



December 28, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: CMS-5528-ANPRM, Document Number 2018-23688

Dear Ms. Verma:

Aimed Alliance is a non-profit organization that seeks to protect and enhance the rights of health care consumers and providers. Aimed Alliance thanks the Centers for Medicare and Medicaid Services (“CMS”) for the opportunity to comment on the Advanced Notice of Proposed Rulemaking (“ANPRM”) titled “International Pricing Index Model for Medicare Part B Drugs.”

We applaud CMS for setting forth bold proposals attempting to reduce the cost of health care in the United States. However, for the reasons set forth below, the demonstration project described in the ANPRM (“Demonstration Project”) may be an overreach of CMS’s statutory authority and could have serious unintended consequences for Medicare beneficiaries and providers. Therefore, we request that CMS implement our recommendations and address our concerns.

## **I. Statutory Authority**

This Demonstration Project does not appear to be within the scope of Center for Medicare and Medicaid Innovation’s (“CMMI”) authority, and we, therefore, request that CMS halt it or modify it to ensure that it is patient-centered. Congress created CMMI to “test innovative payment and service delivery models to reduce program expenditures ...while preserving or enhancing the quality of care” for those individuals who receive Medicare, Medicaid, or Children’s Health Insurance Program (“CHIP”) benefits.”<sup>1</sup> More specifically, CMMI tests “models that improve care, lower costs, and better align payment systems to support patient-centered practices.”<sup>2</sup>

While the Demonstration Project would enact a country-wide cost-containment strategy for the government’s Medicare Part B expenditures, it would neither preserve nor enhance the quality of care for Medicare beneficiaries—contrary to CMMI’s purpose. As such, the Demonstration Project places greater emphasis on the government’s budget than the needs of patients. Rather than improving quality care or reducing costs for patients, the project could result in patients losing access to their providers and medications, traveling long distances to

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<sup>1</sup> 42 U.S.C. § 1315a.

<sup>2</sup> <https://innovation.cms.gov/About/index.html>

obtain treatment, or paying more out-of-pocket for treatments and services, as discussed below. Therefore, CMS should revisit the fundamental design of this Demonstration Project to ensure that it is patient-centered and emphasizes access to quality care.

## **II. Uncertainty about the Patient Protection and Affordable Care Act**

The Demonstration Project should be placed on hold until the U.S. Supreme Court determines the fate of the Patient Protection and Affordable Care Act (“ACA”). On December 14, 2018, the Federal District Court in the Northern District of Texas ruled in *Texas v. United States* that the ACA, in its entirety, was unconstitutional.<sup>3</sup> The case is likely to be appealed in the U.S. Court of Appeals for the Fifth Circuit and then potentially in the U.S. Supreme Court as well. While the ACA remains enforceable during the appeals process, the ultimate fate of the law is uncertain.<sup>4</sup>

CMMI was established by section 1115A of the Social Security Act, as added by section 3021 of the ACA.<sup>5</sup> Therefore, given that the ACA authorized CMMI, the fate of the agency is also uncertain. If *Texas v. United States* is upheld, then CMMI would no longer have authority to operate. If this Demonstration Project is undertaken prematurely and then abruptly abandoned, it would cause unnecessary expense and administrative burden for parties throughout the supply chain who expended resources to implement the program. Therefore, CMMI should not undertake such a widespread Demonstration Project until the fate of the ACA is decided.

## **III. Reduced Access and Increased Out-of-Pocket Costs for Medicare Beneficiaries**

As a result of the Demonstration Project, Medicare beneficiaries may experience decreased access to treatment and health care providers and an increase in out-of-pocket costs.

Under the Demonstration Project, vendors may include pharmacy benefit managers (“PBMs”). PBMs often use benefit utilization management tools, such as prior authorization, to control costs. Yet, overly burdensome prior authorization standards could result in some Medicare beneficiaries losing access to their medications. According to a 2018 report from HHS’s Office of the Inspector General, 56 percent of prior authorization requests for Medicare Advantage plan beneficiaries were inappropriately denied, and 45 percent of Medicare Advantage Organizations (“MAOs”) sent prior authorization denials with incomplete or incorrect information, which may inhibit beneficiaries’ and providers’ ability to file a successful appeal.<sup>6</sup> Moreover, between 2014 and 2016, MAOs overturned 75 percent of their own denials (approximately 216,000 per year), which raises concerns that MAOs are initially denying services and payments that should have been provided.<sup>7</sup> This is especially problematic because only one percent of denials are ever appealed.<sup>8</sup> Therefore, inserting yet another party into the

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<sup>3</sup> <https://www.documentcloud.org/documents/5629711-Texas-v-US-Partial-Summary-Judgment.html>

<sup>4</sup> <https://www.insurancejournal.com/news/national/2018/12/17/512261.htm>

<sup>5</sup> 42 U.S.C. § 1315a

<sup>6</sup> <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>

<sup>7</sup> <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>

<sup>8</sup> <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>

supply chain that could implement benefit utilization management policies may result in unnecessary restrictions on Medicare beneficiaries' access to treatment.

