August 31, 2015

Mr. Andrew Slavitt
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independent Avenue, SW
Washington, DC 20201

Re: Comments to July 8, 2015 Proposed Rule: “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System” (80 Fed. Reg. 39200)

Dear Acting Administrator Slavitt:

The Biosimilars Forum appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (“CMS”) proposed rule regarding hospital outpatient prospective payment system (“OPPS”) payment for biosimilar biological products under Medicare Part B, as published on July 8, 2015.

The Biosimilars Forum is a non-profit organization whose mission is to advance biosimilars in the United States with the intent of expanding access and availability of biological medicines and improving health care. The Forum is a voluntary group working on a consensus basis to develop policy positions to ensure the United States has a competitive, safe, and sustainable biosimilars market, providing more options to patients and physicians.

Summary of the Proposed Rule

On July 8, 2015, CMS proposed that the Medicare Part B OPPS payment for biosimilar biological products be “based on the payment allowance of the product as determined under section 1847A of the [Social Security] Act.”1 Under Section 1847A(b)(8) of the Social Security Act (the “Act”), a biosimilar biological product is paid “the sum of (1) the average sales price (“ASP”) as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes (“NDCs”) assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and (2) 6 percent of the amount determined under paragraph (4) for the reference biological product.” CMS also proposed to extend eligibility for separate, transitional pass-through payments to biosimilar biological products, while nonpass-through biosimilars would be subject to the same $100 per day cost threshold that determines whether a drug or biological should be paid as a packaged or a separately payable item. Finally, CMS proposed that the assignment of HCPCS coding and modifiers for biosimilar biological products be based on the policy established under the 2016 Medicare Physician Fee Schedule (“MPFS”).

Comments to the Proposed Rule

1. Section 1847A of the Social Security Act requires separate payment for each biosimilar product of a reference biological product.

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CMS proposes to rely on the payment amounts determined under Section 1847A of the Act in order to calculate OPPS reimbursement for both separately payable biosimilars and for transitional pass-through payments for eligible biosimilar products. While we generally agree with the use of Section 1847A of the Act to determine Medicare Part B OPPS payment for biosimilar biological products, and support the eligibility of biosimilars for transitional pass-through payments in particular, we believe that the Section 1847A requires CMS to provide separate payment for each biosimilar product of a reference biological product. It is clear from both the plain language of the statute and the intent of Congress in drafting this provision that each biosimilar product should be paid according to its own, volume-weighted ASP as applied to the NDCs assigned to each biosimilar biological product. Specifically, subsection (b)(8) of Section 1847A of the Act states that:

… the amount specified in this paragraph for a biosimilar biological product… is the sum of (1) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and (2) 6 percent of the amount determined under paragraph (4) for the reference biological product.”

(emphasis added)

We note that the statute refers repeatedly to the biosimilar biological product in its singular form, indicating that each biosimilar product is subject to its own separate and distinct payment. The statute requires only the use of a volume-weighted ASP across all NDCs assigned to a single biosimilar product, and not, for instance, the volume-weighted ASP across all NDCs of all biosimilar products of the reference biological.

In addition, Congress intended in its drafting of Section 1847A to provide separate payment for each biosimilar product under Medicare Part B, and not a single payment across multiple biosimilar products. This is apparent in the legislative history of Section 3139 of the Affordable Care Act, as cited below.

The Committee Bill would allow a Part B biosimilar product approved by the Food and Drug Administration and assigned a separate billing code to be reimbursed at the ASP of the biosimilar plus six percent of the ASP of the reference product. A biosimilar biological product would mean a product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under the Public Health Service Act. The term reference biological product means the licensed biological product that is referred to in the application for the biosimilar product.² (emphasis added)

We note again Congress’s repeated use of the term “biosimilar biological product” in its singular form. Any interpretation that would require the calculation of ASP across multiple biosimilar products would set forth a new payment scheme for biosimilars that contradicts what Congress clearly intended and what the statute requires. In order to carry out the intent of Congress, and to ensure proper operationalization of the requirement, we suggest the assignment of a unique Healthcare Common Procedure Coding System (HCPCS) code to each biosimilar product, regardless of whether there are multiple biosimilar products based on a single reference product, to ensure that each biosimilar is paid according to its own separate ASP-based payment.

