March 1, 2019

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP)
428 Senate Dirksen Office Building
Washington, DC 20510-6300

Chairman Alexander and Members of the HELP Committee:

Aimed Alliance is a 501(c)(3) non-profit organization that seeks to protect and enhance the rights of health care consumers and providers. We have received notice of your request for recommendations to address rising health care costs in the United States and appreciate the opportunity to share our views with you. Aimed Alliance is particularly interested in this issue and how it impacts health care consumers, and we have many ideas for how the U.S. health care system can be improved. In addition to this letter, we have published multiple papers on steps that Congress can take to reduce the cost of care in the United States that we hope you will review, including the following:

- *Common-Sense Steps to Reduce the Cost of Health Care in the U.S. Part I*;[1]
- *Common-Sense Steps to Reduce the Cost of Health Care in the U.S. Part II*;[2] and
- *Advancing Quality Health Care in the U.S. A Roadmap for Consumer-Focused Reform*.[3]

We have laid out several recommendations below. Each item addresses specific issues within our health care system that either increase costs or reduce access to essential health care services.

I. Amend ERISA to Prohibit Copay Accumulator Programs in Employer-Sponsored Insurance Plans

Recently, employers have begun adopting policies, referred to as copay accumulator programs, that exclude the value of third-party payments from the calculation of an individual's deductible and maximum out-of-pocket costs.[4] These programs are problematic for patients with chronic health conditions who are in high deductible health plans and rely on expensive medications to maintain their health.[5] Such patients often utilize patient assistance offered by pharmaceutical manufacturers and non-profit patient assistance programs to afford their medications when they are in the deductible phase of their health plan.[6] Without this assistance from third parties, many patients would not be able to afford the out-of-pocket costs associated with their medications.[7] Moreover, while payers often argue that copay accumulator programs are intended to steer patients toward less expensive treatment options, a recent study showed that over 50 percent of medications for which copay assistance is offered have no

[1] https://bit.ly/2TficJR
[2] https://bit.ly/2VtTwe2
[3] https://bit.ly/2T7ECxn
[4] https://www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html
[5] https://chronicdiseasecoalition.org/insurance-discrimination-spreads-to-copay-accumulator-programs/
[6] https://chronicdiseasecoalition.org/insurance-discrimination-spreads-to-copay-accumulator-programs/
[7] https://chronicdiseasecoalition.org/insurance-discrimination-spreads-to-copay-accumulator-programs/

lower cost therapeutic equivalent or only have a similarly priced brand equivalent.[8] Without access to their medication, patients are more likely to ration out their treatment, skip refills, or otherwise not adhere to their treatment plan, which can result in disease progression or relapse.[9] In addition to the health consequences, nonadherence can result in increased health care utilization, thereby increasing health-related expenditures.[10]

Furthermore, plans often do not adequately disclose the existence of copay accumulator programs to plan enrollees or use misleading language when informing enrollees about the implementation of a copay accumulator program.[11] As a result, patients are often surprised to learn that they are still responsible for a significant amount of cost-sharing once the finite amount of copay assistance they receive is expended. Many have not planned for such expenses. While health plans understandably have strong incentives to contain health care costs, this strategy hurts patients.

Copay accumulator programs are gaining popularity in employer-sponsored plans. A 2018 survey of employers by the National Business Group on Health (NBGH) showed that 17 percent of employers already had a copay accumulator program, and 56 percent were considering implementing one in 2019 or by 2020.[12] Currently, eight states have introduced legislation to limit this practice, but the Employee Retirement Income Security Act of 1974 (ERISA) preempts those laws in employer-sponsored plans.[13] We request that Congress amend ERISA to prohibit the implementation of these harmful programs in employer-sponsored health plans. For more information about copay accumulators and the risks they present to patients, you can review our report on the issue, *Employers Beware: Understanding the Costs and Liability Risks of Health Insurance Copay Accumulator Programs*.[14]

II. Amend ERISA to Impose a Fiduciary Duty on PBMs

Pharmacy Benefit Managers (PBMs) have received a large share of public attention for their role in the pharmaceutical supply chain and the perception that they needlessly inflate the costs of pharmaceutical products.[15] Some states have introduced legislation to impose a fiduciary duty on PBMs to force them to act in the best interest of the health plans with which they contract.[16] However, the U.S. Court of Appeals for the D.C. Circuit held in 2010 that a D.C. law imposing a fiduciary duty on PBMs was preempted by ERISA.[17] This decision is not binding on other states, but it offers persuasive precedent for other courts to rule similarly in the future. To avoid legal complications and to bring clarity to this issue, we request that Congress amend the ERISA statute to impose a fiduciary duty on PBMs to the health plans with whom they contract.

