Submitted via http://www.regulations.gov

September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS)
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2018 proposed July 13, 2017 (CMS-1676-P);
allowing biosimilars that reference the same biologic to use unique billing codes

Dear Administrator Verma:

We appreciate the invitation to provide comments on the proposed payment for biosimilar biological products under Section 1847A of the Social Security Act, included in the *Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018* proposed rule (CMS-1676-P). The Biosimilars Council, a division of the Association for Accessible Medicines (AAM), works to ensure a positive environment for patient access to biosimilar medicines. The Biosimilars Council is the leading source for information about the safety and efficacy of these more affordable alternatives to costly brand biologic medicines.

In January 2016, the Centers for Medicare and Medicaid Services (CMS) first proposed assigning a single Healthcare Common Procedure Coding System (HCPCS) billing code and Average Sales Price (ASP) calculation for biosimilars that reference a common innovator biologic under Medicare Part B. As the biosimilar market has begun to develop, CMS is now seeking for future consideration, "new or updated information on the effects of the current biosimilar payment policy that is based on experience with the United States marketplace… particularly market analyses or research articles that provide data and insight into the current economics of the biosimilar marketplace." CMS is also seeking "data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending."

The Biosimilars Council is looking forward to working with CMS to make sure Medicare beneficiaries have access to therapeutically-appropriate, lower-cost alternatives to many expensive biologic medicines available today, and that this market can be developed in a fair and sustainable manner.

Medicare Should Reimburse for Each Biosimilar Based on the Biosimilar's Unique Average Sales Price (ASP)

The Biosimilars Council is greatly concerned that the approach that CMS is taking regarding the reimbursement of biosimilar medicines under Medicare Part B hinders what CMS is hoping to achieve: higher biosimilar uptake when appropriate by health care providers and patients and lower cost through the introduction of multiple biosimilar competitors in individual product classes. It greatly reduces incentives for manufacturers to invest in developing new, more affordable, biosimilars and interchangeable biologics. **Instead of using a single payment calculation for biosimilars, Medicare should reimburse for each non-interchangeable biosimilar based on the product's unique ASP, effective January 1, 2018.**

As a preface, it is important to note that the Council believes it is necessary to clarify that when referring to "biosimilars" CMS is exclusively referring to products that have *not* been approved as interchangeable biologics. The final rule regarding the Physician Fee Schedule for CF 2016 made this distinction very clear:

> While section 7002 of the Affordable Care Act (the Biologics Price Competition and Innovation Act of 2009) outlines specific criteria for a determination of interchangeability, at this point, there are no interchangeable biosimilars products on the market. Thus, we are not addressing whether a product's interchangeability status should be the basis for a different approach to Part B payment in this rule at this time. To the contrary, our proposed approach, which we are finalizing in this rule, would preserve our discretion to group interchangeable biosimilars together for payment purposes in the same manner we will code and pay for biosimilars that do not have a designation of interchangeability under section 7002 of the Affordable Care Act. However, given that no interchangeable biosimilars are currently available, we will consider whether further refinements to our biosimilar payment policy may be necessary as the market develops in the future.[1]

Therefore, throughout these comments, any further reference to biosimilars will exclusively refer to the policy detailed in that final rule. The Biosimilars Council believes that addressing interchangeable biologics at this time would be premature, and that the decision on their ultimate reimbursement should be delayed until further clarity is provided by FDA.

The Biologics Price Competition and Innovation Act (BPCIA) amended the Public Health Service (PHS) Act to establish an abbreviated licensure pathway for biological products that the FDA determines are "biosimilar" to or "interchangeable" with an FDA-licensed biological product ("reference product").[2] The PHS Act defines biosimilarity to mean that "the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."[3] On March 6, 2015, the FDA approved the first application under the abbreviated

[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 42 C.F.R. 405 (Nov. 16, 2015)

[2] Sec. 351(k) of the Public Health Service (PHS) Act.