2. Unique HCPCS codes for each biosimilar product are required for accurate calculation of Medicare Part B OPPS payments.

CMS utilizes Ambulatory Payment Classifications (APCs) to set prospective payment rates for almost all outpatient services and items reimbursable by Medicare Part B OPPS. APCs, in turn, are determined by grouping HCPCS codes under APCs based on similar clinical characteristics and costs.³ For drugs and biologicals specifically, unless these items are automatically packaged under certain APCs by CMS policy, the

³ Hospital Outpatient Prospective Payment System Fact Sheet, CMS Medicare Learning Network, December 2014.
determination of whether a drug or biological is “packaged” under an APC with other items and services, or is separately payable under its own APC, depends on whether the drug or biological exceeds a certain cost per day threshold. This cost per day threshold is calculated for each specific HCPCS code. CMS has proposed a $100 per day cost threshold for the upcoming year.4

It is critical to recognize that biosimilar products of the same reference biological are not identical, as generic drugs are. For instance, based on the data provided, one biosimilar can be approved by the Food and Drug Administration (FDA) for just one indicated use of the reference biologic, whereas other biosimilars for the same reference product can be developed to obtain FDA approval for all indications. In addition, some biosimilar manufacturers may provide additional data to obtain approval by FDA as a designated “interchangeable” product of the reference biologic. As a result, biosimilars of the same reference biologic may be priced differently, because products that are more biologically complex, approved for more indications, or are interchangeable with the reference biological are likely more expensive to develop and produce.

Ultimately, biosimilar products of one reference biological can vary greatly in terms of approved clinical indications and associated costs. CMS must have unique HCPCS codes for each biosimilar product in order to appropriately package biosimilars into existing APCs by appropriate therapeutic use, or to determine that the per day cost of the product requires its own APC.

3. **CMS’s assignment of HCPCS codes for biosimilar biological products will have important consequences on the development and sustainability of a vibrant U.S. biosimilars market.**

CMS has asked that public comments on the assignment of HCPCS codes and modifiers for biosimilar biological products be submitted in response to the 2016 MPFS Proposed Rule. We will provide further comments to CMS’s proposed policy on HCPCS coding for biosimilars in response to the MPFS Proposed Rule as requested. However, for your convenience, we include a copy of a letter we will submit to respond to the MPFS Proposed Rule, as well as a brief summary of key considerations below.

- CMS’s proposed methodology for the assignment of HCPCS codes for biosimilars directly contradicts the language of Section 1847A of the Act, which requires separate payment for each biosimilar product of a reference biological product.
- CMS’s proposed methodology inappropriately treats biosimilar products as if they were multisource or generic drugs. This treatment is inconsistent with not only how FDA classifies biosimilars, but also with how CMS itself defines biosimilar products under Medicaid and Medicare Part D.
- CMS’s proposal fails to account for the wide range of approved uses and interchangeability of biosimilars of the same reference biological, which inhibits the accurate determination of appropriate Medicare Part B payments.
- CMS’s proposal to assign all biosimilars for a reference product under the same HCPCS code hinders FDA’s active pharmacovigilance systems, including FDA’s Sentinel system, as HCPCS codes are one of the few consistent data points available to health care professionals when reporting adverse events.
- CMS’s proposed payment methodology is likely to dramatically reduce investment in, and the availability of, biosimilar products, which is clearly against the intent of Congress in providing for a vibrant U.S. biosimilars market.

If you have any questions or need any additional information, please contact Michael Werner at 202.419.2515 or at michael.werner@hklaw.com.

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