



May 3, 2016

Andy Slavitt, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2016-0036  
Baltimore, MD 21244-8016

Submitted via [www.regulations.gov](http://www.regulations.gov)

Dear Administrator Slavitt:

The Alliance for the Adoption of Innovations in Medicine (“Aimed Alliance”) is a not-for-profit organization that works to improve health care in the United States by supporting the development and utilization of novel, evidence-based technologies. It achieves this mission through legal research and analysis, thought leadership, and organizational collaboration.

As a not-for-profit organization that shares the Obama Administration’s goal of improving access to high-quality health care, Aimed Alliance would like to submit its comments on the proposed rule for *Medicare Program; Party B Drug Payment Model (CMS-1670-P)* (“Part B Demo”). Specially, Aimed Alliance believes that CMS should not implement the Part B Demo because it likely violates the nondiscrimination provision of the Affordable Care Act (“ACA”) by disproportionately affecting patients with cancer, resulting a significant decrease in the quality of care and increase in out-of-pocket costs.

## **I. Facts**

### **A. Overview of Medicare Part B**

Medicare Part B covers medically necessary services and supplies for individuals over the age of 65 or who receive Social Security Disability Income in the diagnosis or treatment of a health condition.<sup>1</sup> Such services and supplies include outpatient services received at a hospital, doctor’s office, clinic, or other health facility.<sup>2</sup> It also covers limited outpatient prescription medication, including injectable, infused, and oral cancer medications, among others.<sup>3</sup>

### **B. Medicare Part B Demo**

On March 8, 2016, the Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule to implement a new Medicare payment model, pursuant to section 1115A of the

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<sup>1</sup> *What Part B Covers*, Centers for Medicare and Medicaid Services, <https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html> (last visited Apr. 24, 2016).

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

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

Social Security Act.<sup>4</sup> Section 1115A permits CMS to test out innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare beneficiaries.<sup>5</sup>

This payment model, referred to as the Medicare Part B Demonstration Project (“Part B Demo”), reduces the statutorily-mandated 6 percent add-on to Medicare Part B drugs’ Average Sales Price (“ASP”) to 2.5 percent plus a flat fee payment of \$16.80 per drug per day (“Proposed Payment Scheme”).<sup>6</sup> However, in 2013, CMS imposed a mandatory 2 percent payment reduction in Medicare fee-for-service claims for Part B services, referred to as “sequestration.”<sup>7</sup> Therefore, with sequestration, the actual payment rate under the Proposed Payment Scheme will be less than 1 percent (plus the flat fee) for some practitioners.<sup>8</sup>

According to CMS, the Part B Demo is designed to test different physician and patient incentives to drive the prescribing of the most effective medications.<sup>9</sup> It will be implemented as a five-year experiment, in which Part B dispensing entities in different geographic areas across the country will be subjected to either the Proposed Payment Scheme, new value-based purchasing tools, or both.<sup>10</sup>

## II. Analysis

The Part B Demo likely violates the ACA nondiscrimination clause because it will disproportionately affect individuals with cancer, significantly reducing the quality of care and imposing additional out-of-pocket costs on patients.

The ACA and its implementing regulations expressly prohibit all health insurers and plans, including those that administer Medicare Part B, from discriminating against any individual on the basis of disability, including cancer.<sup>11</sup> Additionally, in September 2015, the Department of Health and Human Services (“HHS”) issued a rule that further explained that

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<sup>4</sup> *CMS Proposes To Test New Medicare Part B Prescription Drug Model To Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries*, Centers for Medicare and Medicaid Services (Mar. 8, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html>.

<sup>5</sup> 42 U.S.C. § 1315a(a)(1).

<sup>6</sup> *CMS Proposes To Test New Medicare Part B Prescription Drug Model To Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries*, *supra* note 4.

<sup>7</sup> *Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program – “Sequestration,”* Centers for Medicare and Medicaid Services, (Mar. 8, 2013), <https://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf>.

