because doing so could steer patients toward drugs that were not prescribed by their physicians or allow insurers and PBMs to push patients away from their prescribed medication and on to generics that may be less effective or have undesirable side effects.

Finally, the Administration has stated that the Part D modernization plan is an all-or-nothing proposition. However, we urge the Administration to move forward with those portions of the plan we have outlined and endorsed above, which could improve health care for Americans with Medicare while reducing costs. If the individual provisions of the plan are indeed inseparable, then Aimed Alliance does not support the implementation of the Medicare Part D modernization plan.

Thank you in advance for your consideration of our comments.

Sincerely,

Stacey Worthy
Counsel