September 3, 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 Independence Avenue, SW
Washington, DC 20201

Re: Comments to July 15, 2015 Proposed Rule: “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016” (80 Fed. Reg. 41686)

Dear Acting Administrator Slavitt:

The Biosimilars Forum appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (“CMS”) proposed rule regarding the payment for biosimilar biological products under Medicare Part B, as published on July 15, 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 works 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**

CMS has proposed to amend 42 C.F.R. § 414.914(j) to clarify that “the payment amount for a biosimilar biological product is to be based on the average sales price (“ASP”) of all National Drug Codes (“NDCs”) assigned to the biosimilar biological products included within the same billing and payment code.”

CMS plans “to use a single ASP payment limit for biosimilar products assigned to a specific Healthcare Common Procedure Coding System (HCPCS) code,” and further, to group all biosimilar products that rely on a common reference product’s biologics license application under the same HCPCS code in order to pay for all biosimilar products of a reference biological product at that same rate. In the proposal, CMS notes that “In general, this means that products that rely on a common reference product's biologics license application will be grouped into the same payment calculation. This approach…is similar to the ASP calculation for multiple source drugs…”

**General Comments to the Proposed Rule**

We strongly disagree with CMS’s intent to group all biosimilar products of a single reference product under the same HCPCS code. We urge CMS to enact a final payment rule that assigns each biosimilar product of a reference biologic its own payment amount and a unique HCPCS code. CMS’s proposed approach contradicts the statutory language of the Section 1847A of the Social Security Act. In addition, CMS’s interpretation inappropriately treats biosimilar products as if they were multisource or generic drugs. This treatment is inconsistent with not only how the Food and Drug Administration

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2 Id.
(“FDA”) classifies biosimilars, but also how CMS itself defines biosimilar products under Medicaid and Medicare Part D. Finally, 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.

**Specific Comments to the Proposed Rule**

1. CMS’s proposed amendment to 42 C.F.R. § 414.905(j) contradicts the statutory language of Section 1847A of the Social Security Act.

CMS indicates in the July 15, 2015 proposed rule that it intends to amend 42 C.F.R. § 414.905(j) to align with its interpretation of Section 1847A of the Social Security Act (the “Act”). However, 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.

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 the volume-weighted ASP across all NDCs of all biosimilar products of the reference biological, as CMS believes.

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.3 (emphasis added)

We note again Congress’s repeated use of the term “biosimilar biological product” in its singular form. Congress clearly contemplated that multiple biosimilars would attach to a single reference product. Yet, there is absolutely no reference to the calculation of ASP across multiple biosimilar products.

Finally, CMS believes their proposed biosimilar payment policy is authorized by Section 1847A(b)(8)(A) of the Act, specifically citing in the proposed rule to that subsection’s incorporation of paragraph (b)(6).4 Respectfully, CMS’s reliance on this subsection of the statute is misplaced. Section 1847A(b)(6) merely sets

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forth the methodology for calculating volume-weighted ASPs. That subsection, and its instructions for calculating volume-weighted ASPs, is incorporated into other parts of the statute, so that it applies not only to multiple source drugs and biosimilars, but also to single source drugs and biologicals as stated in Section 1847(A)(b)(4) of the Act. The statute cannot be read so far beyond its purpose as to authorize or require the placement of multiple biosimilar products under the same billing and payment code. Such an inference directly contradicts the intent of subsection (b)(8) of Section 1847A to require separate payment amounts for each product. CMS’s interpretation, and its proposed amendment to 42 C.F.R. §414.905(j) to support its interpretation, would set forth a new payment scheme for biosimilars that contradicts what Congress clearly intended and what the statute requires.

2. CMS’s proposed payment methodology would treat biosimilars as if they were multiple source generic drugs, which is scientifically inaccurate and inconsistent with how biosimilars are classified by the FDA.

CMS has characterized its proposed policy for the payment of biosimilar products under Medicare Part B as “similar to the ASP calculation for multisource drugs.”

Biosimilars are manufactured using a scientifically different process from how generic drugs are produced. Biosimilars are made from proteins, and must be created within a living system or organism, while generic drugs are generally manufactured through a chemical synthesis process that typically results in exact copies of the brand drug each time. Biosimilars that have not received an interchangeability designation are only “highly similar” to the reference product, and are not considered to be bioequivalent as generic drugs are. For instance, based on the data provided, one biosimilar can be approved by 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.

Ultimately, biosimilar products of one reference biological can vary greatly in terms of approved uses and interchangeability. However, CMS’s proposal fails to account for these differences, and instead would assign the same HCPCS code across multiple biosimilar products with a wide range of approved medical uses.

3. CMS’s proposed payment methodology under Medicare Part B is inconsistent with how CMS itself defines biosimilars under Medicaid and Medicare Part D.