The Demonstration Project also contemplates a "bonus pool" in which providers would receive bonus payments for prescribing lower-cost drugs or adopting benefit utilization management policies. This bonus pool would create perverse incentives for providers to improperly ration more costly treatments or only prescribe lower cost drugs even when higher cost medications may be most appropriate for individual patients. This type of incentive creates a conflict of interest for providers and reduces access to necessary medications for Medicare beneficiaries.

Medicare beneficiaries may also experience increased out-of-pocket costs and lose access to their providers because they may have to switch their site of care from a clinic to a health system as a result of the Demonstration Project. After the Budget Control Act ("BCA") of 2011 was passed, Part B providers endured a reduction in their reimbursement rates from 106 percent of the medication's Average Sales Price ("ASP + 6") to 104.3 percent ("ASP + 4.3"). This cut is still in effect today. A study by the Community Oncology Alliance ("COA"), published in August 2018, determined that this decrease in reimbursement was partially responsible for a reduction in access to care and an increase in costs for Medicare beneficiaries.<sup>9</sup> The reimbursement reduction caused many oncology clinics to close or merge with larger hospital systems. This led to patients losing access to their current providers and paying more out-of-pocket to receive the same services that they received before the sequestration cut. A similar outcome may occur under the proposed Part B acquisition and reimbursement framework if providers' reimbursement structure is fundamentally altered and they experience financial hardship.

To prevent Medicare beneficiaries from losing access to their treatment providers and medications and from incurring additional out-of-pocket costs, CMS should (1) prohibit PBMs from serving as vendors; (2) clarify that vendors cannot implement benefit utilization management policies as part of the Demonstration Project; (3) not offer bonus pools; and (4) ensure that practitioners are properly compensated.

#### **IV. Discrimination Against Patients**

The Demonstration Project would likely result in discrimination against Medicare beneficiaries in two ways. First, the Project will disproportionately impact individuals with cancer, autoimmune conditions, and other conditions for whom treatments must be administered by a health care practitioner. Second, the Demonstration Project imports the use of the Quality Adjusted Life Years ("QALYs") to set drug prices, which is inherently discriminatory against older and less healthy individuals.

Part B covered medications are administered by a health care practitioner in a physician's office or other outpatient clinical setting. These medications predominantly treat cancer and

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<sup>9</sup> <https://www.ajmc.com/contributor/coa/2018/08/the-financial-impact-of-the-sequester-cut-to-medicare-part-b-drug-reimbursement-in-community-oncology>

autoimmune conditions.<sup>10</sup> Therefore, individuals with these conditions, and other illnesses that require medication administered by a health care practitioner, are more likely than those with other health conditions to experience the access issues and increased out-of-pocket costs described in the section above.

The Demonstration Project would also set payment rates based on the prices available in the IPI “reference countries,” many of which utilize QALYs as a measure of comparative effectiveness to determine the value of available treatment options. QALYs assign a value to human life. Anyone who is healthy is considered whole and, therefore, assigned a value of one. Anyone who has a health condition or illness is assigned a value of less than one. QALYs do not adjust for disease remission. As such, QALYs put a price tag on the value of a human life that merely reflects the individual’s diagnosis and deems those with chronic, debilitating, and rare conditions, such as cancer, as being worth less than the rest of the population. They treat individuals’ lives and health as a commodity and ignore the patients’ and practitioners’ individualized concept of the value of treatment.

Recognizing that QALYs can result in an inappropriate rationing of care, Congress added language to the ACA that prohibited the Patient-Centered Outcomes Research Institute (“PCORI”) from using QALYs as a threshold for determining coverage, reimbursement, or incentives in the Medicare program.<sup>11</sup> The ban reflected a long-standing concern in the U.S. that the approach would lead to discrimination on the basis of age and health status, unfairly favoring younger and healthier populations.

As such, CMS should take care to ensure that individuals with cancer and autoimmune conditions do not disproportionately lose access to their treatment and health care providers or experience increased out-of-pocket costs. Additionally, CMS should exclude reference countries that use QALYs to set price controls from the IPI.

## **V. Penalizing Providers**

The Demonstration Project is likely to have a negative impact on the compensation of both practitioners who must participate and those who do not have to participate in it.