<sup>8</sup> Raina H. Jain, et al., *Part B Payment for Drugs in Medicare: Phase 1 of CMS’ Proposed Pilot and Its Impact on Oncology Care*, Memorial Sloan Kettering Cancer Center (Apr. 11, 2016), <http://www.drugabacus.org/wp-content/uploads/2016/04/Part-B-Payment-Phase-1-Report.pdf>.

<sup>9</sup> *Id.*

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

<sup>11</sup> 42 U.S.C. § 18116; Nondiscrimination in Health Programs and Activities, Department of Health and Human Services, 80 Fed. Reg. 54172 (Sept. 8, 2015) (42 CFR 92.207).

covered entities shall not limit health coverage or impose additional cost sharing or other limitations on the basis of an enrollee's disability.<sup>12</sup>

Of the 14 million Americans who have cancer, 60 percent are Medicare beneficiaries.<sup>13</sup> While Medicare Part B only covers a limited number of medications, many of those medications are for the treatment of cancer.<sup>14</sup>

### **A. The Part B Demo Will Likely Result in Increased Out-of-Pocket Expenses for Patients with Cancer in Violation of the ACA**

The Part B Demo is likely to increase cost sharing for patients with cancer in violation of the ACA regulations. The Part B Demo can be expected to result in fewer private oncology practices, meaning that patients will be forced to obtain treatment from more expensive hospital outpatient departments ("HOPDs"), leading to increased out-of-pocket expenses for patients with cancer.

As originally contemplated, the Part B reimbursement methodology was designed to recognize that practitioners incur costs and complexity associated with acquiring, handling, maintaining, and delivering Part B medicines.<sup>15</sup> The system allowed for patient access while controlling the cost of services for the Medicare program.<sup>16</sup>

Yet, previous sequestration cuts resulted in private oncology practice closures and consolidations with large hospital and health systems.<sup>17</sup> For example, between 2008 and 2013, 46 cancer practices began sending Medicare beneficiaries elsewhere, 313 cancer practices closed, and 693 cancer practices were consolidated with hospital outpatient departments ("HOPDs") either through merger or acquisition.<sup>18</sup> Additionally, according to a recent six-month study, Medicare payments tripled for chemotherapy in HOPDs and dropped 14 percent in physicians' offices as a result of hospitals purchasing more physician practices.<sup>19</sup>

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<sup>12</sup> Nondiscrimination in Health Programs and Activities, Department of Health and Human Services, 80 Fed. Reg. 54172 (Sept. 8, 2015) (42 CFR 92.207).

<sup>13</sup> Cancer and Medicare: A Chartbook, Cancer Action Network American Cancer Society (Feb. 2009), <http://www.allhealth.org/briefingmaterials/CancerandMedicareChartbookFinalfulldocumentMarch11-1412.pdf>.

<sup>14</sup> *What Part B Covers*, *supra* note 1.

<sup>15</sup> Letter to Andy Slavitt, *Acting Administrator of CMS from Cancer Patient Advocate Groups*, (Mar. 7, 2016).

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

<sup>17</sup> *Id.*; R.M. Conti, et al., *The Impact of Provider Consolidation on Outpatient Prescription Drug-Based Cancer Care Spending*, Health Care Cost Institute (2015), <http://www.healthcostinstitute.org/files/HCCI-Issue-Brief-Impact-of-Provider-Consolidation.pdf>.

<sup>18</sup> *Community Oncology Practice Impact Report: The Changing Landscape of Cancer Care*, Community Oncology Alliance (Oct. 21, 2014), [http://www.communityoncology.org/pdfs/Community\\_Oncology\\_Practice\\_Impact\\_Report\\_10-21-14F.pdf](http://www.communityoncology.org/pdfs/Community_Oncology_Practice_Impact_Report_10-21-14F.pdf).

<sup>19</sup> *Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2015-2011 for Medicare Fee-for-Service Beneficiaries*, the Moran Company, (May 29, 2013), [http://glacialblog.com/userfiles/76/Moran\\_Site\\_Shift\\_Study\\_P1.pdf](http://glacialblog.com/userfiles/76/Moran_Site_Shift_Study_P1.pdf).