Imposing a fiduciary duty on PBMs to the health plans will likely reduce health costs because it will require PBMs to act in the best interest of the health plan. Currently, PBMs extract rebates from

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[8] https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more
[9] https://www.healthpopuli.com/2017/02/02/16896/
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5780689/
[11] https://www.nastad.org/sites/default/files/Uploads/2018/copayaccumulatorfactsheet.pdf
[12] https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more
[13] https://www.aclhic.com/filelibrary/ERISA_Primer.pdf
[14] https://aimedalliance.org/wp-content/uploads/2018/11/Employers-Beware.pdf
[15] http://fortune.com/2018/08/28/express-scripts-pbm-drug-prices/
[16] https://nashp.org/wp-content/uploads/2019/01/RxTracker-final-2.11.2019.pdf
[17] http://www.hr.cch.com/news/benefits/072710.asp

pharmaceutical manufacturers to get them to compete for their products to be placed on a health plan's formulary.[18] While the rebates are intended to be passed on to insurers, and ultimately, to consumers in the form of reduced premiums, much of these rebates is retained by PBMs as profit.[19] Imposing a fiduciary duty on PBMs would prevent them from profiteering off the pharmaceutical supply chain in this capacity and would likely reduce the cost of health care.

III. Amend the Anti-Kickback Statute Safe Harbors to Require Pharmaceutical Rebates to be Passed on to Consumers

The Trump Administration recently released a proposal that would alter the safe harbor regulations regarding health care kickbacks. This proposal would eliminate the protection provided to drug manufacturers that offer pharmaceutical rebates to Part D plan sponsors, managed care organizations, and the PBMs that contract with them.[20] At the same time, this proposal would create new safe harbors for pharmaceutical rebates that are provided to pharmacies and passed onto consumers at the point-of-sale.[21] We support this proposal because it will take steps to eliminate incentives that pharmaceutical manufacturers have to continue increasing their list prices that often cause medications to be unaffordable for patients. Additionally, this proposal will ensure that rebates associated with expensive specialty medications are correctly passed onto the patients who are filling prescriptions for that medication instead of being used to lower premiums for all plan enrollees.[22]

The Center for Medicare and Medicaid Services (CMS) states in the proposed rule's fact sheet that this change will only apply to federal health care programs and not commercial insurance plans.[23] We request that Congress enact this policy by statute to extend the benefits of pharmaceutical rebates to all consumers and to create uniformity across all types of health plans.

IV. Restore the Individual Mandate

When the Tax Cuts and Jobs Act of 2017 (TCJA) was signed into law in December 2017, it reduced the individual mandate's penalty for not maintaining insurance coverage to $0.[24] Zeroing out the individual mandate undermines a core feature of the Patient Protection and Affordable Care Act (ACA) that is essential for the law to be effective at reducing the number of uninsured Americans and the cost of coverage.[25] Furthermore, nullifying the individual mandate places the entire ACA in legal jeopardy, as one court has already ruled that the ACA is unconstitutional without the individual mandate.[26]

The individual mandate is essential to achieving affordable coverage because it broadens the insurance risk pool, allowing health care costs to be spread across a greater number of people.[27] The individual mandate also ensures that health care consumers have insurance coverage to protect them if they

