



November 26, 2021

**Via Electronic Communication**

Senator Tom Carper  
513 Hart Senate Office Building  
Washington, DC 20510

Senator Patty Murray  
154 Russell Senate Office Building  
Washington, D.C. 20510

Senator Chris Coons  
218 Russell Senate Office Building  
Washington, DC 20510

Senator Krysten Sinema  
317 Hart Senate Office Building  
Washington, DC 20510

Senator Catherine Cortez Masto  
313 Hart Senate Office Building  
Washington, DC 20510

Senator Chuck Schumer  
322 Hart Senate Office Building  
Washington, D.C. 20510

Senator Bob Menendez  
528 Hart Senate Office Bldg.  
Washington, DC 20510

Senator Ron Wyden  
221 Dirksen Senate Office Bldg.  
Washington, D.C., 20510

Re: Build Back Better

Dear Senators Carper, Coons, Cortez Masto, Menendez, Murray, Sinema, Schumer, and 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. We are writing to express both support and concerns for many provisions within, the Build Back Better Act (BBB). Specifically:

- (1) We support increased transparency of pharmacy benefit managers;**
- (2) We support expanding access to healthcare;**
- (3) We support expanding protections for Medicare beneficiaries;**
- (4) We do not support drug pricing reforms that could impair patient access to innovative medications; and**
- (5) We do not support incentivizing biosimilars in a manner that would penalize providers and result in nonmedical switching.**

In the final version of the BBB, we ask that (1) the provisions we support remain in; and (2) our concerns are addressed.

- I. Transparency of pharmacy benefit manager practices can assist in decreasing the cost of prescription drugs by increasing cost transparency**

Build Back Better Section 26002 would require pharmacy benefit managers (PBMs) to disclose information on the administration of prescription drug benefits, rebates, fees, and other compensation paid to PBMs to group plans every six months.<sup>1</sup> Section 30606 would allow the Secretary of Health and Human Services (HHS), in consultation with the Secretary of Treasury and Secretary of Labor, to enforce this reporting requirement.

Aimed Alliance supports these provisions. PBMs serve as middlemen between plan sponsor, drug manufacturers, and pharmacies by negotiating discounts and rebates, developing formularies, contracting with pharmacies, and processing and paying claims.<sup>2</sup> While PBMs claim that they lower drug prices, the lack of regulation and transparency in this field has resulted in increased administrative waste through the drug distribution chain, higher drug prices, and windfall profits for PBMs at the expense of plan enrollees.<sup>3</sup> Aimed Alliance encourages Congress to ensure these transparency and enforcement measures are included in the final legislation as they will increase drug pricing transparency and can ultimately help reduce patient costs.

## **II. Expanding Access to Healthcare Coverage**

### **A. Establishing a Health Insurance Affordability Fund can help make insurance premiums more affordable for patients.**

Section 20601 of BBB would establish a Health Insurance Affordability Fund that would be available to states in 2023-2025 and would allow states to create a reinsurance program. It would also allow the Centers for Medicare and Medicaid Services (CMS) to establish a reinsurance fund for states that do not create their own reinsurance program.<sup>4</sup>

When an individual is enrolled in a health plan, they are responsible for certain cost-sharing requirements (e.g., deductible). Once a plan enrollee's deductible is met, their plan will cover all if not most of their expenses.<sup>5</sup> Patients may still be responsible for certain copays or coinsurance, depending on the plan type. The cost of coverage after the deductible is met and coinsurance is used can be expensive for health plans, especially with respect to patients with serious, debilitating, and chronic conditions. Therefore, health plans have their own form of insurance known as reinsurance.<sup>6</sup> Reinsurance programs help health plans cover the cost of enrollees who have high health care costs.<sup>7</sup> Reinsurance not only helps to lower health plan costs, but it can also have a positive impact more broadly by reducing individual premiums,

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<sup>1</sup> *Section-by-Section*, [https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Section-by-Section*, [https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>5</sup> *Reinsurance Basics: Considerations as States Look to Reduce Private Market Premiums*, <https://www.cbpp.org/research/health/reinsurance-basics-considerations-as-states-look-to-reduce-private-market-premiums>.

<sup>6</sup> *What is reinsurance?*, <https://www.healthinsurance.org/glossary/reinsurance/#:~:text=Reinsurance%20is%20essentially%20insurance%20for,enrollees%20have%20high%20cost%20claims>.

