AIMED ALLIANCE

June 5, 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

Re: Comments on The Lower Health Care Costs Act of 2019 Discussion Draft

Chairman Alexander and the Members of the HELP Committee:

Aimed Alliance is a 501(c)(3) not-for-profit health policy organization that works to protect and enhance the rights of health care consumers and providers. Aimed Alliance is particularly interested in the issue of lowering health care costs and appreciates the opportunity to comment on the discussion draft of the Lower Health Care Costs Act ("Discussion Draft").

I. Surprise Medical Bills

Aimed Alliance applauds the Committee for taking action to address surprise medical bills. The issue of surprise out-of-network medical bills has become more prevalent in recent years. 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.[1]

The Discussion Draft proposes to end surprise out-of-network medical billing by holding patients harmless from such bills so that they are only required to pay the in-network cost-sharing amount for out-of-network emergency care, care provided by ancillary out-of-network practitioners, and out-of-network diagnostic services at in-network facilities.[2] Facilities and practitioners would be prohibited from sending balance bills to patients for more than the in-network cost-sharing amount.[3] Moreover, the Discussion Draft proposes to improve transparency by requiring that, if a patient is stabilized in an emergency room, the patient must be given advance notice of any out-of-network care, an estimate of the patient's costs for such out-of-network care, and referrals for alternative options for in-network care.[4] If the patient is not adequately informed, he or she would be protected from surprise bills or out-of-network cost-sharing.[5]

Though states have begun crafting policy solutions to resolve this problem, we thank Congress for considering action to ensure that this issue will be addressed consistently across the

[1] https://www.washingtonexaminer.com/policy/healthcare/new-analysis-details-extent-of-surprise-medical-bills-consumers-face
[2] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf
[3] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf
[4] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf
[5] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf

country so consumers can have certainty that they will not fall victim to surprise out-of-network medical bills.[6]

II. Encouraging the Greater Utilization of Telehealth

We would like to thank the Committee for encouraging expanded access to telehealth. Telehealth utilization has been steadily increasing as more private health plans adopt it as a benefit,[7] and the Centers for Medicare and Medicaid Services (CMS) recently implemented policies that would allow greater coverage of telehealth services in Medicare Advantage plans.[8] 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.[9] Additionally, healthcare services delivered via telehealth are often less expensive than in-person visits.[10] This is particularly useful for rural Americans who do not have convenient access to primary care providers and specialists.[11]

Aimed Alliance supports the Discussion Draft's proposal to authorize grants to evaluate, develop, and expand the use of technology-enabled collaborative learning and capacity building models to increase access to specialty health care services in medically underserved areas and for medically underserved populations.[12]

However, the Discussion Draft does not go so far as to address the insurmountable barriers to the full adoption of telehealth imposed by Section 1834(m) of the Social Security Act.[13] Section 1834(m) sets unreasonably strict parameters around the specific telehealth services that may be covered by Medicare and the types of geographic areas in which they can be utilized.[14] For example, Section 1834(m) prohibits coverage of services delivered via telehealth if the patient is not located in a rural health care setting, and it also limits coverage to services that are delivered in real-time, which excludes services that use asynchronous store-and-forward technology.[15] CMS has echoed our concern that Section 1834(m) creates barriers to the expansion of telehealth services.[16]

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[6] https://nashp.org/state-legislators-take-action-to-protect-consumers-from-surprise-billing/
[7] https://www.modernhealthcare.com/article/20171122/NEWS/171129962/telemedicine-is-still-hindered-by-limited-reimbursement
[8] https://www.cms.gov/newsroom/press-releases/cms-finalizes-policies-bring-innovative-telehealth-benefit-medicare-advantage
[9] https://www.urac.org/blog/telehealth-offers-cost-savings-opportunities-hospitals-and-patients
[10] https://www.urac.org/blog/telehealth-offers-cost-savings-opportunities-hospitals-and-patients
[11] https://www.beckershospitalreview.com/healthcare-information-technology/how-telemedicine-is-transforming-treatment-in-rural-communities.html
[12] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf
[13] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf
[14] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf
[15] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf
[16] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf

Though CMS has attempted to expand the availability of telehealth by regulation, CMS is bound by the statutory restrictions set forth in Section 1834(m) of the Social Security Act. Consequently, we are concerned that this provision will continue to prevent Medicare beneficiaries from taking full advantage of telehealth services. We request that Congress take action to amend or remove this statutory provision so that Medicare beneficiaries may have greater access to this innovative method of health care delivery.

III. Pharmacy Benefit Manager Reform

We thank the Committee for making efforts to regulate certain practices of pharmacy benefit managers (PBMs) that can contribute to increased prescription drug costs. PBMs often engage in spread pricing, where they charge a plan sponsor, health insurance plan, or patient more for a drug than the PBM paid to acquire that drug.[17] This price mark-up imposes barriers on patients' access to care so that PBMs may increase their profits. Additionally, pharmaceutical manufacturers often pay significant rebates and other fees to PBMs to ensure that their prescription drugs are covered on the PBMs' formularies.[18] These rebates are often paid for by raising the price of the drug at the point-of-sale.[19] With relatively few PBMs on the market, there is little incentive to keep the costs of these rebates low.[20] Unfortunately, PBMs have contributed to increases in prescription drug prices due to these types of opaque business practices and an alarming lack of competition.[21]

The Trump Administration has recognized how problematic these rebate incentives are and recently issued a proposed rule that would eliminate the safe harbor protection provided to drug manufacturers that offer pharmaceutical rebates to Part D plan sponsors, managed care organizations, and the PBMs that contract with them.[22] This proposal would also create new safe harbors for pharmaceutical rebates that are provided to pharmacies and passed onto consumers at the point-of-sale.[23]

While the Committee's discussion draft does not approach the issue from the same angle as the administration, it proposes to more closely regulate the activities and business practices of PBMs that often make medications unaffordable for patients. Aimed Alliance supports the draft legislation's requirement that PBMs pass on 100 percent of rebates to health plans, its prohibition on spread pricing, and its heightened transparency requirements for PBMs.