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[18] https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf
[19] https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf
[20] http://www.klgates.com/hhs-issues-proposed-rule-to-remove-safe-harbor-for-drug-rebates-02-11-2019/
[21] http://www.klgates.com/hhs-issues-proposed-rule-to-remove-safe-harbor-for-drug-rebates-02-11-2019/
[22] https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf
[23] https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf
[24] https://www.natlawreview.com/article/2018-tax-reform-series-goodbye-to-individual-mandate
[25] https://www.commonwealthfund.org/publications/fund-reports/2018/jul/eliminating-individual-mandate-penalty-behavioral-factors
[26] https://www.healthaffairs.org/do/10.1377/hblog20191231.666628/full/
[27] https://www.americanprogress.org/issues/healthcare/reports/2010/04/08/7720/why-we-need-the-individual-mandate/

experience a catastrophic health event.[28] We recommend that Congress either restore the individual mandate's penalty to its original amount or craft an alternative policy solution that achieves the same goal of incentivizing comprehensive insurance coverage without undermining the ACA.

V. Enact Policies to Further Incentivize Preventive Care

The ACA requires private health plans to offer preventive services to health plan enrollees at no cost, thereby successfully increasing the use of such services.[29] Expanded utilization of preventive services helps individuals identify costly health conditions before they progress to the point where treatment is unaffordable or impossible. For example, a 2005 study analyzed how patient outcomes and health care costs were influenced by the addition of a one-time screening for HIV.[30] This study found that requiring such screenings led to earlier diagnoses and longer projected life-spans for individuals who were HIV-positive with a modest increase in lifetime health care costs as a result of the extended life-span.[31] Furthermore, a single screening was shown to be able to prevent up to 300 secondary transmissions of HIV.[32]

While the requirement for health plans to provide complimentary preventive services has been helpful, more incentives are required to ensure that people are being proactive about their health and to enable them to identify health conditions early. We are pleased to see that CMS has embraced this idea by proposing to allow Medicare Part D and Medicare Advantage plans to offer greater incentives to enrollees to promote healthy behaviors.[33] We think this proposal is moving in the right direction, and we request that Congress embrace policy options that align with this proposal.

VI. Restore Cost-sharing Reduction Payments

Cost-sharing reduction (CSR) payments were halted by the Trump Administration in October 2017, which has created complications for marketplace insurers who are resorting to strategies such as "Silver Loading" to keep their plans affordable.[34] Some insurers have sued the government to collect these payments after they were halted and have been successful.[35] However, without annual appropriations from Congress, CSR payments will be made at the discretion of the current administration. We request that Congress appropriate funding to satisfy the government's obligation to provide CSR payments to health insurers. A legislative solution is necessary because it would provide greater certainty to insurers and enrollees about the cost and availability of coverage. These CSR payments must be appropriated annually by Congress to prevent political headwinds from interfering with the affordability of health insurance.

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[28] https://www.americanprogress.org/issues/healthcare/reports/2010/04/08/7720/why-we-need-the-individual-mandate/
[29] https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-040617-013534
[30] https://www.nejm.org/doi/full/10.1056/NEJMsa042088
[31] https://www.nejm.org/doi/full/10.1056/NEJMsa042088
[32] https://www.nejm.org/doi/full/10.1056/NEJMsa042088
[33] https://www.cms.gov/newsroom/fact-sheets/value-based-insurance-design-model-vbid-fact-sheet-cy-2020
[34] https://www.advisory.com/daily-briefing/2018/04/17/exchanges-silver-load
[35] https://www.mintz.com/insights-center/viewpoints/2146/2018-09-court-rules-federal-government-must-make-cost-sharing

VII. Enact Policies Prohibiting Surprise Out-of-Network Medical Bills

The issue of surprise out-of-network medical bills has become more prevalent in recent years. This problem occurs when consumers are not given adequate information to determine whether the services they need are in-network or out-of-network before utilizing such services.[36] Surprise out-of-network medical bills commonly happen when a patient receives a health care service at a hospital and one member of the care team, such as an anesthesiologist, is out-of-network.[37] According to a recent survey, nearly seven out of 10 individuals with unaffordable out-of-network charges reported that they did not know their provider was out-of-network at the time the care was rendered.[38] Due to this lack of transparency, patients are often left with astronomical medical bills that their insurers refuse to cover and no options for relief.[39] In fact, the average amount charged by a surprise out-of-network medical bill is over $7,000.[40]

States have begun crafting policy solutions to resolve this problem from different angles.[41] We request that Congress ensure that this issue is addressed consistently across the country so consumers can have certainty that they will not fall victim to surprise out-of-network medical bills.