CMS’s intent to treat biosimilars as multisource drugs for payment purposes conflicts with its own position on biosimilars under Medicaid and Medicare Part D. For example, under Section 1927 of the Act, biosimilars are clearly required to enter into a Medicaid rebate agreement as a condition of coverage under the Medicaid program, because they are “covered outpatient drugs,” that are “licensed under section 351 of the Public Health Service Act.”

In determining the amount of the rebate to be paid for biosimilars, CMS needed to determine if they should fall into the category “single source drugs and innovator multisource drugs” or the “other drugs” category, which is defined as “other than single source drugs and innovator multiple source drugs.”

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5 Id.
6 See FDA website at www.fda.gov, FDA Information for Consumers (Biosimilars).
7 Social Security Act, § 1927(k)(2) and § 1927(k)(2)(B)(ii).
8 Id., § 1927(k)(2).(3).
Medicaid Drug Rebate (MDR) program, the definition of single source drugs found at 42 C.F.R. § 447.502 includes covered outpatient drugs licensed under a BLA [biologics license application]. Therefore, in light of this provision, biosimilar biological products fall within the definition of single source drugs in the MDR program.”

This decision is reinforced by the statutory definition of “multiple source drug” in the context of the MDR Program. This definition states that “the term ‘multiple source drug’ means, with respect to a rebate period, a covered outpatient drug… for which there is at least one other drug product which - (1) is rated as therapeutically equivalent (under the Food and Drug Administration’s most recent publication of ‘Approved Drug Products with Therapeutic Equivalence Evaluations’), (2) … is pharmaceutically equivalent and bioequivalent…, as determined by the Food and Drug Administration, and (3) is sold or marketed in the United States during the period.”

Conditions (1) and (2) in the above definition are clearly not applicable to the very nature of biosimilars, and CMS’ decision not to consider biosimilar products as “multiple source drugs” in the context of the MDR program reflects that incongruity. However, the inconsistency inherent in CMS’s decision to then classify biosimilars as “multiple source drugs” in the context of Part B reimbursement is highly questionable and troubling for companies in the process of developing biosimilars for the U.S. market.

Finally, CMS explicitly states that biosimilars are not generic drugs nor multiple source drugs under Medicare Part D, and as a result, requires the same level of patient cost-sharing as would apply for single source drugs. Simply put, by CMS’s own acknowledgement in the context of other federal health programs, biosimilars are not multiple source drugs, and should not be reimbursed under a payment methodology designed for multiple source drugs.

4. CMS’s proposal will lead to confusion and inaccurate data capture, including for the tracking of adverse events by FDA.

The use of the same HCPCS code for multiple biosimilars, particularly when each product can be approved for different therapeutic uses, will lead to confusion and uncertainty for both payors and providers. Medicare Administrative Contractors (“MACs”) and other payors cannot write accurate coverage policies when the same HCPCS codes are assigned to products that are approved for different, clinically appropriate indications. Providers cannot be sure what reimbursement they can expect to receive for the biosimilars they prescribe and administer if they must rely on unclear or confusing coverage standards that fail to distinguish by HCPCS code one appropriate clinical treatment from another.

In addition, as we explain in our previous comments to CMS in response to the agency’s July 8, 2015 Proposed Rule, HCPCS codes are the foundation for how hospital outpatient hospital outpatient prospective payment system (“OPPS”) payments are calculated. 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 based on similar clinical characteristics and costs. For drugs and biologicals specifically, unless these items are automatically packaged under certain APCs by CMS policy, the 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 must have unique HCPCS codes for each

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11 CMS Memo from Amy K. Larrick, Acting Director, Medicare Drug Benefit or C & D Data Group to Part D Sponsors, “Part D Requirements for Biosimilar Follow-On Biological Products (March 30, 2015).
12 Hospital Outpatient Prospective Payment System Fact Sheet, CMS Medicare Learning Network, December 2014.
biosimilar product in order to appropriately package biosimilars into existing APCs by appropriate therapeutic use, or to determine if the per day cost of the product requires its own APC.

Finally, we note that HCPCS J-Codes are a critical data point used by FDA’s Sentinel system to monitor for reported adverse events. As FDA has recently stated, “successful use of active pharmacovigilance systems, (such as FDA’s Sentinel system) for adverse event tracking relies on the standardized coding systems for capturing drug information in administrative and health care claims and billing records.”13 While reports may be submitted to the FDA with certain drug identifiers, such as NDC numbers and proprietary names, FDA acknowledges as “well known that many reports lack key information, and that information identifying products in spontaneous reports can be unreliable.”14 In fact, FDA states that “[m]any therapeutic products are administered in settings, such as physician offices, clinics, or hospitals, where administrative and billing data do not routinely include product identifiers such as brand name, manufacturer, NDC number, or lot number.” This administrative and billing data, however, will include HCPCS codes for reimbursement purposes. The inclusion of all biosimilars under the same HCPCS J-Code, even with J-Code modifiers, would hinder FDA’s ability to use the Sentinel system to provide rigorous, product-specific information and post-market surveillance. It is imperative from a public health and safety perspective that FDA has accurate and appropriately assigned product identifiers to “detect safety signals throughout the lifecycle of a product, so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem.”15

5. CMS’s proposed payment methodology will dramatically reduce investment in, and availability of, biosimilars, which is clearly against the intent of Congress in creating a vibrant U.S. biosimilars market.