<sup>7</sup> *Id.*

encouraging small groups to offer coverage, and ensuring coverage of people with disabilities and chronic conditions that can require complex care.<sup>8</sup>

Currently, fourteen states have operational reinsurance programs, and two more states are adding programs in 2022 and 2023.<sup>9</sup> Further, states such as Kansas and Connecticut have consistently been considering developing reinsurance programs but have failed to pass legislation on the subject.<sup>10</sup> The inclusion of this provision will incentivize states to develop a reinsurance program and reduce premiums for consumers making health insurance more affordable.

### **B. Reducing cost-sharing for individuals 138 percent below the federal poverty line can help ensure more Americans have health coverage.**

Section 30601 of BBB would address the current Medicaid coverage gap by providing cost-sharing assistance through the federal exchange to individuals 138 percent below the federal poverty level.<sup>11</sup> During a global pandemic, it is now more important than ever to ensure that individuals have access to health insurance and can seek care when necessary. One way to do this is through expanding coverage to vulnerable individuals who do not qualify for Medicaid and cannot afford unsubsidized health insurance. While many states have already expanded their Medicaid programs under the Patient Protection and Affordable Care Act (ACA) to include individuals who are 138 percent below the federal poverty line, twelve states still have not. Patients in these states have been left unsupported in the pandemic, crucially at a time when many have lost their jobs and associated health benefits.<sup>12</sup> Notably, the lack of expansion has resulted in more than two million individuals being unable to afford health care.<sup>13</sup> Therefore, Aimed Alliance supports the expansion of cost-sharing assistance to help provide coverage to low-income patients who do not qualify for their state-based Medicaid programs.

### **C. Expansion of healthcare coverage for post-partum women can help address racial disparities and improve maternal health outcomes.**

Section 30721 of BBB would expand coverage for postpartum women for up to 12 months.<sup>14</sup> Aimed Alliance supports this provision and recognizes that expanding coverage to ensure that women have health insurance beyond 60 days post-pregnancy and throughout their reproductive years can help address mental health disorders and ensure early detection and

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<sup>8</sup> *Reinsurance and its Role in Increasing Access to Health Insurance for Workers with Disabilities*, <https://www.dol.gov/sites/dolgov/files/odep/research/reinsurancetoolkit.pdf>.

<sup>9</sup> *What is reinsurance?*,

<https://www.healthinsurance.org/glossary/reinsurance/#:~:text=Reinsurance%20is%20essentially%20insurance%20for,enrollees%20have%20high%2Dcost%20claims>.

<sup>10</sup> *Id.*

<sup>11</sup> *Section-by-Section*,

[https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>12</sup> *The Coverage Gap: Uninsured Poor Adults in States that Do No Expand Medicaid*,

<https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/> .

<sup>13</sup> *Id.*

<sup>14</sup> *Section-by-Section*,

[https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

treatment of conditions that place women at higher-risks for pregnancy-related deaths and complications.<sup>15</sup>

In addition, Section 30721 would also allow for coordinated care of pregnant and postpartum women through home health visits.<sup>16</sup> This provision is important to addressing racial disparities in maternal health as studies have found that racial biases impair care for Black and Hispanic women, which ultimately leads to less favorable health outcomes.<sup>17</sup> By allowing for postpartum care to occur via in-home evidence-based programs, women are more likely to receive community driven and culturally competent care.<sup>18</sup>

In the United States, Black, American Indian, and Alaskan Native women are two to three times more likely than white women to experience pregnancy-related deaths.<sup>19</sup> While Medicaid currently covers the cost of four in ten births, it only covers postpartum care for 60 days.<sup>20</sup> Sixty days is not sufficient to cover a woman's postpartum care. Historically, postpartum care has focused on the traditional six and eight-week visits that were captured in the first 60 days after birth, however, today's postpartum care has expanded to provide a more comprehensive approach to postpartum health.<sup>21</sup> The modern comprehensive approach to postpartum care includes following up on pregnancy complications, managing chronic conditions, family planning, and addressing mental health conditions.<sup>22</sup> This comprehensive approach to postpartum care can take multiple visits that can last up to a year or longer.<sup>23</sup> The consistency in care is important for postpartum women's mental health as 50 percent of women receiving treatment for postpartum depression report still needing treatment one-year after pregnancy.<sup>24</sup> Therefore, Aired Alliance supports the inclusion of these provisions.

