



**STATEMENT OF**

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**ON**

**“EXAMINING IMPLEMENTATION OF THE BIOLOGICS PRICE COMPETITION  
AND INNOVATION ACT”**

**BEFORE THE**

**U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE  
HEALTH SUBCOMMITTEE**

**FEBRUARY 4, 2016**

**Statement of Sean Cavanaugh on**  
**“Examining Implementation of the Biologics Price Competition and Innovation Act”**  
**House Energy and Commerce Committee**  
**Health Subcommittee**  
**February 4, 2016**

Chairman Pitts, Ranking Member Green, and members of the Subcommittee, thank you for the invitation and the opportunity to discuss the Centers for Medicare & Medicaid Services’ (CMS’s) Medicare Part B payment policy for biosimilar biological products, or biosimilars. Biosimilars hold great promise for all Americans, including Medicare beneficiaries, and CMS is committed to a payment approach that will provide a fair payment in a healthy marketplace.

The Affordable Care Act, in addition to creating an abbreviated licensure pathway for the approval of biosimilars by the Food and Drug Administration (FDA) also includes a provision on the establishment of Medicare payment policies for these products, setting the add-on payment rate for biosimilar products under Medicare Part B at 6 percent of the average sales price of the reference product.

Zarxio (filgrastim-sndz), a supportive care product for cancer treatment that is biosimilar to Neupogen (filgrastim), was the first biosimilar to be approved by the Food and Drug Administration (FDA), in March 2015. CMS quickly assigned Zarxio a billing code to facilitate Medicare beneficiaries’ access to this new therapy. In addition, CMS began outreach efforts among the provider community to provide short-term guidance on submitting claims for biosimilar products and to establish an expected timeframe for additional regulations.<sup>1</sup> It is important to implement a Medicare payment policy for biosimilars now, before the second biosimilar for any reference product becomes available, in order to provide certainty for providers and suppliers who will be billing Medicare for these products in the near term.

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<sup>1</sup> Medicare Learning Network newsletter, <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1509.pdf>

## **Medicare Payment Policy on Biosimilars**

CMS first issued regulations regarding Medicare Part B payment for biosimilars in 2010 implementing the payment approach specified by the Affordable Care Act.<sup>2</sup> Since 2010, we have continued to monitor the emerging biosimilar marketplace. As biosimilars now begin to enter the marketplace, we have also reviewed the existing guidance on Medicare payment of these products.

On July 8, 2015, CMS proposed important clarifications to our Medicare Part B biosimilar payment policy in the calendar year 2016 Medicare Physician Fee Schedule (PFS) proposed rule.<sup>3</sup> The PFS is updated on an annual basis and follows the Department of Health and Human Services' standard rulemaking procedure, which includes a comment period open to the public. CMS closely considered and responded to the many comments we received, and on October 30, 2015, CMS finalized the proposed clarifications.<sup>4</sup> Primarily, the final rule clarifies that the payment amount for a biosimilar is based on the average sales price (ASP) of all National Drug Codes assigned to the biosimilars included within the same billing and payment code. This approach is consistent with statute, which directs the Secretary to use the weighted average payment methodology in the same manner as it is applied to multiple source drugs. In addition, the Medicare Payment Advisory Commission (MedPAC) submitted public comments supporting this approach. Under the regulation, and consistent with the statute, Medicare payment will equal the ASP for the biosimilar plus six percent of the ASP for the reference product. The reference product will remain in its own billing code and continue to be paid 106 percent of its own ASP.

We also took this opportunity to discuss and clarify some other details of Part B biosimilar payment policy. We described how payment for newly-approved biosimilars will be determined. As we stated in the calendar year 2011 PFS Final Rule with Comment Period, we anticipate that

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<sup>2</sup>Federal Register, Vol. 75, No. 228: <https://www.gpo.gov/fdsys/pkg/FR-2010-11-29/pdf/2010-27969.pdf>; In the 2011 PFS, we said “the payment amount for biosimilar biological drug product...is the sum of the average sales price of all NDCs assigned to the biosimilar biological product as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product”