However, we would like to encourage the committee to also consider imposing a fiduciary duty on PBMs. Imposing on PBMs a fiduciary duty to the health plans will likely reduce health care costs because it will require PBMs to act in the best interest of the health plan. As mentioned, PBMs extract rebates from pharmaceutical manufacturers to get them to compete for their products to be placed on a health plan's formulary.[24] While the rebates are intended to be passed on to

[17] https://www.bloomberg.com/graphics/2018-drug-spread-pricing/
[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] https://www.healthaffairs.org/do/10.1377/hblog20180823.383881/full/
[21] https://www.statnews.com/2018/08/27/pharmacy-benefit-managers-good-or-bad/
[22] http://www.klgates.com/hhs-issues-proposed-rule-to-remove-safe-harbor-for-drug-rebates-02-11-2019/
[23] http://www.klgates.com/hhs-issues-proposed-rule-to-remove-safe-harbor-for-drug-rebates-02-11-2019/
[24] http://www.hr.cch.com/news/benefits/072710.asp

insurers, and ultimately, to consumers in the form of reduced premiums, much of these rebates is retained by PBMs as profit.[25] 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.

A fiduciary duty would effectively force PBMs to act in the best interest of the health plans with whom they contract. While some states have taken this approach, 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.[26] Though this decision is not binding on other states, 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 urge Congress to consider amending the ERISA statute to impose a fiduciary duty on PBMs to the health plans with whom they contract.

The Discussion Draft would also require PBMs to pass on 100 percent of any rebates or discounts to the plan sponsor, rather than to plan enrollees.[27] This is distinct from the recent proposed rule issued by the Department of Health and Human Services Office of the Inspector General on rebate safe harbor protections.[28] The proposed rule focused on curbing the adverse incentives that this rebate structure may create for PBMs by redirecting the flow of rebates to consumers at the point-of-sale.[29] The provisions in the Discussion Draft, however, do not address these incentives or 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.[30] Moreover, CMS states that the proposed rule will only apply to federal health care programs and not commercial insurance plans.[31] We request that Congress enact the policy proposed by CMS by statute to extend the benefits of pharmaceutical rebates to create uniformity across all types of health plans.

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

When patients cannot afford their medications, they may rely on financial assistance from pharmaceutical manufacturers and other third parties to meet their health plan's cost-sharing responsibilities and fill their prescriptions. The value of this financial assistance typically counts toward the health plan's deductible or maximum out-of-pocket limit, unless the health plan has implemented a copay accumulator program. Copay accumulator programs exclude the value of financial assistance from third parties, such as pharmaceutical manufacturers, from counting toward the health plan's deductible or maximum out-of-pocket limit.[32]

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[25] https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf
[26] https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf
[27] https://www.help.senate.gov/imo/media/doc/LHCC%20Act%20Discussion%20Draft%205_23_2019.pdf
[28] https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals
[29] http://www.klgates.com/hhs-issues-proposed-rule-to-remove-safe-harbor-for-drug-rebates-02-11-2019/
[30] https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf
[31] https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf
[32] https://aimedalliance.org/copay/

The Discussion Draft does not address the issue of copay accumulators in employer-sponsored insurance plans. Yet, copay accumulators have become increasingly common as a way for employer-sponsored plans to control health care costs by excluding the value of third-party payments from the calculation of an individual's deductible and maximum out-of-pocket costs.[33] 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.[34]

Copay Accumulator 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.[35] 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.[36] Without this assistance from third parties, many patients would not be able to afford the out-of-pocket costs associated with their medications.[37] 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 lower cost therapeutic equivalent or only have a similarly priced brand equivalent.[38] 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.[39] In addition to the health consequences, nonadherence can result in increased health care utilization, thereby increasing health-related expenditures.[40]

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.[41] 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 accumulators create barriers to health care access, and, with no legislative prohibition, are becoming more prevalent. Currently, Arizona, Virginia, and West Virginia have enacted laws requiring health plans to count payments made on behalf of enrollees towards their cost-sharing responsibilities, but the Employee Retirement Income Security Act of 1974 (ERISA) preempts those laws in employer-sponsored plans.[42] Moreover, in the 2020 Notice of Benefit and

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[33] https://www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html
[34] https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more
[35] https://chronicdiseasecoalition.org/insurance-discrimination-spreads-to-copay-accumulator-programs/
[36] https://chronicdiseasecoalition.org/insurance-discrimination-spreads-to-copay-accumulator-programs/
[37] https://chronicdiseasecoalition.org/insurance-discrimination-spreads-to-copay-accumulator-programs/
[38] https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more
[39] https://www.healthpopuli.com/2017/02/02/16896/
[40] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5780689/
[41] https://www.nastad.org/sites/default/files/Uploads/2018/copayaccumulatorfactsheet.pdf
[42] https://www.rollcall.com/news/congress/new-state-laws-highlight-escalating-battle-war-drug-pricing

Payment Parameters, CMS has allowed commercial plans to implement copay accumulator programs, but restricted the use of such programs to brand drugs when generic equivalents are available.[43] We urge Congress to take legislative action to prohibit the implementation of copay accumulator programs in all 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*.[44]

V. Conclusion

Thank you for considering our recommendations and your commitment to ensuring that Americans have access to affordable treatments. 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

[43] https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020
[44] https://aimedalliance.org/wp-content/uploads/2018/11/Employers-Beware.pdf