#### **D. Expanding health care coverage for children for 12-months can increase positive outcomes for children.**

Section 30741 of BBB would expand coverage for children enrolled in a Medicaid plan or the Children's Health Insurance Program (CHIP) for 12 consecutive months.<sup>25</sup> This provision is crucial as it ensures that children do not lose their health insurance as a result of mid-year

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<sup>15</sup> <https://www.kff.org/womens-health-policy/issue-brief/expanding-postpartum-medicaid-coverage/> .

<sup>16</sup> *Section-by-Section*,

[https://rules.house.gov/sites/democrats.rules.house.gov/files/Section by Section BBB RCP117-18 .pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>17</sup> *Addressing Racial and Ethnic Disparities in Maternal and Child Health*,

<https://www.chcs.org/resource/addressing-racial-and-ethnic-disparities-in-maternal-and-child-health-through-home-visiting-programs/>.

<sup>18</sup> *Id.*

<sup>19</sup> *Racial Disparities in Maternal and Infant Health: An Overview*, <https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-maternal-infant-health-overview/>

<sup>20</sup> *Expanding Postpartum Medicaid Coverage*, <https://www.kff.org/womens-health-policy/issue-brief/expanding-postpartum-medicaid-coverage/> .

<sup>21</sup> *How long does postpartum depression last?*. <https://www.medicalnewstoday.com/articles/271217#risk-factors> .

<sup>22</sup> *Expanding Postpartum Medicaid Coverage*, <https://www.kff.org/womens-health-policy/issue-brief/expanding-postpartum-medicaid-coverage/> .

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Section-by-Section*,

[https://rules.house.gov/sites/democrats.rules.house.gov/files/Section by Section BBB RCP117-18 .pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

household income changes. Studies have found that when children are uninsured, they have poorer health outcomes and are more likely to miss school.<sup>26</sup> However, when children have insurance, they have better health outcomes, higher quality of childcare, and their families save an estimated \$2886 per child per year.<sup>27</sup> Studies have also found that children who have health insurance coverage are more likely to experience positive long-term outcomes in educational attainment and economic success.<sup>28</sup> Therefore, Amed Alliance supports Congress's inclusion of this provision.

#### **E. Expanding Medicaid coverage to inmates 30 days prior to release from incarceration.**

Section 30741 of BBB would extend Medicaid eligibility to individuals who are incarcerated 30 days prior to release.<sup>29</sup> Allowing incarcerated individuals to have access to care prior to release ensures that as they transition out, they have immediate access to health care, including mental health services, addiction treatment, and other support services.<sup>30</sup> Providing access to these services is crucial in addressing the mental health crisis and ensuring released individuals are supported in rebuilding their lives. Forty percent of individuals who are incarcerated have chronic diseases that are often first diagnosed at intake.<sup>31</sup> However, individuals who are incarcerated struggle to access treatment for these chronic conditions as many states still require copays for visits.<sup>32</sup> Copays can range from \$2 to \$5 per visit.<sup>33</sup> For individuals who are incarcerated, this can be a substantial amount of money, as hourly wages for jobs within prisons and jails are between 14 and 63 cents per hour.<sup>34</sup> Thus, cost is often a barrier to receiving treatment for chronic conditions while incarcerated. The repercussions of denials in access to care while incarcerated extend into an individual's release. A study in Washington found that, two weeks post release, formerly incarcerated individuals were 129 percent more likely to die from a drug overdose than other individuals in the state.<sup>35</sup> This study demonstrates the serious substance use crisis that recently released individuals are experiencing and the urgency to ensure

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<sup>26</sup> *Reasons Why Healthcare for Children is So Important*, <https://www.freewayinsurance.com/knowledge-center/health-insurance/understanding-health-insurance/reasons-why-healthcare-for-children-is-so-important/>.

<sup>27</sup> *The health and healthcare impact of providing insurance coverage to uninsured children: A prospective observational study*, <https://bmcpublihealth.biomedcentral.com/articles/10.1186/s12889-017-4363-z>.

<sup>28</sup> *Key Issues in Children's Health Coverage*, <https://www.kff.org/medicaid/issue-brief/key-issues-in-childrens-health-coverage/>.