[3] Sec. 351(i)(2) of the PHS Act.

biosimilar licensure pathway, Sandoz's Zarxio®(filgrastim-sndz).[4] Since that time, an additional five biosimilars have been approved by the FDA.[5]

As part of their initial application, or subsequently, an applicant may meet the additional requirements for an "interchangeability" designation. This means providing, in addition to the information required to demonstrate biosimilarity, data demonstrating that the biological product "can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."[6,7] Products that the FDA has determined are interchangeable are suitable to be "substituted for the reference product without the intervention of the prescribing healthcare provider."[8] The FDA has yet to approve a biosimilar product as interchangeable with a reference product.[9]

The Biosimilars Council recommends that each biosimilar should be assigned its own code in the HCPCS system and paid at a uniquely-calculated payment rate based on that biosimilar's own ASP. Fundamentally, this is because the statute treats these biosimilar products as non-substitutable. To have a level playing field, the Medicare payment rate for biosimilars should reflect the same approach applied to other non-substitutable products.[10] Without such a level playing field, it is doubtful that biosimilars will ultimately be able to achieve the kind of success envisioned by Congress when they passed the BPCIA ultimately limiting patient access to more affordable therapies.

If Medicare pays for all biosimilars associated with a particular reference product under a single, blended ASP, it could limit Medicare beneficiary access to biosimilar products for which Medicare pays less than the product's average sales price. This dynamic could put physicians under-water financially and therefore make the use of a biosimilar less stable financially and less appealing to utilize when it would otherwise be appropriate. This will then undermine the development of a sustainable biosimilar market and limit the potential for long term savings from

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[4] FDA Approves First Biosimilar Zarxio™ (filgrastim-sndz) from Sandoz (March 6, 2015). https://www.sandoz.com/news/media-releases/fda-approves-first-biosimilar-zarxiotm-filgrastim-sndz-sandoz.

[5] FDA Center for Drug Evaluation and Research. List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date (last updated July 21, 2017). https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM560162.pdf.

[6] Sec. 351(k)(4) of the PHS Act.

[7] FDA Draft Guidance. "Considerations in Demonstrating Interchangeability With a Reference Product." January 2017. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf.

[8] Sec. 351(i)(3) of the PHS Act.

[9] FDA Center for Drug Evaluation and Research. List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date (last updated July 21, 2017). https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM560162.pdf.

[10] Specifically, the ASP for non-interchangeable biosimilars should be calculated based on the same methodology for single-source drugs, as outlined in Sec 1874A(a)(4) of the Social Security Act.

biosimilars to the Medicare program. Therefore, CMS should reimburse for each biosimilar based on the biosimilar's unique ASP.

When considering biosimilars it is important to remember that not all presentations and dosage forms may be available for all biosimilars to a given reference product. In these circumstances, separate HCPCS codes for each product are essential. It is incorrect to group these biosimilars into a single code, when they have not been determined therapeutically equivalent to each other, and may not include all presentations and dosage forms. Biosimilars are not generics, as explained below, and treating them like generics for purposes of reimbursement does not accurately reflect the realities of their development process and FDA approval status.

Similarly, it is also reasonable to presume that Medicare Administrative Contractors (MACs) may wish to implement a coverage policy ensuring that appropriate therapy is used for each beneficiary. Such a coverage policy could restrict coverage of biosimilars to the indications for which the FDA has individually approved them. That may in turn create problems where the price for those products with the more complete FDA label does not comport with the weighted average.

Importance of a Sustainable Biosimilars Market

Today, the United States has the most efficient generic market in the world, with greater rates of substitution and more timely adoption of generics than any other country. Generics today, thirty-three years after the Drug Price Competition and Patent Term Restoration Act, account for 89 percent of prescription dispensed in the United States with only 26 percent of the costs. The Biosimilar Council stresses that this did not occur overnight and it has taken many decades to establish the current market and savings enjoyed today.

It is crucial that CMS recognize not only the importance of developing an equally successful biosimilars market in the United States but also the steps that will be needed to arrive there. A critical piece of that plan needs to be establishing markets that will attract new biosimilar applicants into existing markets. The notable differences between traditional generics and modern biologic markets requires that policymakers consider and address the resulting policy challenges that could potentially significantly hinder biosimilar competition before it ever gets the chance to fully thrive. Without consideration of these important differences, patients will suffer from decreased access to more affordable therapies.

The Biosimilars Council strongly believes that blending biosimilar ASPs does not allow for a sustainable future biosimilars market that leads to a long-term additional future investments by biosimilar manufacturers. Policies that only incent the short-term savings from the first biosimilars, when the investments are up to $250 million per successful biosimilar approval (traditional generics are $1 million to $4 million),[11] will further reduce the number of aspiring biosimilar sponsors. Additionally, it threatens to dampen the number of candidates each sponsor chooses to develop.