Increased HOPD consolidation resulted in increased spending on outpatient cancer treatment.<sup>20</sup> Most HOPDs<sup>21</sup> receive higher Medicare payment rates than private practices, even though there may be no difference in the care that patients receive, simply because Medicare assumes that hospital care is, by definition, more expensive to provide than office-based care.<sup>22</sup> For example, a 2013 Medicare Payment Advisory Commission report found that Medicare was paying 141 percent more for a Level 2 echocardiogram in an outpatient setting than one performed in physicians' offices.<sup>23</sup> Medicare beneficiaries' out-of-pocket costs are also higher because beneficiaries are responsible for roughly 20 percent of the payment amount for outpatient services.<sup>24</sup>

Under the Part B Demo, practitioners in some regions of the country will only receive ASP plus 0.9 percent and the flat fee,<sup>25</sup> which means that even more closures of private oncology practices are likely. Given that the previously decreased rate of 4 percent was not enough for private oncology practices to afford acquiring, handling, maintaining, and delivering Part B medicines, thereby leading to practice closures, a further reduction in payment under the Part B Demo is likely to result in even more oncology practice closures and hospital consolidations, forcing patients with cancer to obtain treatment from more expensive HOPDs.<sup>26</sup> As a result of these practice closures and consolidations, costs will continue to increase for patients with cancer, in violation of the ACA regulations' prohibition on increased cost sharing based on disability.<sup>27</sup>

## **B. The Part B Demo Will Likely Limit Care for Patients with Cancer in Violation of the ACA**

The Part B Demo likely limits care for patients with cancer in violation of the ACA regulations. For example, with practice closures and consolidations, travel will be necessary to obtain care from any practitioner. Patients with cancer who cannot afford HOPDs may be forced to travel long distances to geographic locations for which the Proposed Payment Scheme is not being imposed, which may become unduly onerous. Such travel is especially difficult for patients with cancer who require a family member or loved one to accompany them to treatment because that person may also be forced to take time off from work to travel long distances.

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<sup>20</sup> R.M. Conti, *supra* note 17.

<sup>21</sup> In 2015, CMS adopted a site-neutral payment policy that primarily affects off-campus physician practices that hospitals bought or built after November 2, 2015. Instead of a higher reimbursement rate because of being associated with a hospital, those practices are slated to receive the same payment as physicians who are in stand-alone offices. Jacqueline Fellows, *Medicare Sparks Site-Neutral Payment Showdown*, Healthleaders Media (Feb. 18, 2016), <http://www.healthleadersmedia.com/physician-leaders/medicare-sparks-site-neutral-payment-showdown>.

<sup>22</sup> *Health Policy Brief: Site-Neutral Payments*, Health Affairs, (July 24, 2014), [http://healthaffairs.org/healthpolicybriefs/brief\\_pdfs/healthpolicybrief\\_121.pdf](http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_121.pdf); Margot Sanger-Katz, *When Hospitals Buy Doctors' Offices, and Patients Fees Soar*, The New York Times, (Feb. 6, 2015), [http://www.nytimes.com/2015/02/07/upshot/medicare-proposal-would-even-out-doctors-pay.html?\\_r=0](http://www.nytimes.com/2015/02/07/upshot/medicare-proposal-would-even-out-doctors-pay.html?_r=0).

<sup>23</sup> Shannon Muchmore, *Site-Neutral Medicare Payments on Congress' Agenda*, Modern Healthcare (Jan. 2, 2016), <http://www.modernhealthcare.com/article/20160102/MAGAZINE/301029937>.

<sup>24</sup> *Health Policy Brief: Site-Neutral Payments*, *supra* note 22.

<sup>25</sup> Raina H. Jain, *supra* note 8.

<sup>26</sup> Letter to Andy Slavitt, *supra* note 15.