The Demonstration Project could harm participating practitioners that work in clinics, in particular. When sequestration reduced the Part B reimbursement methodology from ASP + 6 percent to ASP + 4.3 percent, many providers struggled to cover the costs to acquire, store, and administer the medications that their patients need.<sup>12</sup> This 1.7 percent reduction, while small, led to increased consolidation among clinics and health systems. The framework of the IPI could result in dramatic reductions in the reimbursement rate for providers. Moreover, the Demonstration Project requires half of all Part B providers to participate, creating too broad of a

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<sup>10</sup> See, e.g.,,

[https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/dev\\_063727.pdf](https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/dev_063727.pdf)

<sup>11</sup> <https://www.govinfo.gov/content/pkg/USCODE-2017-title42/html/USCODE-2017-title42-chap7-subchapXI-partD.htm>

<sup>12</sup> <https://www.journalofclinicalpathways.com/news/medicare-part-b-sequester-cut-leads-significant-financial-impact-community-oncology>

sample to be considered “demonstration.” There is no exemption process or ability to opt out even if the Demonstration Project may compromise practitioners’ business model. If reimbursement is set too low, many providers may close or have to merge with hospitals. This could burden patients as well, especially in rural areas or areas in which there are a limited number of providers within a certain distance.

Additionally, reimbursement for nonparticipating providers will decrease. Under the Demonstration Project, CMS would calculate drug prices based on a “Target Price” derived from the IPI. When discussing how the model could impact non-participating providers, CMS states that “[t]he model may impact . . . ASP . . . for these affected drugs, reducing both reimbursements as well as rebates.”<sup>13</sup> The incorporation of the IPI’s Target Price into ongoing calculations of ASP will effectuate a payment cut for Part B providers that is much more dramatic than the sequestration cut from 2011.<sup>14</sup> CMS anticipates forcing half of Part B providers to participate in this Demonstration Project and cutting the reimbursements paid to these providers by 30 percent by 2025.<sup>15</sup> The calculation of ASP paid to non-participating providers will incorporate the reduced payment rates to participating providers, representing roughly 50 percent of sales made in the U.S.<sup>16</sup> If a 30 percent payment rate reduction is achieved by 2025, non-participating providers will be subject to a reduction in their reimbursement rate equal to roughly half of that amount – about 15 percent.<sup>17</sup> This would be untenable for a majority of providers who would have to choose between accepting inadequate reimbursement from CMS, charging other patients more to recuperate their losses, declining to participate in the Part B program, or voluntarily opting into the Demonstration Project. As such, this could produce additional access challenges for patients.

The scope of the Demonstration Project must be reduced to a narrower sample of providers, and guardrails must be included to insulate participating providers. An exemption or opt-out process should be developed to ensure that patients and providers are not unduly burdened. At a minimum, the opt-out process should be available to providers who practice in rural geographic area, in an areas with limited numbers of other providers, or to clinics under a certain revenue threshold. Additionally, CMS should preserve the reimbursement methodology for providers who are not participating in the Demonstration Project by uncoupling the prices paid in the Demonstration Project from ongoing calculations of ASP.

## **VI. Barriers to Innovation**

By tying U.S. drug prices to the IPI, CMS is essentially imposing price controls in the U.S. Price controls are inconsistent with a free market and discourage innovation.<sup>18</sup>

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<sup>13</sup> <https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs#open-comment>

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/>

Reference countries identified by CMS’s proposal often refuse to cover medications if they determine prices are too high. As a result, patients do not have access to innovative and lifesaving medications abroad. For example, in the United Kingdom, the National Institute for Health and Care Excellence (“NICE”) determines whether or not the government will pay for new medications. Since March 2000, NICE has determined that UK citizens should not have access to 123 new drugs.<sup>19</sup> Most recently, it rejected a new medication that treats kidney cancer. Consequently, many individuals from the UK travel abroad, including to the U.S., to access life-saving medications that they cannot obtain domestically. It is unclear how the Demonstration Project will address medications that were rejected for payment in reference countries, but access must not be impeded.

Moreover, even when many of the reference countries do determine that they will pay for new medications, the introduction of those treatments into the market lag by approximately 1.6 to 2.6 years behind free-priced markets like the United States.<sup>20</sup> Tying the Target Price to the prices in these countries will import their access delays to the U.S. Given that private health insurers often follow the lead of CMS, both publicly and privately insured individuals are likely to experience these delays in accessing new medications. It is unclear how the Demonstration Project will address new medications that have not been evaluated in reference countries. However, access to such medications must be preserved in the U.S.

Price controls will harm the U.S. market and limit access to medication. At a bare minimum, the Demonstration Project should not apply to new medications that have not been evaluated in reference countries. It also should not apply to medications that reference countries have rejected.