VIII. Enact Policies Requiring Real-Time Insurance Coverage Information for Patients and Providers

The lack of real-time insurance coverage information available to providers during patient visits often leads to patients receiving prescriptions for medications or referrals for treatment that are unaffordable to such patients. A 2018 survey by CoverMyMeds revealed that 75 percent of patients have been prescribed medications that are too expensive for them, and 50 percent indicated that they did not fill prescriptions because they were too expensive.[42] Furthermore, 74 percent of prescribers agreed that they would find it valuable to have real-time benefit information at the point of prescribing.[43]

Ensuring that patients and providers have real-time data about what treatment options are covered by a patient's insurance plan will enable them to have a more robust and meaningful conversation about which treatment option is the best fit for the patient's individual situation. We are pleased to see that CMS has recently proposed implementing this policy in Medicare Part D plans by requiring plan sponsors to use real-time benefit tools (RTBTs) that would integrate health plan and coverage data with the provider's existing Electronic Health Record (EHR) system.[44] We request that Congress require this for all health plans to make the treatment selection process as transparent and straightforward as possible.

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[36] https://www.kff.org/private-insurance/issue-brief/surprise-medical-bills/
[37] https://www.takecommandhealth.com/blog/surprise-er-bills-out-of-network-docs-texas-law
[38] https://www.kff.org/private-insurance/issue-brief/surprise-medical-bills/
[39] https://www.houstonchronicle.com/business/article/Surprise-Out-of-network-medical-bills-still-trap-13649786.php
[40] https://www.kff.org/private-insurance/issue-brief/surprise-medical-bills/
[41] https://nashp.org/state-legislators-take-action-to-protect-consumers-from-surprise-billing/
[42] https://www.covermymeds.com/main/insights/articles/2018-real-time-benefit-check-national-adoption-scorecard-uncovers-implementation-models-and-industry-adoption/
[43] https://www.covermymeds.com/main/insights/articles/2018-real-time-benefit-check-national-adoption-scorecard-uncovers-implementation-models-and-industry-adoption/
[44] https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-costs-modernizing-medicare

IX. Amend the Social Security Act to Encourage Greater Utilization of Telehealth

Telehealth utilization has been steadily increasing as more private health plans adopt it as a benefit and CMS takes steps to implement telehealth benefits in Medicare and Medicaid coverage.[45] Current data shows that telehealth services can provide patients with expanded access to health care services and remote specialists while saving them money on transportation expenses.[46] Additionally, health care services delivered via telehealth are often less expensive than in-person visits.[47] However, Section 1834(m) of the Social Security Act still poses an insurmountable barrier to full adoption of telehealth in Medicare. This provision sets strict parameters around the specific telehealth services that can be offered by Medicare and the types of geographic areas in which they can be utilized.

We ask Congress to remove this restriction to ensure that all Medicare beneficiaries can take advantage of this innovative method of health care delivery. This is particularly useful for rural Americans who do not have convenient access to primary care providers and specialists.[48] To the extent that the lack of rural broadband interferes with the availability of telehealth for rural populations, we request that Congress invest in rural broadband infrastructure to ensure that all Americans have access to health care services delivered via telehealth.

Thank you for your consideration of our recommendations and your commitment to ensuring that Americans have access to the best health care possible. We are available to discuss any of these recommendations further. You can reach me at jwylam@aimedalliance.org or (202) 559-0380.

Sincerely,

John Wylam
Staff Attorney

[45] https://mhealthintelligence.com/news/research-shows-telehealth-service-use-availability-on-the-rise
[46] https://www.urac.org/blog/telehealth-offers-cost-savings-opportunities-hospitals-and-patients
[47] https://www.urac.org/blog/telehealth-offers-cost-savings-opportunities-hospitals-and-patients
[48] https://www.beckershospitalreview.com/healthcare-information-technology/how-telemedicine-is-transforming-treatment-in-rural-communities.html