It is important to acknowledge the high barriers of entry that exist in the biosimilar market. The U.S. Federal Trade Commission (“FTC”) estimates that biosimilar products are likely to take 8 to 10 years to develop, with development costs ranging from $100 million to $200 million, while small molecule generic drug development typically takes only 3 to 5 years, and costs between $1 and $5 million.16 Besides the estimated $100 to $200 million in development costs, there are also the costs of building a suitable manufacturing facility, estimated to be $250 million to $1 billion.17 According to the FTC, “substantial costs to obtain FDA approval, plus the substantial fixed costs to develop manufacturing capacity, will likely limit the number of competitors that undertake entry with follow-on biologic products.”18 Given these already existing barriers to market entry, CMS’s proposal to assign one HCPCS code to all biosimilar products of a reference biologic will likely force biosimilar manufacturers to scale back investment and development in this emerging sector, which would reduce effective treatment options for patients and the clinicians providing their care.

CMS characterizes its proposed payment methodology for biosimilars as similar to the ASP calculation for multisource drugs. Even putting aside CMS’s mischaracterization of biosimilars as being similar to multiple source or generic drugs, CMS has not accounted for the serious unintended consequences its policy will bring to the still fledgling biosimilar market. Under the CMS proposed policy, biosimilars will be paid at the same rate under Medicare Part B no matter the differences in the FDA approved indications of each biosimilar product or the extent of interchangeability with the reference biological. The market will necessarily skew against biosimilars that are more expensive to produce, most likely because these more costly products are also more biologically complex, are approved for more indications, or are interchangeable with the reference product.

14 Id.
15 Id. at 52226-27.
18 Id.
CMS’s proposed policy would in effect penalize biosimilar manufacturers who seek FDA approval for as many indications as possible, as a biosimilar approved for all indications for a reference product would be paid at the exact same rate as a biosimilar that is approved to treat only one indication, no matter the time and costs involved in obtaining approval for a more comprehensively developed product. These more highly developed products will be unable to compete, even if their prices are lower than the reference biologic, thereby reducing the number of competitive products in the market. As we have observed with generic cancer drugs and other generic sterile injectables, drug shortages can result when manufacturers have limited incentive to enter the market and contribute to the range of products available to patients. In addition, manufacturers often operate provider and patient assistance programs that serve to improve clinical outcomes for patients. Manufacturers of reference biological products will price biologics appropriately to accommodate the costs associated with offering additional services for patients and their providers. Biosimilar manufacturers, on the other hand, have no such competitive incentive to provide patients with these services, as their biosimilar products would be limited to the same reimbursement rates that would apply to products that offer minimal clinical support to patients and health care providers.

Finally, in addition to decreasing the treatment options available for patients, evidence suggests that as more products leave the market and competition is reduced, prices of the remaining products will rise. CMS’s policy for coding true multisource drugs is to reimburse brand drugs under the same HCPCS code as the generic drugs of that brand. This serves to maximize pressure on the brand manufacturer to lower its price in order to remain competitive with the available generics on the market. However, CMS’s proposal subjects only the biosimilars, and not the reference biologic, to the same payment rate by grouping them together under the same HCPCS code. As manufacturers withdraw from the biosimilar market, or are deterred from entry into the market in the first place, price competition is reduced not only among competing biosimilar products, but against the reference biological as well. The manufacturer of the reference biological will maintain higher prices in the long run without biosimilar competition to force prices down. If price competition with the reference biologic is reduced in this way, discounting will diminish - and long run pricing will be a lot higher than would be the case if more biosimilars came into the market and stayed there.

Conclusion

Thousands of patients facing cancer, inflammatory disease, kidney disease, and other serious disorders are expected to benefit from biosimilars over the next decade. Congress has clearly recognized the potential that biosimilars bring, and has enacted laws that are meant to foster a robust market for this emerging market sector. CMS should not adopt a reimbursement proposal that would stifle progress. As CMS has itself stated, biosimilars present “a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions.” Since the biosimilars sector is still new (only one product has been approved and as of this writing, is still not on the US market), it is critical that CMS not enact policies that risk stifling product development. CMS should not advance any payment policy that could slow progress in a sector that holds such tremendous promise. We urge CMS to enact a final payment rule that assigns each biosimilar product of a reference biologic its own payment amount and a unique HCPCS code.

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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