<sup>29</sup> *Section-by-Section*,

[https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>30</sup> *Committee discusses bill to extend Medicaid coverage to inmates prior to release*,

<https://stateofreform.com/news/2021/04/committee-discusses-bill-to-extend-medicaid-coverage-to-inmates-prior-to-release/#:~:text=%E2%80%9CThe%20Medicaid%20Reentry%20Act%20would,addiction%20treatment%2C%20and%20COVID%20testing>.

<sup>31</sup> *40% of incarcerated people have chronic conditions – how good is the health care they get behind bars?*,

<https://whyy.org/segments/why-good-health-care-in-u-s-prisons-may-be-hard-to-come-by/>.

<sup>32</sup> *The steep cost of medical co-pays in prison puts health at risk*,

<https://www.prisonpolicy.org/blog/2017/04/19/copays/>.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Committee discusses bill to extend Medicaid coverage to inmates prior to release*,

<https://stateofreform.com/news/2021/04/committee-discusses-bill-to-extend-medicaid-coverage-to-inmates-prior-to-release/#:~:text=%E2%80%9CThe%20Medicaid%20Reentry%20Act%20would,addiction%20treatment%2C%20and%20COVID%20testing>.

continuity of care and immediate access to substance use treatment at release. Thus, Aimed Alliance supports this expansion of Medicaid and encourages Congress to include this provision in the final bill.

### **III. Limiting Cost-Sharing for Medicare Beneficiaries**

#### **A. Placing a cap on Medicare Part D can help ensure patients have access to necessary medications.**

Section 139201 of BBB would reduce the annual out-of-pocket limit for Medicare Part D beneficiaries to \$2,000 by 2024.<sup>36</sup> This requirement would undo previous years' price increases that have risen above inflation and across thousands of drugs. For example, in 2021, Medicare beneficiaries had to pay \$4,130 on covered drugs before beneficiaries were then limited to a co-pay of 25 percent of their drug costs.<sup>37</sup> There is no out-of-pocket cap for the Medicare program once beneficiaries begin paying the 25 percent. This high cost of prescription drugs for Medicare Part D can be especially harmful to the 50 percent of Medicare beneficiaries living on an estimated \$26,000 a year.<sup>38</sup> Aimed Alliance supports this provision because these changes make prescription medications more affordable, and therefore, more accessible, for Medicare beneficiaries.

#### **B. Spreading out-of-pocket costs for Medicare Part D and Medicare Advantage plans throughout the year can help ensure patients can afford their treatments.**

Section 13902 of the BBB would allow for Medicare Part D and Medicare Advantage beneficiaries to pay their annual out-of-pocket costs of \$2,000 through installment payments throughout the year when their first fill of a prescription is estimated to be equal to or above the monthly out-of-pocket limit.<sup>39</sup> In 2019, the National Health Council reported that 45 percent of Medicare beneficiaries pay over \$1,000 a month for their prescription medications, which is not affordable for many.<sup>40</sup> Permitting beneficiaries to spread the cost of medications throughout the plan year can help ensure cost is not a barrier to patients accessing their medications. As with an out-of-pocket cap, Aimed Alliance supports this provision because such changes make prescription medications more affordable for patients.

### **IV. Prescription Drug Pricing for Medicare Beneficiaries**

#### **A. Federal drug price negotiations will stifle innovation and lead to fewer new drugs available to meet currently unmet needs of vulnerable patient populations.**

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<sup>36</sup> *Section-by-Section*, [https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>37</sup> *Costs in the coverage gap*, <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap> .

<sup>38</sup> *How Many Seniors Live in Poverty*, <https://www.kff.org/medicare/issue-brief/how-many-seniors-live-in-poverty/> .

<sup>39</sup> *Section-by-Section*, [https://rules.house.gov/sites/democrats.rules.house.gov/files/Section\\_by\\_Section\\_BBB\\_RCP117-18\\_.pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section_by_Section_BBB_RCP117-18_.pdf).

<sup>40</sup> *Updated: Smoothing the Out Of Pocket Cap*, <https://nationalhealthcouncil.org/blog/blog-updated-smoothing-out-pocket-cap/> .

