AIMED ALLIANCE

November 8, 2019

Congresswoman Nancy Pelosi
Speaker, U.S. House of Representatives
Washington, D.C. Office
1236 Longworth H.O.B.
Washington, D.C. 20515

Senator Chuck Grassley
U.S. Senate
Washington, D.C. Office
135 Hart Senate Office Building
Washington, D.C. 20510

Senator Mitch McConnell
Majority Leader, U.S. Senate
Washington, D.C. Office
317 Russell Senate Office Building
Washington, D.C. 20510

Congressman Frank Pallone
U.S. House of Representatives
Washington, D.C. Office
2107 Rayburn H.O.B.
Washington, D.C. 20515

Congressman Kevin McCarthy
Minority Leader, U.S. House of Representatives
Washington, D.C. Office
2468 Rayburn House Office Building
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Congressman Greg Walden
U.S. House of Representatives
Washington, D.C. Office
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Senator Chuck Schumer
Minority Leader, U.S. Senate
Washington, D.C. Office
322 Hart Senate Office Building
Washington, D.C. 20510

Congressman Ron Wyden
U.S. House of Representatives
Washington, D.C. Office
221 Dirksen Senate Office Bldg.
Washington, D.C., 20510

Re: Comment on H.R. 3, Lower Drug Costs Now Act of 2019

Dear Speaker Pelosi, Majority Leader McConnell, Minority Leader McCarthy, Minority Leader Schumer, Senator Grassley, Representative Pallone, Representative Walden, Representative Wyden:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for the opportunity to provide feedback on H.R. 3, the Lower Health Care Costs Now Act of 2019. Aimed Alliance is committed to finding practical solutions to lower health care costs for consumers while simultaneously ensuring that they have access to high quality care. We commend the drafters for their many efforts to achieve these goals within the bill, including by establishing a cap on out-of-pocket costs for Medicare Part D beneficiaries. However, we are concerned that the amendment that changes the reimbursement rate for biosimilar biologic products from the average sales price (ASP) + 6% to ASP + 8% may actually increase health care costs and compromise access to appropriate care.

I. Out-of-Pocket Cap

Aimed Alliance supports the proposed $2,000 cap on out-of-pocket costs for Medicare Part D. This cap will help to make prescription medications more affordable for Part D beneficiaries, which will in turn, increase adherence to treatment plans and improve health outcomes. As you know, in 2020, millions of seniors and individuals with disabilities could face a large spike in what they pay for medications covered through their Medicare Part D plans, a situation commonly known as the Part D "out-of-pocket cliff." In

2020, the Part D cliff is set to reach $6,350 for individuals who enter the Part D coverage gap, also referred to as the "donut hole," unless Congress takes action.[1]

The Kaiser Family Foundation reported that in 2016, more than 5.2 million Medicare beneficiaries reached the coverage gap,[2] providing a barometer of the number of seniors and individuals with disabilities at financial risk if the out-of-pocket cliff occurs in 2020. Although most Part D beneficiaries do not reach the catastrophic phase of coverage, the estimated 10 percent who do face very high out-of-pocket spending during the coverage gap, leading to significant financial liability in a short period of time.

Consequently, if the out-of-pocket cliff occurs, beneficiaries with life-threatening illnesses are likely to delay or forgo needed treatments. Demonstrating what is possible, a study by IMS Health showed that even among individuals with cancer, the likelihood of abandoning medication increases four-fold when the cost share is greater than $500.[3] Studies also show that when patients abandon their medicines, they experience poorer health outcomes due to avoidable disease progression, health complications, and poorer quality of life.[4] According to a review published in the Annals of Internal Medicine, the decline in health outcomes resulting from patients abandoning treatment costs the health system up to $289 billion in additional medical expenditures annually.[5] By implementing a cap on out-of-pocket costs for Medicare Part D prescriptions, the Part D cliff can be avoided. As such, we thank Congress for recognizing the challenge that high prescription medication costs present for Medicare beneficiaries and support the $2,000 out-of-pocket cap.