[11] Blackstone EA, Joseph PF. The Economics of Biosimilars. *American Health & Drug Benefits*. 2013;6(8):469-478. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/.

Importantly, a sustainable biosimilars market and the associated savings do not solely come from those biosimilars that are first to market. Rather, the sustainable future of biosimilar lies in the second and third to market biosimilars that lead to savings for the healthcare system and on-going competition. Separate codes help stimulate future entrants to the market, as well as investments in the FDA's interchangeability designation for those products for which pharmacists will have an opportunity to substitute.

There is already compelling evidence of biosimilar competition leading to lower costs and improved access for patients. The European experience, with over a decade of biosimilar competition and over 700 million patient days of clinical experience with biosimilars, provides a variety of examples in different therapeutic areas and with different reimbursement mechanisms of the benefits of encouraging a robust and sustainable biosimilars market. Not only has the introduction of biosimilars driven savings across the European Union (EU), but introduction of biosimilars has led to increased availability for patients and so improvements in their timely access to quality care.

According to data compiled by IMS, introduction of biosimilars[12] into EU member countries led to an average per unit price reduction of 16 percent the year after the introduction, across the biosimilar and the reference biologic. Concurrently, the introduction of the biosimilar substantially increased access and led to an average increase in the volume of both the biosimilar and the reference of 41 percent.[13]

The introduction of the biosimilar and competition in the EU markets led to a substantial, immediate reduction in the average price for the biosimilar and reference originator products. At the same time, this led to an even larger increase in volumes and patient access to both biosimilar and their reference originator products. These benefits were precipitated by robust and sustained biosimilar competition continues to be clearly demonstrated by the European experience as more and more biosimilars are approved and launched there.

Equally critical to understand about the European experience with biosimilars is that the success (eg, price discounts and utilization) of biosimilars is dependent on the policies within a given country. Countries with a favorable framework that incents the use of biosimilars have seen much more sustained and robust success than countries with flawed policies that inappropriately categorize biosimilars as generics.

Shared Codes Will Stunt the Development of a Robust Biosimilars Market

As separate codes create the best incentives for a sustainable biosimilars market, shared codes significantly increase the potential for an uneven playing field among biosimilars and their reference products, which could ultimately deter physician adoption of biosimilars and create a

[12] Average of the EU average the year after introduction of biosimilars for Epoetin (EPO), Granulocyte-colony stimulating factor (G-CSF), Human growth hormone (HGH), Anti-tumor necrosis factor (Anti-TNF), Fertility (Follitropin alfa), and Insulins.

[13] IMS Health. The Impact of Biosimilar Competition. June 2016. https://www.imshealth.com/files/web/Market%20Insights/IMS_Health_Impact_of_Biosimilar_Competition_EU_2016.pdf.

disincentive to market entry altogether. Today, the apparent expectation for biosimilars is that their short-term potential price savings is the sole benefit of their introduction, rather than a biosimilars market that produces robust competition and long-term savings. CMS's policy of using a single payment calculation for both biosimilars reflects the expectation that biosimilars are essentially generics and that each is therapeutically equivalent to another when they share a reference product, but not to the reference product itself which is directly contradictory to how the products are approved by FDA.

The current structure of shared codes greatly reduces incentives for manufacturers to invest in developing new biosimilars and enter the market in the first place. In a shared code system independent from the reference product, differentiation between biosimilars is solely based on price between each other, and creates no significant economic incentive to shift from an expensive brand. Biosimilars have less pricing flexibility, due to their substantially greater development costs, than a small molecule generic. Disadvantaging biosimilars relative to the originator product through shared codes only among the biosimilars, leaves biosimilars unable to effectively compete. In the pricing scenario created by current policy, a biosimilars grouped together would have to compete separately against an originator product that has used more than a decade of monopoly pricing to recoup its investment as well as build brand recognition. It may well incent sponsors to consider competition as a new biologic instead or not enter the market at all.

Not only is this a risk, but the incentives set up by shared codes only for biosimilars actively create the potential for anti-competitive behaviors from the originator products. Because all biosimilar entrants will be grouped into a single-code, that will significantly dampen biosimilar manufacturers' ability to maintain consistent reimbursement for their products, particularly for those with varying dosage forms and label indications. At the same time, the branded manufacturer will be completely spared from direct price competition. There is significant risk that the resulting erratic payment for biosimilars will deter physicians from adopting biosimilars due to this inconsistent payment policy.