Section 139001 of BBB would allow HHS to negotiate for certain Part B and D brand drugs beginning in 2025.<sup>41</sup> The legislation would impose price ceilings ranging from 40 percent to 74 percent of the non-federal average manufacturer price (AMP) depending on how long the drug has been on the market.<sup>42</sup> Payments to providers for Part B drugs with negotiated prices would be 106 percent of the “maximum fair price” (which is based on the non-federal AMP) rather than the 106 percent of the average sale price. These negotiations would not apply to orphan drugs, certain drugs made by small biotech companies, or vaccines.<sup>43</sup>

Aimed Alliances supports efforts that reduce the cost of prescription drugs for consumers but does not support forced negotiations with manufacturers that would decrease access to innovative medicines. While we support the exclusion of orphan drugs, small biotech drugs, and vaccines from price negotiations as this ensures that access to such treatments and vaccines are not impaired, we are concerned that this forced negotiation for other treatments will impair patient access. Specifically, the Congressional Budget Office (CBO) found that adopting drug price negotiations would decrease the number of new drugs to market by four drugs per year between 2031-2041. The CBO score estimated that the reduction in new drugs to market would continue increase to five in the decades after 2041.

Furthermore, the term “non-federal average manufacturer price” refers to the “weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account— (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.”<sup>44</sup> It is a calculation used by the U.S. Department of Veterans’ Affairs (VA) when determining drug prices for VA benefits.<sup>45</sup> In making its calculations, the VA also uses the quality adjusted life year (QALY) to measure the value of a drug treatment and determine drug pricing. Aimed Alliance reiterates its longstanding recommendation against relying on QALY measures to evaluate any treatment. The use of QALY measures to evaluate the value of a treatment raises significant ethical concerns. QALY measures put a price tag on the value of human life that merely reflects the individual’s diagnosis and deems those with chronic, debilitating, and rare conditions as being worth less than those with common conditions. They treat individuals’ lives and health as a commodity and ignore patients’ and practitioners’ individualized concept of the value of treatment. QALYs are often used to justify coverage limitations and utilization management policies, such as prior authorization and step therapy programs, that prevent individuals from obtaining treatments that are most appropriate for their individualized needs. For these reasons, we encourage Congress to 1) pursue other drug pricing reforms; and 2) explicitly ban CMS from using the QALY in future drug pricing reforms.

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<sup>41</sup> *Section-by-Section*,

[https://rules.house.gov/sites/democrats.rules.house.gov/files/Section by Section BBB RCP117-18 .pdf](https://rules.house.gov/sites/democrats.rules.house.gov/files/Section%20by%20Section%20BBB%20RCP117-18_.pdf).

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> 38 U.S.C. 8126(h)(5)

<sup>45</sup> 38 U.S.C. 8126

**C. Placing price control on drug manufacturers can impair the research and development of innovative medications for patients with serious health conditions.**

Section 139002 of BBB would impose an excise tax on manufacturers who do not comply with negotiation requirements. Specifically, manufacturers would be subject to a civil penalty beginning at 65 percent and increasing by 10 percent each quarter.<sup>46</sup> As such, the Medicare negotiation provision are akin to anti-competitive government price controls rather than a true negotiation.

Price controls stifle innovation. A 2019 study found that patients in countries that had price control policies had significantly less access to new medications. Specifically, the study found that patients in Germany only had access to 64 percent of new medications; patients in the United Kingdom only had 51 percent of new medications; and patients in France and Canada only had access to 46 percent of new medications.<sup>47</sup> Meanwhile, patients in the United States had access to 90 percent of new medications during that same period.<sup>48</sup> While this excise tax could generate more cost savings, the tax will likely impair innovation and discovery as innovation investors will leave the health industry for other markets with larger returns.<sup>49</sup> Thus, while Aimed Alliance supports reducing drug prices, we do not support efforts that result in fewer innovative medications coming to market for patients with unmet medical needs.

**D. Inflation Rebates will diminish the ability of patients to receive new innovative treatments.**

Section 13901 of BBB would require manufacturers to pay rebates if the cost of their drugs increases faster than inflation. In particular, they would have to pay back the revenue that was generated from drug prices. Inflation rebates can harm consumer access to necessary medications given that the impact on drug manufacturer revenues can impair the ability of manufacturers to research and develop new medications. Additionally, the loss in profits to manufacturers could cause manufacturers to increase the launch price of new medications, resulting in patients paying higher costs to receive medications. Thus, Aimed Alliance encourages Congress to seek other proposals to reduce the cost of prescription drugs and compliance with pricing reform.