## **VII. Waste**

The ANRPM creates opportunity for waste in the health care system. For example, it inserts new middlemen into the business relationships between supply chain stakeholders, which will upset existing business practices. Under the Demonstration Project, vendors, which are tasked with acquiring medications on behalf of providers, may include PBMs. The role of these vendors is not to take physical position of such medications but solely to negotiate acquisition prices with manufacturers on behalf of providers. Yet, PBMs, which currently serve a similar role in negotiating drug prices between manufacturers and insurers, are often criticized for their inefficiency and for adding cost to the pharmaceutical supply chain.<sup>21</sup> The Trump administration, in particular, has been critical of PBMs for their wasteful actions. For example, in May 2018, you stated that PBMs are partly to blame for drug pricing transparency barriers, including because they are financially incentivized to participate in gag clause contracts.<sup>22</sup> PBMs and other vendors could charge additional administrative fees or negotiate rebates, which may be reclassified as administrative fees, thereby driving up medication prices.

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<sup>19</sup> <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/appraisal-recommendations>

<sup>20</sup> <https://voxeu.org/article/does-price-regulation-affect-adoption-new-pharmaceuticals>

<sup>21</sup> <https://patientengagementhit.com/news/how-to-improve-pbm-practices-to-boost-patient-access-to-care>

<sup>22</sup> <https://healthpayerintelligence.com/news/cms-medicare-part-d-gag-clauses-are-unacceptable>

Moreover, the Demonstration Project supplants existing channels for Part B medication acquisition. This could be wasteful for provider practices that already have business relationships in place that efficiently satisfy the medication needs of their patients. Additionally, it is unclear what requirements will be placed on vendors as a condition for their participation and whether vendors be required to fill any prescription, nationally. If vendors are not required to do so, providers may need to contract with numerous vendors to ensure that their patients' needs are met, which could result in increased administrative waste.

Therefore, if CMS allows PBMs to become vendors, it should prevent them from negotiating rebates and should place restrictions on administrative fees. Additionally, CMS should honor existing contracts between providers and distributors. Moreover, vendors should be required to cover all medications, should not be incentivized to exclude certain drugs based on rebates or otherwise, should be able to fill any order for any provider regardless of geographic location, and should not be able to impose benefit utilization management policies.

### **VIII. Strengthen Program Termination Guardrails**

CMS should strengthen the Demonstration Project's termination guardrails in the event that it results in widespread issues for practitioners and patients nationwide. The ANPRM states that the Demonstration Project shall only be terminated if the funding required to administer the program is unavailable or for other reasons anticipated by Sec. 1115A(b)(3)(B) of the Social Security Act. These requirements only relate to program funding and do not include any consideration of the real-world impacts this Demonstration Project could have on patients and providers.<sup>23</sup>

CMS should develop more stringent termination guardrails that would halt the Demonstration Project if patient and provider impacts are significant. For example, if the Demonstration Project results in patients in entire geographic areas being unable to access a provider who can acquire the Part B medications they need, the project should be terminated.

### **IX. Additional Recommendations**

In addition to the recommendations addressed above, we also make the following recommendations:

- Create educational resources for beneficiaries to help them understand what is changing in the prescription drug supply chain for Part B products, why it is being changed, and how it could impact their care. Patients should be able to make informed decisions about their health care, which could include selecting a provider based on their participation in this Demonstration Project. Resources of this nature will assist patients making those decisions.
- Regularly solicit direct feedback from a diverse group of providers and Medicare beneficiaries to evaluate how the Demonstration Project is impacting their medication access. Diversity should be measured by ethnicity, gender, age, geographic location,

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<sup>23</sup> [https://www.ssa.gov/OP\\_Home/ssact/title11/1115A.htm](https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm)

- health status, and socioeconomic status. Data obtained from this feedback should be incorporated into CMS's ongoing evaluation of the program's operation.
- Include patient and provider groups in the continued development of this and similar proposals in the future. Additional stakeholder input will help ensure that policies crafted by CMS will not harm the populations they are attempting to regulate.

## **X. Details Requested**

Aimed Alliance requests that CMS address the following issues in the forthcoming Notice of Proposed Rulemaking:

- How will this Demonstration Project decrease out-of-pocket costs for Medicare beneficiaries?
- How will CMS ensure that Medicare beneficiaries do not lose access to their medications and providers?
- How does CMS plan to encourage enough vendors to participate to ensure that all participating providers to have uninterrupted access to the medications their patients need?
- How will coverage determinations made by reference countries be incorporated into the IPI? If a country refuses to cover a medication, how will the IPI factor that into its pricing calculation? Will such drugs still be available under Part B?
- The ANPRM is unclear regarding the differences between basing the add-on payment on the class of drug, the practice setting, or the provider's specialty. How will the add-on payment be structured?
- Will the Demonstration Project result in reduced access to medications that are prescribed off-label?

Thank you again for providing the opportunity to comment on this ANPRM. For further information, questions, or comments, you can contact me at [jwylam@aimedalliance.org](mailto:jwylam@aimedalliance.org).

Respectfully,

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