II. ASP + 8% Reimbursement Rate for Biosimilar Biologic Products

Aimed Alliance supports the development and adoption of biosimilar products. These products provide additional treatment options for patients and increase competition, which can result in lower drug prices. However, Aimed Alliance cautions against adopting the amendment to change the reimbursement rate for biosimilar products from the ASP of the reference biologic + 6% to ASP + 8%. The proposed amendment would increase reimbursement rates for practitioners who administer biosimilars to Medicare beneficiaries, with the hope of increasing market uptake of biosimilar products.

While we fully support the adoption of biosimilars in the marketplace, this amendment will increase health care costs for both patients and the Medicare system. Medicare Part B beneficiaries are required to pay 20 percent of the Medicare-approved amount after their deductible is met. Under this amendment, that Medicare-approved amount will be 2% more for biosimilars than for biologics. Therefore, patients will be required to pay more for biosimilars than biologics, thereby increasing their health care costs and defeating the purpose of biosimilars, which are intended to be a lower cost alternative to their reference products.

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[1] MapRX. Fifteen Years of Part D: Gaining Perspective on the Medicare Part D. Benefit. September 2018. Accessible at: https://maprx.info/wp-content/uploads/2018/09/Fifteen-Years-of-Part-D-Gaining-Perspective-on-theMedicare-Prescription-Drug-Benefit.pdf

[2] Henry J. Kaiser Family Foundation. Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead. August 21, 2018. Accessible at: https://www.kff.org/medicare/issue-brief/closing-the-medicare-partd-coverage-gap-trends-recent-changes-and-whats-ahead/

[3] "Global Oncology Trend Report: A Review of 2015 and Outlook to 2020." IMS Health, June 2, 2016. Accessible at: https://morningconsult.com/wp-content/uploads/2016/06/IMS-Institute-Global-Oncology-Report-05.31.16.pdf

[4] National Council on Patient Information and Education. Enhancing prescription medicine adherence: a national action plan. National Council on Patient Information and Education; Rockville, MD: 2007.

[5] Viswanathan M, et al. "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." Ann Intern Med. 2012 Dec 4;157(11):785-95.

Additionally, the ASP + 8% amendment assumes that practitioners' prescribing practices are motivated by reimbursement rates, rather than prescribing the treatment that they think its most appropriate for their patients. Yet, research shows that there is not a strong, positive correlation between reimbursement rates and utilization.[6] To the extent that it does influence certain practitioners to prescribe biosimilars over their reference products based solely on reimbursement rate, it could result in nonmedical switching. Nonmedical switching occurs when a health insurer requires a stable patient to switch from his or her current, effective medication to an alternative therapy. While biosimilars are safe, effective, and highly similar to their reference products, some patients may need to remain on their current, effective therapy. Forcing a patient to switch treatments can upset his or her medication stability, which can expose the patient to avoidable negative health outcomes and increased costs. This can be particularly detrimental for patients with chronic conditions that require treatment with biologics. Treatment with a biologic is complex and should be based on what is most appropriate for the patient.[7] A law that incentivizes practitioners to make prescribing decisions based on payment – rather than the needs of their patients – may consequently compromise access to appropriate care. This can result in diminished efficacy of treatment, medication-related side effects, and increased health care utilization.[8]

III. Conclusion

For the foregoing reasons, Aimed Alliance thanks Congress for its commitment to lowering health care costs for Americans, but cautions against increasing the reimbursement rate for biosimilar biologic products to ASP + 8%. If you have any questions or comments, you can reach me at policy@aimedalliance.org or 202-559-0380.

Kind Regards,

Taylor Kelly
Policy Advisor

[6] Xcenda. Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount? AmerisourceBergen, September 19, 2018. Accessible at: https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_provider-utilization_final.pdf?la=en&hash=10C08EB05341DA86090D8ED3B4DC7030ACAE852B

[7] BIO Principles on Patient Safety in the Substitution of Biologic Products. Accessible at: https://www.bio.org/advocacy/letters/bio-principles-patient-safety-substitution-biologic-products.

[8] Gibofsky A. Effects of non-medical switching on outcomes patients prescribed tumor necrosis factor inhibitors. September 21, 2017. Accessible at: https://www.tandfonline.com/doi/full/10.1080/03007995.2017.1375903