**E. Repealing the rebate rule will increase Medicare Part D premiums.**

Section 13901 of BBB would repeal the Prescription Drug Rebate Rule (Rebate Rule). Enacted during the previous administration, the Rebate Rule had addressed rebates that drug

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<sup>46</sup> <https://docs.house.gov/meetings/BU/BU00/20210925/114090/BILLS-117pih-BuildBackBetterAct.pdf> at 2406; <https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/>.

<sup>47</sup> <https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Gov-Mandated-Price-ControlFINAL.pdf> at p. 1.

<sup>48</sup> <https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Gov-Mandated-Price-ControlFINAL.pdf> at p. 1.

<sup>49</sup> <https://www.cato.org/commentary/problems-price-controls>.



manufacturers provide to PBMs so that their drugs are included in the PBMs' formularies.<sup>50</sup> Aimed Alliance had supported the inclusion of the rebate rule as we believed it would incentivize drug makers to lower drug prices while simultaneously disincentivizing PBMs to give more costly medications preferential formulary placement based primarily on the value and volume of rebates collected.<sup>51</sup> If maintained, the rebate rule would eliminate the safe harbor protection that allows PBMs to selectively determine which drugs are listed on formularies and encourage drug manufacturers to offer more options in formularies. Ultimately, by lowering drug prices and decreasing middlemen rebates, consumers could benefit from the discounts that are negotiated on their behalf and have access to a wider variety of medications. Thus, we encourage Congress to maintain the Rebate Rule.

#### **F. Increasing reimbursement rates for biosimilars could result in nonmedical switching.**

Section 139404 of BBB requires CMS to compensate health care providers who administer biosimilars to Medicare Part B beneficiaries at a rate of average sales price (ASP) plus eight percent. In contrast, providers who administer reference list biologics would receive ASP plus six percent. This provision is intended to incentivize providers to administer biosimilars instead of biologics. 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 increasing the reimbursement rate solely for biosimilars.

While we fully support the use of biosimilars in the marketplace, we do not support increasing the reimbursement rate from six percent to eight percent as it will increase costs for Medicare Part B beneficiaries, and it perpetuates a misconception on how providers determine which medications should be prescribed. First, Medicare Part B beneficiaries are required to pay 20 percent of the negotiated price after their deductible is met. Therefore, if the ASP is increase from six percent to eight percent, beneficiaries cost sharing will also be increased by two percent. Thus, although this provision is intended to lower costs, in practice it would result in increased cost for patients. Second, the increase from six percent to eight percent relies on the assumption that providers are prescribing drug based on their reimbursement rate. However, studies have shown that there is not a strong, positive correlation between reimbursement rates and utilization.<sup>52</sup> Moreover, even if such an incentive did influence providers prescriptions this could have negative impacts on patients and result in non-medical switching. Non-medical switching occurs when stable patients are forced to switch medications for financial rather than

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<sup>50</sup> *Congress to add delay to Part D rebate rule to help pay for infrastructure package*, <https://www.fiercehealthcare.com/payer/pharma-pushes-back-congress-flirtation-delaying-rebate-rule-to-help-pay-for-infrastructure#:~:text=The%20rebate%20rule%20was%20released,from%20federal%20anti%20kickback%20laws>.

<sup>51</sup> *Docket OIG-0936-P Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription and Creation fo New Safe Harbor Protections for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceutical and Certain Pharmacy Benefit Manager Services*, at 1, <https://aimedalliance.org/wp-content/uploads/2019/04/FINAL-Rebate-Safe-Harbor-Comment-190408.pdf> .

<sup>52</sup> *Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount?*, [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](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).

medical reasons. While biosimilars are safe, effective, and highly similar to their reference product they are just that, similar not the same. Therefore, some patients may be unable to switch from a biologic to a biosimilar without experience negative health outcomes and increased healthcare costs. Treatment with biologics is complex and the providers judgement should be based on clinical experience rather than financial incentives. Therefore, Amed Alliance urges congress to keep the reimbursement rate at ASP plus six percent.

In conclusion, Amed Alliance supports Congress efforts to lower the price of prescription medication and expand health insurance coverage; however, we reiterate that decreases in drug pricing should limit innovation and deprive patients access to life saving medications.

Sincerely,

Ashira Vantrees  
Policy Manager