

Biosimilars FORUM

January 16, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P

Dear Ms. Verma:

The Biosimilars Forum appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Proposed Rule, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program."

The founding members of the Biosimilars Forum represent the majority of companies with the most significant U.S. biosimilars development portfolios, including: Amgen, Boehringer Ingelheim, Coherus BioSciences, Fresenius-Kabi SwissBioSim (formerly EMD Serono), Merck & Co., Pfizer, Samsung Bioepis, Sandoz, and Teva.

The Forum is a non-profit organization whose mission is to educate stakeholders on the value of biosimilars and advance biosimilars in the United States with the intent of expanding access to 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. The Biosimilars Forum provides evidence-based information to inform and support public policies that encourage access to and awareness and adoption of biosimilars.

Treatment of Biosimilars as Generics for Non-LIS Catastrophic and LIS Cost-Sharing

The Forum appreciates CMS' efforts to address biosimilars in this Proposed Rule. Specifically, CMS proposes to revise the definition of a generic drug to include follow-on biologics approved under section 351(k) of the *Public Health Service Act* solely for purposes of Medicare Part D low-income subsidy (LIS) cost-sharing. The proposal would limit inclusion of follow-on biological products in the definition of generic drug to non-LIS catastrophic cost-sharing and LIS cost-sharing.

Currently, under the LIS and the catastrophic cost-sharing programs in Medicare Part D, biosimilars do not meet the CMS definition of either a “generic” or a “multiple source” drug.¹ Biosimilars are therefore subject to the higher maximum copayments for LIS-eligible individuals applicable to all other Part D drugs. The new proposal by CMS attempts to rectify the situation for those receiving the LIS or those utilizing catastrophic cost-sharing. If finalized, CMS predicts that this policy will improve enrollee incentives to choose follow-on biologics over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program.

While the Forum recognizes the Agency’s efforts to encourage uptake of follow-on biologicals for these populations, it is important to note that biosimilar products are not generic versions of their reference biological nor are they multiple source drugs. There are important differences between biosimilars and generic drugs. The FDA has made public statements acknowledging that biosimilars are not generics, and accordingly has created a separate approval process for biosimilar products. 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 the combination of chemicals that typically result in exact copies of the brand drug each time. Biosimilars, that have not received an interchangeability rating, are “highly similar” to the reference product, and are not bioequivalent as generic drugs are. Ultimately, biosimilar products of one reference biological can vary in terms of approved uses and interchangeability.

Notably, CMS’s proposal fails to explain why a biosimilar could logically be categorized as “generic.” Further, CMS expressed that clarifying biosimilars as generics could cause confusion and would have to be limited to the purpose of setting maximum LIS and catastrophic coverage copays as this classification would not be appropriate for purposes of other Part D policies that hinge on whether a drug is “generic.”

The Forum appreciates the intent of this Proposed Rule; however, we believe there are different steps in regard to biosimilar classification that the Agency can pursue to promote the development of a vibrant and competitive biosimilar marketplace. CMS acknowledged this in the Medicare Physician Fee Schedule (MPFS) CY 2018 Part B Final Rule, when the agency revised a reimbursement policy that originally treated biosimilars as multiple source drugs. The new reimbursement policy reflects the complexity of these important therapies and intends to drive patient and provider access by encouraging market competition between manufacturers of biologics and biosimilars.

We encourage the Agency to look at other opportunities to encourage biosimilar utilization and assess whether any of them may offer a better benefit than this proposal. The Forum welcomes the opportunity to work with CMS to refine this proposal and/or identify an alternative approach.

Inconsistent Definition of Biosimilars

As noted above, there is a great deal of inconsistency across Medicare and Medicaid as it pertains to the definition and treatment of biosimilars. In this Proposed Rule, CMS notes “we propose to limit inclusion of follow-on biological products in the definition of generic drug to purposes of non-LIS catastrophic cost sharing and LIS cost sharing only because we want to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations... Accordingly, CMS

¹ See Definition “generic drug,” 42 C.F.R. Section 423.4; Definition “multiple source drug,” 42 U.S.C. Section 1396r-8(k)(7).

currently considers biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable.”

Further exacerbating this incongruity, biosimilars are treated as single source drugs in the context of the Medicaid Drug Rebate Program. This means that manufacturers must pay states the innovator rebate for Medicaid utilization of biosimilar products. Biosimilars will therefore be subject to pay rebates on state Medicaid utilization based on the rebate formula for single source (branded) drug products not based on the rebate formula for multiple source drugs.

Additionally, this proposed rule does not include language to address the requirement for a biosimilar manufacturer to provide a 50 percent rebate under the Medicare Coverage Gap Discount Program (CGDP). In 2018, the health plan pays 15 percent of the costs in the gap (this increases through 2020 to 25 percent), and the beneficiary pays 35 percent (which decreases by 2020 to 25 percent). For generics and biosimilars, patients pay 44 percent of the cost, as CMS assumed that the prices of these drugs would be far lower than that of brands. However, this is not the case with biosimilars as noted in Avalere’s April 2016 report *Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D*. The report states that patients in the coverage gap would actually pay more for a Part D biosimilar than for a brand until the coverage gap disappears. The impact of this is significant. Since biosimilars are excluded from the CGDP, any discount offered to the plan on the biosimilar would not count toward the patient’s true-out-of-pocket (TrOOP) costs and therefore, the patient has both a higher cost share and is in the donut hole longer than if they were on a branded drug. Further, the cost of the biosimilar is also higher for the insurer and thus the policy makes it unlikely for an insurer to promote the use of the biosimilar under Medicare Part D.

With respect to the CGDP, the Forum recognizes that CMS did not speak specifically to their authority around the program in the Proposed Rule and that statute does not include biosimilars in the CGDP definition of “applicable drug.”² As such, the Forum strongly encourages CMS to work with Congress to address this issue statutorily so CMS may advance a policy that treats biosimilars consistently as single source drugs and encourages biosimilar uptake that will ultimately yield lower costs and increased access for patients.

Simply put, by CMS’ own acknowledgement in the context of federal health programs biosimilars are typically treated as single source drugs but on occasion are treated as multiple source drugs. Thus, the Biosimilars Forum strongly encourages CMS to continue to build off of its recent efforts to revise Medicare Part B policy with respect to biosimilars to create a standard treatment of biosimilars across programs with the intention of fostering a robust and competitive biosimilar marketplace. In doing so, patients with some of the most difficult diseases to treat in the United States, including cancer, anemia, and autoimmune disorders such as rheumatoid arthritis and psoriasis, will have access to these lifesaving therapies.

If you have any questions or need any additional information, please contact Miranda Franco at miranda.franco@hklaw.com.

² See Definition “applicable drug,” [§ 423.2305](#)