Without reasonable certainty that they will be able to rely on some level of physician adoption, biosimilar manufacturers may simply decide not to enter potentially competitive markets. Such an outcome would significantly decrease competition. As such, the Biosimilars Council believes that adjusting the current CMS policy will play a vital role in the development of robust markets. While the shift in policy may have a marginal cost in the immediate future, ensuring that there is robust competition for biological products stands to produce significant savings over time, including outside of traditional ten year budget windows.

These risks exist in the market regardless of the reimbursement decisions for biosimilars. However, shared codes substantially add to this risk and reduces the potential for biosimilars to achieve a sustainable market yet further. Shared codes limit biosimilar manufacturers' abilities to respond to a competitive market forces, and will likely seriously discourage appropriate physician adoption. Without providing a sustainable payment policy for these products, CMS ultimately places significant savings at risk.

Patients, Physicians, and Payers Will All Be Disadvantaged by the Current CMS Policy

The Biosimilars Council has begun various economic analyses examining:

- The detrimental effects of the current CMS policy;
- The competitive effect separately coded products can have on one another and;
- Cost or savings associated with separate codes.

The Council will supplement this submission at a later date when those analyses are complete. At this time however, Bates White Economic Consulting has provided a preliminary analysis of the economic pressures faced by the various stakeholders who stand to benefit from robust biosimilar competition.

Their preliminary analysis suggests the following:

Patients
Patients will have fewer biosimilar product choices at higher costs, decreased access, and greater risk of disruption under a shared HCPCS system for biosimilar reimbursement. Eliminating shared HCPCS codes removes a distortion to competition, eliciting a broader range of products at better value. For patients this means more suitable options for treatment and greater access affordable medicine. Moreover, a robust biosimilar market reduces the risk of disruption to patient care, which has been a periodic affliction in the generic injectable market.

Physicians
Physicians face a significant disincentive to use biosimilars because of the greater reimbursement risks they face under the shared ASP system. The risk for physicians is that the shared biosimilar ASP can change in ways that have nothing to do with the price they paid for the biosimilar they chose to purchase. A drop in the shared ASP can even lead to a situation where the doctor is "upside down" and will be reimbursed less than he or she has paid for the biosimilar. This financial risk to the doctor does not exist for the reference biologic because it has its own HCPCS code. These distortions hamper competition, and create disincentives for biosimilar entry. Physicians will thus have a narrower range of treatment alternatives to offer patients under a shared HCPCS system for biosimilar reimbursement.

Eliminating the adverse incentives associated with the shared biosimilar HCPCS codes will aid their adoption by physicians, and removes a distortion to competition. For physicians this means a broader range of suitable options and better access to treatments for their patients. Increased utilization and adherence will likely lead to better patient outcomes, which matters to physicians. Moreover, a robust biosimilar market reduces the risk of disruption to patient care due to supply disruptions, which have been a periodic affliction in the generic injectable market

Payers
Payers will have fewer biosimilar choices, and will be less able to leverage competition in markets affected by shared HCPCS codes. Eliminating shared HCPCS codes removes a

distortion to competition, eliciting a broader range of products. Payers can leverage this competitive environment to achieve better value and provide more affordable access to their covered patients. Better patient access leads to better outcomes, which can lower system costs.

Manufacturers

Manufacturers of biosimilars are arbitrarily disadvantaged relative to the reference biologic by the shared ASP system. This policy prioritizes pricing for the reference biologic relative to biosimilars by giving the reference product its own HCPCS code. This separate treatment is arbitrary because differences between the reference biologic and its biosimilars are likely neither more, nor less relevant than differences among biosimilars. However, imposing a shared ASP reimbursement for biosimilars introduces a number of distortions that are likely to hinder competition. As noted above, it creates a disincentive for physicians to use a biosimilar instead of the reference product. The price dynamics and product demand under shared ASP are also inherently less predictable. These factors will contribute to reduced viability of biosimilar investment, a reduction in entry, and ultimately less competition.

Eliminating shared HCPCS codes creates better incentives for manufacturers to invest and compete in biosimilars markets. This competition would elicit a broader range of products at better value, creating benefits for all stakeholders.