<sup>3</sup> <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-P.html>

<sup>4</sup> Federal Register, Vol. 80, No. 220, <https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28860.pdf>

as subsequent biosimilar biological products are approved, we will receive manufacturers' ASP sales data through the ASP data submission process and publish national payment amounts in a manner that is consistent with our current approach to other drugs and biologicals. Until we have collected sufficient sales data as reported by manufacturers, payment limits will be determined in accordance with the provisions in section 1847A(c)(4) of the Social Security Act. If no manufacturer data are collected, prices will be determined by local contractors using any available pricing information, including provider invoices. As with newly approved drugs and biologicals (including biosimilars), Medicare Part B payment would be available once the product is approved by the FDA. Payment for biosimilars (and other drugs and biologicals that are paid under Part B) may be made before a HCPCS code has been released, provided that the claim is reasonable and necessary, and meets applicable coverage and claims submission criteria.

In addition, we clarified how wholesale acquisition cost (WAC) data may be used by CMS for Medicare payment of biosimilars. In cases where the ASP during the first quarter of sales is not sufficiently available from the manufacturer to compute an ASP-based payment amount, a WAC-based payment amount may be used. Once the WAC data are available from the pharmaceutical pricing compendia and when WAC-based payment amounts are utilized by CMS to determine the national payment limit for a biosimilar product, the payment limit will be 106 percent of the WAC of the biosimilar product; the reference biological product will not be factored into the WAC-based payment limit determination. This approach is consistent with partial quarter pricing that was discussed in rulemaking in the calendar year 2011 PFS final rule with comment period and with statutory language. Once ASP information is available for a biosimilar, and when partial quarter pricing requirements no longer apply, the Medicare payment limit for a biosimilar will be determined based on ASP data.

In the final rule, we also addressed concerns about the need to track the particular biosimilar a beneficiary receives. We noted that we were developing an approach for using manufacturer-specific modifiers on claims to assist with pharmacovigilance, and we would be providing guidance on mechanisms for tracking drug use through claims information in the near future. Since the publication of the final rule, CMS has implemented a requirement that claims for

biosimilars must include a modifier that identifies the manufacturer of the specific product and has published guidance on the use of the modifier.<sup>5</sup>

The Affordable Care Act contains two provisions for biosimilars: one setting forth a Medicare Part B payment methodology (section 3139); and one setting forth an approval pathway (section 7002). The definitions included in the statute establish that biosimilars and their reference products share a number of significant similarities. While we appreciate that there are differences between multiple source drugs and biosimilars, multiple source drugs are biosimilars' closest analogues compared to the other categories of drugs and biologicals for which we make payment under section 1847A of the Social Security Act, such as single source drugs. The abbreviated pathway for biosimilar approval and the abbreviated pathway for generic drug approval have relevant parallels, such as the approval of a predecessor product (a reference product for biosimilars; an innovator product for drugs) and the comparison of a product that is being approved through an abbreviated pathway to the predecessor. Moreover, the statute directs us to the methodology for multiple source drugs to determine payment for biosimilars.

### **Encouraging Competition**

Competition fosters innovations that redefine markets. Overall, the availability of generic drugs, in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries-improving the quality, price, and access. Like multiple source drugs, CMS sees biosimilars competing for market share with each other, as well as competing with the reference product. MedPAC used a similar line of reasoning in supporting CMS's proposed policy saying that "it would be expected to lead to lower prices, which would mean a better price for beneficiaries and taxpayers, as well as potentially greater access to these products."<sup>6</sup>

### **Moving Forward**

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<sup>5</sup> <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html>

<sup>6</sup> <http://www.medpac.gov/documents/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-physician-fee-schedule-and-other-revisions-to-part-b.pdf?sfvrsn=0>

The field of biosimilars is a new advancement in health technology and holds great promise for future improvements in health value and outcomes. CMS policies will continue to ensure Medicare beneficiaries have access to biosimilars and other innovative treatments that receive FDA approval. It will be important for Medicare beneficiaries and the biosimilar industry that CMS create payment policies that support innovation, access, and affordability of these medications. We will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market. We look forward to continuing to work with this Committee and to gathering feedback from providers, suppliers, and other stakeholders in order to better inform our guidance and regulations.