<sup>27</sup> *Id.*

Patients who are unable to afford care at an HOPD and are unable to travel may choose to forego proper adherence to their treatment plans, leading to higher treatment costs and lower survival rates. For example, a recent study found that patients with higher cost-sharing are 70 percent more likely to stop taking their cancer treatment and 42 percent more likely to skip doses.<sup>28</sup> Patients who miss even 15 percent of a prescribed dose can relapse because the cancer develops a resistance to the drug.<sup>29</sup> Recurrence of cancer is associated with higher mortality and health care costs.<sup>30</sup> Therefore, the Part B Demo is likely to limit care for patients with cancer in violation of the ACA regulations.

### **C. The Part B Demo Will Likely Result in Inferior Quality of Cancer Treatment in Violation of the ACA**

The Part B Demo will likely result in inferior quality of cancer treatment in violation of the ACA. It encourages oncologists to prescribe less costly medications despite their lower effectiveness because such lower cost medications are more profitable.

CMS claimed that the purpose of the Part B Demo is to drive prescribing of the most effective medications.<sup>31</sup> In actuality, the Part B Demo favors cost savings over quality of care, especially in the area of oncology.<sup>32</sup> The Proposed Payment Scheme is expected to result in rising profits for the administration of inexpensive drugs and decreasing profits for more expensive drugs, with a “breakeven point” of \$480 for treatment.<sup>33</sup> As compared with current rates, prescribers will receive a higher reimbursement rate under the Proposed Payment Scheme for medications costing less than \$480, and a lower reimbursement rate for medication costing more than \$480.<sup>34</sup>

Yet, many of the most effective cancer drugs cost more than \$480. In some cases, lower cost alternatives mean older, less effective, or potentially even ineffective treatment. Moreover, more than 50 percent of payment reductions resulting from the Part B Demo will come from 10 medications, seven of which are used to treat cancer.<sup>35</sup> As a result, patients with cancer can be expected to receive a lower quality of treatment and poorer treatment outcomes than under the

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<sup>28</sup> *Out-of-pocket Costs Pay Major Role in Treatment Adherence for Cancer Patients*, University of North Carolina (Jan. 6, 2014), <http://sph.unc.edu/sph-news/out-of-pocket-costs-play-major-role-in-treatment-adherence-for-cancer-patients/>.

<sup>29</sup> *Out-of-pocket Costs Pay Major Role in Treatment Adherence for Cancer Patients*, University of North Carolina (Jan. 6, 2014), <http://sph.unc.edu/sph-news/out-of-pocket-costs-play-major-role-in-treatment-adherence-for-cancer-patients/>.

<sup>30</sup> See, e.g., Nicole M. Engel-Nitz, et. al., *Abstract: Cost of Recurrence Among Patients with HR+HER2- Metastatic Breast Cancer*, ASCO University (2015), <http://meetinglibrary.asco.org/content/143086-156>.

<sup>31</sup> *CMS Proposes To Test New Medicare Part B Prescription Drug Model To Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries*, *supra* note 4.

<sup>32</sup> See *Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers*, Avalere (Apr. 7, 2016); Raina H. Jain, *supra* note 8.

<sup>33</sup> Raina H. Jain, *supra* note 8.

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

<sup>35</sup> *Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers*, *supra* note 32.

current payment system, in violation of the ACA's prohibition on discrimination based on disability and limitations on care.

### **III. Conclusion**

In sum, this mandatory experiment will likely result in discrimination against patients with cancer in violation of the ACA by decreasing the quality of oncology care. It will also likely violate the ACA's regulations because it will result in additional cost sharing for patients with cancer. It will likely violate the ACA's regulations by limiting health coverage because many private oncology practices are likely to close and patients may have to travel long distances to obtain care. Therefore, Amed Alliance recommends that CMS not proceed with the implementation of the Medicare Part B Demo.

We appreciate your consideration of our comments and would be pleased to discuss this matter in greater detail with you.

Sincerely,

A handwritten signature in black ink, appearing to read "Stacey L. Worthy". The signature is fluid and cursive, with the first name being the most prominent.

Stacey L. Worthy  
Director of Public Policy