Stakeholder	Separate HCPCS code	Shared HCPCS code	Impact
Patients	• More biosimilar products available • Broader range of suitable products • Lower out of pocket costs • Better access and adherence • Less risk of therapy disruption	• Fewer biosimilar products available • Smaller range of suitable products • Higher out of pocket costs • Decreased access and adherence • More risk of therapy disruption	**Patients will face fewer product choices at higher costs, decreased access, and greater risk of disruption with shared HCPCS codes**
Physicians	• Less reimbursement risk and potential to be "upside-down" on drug costs relative to reference product • Broader range of suitable products for patients • Lower patient costs drives better access and adherence to prescribers' protocols • Less risk of supply disruption	• Financial disincentive to use biosimilar due to reimbursement risk and potential to be "upside-down" on drug costs relative to reference biologic • Fewer suitable products for patients • Higher patient costs with lower access and adherence • More risk of supply disruption	**Physicians will have financial disincentive to use biosimilars, and thus have fewer products at higher prices available for patients under shared HCPCS codes**
Payers	• Better able to leverage competition if there are more products available • Better able to offer patient affordable access to medication • Better patient access leads to better outcomes • Lower system costs	• Less able to leverage competition if there are fewer products available • Less able to offer patient affordable access to medication • Less patient access avoids better outcomes • Higher system costs	**Payers will be less able to leverage competition to drive better access and outcomes for patients under shared HCPCS codes**
Manufacturers	• Puts biosimilars on similar footing with reference biologic • Fewer distortions in pricing and demand environment • Buyers (physicians) placed at less financial risk when using biosimilars • More predictable investment environment • More incentive to invest in new products and enter the market	• Arbitrarily advantages reference biologic • Buyers (physicians) placed at financial risk when using biosimilars • Greater distortions in pricing and demand environment • Riskier investment environment • Less incentive to invest in new products and enter the market	**Manufacturers will be less willing to invest in new products and enter given the riskier pricing and demand environment and arbitrary disadvantages they face relative to the reference brand under shared HCPCS codes**

CMS Should Also Encourage Congress to Promote Biosimilars in Part D

In addition to CMS's reconsideration of its existing policy surrounding reimbursement for biosimilars in Part B, the agency should take additional steps to support a legislative fix to

significant disincentives for the adoption of biosimilars in Medicare Part D. The current framework for the Part D Coverage Gap Discount Program currently excludes biosimilars manufacturers from providing discounts to payers and patients for their products in the coverage gap in the way brands do. This setup has created a system that will make it extremely difficult for biosimilars to get preferential formulary placement from their reference products, and force patients into higher cost therapies when another would be appropriate. CMS should encourage Congress to amend the program to better incentivize biosimilar adoption.

Conclusion

The biosimilars market in the United States is fledging today and CMS has an opportunity to help facilitate the creation of a thriving biosimilars market, while balancing short term price savings from biosimilars and the long-term benefits of a sustainable competitive environment for all biologics, biosimilars, and interchangeable biologics.

Shifting to reimbursement based on a biosimilar's unique ASP with separate HCPCS codes provides for these opportunities and will have a positive impact on the future viability of the biosimilars market. Enacting these policies early in the development of a competitive biosimilars market is essential, as it will stimulate more entrants as each sponsor feels in better control of their own destiny. Recombining codes later, if it were ever to make sense, is always an option once a truly sustainable market has emerged. To impose shared codes now is to risk never achieving a sustainable multisource biologics environment in the US in the first place.

As such, for the forgoing reasons, we respectfully request that CMS adopt the following policies in future rulemaking:

- CMS should assign unique HCPCS codes to each biosimilar;
- Medicare should reimburse for each non-interchangeable biosimilar based on the biosimilar's unique ASP; and
- CMS should encourage Congress to amend the Part D Coverage Gap Discount Program to promote biosimilar adoption.

We appreciate the opportunity to provide these comments, and we look forward to working with CMS to expand beneficiary access to these affordable alternatives to biologic products. As mentioned previously, the Council is still engaged in various economic analyses of the current policy, and will supplement these comments once those projects are complete. If you have any additional questions, please do not hesitate to contact Christine Simmon, Executive Director of the Biosimilars Council and Senior Vice President Policy & Strategic Alliances of AAM, at (202) 249-7100 or Christine.Simmon@accessiblemeds.org.

Sincerely,

Christine Simmon
Executive Director, Biosimilars Council
Senior Vice President Policy & Strategic Alliances, AAM